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

FORM 10-K

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

FOR THE ANNUAL PERIOD ENDED MARCH 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 incorporation or organization)	(I.R.S. Employer Identification No.)
165 LUDLOW AVENUE NORTHVALE, NEW JERSEY	**07647**
(Address of principal executive offices)	(Zip Code)

(201) 750-2646
(Registrant's telephone number, including area code)

Securities Registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Exchange on Which Registered

Securities Registered pursuant to Section 12(g) of the Act:

Common Stock, $0.001 par value

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934. Yes ☐ No ☒

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	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 ☒

State the aggregate market value of the voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold as of the last business day of the registrant's most recently completed second fiscal quarter (for purposes of determining this amount, only directors, executive officers and, based on Schedule 13(d) filings as of September 30, 2017, 10% or greater stockholders, and their respective affiliates, have been deemed affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes).

Title of Class	Aggregate Market Value	As of Close of Business on
Common Stock - $0.001 par value	$ 79,380,644	September 30, 2017

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date:

Title of Class	Shares Outstanding	As of Close of Business on
Common Stock - $0.001 par value	803,638,617	June 7, 2018

DOCUMENTS INCORPORATED BY REFERENCE

None.

FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K and the documents incorporated herein contain "forward-looking statements". Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the Company, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. When used in this report, statements that are not statements of current or historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words "plan", "intend", "may," "will," "expect," "believe", "could," "anticipate," "estimate," "forecast", "contemplate", "envisage", or "continue" or similar expressions or other variations or comparable terminology are intended to identify such forward-looking statements. All statements other than statements of historical fact included in this report regarding our financial position, business strategy and plans or objectives for future operations are forward-looking statements. Without limiting the broader description of forward-looking statements above, we specifically note, without limitation, that statements regarding the preliminary nature of the clinical program results and the potential for further product development, that involve known and unknown risks, delays, uncertainties and other factors not under our control, the requirement of substantial future testing, clinical trials, regulatory reviews and approvals by the Food and Drug Administration and other regulatory authorities prior to the commercialization of products under development, and our ability to manufacture and sell any products, gain market acceptance earn a profit from sales or licenses of any drugs or our ability to discover new drugs in the future are all forward-looking in nature. These risks and other factors are discussed in our filings with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the Company undertakes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Table of Contents

PART I

ITEM 1 BUSINESS

General

Elite Pharmaceuticals, Inc., a Nevada corporation (the "Company", "Elite", "Elite Pharmaceuticals", the "registrant", "we", "us" or "our") wa incorporated on October 1, 1997 under the laws of the State of Delaware, and its wholly-owned subsidiary, Elite Laboratories, Inc. ("Elite Labs"), wa 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 th State of Nevada.

We are a specialty pharmaceutical company principally engaged in the development and manufacture of oral, controlled-release products, using proprietary know-how and technology, particularly as it relates to abuse resistant products and the manufacture of generic pharmaceuticals. Our strategy includes improving off-patent drug products for life cycle management, developing generic versions of controlled-release drug products with high barriers to entry and the development of branded and generic products that utilize our proprietary and patented abuse resistance technologies.

We own and occupy manufacturing, warehouse, laboratory and office space at 165 Ludlow Avenue and 135 Ludlow Avenue in Northvale, NJ (the "Northvale Facility"). The Northvale Facility operates under Current Good Manufacturing Practice ("cGMP") and is a United States Drug Enforcem Agency ("DEA") registered facility for research, development, and manufacturing.

Strategy

We focus our efforts on the following areas: (i) development of our pain management products; (ii) manufacturing of a line of generic pharmaceutical products with approved Abbreviated New Drug Applications ("ANDAs"); (iii) development of additional generic pharmaceutical products; (iv) development o the other products in our pipeline including the products with our partners; (v) commercial exploitation of our products either by license and the collection of royalties, or through the manufacture of our formulations; and (vi) development of new products and the expansion of our licensing agreements with other pharmaceutical companies, including co-development projects, joint ventures and other collaborations.

Our focus is on the development of various types of drug products, including branded drug products which require New Drug Applications ("NDAs" under Section 505(b)(1) or 505(b)(2) of the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Drug Price Competition Act") as well a generic drug products which require ANDAs.

We believe that our business strategy enables us to reduce its risk by having a diverse product portfolio that includes both branded and generic products in various therapeutic categories and to build collaborations and establish licensing agreements with companies with greater resources thereby allowing us to share costs of development and improve cash-flow.

Commercial Products

We own, license or contract manufacture the following products currently being sold commercially:

Product	Branded Product Equivalent	Therapeutic Category	Launch Date
Phentermine HCl 37.5mg tablets ("Phentermine 37.5mg")	Adipex-P®	Bariatric	April 2011
Lodrane D ® Immediate Release capsules ("Lodrane D")	n/a	OTC Allergy	September 2011
Methadone HCl 10mg tablets ("Methadone 10mg")	Dolophine®	Pain	January 2012
Hydromorphone HCl 8mg tablets ("Hydromorphone 8mg")	Dilaudid®	Pain	March 2012
Phendimetrazine Tartrate 35mg tablets ("Phendimetrazine 35mg")	Bontril®	Bariatric	November 2012
Phentermine HCl 15mg and 30mg capsules ("Phentermine 15mg" and "Phentermine 30mg")	Adipex-P®	Bariatric	April 2013
Naltrexone HCl 50mg tablets ("Naltrexone 50mg")	Revia®	Pain	September 2013
Isradipine 2.5mg and 5mg capsules ("Isradipine 2.5mg" and "Isradipine 5mg")	n/a	Cardiovascular	January 2015
Hydroxyzine HCl 10mg, 25mg and 50mg tablets ("Hydroxyzine 10mg" and "Hydroxyzine 25mg" and "Hydroxyzine 50mg")	Atarax®, Vistaril®	Antihistamine	April 2015
Oxycodone HCl Immediate Release 5mg, 10mg, 15mg, 20mg and 30mg tablets ("OXY IR 5mg", "Oxy IR 10mg", "Oxy IR 15mg", "OXY IR 20mg" and "Oxy IR 30mg")	Roxycodone®	Pain	March 2016
Trimipramine Maleate Immediate Release 25mg, 50mg and 100mg capsules ("Trimipramine 25mg", "Trimipramine 50mg", "Trimipramine 100mg")	Surmontil®	Antidepressant	May 2017

Note: Phentermine 15mg and Phentermine 30mg are collectively and individually referred to as "Phentermine Capsules". Isradipine 2.5mg and Isradipine 5mg are collectively and individually referred to as "Isradipine Capsules". Hydroxyzine 10mg, Hydroxyzine 25mg and Hydroxyzine 50mg are collectively and individually referred to as "Hydroxyzine". Oxy IR 5mg, Oxy IR 10mg, Oxy IR 15mg Oxy IR 20mg and Oxy IR 30mg are collectively and individually referred to as "Oxy IR". Trimipramine 25mg, Trimipramine 50mg, and Trimipramine 100mg are collectively and individually referred to as "Trimipramine".

Phentermine 37.5mg

The approved ANDA for Phentermine 37.5mg was acquired pursuant to an asset purchase agreement with Epic Pharma LLC ("*Epic*") dated September 10, 2010 (the "*Phentermine Purchase Agreement*").

Sales and marketing rights for Phentermine 37.5mg are included in the licensing agreement between the Company and Precision Dose Inc ("*Precision Dose*") dated September 10, 2010 (the "*Precision Dose License Agreement*"). Please see the section below titled "*Precision Dose License Agreement*" for further details of this agreement.

The first shipment of Phentermine 37.5mg was made to Precision Dose's wholly owned subsidiary, TAGI Pharmaceuticals Inc. ("*TAGI*"), pursuant to the Precision Dose License Agreement, with such initial shipment triggering a milestone payment under this agreement. Phentermine 37.5mg is currently being manufactured by Elite and distributed by TAGI under the Precision Dose License Agreement.

Lodrane D®

On September 27, 2011, the Company, along with ECR Pharmaceuticals ("*ECR*"), launched Lodrane D®, an immediate release formulation of brompheniramine maleate and pseudoephedrine HCl, an effective, low-sedating antihistamine combined with a decongestant.

Lodrane D® is marketed under the Over-the-Counter Monograph (the "*OTC Monograph*") and accordingly, under the Code of Federal Regulations can be lawfully marketed in the US without prior approval of the United States Food and Drug Administration ("*FDA*"). Within the past few years, the FDA has revised its enforcement policies, significantly limiting the circumstances under which these unapproved products may be marketed. If the FDA determines that a company is distributing an unapproved product that requires approval, the FDA may take enforcement action in a variety of ways, including, without limitation, product seizures and seeking a judicial injunction against distribution.

ECR products have since been divested, and there have been several mergers relating to ECR and successor entities and transfer of brand name ownership, so that Lodrane D® is promoted and distributed in the United States of America ("*U.S.*") now by Valeant Pharmaceuticals International Inc. Lodrane D® is available over-the-counter but also has physician promotion. Lodrane D® is one of the only adult brompheniramine containing products available to the consumer at this time.

Elite manufactured this product for Valeant during the fiscal year ended March 31, 2018 but does not expect to manufacture this product for Valeant in subsequent periods.

Methadone 10mg

Methadone 10mg is contract manufactured by Elite for Ascend Laboratories, LLC ("*Ascend*"), the owner of the approved ANDA.

On January 17, 2012, Elite commenced shipping Methadone 10mg tablets to Ascend pursuant to a commercial manufacturing and supply agreement dated June 23, 2011, as amended on September 24, 2012, January 19, 2015, July 20, 2015 and as extended on August 9, 2016, between Elite and Ascend (the "*Methadone Manufacturing and Supply Agreement*"). Under the terms of the Methadone Manufacturing and Supply Agreement, Elite performed manufacturing and packaging of Methadone 10mg for Ascend. The Methadone Manufacturing and Supply Agreement expired on December 31, 2017.

Hydromorphone 8mg

The approved ANDA for Hydromorphone 8mg was acquired pursuant to an asset purchase agreement with Mikah Pharma LLC ("*Mikah Pharma*") dated May 18, 2010 (the "*Hydromorphone Purchase Agreement*"). Transfer of the manufacturing process of Hydromorphone 8mg to the Northvale Facility, a prerequisite of the Company's commercial launch of the product, was approved by the FDA on January 23, 2012.

Sales and marketing rights for Hydromorphone 8mg are included in the Precision Dose License Agreement. Please see the section below titled "*Precision Dose License Agreement*" for further details of this agreement.

The first shipment of Hydromorphone 8mg was made to TAGI, pursuant to the Precision Dose License Agreement, in March 2012, with such initial shipment triggering a milestone payment under this agreement. Hydromorphone 8mg is currently being manufactured by Elite and distributed by TAGI under the Precision Dose License Agreement.

Phendimetrazine Tartrate 35mg

The ANDA for Phendimetrazine 35mg was acquired by Elite as part of the asset purchase agreement between the Company and Mikah Pharma dated August 1, 2013 (the "*Mikah ANDA Purchase*"). Please see "*Thirteen Abbreviated New Drug Applications*" below for more information on this agreement. The Northvale Facility was already an approved manufacturing site for this product as of the date of the Mikah ANDA Purchase. Prior to the acquisition of this ANDA, Elite had been manufacturing this product on a contract basis pursuant to a manufacturing and supply agreement with Mikah Pharma, dated June 1, 2011.

Phendimetrazine 35mg is currently a commercial product being manufactured by Elite and distributed by Epic on a non-exclusive basis, and by Elite.

On January 2, 2018, the Company announced that it received approval of its abbreviated new drug application ("*ANDA*") from the FDA for Phendimetrazine Tartrate Tablets USP, 35mg. This product approval is from an ANDA that the Company filed approximately six years ago. This approval resulted in the Company having a second, approved ANDA for this product. The Company has been selling this product pursuant to the marketing authorization achieved from the first approved ANDA. The Company is currently considering strategic options for utilization of this approved ANDA, with such options including, without limitation, divestiture.

Phentermine 15mg and Phentermine 30mg

Phentermine 15mg capsules and Phentermine 30mg capsules were developed by the Company, with Elite receiving approval of the related ANDA in September 2012.

Sales and marketing rights for Phentermine 15mg and Phentermine 30mg are included in the Precision Dose License Agreement. Please see the section below titled "*Precision Dose License Agreement*" for further details of this agreement.

The first shipments of Phentermine 15mg and Phentermine 30mg were made to TAGI, pursuant to the Precision Dose License Agreement, in April 2013, with such initial shipments triggering a milestone payment under this agreement. Phentermine 15mg and Phentermine 30mg are currently being manufactured by Elite and distributed by TAGI under the Precision Dose License Agreement.

Naltrexone 50mg

The approved ANDA for Naltrexone 50mg was acquired by the Company pursuant to an asset purchase agreement between the Company and Mikah Pharma dated August 27, 2010 (the "*Naltrexone Acquisition Agreement*") for aggregate consideration of $200,000.

Sales and marketing rights for Naltrexone 50mg are included in the Precision Dose License Agreement. Please see the section below titled "*Precision Dose License Agreement*" for further details of this agreement.

The first shipment of Naltrexone 50mg was made to TAGI, pursuant to the Precision Dose License Agreement, in September 2013, with such initial shipment triggering a milestone payment under this agreement. Naltrexone 50mg is currently being manufactured by Elite and distributed by TAGI under the Precision Dose License Agreement.

Isradipine 2.5mg and Isradipine 5mg

The approved ANDAs for Isradipine 2.5mg and Isradipine 5mg were acquired by Elite as part of the Mikah ANDA Purchase.

Sales and marketing rights for Isradipine 2.5mg and Isradipine 5mg are included in the Epic Manufacturing and License Agreement. Please see the section below titled "*Manufacturing and License Agreement with Epic Pharma LLC*" for further details of this agreement.

The first shipment of Isradipine 2.5mg and Isradipine 5mg were made to Epic, pursuant to the Epic Manufacturing and License Agreement, in January 2015. Isradipine 2.5mg and Isradipine 5mg are currently being manufactured by Elite and distributed by Epic under the Epic Manufacturing and License Agreement.

Hydroxyzine 10mg, Hydroxyzine 25mg and Hydroxyzine 50mg

The approved ANDAs for Hydroxyzine 10mg, Hydroxyzine 25mg and Hydroxyzine 50mg were acquired by Elite as part of the Mikah AND Purchase.

Sales and marketing rights for Hydroxyzine 10mg, Hydroxyzine 25mg and Hydroxyzine 50mg are included in the Epic Manufacturing and Licens Agreement.

The first shipment of Hydroxyzine 10mg, Hydroxyzine 25mg and Hydroxyzine 50mg were made by Epic, pursuant to the Epic Manufacturing an License Agreement, in April 2015. Hydroxyzine 10mg, Hydroxyzine 25mg and Hydroxyzine 50mg are currently being manufactured and distributed by Epi under the Epic Manufacturing and License Agreement.

Oxycodone 5mg, Oxycodone 10mg, Oxycodone 15mg, Oxycodone 20mg and Oxycodone 30mg ("Oxy IR")

We received notification from Epic in October 2015 of the approval by the FDA of Epic's ANDA for Oxy IR. This product was an Identified I Product in the Epic Strategic Alliance Agreement Dated March 18, 2009 (the "*Epic Strategic Alliance*"). Oxy IR was developed at the Northvale Facilit pursuant to the Epic Strategic Alliance, in which we are entitled to a Product Fee of 15% of Profits as defined in the Epic Strategic Alliance. The firs commercial sale of Oxy IR occurred in March 2016, and sales by Epic of this product are ongoing.

Trimipramine 25mg, Trimipramine 50mg, and Trimipramine 100mg

Through Elite Labs, Elite acquired an approved and currently marketed ANDA for Trimipramine Maleate Capsules ("*Trimipramine*") 25, 50 and 100 mg, from Mikah Pharma. Through agreements assigned to Elite in the acquisition, Dr. Reddy's Laboratories, Inc. will market and sell the Trimipramin products and Epic Pharma will manufacture the products. The Epic Pharma agreement insures the uninterrupted supply of generic Trimipramine. Trimipramin is a generic version of Surmontil®, a tricyclic antidepressant. Surmontil® and generic Trimipramine have total US sales of approximately $2 million in 201 according to IMS Health Data. The ANDA purchased by Elite is currently the only marketed generic Trimipramine product.

Filed products under FDA review

SequestOx™ - Immediate Release Oxycodone with sequestered Naltrexone

SequestOx™ is our lead abuse-deterrent candidate for the management of moderate to severe pain where the use of an opioid analgesic is appropriate. SequestOx™ is an immediate-release Oxycodone Hydrochloride containing sequestered Naltrexone which incorporates 5mg, 10mg, 15mg, 20m and 30mg doses of oxycodone into capsules.

In January 2016, the Company submitted a 505(b)(2) New Drug Application for SequestOx™, after receiving a waiver of the $2.3 million filing fe from the FDA. In March 2016, the Company received notification of the FDA's acceptance of this filing and that such filing has been granted priority reviev by the FDA with a target action under the Prescription Drug User Fee Act ("*PDUFA*") of July 14, 2016.

On July 15, 2016, the FDA issued a Complete Response Letter, or CRL, regarding the NDA. The CRL stated that the review cycle for t SequestOx™ NDA is complete and the application is not ready for approval in its present form.

On December 21, 2016, the Company met with the FDA for an end-of-review meeting to discuss steps that the Company could take to obtai approval of SequestOx™. Based on the FDA response, the Company believes that there is a clear path forward to address the issues cited in the CRL. Th Company believes that the meeting minutes, received from the FDA on January 23, 2017, supported a plan to address the issues cited by the FDA in the CR by modifying the SequestOx™ formulation. Such plan includes, without limitation, conducting bioequivalence and bioavailability fed and fasted studies comparing the modified formulation to the original formulation.

On July 7, 2017, the Company reported topline results from a pivotal bioequivalence fed study for or SequestOx™. The mean Tmax (the amount o time that a drug is present at the maximum concentration in serum) of SequestOx™ was 4.6 hr. with a range of 0.5 hr. to 12 hr. and the mean Tmax of the comparator, Roxicodone®, was 3.4 hr. with a range of 0.5 hr. to 12 hr. A key objective for the study was to determine if the reformulated SequestOx™ had a similar Tmax to the comparator when taken with a high fat meal. Based on these results, the Company paused clinical trials for this formulation o SequestOx™. On January 30, 2018, the Company reported positive topline results from a pilot study conducted for a modified SequestOx™ wherein, based o the results of this pilot study, the modified SequestOx™ formulation is expected to achieve bioequivalence with a Tmax range equivalent to the reference product when conducted in a pivotal trial under fed conditions. The Company intends to review these study results with the FDA and discuss pharmacokinetic study requirements for a re-submission of the NDA. The Company will continue to pursue extended release products with its proprietary abuse deterren technology.

There can be no assurances of the success of any future clinical trials, or if such trials are successful, there can be no assurances that an intended future resubmission of the NDA product filing, if made, will be accepted by or receive marketing approval from the FDA, and accordingly, there can be no assurances that the Company will earn and receive the additional $7.5 million or future license fees (see "Licensing, Manufacturing and Development Agreements; Sales and Distribution Licensing Agreement with Epic Pharma LLC for SequestOx™" below). If the Company does not receive these payments or fees, it will materially and adversely affect our financial condition. In addition, even if marketing authorization is received, there can be no assurances that there will be future revenues or profits, or that any such future revenues or profits would be in amounts that provide adequate return on the significant investments made to secure this marketing authorization.

Oxycodone hydrochloride and acetaminophen USP CII (generic version of Percocet®)

On August 9, 2016, the Company filed an ANDA with the FDA for a generic version of Percocet® (oxycodone hydrochloride and acetaminophen USP CII) 5mg, 7.5mg and 10mg tablets with 325mg of acetaminophen. Percocet® is a combination medication and is used to help relieve moderate to severe pain. The FDA requested additional information relating to this filing, which was provided. The Company awaits the FDA's response.

Hydrocodone bitartrate and acetaminophen tablets USP CII (generic version of Norco®)

On December 12, 2016, the Company filed an ANDA with the FDA for a generic version of Norco® (hydrocodone bitartrate and acetaminophen tablets USP CII) 2.5mg/325mg, 5mg/325mg, 7.5mg/325mg and 10mg/325mg tablets. Norco is a combination medication and is used to help relieve moderate to moderately severe pain. The combination products of hydrocodone and acetaminophen have total annual US sales of approximately $700 million, according to IMS Health Data. The FDA requested additional information relating to this filing, which was provided. The Company awaits the FDA's response.

Generic version of a synthetic narcotic analgesic

On April 4, 2017, the Company filed an ANDA with the FDA for a generic version of a synthetic narcotic analgesic indicated for the management of pain. The branded product and its equivalents have annual sales in excess of $30 million according to IMS Health Data. The Company expects a response from the FDA relating to this ANDA during the third quarter of the calendar year ended December 31, 2018. This product is an identified product in the Strategic Marketing Alliance between the Company and Glenmark Pharmaceuticals Inc USA ("*Glenmark*") dated May 29, 2018, pursuant to which, subsequent to ANDA approval by the FDA, it will be manufactured by Elite and marketed/distributed by Glenmark. Please see the section below titled "*Strategic Marketing Alliance with Glenmark Pharmaceuticals, Inc. USA"* for further details.

Oxycodone Hydrochloride extended release (generic version of Oxycontin®)

On September 20, 2017, the Company filed an ANDA with the FDA for generic version of Oxycontin® (extended release Oxycodone Hydrochloride). OxyContin® is approved for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. OxyContin® is formulated such that the tablets provide physical abuse deterrent properties. IMS reported approximately $2.3 billion in revenue for OxyContin® and its equivalents in 2016. The FDA requested additional information relating to this filing. The Company's response to the FDA's request is in progress.

Generic version of immediate release Central Nervous System stimulant

On February 8, 2018, the Company filed an ANDA with the FDA for a generic version of an immediate release central nervous system ("*CNS*") stimulant. The ANDA represents the first filing for a product co-developed with SunGen Pharma LLC ("*SunGen*") under the Development and License Agreement between SunGen and the Company dated August 24, 2016 (the "*SunGen Agreement*"). According to IMS Health data, the branded product and its equivalents had total U.S. sales of more than $400 million for the twelve months ended September 30, 2017. The Company has not yet received a response from the FDA on this filing.

Under the terms of the SunGen Agreement, the product will be owned jointly by the Company and SunGen. Elite shall have exclusive rights to market and sell the product under its own label. Elite will also manufacture and package the product on a cost-plus basis.

Generic version of extended release Central Nervous System stimulant

On May 24, 2018, the Company filed an ANDA with the FDA for a generic version of an extended release CNS stimulant. The ANDA represents the second filing for a product co-developed with SunGen under the SunGen Agreement. According to IMS Health data, the branded product and its equivalents had total U.S. sales of approximately $1.6 billion for the twelve months ended September 30, 2017. The Company has not yet received a response from the FDA on this filing.

Under the terms of the SunGen Agreement, the product will be owned jointly by the Company and SunGen. Elite shall have exclusive rights to market and sell the product under its own label. Elite will also manufacture and package the product on a cost-plus basis.

Please see the section below titled "*Master Development and License Agreement with SunGen Pharma LLC*" for further details on the SunGen Agreement.

There can be no assurances that any of these products will receive marketing authorization and achieve commercialization within this time period, or at all. In addition, even if marketing authorization is received, there can be no assurances that there will be future revenues of profits, or that any such future revenues or profits would be in amounts that provide adequate return on the significant investments made to secure these marketing authorizations.

Approved Products Not Yet Commercialized

We currently own seven different approved ANDAs, all of which were acquired as part of the Mikah ANDA Purchase. Each approved ANDA requires manufacturing site transfers as a prerequisite to commencement of commercial manufacturing and distribution. The products relating to each approved ANDA are included in the Epic Manufacturing and License Agreement, with Elite granting ANDA specific, exclusive, or non-exclusive market right (depending on the ANDA) to Epic. Commercial manufacturing of these products is expected to be transferred to either Epic or the Northvale Facility, with th required supplements to be filed with FDA in the manner and time frame that is economically beneficial to us.

Asset Acquisition Agreements

Generic Phentermine Capsules

On September 10, 2010, together with our wholly owned subsidiary, Elite Laboratories, Inc., executed a purchase agreement (the "*Phentermine Purchase Agreement*") with Epic for the purpose of acquiring from Epic, an ANDA for a generic phentermine product (the "*Phentermine ANDA*"), with such being filed with the FDA at the time the Phentermine Purchase Agreement was executed. On February 4, 2011, the FDA approved the Phentermine ANDA The acquisition of the Phentermine ANDA closed on March 31, 2011 and Elite paid the full acquisition price of $450,000 from the purchase agreement with Epic Pharma.

This product is being marketed and distributed by Precision Dose and its wholly owned subsidiary, TAGI, pursuant to the Precision Dose Licens Agreement, a description of which is set forth below.

Generic Hydromorphone HCl Product

On May 18, 2010, we executed an asset purchase agreement with Mikah Pharma (the "*Hydromorphone Purchase Agreement*"). Pursuant to the Hydromorphone Purchase Agreement, the Company acquired from Mikah Pharma an approved ANDA for Hydromorphone 8 mg for aggregate consideratio of $225,000, comprised of an initial payment of $150,000, which was made on May 18, 2010. A second payment of $75,000 was due to be paid to Mikah Pharma on June 15, 2010, with the Company having the option to make this payment in cash or by issuing to Mikah Pharma 937,500 shares of our common stock. We elected and did issue 937,500 shares of Common Stock during the quarter ended December 31, 2010, in full payment of the $75,000 due to Mikah Pharma pursuant to the Hydromorphone Purchase Agreement dated May 18, 2010.

This product is currently being marketed and distributed by Precision Dose and its wholly owned subsidiary, TAGI, pursuant to the Precision Dos License Agreement, a description of which is set forth below.

Generic Naltrexone Product

On August 27, 2010, we executed an asset purchase with Mikah Pharma (the "*Naltrexone Acquisition Agreement*"). Pursuant to the Naltrexone Acquisition Agreement, Elite acquired from Mikah Pharma the ANDA number 75-274 (Naltrexone Hydrochloride Tablets USP, 50 mg), and all amendment thereto, that have to date been filed with the FDA seeking authorization and approval to manufacture, package, ship and sell the products described in this ANDA within the United States and its territories (including Puerto Rico) for aggregate consideration of $200,000. In lieu of cash, Mikah Pharma agreed t accept product development services to be performed by us.

This product is being marketed and distributed by Precision Dose and its wholly owned subsidiary, TAGI, pursuant to the Precision Dose Licens Agreement, a description of which is set forth below.

Thirteen Abbreviated New Drug Applications

On August 1, 2013, Elite executed the Mikah ANDA Purchase with Mikah Pharma and acquired a total of thirteen ANDAs, consisting of twelv ANDAs approved by the FDA and one ANDA under active review with the FDA, and all amendments thereto (the "*Mikah Thirteen ANDA Acquisition*") for aggregate consideration of $10,000,000, payable pursuant to a secured convertible note due in August 2016.

Each of the products referenced in the twelve approved ANDAs require manufacturing site approval with the FDA. We believe that the site transfer qualify for Changes Being Effected in 30 Days ("*CBE 30*") review, with one exception, which would allow for the product manufacturing transfer on an expedited basis. However, we can give no assurances that all will qualify for CBE 30 review, or on the timing of these transfers of manufacturing site, or on the approval by the FDA of the transfers of manufacturing site.

As of the date of filing of this Annual Report on Form 10-K, the following products included in the Mikah Purchase Agreement have successfully achieved manufacturing site transfers:

- Phendimetrazine 35mg
- Isradipine 2.5mg and Isradipine 5mg
- Hydroxyzine 10mg, Hydroxyzine 25mg and Hydroxyzine 50mg

We have executed the Epic Pharma Manufacturing and License Agreement, relating to the manufacturing, marketing, and sale of these twelve ANDAs. Please see below for further details on the Epic Pharma Manufacturing and License Agreement.

Trimipramine

In May 2017, through Elite Labs, we acquired from Mikah Pharma an FDA approved ANDA for Trimipramine for aggregate consideration of $1,200,000. In conjunction with this acquisition, we also acquired from Mikah Pharma all rights, interests, and obligations under a supply and distribution agreement with Dr. Reddy's Laboratories, Inc. relating to the supply, sale and distribution of generic Trimipramine, and under a manufacturing and supply agreement with Epic Pharma relating to the manufacture and supply of Trimipramine.

Please see Item 13: "*Certain Relationships and Related Transactions and Director Independence; Certain Related Person Transactions Transactions with Nasrat Hakim and Mikah Pharma LLC"* below.

Licensing, Manufacturing and Development Agreements

Sales and Distribution Licensing Agreement with Epic Pharma LLC for SequestOx™

On June 4, 2015, we executed an exclusive License Agreement (the "*2015 SequestOx™ License Agreement*") with Epic, to market and sell in the U.S., SequestOx™, an immediate release oxycodone with sequestered naltrexone capsule, owned by us. Epic will have the exclusive right to market ELI-20 and its various dosage forms as listed in Schedule A of the Agreement. Epic is responsible for all regulatory and pharmacovigilance matters related to the products. Pursuant to the 2015 SequestOx™ License Agreement, Epic will pay us non-refundable payments totaling $15 million, with such amount representing the cost of an exclusive license to SequestOx™, the cost of developing the product, the filing of an NDA with the FDA and the receipt of the approval letter for the NDA from the FDA. As of the date of filing of this annual report on Form 10-K, the Company has received $7.5 million of the $15 million in non-refundable payments due pursuant to the 2015 SequestOx™ License Agreement, with such amount consisting of $5 million being due and owing on the execution date of the 2015 SequestOx™ License Agreement, and $2.5 million being earned as of January 14, 2016, the date of Elite's filing of an NDA with the FDA for the relevant product. Both of these non-refundable fees (i.e., the $5 million fee and the $2.5 million fee), have been paid by Epic.

The remaining $7.5 million in non-refundable payments due pursuant to the 2015 SequestOx™ License Agreement is due on the FDA's approval of SequestOx™ for commercial sale in the United States of America (please see the paragraph below for further details). In addition, we will receive a license fee computed as a percentage (50%) of net sales of the products as defined in the 2015 SequestOx™ License Agreement and is entitled to multi-million-dollar minimum annual license fees we will manufacture the product for sale by Epic on a cost-plus basis and both parties agree to execute a separate Manufacturing and Supply Agreement. The license fee is payable quarterly for the term of the 2015 SequestOx™ License Agreement. The term of the 2015 SequestOx™ License Agreement is five years and may be extended for an additional five years upon mutual agreement of the parties. Elite can terminate the 2015 SequestOx™ License Agreement on 90 days' written notice in the event that Epic does not pay us certain minimum annual license fees over the initial five-year term of the 2015 SequestOx™ License Agreement. Either party may terminate this 2015 SequestOx™ License Agreement upon a material breach and failure to cure that breach by the other party within a specified period.

Please see the above section titled *"SequestOx™ - Immediate Release Oxycodone with sequestered Naltrexone"* for further details on this product and especially note that, as of the date of filing of this Annual Report on Form 10-K, the NDA filed for this product has not been approved by the FDA. Furthermore, the 2015 SequestOx™ License Agreement has a five-year term, expiring on June 4, 2020, and Epic has previously advised the Company of their desire to extend this agreement. While discussions are ongoing, they are directly correlated to the regulatory status of SequestOx™. Furthermore, there can be no assurances that the parties will reach mutual agreement to extend the term of this agreement and no assurances that the terms and conditions of the agreement will be similar in all material aspects in the event that the agreement is extended by mutual agreement of the parties.

Manufacturing and License Agreement with Epic Pharma LLC

On October 2, 2013, we executed the Epic Pharma Manufacturing and License Agreement (the "*Epic Manufacturing and License Agreement*"). This agreement granted Epic certain rights to manufacture, market and sell in the United States and Puerto Rico the twelve approved ANDAs acquired by u pursuant to the Mikah Thirteen ANDA Acquisition. Of the twelve approved ANDAs, Epic will have the exclusive right to market six products as listed Schedule A of the Epic Manufacturing and License Agreement, and a non-exclusive right to market six products as listed in Schedule D of the Epi Manufacturing and License Agreement. Epic will manufacture the products and is responsible for all regulatory and pharmacovigilance matters related to the products and for all costs related to the site transfer for all products. We have no further obligations or deliverables under the Epic Manufacturing and License Agreement. Pursuant to the Epic Manufacturing and License Agreement, we will receive a license fee and milestone payments. The license fee will b computed as a percentage of the gross profit, as defined in the Epic Manufacturing and License Agreement, earned by Epic a result of sales of the products The manufacturing cost used for the calculation of the license fee is a predetermined amount per unit plus the cost of the active pharmaceutical ingredient ("*API*") and the sales cost for the calculation is predetermined based on net sales.

If we manufacture any product for sale by Epic, then Epic shall pay us the same predetermined manufacturing cost per unit plus the cost of the API The license fee is payable monthly for the term of the Epic Manufacturing and License Agreement. Epic shall pay to us certain milestone payments as define by the Epic Manufacturing and License Agreement. The term of the Epic Manufacturing and License Agreement is five years and may be extended for a additional five years upon mutual agreement of the parties. Twelve months following the launch of a product covered by the Epic Manufacturing and License Agreement, we may terminate the marketing rights for any product if the license fee paid, by Epic, falls below a designated amount for a six-month period of that product. We may also terminate the exclusive marketing rights if Epic is unable to meet the annual unit volume forecast for a designated product group for any year, subject to the ability of Epic, during the succeeding six-month period, to achieve at least one-half of the prior year's minimum annual unit forecast. The Epic Manufacturing and License Agreement may be terminated by mutual agreement, as a result of a breach by either party that is not cured within 60 days' notice of the breach, or by us as a result of Epic Pharma becoming a party to a bankruptcy, reorganization or other insolvency proceeding that continues for a period of 30 days or more.

The Epic Manufacturing and License Agreement expires on October 2, 2018. The Company is evaluating options available for the manufacture an marketing of products included in this agreement, with such options including, without limitation, extension of the agreement by mutual consent of Epic and Elite, marketing and/or manufacturing by a third party other than Epic, marketing and/or manufacturing by Elite, marketing and/or manufacturing by Epic under a new agreement. While Epic has launched four of the six exclusive products and Elite has collected $1.0 million of the $1.8 million total fee, collection of the remaining $800,000 is contingent upon Epic filing the required supplements with and receiving approval from the FDA for the remaining exclusive generic products. As the Epic Generic Agreement expires on October 2, 2018, it is unlikely that Epic will secure the required FDA approvals related to their payment to Elite of the remaining $800,000 milestones.

Trimipramine Acquisition

On May 16, 2017, we executed an asset purchase agreement with Mikah Pharma, and acquired from Mikah Pharma (the "*Trimipramine Acquisition*") an FDA approved ANDA for Trimipramine for aggregate consideration of $1,200,000, payable pursuant to a senior secured note due on December 31, 2020 (the "*Trimipramine Note*"). Mikah Pharma is owned by Nasrat Hakim, the CEO, President, and a director of the Company.

The Trimipramine Note bears interest at the rate of 10% per annum, payable quarterly. All principal and unpaid interest is due and payable on December 31, 2020. Pursuant to a security agreement, repayment of the Note is secured by the ANDA acquired in the Acquisition.

Trimipramine Distribution Agreement with Dr. Reddy's Laboratories, Inc. and Manufacturing Agreement with Epic

On May 17, 2017, in conjunction with the Trimipramine Acquisition, the Company executed an assignment agreement with Mikah Pharma, pursuant to which the Company acquired all rights, interests, and obligations under a supply and distribution agreement (the "*Reddy's Trimipramine Distribution Agreement*") with Dr. Reddy's Laboratories, Inc. ("*Dr. Reddy's*") originally entered into by Mikah Pharma on May 7, 2017 and relating to the supply, sale and distribution of generic Trimipramine Maleate Capsules 25mg, 50mg and 100mg.

On May 22, 2017, the Company executed an assignment agreement with Mikah Pharma, pursuant to which the Company acquired all rights, interest and obligations under a manufacturing and supply agreement with Epic originally entered into by Mikah in 2011 and amended on June 30, 2015 and relating to the manufacture and supply of Trimipramine (the "*Trimipramine Manufacturing Agreement*").

Under the Trimipramine Manufacturing Agreement, Epic will manufacture Trimipramine under license from the Company pursuant to the FDA approved and currently marketed Abbreviated New Drug Application that was acquired in conjunction with the Company's entry into these agreements.

Under the Reddy's Trimipramine Distribution Agreement, the Company will supply Trimipramine on an exclusive basis to Dr. Reddy's and Dr Reddy's will be responsible for all marketing and distribution of Trimipramine in the United States, its territories, possessions, and commonwealth. The Trimipramine will be manufactured by Epic and transferred to Dr. Reddy's at cost, without markup.

Dr. Reddy's will pay to the Company a share of the profits, calculated without any deduction for cost of sales and marketing, derived from the sale of Trimipramine. The Company's share of these profits is in excess of 50%.

Methadone Manufacturing and Supply Agreement

On June 23, 2011 and as amended on September 24, 2012, January 19, 2015, July 20, 2015 and as extended on August 9, 2016, we entered into an agreement to manufacture and supply Methadone 10mg to ThePharmaNetwork LLC (the "*Methadone Manufacturing and Supply Agreement*"). ThePharmaNetwork LLC was subsequently acquired by Alkem Laboratories Ltd ("*Alkem*") and now goes by the name Ascend Laboratories LLC ("*Ascend*") and is a wholly owned subsidiary of Alkem.

Ascend is the owner of the approved ANDA for Methadone 10mg, and the Northvale Facility is an approved manufacturing site for this ANDA. The Methadone Manufacturing and Supply Agreement provides for the manufacturing and packaging by the Company of Ascend's methadone hydrochloride 10mg tablets.

The initial shipment of Methadone 10mg pursuant to the Methadone Manufacturing and Supply Agreement occurred in January 2012.

On August 26, 2016, the Methadone Manufacturing and Supply Agreement was amended and extended through December 31, 2017.

Subsequent to the expiration of the Methadone Manufacturing and Supply Agreement, the Company honored purchase orders from Ascend, to manufacture Methadone. The commercial terms on those purchase orders honored were similar to those included in the expired agreement. There can be no assurances of purchase orders being received in the future from Ascend for the supply of Methadone. Furthermore, in the event that the Company receives a purchase order from Ascend for the manufacture/supply of Methadone, there can be no assurances of the Company's acceptance of such purchase or of its ability to manufacture Methadone for Ascend going forward, as well as there being no assurances of the commercial terms of any such activities going forward.

Precision Dose License Agreement

On September 10, 2010, we executed a License Agreement with Precision Dose (the "*Precision Dose License Agreement*") to market and distribute Phentermine 37.5mg, Phentermine 15mg, Phentermine 30mg, Hydromorphone 8mg, Naltrexone 50mg, and certain additional products that require approval from the FDA, through its wholly-owned subsidiary, TAGI, in the United States, Puerto Rico and Canada. Phentermine 37.5mg was launched in April 2011 Hydromorphone 8mg was launched in March 2012. Phentermine 15mg and Phentermine 30mg were launched in April 2013. Naltrexone 50mg was launched in September 2013. Precision Dose will have the exclusive right to market these products in the United States and Puerto Rico and a non-exclusive right to market the products in Canada.

Pursuant to the Precision Dose License Agreement, Elite will receive a license fee and milestone payments. The license fee will be computed as a percentage of the gross profit, as defined in the Precision Dose License Agreement, earned by Precision Dose as a result of sales of the products. The license fee is payable monthly for the term of the Precision Dose License Agreement. The milestone payments will be paid in six installments. The first installment was paid upon execution of the Precision Dose License Agreement. The remaining installments are to be paid upon FDA approval and initial shipment of the products to Precision Dose. The term of the Precision Dose License Agreement is 15 years and may be extended for 3 successive terms, each of 5 years.

Master Development and License Agreement with SunGen Pharma LLC

On August 24, 2016, as amended we entered into an agreement with SunGen Pharma LLC ("SunGen") (the "SunGen Agreement") to undertake an engage in the research, development, sales and marketing of eight generic pharmaceutical products. Two of the products are classified as CNS stimulants (the "CNS Products"), two of the products are classified as beta blockers and the remaining four products consist of antidepressants, antibiotics and antispasmodics. To date, the Company has filed ANDAs with the FDA for the two CNS Products identified in the SunGen Agreement.

Under the terms of the SunGen Agreement, Elite and SunGen will share in the responsibilities and costs in the development of these products and will share substantially in the profits from sales. Upon approval, the know-how and intellectual property rights to the products will be owned jointly by Elite and SunGen. Three of the eight products will be jointly owned, three products will be owned by SunGen, with Elite having exclusive marketing rights and the remaining two products will be owned by Elite, with SunGen having exclusive marketing rights. Elite will manufacture and package all eight products on a cost-plus basis.

On January 10, 2018, the Company reported positive topline results from pivotal bioequivalence studies for an undisclosed extended-release generic product in co-development with SunGen Pharma. The topline results indicate that the generic product is bioequivalent to the branded product. The studies were single dose crossover comparative bioavailability studies in healthy male and female volunteers in both the fed and fasting states. A fasting study with product beads sprinkled on to applesauce also demonstrated bioequivalence to the branded product. MS Health reported approximately $1.6 billion in revenue for the generic market for this product in 2017.

On February 8, 2018, the Company filed an ANDA with the FDA for a generic version of an immediate release central nervous system ("*CNS*") stimulant. The ANDA represents the first filing for a product co-developed with SunGen Pharma LLC ("*SunGen*") under the Development and License Agreement between SunGen and the Company dated August 24, 2016 (the "*SunGen Agreement*"). According to IMS Health data, the branded product and its equivalents had total U.S. sales of more than $400 million for the twelve months ended September 30, 2017. The Company has not yet received a response from the FDA on this filing.

On May 24, 2018, the Company filed an ANDA with the FDA for a generic version of an extended release CNS stimulant. The ANDA represents the second filing for a product co-developed with SunGen under the SunGen Agreement. According to IMS Health data, the branded product and its equivalents had total U.S. sales of approximately $1.6 billion for the twelve months ended September 30, 2017. The Company has not yet received a response from the FDA on this filing.

There can be no assurances that any of these products will receive marketing authorization and achieve commercialization within this time period, or at all. In addition, even if marketing authorization is received, there can be no assurances that there will be future revenues of profits, or that any such future revenues or profits would be in amounts that provide adequate return on the significant investments made to secure these marketing authorizations.

Strategic Marketing Alliance with Glenmark Pharmaceuticals, Inc. USA

On May 29, 2018, we entered into a license, manufacturing and supply agreement with Glenmark Pharmaceuticals Inc. USA ("*Glenmark*") to market the two Elite generic products described below in the United States with the option to add products in the future (the "*Glenmark Alliance*").

Pursuant to the Glenmark Alliance, Glenmark will purchase the products from Elite and then sell and distribute them. In addition to the purchase prices for the products, Elite will receive license fees well in excess of 50% of gross profits. Gross profits is defined as net sales less the price paid to Elite for the products, distribution fees (less than 10%) and shipping costs. Glenmark will have semi-exclusive marketing rights to the ANDA approved generic product phendimetrazine 35mg tablets, and exclusive marketing rights to an undisclosed generic version of a synthetic narcotic analgesic indicated for the management of pain, currently under review by the FDA with an expected approval date in the third quarter of calendar year 2018. Collectively, the brand products and their generic equivalents had total annual sales of approximately $33.6 million in 2017, according to Quintiles IMS Health data. The Agreement has an initial term of three years and automatically renews for one year periods absent prior written notice of non-renewal. In addition to customary termination provisions, the Agreement permits Glenmark to terminate with regard to a product on at least three months' prior written notice if it determines to stop marketing and selling such product, and it permits Elite to terminate with regard to a product if at anytime after the first twelvemonths from the first commercial sale, the average license fee paid by Glenmark for such product is less than a defined minimum amount.

Products Under Development

Elite's research and development activities are primarily focused on developing its proprietary abuse deterrent technology and the development of a range of abuse deterrent opioid products that utilize this technology or other approaches to abuse deterrence.

Elite's proprietary abuse-deterrent technology utilizes the pharmacological approach to abuse deterrence and consists of a multi-particulate capsule which contains an opioid agonist in addition to naltrexone, an opioid antagonist used primarily in the management of alcohol dependence and opioid dependence. When this product is taken as intended, the naltrexone is designed to pass through the body unreleased while the opioid agonist releases over time providing therapeutic pain relief for which it is prescribed. If the multi-particulate beads are crushed or dissolved, the opioid antagonist, naltrexone, is designed to release. The absorption of the naltrexone is intended to block the euphoria by preferentially binding to same receptors in the brain as the opioid agonist and thereby reducing the incentive for abuse or misuse by recreational drug abusers.

We filed an NDA for the first product to utilize our abuse deterrent technology, Immediate Release Oxycodone 5mg, 10mg, 15mg, 20mg and 30mg with sequestered Naltrexone (collectively and individually referred to as "*SequestOx™*"), on January 14, 2016. Please see "*Filed products under FDA review; SequestOx™ - Immediate Release Oxycodone with sequestered Naltrexone*" above.

On August 9, 2016, the Company filed an ANDA with the FDA for a generic version of Percocet® (oxycodone hydrochloride and acetaminophen USP CII) 5mg, 7.5mg and 10mg tablets with 325mg of acetaminophen ("*Generic Oxy/APAP*"). Please see "*Filed products under FDA review; Oxycodone hydrochloride and acetaminophen USP CII (generic version of Percocet®)*" above. Please note that there can be no assurances of this product receiving marketing authorization or achieving commercialization. In addition, even if marketing authorization is received and the product is commercialized, there can be no assurances of future revenues or profits in such amounts that would provide adequate return on the significant investments made to secure marketing authorization for this product.

On December 12, 2016, the Company filed an ANDA with the FDA for a generic version of Norco® (hydrocodone bitartrate and acetaminophe tablets USP CII) 2.5mg/325mg, 5mg/325mg, 7.5mg/325mg and 10mg/325mg tablets ("*Generic Hydrocodone/APAP*"). Please see "*Filed products under FDA review; Hydrocodone bitartrate and acetaminophen tablets USP CII (generic version of Norco)*" above. Please note that there can be no assurances of this product receiving marketing authorization or achieving commercialization. In addition, even if marketing authorization is received and the product is commercialized, there can be no assurances of future revenues or profits in such amounts that would provide adequate return on the significant investments made to secure marketing authorization for this product.

On April 4, 2017, the Company filed an ANDA with the FDA for a generic version of a synthetic narcotic analgesic indicated for the management o pain. The branded product and its equivalents have annual sales in excess of $30 million according to IMS Health Data. The Company expects a response from the FDA relating to this ANDA during the third quarter of the calendar year ended December 31, 2018. This product is an identified product in the Glenmar Alliance pursuant to which, subsequent to ANDA approval by the FDA, it will be manufactured by Elite and marketed/distributed by Glenmark. Please see th section above titled "*Strategic Marketing Alliance with Glenmark Pharmaceuticals, Inc. USA*" for further details. Please note that there can be no assurances of this product receiving marketing authorization or achieving commercialization. In addition, even if marketing authorization is received and the product is commercialized, there can be no assurances of future revenues or profits in such amounts that would provide adequate return on the significant investments made to secure marketing authorization for this product.

On September 20, 2017, the Company filed an ANDA with the FDA for generic version of Oxycontin® (extended release Oxycodon Hydrochloride). Please see "*Filed products under FDA review; Oxycodone Hydrochloride extended release (generic version of Oxycontin®*" above. Please note that there can be no assurances of this product receiving marketing authorization or achieving commercialization. In addition, even if marketing authorization is received and the product is commercialized, there can be no assurances of future revenues or profits in such amounts that would provide adequate return on the significant investments made to secure marketing authorization for this product.

On February 8, 2018, the Company filed an ANDA with the FDA for a generic version of an immediate release central nervous system ("*CNS*") stimulant. The ANDA represents the first filing for a product co-developed with SunGen Pharma LLC ("*SunGen*") under the SunGen Agreement. Please see "*Filed products under FDA review Generic version of immediate release Central Nervous System stimulant*" above. Please note that there can be no assurances of this product receiving marketing authorization or achieving commercialization. In addition, even if marketing authorization is received and the product is commercialized, there can be no assurances of future revenues or profits in such amounts that would provide adequate return on the significant investments made to secure marketing authorization for this product. Please also see the section below titled "*Master Development and License Agreement with SunGen Pharma LLC*".

On May 30, 2018, the Company filed an ANDA with the FDA for a generic version of an extended release CNS stimulant. The ANDA represen the second filing for a product co-developed with SunGen under the SunGen Agreement. Please see "*Filed products under FDA review Generic version of extended release Central Nervous System stimulant*" above. Please note that there can be no assurances of this product receiving marketing authorization or achieving commercialization. In addition, even if marketing authorization is received and the product is commercialized, there can be no assurances of future revenues or profits in such amounts that would provide adequate return on the significant investments made to secure marketing authorization for this product. Please also see the section below titled "*Master Development and License Agreement with SunGen Pharma LLC*".

The Company believes that the abuse deterrent technology can be applied to and incorporated into a wide range of opioids used today for pain management and has, to date, identified 10 additional products for potential development. All of these products are at early stages of development, with research and development activities mainly consisting of in-house process development and laboratory studies. Extensive efficacy and safety studies, similar to those conducted for SequestOx™, Generic Oxy/APAP and Generic Hydrocodone/APAP, have not yet been conducted for these other products. As a resul costs incurred in relation to the development of these 10 products have not been material.

Research and development costs were $9.6 million, $8.3 million, and $12.4 million for years ended March 31, 2018, 2017, and 2016, respectively. Costs incurred during the prior fiscal years relate almost entirely to the development of the abuse deterrent opioid product, SequestOx™ and the ongoing development of our abuse deterrent opioid and other products in addition to a focus on clinical trials for generic products. Costs incurred during the current fiscal year relate to bio equivalency and pilot studies for SequestOx™ and related costs, various clinical trials and studies relating to the development of multiple generic products, resulting in the filing of four ANDAs since the conclusion of the prior fiscal year, and costs relating to the development of additional generic products and the transfer of manufacturing operations of ANDAs previously approved.

On June 4, 2015, the Company entered into a sales and distribution licensing agreement which included a non-refundable payment of $5.0 million to Elite for prior research and development activities, with such representing the first material net cash inflows being generated by ELI-200. On January 14, 2016 the Company filed an NDA with the FDA for SequestOx™, thereby earning a non-refundable $2.5 million milestone. An additional $7.5 million non-refundabl milestone is due upon the FDA's approval of Elite's NDA. Please see the section above titled "*Licensing, Manufacturing and Development Agreements – Sales and Distribution Licensing Agreement with Epic Pharma LLC for SequestOx™*" for further details. Please also note that the non-receipt by the Company of these payments and or fees may materially and adversely affect our financial condition.

Please note that, while the FDA is required to review applications within certain timeframes, during the review process, the FDA frequently requests that additional information be submitted. The effect of such request and subsequent submission can significantly extend the time for the NDA review process. Until an NDA is actually approved, there can be no assurances that the information requested and submitted will be considered adequate by the FDA to justify approval. The packaging and labeling of our developed products are also subject to FDA regulation. Based on the foregoing, it is impossible to anticipate the amount of time that will be needed to obtain FDA approval to market any product. In addition, there can be no assurances of the Company filing the required application(s) with the FDA or of the FDA approving such application(s) if filed, and the Company's ability to successfully develop and commercialize products incorporating its abuse deterrent technology is subject to a high level of risk as detailed in "*Item 1A-Risk Factors-Risks Related to our Business*" of this Annual Report on Form 10-K.

Abuse-Deterrent and Sustained Release Opioids

The abuse-deterrent opioid products utilize our patented abuse-deterrent technology that is based on a pharmacological approach. These products are combinations of a narcotic agonist formulation intended for use in patients with pain, and an antagonist, formulated to deter abuse of the drug. Both, agonist and antagonist, have been on the market for a number of years and sold separately in various dose strengths. We have filed INDs for two abuse resistant products under development and have tested products in various pharmacokinetic and efficacy studies. We expect to continue to develop multiple abuse resistant products. Products utilizing the pharmacological approach to deter abuse such as Suboxone®, a product marketed in the United States by Reckitt Benckiser Pharmaceuticals, Inc., and Embeda®, a product marketed in the United States by Pfizer, Inc., have been approved by the FDA and are being marketed in the United States.

We have developed, licensed to Epic the marketing rights to SequestOx™, immediate release Oxycodone with Naltrexone, and retain the rights to the remainder of these abuse resistant and sustained release opioid products. We may license these products at a later date to a third party who could provide funding for the remaining clinical studies and who could provide sales and distribution for the product.

We also developed controlled release technology for oxycodone under a joint venture with Elan which terminated in 2002. According to the Elan Termination Agreement, we acquired all proprietary, development and commercial rights for the worldwide markets for the products developed by the joint venture, including the sustained release opioid products. Upon licensing or commercialization of an oral controlled release formulation of oxycodone for the treatment of pain, we will pay a royalty to Elan pursuant to the Elan Termination Agreement. If we were to sell the product itself, we will pay a 1% royalty to Elan based on the product's net sales, and if we enter into an agreement with another party to sell the product, we will pay a 9% royalty to Elan based on our net revenues from this product. We are allowed to recoup all development costs including research, process development, analytical development, clinical development and regulatory costs before payment of any royalties to Elan.

Patents

Since our incorporation, we have secured the following patents, of which two have been assigned for a fee to another pharmaceutical company. Our patents are:

PATENT	EXPIRATION DATE
U.S. patent 5,837,284 (assigned to Celgene Corporation)	November 2018
U.S. patent 6,620,439	October 2020
U.S. patent 6,926,909	April 2023
U.S. patent 8,182,836	April 2024
U.S. patent 8,425,933	April 2024
U.S. patent 8,703,186	April 2024
Canadian patent 2,521,655	April 2024
Canadian patent 2,541,371	September 2024
U.S. patent 9,056,054	June 2030
E.P. patent 1615623	April 2024

We also have pending applications for three additional U.S. patents non-provisional patents and one provisional patent and one foreign patent. We intend to apply for patents for other products in the future; however, there can be no assurance that any of the pending applications or other applications which we may file will be granted. We have also filed corresponding foreign applications for key patents.

Prior to the enactment in the United States of new laws adopting certain changes mandated by the General Agreement on Tariffs and Trade ("*GATT*"), the exclusive rights afforded by a U.S. Patent were for a period of 17 years measured from the date of grant. Under GATT, the term of any U.S Patent granted on an application filed subsequent to June 8, 1995 terminates 20 years from the date on which the patent application was filed in the United States or the first priority date, whichever occurs first. Future patents granted on an application filed before June 8, 1995, will have a term that terminates 20 years from such date, or 17 years from the date of grant, whichever date is later.

Under the Drug Price Competition Act, a U.S. product patent or use patent may be extended for up to five years under certain circumstances t compensate the patent holder for the time required for FDA regulatory review of the product. Such benefits under the Drug Price Competition Act ar available only to the first approved use of the active ingredient in the drug product and may be applied only to one patent per drug product. There can be no assurance that we will be able to take advantage of this law.

Also, different countries have different procedures for obtaining patents, and patents issued by different countries provide different degrees of protection against the use of a patented invention by others. There can be no assurance, therefore, that the issuance to us in one country of a patent covering an invention will be followed by the issuance in other countries of patents covering the same invention, or that any judicial interpretation of the validity, enforceability, or scope of the claims in a patent issued in one country will be similar to the judicial interpretation given to a corresponding patent issued in another country. Furthermore, even if our patents are determined to be valid, enforceable, and broad in scope, there can be no assurance that competitors will not be able to design around such patents and compete with us using the resulting alternative technology.

Trademarks

SequestOx™ is a trademark owned by Elite, which received a Notice of Allowance by the United States Patent and Trademark Office on Decembe 22, 2015.

We currently plan to license at least some of our products to other entities in the marketing of pharmaceuticals but may also sell products under our own brand name in which case we may register trademarks for those products.

Terminated Agreements

Terminated Agreement – Mikah Development Agreement

On January 28, 2015, The Development and License Agreement dated August 27, 2010 and between the Company and Mikah Pharma LLC (th "*Mikah Development Agreement*") was terminated by mutual agreement of the Company and Mikah Pharma LLC.

Pursuant to the Mikah Development Agreement, Mikah Pharma LLC ("*Mikah*") made advance consideration payments to the Company totaling $200,000 in exchange for product development services to be provided at a future date. Subsequent to the execution of the Mikah Development Agreement and before any development milestones were achieved, the sole owner of Mikah, Mr. Nasrat Hakim, became the President and CEO of the Company. Mika has accordingly ceased operating and is in the process of winding down and liquidating its assets.

Any further development of the product related to this agreement will belong to the Company, although there can be no assurances that such development will occur or be successful.

The Mikah Development Agreement requires that the consideration paid in advance to the Company be refunded in the event of no milestones being achieved. Mr. Hakim, as owner of Mikah, has directed that the $200,000 refund due to Mikah not be paid currently, but rather be added to the amounts due under the Hakim Credit Line.

For further details on the Mikah Development Agreement, please see Exhibit 10.6 of the Quarterly Report on Form 10-Q filed with the Securities an Exchange Commission (the "*SEC*") on November 14, 2010, with such filing being herein incorporated by reference.

For further details on the termination of the Mikah Development Agreement, please see Exhibit 10.84 of the Quarterly Report on Form 10-Q, file with the SEC on February 17, 2015, with such filing being herein incorporated by reference.

Terminated Agreement - Development and License Agreement with Hong Kong Based Company

On January 19, 2016, the Development and License Agreement ("*D&L Agreement*") between the Company and a private Hong-Kong based company dated March 16, 2012 was terminated. The D&L Agreement was for Elite to develop for the Hong Kong-based Customer a branded prescriptio pharmaceutical product in the United States. The Hong Kong-based Customer has informed us that it has been in business for more than five years and it ha multiple FDA approved manufacturing sites outside of the United States.

Pursuant to the D&L Agreement, the Hong Kong-based Customer engaged Elite to develop and manufacture a prescription pharmaceutical produc (the "*Prescription Product*"), with such development not being successfully completed.

For further details on the D&L Agreement, please refer to Exhibit 10.77 to the Annual Report on Form 10-K filed with the SEC on June 29, 2012.

Terminated Agreement – Methadone Manufacturing and Supply Agreement

On December 31, 2017, the Methadone Manufacturing and Supply Agreement terminated in accordance with the terms of the agreement.

Other Business Factors and Details

Government Regulation and Approval

The design, development, and marketing of pharmaceutical compounds, on which our success depends, are intensely regulated by governmental regulatory agencies, in particular the FDA. Non-compliance with applicable requirements can result in fines and other judicially imposed sanctions, including product seizures, injunction actions and criminal prosecution based on products or manufacturing practices that violate statutory requirements. In addition, administrative remedies can involve voluntary withdrawal of products, as well as the refusal of the FDA to approve ANDAs and NDAs. The FDA also ha the authority to withdraw approval of drugs in accordance with statutory due process procedures.

Before a drug may be marketed, it must be approved by the FDA either by an NDA or an ANDA, each of which is discussed below.

Lodrane D® which is an immediate release product that is different from the Lodrane Products that were included in the list of products removed from the market by the FDA, is marketed under the Over-the-Counter Monograph (the "*OTC Monograph*") and accordingly, under the Code of Federal Regulations can be lawfully marketed in the U.S. without prior approval. Under the Federal Food Drug and Cosmetic Act ("*FDCA*"), FDA regulations and statements of FDA policy, certain drug products are permitted to be marketed in the U.S. without prior approval. Within the past few years, the FDA has revised its enforcement policies, significantly limiting the circumstances under which these unapproved products may be marketed. If the FDA determines that a company is distributing an unapproved product that requires approval, the FDA may take enforcement action in a variety of ways, including, without limitation, product seizures and seeking a judicial injunction against distribution.

NDAs and NDAs under Section 505(b) of the Drug Price Competition Act

The FDA approval procedure for an NDA is generally a two-step process. During the Initial Product Development stage, an investigational new dru application ("*IND*") for each product is filed with the FDA. A 30-day waiting period after the filing of each IND is required by the FDA prior to th commencement of initial clinical testing. If the FDA does not comment on or question the IND within such 30-day period, initial clinical studies may begin. I however, the FDA has comments or questions, they must be answered to the satisfaction of the FDA before initial clinical testing may begin. In some instances, this process could result in substantial delay and expense. Initial clinical studies generally constitute Phase I of the NDA process and are conducted to demonstrate the product tolerance/safety and pharmacokinetic in healthy subjects.

After Phase I testing, extensive efficacy and safety studies in patients must be conducted. After completion of the required clinical testing, an NDA is filed, and its approval, which is required for marketing in the United States, involves an extensive review process by the FDA. The NDA itself is a complicate and detailed application and must include the results of extensive clinical and other testing, the cost of which is substantial. However, the NDA filings contemplated by us, which are already marketed drugs, would be made under Sections 505 (b)(1) or 505 (b)(2) of the Drug Price Competition Act, which do not require certain studies that would otherwise be necessary; accordingly, the development timetable should be shorter. While the FDA is required to review applications within a certain timeframe, during the review process, the FDA frequently requests that additional information be submitted. The effect of such request and subsequent submission can significantly extend the time for the NDA review process. Until an NDA is actually approved, there can be no assurance that the information requested and submitted will be considered adequate by the FDA to justify approval. The packaging and labeling of our developed products are also subject to FDA regulation. It is impossible to anticipate the amount of time that will be needed to obtain FDA approval to marke any product.

Whether or not FDA approval has been obtained, approval of the product by comparable regulatory authorities in any foreign country must be obtained prior to the commencement of marketing of the product in that country. We intend to conduct all marketing in territories other than the United States through other pharmaceutical companies based in those countries. The approval procedure varies from country to country, can involve additional testing, and the time required may differ from that required for FDA approval. Although there are some procedures for unified filings for certain European countries, in genera each country has its own procedures and requirements, many of which are time consuming and expensive. Thus, there can be substantial delays in obtaining required approvals from both the FDA and foreign regulatory authorities after the relevant applications are filed. After such approvals are obtained, further delays may be encountered before the products become commercially available.

ANDAs

The FDA approval procedure for an ANDA differs from the procedure for an NDA in that the FDA waives the requirement of conducting complet clinical studies, although it normally requires bioavailability and/or bioequivalence studies. "*Bioavailability*" indicates the rate and extent of absorption and levels of concentration of a drug product in the blood stream needed to produce a therapeutic effect. "*Bioequivalence*" compares the bioavailability of one drug product with another, and when established, indicates that the rate of absorption and levels of concentration of the active drug substance in the body are equivalent for the generic drug and the previously approved drug. An ANDA may be submitted for a drug on the basis that it is the equivalent of a previously approved drug or, in the case of a new dosage form, is suitable for use for the indications specified.

The timing of final FDA approval of an ANDA depends on a variety of factors, including whether the applicant challenges any listed patents for the drug and whether the brand-name manufacturer is entitled to one or more statutory exclusivity periods, during which the FDA may be prohibited from accepting applications for, or approving, generic products. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, and thus block ANDAs from being approved on the patent expiration date.

In May 1992, Congress enacted the Generic Drug Enforcement Act of 1992, which allows the FDA to impose debarment and other penalties o individuals and companies that commit certain illegal acts relating to the generic drug approval process. In some situations, the Generic Drug Enforcement Ac requires the FDA to not accept or review ANDAs for a period of time from a company or an individual that has committed certain violations. It also provide for temporary denial of approval of applications during the investigation of certain violations that could lead to debarment and also, in more limited circumstances, provides for the suspension of the marketing of approved drugs by the affected company. Lastly, the Generic Drug Enforcement Act allows for civil penalties and withdrawal of previously approved applications. Neither we nor any of our employees have ever been subject to debarment. We do not believe that we receive any services from any debarred person.

Controlled Substances

We are also subject to federal, state, and local laws of general applicability, such as laws relating to working conditions. We are also licensed by, registered with, and subject to periodic inspection and regulation by the Drug Enforcement Agency ("*DEA*") and New Jersey state agencies, pursuant to federal and state legislation relating to drugs and narcotics. Certain drugs that we currently develop or may develop in the future may be subject to regulations under the Controlled Substances Act and related statutes. As we manufacture such products, we may become subject to the Prescription Drug Marketing Act which regulates wholesale distributors of prescription drugs.

cGMP

All facilities and manufacturing techniques used for the manufacture of products for clinical use or for sale must be operated in conformity with cGMP regulations issued by the FDA. We engage in manufacturing on a commercial basis for distribution of products and operate our facilities in accordance with cGMP regulations. If we hire another company to perform contract manufacturing for us, we must ensure that our contractor's facilities conform to cGMP regulations.

Compliance with Environmental Laws

We are subject to comprehensive federal, state and local environmental laws and regulations that govern, among other things, air polluting emissions, waste water discharges, solid and hazardous waste disposal, and the remediation of contamination associated with current or past generation handling and disposal activities, including the past practices of corporations as to which we are the legal successor or in possession. We do not expect that compliance with such environmental laws will have a material effect on our capital expenditures, earnings, or competitive position in the foreseeable future. There can be no assurance, however, that future changes in environmental laws or regulations, administrative actions or enforcement actions, or remediation obligations arising under environmental laws will not have a material adverse effect on our capital expenditures, earnings, or competitive position.

Competition

We have competition with respect to our principal areas of operation. We develop and manufacture generic products, products using controlled-release drug technology, products utilizing abuse deterrent technologies, and we develop and market (either on our own or by license to other companies) generic and proprietary controlled-release and abuse deterrent pharmaceutical products. In both areas, our competition consists of those companies which develop controlled-release, abuse deterrent drugs and alternative drug delivery systems. We do not represent a significant presence in the pharmaceutical industry.

An increasing number of pharmaceutical companies have become interested in the development and commercialization of products incorporating advanced or novel drug delivery systems. Some of the major pharmaceutical companies have invested and are continuing to invest significant resources in the development of their own drug delivery systems and technologies and some have invested funds in such specialized drug delivery companies. Many of these companies have greater financial and other resources as well as more experience than we do in commercializing pharmaceutical products. Certain companies have a track record of success in developing controlled-release drugs. Significant among these are, without limitation, Pfizer, Sandoz (a Novartis company) Durect Corporation, Mylan Laboratories, Inc., Par Pharmaceuticals, Inc., Alkermes, Inc., Teva Pharmaceuticals Industries Ltd., Impax Laboratories, Inc., a Allergen. Each of these companies has developed expertise in certain types of drug delivery systems, although such expertise does not carry over to developing a controlled-release version of all drugs. Such companies may develop new drug formulations and products or may improve existing drug formulations and products more efficiently than we can. In addition, almost all of our competitors have vastly greater resources than we do. While our product development capabilities and, if obtained, patent protection may help us to maintain our market position in the field of advanced drug delivery, there can be no assurance that others will not be able to develop such capabilities or alternative technologies outside the scope of our patents, if any, or that even if patent protection is obtained, such patents will not be successfully challenged in the future.

In addition to competitors that are developing products based on drug delivery technologies, there are also companies that have announced that they are developing opioid abuse-deterrent products that might compete directly or indirectly with Elite's products. These include, but are not limited to Pfizer Inc. Pain Therapeutics (which has an agreement with Durect Corporation and Pfizer Inc.), Collegium Pharmaceuticals, Inc., Purdue Pharma LP, and Acu Pharmaceuticals, Inc.

We also face competition in the generic pharmaceutical market. The principal competitive factors in the generic pharmaceutical market include: (i) introduction of other generic drug manufacturers' products in direct competition with our products under development, (ii) introduction of authorized generic products in direct competition with any of our products under development, particularly if such products are approved and sold during exclusivity periods, (iii) consolidation among distribution outlets through mergers and acquisitions and the formation of buying groups, (iv) ability of generic competitors to quickly enter the market after the expiration of patents or exclusivity periods, diminishing the amount and duration of significant profits, (v) the willingness of generic drug customers, including wholesale and retail customers, to switch among pharmaceutical manufacturers, (vi) pricing pressures and product deletions by competitors, (vii) a company's reputation as a manufacturer and distributor of quality products, (viii) a company's level of service (including maintaining sufficient inventory levels for timely deliveries), (ix) product appearance and labeling and (x) a company's breadth of product offerings.

Sources and Availability of Raw Materials; Manufacturing

A significant portion of our raw materials may be available only from foreign sources. Foreign sources can be subject to the special risks of doing business abroad, including:

- greater possibility for disruption due to transportation or communication problems;
- the relative instability of some foreign governments and economies;
- interim price volatility based on labor unrest, materials or equipment shortages, export duties, restrictions on the transfer of funds, or fluctuations in currency exchange rates; and,
- uncertainty regarding recourse to a dependable legal system for the enforcement of contracts and other rights.

While we currently obtain the raw materials that we need from over 20 suppliers, some materials used in our products are currently available from only one supplier or a limited number of suppliers. The FDA requires identification of raw material suppliers in applications for approval of drug products. I raw materials were unavailable from a specified supplier, FDA approval of a new supplier could delay the manufacture of the drug involved.

We have acquired pharmaceutical manufacturing equipment for manufacturing our products. We have registered our facilities with the FDA and the DEA.

Please see the Risk Factor in Part I, Item 1A entitled "*We are dependent on a small number of suppliers for our raw materials and any delay or unavailability of raw materials can materially adversely affect our ability to produce products*".

Dependence on One or a Few Major Customers

Each year we have had one or a few customers that have accounted for a large percentage of our limited revenues, therefore the termination or restructuring of a contract with a customer may result in the loss of material amount or substantially all of our revenues. We are constantly working to develop new relationships with existing or new customers, but despite these efforts we may not, at the time that any of our current contracts expire, have other contracts in place generating similar or material revenue. We have agreements with Epic, Precision Dose and Ascend for the licensing, sales and distribution of products that we manufacture. We are currently renegotiating a licensing contract with Epic, which may result in the termination of an existing contract or an amended licensing contract that is materially different from that already in place. We receive revenues to manufacture these products and also receive a profit split or royalties based on in-market sales of the products. Please see the Risk Factor in Part I, Item 1A entitled "*We depend on a limited number of customers and any reduction, delay or cancellation of an order from these customers or the loss of any of these customers could cause our revenue to decline*."

Our Reporting Segments

We currently operate in two segments, which are products whose marketing approvals were secured via an ANDA and products whose marketing approvals were secured via an NDA. ANDA products are referred to as generic pharmaceuticals and NDA products are referred to as brande pharmaceuticals. For the years ended March 31, 2018, 2017 and 2016 revenue from our ANDA segment was $6.5 million, $8.6 million and $9.2 million respectively. For the years ended March 31, 2018, 2017 and 2016 revenue from our NDA segment was $1.0 million, $1.0 million and $3.3 million, respectively.

Segment information is consistent with the financial information regularly reviewed by our chief operating decision maker, who we have determined to be the chief executive office, for the purposes of making decisions about allocating resources and assessing performance of the Company. 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.

Employees

As of June 7, 2018, we had 43 full time employees. Full-time employees are engaged in operations, administration, research, and development. None of our employees is represented by a labor union and we have never experienced a work stoppage. We believe our relationship with our employees to be good. However, our ability to achieve our financial and operational objectives depends in large part upon our continuing ability to attract, integrate, retain, and motivate highly qualified personnel, and upon the continued service of our senior management and key personnel.

Available Information

We file our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Exchange Act electronically with the Securities and Exchange Commission, or SEC. The public may read or copy any materials we file with the SEC at th SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Roo by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other informatio regarding issuers that file electronically with the SEC. The address of that site is http://www.sec.gov.

You may obtain a free copy of our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K and amendments to those reports on the day of filing with the SEC on our website athttp://www.Elitepharma.com under the Investor Relations tab for SEC Filings or b contacting the Investor Relations Department by calling (518) 398-6222 or sending an e-mail message to dianne@elitepharma.com.

ITEM 1A. RISK FACTORS

An investment in the Company's Common Stock involves a high degree of risk. You should carefully consider the risks described below as well as other information provided to you in this report, including information in the section of this document entitled "*Forward Looking Statements*." The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial may also impair our business operations. If any of the following risks actually occur, our business, financial condition or results of operations could be materially adversely affected, the value of our Common Stock could decline, and you may lose all or part of your investment.

In addition to the other information contained in this report, the following risk factors should be considered carefully in evaluating an investment in us and in analyzing our forward-looking statements.

Risks Related to Our Business

Our revenues and operating results could fluctuate significantly

Our revenues and operating results may vary significantly from year-to-year and quarter-to-quarter as well as in comparison to the corresponding quarter of the preceding year. Variations my result from one or more factors, including, without limitation:

- Timing of approval of applications filed with the FDA;
- Timing of process validation, product launches and market acceptance of products launched;
- Changes in the amounts spent to research, develop, acquire, license or promote new and existing products;
- Results of clinical trial programs;
- Serious or unexpected health or safety concerns with our products, brand products which we have genericized, products currently under development or any other product candidates;
- Introduction of new products by others that render our products obsolete or noncompetitive;
- The ability to maintain selling prices and gross margin on our products;

- The cost and outcome of litigation, in the event that such occurs in relation to, without limitation, intellectual property issues, regulatory or other matters;
- The ability to comply with complex and numerous governmental regulations and regulatory authorities which oversee and regulate many aspects of our business and operations;
- Changes in coverage and reimbursement policies of health plans and other health insurers, including changes to Medicare, Medicaid, and similar state programs, especially in relation to those products that are currently manufactured, under development or identified for future development by the Company;
- Increases in the cost of raw materials contained within our products;
- Manufacturing and supply interruptions, including product rejections or recalls due to failure to comply with manufacturing specifications;
- Timing of revenue recognition relating to our licensing and other agreements;
- The ability to protect our intellectual property from being acquired by other entities;
- The ability to avoid infringing the intellectual property of others;
- Our ability to manage growth and integrate acquired products and assets successfully; and
- The addition or loss of customers.

We have a relatively limited operating history, which makes it difficult to evaluate our future prospects.

Although we have been in operation since 1990, we have a relatively short operating history and limited financial data upon which you may evaluate our business and prospects. In addition, our business model is likely to continue to evolve as we attempt to expand our product offerings and our presence in the generic pharmaceutical market. As a result, our potential for future profitability must be considered in view of the risks, uncertainties, expenses, and difficulties frequently encountered by companies that are attempting to move into new markets and continuing to innovate with new and unproven technologies. Some of these risks relate to our potential inability to:

- develop new products;
- obtain regulatory approval of our products;
- manage our growth, control expenditures and align costs with revenues;
- attract, retain, and motivate qualified personnel; and respond to competitive developments.

If we do not effectively address the risks we face, our business model may become unworkable and we may not achieve or sustain profitability or successfully develop any products.

We have not been profitable and expect future losses.

To date, we have not been profitable, and we may never be profitable or, if we become profitable, we may be unable to sustain profitability. We have sustained losses from operations in each year since our incorporation in 1990. During the years ended March 31, 2018, 2017 and 2016, we incurred net losses from operations of approximately ($9.1) million, ($7.4) million, and ($8.3) million, respectively. We expect to continue to incur losses until we are able to generate sufficient revenues to support our operations and offset operating costs.

We may require additional financing to meet our business objectives

Although we believe that we have adequate financial resources on hand as of March 31, 2018 to support the anticipated commercial launch of SequestOx™ and also ensure operations through March 31, 2019, we cannot assure that we will not need additional funding to accomplish our plans to conduct the clinical development and commercialization of a range of multiple abuse resistant opioids on an accelerated pace.

As of March 31, 2018, we had cash on hand of approximately $7.2 million and a working capital surplus of $8.6 million, and, for the fiscal year ended March 31, 2018, we had losses from operations totaling ($9.1) million, net other income totaling $4.4 million and net loss of ($3.7) million.

On May 1, 2017, we entered into another 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, we have the right to sell to and Lincoln Park is obligated to purchase up to $40 million in shares of our common stock, subject to certain limitations, from time to time, over the 36-month period commencing on June 5, 2017.

The extent we rely on Lincoln Park as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. If obtaining sufficient funding from Lincoln Park were to prove unavailable or prohibitively dilutive, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we sell all shares under the 2017 LPC Purchase Agreement, we may still need additional capital to fully implement our business, operating and development plans. For more information on the Lincoln Park Capital transaction, see Part II, Item 7 "*Management's Discussion and Analysis of Financial Condition and Results of Operations; Liquidity and Capital Resources; Lincoln Park Capital*".

We are anticipating that, with the growth of the current generic product line consisting of generic phentermine tablets and capsules, hydromorphone, naltrexone, phendimetrazine, isradipine, hydroxyzine and trimipramine, combined with the successful transfer of manufacturing site and commercial launch of the six remaining approved generic products acquired pursuant to the Mikah Thirteen ANDA Acquisition, profit splits earned from the commercial sale of Oxy IR by Epic, pursuant to the Epic Strategic Alliance Agreement, profit splits earned from the commercial sale of products under the Epic Manufacturing an License Agreement, manufacturing revenues and profit splits earned from the commercial sales of products under the Glenmark Alliance, profit splits earned from the commercial sale of Trimipramine pursuant to the Reddy's Trimipramine Distribution Agreement, revenues and profits earned pursuant to the SunGer Agreement and other opportunities in our pipeline, Elite eventually could be profitable. However, there can be no assurances of Elite becoming profitable, with such being attributed in large part to there being no assurances of the continuation of revenues being earned from the current generic product line, no assurances of Elite's successful transfer of the six remaining approved generic products acquired pursuant to the Mikah Thirteen ANDA Acquisition, nc assurances of continued profit splits being earned from the commercial sales Oxy-IR by Epic and no assurances of manufacturing revenues and profit splits being earned pursuant to the Glenmark Alliance. In addition, there can be no assurances of Elite being able to raise additional funds in a timely manner, or acceptable terms, if needed to support commercial operations, whether from the 2017 LPC Purchase Agreement or otherwise, resulting in a materia detrimental effect on Elite's ability to become profitable.

To sustain operations and meet our business objectives we must be able to commercialize our products and other products or pipeline opportunities. If we are unable to timely obtain additional financing, if necessary, and/or we are unable to timely generate greater revenues from our operations, we will be required to reduce and, possibly, cease operations and liquidate our assets. No assurance can be given that we will be able to commercialize the new opportunities or consummate such other financing or strategic alternative in the time necessary to avoid the cessation of our operations and liquidation of our assets.

Furthermore, the capital and credit markets have experienced extreme volatility. Disruptions in the credit markets make it harder and more expensive to obtain funding. In the event current resources do not satisfy our needs, we may have to seek additional financing. The availability of additional financing wil depend on a variety of factors such as market conditions and the general availability of credit. Future debt financing may not be available to us when required or may not be available on acceptable terms, and as a result we may be unable to grow our business, take advantage of business opportunities, or respond to competitive pressures.

We depend on a limited number of customers and any reduction, delay or cancellation of an order from these customers or the loss of any of these customers could cause our revenue to decline.

Each year we have had one or a few customers that have accounted for a large percentage of our limited revenues therefore the termination of a contract with a customer may result in the loss of substantially all of our revenues. We are constantly working to develop new relationships with existing or new customers, but despite these efforts we may not, at the time that any of our current contracts expire, have other contracts in place generating similar or material revenue. We have agreements with Epic, Ascend and Precision Dose for the sales and distribution of products that we manufacture. We receive revenues to manufacture these products and also receive a profit split or royalties based on in-market sales of the products.

In addition, since a significant portion of our revenues is derived from a relatively few customers, any financial difficulties experienced by any one of these customers, or any delay in receiving payments from any one of these customers, could have a material adverse effect on our business, results of operations, financial condition, and cash flows.

A notice of default was issued by the New Jersey Economic Development Authority in relation to prior obligations of our tax-exempt bonds Although we are current in our payments under these bonds, if the principal balances due under these bonds are accelerated pursuant to the notice of default, our ability to operate in the future will be materially and adversely affected.

Although we are current in our payments under the NJEDA Bonds, we previously were in default and a notice of default was issued in March 2009 Should the principal balances due under the NJEDA Bonds be accelerated pursuant to such notice of default, our ability to operate in the future will b materially and adversely affected.

For more information on the NJEDA Bonds, see Part II, Item 7 "*Management's Discussion and Analysis of Financial Condition and Results o Operations; Liquidity and Capital Resources; NJEDA Bonds*".

Elite's pipeline consists of products in various stages of development, including products in early development.

Elite's product pipeline, including its abuse deterrent opioid products, are in various stages of development. Prior to commercialization, product development must be completed that could include scale-up, clinical studies, regulatory filing, regulatory review, approval by the FDA, and/or other development steps. Additionally, Elite has 6 approved generic products for which a site transfer must be completed prior to product launches. For these generic products, Elite must complete site transfer studies, file change being effective in 30 days ("*CBE 30*") and await FDA review and approval. Development is subject to risks. We cannot assure you that development will be successful, or that during development unexpected delays might occur or additional costs might be incurred.

The pharmaceutical industry is heavily regulated, which creates uncertainty about our ability to bring new products to market and imposes substantial compliance costs on our business in relation to product development as well as commercial operations.

Governmental authorities such as the FDA impose substantial requirements on the development, manufacture, holding, labeling, marketing, advertising promotion, distribution and sale of therapeutic pharmaceutical products through lengthy and detailed laboratory and clinical testing and other costly and time-consuming procedures. In addition, before obtaining regulatory approvals for certain generic products, we must conduct limited bioequivalence studies and other research to show comparability to the branded products. A failure to obtain satisfactory results in required pre-marketing trials may prevent us from obtaining required regulatory approvals. The FDA may also require companies to conduct post-approval studies and post-approval surveillance regarding their drug products and to report adverse events.

Before obtaining regulatory approvals for the sale of any of our new product candidates, we must demonstrate through preclinical studies and clinical trials that the product is safe and effective for each intended use. Preclinical and clinical studies may fail to demonstrate the safety and effectiveness of a product. Likewise, we may not be able to demonstrate through clinical trials that a product candidate's therapeutic benefits outweigh its risks. Even promising results from preclinical and early clinical studies do not always accurately predict results in later, large scale trials. A failure to demonstrate safety and efficacy could or would result in our failure to obtain regulatory approvals. Clinical trials can be delayed for reasons outside of our control, which can lead to increased development costs and delays in regulatory approval. For example, due to competition to enroll patients in clinical trials, there have been instances of delays in clinical development of our products in the past, as a result of patients not enrolling in clinical trials at the rate expected, or patients dropping out of trials after enrolling, at rates that were higher than expected. In addition, we rely on collaboration partners and third-party subject matter experts that may recommend changes in trial protocol and design enhancements that are put into effect, or encounter clinical trial compliance-related issues, which may also delay clinical trials. Product supplies may be delayed or be insufficient to treat the patients participating in the clinical trials, or manufacturers or suppliers may not meet the requirements of the FDA or foreign regulatory authorities, such as those relating to Current Good Manufacturing Practices. We also may experience delays in obtaining, or we may not obtain, required initial and continuing approval of our clinical trials from institutional review boards. We cannot confirm to you that we will not experience delays or undesired results in these or any other of our clinical trials.

We cannot confirm to you that the FDA will approve, clear for marketing or certify any products developed by us or that such approval will not subject the marketing of our products to certain limits on indicated use. The FDA may not agree with our assessment of the clinical data or they may interpret it differently. Such regulatory authorities may require additional or expanded clinical trials. Any limitation on use imposed by the FDA or delay in or failure to obtain FDA approvals or clearances of products developed by us would adversely affect the marketing of these products and our ability to generate product revenue, which would adversely affect our financial condition and results of operations.

In addition, with respect specifically to pharmaceutical products, the submission of a New Drug Application (NDA), such as SequestOx™, or ANDA to the FDA with supporting clinical safety and efficacy data, for example, does not guarantee that the FDA will grant approval to market the product. Meeting the FDA's regulatory requirements to obtain approval to market a drug product, which varies substantially based on the type, complexity and novelty of the pharmaceutical product, typically takes years and is subject to uncertainty.

Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. Although the FDA is not required to follow the recommendations of its Advisory Committees, it usually does. A negative Advisory Committee meeting could signal a lower likelihood of approval, although the FDA may still end up approving our application. Regardless of an Advisory Committee meeting outcome or the FDA's final approval decision, public presentation of our data may shed positive or negative light on our application.

Some drugs are available in the United States that are not the subject of an FDA-approved NDA. In 2011, the FDA's Center for Drug Evaluation and Research ("*CDER*") Office of Compliance modified its enforcement policy with regard to the marketing of such "unapproved" marketed drugs. Under CDER's revised guidance, the FDA encourages manufacturers to obtain NDA approvals for such drugs by requiring unapproved versions to be removed from the market after an approved version has been introduced, subject to a grace period at the FDA's discretion. This grace period is intended to allow an orderly transition of supply to the market and to mitigate any potential related drug shortage. Depending on the length of the grace period and the time it takes for subsequent applications to be approved, this may result in a period of de facto market exclusivity to the first manufacturer that has obtained an approved NDA for the previously unapproved marketed drug. We may seek FDA approval for certain unapproved marketed drug products through the 505(b)(2) regulatory pathway. Even if we receive approval for an NDA under Section 505(b)(2), the FDA may not take timely enforcement action against companies marketing unapproved versions of the drug; therefore, we cannot be sure that that we will receive the benefit of any de facto exclusive marketing period or that we will fully recoup the expenses incurred to obtain an approval. In addition, certain competitors and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, this could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

Moreover, even if our product candidates are approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

The ANDA approval process for a new product varies in time, is difficult to estimate and can vary significantly, from as little as 10 months from the date of application, to several years or more. Furthermore, ANDA approvals, if granted, may not include all indications for which the Company may seek to market each product.

Further, once a product is approved or cleared for marketing, failure to comply with applicable regulatory requirements can result in, among other things, suspensions or withdrawals of approvals or clearances, seizures or recalls of products, injunctions against the manufacture, holding, distribution, marketing and sale of a product, and civil and criminal sanctions. Furthermore, changes in existing regulations or the adoption of new regulations could prevent us from obtaining, or affect the timing of, future regulatory approvals or clearances. Meeting regulatory requirements and evolving government standards may delay marketing of our new products for a considerable period of time, impose costly procedures upon our activities and result in a competitive advantage to larger companies that compete against us.

Based on scientific developments, post-market experience, or other legislative or regulatory changes, the current FDA standards of review for approving new pharmaceutical products, or new indications or uses for approved or cleared products, are sometimes more stringent than those that were applied in the past.

Some new or evolving FDA review standards or conditions for approval or clearance were not applied to many established products currently on the market, including certain opioid products. As a result, the FDA does not have as extensive safety databases on these products as on some products developed more recently. Accordingly, we believe the FDA has expressed an intention to develop such databases for certain of these products, including many opioids. In particular, the FDA has expressed interest in specific chemical structures that may be present as impurities in a number of opioid narcotic active pharmaceutical ingredients, such as oxycodone, which based on certain structural characteristics and laboratory tests may indicate the potential for having mutagenic effects. FDA has required, and may continue to require, more stringent controls of the levels of these impurities in drug products for approval.

Also, the FDA may require labeling revisions, formulation, or manufacturing changes and/or product modifications for new or existing products containing such impurities. The FDA's more stringent requirements, together with any additional testing or remedial measures that may be necessary, could result in increased costs for, or delays in, obtaining approval for certain of our products in development. Although we do not believe that the FDA would seek to remove a currently marketed product from the market unless such mutagenic effects are believed to indicate a significant risk to patient health, we cannot make any such assurance.

In May of 2016, an FDA advisory panel recommended mandatory training of all physicians who prescribe opioids on the risks of prescription opioids. In 2016, the CDC also issued a guideline for prescribing opioids for chronic pain that provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. In addition, state health departments and boards of pharmacy have authority to regulate distribution and may modify their regulations with respect to prescription narcotics in an attempt to curb abuse. In either case, any such new regulations or requirements may be difficult and expensive for us to comply with, may delay our introduction of new products, may adversely affect our total revenues, and may have a material adverse effect on our business, results of operations, financial condition and cash flows.

The FDA has the authority to require companies to undertake additional post-approval studies to assess known or signaled safety risks and to make any labeling changes to address those risks. The FDA also can require companies to formulate approved Risk Evaluation and Mitigation Strategies (REMS) to confirm a drug's benefits outweigh its risks.

The FDA's exercise of its authority under the FFDCA could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with additional post-approval regulatory requirements and potential restrictions on sales of approved products. Foreign regulatory agencies often have similar authority and may impose comparable requirements and costs. Post-marketing studies and other emerging data about marketed products, such as adverse event reports, may also adversely affect sales of our products. Furthermore, the discovery of significant safety or efficacy concerns or problems with a product in the same therapeutic class as one of our products that implicate or appear to implicate the entire class of products could have an adverse effect on sales of our product or, in some cases, result in product withdrawals. The FDA has continuing authority over the approval of an NDA or ANDA and may withdraw approval if, among other reasons, post-marketing clinical or other experience, tests, or data show that a drug is unsafe for use under the conditions upon which it was approved, or if FDA determines that there is a lack of substantial evidence of the drug's efficacy under the conditions described in its labeling. Furthermore, new data and information, including information about product misuse or abuse at the user level, may lead government agencies, professional societies, practice management groups or patient or trade organizations to recommend or publish guidance or guidelines related to the use of our products, which may lead to reduced sales of our products.

The FDA and the DEA have important and complementary responsibilities with respect to our business. The FDA administers an application and post-approval monitoring process to confirm that products that are available in the market are safe, effective, and consistently of uniform, high quality. The DEA administers registration, drug allotment and accountability systems to satisfy against loss and diversion of controlled substances. Both agencies have trained investigators that routinely, or for cause, conduct inspections, and both have authority to seek to enforce their statutory authority and regulations through administrative remedies as well as civil and criminal enforcement actions. The FDA regulates and monitors the quality of drug clinical trials to provide human subject protection and to support marketing applications. The FDA may place a hold on a clinical trial and may cause a suspension or withdrawal of product approvals if regulatory standards are not maintained. The FDA also regulates the facilities, processes, and procedures used to manufacture and market pharmaceutical products in the U.S. Manufacturing facilities must be registered with the FDA and all products made in such facilities must be manufactured in accordance with the latest cGMP regulations, which are enforced by the FDA. Compliance with clinical trial requirements and cGMP regulations requires the dedication of substantial resources and requires significant expenditures. In the event an approved manufacturing facility for a particular drug is required by the FDA to curtail or cease operations, or otherwise becomes inoperable, or a third-party contract manufacturing facility faces manufacturing problems, obtaining the required FDA authorization to manufacture at the same or a different manufacturing site could result in production delays, which could adversely affect our business, results of operations, financial condition, and cash flow.

The FDA is authorized to perform inspections of U.S. and foreign facilities under the FFDCA. At the end of such an inspection, FDA could issue Form 483 Notice of Inspectional Observations, which could cause us to modify certain activities identified during the inspection. Following such inspections, the FDA may issue an untitled letter as an initial correspondence that cites violations that do not meet the threshold of regulatory significance of a Warning Letter. FDA guidelines also provide for the issuance of Warning Letters for violations of "regulatory significance" for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action. FDA also may issue Warning Letters and untitled letters in connection with events or circumstances unrelated to an FDA inspection.

Similar to other pharmaceutical companies, during Fiscal 2017, our facilities were subject to routine and new-product related inspections by the FDA. These inspections resulted in FDA Form 483 observations and a warning letter regarding post marketing adverse drug experience reporting. We have responded to all inspection observations within the required time frame and have implemented, or are continuing to implement, the corrective action plans as agreed with the relevant regulatory agencies. Please also see the risk factor titled "*We received a Warning Letter from the U.S. Food and Drug Administration regarding Post marketing Adverse Drug Experience reporting. The Warning Letter does not restrict the production or shipment of any of the Company's products, or the sale or marketing of the Company's products, however, unless and until the Company is able to correct the outstanding issues identified, to the FDA's satisfaction, the FDA may withhold approval of pending drug applications or take other actions that would have a material adverse impact on the Company*".

Many of our products contain controlled substances. The stringent DEA regulations on our use of controlled substances include restrictions on their use in research, manufacture, distribution, and storage. A breach of these regulations could result in imposition of civil penalties, refusal to renew or action to revoke necessary registrations, or other restrictions on operations involving controlled substances. In addition, failure to comply with applicable legal requirements subjects the manufacturing facilities of our subsidiaries and manufacturing partners to possible legal or regulatory action, including shutdown. Any such shutdown may adversely affect their ability to supply us with product and thus, our ability to market affected products. This could have a negative impact on our business, results of operations, financial condition, cash flows and competitive position. See also the risk described under the caption "*The DEA limits the availability of the active ingredients used in many of our current products and products in development, as well as the production of these products, and, as a result, our procurement and production quotas may not be sufficient to meet commercial demand or complete clinical trials.* " In addition, we are subject to the Federal Drug Supply Chain Security Act (DSCSA). The U.S. government has enacted DSCSA which requires development an electronic pedigree to track and trace each prescription drug at the salable unit level through the distribution system, which will be effective incrementally over a 10-year period. Compliance with DSCSA and future U.S. federal or state electronic pedigree requirements may increase our operational expenses and impose significant administrative burdens.

We cannot determine what effect changes in regulations or legal interpretations or requirements by the FDA or the courts, when and if promulgated or issued, may have on our business in the future. Changes could, among other things, require different labeling, monitoring of patients, interaction with physicians, education programs for patients or physicians, curtailment of necessary supplies, or limitations on product distribution. These changes, or others required by the FDA or DEA could have an adverse effect on the sales of these products. The evolving and complex nature of regulatory science and regulatory requirements, the broad authority and discretion of the FDA and the generally high level of regulatory oversight results in a continuing possibility that, from time to time, we will be adversely affected by regulatory actions despite our ongoing efforts and commitment to achieve and maintain full compliance with all regulatory requirements.

Furthermore, once a product receives marketing approval, the manufacturing, distribution, processing, formulation, packaging, labeling, promotion and sale of our products are subject to extensive regulation by federal agencies, including, without limitation, the FDA, DEA, FTC, Consumer Product Safety Commission, and Environmental Protection Agency, among others. We are also subject to state and local laws, regulations, and agencies in New Jersey and elsewhere. Such regulations are also subject to change by the relevant federal, state and local agencies. For instance, beginning from January 1, 2015 manufacturers, wholesale distributors, and repackages of certain prescription drugs are required to provide and capture certain product tracing information under the Drug Quality and Security Act ("*DQSA*"). Title II of the DQSA, referred to as the Drug Supply Chain Security Act, requires companies in certain prescription drugs' chain of distribution to build electronic, interoperable systems to identify and trace the products as they are distributed in the United States. Compliance with the DQSA or any future federal or state electronic pedigree requirements may increase the Company's operational expenses and impose significant administrative burdens.

Regulatory agencies such as the FDA regularly inspect our manufacturing facilities and the facilities of our third-party suppliers. The failure of the Northvale Facility, or a facility of one of our third-party suppliers, to comply with applicable laws and regulations may lead to breach of representations made to our customers or to regulatory or government action against us related to products made in that facility. We have in the past received and successfully resolved Form 483 observations from the FDA regarding certain operations within our manufacturing network. Although we remain committed to continuing to improve our quality control and manufacturing practices, we cannot be assured that the FDA will continue to be satisfied with our quality control and manufacturing systems and standards. If we receive any future FDA observations, we may be subject to regulatory action including, among others, monetary sanctions or penalties, product recalls or seizure, injunctions, total or partial suspension of production and/or distribution, and suspension or withdrawal of regulatory approvals. Further, other federal agencies, our customers and partners in our alliance, development, collaboration, and other partnership agreements with respect to our products and services may take any such Form 483 observations into account when considering the award of contracts or the continuation or extension of such partnership agreements. If we receive any future Form 483 observations or warning letters from the FDA, our business, consolidated results of operations and consolidated financial condition could be materially and adversely affected.

With respect to environmental, safety and health laws and regulations, we cannot accurately predict the outcome or timing of future expenditures that we may be required to make in order to comply with such laws as they apply to our operations and facilities. We are also subject to potential liability for the remediation of contamination associated with both present and past hazardous waste generation, handling, and disposal activities. We are subject periodically to environmental compliance reviews by environmental, safety, and health regulatory agencies. Environmental laws are subject to change and we may become subject to stricter environmental standards in the future and face larger capital expenditures in order to comply with environmental laws.

Compliance with federal and state and local law regulations, including compliance with any newly enacted regulations, requires substantial expenditures of time, money, and effort to ensure full technical compliance. Failure to comply with the FDA, DEA, EPA and other governmental regulation can result in fines, disgorgement, unanticipated compliance expenditures, recall or seizure of products, exposure to product liability claims, total or partial suspension of production or distribution, suspension of the FDA's review of NDAs or ANDAs, enforcement actions, injunctions and civil or criminal prosecution, any of which could have a material and adverse effect on our business, results of operations and financial condition.

Legislative or regulatory reform of the healthcare system in the United States may harm our future business.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively commonly referred to as the "*Affordable Care Act*" may affect the operational results of companies in the pharmaceutical industry such as ours by imposing additional costs. Effective January 1, 2010, the Affordable Care Act, amongst other changes, increased the minimum Medicaid drug rebates for pharmaceutical companies and revised the definition of "*average manufacturer price*" for reporting purposes, which may affect the amount of Medicaid drug rebates to states related to the sales of our products, whether such sales are made directly by Company or by one of the Company's licensees. Beginning in 2011, the law also imposed a significant annual fee on companies that manufacture or import branded prescription drug products.

The Affordable Care Act contemplates the promulgation of significant future regulatory action which may also further affect our business. In addition since its enactment, the legislative and executive branches of the federal government have proposed multiple revisions to the Affordable Care Act, the effect of which, if implemented, may result in changes to the health care laws or regulatory framework that could result in the reduction of revenues or increased costs which could also have a material adverse effect on our business, results of operations and financial condition.

If we are unable to satisfy FDA regulatory requirements, we may not be able to commercialize our product candidates.

We need FDA approval prior to marketing our product candidates in the United States of America. If we fail to obtain FDA approval to market our product candidates, we will be unable to sell our product candidates in the United States of America and we will not generate any revenue from the sale of such products.

This regulatory review and approval process, which includes evaluation of preclinical studies and clinical trials of our product candidates, is lengthy, expensive, and uncertain. To receive approval, we must, among other things, demonstrate with substantial evidence from well-controlled clinical trials that our product candidates are both safe and effective for each indication where approval is sought. Satisfaction of these requirements typically takes several years, and the time needed to satisfy them may vary substantially, based on the type, complexity, and novelty of the pharmaceutical product. We cannot predict if or when we might submit for regulatory approval any of our product candidates currently under development. Any approvals we may obtain may not cover all of the clinical indications for which we are seeking approval. Also, an approval might contain significant limitations in the form of narrow indications, warnings, precautions, or contra-indications with respect to conditions of use.

The FDA has substantial discretion in the approval process and may either refuse to accept an application for substantive review or may form the opinion after review of an application that the application is insufficient to allow approval of a product candidate. If the FDA does not accept our application for review or approve our application, it may require that we conduct additional clinical, preclinical or manufacturing validation studies and submit the data before it will reconsider our application. Depending on the extent of these or any other studies that might be required, approval of any applications that we submit may be delayed by several years, or we may be required to expend more resources than we have available. It is also possible that any such additional studies, if performed and completed, may not be considered sufficient by the FDA to make our applications approvable. If any of these outcomes occur, we may be forced to abandon our applications for approval.

We will also be subject to a wide variety of foreign regulations governing the development, manufacture and marketing of our products. Whether or not an FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must still be obtained prior to manufacturing or marketing the product in those countries. The approval process varies from country to country and the time needed to secure approval may be longer or shorter than that required for FDA approval. We cannot assure you that clinical trials conducted in one country will be accepted by other countries or that approval of our product in one country will result in approval in any other country.

Before we can obtain regulatory approval, we need to successfully complete clinical trials, outcomes of which are uncertain.

In order to obtain FDA approval to market a new drug product, we must demonstrate proof of safety and effectiveness in humans. To meet these requirements, we must conduct extensive preclinical testing and "*adequate and well-controlled*" clinical trials. Conducting clinical trials is a lengthy, time-consuming, and expensive process. Completion of necessary clinical trials may take several years or more. Delays associated with products for which we are directly conducting preclinical or clinical trials may cause us to incur additional operating expenses. The commencement and rate of completion of clinical trials may be delayed by many factors, including, without limitation, for example:

- ineffectiveness of our product candidate or perceptions by physicians that the product candidate is not safe or effective for a particular indication;
- inability to manufacture sufficient quantities of the product candidate for use in clinical trials;
- delay or failure in obtaining approval of our clinical trial protocols from the FDA or institutional review boards;
- slower than expected rate of patient recruitment and enrollment;
- inability to adequately follow and monitor patients after treatment;
- difficulty in managing multiple clinical sites;
- unforeseen safety issues;
- government or regulatory delays; and,
- clinical trial costs that are greater than we currently anticipate.

Even if we achieve positive interim results in clinical trials, these results do not necessarily predict final results, and positive results in early trials may not be indicative of success in later trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after achieving promising results in earlier trials. Negative or inconclusive results or adverse medical events during a clinical trial could cause us to repeat or terminate a clinical trial or require us to conduct additional trials. We do not know whether our existing or any future clinical trials will demonstrate safety and efficacy sufficiently to result in marketable products. Our clinical trials may be suspended at any time for a variety of reasons, including if the FDA or we believe the patients participating in our trials are exposed to unacceptable health risks or if the FDA finds deficiencies in the conduct of these trials.

Failures or perceived failures in our clinical trials will directly delay our product development and regulatory approval process, damage our business prospects, make it difficult for us to establish collaboration and partnership relationships, and negatively affect our reputation and competitive position in the pharmaceutical community.

Because of these risks, our research and development efforts may not result in any commercially viable products. Any delay in, or termination of, our preclinical or clinical trials will delay the filing of our drug applications with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. If a significant portion of these development efforts are not successfully completed, required regulatory approvals are not obtained, or any approved products are not commercially successful, our business, financial condition, and results of operations may be materially harmed.

If our collaboration or licensing arrangements are unsuccessful, our revenues and product development may be limited.

We have entered into several collaborations and licensing arrangements for the development of products. However, there can be no assurance that any of these agreements will result in FDA approvals, or that we will be able to market any such finished products at a profit. Collaboration and licensing arrangements pose the following risks:

- collaborations and licensing arrangements may be terminated, in which case we will experience increased operating expenses and capital requirements if we elect to pursue further development of the related product candidate;
- collaborators and licensees may delay clinical trials and prolong clinical development, under-fund a clinical trial program, stop a clinical trial, or abandon a product candidate;
- expected revenue might not be generated because milestones may not be achieved, and product candidates may not be developed;

- collaborators and licensees could independently develop, or develop with third parties, products that could compete with our future products;
- the terms of our contracts with current or future collaborators and licensees may not be favorable to us in the future;
- a collaborator or licensee with marketing and distribution rights to one or more of our products may not commit enough resources to the marketing and distribution of our products, limiting our potential revenues from the commercialization of a product;
- disputes may arise delaying or terminating the research, development, or commercialization of our product candidates, or result in significant and costly litigation or arbitration; and,
- one or more third-party developers could obtain approval for a similar product prior to the collaborator or licensee resulting in unforeseen price competition in connection with the development product.

If we are unable to protect our intellectual property rights or avoid claims that we infringed on the intellectual property rights of others, our ability to conduct business may be impaired.

Our success depends on our ability to protect our current and future products and to defend our intellectual property rights. If we fail to protect our intellectual property adequately, competitors may manufacture and market products similar to ours.

We currently hold eleven patents and we have four patent applications. We intend to file further patent applications in the future. We cannot be certain that our pending patent applications will result in the issuance of patents. If patents are issued, third parties may sue us to challenge our patent protection, and although we know of no reason why they should prevail, it is possible that they could. In addition to modification or revocation of patents in legal proceedings, issued patents may later be modified or revoked by the U.S. Patent and Trademark Office or by analogous foreign offices. It is likewise possible that our patent rights may not prevent or limit our present and future competitors from developing, using or commercializing products that are similar or functionally equivalent to our products.

In addition, we may be required to obtain licenses to patents, or other proprietary rights of third parties, in connection with the development and use of our products and technologies as they relate to other persons' technologies. At such time as we discover a need to obtain any such license, we will need to establish whether we will be able to obtain such a license on favorable terms, if at all. The failure to obtain the necessary licenses or other rights could preclude the sale, manufacture or distribution of our products.

We rely particularly on trade secrets, unpatented proprietary expertise and continuing innovation that we seek to protect, in part, by entering into confidentiality agreements with licensees, suppliers, employees, and consultants. We cannot provide assurance that these agreements will not be breached or circumvented. We also cannot be certain that there will be adequate remedies in the event of a breach. Disputes may arise concerning the ownership of intellectual property or the applicability of confidentiality agreements. We cannot be sure that our trade secrets and proprietary technology will not otherwise be obtained by other entities or become known, obtained, or independently developed by our competitors or by other entities. We also cannot be sure that, if patents are not issued with respect to products arising from research, we will be able to maintain the confidentiality of information relating to these products. In addition, efforts to ensure our intellectual property rights can be costly, time-consuming, and/or ultimately unsuccessful.

Litigation is common in the pharmaceutical industry and can be protracted and expensive and could delay and/or prevent entry of our products into the market, which, in turn, could have a material adverse effect on our business.

Litigation concerning patents and proprietary rights can be protracted and expensive. Companies routinely bring litigation against applicants and allege patent infringement or other violations of intellectual property rights as the basis for filing suit against an applicant. Elite develops, owns, and/or manufactures generic and branded pharmaceutical products and such drug products may be subject to such litigation. Litigation often involves significant expense and can delay or prevent introduction or sale of our products.

There may also be situations where we use our business judgment and decide to market and sell products, notwithstanding the fact that allegations of patent infringement(s) have not been finally resolved by the courts. The risk involved in doing so can be substantial because the remedies available to the owner of a patent for infringement include, among other things, damages measured by the profits lost by the patent owner and not by the profits earned by the infringer. In the case of a willful infringement, the definition of which is subjective, such damages may be trebled. Moreover, because of the discount pricing typically involved with bioequivalent products, patented brand products generally realize a substantially higher profit margin than bioequivalent products. An adverse decision in a case such as this or in other similar litigation could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our Common Stock to decline.

Please also see "*Item 3. Legal Proceedings*" below for further details.

The pharmaceutical industry is highly competitive and subject to rapid and significant technological change, which could impair our ability to implement our business model.

The pharmaceutical industry is highly competitive, and we may be unable to compete effectively. In addition, the pharmaceutical industry is undergoing rapid and significant technological change, and we expect competition to intensify as technical advances in each field are made and become more widely known. An increasing number of pharmaceutical companies have been or are becoming interested in the development and commercialization of products incorporating advanced or novel drug delivery systems. We expect that competition in the field of drug delivery will increase in the future as other specialized research and development companies begin to concentrate on this aspect of the business. Some of the major pharmaceutical companies have invested and are continuing to invest significant resources in the development of their own drug delivery systems and technologies and some have invested funds in specialized drug delivery companies. Many of our competitors have longer operating histories and greater financial, research and development, marketing, and other resources than we do. Such companies may develop new formulations and products, or may improve existing ones, more efficiently than we can. Our success, if any, will depend in part on our ability to keep pace with the changing technology in the fields in which we operate.

As we expand our presence in the generic pharmaceuticals market our product candidates may face intense competition from brand-name companies that have taken aggressive steps to thwart competition from generic companies. In particular, brand-name companies continue to sell or license their products directly or through licensing arrangements or strategic alliances with generic pharmaceutical companies (so-called "authorized generics"). No significant regulatory approvals are required for a brand-name company to sell directly or through a third party to the generic market, and brand-name companies do not face any other significant barriers to entry into such market. In addition, such companies continually seek to delay generic introductions and to decrease the impact of generic competition, using tactics which include, without limitation:

- obtaining new patents on drugs whose original patent protection is about to expire;
- filing patent applications that are more complex and costly to challenge;
- filing suits for patent infringement that automatically delay approval from the FDA;
- filing citizens' petitions with the FDA contesting approval of the generic versions of products due to alleged health and safety issues;
- developing controlled-release or other "next-generation" products, which often reduce demand for the generic version of the existing product for which we may be seeking approval;
- changing product claims and product labeling;
- developing and marketing as over-the-counter products those branded products which are about to face generic competition; and,
- making arrangements with managed care companies and insurers to reduce the economic incentives to purchase generic pharmaceuticals.

These strategies may increase the costs and risks associated with our efforts to introduce our generic products under development and may delay or prevent such introduction altogether.

If our product candidates do not achieve market acceptance among physicians, patients, health care payors and the medical community, they will not be commercially successful, and our business will be adversely affected.

The degree of market acceptance of any of our approved product candidates among physicians, patients, health care payors and the medical community will depend on a number of factors, including, without limitation:

- acceptable evidence of safety and efficacy;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- availability of alternative treatments;
- pricing and cost effectiveness;
- effectiveness of sales and marketing strategies; and,
- ability to obtain sufficient third-party coverage or reimbursement.

If we are unable to achieve market acceptance for our product candidates, then such product candidates will not be commercially successful, and our business will be adversely affected.

In addition, even if we are able to obtain regulatory approvals for our new products, the success of those products as well as the success of our previously approved products, is dependent upon market acceptance. Levels of market acceptance for our new products could be affected by several factors, including, without limitation:

- the availability of alternative products from our competitors;
- the prices of our products relative to those of our competitors;
- the timing of our market entry;
- the ability to market our products effectively at the retail level;
- the perception of patients and the healthcare community, including third-party payers, regarding the safety, efficacy and benefits of our drug products compared to those of competing products; and,
- the acceptance of our products by government and private formularies.

Some of these factors are not within our control, and our products may not achieve expected levels of market acceptance. Additionally, continuing and increasingly sophisticated studies of the proper utilization, safety and efficacy of pharmaceutical products are being conducted by the industry, government agencies and others which can call into question the utilization, safety, and efficacy of previously marketed products. In some cases, studies have resulted, and may in the future result, in the discontinuance of product marketing or other risk management programs such as the need for a patient registry.

Legislative or regulatory programs that may influence prices of prescription drugs could have a material adverse effect on our business.

Current or future federal or state laws and regulations may influence the prices of drugs and, therefore, could adversely affect the prices that we receive for our products. Programs in existence in certain states seek to set prices of all drugs sold within those states through the regulation and administration of the sale of prescription drugs. Expansion of these programs, in particular, state Medicaid programs, or changes required in the way in which Medicaid rebates are calculated under such programs, could adversely affect the price we receive for our products and could have a material adverse effect on our business, results of operations and financial condition. Further, prescription drug prices have been the focus of increased scrutiny by the government, including certain state attorneys general, members of congress and the U.S. Department of Justice. Decreases in health care reimbursements or prices of ou prescription drugs could limit our ability to sell our products or decrease our revenues, which could have a material adverse effect on our business, results of operations and financial condition.

We may experience pricing pressure on the price of our products due to social or political pressure to lower the cost of drugs, which would reduce our revenue and future profitability.

We may experience downward pricing pressure on the price of our products due to social or political pressure to lower the cost of drugs, which would reduce our revenue and future profitability. Recent events have resulted in increased public and governmental scrutiny of the cost of drugs, especially in connection with price increases following companies' acquisition of the rights to certain drug products. In particular, U.S. federal prosecutors have issued subpoenas to pharmaceutical companies seeking information about drug pricing practices. In addition, the U.S. Senate is publicly investigating a number o pharmaceutical companies relating to drug-price increases and pricing practices. Our revenue and future profitability could be negatively affected if these inquiries were to result in legislative or regulatory proposals that limit our ability to increase the prices of our products.

In addition, in September 2016, a group of U.S. Senators introduced legislation that would require pharmaceutical manufacturers to justify price increases of more than 10% in a 12-month period, and a large number of individual States have introduced legislation aimed at drug pricing regulation, transparency or both. While this proposed legislation has not been enacted into law to date, our revenue and future profitability could be negatively affected by the passage of this law or similar federal or state legislation. Furthermore, pressure from social activist groups and future government regulations may also put downward pressure on the price of drugs, which could result in downward pressure on the prices of our products in the future.

We are dependent on a small number of suppliers for our raw materials and any delay or unavailability of raw materials can materially adversely affect our ability to produce products.

The FDA requires identification of raw material suppliers in applications for approval of drug products. If raw materials were unavailable from a specified supplier, FDA approval of a new supplier could delay the manufacture of the drug involved.

In addition, some materials used in our products are currently available from only one supplier or a limited number of suppliers and there is a risk of a sole approved supplier significantly raising prices. Please note that such an occurrence has taken place recently, wherein significant price increases from a sole supplier greatly reduced profit margins, sales, and delayed product launches. These occurrences were ultimately resolved by the successful FDA approval of an alternate supplier, with such approval process being lengthy and costly.

Further, a significant portion of our raw materials may be available only from foreign sources. Foreign sources can be subject to the special risks of doing business abroad, including, without limitation:

- greater possibility for disruption due to transportation or communication problems;
- the relative instability of some foreign governments and economies;
- interim price volatility based on labor unrest, materials or equipment shortages, export duties, restrictions on the transfer of funds, or fluctuations in currency exchange rates; and,
- uncertainty regarding recourse to a dependable legal system for the enforcement of contracts and other rights.

In addition, patent laws in certain foreign jurisdictions (primarily, but not necessarily, in Europe) may make it increasingly difficult to obtain raw materials for research and development prior to expiration of applicable United States or foreign patents. Any delay or inability to obtain raw materials on a timely basis, or any significant price increases that cannot be passed on to customers, can materially adversely affect our ability to produce products. This can materially adversely affect our business and operations.

Even after regulatory approval, we will be subject to ongoing significant regulatory obligations and oversight as evidenced by the FDA's removal from the market of our Lodrane® extended release product line. In addition, although Lodrane D® is marketed under the Over-the-Counter Monograph and, accordingly, can be lawfully marketed in the US without prior regulatory approval, the FDA has revised its enforcement policies during the past few years, significantly limiting the circumstances under which unapproved products may be marketed.

Even if regulatory approval is obtained for a particular product candidate, the FDA and foreign regulatory authorities may, nevertheless, impose significant restrictions on the indicated uses or marketing of such products, or impose ongoing requirements for post-approval studies. Following any regulatory approval of our product candidates, we will be subject to continuing regulatory obligations, such as safety reporting requirements, and additional post-marketing obligations, including regulatory oversight of the promotion and marketing of our products. If we become aware of previously unknown problems with any of our product candidates here or overseas or at our contract manufacturers' facilities, a regulatory agency may impose restrictions on our products, our contract manufacturers or on us, including requiring us to reformulate our products, conduct additional clinical trials, make changes in the labeling of our products, implement changes to or obtain re-approvals of our contract manufacturers' facilities or withdraw the product from the market. In addition, we may experience a significant drop in the sales of the affected products, our reputation in the marketplace may suffer and we may become the target of lawsuits, including class action suits. Moreover, if we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution. Any of these events could harm or prevent sales of the affected products or could substantially increase the costs and expenses of commercializing and marketing these products.

On March 4, 2011, the FDA issued a directive removing from the market approximately 500 cough/cold and allergy products, including our Lodrane® extended release product line. The Lodrane® extended release products constituted approximately 97% of our revenues at the time of FDA's directive.

Lodrane D® is marketed under the Over-the-Counter Monograph (the "*OTC Monograph*") and accordingly, under the Code of Federal Regulations can be lawfully marketed in the US without prior approval. Under the Federal Food Drug and Cosmetic Act ("*FDCA*"), FDA regulations and statements of FDA policy, certain drug products are permitted to be marketed in the U.S. without prior approval. Within the past few years, the FDA has revised its enforcement policies, significantly limiting the circumstances under which these unapproved products may be marketed. If the FDA determines that a company is distributing an unapproved product that requires approval, the FDA may take enforcement action in a variety of ways, including, without limitation, product seizures and seeking a judicial injunction against distribution.

We depend on qualified scientific and technical employees and are increasingly dependent on our direct sales force, if key personnel were to leave us or if we are unsuccessful in attracting qualified personnel, our ability to develop products and grow our business could be materially harmed.

Because of the specialized scientific nature of our business, we are highly dependent upon our ability to continue to attract and retain qualified scientific and technical personnel. We are not aware of any pending, significant losses of scientific or technical personnel. Loss of the services of, or failure to recruit, key scientific and technical personnel, however, would be significantly detrimental to our product-development programs. As a result of our small size and limited financial and other resources, it may be difficult for us to attract and retain qualified officers and qualified scientific and technical personnel.

In addition, marketing of our branded product, SequestOx™ requires much greater use of a direct sales force compared to marketing of our generic products. Our ability to realize significant revenues from marketing and sales activities depends on our ability or the ability of our partners to attract and retain qualified sales personnel. Competition for qualified sales personnel is intense. Any failure to attract or retain qualified sales personnel could negatively impact our sales revenue and have a material adverse effect on our business, results of operations and financial condition.

We have entered into employment agreements with our executive officers and certain other key employees. We do not maintain "*Key Man*" life insurance on any executives.

If we were sued on a product liability claim, an award could exceed our insurance coverage and cost us significantly.

The design, development and manufacture of our products involve an inherent risk of product liability claims. We have procured product liability insurance; however, a successful claim against us in excess of the policy limits could be very expensive to us, damaging our financial position. The amount of our insurance coverage, which has been limited due to our limited financial resources, may be materially below the coverage maintained by many of the other companies engaged in similar activities. To the best of our knowledge, no product liability claim has been made against us as of the date hereof.

Our pipeline of products under development include products that would be filed as branded pharmaceuticals and if generic manufacturers use litigation and regulatory means to obtain approval for generic versions of one or more of such branded drugs, our sales may be adversely affected.

Under the Hatch-Waxman Act, the FDA can approve an ANDA for a generic bioequivalent version of a previously approved drug, without undertaking the full clinical testing necessary to obtain approval to market a new drug. In place of such clinical studies, an ANDA applicant usually needs only to submit data demonstrating that its generic product is bioequivalent to the branded product.

Our product development pipeline includes a range of abuse resistant opioid products, with full clinical testing activity being currently planned, in progress or successfully completed. In recent years, various generic manufacturers have filed ANDAs seeking FDA approval for generic versions of opioid and opioids with abuse resistant characteristics. In connection with our filings, these manufacturers may challenge the validity and/or enforceability of one or more of the underlying patents protecting our products. While it is the Company's intention to vigorously defend and pursue all available legal and regulatory avenues in defense of the intellectual property rights protecting our products, it must also be stressed that litigation is inherently uncertain, and we cannot predict the timing or outcome of our efforts. There can also be no assurance that our efforts in defense of the intellectual property rights protecting our products will be successful.

If we are not successful in defending our intellectual property rights, or opt to settle, or if a product's marketing exclusivity rights expire or become otherwise unenforceable, our competitors could ultimately launch generic versions of one or more of our branded products, after such products have been approved by the FDA, which could significantly decrease our revenues and could have a material adverse effect on our business, financial conditions, results of operations and cash flow. Furthermore, such a material adverse effect may result in a material adverse effect on our share price.

Agreements between branded pharmaceutical companies and generic pharmaceutical companies are facing increased government scrutiny in the United States and Internationally.

There are numerous and continuing litigation in which generic companies challenge the validity or enforceability of an innovator products patents and/or the applicability of such patents to a generic applicant's products. Settlement of such litigation is a common outcome, with review of such agreements by the U.S. Federal Trade Commission (the "*FTC*") and the Antitrust Division of the Department of Justice (the "*DOJ*") being required by law. The FTC has stated publicly its view that some of these settlement agreements violate antitrust laws and has commenced actions against the branded and generic companies that are parties to these agreements. Accordingly, in the event of the Company being party to a settlement agreement, either as the branded, innovator product owner, or as the generic applicant, we may receive formal or informal requests from the FTC for information about a settlement agreement and there is a risk of the FTC alleging a violation of antitrust laws and commencing an action against us.

In addition, the United States Congress has proposed legislation that would limit the types of settlement agreements generic manufacturers can enter into with brand companies. In 2013, the Supreme Court, in *FTC v. Actavis*, determined that reverse payment patent settlements between generic and brand companies should be evaluated under the rule of reason, and provided limited guidance beyond the selection of this standard. Due to the court's non-articulation of a precise rule of lawfulness for such settlements, there may be extensive litigation over what constitutes a reasonable and lawful patent settlement between and brand and generic company.

The impact of such future litigation, if any, legislative proposals, and potential future court decisions is uncertain, and there can be no assurances that such impact will not have an adverse effect on the Company's business, its financial condition, results of operations, cash flows and its stock price.

We may incur significant liability if it is determined that we are promoting or have in the past promoted the "off-label" use of drugs.

In jurisdictions including, without limitation, the United States, a company is not permitted to promote drugs for uses that are not described in the product's labeling and that differ from those that were approved or cleared by the FDA. Such users are commonly referred to as "off-label uses". Under what is known as the "practice of medicine", physicians and other healthcare practitioners may prescribe drug products for off-label or unapproved uses. While the FDA does not regulate a physician's choice of medications, treatments, or product uses, the Federal Food Drug and Cosmetic Act ("*FFDC*") and FDA regulations significantly restrict permissible communications on the subject of off-label uses of drug products by pharmaceutical companies. The FDA, FTC, the Office of the Inspector General of the Department of Health and Human Services ("*HHS*"), the DOJ and various state Attorneys General actively enforce laws and regulations that prohibit the promotion of off-label uses. A company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil fines, criminal fines and penalties, civil damages, exclusion from federal funded healthcare programs and potential liability under the federal False Claims Act and any applicable state false claims act. Conduct giving rise to such liability could also form the basis for private civil litigation by third-party payers or other persons claiming to be harmed by such conduct.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA's regulations and judicial case law allows companies to engage in some forms of truthful, non-misleading and non-promotional speech concerning the off-label use of products. Elite believes it and its marketing partners comply with these restrictions.

Nonetheless, the FDA, HHS, DOJ, and/or state Attorneys General, and *qui tam* relators may take the position that the Company is not in compliance with such requirements, and if such non-compliance is proven, the consequences of such may have an adverse material effect on our business, financial condition, results of operations, cash flows and stock price.

We have significant intangible assets on our balance sheet. Consequently, potential impairment of intangible assets may have an adverse material effect on our profitability.

Intangible assets represent a significant portion of our assets. As of March 31, 2018, intangible assets were approximately $7.7 million, or approximately 25% of our assets.

Generally accepted accounting principles in the United States ("*GAAP*") requires that intangible assets be subject to regular impairment analysis to determine if changes in circumstances indicate that the value of the asset as recorded may not be recoverable. Such events or changes in circumstances are an inherent risk in the pharmaceutical industry and often cannot be predicted. However, should a change in circumstance occur, requiring the impairment of an intangible asset, the result of such an impairment may have an adverse material effect on our business, financial condition, results of operations, cash flows and stock price.

Our products contain narcotic ingredients. As a result of reports of misuse or abuse of prescription narcotics, the sale of such drugs may be subject to increased litigation risk and new regulation, including the development of Risk Evaluation and Mitigation Strategy ("*REMS*"), which may prove difficult or expensive to comply with.

Many of our current products and products under development contain narcotics. Misuse or abuse of such drugs can lead to physical or other hard. The FDA and/or the DEA may impose new regulations concerning the manufacture, storage, transportation, distribution, and sale of prescription narcotics. Such regulations may include new labeling requirements, the development and implementation of a formal REMS, restrictions on prescription and sale of such products and mandatory reformulation in order to make abuse of such products more difficult. In 2007, Congress passed legislation authorizing the FDA to require companies to undertake post-approval studies in order to assess known or signaled potential serious safety risks and to make any labeling changes necessary to address safety risks. Congress also empowered the FDA to require companies to formulate REMS to confirm a drug's benefits exceed its risks. In 2011, the FDA issued letters to manufacturers of long-acting and extended-release opioids requiring them to develop and submit to the FDA a post-market REMS plan to require that training is provided to prescribers of these products and that information is provided to prescribers that they can use in counseling patients on the risks and benefits of opioid drug use. Elite does not currently own a product that requires a REMS plan, but some of the products in our pipeline may require a REMS plan. The federal government has also released a comprehensive action plan to reduce prescription drug abuse, which may include proposed legislation to amended existing controlled substances laws to require healthcare practitioners who request DEA registration to prescribe controlled substances to receive training on opioid prescribing practices as a condition of registration. In addition, state health departments and boards of pharmacy have authority to regulate distribution and may modify their regulations with respect to prescription narcotics in an attempt to curb abuse.

Such new regulations or requirements may be difficult or cost prohibitive for us to comply with, resulting in delays in the commercialization of new products, and decreased profitability of existing and new products. Such occurrences may have material adverse effects on our business, financial condition, results of operations, cash flows and stock price.

Public concern over the abuse of opioid medications, including increased legal and regulatory action, could negatively affect our business.

Included in our commercial products and development pipeline are medications containing opioids. Certain governmental and regulatory agencies, as well as state and local jurisdictions, are focused on the abuse of opioid medications in the United States. State and local governmental agencies may investigate us as a manufacturer and/or distributor of medicines containing opioids or in conjunction with their investigation of other pharmaceutical wholesale distributors, and others in the supply chain that have a direct or indirect connection to our operations in relation to the distribution of opioid medications. In addition, multiple lawsuits have been filed against other pharmaceutical manufacturers and distributors alleging, among other claims, that they failed to provide effective controls and procedures to guard against the diversion of controlled substances, acted negligently by distributing controlled substances to pharmacies that serve individuals who abuse controlled substances, and failed to report suspicious orders of controlled substances in accordance with regulations. Additional governmental entities have indicated an intent to sue these other manufacturers and distributors. While no such actions have been taken against us, defense against such lawsuits could be prohibitive with regards to cost resulting in an adverse material effect on our business, financial condition, results of operations, cash flows and stock price. Similar allegations made against us, even without litigation, could also negatively affect our business in various ways, including through increased costs and harm to our reputation. In addition, an adverse resolution of any lawsuit or investigation could also have a material adverse effect on our business, results of operations, cash flows and stock price.

The DEA limits the availability of the active ingredients used in many of our current products and products in development, as well as the production and distribution of these products, and, as a result, our procurement, production, and distribution quotas may not be sufficient to meet commercial demand or complete clinical trials.

The DEA regulates chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest ri of substance abuse and Schedule V substances the lowest risk. The active ingredients in some of our current products and products in development, including, without limitation, hydromorphone, methadone, phentermine, phendimetrazine and oxycodone, are listed by the DEA as Scheduled substances under the Controlled Substances Act of 1970. Consequently, their manufacture, shipment, storage, sale, and use are subject to a high degree of regulation. Furthermore, the DEA limits the availability of the active ingredients used in many of our current products and products in development and we and/or our contract customers and suppliers, must annually apply to the DEA for procurement quotas in order to obtain and distribute these substances. As a result, our procurement and production quotas may not be sufficient to meet commercial demand or to complete clinical trials. Moreover, the DEA may adjust these quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. Any delay or refusal by the DEA in establishing our quotas, or modification of our quotas, for controlled substances could delay or result in the stoppage of our clinical trials or product launches or could cause trade inventory disruptions for those products that already been launched, which could have a material adverse effect on our business, financial position, cash flows and stock price.

The growth of Elite will depend on developing, commercializing and marketing new products.

Our future revenues and profitability is significantly dependent on our ability to successfully commercialize new branded and generic pharmaceutical products in a timely manner. Accordingly, we must continually develop, test, file, receive marketing authorization and manufacture new products. While we are currently developing products and have plans in place for future products beyond those currently in development, there can be no assurances that any of these products will receive marketing authorization and achieve commercialization. In addition, even if a product receives marketing authorization, there can be no assurances that there will be future revenues or profits, or that any such future revenues or profits would be in amounts that provide adequate return on the significant investments made to secure the marketing authorization and create/support the infrastructure required for the commercial manufacture of such product.

We are engaged in the research and development of pharmaceutical products with the objective of achieving marketing authorizations that enable us to manufacture and sell pharmaceuticals in accordance with specific government regulations. Due to the inherent risk associated with pharmaceutical product research and development, particularly with respect to new/innovative drugs, our research and development expenditures and efforts may not result in a successful regulatory approval and commercialization of new products. Furthermore, after we submit a regulatory application, the relevant government authority may require that we conduct additional studies, resulting in an inability for us to reasonably predict the total research and development costs for a new product.

Circumstances in which the Company is unable to successfully commercialize new products in a timely manner, or circumstances in which the profitability of a new product is not sufficient with respect to the costs and investments required to develop such product may have a material adverse effect on our business, financial condition, results of operations, cash flows and stock price.

If our manufacturing facilities are unable to manufacture our products or the manufacturing process is interrupted due to failure to comply with regulations or for other reasons, it could have a material adverse impact on our business.

If any of our manufacturing facilities, quality and regulatory operations and other business and commercial functions fail to comply with complex and numerous regulatory requirements or encounter other manufacturing difficulties, it could adversely affect our ability to supply products. All facilities and manufacturing processes used for the manufacture of pharmaceutical products must be operated in conformity with cGMP and, in the case of controlled substances, DEA regulations. Compliance with the FDA's cGMP and DEA requirements applies to both drug products seeking regulatory approval and to approved drug products. In complying with cGMP requirements, pharmaceutical manufacturing facilities must continually expend significant time, money and effort in production, record-keeping and quality assurance and control so that their products meet applicable specifications and other requirements product safety, efficacy, and quality. Failure to comply with applicable legal requirements subjects our manufacturing facilities to possible legal or regulatory action, including, without limitation, shutdown, which may adversely affect our ability to manufacture product. Were we not able to manufacture products at our manufacturing facilities because of regulatory, business or any other reason, the manufacture and marketing of these products would be interrupted. This could have a material adverse impact on our business, results of operations, financial condition, cash flows, competitive position, and stock price.

Sales of our products may be adversely affected by the continuing consolidation within the retail and wholesale pharmaceutical markets.

Our products, whether sold directly by the Company or through third parties that are licensed to market and distribute our products are sold in large part to a market that is comprised of a relatively few retail drug chains, wholesalers, and managed care organizations, with such entities continuing to undergo consolidation. Such consolidation may provide these customers or our products with additional purchasing leverage, and consequently, may increase the pricing pressures faced by us. Additionally, the emergence of large buying groups representing independent retail pharmacies, and the prevalence and influence of managed care organizations and similar institutions, enable those groups to extract price discounts on our products.

In addition, our revenues and quarterly results comparisons may also be affected by fluctuations in the buying patterns of retail chains, major distributors, and other trade buyers.

Any delays or unanticipated expenses in connection with the operation of our limited number of facilities could have a material adverse effect on our business.

All of our manufacturing operations are conducted at the Northvale Facility. A significant disruption at this facility, even on a short-term basis, whether due to, without limitation, an adverse quality or compliance observation, including a total or partial suspension of production and/or distribution by regulatory authorities, an act of God, civil or political unrest, force majeure situation or other events could impair our ability to produce and ship products on a timely basis, and could, among other consequences, subject us to exposure to claims from customers. Any of these events could have a material adverse effect on our business, results of operations, financial condition, and cash flows.

Our business is dependent on market perceptions of us and the safety and efficacy or our products. Negative publicity relating to us or our products could have a material adverse effect on our business, results of operations, financial condition, and cash flows.

Market perceptions or our business are important to us, especially market perceptions of the safety and quality of our products. If any of our products or similar products that other companies distribute are subject to market withdrawal, recall, or are proven to be, or are claimed to be, harmful to consumers, then this could have a material adverse effect on our business, results of operations, financial condition, and cash flows. Furthermore, due to the importance of market perceptions, negative publicity associated with product quality, illness or other adverse effects resulting from, or perceived to be resulting from, our products, or similar products made by other companies, could have a material adverse effect on our business, results of operations, financial condition, and cash flows.

We may discontinue the manufacture and distribution of certain existing products, which may adversely affect our business, results of operations, financial condition, and cash flows.

As part of regular evaluations of product performance, we may determine that it is in our best interest to discontinue the manufacture and distribution of certain of our products. We cannot guarantee that we have correctly forecasted, or will correctly forecast in the future, the appropriate products to discontinue or that a decision to discontinue various products is prudent if market conditions change. In addition, there can be no assurances that the discontinuance of products will reduce operating expense or no cause the incurrence of material charges associated with such a decision. Furthermore, the discontinuance of existing products, entails various risks, including, without limitation, the ability to find a purchaser for such products, if there is a decision to sell the product, as well as the risk that the purchase price obtained will not be equal to at least the book value of the net assets relating to such products. Other risks associated with a product discontinuance, include, without limitation, managing the expectations of and maintaining good relations with our customers who previously purchased a discontinued product from us, and the effects such would have on future sales to these customers. We may also incur significant liabilities and costs associated with our product discontinuance. All of the foregoing could have a material adverse effect on our business, results of operations, financial condition, and cash flows.

The time necessary to develop generic drugs may adversely affect whether, and the extent to which, we receive a return on our capital.

The development process for branded and generic products, including, without limitation, drug formulation, testing, and FDA review and approval often takes three or more years. This process requires that we expend considerable capital to pursue activities that do not yield an immediate or near-term return. Also, because of the significant time necessary to develop a product, the actual market for a product at the time it is available for sale may be significantly less than the originally projected market for the product. If this were to occur, our potential return on our investment in developing the product, if approved for marketing by the FDA, would be adversely affected and we may never receive a return on our investment in the product. It is also possible for the manufacturer of the brand-name product for which we are developing a generic drug to obtain approvals from the FDA to switch the brand-name drug from the prescription market to the OTC market. If this were to occur, we would be prohibited from marketing our product other than as an OTC drug, in which case revenues could be substantially less than we anticipated.

Research and development efforts invested in our branded pharmaceutical products may not achieve expected results.

The development of branded products requires significant resources from the Company, as well as the potential for resources being acquired through collaborations, in-licensing, or third-party product acquisitions. The development of proprietary branded drugs involves processes and expertise that is different from that required by the development of generic products, resulting in an increased risk profile for branded development. For example, the time frame from discovery to commercial launch of a branded product can be more than 10 years, involving multiple stages which may consist of intensive preclinical and clinical testing and a highly complex, lengthy, and expensive approval process. The longer time frames and increased costs adds increasing risk of achieving product approvals, and if approved, our ability to recover development costs and generate profits.

During each development stage, we may encounter obstacles that delay the process or approval and increase expenses, leading to significant risks that we will not achieve our goals and may be forced to abandon a potential product in which we have invested substantial amounts of time and money. These obstacles may include: preclinical failures; difficulty enrolling patients in clinical trials; delays in completing formulation and other work needed to support an application for approval; adverse reactions or other safety concerns arising during clinical testing; insufficient clinical trial data to support the safety or efficacy of the product candidate; and failure to obtain, or delays in obtaining, the required regulatory approvals for the product candidate or the facilities in which it is manufactured. As a result of the obstacles noted above, our investment in research and development of branded products can involve significant costs with no assurances of future revenues or profits.

Approvals for our new generic drug products may be delayed or become more difficult to obtain if the FDA institutes changes to its approval requirements.

The FDA may institute changes to its ANDA approval requirements, which may make it more difficult or expensive for us to obtain approval for our new generic products. For instance, in July 2012, the Generic Drug Fee User Amendments of 2012 ("*GDUFA*") was enacted into law. The GDUFA legislation implemented fees for new ANDAs, Drug Master Files, product and establishment fees and a one-time fee for back-logged ANDAs pending approval as of October 1, 2012. In return, the program is intended to provide faster and more predictable ANDA reviews by the FDA and increased inspections of drug facilities. Under GDUFA, generic product companies face significant penalties for failure to pay the new user fees, including rendering an ANDA not "substantially complete" until the fee is paid. Any failure by us or our suppliers to pay the fees or to comply with the other provisions of GDFUA may impact or delay our ability to file ANDAs, obtain approvals for new generic products, generate revenues and thus may have a material adverse effect on our business, results of operations and financial condition.

In addition to the implementation of new fees and review procedures by the FDA, the FDA may also implement other changes that may directly affect some of our ANDA filings pending approval from the FDA, such as changes to guidance from the FDA regarding bioequivalency requirements for particular drugs. Such changes may cause our development of such generic drugs to be significantly more difficult or result in delays in FDA approval or result in our decision to abandon or terminate certain projects. Any changes in FDA requirements may make it more difficult for us to file ANDAs or obtain approval of our ANDAs and generate revenues and thus have a material adverse effect on our business, results of operations and financial condition.

The risks and uncertainties inherent in conducting clinical trials could delay or prevent the development and commercialization of our own branded products, which could have a material adverse effect on our business, results of operations and financial condition.

With respect to our branded products which do not qualify for the FDA's abbreviated application procedures, we must demonstrate through clinical trials that these products are safe and effective for use. We have only limited experience in conducting and supervising clinical trials. The process of completing clinical trials and preparing an NDA may take several years and requires substantial resources. Our studies and filings may not result in FDA approval to market our new drug products and, if the FDA grants approval, we cannot predict the timing of any approval. There are substantial filing fees for NDAs, often in excess of $1 million in addition to the cost of product development and clinical trials, that are not refundable if FDA approval is not obtained.

There are a number of risks and uncertainties associated with clinical trials. The results of clinical trials may not be indicative of results that would be obtained from large scale testing. Clinical trials are often conducted with patients having advanced stages of disease and, as a result, during the course of treatment these patients can die or suffer adverse medical effects for reasons that may not be related to the pharmaceutical agents being tested, but which nevertheless affect the clinical trial results. In addition, side effects experienced by the patients may cause delay of approval or limit the profile of an approved product. Moreover, our clinical trials may not demonstrate sufficient safety and efficacy to obtain approval from the FDA or foreign regulatory authorities. The FDA or foreign regulatory authorities may not agree with our assessment of the clinical data or they may interpret it differently. Such regulatory authorities may require additional or expanded clinical trials. Even if the FDA or foreign regulatory authorities approve certain products developed by us, there is no assurance that such regulatory authorities will not subject marketing of such products to certain limits on indicated use.

Failure can occur at any time during the clinical trial process and, in addition, the results from early clinical trials may not be predictive of results obtained in later and larger clinical trials, and product candidates in later clinical trials may fail to show the desired safety or efficacy despite having progressed successfully through earlier clinical testing.

Completion of clinical trials for our product candidates may be delayed or halted for the reasons noted above in addition to many other reasons, including, without limitation:

- Delays in patient enrollment, and variability in the number and types of patients available for clinical trials;
- Regulators or institutional review boards may not allow us to commence or continue a clinical trial;
- Our inability, or the inability of our partners, if any, to manufacture or obtain from third parties those materials required to complete clinical trials;

- Delays or failure in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective clinical trial sites;
- Risks associated with trial design, which may result in a failure of the trial to show statistically significant results even if the product candidate is effective;
- Difficulty in maintaining contact with patients after treatment commences, resulting in incomplete data
- Poor effectiveness of product candidates during clinical trials;
- Safety issues, including adverse events associated with product candidates;
- Failure of patients to complete clinical trials due to adverse side effects, dissatisfaction with the product candidate, or other reasons;
- Governmental or regulatory delays or changes in regulatory requirements, policy, and guidelines; and,
- Varying interpretation of data by the FDA or other relevant regulatory authorities.

In addition, our product candidates could be subject to competition for clinical study sites and patients from other therapies under development which may delay the enrollment in or initiation of our clinical trials.

The FDA or other relevant regulatory authorities may require us to conduct unanticipated additional clinical trials, which could result in additiona expense and delays in bringing our product candidates to market. Any failure or delay in completing clinical trials for our product candidates would prevent or delay the commercialization of our product candidates. We cannot assure that our expenses related to clinical trials will lead to the development of brand-name drugs that will generate revenues in the near future. Delays or failure in the development and commercialization of our own branded products could have a material adverse effect on our business, results of operations and financial condition.

We rely on third parties to conduct clinical trials and testing for our product candidates, and if they do not properly and successfully perform their legal and regulatory obligations, as well as their contractual obligations to us, we may not be able to obtain regulatory approvals for our product candidates.

We design the clinical trials for our product candidates but rely on contract research organizations and other third parties to assist us in managing, monitoring and otherwise carrying out these trials, including, without limitation, with respect to site selection, contract negotiation, analytical testing, and data management. We do not control these third parties and, as a result, delays may occur as a result of the priorities and operations of these third parties differing from those which we may feel would be most optimal to the completion of such activities in the most efficient manner possible.

Although we rely on third parties to conduct our clinical trials and related activities, we are responsible for confirming that each of our clinical trials is conducted in accordance with our general investigational plan and protocol. Moreover, the FDA and other relevant regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practices and good laboratory practices, for conducting, recording, and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. The FDA enforces good clinical practices and good laboratory practices through periodic inspections of trial sponsors, principal investigators, and trial sites. If we, our contract research organizations, or our study sites fail to comply with applicable good clinical practices and good laboratory practices, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply with good clinical practices and good laboratory practices. In addition, our clinical trials must be conducted with product manufactured under the FDA's current Good Manufacturing Practices, or cGMP, regulations. Our failure or the failure of our contract manufacturers if any are involved in the process, to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If third parties do not successfully carry out their duties under their agreements with us, if the quality or accuracy of the data they obtain is compromised due to failure to adhere to our clinical protocols or regulatory requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, our clinical trials may not meet regulatory requirements. If our clinical trials do not meet regulatory requirements or if these third parties need to be replaced, our clinical trials may be extended, delayed, suspended, or terminated. If any of these events occur, we may not be able to obtain regulatory approval of our product candidates, which could have a material adverse effect on our business, results of operations and financial condition.

The illegal distribution and sale by third parties of counterfeit versions of our products or of stolen products could have a negative impact on our reputation and a material adverse effect on our business, results of operations and financial condition.

Third parties could illegally distribute and sell counterfeit versions of our products, which do not meet the rigorous manufacturing and testing standards that our products undergo. Counterfeit products are frequently unsafe or ineffective and can be life-threatening. Counterfeit medicines may contain harmful substances, the wrong dose of the active pharmaceutical ingredient or no active pharmaceutical ingredients at all. However, to distributors and users, counterfeit products may be visually indistinguishable from the authentic version.

Reports of adverse reactions to counterfeit drugs or increased levels of counterfeiting could materially affect patient confidence in the authentic product. It is possible that adverse events caused by unsafe counterfeit products will mistakenly be attributed to the authentic product. In addition, thefts of inventory at warehouses, plants or while in-transit, which are not properly stored, and which are sold through unauthorized channels could adversely impact patient safety, our reputation, and our business.

Public loss of confidence in the integrity of pharmaceutical products as a result of counterfeiting or theft could have a material adverse effect on our business, results of operations and financial condition.

Policies regarding returns, rebates, allowances and chargebacks, and marketing programs adopted by wholesalers may reduce our revenues in future fiscal periods.

Based on industry practice, generic drug manufacturers have liberal return policies and have been willing to give customers post-sale inventory allowances. Such industry practices apply to the current sales of our products by our marketing partners, which in turn effect profit splits and license fees received, and they will also affect prospective future sales made directly by Company.

Under these arrangements, from time to time, customers are given credits on our generic products that are held by them in inventory after there is a decrease in the market prices of the same generic products due to competitive pricing. Therefore, if new competitors enter the marketplace and significantly lower the prices of any of their competing products, the price of our products would also likely be reduced. As a result, we, or are marketing partners, would be obligated to provide credits to our customers who are then holding inventories of such products, which could reduce sales revenue, profit splits, license fees and gross margin for the period the credit is provided. Like most competitors in this market, our marketing partners, or us in the case of prospective direct sales made by the Company, also give credits for chargebacks to wholesalers that have contracts with our marketing partners, or us, prospectively, for their sales to hospitals, group purchasing organizations, pharmacies, or other customers. A chargeback is the difference between the price the wholesaler pays and the price that the wholesaler's end-customer pays for a product. Although, our marketing partners establish, and prospectively we would also establish reserves based on prior experience and best estimates of the impact that these policies may have in subsequent periods, we cannot ensure that such reserves established are adequate or that actual product returns, rebates, allowances, and chargebacks will not exceed estimates.

Unstable economic conditions may adversely affect our industry, business, results of operations and financial condition.

The global economy has undergone a period of significant volatility which has led to diminished credit availability, declines in consumer confidence, and increases in unemployment rates. There remains caution about the stability of the U.S. economy, and we cannot assure that further deterioration in the financial markets will not occur. These economic conditions have resulted in, and could lead to further, reduced consumer spending related to healthcare in general and pharmaceutical products in particular.

In addition, we have exposure to many different industries and counterparties, including our partners under our alliance and collaboration agreements, suppliers of raw chemical materials, drug wholesalers and other customers that may be affected by an unstable economic environment. Any economic instability may affect these parties' ability to fulfill their respective contractual obligations to us, cause them to limit or place burdensome conditions upon future transactions with us or drive us and our competitors to decrease prices, each of which could materially and adversely affect our business, results of operations and financial condition.

We received a Complete Response Letter from the FDA that indicated that our SequestOx™ NDA is not ready for approval in its preser form. While we plan on proceeding with our application for SequestOx™, we cannot assure if or whether our efforts will be successful. If we are unable to obtain approval for SequestOx™ or if we incur significant costs or delays in obtaining such approval, our ability to commercialize SequestOx™ may be materially adversely affected.

In July 2016, the FDA issued a Complete Response Letter, or CRL, regarding the NDA. The CRL stated that the review cycle for the Sequest NDA is complete and the application is not ready for approval in its present form. On December 21, 2016, we met with the FDA for an end-of-review meetin to discuss steps that we could take to obtain approval of SequestOx. Based on the FDA response, we believe there is a path forward to address the issue cited in the CRL, with such path forward including modification of the SequestOx formulation, and the successful completion of in vitro and in vivo studies. I we are unable to modify the formulation or if we are unable to successfully complete the required studies, we will not meet the requirements specified by the FDA for resubmission of the NDA. Furthermore, there can be no assurances given that the FDA will eventually approve our NDA. If we are unable to obta approval for SequestOx, or if we incur significant costs or delays in obtaining such approval, our ability to commercialize SequestOx may be materially adversely affected. Furthermore, in the event that the Company does receive marketing approval for SequestOx™, there can be no assurances of the Company realizing future revenues or profits related to this product, or that any such future revenues and profits would be in amounts that provide adequate return on the significant investments made to secure this marketing authorization.

We previously received a Warning Letter from the FDA regarding Postmarketing Adverse Drug Experience reporting. The Warning Lette did not restrict the production, sale, marketing or shipment of any of our products, however, until the we were able to correct the issues, the FDA withheld approval of pending drug applications. While we subsequently satisfied the FDA's concerns, no assurance can be given that future similar issues will not arise.

On August 26, 2016, Elite received a Warning Letter from the FDA regarding Postmarketing Adverse Drug Experience (PADE) reporting. Th Warning Letter related to certain observations that the FDA believed were inadequately addressed by the Company's response to a Form 483 issued by the FDA from a recent inspection at its facility. The Warning Letter cited that Elite's Standard Operating Procedures (SOPs) did not adequately address how t monitor and receive adverse drug experiences (ADEs). While Elite has a contract with an external service provider for follow-up to ADEs, Elite remain responsible for ensuring the ADEs are appropriately investigated and that follow-up information is submitted in a timely manner to the FDA. The FDA believe that Elite did not have adequate SOPS for ADEs, and failed to investigate, evaluate, and timely report ADEs. Elite successfully addressed the deficiencies cited in the letter and, on December 15, 2017, the FDA issued a closeout letter, removing any restrictions placed on us by the warning letter.

Despite the successful resolution of the warning letter previously received, there can be no assurances that Elite will not receive warning letters in the future, and furthermore there can be no assurances of the successful resolution of such future warning letter(s), if any. In addition to the approval of pending drug applications being delayed or denied as a result of the issuance of a warning letter, the cost of resolving any issues cited in such warning letter could be material. In all cases, the issuance of warning letter by the FDA could have a material detrimental effect on our business, results of operations, financia condition and stock price.

Our operations could be disrupted if our information systems fail, if we are unsuccessful in implementing necessary upgrades or if we are subject to cyber-attacks.

Our business depends on the efficient and uninterrupted operation of our computer and communications systems and networks, hardware and software systems and our other information technology. We collect and maintain information, which includes confidential and proprietary information as well as personal information regarding our customers and employees, in digital form. Data maintained in digital form is subject to risk of cyber-attacks, which are increasing in frequency and sophistication. Cyber-attacks could include the deployment of harmful malware, viruses, worms, and other means to affect service reliability and threaten data confidentiality, integrity and availability. Despite our efforts to monitor and safeguard our systems to prevent data compromise, the possibility of a future data compromise cannot be eliminated entirely, and risks associated with intrusion, tampering, and theft remain. In addition, we do not have insurance coverage with respect to system failures or cyber- attacks. A failure of our systems, or an inability to successfully expand the capacity of these systems, or an inability to successfully integrate new technologies into our existing systems could have a material adverse effect on our business, results of operations, financial condition, and cash flows.

We also have outsourced significant elements of our information technology infrastructure to third parties, some of which may be outside the U.S. Accordingly, significant elements of our information technology infrastructure, require our management of multiple independent vendor relationships with third parties who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of our third-party vendors with whom we contract, make such systems potentially vulnerable to service interruptions. The size and complexity of our and our vendors' systems and the large amounts of confidential information that is present on them also makes them potentially vulnerable to security breaches from inadvertent or intentional actions by our employees, partners, or vendors, or from attacks by malicious third parties.

The Company and its vendors' sophisticated information technology operations are spread across multiple, sometimes inconsistent, platforms, which pose difficulties in maintaining data integrity across systems. The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the unintentional or improper dissemination or destruction of confidential information stored in the Company's systems.

Impact of New Tax Legislation

On December 22, 2017, President Trump signed into law new tax legislation, the Tax Act, that significantly changes the Internal Revenue Code o 1986, as amended. The Tax Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Any federal net operating loss carryovers created in 2018 and thereafter will be carried forward indefinitely pursuant to the Tax Act. We continue to examine the impact this tax legislation may have on our business.

The risks described herein are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and operating results.

Natural disasters or other unexpected events may disrupt our operations, adversely affect our results of operations and financial condition, and may not be covered by insurance.

The occurrence of one or more unexpected events, including fires, tornadoes, tsunamis, hurricanes, earthquakes, floods, and other forms of severe hazards in the United States or in other countries in which we or our suppliers operate or are located could adversely affect our operations and financial performance. We have lost power or had to shut down operations as a result of extreme weather, natural disasters, most notably Superstorm Sandy. These types of unexpected events could result in physical damage to and complete or partial closure of one or more of distribution centers or manufacturing facilities, or the temporary or long-term disruption in the supply of products, and/or disruption of our ability to deliver products to customers. Further, the long-term effects of climate change on general economic conditions and the pharmaceutical manufacturing and distribution industry in particular are unclear, and changes in the supply, demand or available sources of energy and the regulatory and other costs associated with energy production and delivery may affect the availability or cost of goods and services, including natural resources, necessary to run our businesses. Existing insurance arrangements may not provide protection for the costs that may arise from such events, particularly if such events are catastrophic in nature or occur in combination. Any long-term disruption in our ability to service our customers from one or more distribution centers or outsourcing facilities could have a material adverse effect on our operations, our business, results of operations and stock price.

Risk Related to Our Common Stock

Our stock price has been volatile and may fluctuate in the future.

The market price for the publicly traded stock of pharmaceutical companies is generally characterized by high volatility. There has been significant volatility in the market prices for our Common Stock. For the twelve months ended March 31, 2018, the closing sale price on the OTC Bulletin Board (*OTC-BB*") of our Common Stock fluctuated from a high of $0.24 per share to a low of $0.08 per share. The price per share of our Common Stock may not exceed or even remain at current levels in the future. The market price of our Common Stock may be affected by a number of factors, including, without limitation:

- Results of our clinical trials;
- Approval or disapproval of our ANDAs or NDAs;
- Announcements of innovations, new products, or new patents by us or by our competitors;
- Announcements of other material events;
- Governmental regulation;
- Patent or proprietary rights developments;
- Proxy contests or litigation;
- News regarding the efficacy of, safety of or demand for drugs or drug technologies;
- Economic and market conditions, generally and related to the pharmaceutical industry;
- Healthcare legislation;
- Changes in third-party reimbursement policies for drugs; and
- Fluctuations in our operating results.

The sale or issuance of our common stock to Lincoln Park or upon conversion of outstanding preferred stock or exercise of outstanding warrants and options may cause dilution and the sale of the shares of common stock acquired by Lincoln Park or the issuance of shares upon conversion or exercise of outstanding preferred stock and warrants, or the perception that such sales and issuances may occur, could cause the price of our common stock to fall.

On May 1, 2017, we entered into the Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park has committed to purchase up to $40,000,000 of our common stock. Concurrently with the execution of the Purchase Agreement, we issued 5,540,551 shares of our common stock to Lincoln Park as an initial fee for its commitment to purchase shares of our common stock under the Purchase Agreement. Furthermore, for each additional purchase by Lincoln Park, additional commitment shares in commensurate amounts up to a total of 5,540,551 shares will be issued based upon the relative proportion of the aggregate amount of $40,000,000 purchased by Lincoln Park. The purchase shares that may be sold pursuant to the Purchase Agreement may be sold by us to Lincoln Park at our discretion from time to time over a 36-month period commencing after June 5, 2017. The purchase price for the shares that we may sell to Lincoln Park under the Purchase Agreement will fluctuate based on the price of our common stock. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall.

We generally have the right to control the timing and amount of any sales of our shares to Lincoln Park. Additional sales of our common stock, if any, to Lincoln Park will depend upon market conditions and other factors to be determined by us. Lincoln Park may ultimately purchase all, some, or none of the shares of our common stock that may be sold pursuant to the Purchase Agreement and, after it has acquired shares, Lincoln Park may sell all, some or none of those shares.

In addition, as of March 31, 2018, there were outstanding shares of preferred stock convertible into approximately 158 million shares of Common Stock and warrants to purchase an aggregate of approximately 79 million shares of Common Stock at an exercise price of $0.1521 per share, vested options to purchase an aggregate of approximately 5.4 million shares at a weighted average exercise price of $0.15. Additional shares of Common Stock may be issuable as a result of anti-dilution provisions in the outstanding preferred stock and warrants.

As a result of the above discussed potential issuance of securities, such issuances by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park or pursuant to the conversion or exercise of outstanding shares of preferred stock and warrants, or the anticipation of such issuances, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

The issuance of our common stock to Directors, Employees, and Consultants in payment of fees and salaries cause dilution and the sale o these shares of common stock so issued, or the perception that sales of these shares so issued may occur, could cause the price of our common stock to fall.

Pursuant to the Company's policies relating to the compensation of Directors, all director fees are paid via the issuance of shares of Common Stock with such shares being valued at the simple average of the closing price of the Company's Common Stock for each day in the period for which the director fees were incurred. In addition, members of the Company's management, certain employees and consultants receive a portion of their salaries or compensation via the issuance of shares Common Stock, with such shares being valued by the same method as that used for the shares issued in payment of director fees.

The issuance of these shares is dilutive to holders of our Common Stock, and the subsequent sale of these shares, or the perception that the sale of these shares may occur, could cause the price of our common stock to fall.

Raising of additional funding through sales of our securities could cause existing holders of our Common Stock to experience substantial dilution.

Any additional financing that involves the further sale of our securities could cause existing holders of our Common Stock to experience substantial dilution. On the other hand, if we incurred debt, we would be subject to risks associated with indebtedness, including the risk that interest rates might fluctuate, and cash flow would be insufficient to pay principal and interest on such indebtedness.

The issuance of additional shares of our Common Stock or our preferred stock could make a change of control more difficult to achieve.

The issuance of additional shares of our Common Stock, including those shares issued pursuant to conversion of convertible preferred shares, or the issuance of shares of an additional series of preferred stock could be used to make a change of control of us more difficult and expensive. Under certain circumstances, such shares could be used to create impediments to, or frustrate persons seeking to cause, a takeover or to gain control of us. Such shares could be sold to purchasers who might side with our Board of Directors in opposing a takeover bid that the Board of Directors determines not to be in the best interests of our shareholders. It might also have the effect of discouraging an attempt by another person or entity through the acquisition of a substantial number of shares of our Common Stock to acquire control of us with a view to consummating a merger, sale of all or part of our assets, or a similar transaction, since the issuance of new shares could be used to dilute the stock ownership of such person or entity.

Provisions of our Articles of Incorporation and By-Laws could defer a change of our Management which could discourage, or delay offers to acquire us.

Provisions of our Articles of Incorporation and By-Laws law may make it more difficult for someone to acquire control of us or for our shareholders to remove existing management and might discourage a third party from offering to acquire us, even if a change in control or in Management would be beneficial to our shareholders. For example, as discussed above, our Articles of Incorporation allows us to issue shares of preferred stock without any vote or further action by our shareholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further shareholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In this regard, on November 15, 2013, we entered into a Shareholder Rights Plan and, under the Rights Plan, our Board of Director declared a dividend distribution of one Right for each outstanding share of our common stock and one right for each share of Common Stock into which any of our outstanding Preferred Stock is convertible, to shareholders of record at the close of business on that date. Each Right entitles the registered holder to purchase from us one "Unit" consisting of one one-millionth (1/1,000,000) of a share of Series H Junior Participating preferred stock, at a purchase price of $2.10 per Unit, subject to adjustment, and may be redeemed prior to November 15, 2023, the expiration date, at $0.000001 per Right, unless earlier redeemed by the Company. The Rights generally are not transferable apart from the common stock and will not be exercisable unless and until a person or group acquires or commences a tender or exchange offer to acquire, beneficial ownership of 15% or more of our common stock. However, for Mr. Hakim, our Chief Executive Officer, the Rights Plan's the 15% threshold excludes shares beneficially owned by him as of November 15, 2013 and all shares issuable to him pursuant to his employment agreement and the Mikah Note. Our By-Laws provide for the classification of our Board of Directors into three classes.

There are inherent uncertainties involved in estimates, judgments and assumptions used in the preparation of financial statements in accordance with GAAP. Any future changes in estimates, judgments and assumptions used or necessary revisions to prior estimates, judgments or assumptions could lead to a restatement of our results.

The consolidated financial statements included in this Annual Report on Form 10-K are prepared in accordance with GAAP. This involves makin estimates, judgments and assumptions that affect reported amounts of assets (including intangible assets), liabilities, mezzanine equity, stockholders' equity, operating revenues, costs of sales, operating expenses, other income, and other expenses. Estimates, judgments, and assumptions are inherently subject to change in the future and any necessary revisions to prior estimates, judgments or assumptions could lead to a restatement. Any such changes could result in corresponding changes to the amounts of assets (including goodwill and other intangible assets), liabilities, mezzanine equity, stockholders' equity, operating revenues, costs of sales, operating expenses, other income and other expenses.

Our Common Stock is considered a "penny stock". The application of the "penny stock" rules to our Common Stock could limit the tradin and liquidity of our Common Stock, adversely affect the market price of our Common Stock, and increase the transaction costs to sell shares o our Common Stock.

Our common stock is a "low-priced" security or "penny stock" under rules promulgated under the Securities Exchange Act of 1934, as amended. In accordance with these rules, broker-dealers participating in transactions in low-priced securities must first deliver a risk disclosure document which describes the risks associated with such stocks, the broker-dealer's duties in selling the stock, the customer's rights and remedies and certain market and other information. Furthermore, the broker-dealer must make a suitability determination approving the customer for low-priced stock transactions based on the customer's financial situation, investment experience and objectives. Broker-dealers must also disclose these restrictions in writing to the customer, obtain specific written consent from the customer, and provide monthly account statements to the customer. The effect of these restrictions will likely decrease the willingness of broker-dealers to make a market in our Common Stock, will decrease liquidity of our Common Stock and will increase transaction costs for sales and purchases of our Common Stock as compared to other securities.

Our Common Stock is quoted on the Over-the-Counter Bulletin Board. The Over-the-Counter Bulletin Board is a quotation system, not a issuer listing service, market, or exchange, therefore, buying and selling stock on the Over-the-Counter Bulletin Board is not as efficient as buying and selling stock through an exchange. As a result, it may be difficult to sell our Common Stock for an optimum trading price or at all.

The Over-the-Counter Bulletin Board (the "OTCBB") is a regulated quotation service that displays real-time quotes, last sale prices and volum limitations in over-the-counter securities. Because trades and quotations on the OTCBB involve a manual process, the market information for such securitie cannot be guaranteed. In addition, quote information, or even firm quotes, may not be available. The manual execution process may delay order processing and intervening price fluctuations may result in the failure of a limit order to execute or the execution of a market order at a significantly different price. Execution of trades, execution reporting and the delivery of legal trade confirmations may be delayed significantly. Consequently, one may not be able to sell shares of our Common Stock at the optimum trading prices.

When fewer shares of a security are being traded on the OTCBB, volatility of prices may increase, and price movement may outpace the ability t deliver accurate quote information. Lower trading volumes in a security may result in a lower likelihood of an individual's orders being executed, and current prices may differ significantly from the price one was quoted by the OTCBB at the time of the order entry. Orders for OTCBB securities may be canceled o edited like orders for other securities. All requests to change or cancel an order must be submitted to, received, and processed by the OTCBB. Due to th manual order processing involved in handling OTCBB trades, order processing and reporting may be delayed, and an individual may not be able to cancel o edit his order. Consequently, one may not be able to sell shares of Common Stock at the optimum trading prices.

The dealer's spread (the difference between the bid and ask prices) may be large and may result in substantial losses to the seller of securities on the OTCBB if the Common Stock or other security must be sold immediately. Further, purchasers of securities may incur an immediate "paper" loss due to th price spread. Moreover, dealers trading on the OTCBB may not have a bid price for securities bought and sold through the OTCBB. Due to the foregoin demand for securities that are traded through the OTCBB may be decreased or eliminated.

The Series J Convertible Preferred Stock includes a provision for the payment of an annual dividend equal to twenty percent of the stated value of outstanding shares, beginning four years subsequent to the date of issuance of share of Series J Convertible Preferred if the Company is unable to obtain shareholder approval of an increase in authorized shares of Common Stock. These dividends may require expenditure of Company resources in the future, and they may make it difficult to sell our Common Stock for an optimum trading price or at all.

The Company issued 24.0344 shares of Series J Convertible Preferred Stock ("*Series J Preferred*") in April 2017, with such shares having an aggregate stated value of $23.0 million and are convertible, four years subsequent to their date of issue, into 158.0 million shares of Common Stock. The Company does not have sufficient unissued and unreserved shares in its currently authorized share capital and would require shareholder approval to increase the number of authorized shares to an amount that is sufficient to allow the issuance of Common Stock pursuant to a future conversion of Series J Preferred (the "*Shareholder Approval*"). In the event that such an increase in authorized shares is not approved by the shareholders on or before four years of the issuance of the Series J Preferred shares, holders of Series J Preferred shares are entitled to an annual dividend equal to twenty percent of the stated value of Series J Preferred shares held, with such dividends accruing from the date that is 4 years subsequent to the date of issuance of each share of Series J Preferred. This dividend is payable in cash, if such is legally available for the payment of this dividend, or payable by the issuance of additional shares of Series J Preferred. Accordingly, in the event that dividends become payable on Series J Preferred because the Company did not timely obtain Shareholder Approval the Company will be required to use its cash resources to pay these dividends, if such cash is legally available for the payment of dividends, or will issue additional shares of Series J Preferred, which are convertible into additional shares of Common Stock, which in turn would require shareholder approval of a further increase in authorized shares. Both potential scenarios could result in the expenditure of Company resources, or a difficulty in the ability to sell our Common Stock for an optimum trading price or at all, or both, in the event that dividends become due and owing on shares of Series J Preferred.

ITEM 1B UNRESOLVED STAFF COMMENTS

None.

ITEM 2 PROPERTIES

We own a facility located at 165 Ludlow Avenue, Northvale, New Jersey ("*165 Ludlow*") which contains approximately 15,000 square feet of floor space. This real property and the improvements thereon are encumbered by a mortgage in favor of the New Jersey Economic Development Authority ("*NJEDA*") as security for a loan through tax-exempt bonds from the NJEDA to Elite. The mortgage contains certain customary provisions including, without limitation, the right of NJEDA to foreclose upon a default by Elite. The NJEDA has declared the payment of this bond to be in default (for more information on the NJEDA Bonds, see Part II, Item 7 *"Management's Discussion and Analysis of Financial Condition and Results of Operations; Liquidity and Capital Resources; NJEDA Bonds")*. We are currently using the Facility as a laboratory, manufacturing, storage, distribution, and office space.

We 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, we 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*").

The 135 Ludlow Ave. modified lease includes an initial term, which expires 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. Additional renovations and construction to further expand the Company's manufacturing resources are in progress.

165 Ludlow and 135 Ludlow are hereinafter referred to as the "*Facilities*" or the "*Northvale Facility*".

Properties used in our operation are considered suitable for the purposes for which they are used, at the time they are placed into service, and are believed adequate to meet our needs for the reasonably foreseeable future.

ITEM 3 LEGAL PROCEEDINGS

In the ordinary course of business, we may be subject to litigation from time to time. There is no current, pending or, to our knowledge, threatened litigation or administrative action to which we are a party or of which our property is the subject (including litigation or actions involving our officers, directors, affiliates, or other key personnel, or holders of record or beneficially of more than 5% of any class of our voting securities, or any associate of any such party) which in our opinion has, or is expected to have, a material adverse effect upon our business, prospects financial condition or operations.

ITEM 4 MINE SAFETY DISCLOSURES

Not Applicable.

PART II

ITEM 5 MARKET FOR COMPANY'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHA EQUITY SECURITIES

Market Information

Our Common Stock is quoted on the Over-the-Counter Bulletin Board under the ticker symbol "ELTP". The following table shows, for the perioc indicated, the high and low bid prices per share of our Common Stock as by OTC Bulletin Board. Over-the-counter market quotations reflect inter-deale prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

Quarter Ended	High	Low
Fiscal Year Ending March 31, 2018		
March 31, 2018	$ 0.14	$ 0.10
December 31, 2017	$ 0.10	$ 0.08
September 30, 2017	$ 0.19	$ 0.09
June 30, 2017	$ 0.24	$ 0.14
Fiscal Year Ending March 31, 2017		
March 31, 2017	$ 0.18	$ 0.13
December 31, 2016	$ 0.17	$ 0.13
September 30, 2016	$ 0.38	$ 0.15
June 30, 2016	$ 0.36	$ 0.29

As of June 7, 2018, the last reported sale price of our Common Stock, as reported by the OTCBB, was $0.09.

Holders

As of June 7, 2018, there were, respectively, approximately 122 and 1 holders of record of our Common Stock and Series J Preferred Stock.

Dividends

We have never paid cash dividends on our Common Stock. We currently anticipate that we will retain all available funds for use in the operation and expansion of our business.

Stock Performance Graph

The following graph provide a comparison of the cumulative 5-year total shareholder return on the Company's Common Stock with that of the cumulative total shareholder return on the Russell 3000 Index and a five stock custom composite index, with all cases assuming reinvestment of dividends. The custom composite index consists of the following companies which were selected as a peer group with comparable market segments and market capitalizations to those of the Company: Durect Corp, Biotime Inc., Biospecifics Technologies Corp, Athersys Inc, Acura Pharmaceuticals Inc. (the "Custom Composi Index").

(performance data provided by: S&P Capital IQ)

	Value of $100 Invested on March 31, 2013 March 31,					
	2013	2014	2015	2016	2017	2018
Elite Pharmaceuticals Inc.	$ 100.00	$ 538.11	$ 321.94	$ 407.36	$ 194.35	$ 131.41
Russell 3000 Index	$ 100.00	$ 120.24	$ 132.58	$ 129.47	$ 149.81	$ 167.35
Custom Composite Index	$ 100.00	$ 113.16	$ 141.54	$ 105.90	$ 118.41	$ 119.77

(source: S&P Capital IQ)

Recent Sales of Unregistered Securities

During the year ended March 31, 2018, the Company issued an aggregate of 9.0 million shares of Common Stock, with such shares constituting unregistered securities, consisting of 3.3 million shares of Common Stock issued to Directors and Officers in payment of Directors Fees and Salaries in accordance with the Company's policy on Director Compensation, or the employment agreements with officers of the Company, as appropriate, 5.7 million shares of Common Stock issued pursuant to the exercise of cash warrants. Please see Note 13 to the audited financial statements '*Shareholders' Equity (Deficit)*".

Securities Authorized for Issuance under Equity Compensation Plans

The following table sets forth certain information regarding Elite's equity compensation plans as of March 31, 2018:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price per share of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders [1]	—	—	3,000,000
Equity compensation plans not approved by security holders	—	—	2,336,420[2]
Total	—	—	**5,336,420**

(1) Represents securities reserved and available for grant under the 2014 Equity Incentive Plan
(2) Represents securities reserved and available for grant under the 2009 Equity Incentive Plan

2014 Equity Incentive Plan

Our 2014 Equity Incentive Plan (the "*2014 Plan*") was adopted by the Board on March 17, 2014, to attract, motivate and retain officers, employees, consultants, and directors by issuing common stock-based incentives to directors, officers, employees, and consultants who are selected for participation. By relating incentive compensation to increases in shareholder value, it is hoped that these individuals will both continue in the long-term service of the Company and be motivated to experience a heightened interest and participate in the future success of Company operations. An aggregate of 3,000,000 shares of Common Stock are reserved for grant and issuance pursuant to the 2014 Plan. The 2014 Plan is administered and interpreted by our Compensation Committe (the "*Administrator*"). Awards under the 2014 Plan may be granted in any one or all of the following forms: (i) incentive stock options ("ISOs") intended to qualify under Section 422 of the Internal Revenue Code of 1986, as amended (the "Code"); (ii) non-qualified stock options ("NSOs"); (iii) stock appreciatio rights, which may be granted in tandem with options or on a stand-alone basis; (iv) shares of restricted stock; (v) shares of unrestricted stock; (vi) performance shares, and (vii) performance units.

Options may not be granted under the 2014 Plan at an exercise price of less than the fair market value of the common stock on the date of grant and the term of options cannot exceed ten years. ISOs may only be granted to persons who are employees of the Company. The exercise price of an ISO grante to a holder of more than 10% of the common stock must be at least 110% of the fair market value of the common stock on the date of grant, and the term of these options cannot exceed five years.

The Administrator also may grant stock appreciation rights. Stock appreciation rights represent the right to receive upon exercise an amount payable in cash or common stock equal to (A) the number of shares with respect to which the stock appreciation right is being exercised multiplied by (B) the excess of (i) the fair market value of a share of common stock on the date the award is exercised over (ii) the exercise price specified in the award agreement.

Under the performance award component of the 2014 Plan, participants may be granted an award denominated in shares of common stock or in dollars. Achievement of the performance targets, or multiple performance targets established by the Administrator relating to corporate, group, unit or individual performance based upon standards set by the Administrator shall entitle the participant to payment at the full amount or a portion of the amount specified with respect to the award, at the discretion of the Administrator based on its evaluation of the performance of the target goals applicable to such award. Payment may be made in cash, common stock or any combination thereof, as determined by the Administrator, and shall be adjusted in the event the participant ceases to be an employee of the Company before the end of a performance cycle by reason of death, disability, or retirement.

Under the stock component of the 2014 Plan, the Administrator may, in selected cases, grant to a plan participant a given number of shares of restricted stock or unrestricted stock. Restricted stock under the 2014 Plan is common stock restricted as to sale pending fulfillment of such vesting schedule and employment requirements as the Administrator shall determine. Prior to the lifting of the restrictions, the participant will nevertheless be entitled to receive distributions in liquidation and dividends on, and to vote the shares of, the restricted stock. The 2014 Plan provides for forfeiture of restricted stock for breach of conditions of grant.

The 2014 Plan also permits the board of directors (and not the Compensation Committee) to grant awards of NSOs, restricted stock or unrestricte stock to non-employee directors. The board may authorize individual grants or adopt one or more formulas for grants of awards to the non-employee directors. All options granted to non-employee directors must have an exercise price equal to the fair market value at the date of grant.

The exercise price of awards may be paid in cash, in shares of common stock (valued at fair market value at the date of exercise), by delivery of a notice of exercise together with irrevocable instructions to a broker to deliver to the Company the proceeds of the sale of common stock or of a loan from the broker sufficient to pay the exercise price, by having the Company withhold from shares being exercised the number of shares having a fair market value equal to the exercise price for all shares being exercised, or by a combination of the foregoing means of payment, as may be determined by the Administrator.

2009 Equity Incentive Plan

Our 2009 Equity Incentive Plan was adopted by the Board on November 24, 2009, to provide incentives to attract, retain and motivate eligible person whose present and potential contributions are important to the success of Elite and its subsidiaries, by offering them an opportunity to participate in our future performance through awards of Options, the right to purchase Common Stock and Stock Bonuses. An aggregate of 8,000,000 shares of Common Stock ar reserved for grant and issuance pursuant to the 2009 Equity Incentive Plan. The 2009 Equity Incentive Plan is administered and interpreted by ou Compensation Committee (the "*Compensation Committee*"). Under the 2009 Equity Incentive Plan, we are permitted to grant both incentive stock options ("Incentive Stock Options" or "ISOs") within the meaning of Section 422 of the Internal Revenue Code (the "Code") to employees, and other options which d not qualify as Incentive Stock Options (the "*Non-Qualified Options*") to employees, officers, Directors of and consultants to Elite. The per share purchase price of options granted under the 2009 Equity Incentive Plan may not be less than the fair market value of the shares on the date of the grant, provided tha the exercise price of any ISO granted to a ten percent stockholder will not be less than 110% of the fair market value on the date of the grant. Recipients of ISO's and Non-Qualified Options have no voting, dividend, or other rights as stockholders with respect to shares of Common Stock covered by options prior t becoming the holders of record of such shares.

Under the 2009 Equity Incentive Plan, we also are permitted to offer stock awards ("*2009 Equity Incentive Plan Stock Awards*") to eligible persons. The 2009 Equity Incentive Plan defines such stock awards as an offer by us to sell to an eligible person shares that may or may not be subject to restrictions. The purchase of price of shares sold pursuant to a 2009 Equity Incentive Plan Stock Award may not be less than the fair market value of the shares on the grant date, provided, however, that the number of shares issued for the payment of employee and officers' salaries, or directors' fees will be computed using the average daily closing price, which is defined as the simple average of the closing price of each trading day in the quarter or other applicable period for which payment is due.

We also are permitted to award stock bonuses under the 2009 Equity Incentive Plan, which defines such stock bonuses as an award of shares for extraordinary services rendered to the Company.

Issuer Purchases of Equity Securities

None.

ITEM 6 SELECTED FINANCIAL DATA

The consolidated financial data presented below have been derived from our financial statements. The selected historical consolidated financial data presented below should be read in conjunction with Part II, Item 7. of this report "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" and Part II, Item 8. of this report "*Financial Statements and Supplementary Data*". The selected data in this section is not intended to replace the Consolidated Financial Statements. The information presented below is not necessarily indicative of the results of our future operations. Certain prior period amounts have been restated to reflect corrections to errors in accounting done on a prospective basis.

	Years Ended March 31,				
	2018	2017	2016	2015	2014
	(dollars in thousands, except per share amounts)				
Consolidated Statement of Operations Data:					
Total revenue	$ 7,459	$ 9,638	$ 12,498	$ 5,015	$ 4,601
Loss from operations	(9,051)	(7,356)	(8,317)	(16,507)	(5,284)
Other income (expense), net	4,332	9,300	7,113	21,724	(36,270)
Benefit from sale of state net operating loss credits	1,046	1,868	520	3	293
Net (loss) income	(3,673)	3,811	(683)	5,221	(41,261)
Change in carrying value of convertible preferred share mezzanine equity	-	20,714	(9,286)	23,709	(55,314)
Net (loss) income attributable to common shareholders	(3,673)	24,525	(9,969)	28,930	(96,575)
Basic (loss) income per share attributable to common shareholders	(0.00)	0.03	(0.01)	0.05	(0.21)
Diluted loss per share attributable to common shareholders	(0.01)	(0.01)	(0.01)	(0.02)	(0.21)
Consolidated Balance Sheet Data:					
Cash	$ 7,179	$ 10,595	$ 11,512	$ 7,464	$ 6,942
Current assets	13,702	18,413	16,714	12,331	9,925
Total assets	30,883	34,311	31,674	25,920	24,318
Current liabilities	5,115	3,345	4,640	5,069	6,161
Working capital	8,588	15,068	12,074	7,262	3,764
Long-term liabilities	7,292	5,302	15,870	20,583	38,373
Convertible preferred share mezzanine equity	13,904	-	44,286	35,000	60,982
Total shareholders' equity (deficit)	4,572	25,664	(33,122)	(34,731)	(81,198)
Other Financial Data:					
Cash used in operating activities	$ (4,809)	$ (7,884)	$ (2,765)	$ (15,103)	$ (4,217)
Cash (used in) provided by investing activities	(277)	(1,105)	(1,949)	2,879	(558)
Cash provided by financing activities	1,671	8,071	8,762	12,746	11,347

The comparability of the foregoing is impacted by the change in classification of the NJEDA bond liabilities made subsequent to the Company's repayment of all amounts in arrears during the year ended March 31, 2015. Prior to the year ended March 31, 2015, the entire bond liability was recorded as a current liability as a result of a notice of default being issued pursuant to the Company's non-payment of scheduled amounts due. As these in arrears amounts were paid in the year ended March 31, 2015, and the Company has remained current on all payments scheduled pursuant to the bond agreement, bond liabilities included in current liabilities consist only of those amounts due within 12 months of the balance sheet date, with all remaining amounts due being classified as non-current liabilities. Please see Note 6 to the audited financial statements: "*NJEDA Bonds*" for a further discussion of the bond liability.

The comparison of net income (loss) and long-term obligations is significantly impacted by the change in fair value of warrant derivatives, with net income (loss) having a strong inverse correlation to the trading price of the Company's Common Stock.

ITEM 7 MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION

Management's Discussion and Analysis of Financial Condition and Results of Operations, or MD&A, is intended to provide a reader of ou consolidated financial statements with a narrative from the perspective of our management on our financial condition, results of operations, liquidity and certain other factors that may affect our future results. You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial data included elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review Item 1A of this Annual Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Background

We are a specialty pharmaceutical company principally engaged in the development and manufacture of oral, controlled-release products, using proprietary know-how and technology, particularly as it relates to abuse resistant products.

We occupy manufacturing, warehouse, laboratory and office space at 165 Ludlow Avenue and 135 Ludlow Avenue in Northvale, NJ. The Northvale Facility operates under Current Good Manufacturing Practice ("*cGMP*") and is a United States Drug Enforcement Agency ("*DEA*") registered facility for research, development, and manufacturing.

Strategy

We focus our efforts on the following areas: (i) development of our pain management products; (ii) manufacturing of a line of generic pharmaceutical products with approved Abbreviated New Drug Application's ("*ANDAs*"); (iii) development of additional generic pharmaceutical products; (iv) development of the other products in our pipeline including the products with our partners; (v) commercial exploitation of our products either by license and the collection of royalties, or through the manufacture of our formulations; and (vi) development of new products and the expansion of our licensing agreements with other pharmaceutical companies, including co-development projects, joint ventures and other collaborations.

Our focus is on the development of various types of drug products, including branded drug products which require new drug applications ("*NDAs*") under Section 505(b)(1) or 505(b)(2) of the Drug Price Competition and Patent Term Restoration Act of 1984 (the "*Drug Price Competition Act*") as well as generic drug products which require ANDAs.

We believe that our business strategy enables us to reduce its risk by having a diverse product portfolio that includes both branded and generic products in various therapeutic categories and to build collaborations and establish licensing agreements with companies with greater resources thereby allowing us to share costs of development and improve cash-flow.

Product Development Activities

In January 2016, we submitted a 505(b)(2) New Drug Application for SequestOx™, after receiving a waiver of the $2.3 million filing fee from th FDA. Please see the section entitled:*"Filed Products Under FDA Review – SequestOx™ - Immediate Release Oxycodone with sequestere Naltrexone"* for further details.

On August 9, 2016, the Company filed an ANDA with the FDA for a generic version of Percocet® (oxycodone hydrochloride and acetaminophen USP CII) 5mg, 7.5mg and 10mg tablets with 325mg of acetaminophen ("*Generic Oxy/APAP*"). Please see the section entitled: "*Filed Products Under FDA Review – Oxycodone hydrochloride and acetaminophen USP CII (generic version of Percocet®)"* for further details.

On December 12, 2016, the Company filed an ANDA with the FDA for a generic version of Norco® (hydrocodone bitartrate and acetaminophen tablets USP CII) 2.5mg/325mg, 5mg/325mg, 7.5mg/325mg and 10mg/325mg tablets ("*Generic Hydrocodone/APAP*"). Please see section entitled: "*Filed Products Under FDA Review – Hydrocodone bitartrate and acetaminophen tablets USP CII (generic version of Norco®)"* for further details.

On April 4, 2017, the Company filed an ANDA with the FDA for a generic version of a synthetic narcotic analgesic indicated for the management o pain. Please see section entitled: "*Filed Products Under FDA Review – Generic version of a synthetic narcotic analgesic"* for further details.

On September 20, 2017, the Company filed an ANDA with the FDA for generic version of Oxycontin® (extended release Oxycodon Hydrochloride). Please see the section entitled: "*Filed Products Under FDA Review – Oxycodone Hydrochloride extended release (generic version o Oxycontin®)"* for further details.

On February 8, 2018, the Company filed an ANDA with the FDA for a generic version of an immediate release central nervous system ("CNS" stimulant. The ANDA represents the first filing for a product co-developed with SunGen under the SunGen Agreement. Please see the section entitled: *"Filed Products Under FDA Review – Generic version of immediate release Central Nervous System stimulant"* for further details.

On May 24, 2018, the Company filed an ANDA with the FDA for a generic version of an extended release CNS stimulant. The ANDA represer the second filing for a product co-developed with SunGen under the SunGen Agreement. According to IMS Health data, the branded product and it equivalents had total U.S. sales of approximately $1.6 billion for the twelve months ended September 30, 2017. The Company has not yet received a respons from the FDA on this filing. Please note that there can be no assurances of this product receiving marketing authorization or achieving commercialization. In addition, even if marketing authorization is received and the product is commercialized, there can be no assurances of future revenues or profits in such amounts that would provide adequate return on the significant investments made to secure marketing authorization for this product. Please also see the section entitled "*Filed products under FDA review*" as well as the section entitled "*Master Development and License Agreement with SunGen Pharma LLC.* Under the terms of the SunGen Agreement, the product will be owned jointly by the Company and SunGen. Elite shall have exclusive rights to market and se the product under its own label. Elite will also manufacture and package the product on a cost-plus basis. Please see the section entitled "*Master Development and License Agreement with SunGen Pharma LLC*" for further details on the SunGen Agreement.

There can be no assurances that any of these products will receive marketing authorization and achieve commercialization within this time period, or at all. In addition, even if marketing authorization is received, there can be no assurances that there will be future revenues of profits, or that any such future revenues or profits would be in amounts that provide adequate return on the significant investments made to secure these marketing authorizations.

On March 22, 2017, European Patent No. 1615623 titled "*Abuse-Resistant Oral Dosage Forms and Method of Use Thereof*" was issued. This patent expands the intellectual property for the Company's opioid abuse deterrent technology. Elite now has four US patents, one European patent, and two Canadian patents issued in this area with additional patents pending in the U.S., Canada and Europe.

Results of Operations:

Years Ended March 31, 2018 and 2017

Revenue, Cost of revenue and Gross profit:

	Years Ended March 31,		Change	
	2018	2017	Dollars	Percentage
Manufacturing fees	$ 5,199,006	$ 7,326,959	$ (2,127,953)	-29%
Licensing fees	2,259,705	2,310,756	(51,051)	-2%
Total revenue	7,458,711	9,637,715	(2,179,004)	-23%
Cost of revenue	3,511,123	5,898,405	(2,387,282)	-40%
Gross profit	$ 3,947,588	$ 3,739,310	$ 208,278	6%
Gross profit - percentage	53%	39%		

Total revenues for the year ended March 31, 2018 decreased by $2.2 million or 23%, to $7.4 million, as compared to $9.6 million, for the corresponding year.

Manufacturing fees decreased by $2.1 million, or 29%, due to decreases in generic Methadone and Naltrexone sales, partially offset by increases in generic Phentermine and Hydromorphone sales.

Licensing fees decreased by $0.05 million, or 2% due to decreases in licensing fees earned from generic Naltrexone sales.

Costs of revenue consists of manufacturing and assembly costs. Our costs of revenue decreased by $2.4 million or 40%, to $3.5 million as compared to $5.9 million for the corresponding period. The decrease in costs of revenue is due to decreased manufacturing operations and a greater allocation of manufacturing resources to product development.

Our gross profit margin was 53% during the year ended March 31, 2018 as compared to 39% during the year ended March 31, 2017. The increase in profit margin percentage is due to difference in manufacturing product mix on a year on year basis, combined with the Company's greater allocation of available resources to product development activities, resulting in decreased overhead absorption by manufacturing operations.

Operating expenses:

	Years Ended March 31,		Change	
	2018	2017	Dollars	Percentage
Operating expenses:				
Research and development	$ 9,621,365	$ 8,301,693	$ 1,319,672	16%
General and administrative	2,332,289	2,083,226	249,063	12%
Non-cash compensation through issuance of stock options	244,753	357,955	(113,202)	-32%
Depreciation and amortization	800,460	352,369	448,091	127%
Total operating expenses	$ 12,998,867	$ 11,095,243	$ 1,903,624	17%

Operating expenses consist of research and development costs, general and administrative, non-cash compensation and depreciation and amortization expenses. Operating expenses for the year ended March 31, 2018 increased by $1.9 million, or 17%, to $13.0 million, as compared to $11.1 million for the prior year.

Research and development costs for the year ended March 31, 2018 were $9.6 million, an increase of $1.3 million or 16% from $8.3 million of such costs for the prior year. The increase was due to the timing and composition of ongoing development of our abuse deterrent opioid and other generic products combined with an increased focus of available resources on research and development activities.

General and administrative expenses for the year ended March 31, 2018 were $2.3 million, an increase of $0.2 million or 12% from $2.1 million of such costs for the prior year. The increase was due to increased regulatory and compliance costs, including, without limitation increases in FDA regulatory compliance and activities relating to the Company's improvement in internal controls over financial reporting in accordance with requirements of Section 404 of the Sarbanes Oxley legislation and related regulations.

Non-cash compensation expense for the year ended March 31, 2018 was $0.245 million, a decrease of $0.113 million or 32% from $0.358 million of such costs for the prior year. Non-cash compensation expense derives from the timing in amortization of the value of employee stock options issued over the course of the last three years.

Depreciation and amortization expense for the year ended March 31, 2018 was $0.8 million, an increase of $0.4 million, or 127% from $0.4 million of such costs for the comparable period of the prior year. The increase was due to acquisitions of additional fixed assets as well as higher depreciation absorption rates as compared to the prior year.

As a result of the foregoing, our loss from operations for the year ended March 31, 2018 was ($9.1) million, compared to a loss from operations of ($7.4) million for the year ended March 31, 2017.

Other income (expense):

	Years Ended March 31,		Change	
	2018	2017	Dollars	Percentage
Other income (expense):				
Interest expense and amortization of debt issuance costs	$ (335,498)	$ (238,223)	$ (97,275)	-41%
Change in fair value of derivative instruments	4,650,266	9,525,103	(4,874,837)	-51%
Interest income	17,510	12,620	4,890	39%
Other income, net	$ 4,332,278	$ 9,299,500	$ (4,967,222)	-53%

Other income (expense), net for the year ended March 31, 2018 was net other income of $4.3 million, a decrease in net other income of $5.0 million from the net other income of $9.3 million for the comparable period of the prior year. The decrease in other income was due to the change in the fair value of our outstanding warrants (derivative instruments) during the year ended March 31, 2018 totaling other income of $4.7 million, as compared to $9.5 million for the prior year. Please note that the change in fair value of derivative instruments is determined in large part by the number of warrants outstanding and the change in the closing price of our Common Stock as of the end of the year, as compared to the closing price at the beginning of the year, with a strong inverse relationship between derivative revenues and increases in the closing price of our Common Stock.

As a result of the foregoing, our net loss from operations before the net benefit from sale of state net operating loss credits for the year ended March 31, 2018 was ($4.7) million, compared to net income of $1.9 million for the prior year.

Net benefit from sale of state net operating loss credits

During the year ended March 31, 2018, Elite Labs, a wholly owned subsidiary of Elite, received final approval from the New Jersey Economi Development Authority for the sale of net tax benefits. The Company sold the net tax benefits approved for total net proceeds of $1.0 million, compared to $1.9 million for the prior year.

Change in value of convertible preferred share mezzanine equity:

There was no change in the value of our convertible preferred stock, which is included in the calculation of net income (loss) attributable to common shareholders for the year ended March 31, 2018, as compared to an increase in net income of $20.7 million for the prior year. Accordingly, net loss attributable to common shareholders for the year ended March 31, 2018 was ($3.7) million, as compared to net income of $24.5 million for the prior year.

Years Ended March 31, 2017 and 2016

Revenue, Cost of revenue and Gross profit:

	Years Ended March 31,		Change	
	2017	2016	Dollars	Percentage
Manufacturing fees	$ 7,326,959	$ 8,002,866	$ (675,907)	-8%
Licensing fees	2,310,756	4,495,466	(2,184,710)	-49%
Total revenue	9,637,715	12,498,332	(2,860,617)	-23%
Cost of revenue	5,898,405	4,484,162	1,414,243	32%
Gross profit	$ 3,739,310	$ 8,014,170	$ (4,274,860)	-53%
Gross profit - percentage	39%	64%		

Total revenues for the year ended March 31, 2017 decreased by $2.9 million or 23%, to $9.6 million, as compared to $12.5 million, for the corresponding year.

Manufacturing fees decreased by $0.7 million, or 8%, due to decrease in generic Methadone, Hydromorphone and Phentermine sales, partially offse by increases in generic Naltrexone sales.

Licensing fees decreased by $2.2 million, or 49%. This decrease is primarily due to the Company earning a one-time, non-refundable $2.5 millior milestone in January 2016 related to the filing of a New Drug Application for SequestOx™. This milestone payment was offset by increases in license fee from generic sales licensed to TAGI and Epic.

Costs of revenue consists of manufacturing and assembly costs. Our costs of revenue increased by $1.4 million or 32%, to $5.9 million as compared to $4.5 million for the corresponding period. The increase in costs of revenue is primarily due to increased and continued investments in Company's facility and resources, and increased regulatory costs, leading to higher overhead absorption rates.

Our gross profit margin was 39% during the year ended March 31, 2017 as compared to 64% during the year ended March 31, 2016. The decrease i gross margin is due to the Company earning a one-time, non-refundable $2.5 million milestone in January 2016 related to the filing of an NDA fo SequestOx™, which resulted in a greater gross profit margin in the prior year, as compared to the current year, combined with a product mix consisting of lower margin products and higher overhead absorption rates in the current year, as compared to the prior year.

Operating expenses:

	Years Ended March 31,		Change	
	2017	2016	Dollars	Percentage
Operating expenses:				
Research and development	$ 8,301,693	$ 12,428,783	$ (4,127,090)	-33%
General and administrative	2,083,226	2,903,178	(819,952)	-28%
Non-cash compensation	357,955	333,362	24,593	7%
Depreciation and amortization	352,369	665,647	(313,278)	-47%
Total operating expenses	$ 11,095,243	$ 16,330,970	$ (5,235,727)	-32%

Operating expenses consist of research and development costs, general and administrative, non-cash compensation and depreciation and amortization expenses. Operating expenses for the year ended March 31, 2017 decreased by $5.2 million, or 32%, to $11.1 million, as compared to $16.3 million for the prior year.

Research and development costs for the year ended March 31, 2017 were $8.3 million, a decrease of $4.1 million or 33% from $12.4 million of such costs for the prior year. The decrease was due to the timing and composition of ongoing development of our abuse deterrent opioid and other products in addition to a focus on clinical trials for generic products.

General and administrative expenses for the year ended March 31, 2017 were $2.1 million, a decrease of $0.8 million or 28% from $2.9 million of such costs for the prior year. The decrease was due to ongoing cost reduction initiatives focused on an actual and proportionate reduction of general and administrative expenses, as compared to commercial and product development activities and achieving an operating expense profile with an increased direct correlation to these commercial and product development activities.

Non-cash compensation expense for the year ended March 31, 2017 was $0.358 million, an increase of $0.025 million or 7% from $0.333 million of such costs for the prior year. Non-cash compensation expense derives from the timing in amortization of the value of employee stock options issued over the course of the last three years.

Depreciation and amortization expense for the year ended March 31, 2017 was $0.4 million, a decrease of $0.3 million, or 47% from $0.7 million of such costs for the comparable period of the prior year. The decrease was due to the combination of increased facility utilization and higher depreciation absorption rates currently as a result of facility expansion and improvements over the last year.

As a result of the foregoing, our loss from operations for the year ended March 31, 2017 was ($7.4) million, compared to a loss from operations of ($8.3) million for the year ended March 31, 2016.

Other income (expense):

	Years Ended March 31,		Change	
	2017	2016	Dollars	Percentage
Other income (expense):				
Interest expense and amortization of debt issuance costs	$ (238,223)	$ (280,670)	$ 42,447	15%
Change in fair value of derivative instruments	9,525,103	7,394,006	2,131,097	29%
Interest income	12,620	-	12,620	0%
Other income, net	$ 9,299,500	$ 7,113,336	$ 2,186,164	31%

Other income, net for the year ended March 31, 2017 was net other income of $9.3 million, an increase in net other income of $2.2 million from the net other income of $7.1 million for the comparable period of the prior year. The increase in other income was due to the change in the fair value of our outstanding warrants (derivative instruments) during the year ended March 31, 2017 totaling other income of $9.5 million, as compared to $7.4 million for the prior year. Please note that the change in fair value of derivative instruments is determined in large part by the number of warrants outstanding and the change in the closing price of our Common Stock as of the end of the year, as compared to the closing price at the beginning of the year, with a strong inverse relationship between derivative revenues and increases in the closing price of our Common Stock.

As a result of the foregoing, our net income from operations before the net benefit from sale of state net operating loss credits for the year ended March 31, 2017 was $1.9 million, compared to a net loss of ($1.2) million for the prior year.

Net benefit from sale of state net operating loss credits

During the year ended March 31, 2017, Elite Labs, a wholly owned subsidiary of Elite, received final approval from the New Jersey Economi Development Authority for the sale of net tax benefits. The Company sold the net tax benefits approved for total net proceeds of $1.9 million, compared to $0.5 million for the prior year.

Change in value of Convertible Preferred Share Mezzanine Equity

Changes in the value in our Series I convertible preferred stock, which is included in the calculation of net income (loss) attributable to common shareholders resulted in an increase in net income of $20.7 million for the year ended March 31, 2017, as compared to an increase in net loss of $9.3 million for the prior year. Accordingly, net income attributable to common shareholders for the year ended March 31, 2017 was a net income of $24.5 million, compared to a net loss of ($10.0) million for the prior year.

Liquidity and Capital Resources

Capital Resources

	March 31,		
	2018	2017	Change
Current assets	$ 13,702,401	$ 18,412,720	$ (4,710,319)
Current liabilities	5,114,704	3,344,746	1,769,958
Working capital	8,587,697	15,067,974	(6,480,277)

The Company considers cash and working capital balances as several of the factors the Company uses in evaluating its performance, without limitation. As of March 31, 2018, the Company had cash on hand of $7.2 million and a working capital surplus of $8.6 million. The Company believes that such resources, combined with the Company's access to the equity line with Lincoln Park Capital (see below), are sufficient to fund operations through the current operating cycle. For the year ended March 31, 2018, the Company had losses from operations totaling ($9.1) million, net other income totaling $4.3 million and net loss of ($3.7) million. In addition, there were no changes in the carrying value of preferred share mezzanine equity for the year ended March 31, 2018 as compared to an increase of $20.7 million in the prior fiscal year, with such amount being charged to net income (loss) available to common shareholders. Please note that the Company's other income (expenses) and net income (loss) available to common shareholders are significantly influenced by the fluctuations in the fair value of warrant derivatives, change in carrying value of convertible preferred share mezzanine equity; such fair values bear a strong inverse correlation to the market share price of the Company's Common Stock.

Our working capital (total current assets less total current liabilities) decreased by $6.5 million from $15.1 million as of March 31, 2017 to $8.6 million as of March 31, 2018, with such decrease being primarily related to the loss from operations of $9.1 million, combined with a $1.8 million increase in current liabilities and purchases of fixed assets and intellectual property costs totaling $0.3 million.

The Company does not anticipate being profitable for the fiscal year ending March 31, 2019, due in large part to its plans to conduct clinical development and commercialization activities on a range of abuse deterrent opioid products, on an accelerated and simultaneous basis. Such activities require the investment of significant amounts in clinical trials, safety and efficacy studies, bioequivalence studies, product manufacturing, regulatory expertise and filings, as well as investments in manufacturing and lab equipment and software. In order to finance these significant expenditures, the Company entered into a new purchase agreement with Lincoln Park Capital Fund, with such agreement providing the Company with an equity line totaling $40.0 million. We believe this amount of financing, if received, is sufficient to fund the commercialization of the abuse deterrent opioid products identified. Please see below for further details on the financing transactions with Lincoln Park.

In addition, the Company had previously received Notices of Default from the Trustee of the NJEDA Bonds as a result of the utilization of the debt service reserve being used to pay interest payments as well as the company's failure to make scheduled principal payments. All monetary defaults have been cured during Fiscal 2015 and the Company is current on all NJEDA Bond interest and principal payments. See "*NJEDA Bonds*" below and the Risk Factor in Part I, Item 1A entitled "*A notice of default was issued by the New Jersey Economic Development Authority in relation to prior obligations of our tax-exempt bonds. Although we are current in our payments under these bonds, If the principal balances due under these bonds are accelerated pursuant to the notice of default, our ability to operate in the future will be materially and adversely affected*".

Summary of Cash Flows:

	Years Ended March 31,		
	2018	2017	2016
Net cash used in operating activities	$ (4,809,191)	$ (7,883,861)	$ (2,765,421)
Net cash used in investing activities	(277,332)	(1,104,976)	(1,948,829)
Net cash provided by financing activities	1,671,067	8,071,351	8,762,249

Year Ended March 31, 2018

Net cash used in operating activities for the year ended March 31, 2018 was $4.8 million, which included a net loss of ($3.7) million, and changes in operating assets and liabilities of $0.9 million. The changes in the balance of assets and liabilities include decreases in account receivables and inventory of $0.3 million and $1.5 million, respectively, which result in a net increase in cash offset by decreases in deferred revenues of $1.0 million, accounts payables, other current liabilities and prepaid expenses and other current assets of $0.5 million, each of which result in a net decrease in cash. These instances of decreases in cash are offset by change in non-cash compensation accrued of $0.9 million, non-cash change in fair value of derivative financial instruments – warrants of $4.7 million, and non-cash compensation from the issuance of common stock of $0.2 million.

Net cash used in investing activities for the year ended March 31, 2018 was $0.3 million, which primarily was for the purchases of property and equipment and intellectual property costs.

Net cash provided by financing activities for the year ended March 31, 2018 was $1.7 million. This consisted of proceeds from the sale of common stock to Lincoln Park Capital of $2.0 million, proceeds from cash warrants and options exercises of $0.4 million; offset by $0.5 million in loan principal payments, including repayment of an NJEDA Bonds of $0.1 million.

Overall, as a result of the foregoing, the Company had a net decrease in cash of $3.4 million during the year ended March 31, 2018.

Year Ended March 31, 2017

Net cash used in operating activities for the year ended March 31, 2017 was $7.9 million, which included net income of $3.8 million, and changes in operating assets and liabilities of $4.6 million. The changes in the balance of assets and liabilities include a decrease in account receivables totaling $0.6 million which resulted in a net increase in cash, offset by an increase in inventories of $3.1 million and decreases in deferred revenues of $1.0 million, accounts payables, other current liabilities and prepaid expenses and other current assets of $1.0 million, each of which result in a net decrease in cash. These instances of decreases in cash are offset by change in non-cash compensation accrued of $0.4 million, non-cash change in fair value of derivative financial instruments – warrants of $9.5 million, and non-cash compensation from the issuance of common stock of $0.4 million.

Net cash used in investing activities for the year ended March 31, 2017 was $1.1 million, which primarily was for the purchases of property and equipment.

Net cash provided by financing activities for the year ended March 31, 2017 was $8.1 million. This consisted of proceeds from the sale of common stock to Lincoln Park Capital of $7.6 million, proceeds from cash warrant and options exercises of $1.9 million; offset by $1.3 million in bond and loan principal payments, including repayment of a related party line of credit of $0.7 million.

Overall, as a result of the foregoing, the Company had a net decrease in cash of $0.9 million during the year ended March 31, 2017.

Year Ended March 31, 2016

Net cash used in operating activities for the year ended March 31, 2016 was $2.8 million, which included a net loss of ($0.7) million. This decrease in cash is offset by changes in operating assets and liabilities of $1.9 million. The changes in the balance of assets and liabilities include a decrease in account receivables and prepaid expenses totaling $0.2 million, and an increase in deferred revenues of $4.2 million, each of which result in a net increase in cash, offset by increases in inventories of $0.3 million and decreases in accounts payables and other current liabilities of $2.2 million, each of which result in a net decrease in cash. In addition, there was a non-cash change in the fair value of derivative financial instruments – warrants of $7.4 million, change in non-cash compensation accrued of $0.6 million, and non-cash compensation from the issuance of common stock of $0.3 million.

Net cash used in investing activities for the year ended March 31, 2016 was $1.9 million, which primarily was for the purchases of property and equipment.

Net cash provided by financing activities for the year ended March 31, 2017 was $8.8 million. This consisted of proceeds from the sale of common stock to Lincoln Park Capital of $6.2 million, proceeds from cash warrant and options exercises of $3.0 million; offset by $0.4 million in bond and loan principal payments.

Overall, as a result of the foregoing, the Company had a net increase in cash of $4.0 million during the year ended March 31, 2016.

Lincoln Park Capital

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

Upon execution of the Purchase Agreement, we issued 1,928,641 shares of our common stock to Lincoln Park pursuant to the Purchase Agreement 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 our 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, we sold an aggregate of 110 million shares to Lincoln Park, for aggregate gross proceeds of approximately $27.0 million. In addition, we issued an aggregate of 3.2 million commitment shares.

On May 1, 2017, we 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, we have the right to sell to and Lincoln Park is obligated to purchase up to $40 million in shares of our Common Stock, subject to certain limitations, from time to time, over the 36-month period commencing on June 5, 2017. We may direct Lincoln Park, at our 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, we may direct Lincoln Park to purchase additional amounts as accelerated purchases under certain circumstances. Our 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.

In connection with the 2017 LPC Purchase Agreement, we issued to Lincoln Park 5,540,551 shares of Common Stock and we are required to issue up to 5,540,551 additional shares of Common Stock pro rata as we require Lincoln Park to purchase our shares under the Purchase Agreement over the term o the agreement. Lincoln Park has represented to us, among other things, that it is an "accredited investor" (as such term is defined in Rule 501(a) of Regulatior D under the Securities Act of 1933, as amended (the "*Securities Act*")). We 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 fron registration requirements.

The 2017 LPC Purchase Agreement and the 2017 LPC Registration Rights Agreement contain customary representations, warranties, agreemen and conditions to completing future sale transactions, indemnification rights and obligations of the parties. We have 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 Purchase Agreement will depen 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 Purchase Agreement. Lincoln Park has no right to require any sales by us but is obligated tc make purchases from us as we direct 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 our shares.

The net proceeds received by us under the 2017 LPC Purchase Agreement will depend on the frequency and prices at which we sell shares of ou stock to Lincoln Park. We anticipate that any proceeds received by us from such sales to Lincoln Park under the 2017 LPC Purchase Agreement will be use for research and product development, general corporate purposes and working capital requirements.

A registration statement on form S-3 was filed with the SEC on May 10, 2017 and was declared effective on June 5, 2017.

During the fiscal year ended March 31, 2018, the Company issued under the 2017 LPC Purchase Agreement 5,540,551 shares of its common stock a initial commitment shares, 277,009 shares of its common stock as additional commitment shares and sold 17,818,950 shares of its common stock for proceeds totaling $1,999,878.

NJEDA Bonds

On August 31, 2005, the Company successfully completed a refinancing of a prior 1999 bond issue through the issuance of new tax-exempt bonds (the "Bonds"). The refinancing involved borrowing $4,155,000, evidenced by a 6.5% Series A Note in the principal amount of $3,660,000 maturing on September 1 2030 and a 9% Series B Note in the principal amount of $495,000 maturing on September 1, 2012. The net proceeds, after payment of issuance costs, were used (i) to redeem the outstanding tax-exempt Bonds originally issued by the Authority on September 2, 1999, (ii) refinance other equipment financing and (iii) for the purchase of certain equipment to be used in the manufacture of pharmaceutical products. As of March 31, 2016, all of the proceeds were utilized by the Company for such stated purposes.

Interest is payable semiannually on March 1 and September 1 of each year. The 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 related Indenture requires the maintenance of a Debt Service Reserve Fun of $366,000 in relation to the Series A Notes.

Bond issue costs of $354,000 were paid from the bond proceeds and are being amortized over the life of the bonds. Amortization of bond issuance costs amounted to $14,179 for the fiscal year ended March 31, 2018.

The NJEDA Bonds require the Company to make an annual principal payment on September 1st of varying amounts as specified in the loa documents and semi-annual interest payments on March 1st and September 1st, equal to interest due on the outstanding principal at the applicable rate for the semi-annual period just ended.

As of the date of filing of this Annual Report on Form 10-K, there are no interest or principal amounts in arrears. The Series B Notes were retired, a par in July 2014.

Exchange Agreement

On April 28, 2017, we entered into an exchange agreement (the "*Exchange Agreement*") with Nasrat Hakim, our Chief Executive Officer, pursuan to which we issued to Mr. Hakim 24.0344 shares of our newly designated Series J Convertible Preferred Stock and Warrants to purchase an aggregate o 79,008,661 shares of our Common Stock in exchange for 158,017,321 shares of our common stock owned by Mr. Hakim. Please see "*Item 13 Certain Relationships And Related Transactions, And Director Independence; Certain Related Person Transactions; Transactions with Nasrat Hakim an Mikah Pharma LLC*" in Part III.

Contractual Obligations

The following table lists our enforceable and legally binding non-cancellable obligations as of March 31, 2018:

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Long term debt	$ 2,535,649	$ 289,167	$ 571,037	$ 315,445	$ 1,360,000
Capital lease obligations	31,979	31,979	-	-	-
Operating lease obligations [1]	1,045,434	212,085	436,971	396,378	-
Purchase obligations	-	-	-	-	-
Interest expense	1,075,335	173,503	269,796	197,511	434,525
Other Long-Term Liabilities	-	-	-	-	-

(1) Consists of lease payments pursuant to the operating lease for 135 Ludlow Ave for a period, exclusive of taxes and insurance, expiring on December 31, 2021. The lease also includes an additional five-year option, exercised at the sole discretion of the Company and at fixed rates, which are defined in the lease. Due to the relevance to the Company's operations, of the facility at 135 Ludlow Avenue, the Company expects to exercise the first five-year option. If such option were to be exercised, a new contractual obligation would be created, with payments totaling $1.2 million, exclusive of real estate taxes and insurance, over the full five-year term of the option period.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues, or expenses, results of operations, liquidity, capital expenditures, or capital resources that would be considered material to investors.

Effects of Inflation

We are subject to price risks arising from price fluctuations in the market prices of the products that we sell. Management does not believe that inflation risk is material to our business or our consolidated financial position, results of operations, or cash flows.

Cybersecurity

As of March 31, 2018, the Company had no reportable incidents of cybersecurity.

Critical Accounting Policies and Estimates

Our significant accounting policies are disclosed in Note 1 of our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K. The following discussion addresses our most critical accounting policies, which are those that are both important to the portrayal of our financial condition and results of operations and that require significant judgment or use of complex estimates.

Revenue Recognition

The Company enters into licensing, manufacturing and development agreements, which may include multiple revenue generating activities, including, without limitation, milestones, licensing fees, product sales and services. These multiple elements are assessed in accordance with ASC 605-25,*Revenue Recognition – Multiple-Element Arrangements* in order to determine whether particular components of the arrangement represent separate units of accounting.

An arrangement component is considered to be a separate unit of accounting if the deliverable relating to the component has value to the customer on a standalone basis, and if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in control of the Company.

The Company recognizes payments received pursuant to a multiple revenue agreement as revenue, only if the related delivered item(s) have stand-alone value, with the arrangement being accordingly accounted for as a separate unit of accounting. If such delivered item(s) are considered to either not have stand-alone value, the arrangement is accounted for as a single unit of accounting, and the payments received are recognized as revenue over the estimated period of when performance obligations relating to the item(s) will be performed.

Whenever the Company determines that an arrangement should be accounted for as a single unit of accounting, it determines the period over which the performance obligations will be performed, and revenue will be recognized. If it cannot reasonably estimate the timing and the level of effort to complete its performance obligations under a multiple-element arrangement, revenues are then recognized on a straight-line basis over the period encompassing the expected completion of such obligations, with such period being reassessed at each subsequent reporting period.

Arrangement consideration is allocated at the inception of the arrangement to all deliverables on the basis of their relative selling price (the relative selling price method). When applying the relative selling price method, the selling price of each deliverable is determined using vendor-specific objective evidence of selling price, if such exists; otherwise, third-part evidence of selling price. If neither vendor-specific objective evidence nor third-party evidence of selling price exists for a deliverable, the Company uses its best estimate of the selling price for that deliverable when applying the relative selling price method. In deciding whether we can determine vendor-specific objective evidence or third-party evidence of selling price, the Company does not ignore information that is reasonably available without undue cost and effort.

When determining the selling price for significant deliverables under a multiple-element revenue arrangement, the Company considers any or all of the following, without limitation, depending on information available or information that could be reasonably available without undue cost and effort: vendor-specific objective evidence, third party evidence or best estimate of selling price. More specifically, factors considered can include, without limitation and as appropriate, size of market for a specific product, number of suppliers and other competitive market factors, forecast market shares and gross profits, barriers/time frames to market entry/launch, intellectual property rights and protections, exclusive or non-exclusive arrangements, costs of similar/identical deliverables from third parties, contractual terms, including, without limitation, length of contract, renewal rights, commercial terms, profit allocations, and other commercial, financial, tangible and intangible factors that may be relevant in the valuation of a specific deliverable.

Milestone payments are accounted for in accordance with ASC 605-28,*Revenue Recognition – Milestone Method* for any deliverables or units of accounting under which the Company must achieve a defined performance obligation which is contingent upon future events or circumstances that are uncertain as of the inception of the arrangement providing for such future milestone payment. Determination of the substantiveness of a milestone is a matter of subjective assessment performed at the inception of the arrangement, and with consideration earned from the achievement of a milestone meeting all of the following:

- It must be either commensurate with the Company's performance in achieving the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the Company's performance to achieve the milestone; and
- It relates solely to past performance; and
- It is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement.

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, 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.

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.

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

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.

The Company recognizes the benefit of an uncertain tax position that it has taken or expects to take on income tax returns it files if such tax position is more likely than not to be sustained on examination by the taxing authorities, based on the technical merits of the position. These tax benefits are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate resolution.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with ASC Topic 718,*Compensation-Stock Compensation*. Under the fair value recognition provisions of this topic, 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 simple average closing price of the Company's common stock.

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.

Recently Adopted Accounting Standards

In January 2017, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") 2017-01,*Business Combinations: Clarifying the Definition of a Business*, which amends the current definition of a business. Under ASU 2017-01, to be considered a business an acquisition would have to include an input and a substantive process that together significantly contributes to the ability to create outputs. ASU 2017-01 further states that when substantially all of the fair value of gross assets acquired is concentrated in a single asset (or a group of similar assets), the assets acquired would not represent a business. The new guidance also narrows the definition of the term "outputs" to be consistent with how it is described in Topic 606, Revenue from Contracts with Customers. The changes to the definition of a business will likely result in more acquisitions being accounted for as asset acquisitions. The guidance is effective for the annual period beginning after December 15, 2017, with early adoption permitted. The Company has elected to early adopt ASU 2017-01 and to apply it to any transaction, which occurred prior to the issuance date that has not been reported in financial statements that have been issued or made available for issuance.

Recently Issued Accounting Pronouncements

In May 2014, the FASB issued ASU No. 2014-09 *Revenue from Contracts with Customers* ("ASU 2014-09"), which supersedes nearly all existing revenue recognition guidance under GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five-step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing GAAP. In addition, this guidance requires new or expanded disclosures related to the judgments made by companies when following this framework and additional quantitative disclosures regarding contract balances and remaining performance obligations. ASU No. 2014-09 may be applied using either a full retrospective approach, under which all years included in the financial statements will be presented under the revised guidance, or a modified retrospective approach, under which financial statements will be prepared under the revised guidance for the year of adoption, but not for prior years. Under the latter method, entities will recognize a cumulative catch-up adjustment to the opening balance of retained earnings at the effective date for contracts that still require performance by the entity.

On July 9, 2015, the FASB voted to defer the effective date by one year to December 15, 2017 for interim and annual reporting periods beginning after that date. ASU No. 2014-09 is effective for annual reporting periods beginning after December 15, 2017, including interim periods within those annual reporting periods. The Company developed an implementation plan to adopt this new guidance, which included an assessment of the impact of the new guidance on our financial position and results of operations. The Company has completed its assessment and has determined that this standard will have no material impact on its financial position or results of operations, except enhanced disclosure regarding revenue recognition, including disclosures of revenue streams, performance obligations, variable consideration and the related judgments and estimates necessary to apply the new standard. On April 1, 2018, the Company adopted the new accounting standard ASC 606, Revenue from Contracts with Customers and for all open contracts and related amendments as of April 1, 2018 using the modified retrospective method. Results for reporting periods beginning after April 1, 2018 will be presented under ASC 606, while the comparative information will not be restated and will continue to be reported under the accounting standards in effect for those periods.

From March 2016 through December 2017, the FASB issued ASU 2016-08 *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net),* ASU 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing,* ASU 2016-11, *Revenue Recognition (Topic 605) and Derivatives and Hedging (Topic 815): Rescission of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 EITF Meeting,* ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606):Narrow-Scope Improvements and Practical Expedients* and ASU No. 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers.* These amendments are intended to improve and clarify the implementation guidance of Topic 606. The effective date and transition requirements for the amendments are the same as the effective date and transition requirements of ASU No. 2014-09 and ASU No. 2015-14.

In February 2016, the FASB issued ASU No. 2016-02 *Leases (Topic 842)* ("ASU 2016-02"), which is effective 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. The Company is currently evaluating the effects of ASU 2016-02 on its audited consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230) Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"). ASU 2016-15 eliminates the diversity in practice related to the classification of certain cash receipts and payments for debt prepayment or extinguishment costs, the maturing of a zero-coupon bond, the settlement of contingent liabilities arising from a business combination, proceeds from insurance settlements, distributions from certain equity method investees and beneficial interests obtained in a financial asset securitization. ASU 2016-15 designates the appropriate cash flow classification, including requirements to allocate certain components of these cash receipts and payments among operating, investing and financing activities. The guidance is effective for fiscal years beginning after December 15, 2017. The Company is currently evaluating the effects of ASU 2016-15 on its audited consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230) Restricted Cash a consensus of the FASB Emerging Issues Task Force* ("ASU 2016-18"). ASU 2016-18 requires restricted cash and cash equivalents to be included with cash and cash equivalents on the statement cash flows. The guidance is effective for fiscal years beginning after December 15, 2017. The Company is currently evaluating the effects of ASU 2016-18 on its audited consolidated financial statements.

In January 2017, the FASB issued ASU No 2017-04 *Intangibles-Goodwill and Other (Topic 350): Simplifying the Accounting for Goodwill Impairment* ("ASU 2017-04"). ASU 2017-04 simplifies the subsequent measurement of goodwill by eliminating Step 2 from the goodwill impairment test. In computing the implied fair value of goodwill under Step 2, an entity had to perform procedures to determine the fair value at the impairment testing date of its assets and liabilities (including unrecognized assets and liabilities) following the procedure that would be required in determining the fair value of assets acquired and liabilities assumed in a business combination. Instead, under ASU 2017-04, an entity should perform its annual or interim goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. Additionally, an entity should consider income tax effects from any tax-deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss, if applicable. ASU 2017-04 is effective for annual or any interim goodwill impairment tests for fiscal years beginning after December 15, 2019 and an entity should apply the amendments of ASU 2017-04 on a prospective basis. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company is currently evaluating the effects of ASU 2017-04 on its audited consolidated financial statements.

In May 2017, the FASB issued ASU No 2017-09 *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting* ("ASU 2017-09"). ASU 2017-09 provides clarity and reduces both (i) diversity in practice and (ii) cost and complexity when applying the guidance in Topic 718, Compensation-Stock Compensation, to a change to the terms or conditions of a share-based payment award. The amendments in ASU 2017-09 provid guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. An entity should account for the effects of a modification unless all three of the following are met: (1) The fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the modified award is the same as the fair value (or calculated value or intrinsic value, if such an alternative measurement is used) of the original award immediately before the original award is modified. If the modification does not affect any of the inputs to the valuation technique that the entity uses to value the award, the entity is not required to estimate the value immediately before and after the modification. (2) The vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified. (3) The classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified. Note that the current disclosure requirements in Topic 718 apply regardless of whether an entity is required to apply modification accounting under the amendments in ASU 2017-09. ASU 2017-09 is effective for all annual periods, and interim periods within those annua periods, beginning after December 15, 2017, with early adoption permitted. The Company is currently evaluating the effects of ASU 2017-09 on its audite consolidated financial statements.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) ana Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features; II. Replacement of the Indefini Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrollin Interests with a Scope Exception.* Part I of this update 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 this update 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. The amendments in Part II of this update do no have an accounting effect. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018. The Company i currently assessing the potential impact of adopting ASU 2017-11 on its audited consolidated 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.

ITEM 7A QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We believe that our market risk exposures are immaterial as we do not have instruments for trading purposes, and reasonable possible near-term changes in market rates or prices will not result in material near-term losses in earnings, material changes in fair values or cash flows for all instruments.

We maintain all of our cash, cash equivalents and restricted cash in two financial institutions, and we perform periodic evaluations of the relative credit standing of these institutions. However, no assurances can be given that the third-party institutions will retain acceptable credit ratings or investment practices.

ITEM 8 FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Attached hereto and filed as a part of this Annual Report on Form 10-K are our Consolidated Financial Statements, beginning on page F-1.

ITEM 9 CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None

ITEM 9A CONTROLS AND PROCEDURES

The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, have evaluated th effectiveness of the Company's 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 March 31, 2018. Based on that evaluation, the Company's Chief Executive Officer and the Company's Chie Financial Officer have concluded that the Company's disclosure controls and procedures were effective as of March 31, 2018 to ensure that information required to be disclosed by our Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms and such information is accumulated and communicated to management as appropriate to allow timely decisions regarding required disclosures.

Management's Annual Report on Internal Control over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. The Company's internal control over financial reporting was designed to provide reasonable assurance regarding the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Please note, however, as a result of inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Furthermore, projections of any evaluation of effectiveness of current internal controls over financial reporting to future periods, are subject to the risk that such current controls may become inadequate due to changes in conditions, or that a future deterioration in the degree of compliance with current policies and procedures may occur.

The Company's management assessed the effectiveness of the Company's internal control over financial reporting as of March 31, 2018, with such assessment being pursuant to the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in *Internal Control-Integrated Framework (2013)*. Based on our assessment, we determined that, based on those criteria, as of March 31, 2018, the Company's internal control over financial reporting is effective.

The Company's independent registered public accounting firm has also issued its report on the effectiveness of the Company's internal control over financial reporting as of March 31, 2018. This report appears on page F-1 of this Annual Report on Form 10-K.

Changes in internal control over financial reporting

There have been no changes in our internal control over financial reporting during the year-ended March 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B OTHER INFORMATION

None.

PART III

ITEM 10 DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following sets forth biographical information about each of our directors and executive officers as of the date of this report:

Name	Age	Position	Director/Officer Since	Director Tier
Nasrat Hakim	57	President, Chief Executive Officer and Director	August 2013	III
Barry Dash, Ph. D.	87	Director	April 2005	II
Jeffrey Whitnell	62	Director	October 2009	III
Eugene Pfeifer [(1)]	78	Director	April 2016	I
Davis Caskey	70	Director	April 2016	I
Carter J. Ward	54	Chief Financial Officer, Secretary and Treasurer	July 2009	
Douglas Plassche	54	Executive Vice President of Operations	August 2013	

(1) Mr. Pfeifer was a Director of the Company from April 2016 until his passing on June 10, 2018

The principal occupations and employment of each Director during the past five years is set forth below. In each instance in which dates are not provided in connection with a director's business experience, such nominee has held the position indicated for at least the past five years.

Each director currently holds office until the expiration of his Tier (each for three years) or until such director's death, resignation, or removal. Pursuant to our recently amended and restated bylaws, our Board of Directors is now classified into three separate tiers of directors, with each respective tier to serve a three-year term and until their successors are duly elected and qualified.

Nasrat Hakim

Nasrat Hakim has served as a Director, President, and Chief Executive officer since August 2013. He has been a member of the Audit Committee member and chairman of the nominating Committee and member of the Compensation Committee since September 2016. Mr. Hakim has more than 30 years of pharmaceutical and medical industry experience in Quality Assurance, Analytical Research and Development, Technical Services, and Regulatory Compliance. He brings with him proven management experience, in-depth knowledge of manufacturing systems, development knowledge in immediate and extended release formulations and extensive regulatory experience of GMP and FDA regulations. From 2004 to 2013, Mr. Hakim was employed by Actavis Watson and Alpharma in various senior management positions. Most recently, Mr. Hakim served as International Vice President of Quality Assurance at Actavis, overseeing 25 sites with more than 3,000 employees under his leadership. Mr. Hakim also served as Corporate Vice President of Technical Services Quality and Regulatory Compliance for Actavis U.S., Global Vice President, Quality, and Regulatory Compliance for Alpharma, as well as Executive Direct of Quality Unit at TheraTech, overseeing manufacturing and research and development. In 2009, Mr. Hakim founded Mikah Pharma, LLC, a virtual, full functional pharmaceutical company. Mr. Hakim holds a Bachelor in Chemistry/Bio-Chemistry and Masters of Science in Chemistry from California Stat University at Sacramento, Sacramento, CA; a Masters in Law with Graduate Certification in U.S. and International Taxation from St. Thomas Universi School of Law, Miami, FL.; and a Graduate Certification in Regulatory Affairs (RAC) from California State University at San Diego, San Diego, CA. M Hakim's leadership experience (consisting of extensive experience in senior management positions, responsible for 25 global manufacturing/regulatory sites with more than 3,000 employees under his leadership), industry experience (comprising more than 30 years of pharmaceutical and medical industry experience served in various quality assurance, analytical research and development/technical services and compliance positions) and academic experience (including Bachelor degrees in Chemistry and Bio-Chemistry, Masters degrees in Chemistry and Law, with Graduate Certification in U.S. and International Taxation, an a Graduate Certification in Regulatory Affairs) led to the conclusion that he is qualified to serve as a director.

Barry Dash, Ph.D.

Dr. Barry Dash has served as a Director since April 2005, member of the Audit Committee since April 2005, member of the Nominating Committee since April 2005 and member and Chairman of the Compensation Committee since June 2007. Dr. Dash has been, since 1995, President and Managing Member of Dash Associates, L.L.C., an independent consultant to the pharmaceutical and health industries. From 1983 to 1996 he was employed by Whitehall-Robins Healthcare, a division of American Home Products Corporation (now known as Wyeth), initially as Vice President of Scientific Affairs, then as Senior Vice President of Scientific Affairs and then as Senior Vice President of Advanced Technologies, during which time he personally supervised six separate departments: Medical and Clinical Affairs, Regulatory Affairs, Technical Affairs, Research and Development, Analytical R&D and Quality Management/Q.C Dr. Dash had been employed by the Whitehall Robins Healthcare from 1960 to 1976, during which time he served as Director of Product Development Research, Assistant Vice President of Product Development and Vice President of Scientific Affairs. Dr. Dash had been employed by J.B. Williams Compar (Nabisco Brands, Inc.) from 1978 to 1982. From 1976 to 1978 he was Vice President and Director of Laboratories of the Consumer Products Division o American Can Company. Dr. Dash holds a Ph.D. from the University of Florida and M.S. and B.S. degrees from Columbia University where he w Assistant Professor at the College of Pharmaceutical Sciences from 1956 to 1960. He is a member of the American Pharmaceutical Association, th American Association for the Advancement of Science and the Society of Cosmetic Chemist, American Association of Pharmaceutical Scientists, Dru Information Association, American Foundation for Pharmaceutical Education, and Diplomate American Board of Forensic Examiners. He is the author o scientific publications and patents in the pharmaceutical field. Dr. Dash's extensive education in pharmaceutical sciences and his experience in the development of scientific products, including his experience in regulatory affairs, led to the conclusion that he is qualified to serve as a director.

Jeffrey Whitnell

Jeffrey Whitnell has served as a Director since October 23, 2009, Chairman of the Audit Committee, member of the Compensation Committee sinc October 2009 and designated by the Board as an "*audit committee financial expert*" as defined under applicable rules under the Exchange Act. Since Apri 2015, Mr. Whitnell has provided financial advisory services, primarily to the healthcare industry, including LifeWatch Services, where he served as the Vice President, Finance & Controller. From June2010 to March 2015, Mr. Whitnell was the Chief Financial Officer for ReliefBand Medical Technologies, a medic device company. From June 2009 to June 2010, Mr. Whitnell provided financial advisory services to various healthcare companies, including ReliefBan Medical Technologies. From June 2004 to June 2009, Mr. Whitnell was Chief Financial Officer and Senior Vice President of Finance at Akorn, Inc. From Ju 2002 to June 2004, Mr. Whitnell was Vice President of Finance and Treasurer for Ovation Pharmaceuticals. From 1997 to 2001, Mr. Whitnell was Vic President of Finance and Treasurer for MediChem Research. Prior to 1997, Mr. Whitnell held various finance positions at Akzo Nobel and Motorola. M Whitnell began his career as an auditor with Arthur Andersen & Co. He is a certified public accountant and holds an M.B.A. in Finance from the University c Chicago Booth School of Business and a B.S. in Accounting from the University of Illinois. Mr. Whitnell's qualifications as an accounting and audit expe provide specific experience to serve as a director for the Company.

Eugene Pfeifer

Eugene Pfeifer has served as a Director from April 2016 and a member of the Nominating Committee and Compensation Committee fron September 2016, until his passing on June 10, 2018. Mr. Pfeifer brought with him more than 45 years of regulatory and trade experience, most recently having served as a law partner at King & Spalding in Washington DC from 1986 to 2009 and prior to that as a law partner at the Burditt, Bowles & Radzius fron 1980 to 1985. Since retiring from legal practice in 2009, Mr. Pfeifer worked as a consultant to companies, including consultation for the Company, by providing his expertise regarding FDA and FTC issues. Among his many accomplishments, he was a major participant in the development of the Drug Price Competitio and Patent Term Restoration Act of 1984 and provided strategic counseling to companies affected by that statue. In addition, he has provided regulatory advice and representation on a wide variety of FDA, FTC, and DEA regulated activities, including product approval, advertising, promotion, and compliance issue with such also being provided to the Company on a consulting basis, in addition to Mr. Pfeifer's services as a Director and committee member.

Prior to working at Burditt, Bowles and Radzius, Mr. Pfeifer served from 1974 to 1975 in the General Counsel's office of the Federal Trad Commission, where he represented the FTC in Federal Court to enjoin violations of the Federal Trade Commission Act and served ten years in the Chi Counsel's Office at the FDA as Associated Chief Counsel for Enforcement, Associate Chief Counsel for Drugs and Deputy Chief Counsel for Regulations and Hearings. During his tenure at the FDA, he was the FDA's lead litigator and Appellate Court advocate, and he briefed the FDA's cases before the Supren Court. Mr. Pfeifer is a graduate of Brown University and the Georgetown University Law Center. Mr. Pfeifer's qualifications and extensive experience in th areas of regulatory affairs, legislation, and FDA representation, led the Board to conclude that Mr. Pfeifer is qualified to be a member of the Company's Boar of Directors.

Mr. Pfeifer passed away on June 10, 2018. The Company has not yet nominated his replacement.

Davis Caskey

Davis Caskey has served as a Director since April 2016, and a member of the Audit Committee, the nominating Committee and the Compensatio Committee since September 2016. He brings more than 40 years of pharmaceutical industry experience to this position. Mr. Caskey is currently President & CEO of Caskey LLC, which he formed in 2013 to serve as an umbrella to manage his pharmaceutical consulting and other business interests. From 1990 t 2013, Davis served as the operating officer of ECR Pharmaceuticals, of which he was a founding member. HiTech Pharmacal acquired the privately held ECR in 2009 and Mr. Caskey continued in his role until retiring in 2013. At ECR, Mr. Caskey was credited with the establishment of the company's sales an marketing structure, its product distribution format, and the development and management of the firm's internal organization. His responsibilities included the oversight of drug development and regulatory filings, product acquisitions, and acquisition of other companies. A primary focus was to conceive and develop, with the assistance of key strategic partners, unique dosage forms and extended release formulations of products which enhance patient compliance and safety. Prior to ECR, Mr. Caskey was employed by A.H. Robins for 18 years in various field and home office management positions. His experience bring critical insight into the marketing and distribution of pharmaceutical products in a rapid and ever changing competitive marketplace. Mr. Caskey attended the University of Texas (Austin) and Lamar University, and holds bachelor's and master's degrees.

Carter J. Ward

Carter J. Ward has served as Chief Financial Officer, Secretary, and Treasurer of the Company since July 1, 2009. Prior to joining the Company from July 2005 to April 2009, Mr. Ward filled multiple finance and supply chain leadership roles with the Actavis Group and its U.S. subsidiary, Amide Pharmaceuticals. From September 2004 to June 2005, Mr. Ward was a consultant, mainly engaged in improving internal controls and supporting Sarbanes Oxley compliance of Centennial Communications Inc., a NASDAQ listed wireless communications provider. From 1999 to September 2004, Mr. Ward was the Chief Financial Officer for Positive Healthcare/Ceejay Healthcare, a U.S.-Indian joint venture engaged in the manufacture and distribution of gener pharmaceuticals and nutraceuticals in India. Mr. Ward began his career as a certified public accountant in the audit department of KPMG and is a Certifie Supply Chain Professional ("CSCP"). Mr. Ward holds a B.S. in Accounting from Long Island University, Brooklyn, NY, from where he graduated summa cum laude Mr. Ward's experience and expertise in the area of finance and more specifically, as a Certified Supply Chain Professional, provides the qualifications, attributes, and skills to serve as an officer for the Company.

Douglas Plassche

Douglas Plassche has served as Executive Vice President of Operations since August 2013. Prior to joining the Company, from 2009 to 2013, Mr Plassche served as the Managing Director of the New Jersey Solid Oral Dose Operations of Actavis, overseeing 450 employees and the production of mor than 100 products. From 2007 to 2009, Mr. Plassche was the Senior Director of Manufacturing for PAR Pharmaceuticals, overseeing 200 employees and th production of more than 70 products. From 1990 – 2007, Mr. Plassche was employed by Schering-Plough, progressing steadily through multiple disciplines locations, and technical operations sectors with increasing levels of responsibility. Mr. Plassche has a Bachelor's Degree in Economics from Rochester University.

There are no family relationships between any of our directors and executive officers.

Compliance with Section 16(a) of the Exchange Act

Section 16(a) of the Exchange Act requires our Officers, Directors, and persons who own more than ten percent of a registered class of equity securities, to file reports with the Securities and Exchange Commission reflecting their initial position of ownership on Form 3 and changes in ownership on Form 4 or Form 5.

Committees of the Board

The Board of Directors has an Audit Committee, a Compensation Committee, and a Nominating Committee.

Audit Committee

During Fiscal 2018, the members of the Audit Committee were Jeffrey Whitnell (Chairman of the Audit Committee), Dr. Barry Dash. Davis Caske and Nasrat Hakim. We deem Messrs. Whitnell, Dash, and Caskey to be independent and Mr. Whitnell to be qualified as an audit committee financial expert The Board of Directors has determined that Messrs. Whitnell, Dash and Caskey are independent directors as (i) defined in Rule 10A-3(b)(1)(ii) under th Exchange Act and (ii) under Sections 803A(2) and 803B(2)(a) of the NYSE MKT LLC Company Guide (although our securities are not listed on the NY MKT LLCE or any other national exchange).

Nominating Committee

During Fiscal 2018, the members of the Nominating Committee were Nasrat Hakim (Chairman of the Nominating Committee), Dr. Barry Das Eugene Pfeifer and Davis Caskey. There were no material changes to the procedures by which security holders may recommend nominees to our Board o Directors since the filing of our last Annual Report on Form 10-K. Please note that Mr. Pfeifer passed away on June 10, 2018. The Company has not ye nominated his replacement.

Compensation Committee

During Fiscal 2018, the members of the Compensation Committee were Dr. Barry Dash (Chairman of the Compensation Committee), Jeffre Whitnell, Eugene Pfeifer, Davis Caskey and Nasrat Hakim. Please note that Mr. Pfeifer passed away on June 10, 2018. The Company has not yet nominate his replacement.

Code of Conduct and Ethics

At the first meeting of the Board of Directors following the annual meeting of stockholders held on June 22, 2004, and as further updated effective July 2009, the Board of Directors adopted a Code of Business Conduct and Ethics that is applicable to the Company's directors, officers, and employees. A copy of the Code of Business Conduct and Ethics is available on our website at www.elitepharma.com, under Investor Relations.

ITEM 11 EXECUTIVE COMPENSATION

Compensation discussion and analysis summary

Our approach to executive compensation, one of the most important and complex aspects of corporate governance, is influenced by our belief in rewarding people for consistently strong execution and performance. We believe that the ability to attract and retain qualified executive officers and other key employees is essential to our long-term success.

Compensation Linked to Attainment of Performance Goals

Our plan to obtain and retain highly skilled employees is to provide significant incentive compensation opportunities and market competitive salaries. The plan was intended to link individual employee objectives with overall company strategies and results, and to reward executive officers and significant employees for their individual contributions to those strategies and results. Furthermore, we believe that equity awards serve to align the interests of our executives with those of our stockholders. As such, equity is a key component of our compensation program.

Role of the Compensation Committee

The Company formed the Compensation Committee in June 2007. Since the formation of the Compensation Committee all elements of the executives compensation are determined by the Compensation Committee, which currently is comprised of four independent non-employee directors, and one director who is also the Company's Chief Scientific Officer. However, the Compensation Committee's decisions concerning the compensation of the Company's Chief Executive Officer are subject to ratification by the independent directors of the Board of Directors. From September 2016 to June 2018, the members of the Compensation Committee were Dr. Barry Dash (Chairman of the Compensation Committee), Jeffrey Whitnell, Eugene Pfeiffer, Davis Caskey and Nasrat Hakim. Mr. Pfeifer passed away on June 10, 2018 and the Company has not yet nominated a replacement. The Committee operates pursuant to a charter. Under the Compensation Committee charter, the Compensation Committee has authority to retain compensation consultants, outside counsel, and other advisors that the committee deems appropriate, in its sole discretion, to assist it in discharging its duties, and to approve the terms of retention and fees to be paid to such consultants. The Compensation Committee did not engage any advisors.

Named Executive Officers

The named executive officers for the fiscal year ended March 31, 2018 were:

- Nasrat Hakim, Chief Executive Officer, and President for the full year;
- Carter J. Ward, Chief Financial Officer, Secretary, and Treasurer for the full year;
- Douglas Plassche, Executive Vice President for the full year.

These individuals are referred to collectively as the "*Named Executive Officers*".

We also had one key employee during the fiscal year ended March 31, 2018 - George Kenneth Smith.

Our executive compensation program

Overview

The primary elements of our executive compensation program are base salary, incentive cash and stock bonus opportunities and equity incentives typically in the form of stock option grants or payment of a portion of annual salary as stock. Although we provide other types of compensation, these three elements are the principal means by which we provide the Named Executive Officers with compensation opportunities.

The annual bonus opportunity and equity compensation components of the executive compensation program reflect our belief that a portion of an executive's compensation should be performance-based. This compensation is performance-based because payment is tied to the achievement of corporate performance goals. To the extent that performance goals are not achieved, executives will receive a lesser amount of total compensation.

Elements of our executive compensation program

Base Salary

We pay a base salary to certain of the Named Executive Officers, with such payments being made in either cash, Common Stock or a combination of cash and Common Stock. In general, base salaries for the Named Executive Officers are determined by evaluating the responsibilities of the executive's position, the executive's experience, and the competitive marketplace. Base salary adjustments are considered and take into account changes in the executive's responsibilities, the executive's performance, and changes in the competitive marketplace. We believe that the base salaries of the Named Executive Officers are appropriate within the context of the compensation elements provided to the executives and because they are at a level which remains competitive in the marketplace.

Bonuses

The Board of Directors may authorize us to give discretionary bonuses, payable in cash or shares of Common Stock, to the Named Executive Officers and other key employees. Such bonuses are designed to motivate the Named Executive Officers and other employees to achieve specified corporate, business unit and/or individual, strategic, operational, and other performance objectives.

Stock Options

Stock options constitute performance-based compensation because they have value to the recipient only if the price of our Common Stock increases. Stock options for each of the Named Executive Officers generally vest over time, obtainment of a corporate goal or a combination of the two.

The grant of stock options at Elite is designed to motivate our Named Executive Officers to achieve our short-term and long-term corporate goals.

Retirement and Deferred Compensation Benefits

We do not presently provide the Named Executive Officers with a defined benefit pension plan or any supplemental executive retirement plans, nor do we provide the Named Executive Officers with retiree health benefits. We have adopted a deferred compensation plan under Section 401(k) of the Code. The plan provides for employees to defer compensation on a pretax basis subject to certain limits, however, Elite does not provide a matching contribution to its participants.

The retirement and deferred compensation benefits provided to the Named Executive Officers are not material factors considered in making other compensation determinations with respect to Named Executive Officers.

Post-Termination/Change of Control Compensation

Pursuant to his employment agreement, Nasrat Hakim, our Chief Executive Officer, is entitled to a payment in an amount equal to two year's base annual salary in effect upon the date of termination, less applicable deductions, and withholdings, payable in Common Stock upon a Change of Control (as defined in the Hakim Employment Agreement). For more detailed information, please see "*Agreements with Named Executive Officers*" below.

We do not presently provide the Named Executive Officers with any plan or arrangement, other than those that may be contained in employment contracts, in connection with any termination, including, without limitation, through retirement, resignation, severance, or constructive termination (including a change in responsibilities) of such Named Executive Officer's employment with the Company.

As part of the Company's efforts to ensure the retention and continuity of key employees, officers, and directors in the event of a change of control of the ownership of the Company, unless otherwise stated in applicable employment contracts, key executives would receive an amount equal to twelve months of such executive's salary, and certain Directors and managers would receive an amount equal to six months of such Director's or manager's fees or salaries, as applicable. In addition, any outstanding and unvested options would immediately vest, in the event of a change of control.

Perquisites

As described in more detail below, the perquisites provided to certain of the Named Executive Officers consist of car allowances and life insurance premiums. These perquisites represent a small fraction of the total compensation of each such Named Executive Officer. The value of the perquisites we provide are taxable to the Named Executive Officers and the incremental cost to us of providing these perquisites is reflected in the Summary Compensation Table. The Board of Directors believes that the perquisites provided are reasonable and appropriate. For more information on perquisites provided to the Named Executive Officers, please see the "*All Other Compensation*" column of the Summary Compensation Table and "*Agreements with Named Executive Officers*," below.

Agreements with Named Executive Officers

Nasrat Hakim

Pursuant to his August 2013 employment agreement, and as amended on January 12, 2016 (the "*Hakim Employment Agreement*"), Mr. Hakim receives an annual salary of $500,000 per year. The Salary is paid in shares of the Company's Common Stock pursuant to the Company's current procedures for paying Company executives in Stock. He also is entitled to an annual bonus equal to up to 100% of his annual salary, payable in accordance with the Company's payroll practices. The Board may also award discretionary bonuses in its sole discretion. Mr. Hakim is entitled to employee benefits (e.g., health vacation, employee benefit plans and programs) consistent with other Company employees of his seniority and a car allowance. The Hakim Employment Agreement contains confidentially, non-competition and other standard restrictive covenants.

Mr. Hakim's employment is terminable by the Company for cause (as defined in the Hakim Employment Agreement). The Hakim Employment Agreement also may be terminated by the Company upon at least 30 days written notice due to disability (as defined in the Hakim Employment Agreement) or without cause. Mr. Hakim can terminate the Hakim Employment Agreement by resigning, provided he gives notice at least 60 days prior to the effective resignation date. If Mr. Hakim is terminated for cause or he resigns, he only is entitled to accrued and unpaid annual salary, accrued vacation time and any reasonable and necessary business expenses, all through the date of termination and payable in stock ("Basic Termination Benefits"). If Mr. Hakim is terminated because of disability or death, in addition to Basic Termination Benefits, He is entitled his pro rata annual bonus through the date of termination (payable in Stock). If the Company terminates Mr. Hakim without cause, in addition to Basic Termination Benefits, Mr. Hakim is entitled to his pro rata annual bonus through the date of termination and an amount equal to two years' annual salary (all payable in Stock).

Upon a Change of Control (as defined in the Hakim Employment Agreement), Mr. Hakim is entitled to a payment in an amount equal to two year' base annual salary in effect upon the Date of Termination, less applicable deductions, and withholdings, payable in Stock computed in the same manner as set forth as the Salary.

Carter J. Ward

On November 12, 2009, the Company entered into an employment agreement with Mr. Carter J. Ward (the "*Ward Employment Agreement*"). Pursuant to the terms of the Ward Employment Agreement, Mr. Ward continues as an at-will employee of the Company as its Chief Financial Officer. Mr Ward receives a base salary of $150,000, with $125,000 of such amount being paid in accordance with the Company's payroll practices and $25,000 of such amount being paid by the issuance of restricted shares of Common Stock, in lieu of cash. The Common Stock component of Mr. Ward's compensation is to be computed on a quarterly basis, with the number of shares issued equal to the quotient of the quarterly amount due of $6,250 divided by the average daily closing price of the Company's Common Stock for the quarter just ended.

On February 2, 2013, the Board of Directors increased Mr. Ward's base salary to $155,000 retroactive to January 1, 2013. This $5,000 increase to be paid by the issuance of restricted shares of Common Stock. The Common Stock component of Mr. Ward's compensation is to be computed on a quarterly basis, with the number of shares issued equal to the quotient of the quarterly amount due of $7,500 divided by the average daily closing price of the Company's Common Stock for the quarter just ended.

On March 1, 2015, Mr. Ward's compensation was adjusted to include a total compensation of $187,200, consisting of $157,200 being paid in accordance with the Company's payroll practices and $30,000 being paid by the issuance of restricted shares of Common Stock in lieu of cash.

On March 1, 2016, Mr. Ward's compensation was adjusted to include a total compensation of $192,816, consisting of $162,816 being paid in accordance with the Company's payroll practices and $30,000 being paid by the issuance of restricted shares of Common Stock in lieu of cash.

Mr. Ward's rate of compensation has not changed since March 1, 2016.

The Common Stock component of Mr. Ward's compensation is to be computed on a quarterly basis, with the number of shares issued being equal to the quotient of the quarterly amount due, divided by the average daily closing price of the Company's Common Stock for the quarter just ended.

Douglas Plassche

On July 20, 2013, the Company entered into an employment agreement with Mr. Douglas Plassche (the "*Plassche Employment Agreement*"). Pursuant to the Plassche Employment Agreement, Mr. Plassche serves as an at-will employee, in the position of Vice President of Operations, commencing on August 12, 2013. The Plassche Employment Agreement includes a total base compensation of $236,000, consisting of $211,000 being paid in accordance with the Company's payroll practices and $25,000 being paid by the issuance of restricted shares of Common Stock in lieu of cash. Mr. Plassche is also eligible for an annual bonus in cash and/or equity-based awards for up to an equivalent of 30% of base salary, with such annual bonus being granted based upon the achievement of agreed milestones and at the discretion of the Company and its Chief Executive Officer. In addition, pursuant to the Plassche Employment Agreement, he was granted options to purchase 3,000,000 shares of Common Stock, at a price of $ 0.07 per share, (the closing price of the Common Stock on the date of the Plassche Employment Agreement). The options were issued pursuant to the 2004 Employee Stock Option Plan and vest over a period of three years with the vesting period commencing one year from the date of issuance.

Mr. Plassche's employment is terminable by either party. If the Company terminates Mr. Plassche without cause, Mr. Plassche is entitled to ar amount equal to six months of base annual salary in effect upon the date of termination.

On March 1, 2015, Mr. Plassche's compensation was adjusted to include a total base compensation of $249,800, consisting of $224,800 being paid in accordance with the Company's payroll practices and $25,000 being paid by the issuance of restricted shares of Common Stock in lieu of cash.

On March 1, 2016, Mr. Plassche's compensation was adjusted to include a total base compensation of $253,552, consisting of $228,552 being paid in accordance with the Company's payroll practices and $25,000 being paid by the issuance of restricted shares of Common Stock in lieu of cash.

Mr. Plassche's rate of compensation has not changed since March 1, 2016.

The Common Stock component of Mr. Plassche's compensation is to be computed on a quarterly basis, with the number of shares issued being equa to the quotient of the quarterly amount due, divided by the average daily closing price of the Company's Common Stock for the quarter just ended.

George Kenneth Smith

On October 20, 2014, the Company entered into an employment agreement with Mr. George Kenneth Smith (the "*Smith Employment Agreement*"). Pursuant to the Smith Employment Agreement, Mr. Smith serves as an at-will employee, in the position of Vice President, Legal, commencing on October 20 2014. The Smith Employment Agreement includes a total base compensation of $400,000, consisting of $150,000 being paid in accordance with the Company's payroll practices and $250,000 being paid by the issuance of restricted shares of Common Stock in lieu of cash. Mr. Smith is also eligible for an annual bonus and discretionary bonus, with such being at the discretion of the Company and its Chief Executive Officer. In addition, pursuant to the Smith Employmen Agreement, Mr. Smith was granted options to purchase 1,500,000 shares of Common Stock, at a price of $ 0.29 per share, (the closing price of the Commor Stock on the date of the Smith Employment Agreement). The options were issued pursuant to the 2009 Employee Stock Option Plan and vest over a period c three years with the vesting period commencing one year from the date of issuance.

Mr. Smith's employment is terminable by either party. If the Company terminates Mr. Smith without cause, or if Mr. Smith is terminated upon a change of control event, as defined in the Smith Employment Agreement, Mr. Smith is entitled to an amount equal to one year of base annual salary in effec upon the date of termination.

On March 1, 2016, Mr. Smith's compensation was adjusted to include a total base compensation of $412,000, consisting of $162,000 being paid in accordance with the Company's payroll practices and $250,000 being paid by the issuance of restricted shares of Common Stock in lieu of cash.

Mr. Smith's rate of compensation has not changed since March 1, 2016.

The Common Stock component of Mr. Smith's compensation is to be computed on a quarterly basis, with the number of shares issued being equal to the quotient of the quarterly amount due, divided by the average daily closing price of the Company's Common Stock for the quarter just ended.

Hedging Policy

We do not permit the Named Executive Officers to "hedge" ownership by engaging in short sales or trading in any options contracts involving securities.

Options Exercised and Stock Vested

No options have been exercised by our Named Executive Officers during the 2018 Fiscal Year.

Options to purchase an aggregate of 500,000 shares of Common Stock and issued to Named Executive Officers in prior fiscal years vested during Fiscal 2018.

Pension Benefits

We do not provide pension benefits to the Named Executive Officers.

Nonqualified Deferred Compensation

We do not have any defined contribution or other plan that provides for the deferral of compensation on a basis that is not tax-qualified.

Potential Payments Upon Termination or Change of Control

We do not presently provide the Named Executive Officers with any plan or arrangement, other than those that may be contained in the employment contracts of Mr. Nasrat Hakim, Mr. Douglass Plassche, and Mr. George Kenneth Smith, as disclosed above, in connection with any termination, including without limitation, through retirement, resignation, severance, or constructive termination (including a change in responsibilities) of such Named Executive Officer's employment with the Company.

As part of the Company's efforts to ensure the retention and continuity of key employees, officers, and directors in the event of a change of control of the ownership of the Company, unless otherwise stated in applicable employment contracts, key executives would receive an amount equal to twelve months of such executive's salary, and certain Directors and managers would receive an amount equal to six months of such Director's or manager's fees or salaries, as applicable. In addition, any outstanding and unvested options would immediately vest, in the event of a change of control.

Compensation of named executive officers:

Name and Principal Position	Fiscal Year	Salary [1] ($)	Bonus [1] ($)	Option Awards [1] ($)	All Other Compensation [1] ($)	Total ($)
Nasrat Hakim, President, Chief Executive Officer and Chairman of the Board of Directors						
	2018(1)	500,000(2)	500,000(3)	—	18,000(4)	1,018,000
	2017(1)	500,000(2)	500,000(3)	—	18,000(4)	1,018,000
	2016(1)	387,500(2)	387,500(3)	—	18,000(4)	793,000
Carter J. Ward, Chief Financial Officer						
	2018(1)	192,816(5)	25,000(6)	—	—	217,816
	2017(1)	192,816(5)	—	—	—	192,816
	2016(1)	187,668(5)	30,000(6)	—	—	217,668
Douglas Plassche, Executive Vice President						
	2018(1)	253,552(7)	75,000(8)	—	6,000(4)	334,552
	2017(1)	253,552(7)	76,066(8)	—	6,000(4)	335,618
	2016(1)	244,613(7)	73,140(8)	—	6,000(4)	323,753
George Kenneth Smith, Vice President						
	2018(1)	412,000(9)	—	—	—	412,000
	2017(1)	412,000(9)	—	—	—	412,000
	2016(1)	401,000(9)	—	—	—	401,000

(1) Represents amounts paid or accrued for the fiscal years ended March 31, 2018, 2017, and 2016, respectively.

(2) Represents total salaries paid or accrued to Mr. Hakim pursuant to the Hakim Employment Agreement, with such amounts to be paid via the issuance of Common Stock in lieu of cash.
No Common Stockhave been issued to Mr. Hakim in payment of salaries due for Fiscal 2018. A total of 4,329,135 shares of Common Stock are due and owing to Mr. Hakim in relation to salaries earned by Mr. Hakim during Fiscal 2018. A total of 1,832,626 shares of Common Stock have been issued and an additional 845,004 shares are due and owing to Mr. Hakim in relation to salaries earned by Mr. Hakim during Fiscal 2017. In aggregate, a total of 5,174,139 shares of Common Stock are due and owing to Mr. Hakim for salaries earned during Fiscal 2018 and Fiscal 2017. A total of 1,445,445 shares of Common Stock have been issued to Mr. Hakim in full payment of salaries earned by Mr. Hakim during Fiscal 2016.

(3) Represents bonuses paid or accrued to Mr. Hakim pursuant to the Hakim Employment Agreement, with amounts accrued for periods prior to January 1, 2016 being paid via the issuance of Common Stock in lieu of cash and amounts accrued for periods subsequent to January 1, 2016 to be paid in accordance with the Company's payroll practices.
Bonus earned by Mr. Hakim during Fiscal 2018 was accrued and is owing to Mr. Hakim. A total of $375,000 of bonuses earned by Mr. Hakim during Fiscal 2017 was paid in accordance with the Company's payroll practices, with the balance of $125,000 in bonuses earned by Mr. Hakim during Fiscal 2017 being accrued and owing to Mr. Hakim. In aggregate, bonuses totaling $625,000 earned by Mr. Hakim during Fiscal 2018 and Fiscal 2018 are accrued and owing. Pursuant to the Hakim Employment Agreement, these bonuses are to be paid in accordance with the Company's payroll practices.
A total of 1,061,079 shares of Common Stock were issued to Mr. Hakim in payment of bonuses totaling $262,500 accrued during Fiscal 2016. The remaining $125,000 in bonuses owed to Mr. Hakim for Fiscal 2016 was paid in accordance with the Company's payroll practices.

(4) Represents amounts paid for auto allowances.

(5) Represents salaries earned by Mr. Ward pursuant to the Ward Employment Agreement.
Fiscal 2018 salaries consist of $162,816 being paid in accordance with the Company's payroll practices and $30,000 being paid via the issuance of 191,360 shares of Common Stock in lieu of cash with an additional 68,389 shares of Common Stock being owed. Fiscal 2017 salaries consist of $162,816 being paid in accordance with the Company's payroll practices and $30,000 being paid via the issuance of 160,658 shares of Common Stock in lieu of cash. Fiscal 2016 salaries consist of $157,668 being paid in accordance with the Company's payroll practices and $30,000 being paid via the issuance of 114,012 shares of Common Stock in lieu of cash.

(6) Discretionary cash bonuses awarded by the Chief Executive Officer.
Bonus awarded during Fiscal 2018 was accrued as of March 31, 2018 and paid in April 2018 in accordance with the Company's payroll practices.

(7) Represents salaries earned by Mr. Plassche pursuant to the Plassche Employment Agreement.
Fiscal 2018 salaries consist of $228,552 being paid in accordance with the Company's payroll practices and $25,000 being paid via the issuance of 159,467 shares of Common Stock in lieu of cash, with an additional 56,991 shares of Common Stock being owed. Fiscal 2017 salaries consist of $228,552 being paid in accordance with the Company's payroll practices and $25,000 being paid via the issuance of 133,881 shares of Common Stock in lieu of cash. Fiscal 2016 salaries consist of $219,613 being paid in accordance with the Company's payroll practices and $25,000 being paid via the issuance of 95,009 shares of Common Stock in lieu of cash.

(8) Cash bonuses paid pursuant to the Plassche Employment Agreement.
Bonus awarded during Fiscal 2018 was accrued as of March 31, 2018 and paid in April 2018 in accordance with the Company's payroll practices.

(9) Represents salaries earned by Mr. Smith pursuant to the Smith Employment Agreement.
Fiscal 2018 salaries consist of $162,000 being paid in accordance with the Company's payroll practices and $250,000 being paid via the issuance of 1,594,661 shares of Common Stock in lieu of cash with an additional 569,905 shares of Common stock being owed. Fiscal 2017 salaries consist of $162,000 being paid in accordance with the Company's payroll practices and $250,000 being paid via the issuance of 1,338,815 shares of Common Stock in lieu of cash. Fiscal 2016 salaries consist of $151,800 being paid in accordance with the Company's payroll practices and $250,000 being paid via the issuance of 950,097 shares of Common Stock in lieu of cash.

Pay Ratio Disclosure

As required by Section 953(b) of the Dodd-Frank Wall Street Reform and Consumer Protection Act, and Item 402(u) of Regulation S-K, we are providing the following information regarding the ratio of the annual total compensation of our Chief Executive Officer to the median of the annual total compensation of the rest of our employees for the fiscal year ended March 31, 2018.

The annual total compensation for Mr. Nasrat Hakim, our Chief Executive Officer, as reported in the compensation table above was $1,018,000. Mr. Hakim's annual compensation consists of $500,000 in salary, $500,000 in bonus and $18,000 in car allowance. To date, neither the salary or the bonus has been paid to Mr. Hakim, in accordance with Mr. Hakim's instructions to defer such payments to a later, undetermined date. When paid, a total of 4,329,135 shares of Common Stock will be issued in lieu of cash for salaries due to Mr. Hakim and the bonus will be paid in accordance with the Company's payroll practices.

The median annual total compensation of our employees, exclusive of our Chief Executive Officer was $60,631. To determine our median employee we identified each individual employed by us at any time, whether employed on a full-time or part-time basis, during the twelve-month period ended March 31, 2018. Employee compensation was based on payroll records, with compensation for part-time employees and for employees that were employed by us for less than the full twelve-month period being adjusted to the full-time, full-year equivalent, to ensure that all amounts included in the ratio calculation represented equal employment status and periods of earning.

Based on the foregoing, the ratio of the annual total compensation of our Chief Executive Officer to the annual total compensation of our median employee was approximately 16.8 to 1.

We believe that this pay ratio is a reasonable estimate calculated in a manner consistent with SEC rules based on our payroll and employment records and the methodology described above. The SEC rules for identifying the median employee and calculating the pay ratio based on that employee's annual tota compensation allow companies to adopt a variety of methodologies, to apply certain exclusions, and to make reasonable estimates and assumptions that reflect their compensation practices. As such, the pay ratio reported by other companies may not be comparable to the pay ratio reported above, as other companies may have different employment and compensation practices and may utilize different methodologies, exclusions, estimates and assumptions in calculating their own pay ratios.

Outstanding Equity Awards at March 31, 2018

Name	Number of securities underlying unexercised options Exercisable (#)	Number of securities underlying unexercised options Unexercisable (#)	Equity Incentive Plan Awards: Number of securities underlying unexercised unearned options (#)	Options Exercise Price ($)	Option Expiration Date
Carter Ward	200,000	-	-	0.10	1/17/2020
Carter Ward	150,000	-	-	0.12	6/19/2022
Douglas Plassche	3,000,000	-	-	0.07	7/23/2023
George Kenneth Smith	1,500,000	-	-	0.29	10/20/2024

The following table sets forth information concerning director compensation for the year ended March 31, 2018:

Name	Fees Earned or Paid In Cash [1] ($)	Stock Awards [1] ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Non-qualified Deferred Compensation ($)	All Other Compensation ($)	Total ($)
Barry Dash [2]	10,000(3)	20,000(4)	-	-	-	-	30,000
Jeffrey Whitnell [2]	10,000(3)	20,000(4)	-	-	-	-	30,000
Eugene Pfeifer [2][5]	10,000(3)	20,000(4)	-	-	-	-	30,000
Davis Caskey [2]	10,000(3)	20,000(4)	-	-	-	-	30,000

(1) Please refer to the section below titled "*Director Fee Compensation*" for details on the Company's director fee compensation policy.

(2) Amounts represent Director compensation earned during the fiscal year ended March 31, 2018.

(3) $7,500 of this amount was paid in March 2018 and $2,500 is owed and expected to be paid on or before March 31, 2019.

(4) A total of 127,574 shares of Common Stock were issued and 45,592 shares of Common Stock are due and owing to Dr. Dash, Mr. Whitnell, Mr Pfeifer and Mr. Caskey for Director's fees that are paid via the issuance of Common Stock and earned during Fiscal 2018.

(5) Mr. Pfeifer passed away on June 10, 2018.

Director Fee Compensation

The Company's policy regarding director fees is as follows: (i) Directors who are employees or consultants of the Company (and/or any of its subsidiaries) receive no additional remuneration for serving as directors or members of committees of the Board; (ii) all Directors are entitled to reimbursement for out-of-pocket expenses incurred by them in connection with their attendance at the Board or committee meetings; (iii) Directors who are not employees or consultants of the Company (and/or any of its subsidiaries) receive a $30,000 annual retainer fee, with $20,000 of this amount being paid via the issuance of restricted Common Stock of the Company in lieu of cash, as described below, and the remaining $10,000 being paid in cash; (iv) The Chairman of the Board receives a $30,000 annual retainer fee paid via the issuance of restricted shares of Common Stock of the Company in lieu of cash, as described below; (v) Directors and the Chairman do not receive any additional compensation for attendance at or chairing of any meetings; and, (vi) Mr. Nasrat Hakim received no additional compensation, above the annual retainer fee due to the Chairman of the Board, for the period that he also served as Chief Executive Officer.

Director Equity Compensation

Members of the Board of Directors and the Chairman are paid their annual retainer fees via the issuance of restricted shares of Common Stock of the Company, in lieu of cash. The number of shares to be issued to each Director and the Chairman is equal to the quotient of the quarterly amount due to each Director and the Chairman, respectively, divided by the average daily closing price of the Company's stock for the quarter just ended.

Members of the Board of Directors during the fiscal years ended March 31, 2018 and March 31, 2017 did not receive any options or equity compensation for serving as directors other than shares of Common Stock earned in lieu of cash in relation to Director fees due.

Other

The Company's Articles of Incorporation provide for the indemnification of each of the Company's directors to the fullest extent permitted under Nevada General Corporation Law.

ITEM 12 SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth certain information, as of June 7, 2018 (except as otherwise indicated), regarding beneficial ownership of our Common Stock and our Series J Preferred Stock by (i) each person who is known by us to own beneficially more than 5% of each such class, (ii) each of our directors (iii) each of our executive officers and (iv) all our directors and executive officers as a group. As of June 7, 2018, we had 803.6 million shares of Common Stock outstanding (exclusive of 0.1 million treasury shares) and 24.0344 shares of Series J Preferred Stock outstanding. On any matter presented to the holders of our Common Stock for their action or consideration at any meeting of our Shareholders, each share of Common Stock entitles the holder to one vote and each share of Series J Preferred Stock entitles the holder to the number of votes equal to the number of shares of Common Stock into which such share of Series J Preferred Stock is convertible (6,574,631 shares of Common Stock per whole share of Series J Preferred Stock).

As used in the table below and elsewhere in this report, the term beneficial ownership with respect to a security consists of sole or shared voting power, including the power to vote or direct the vote, and/or sole or shared investment power, including the power to dispose or direct the disposition, with respect to the security through any contract, arrangement, understanding, relationship, or otherwise, including a right to acquire such power(s) during the 60 days immediately following June 7, 2018. Except as otherwise indicated, the Shareholders listed in the table have sole voting and investment powers with respect to the shares indicated.

Name and Address Of Beneficial Owner of Common Stock	Amount and Nature of Beneficial Ownership		Percent (%) of Voting Securities Beneficially Owned (11)
	Common Stock	Series J Preferred Stock	
Nasrat Hakim, President, Chief Executive Officer and Chairman of the Board of Directors*	16,971,700(1)	24.0344(2)	18.2%
Barry Dash, Director*	1,461,603(3)		**%
Jeffrey Whitnell, Director*	1,413,068(4)		**%
Eugene Pfeifer, Director*	275,484(5)		**%
Davis Caskey, Director*	279,006(6)		**%
Carter J. Ward, Chief Financial Officer *	4,190,308(7)		**%
Douglas Plassche, Executive Vice President *	3,554,587(8)		**%
Ashok Nigalaye, Former Director	50,115,539(9)		5.2%
All Directors and Officers as a group	28,145,756(10)	24.0344(2)	19.4%

* The address is c/o Elite Pharmaceuticals Inc., 165 Ludlow Avenue, Northvale, NJ 07647.
** Less than 1%

(1) Includes 11,797,561 shares of Common Stock held as per the most recent Form 4 filing, and 5,174,139 shares of Common Stock due and owing to Mr Hakim as of March 31, 2018 (the latest practicable date) for compensation earned pursuant to Mr. Hakim's employment agreement with the Company. Excludes warrants to purchase 79,008,661 shares of Common Stock which are not currently exercisable.

(2) Series J Preferred Stock has an aggregate of 158,017,321 voting rights.

(3) Includes 1,416,011 shares of Common Stock held as per the most recent Form 4 filing and 45,592 shares of Common Stock due and owing to Dr Dash as of March 31, 2018 (the latest practicable date) for Directors fees accrued as of such date.

(4) Includes 1,367,476 shares of Common Stock held as per the most recent Form 4 filing and 45,592 shares of Common Stock due and owing to Mr Whitnell as of March 31, 2018 (the latest practicable date) for Directors fees accrued as of such date.

(5) Mr. Pfeifer passed away on June 10, 2018.
Includes 229,892 shares of Common Stockheld as per the most recent Form 4 filing and 45,592 shares of Common Stock due and owing to Mr Pfeifer as of March 31, 2018 (the latest practicable date) for Directors fees accrued as of such date.

(6) Includes 233,414 shares of Common Stock held as per the most recent Form 4 filing and 45,592 shares of Common Stock due and owing to Mr Caskey as of March 31, 2018 (the latest practicable date) for Directors fees accrued as of such date.

(7) Includes 3,771,919 shares of Common Stock held and 68,389 shares of Common Stock due and owing to Mr. Ward as of March 31, 2017 (the lates practicable date) for salaries earned pursuant to Mr. Ward's employment agreement with the Company, and vested options to purchase 350,000 shares of Common Stock.

(8) Includes 487,596 shares of Common Stock held as per the most recent Form 4 filing, 56,991 shares of Common Stock due and owing to Mr. Plassch as of March 31, 2017 (the latest practicable date) for salaries earned pursuant to Mr. Plassche's employment agreement with the Company, and vested options to purchase 3,000,000 shares of Common Stock.

(9) Dr. Nigalaye resigned on June 5, 2015. Address is c/o Granulation Technology Inc. 12 Industrial Road, Fairfield, NJ 07004. Includes 50,115,539 share of Common Stock held with the Company's transfer agent in account(s) that is (are) beneficially owned by Dr. Nigalaye.

(10) Relates only to current directors and officers. Includes 19,303,869 shares of Common Stock held, as per the applicable most recent Form 3 or Form 4 filings, 5,481,887 shares of Common Stock due and owing as of March 31, 2018 (the latest practicable date) for director's fees and salaries accrued as of such date, and vested options to purchase 3,350,000 shares of Common Stock. Excludes warrants to purchase 79,008,661 shares of Common Stock which are not currently exercisable and 24.0344 Series J Preferred Convertible Shares.

(11) The denominator includes 158,017,321 votes attributable to the outstanding Series J Preferred Stock. Accordingly, the percentage of Common Stock beneficially owned by each Owner listed in the table other than Mr. Hakim is slightly greater than the percentage listed in this column.

ITEM 13 CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Certain Related Person Transactions

Transactions with Nasrat Hakim and Mikah Pharma LLC

On August 1, 2013, Elite Labs executed an asset purchase agreement (the "*Mikah Purchase Agreement*") with Mikah Pharma and acquired from Mikah a total of 13 ANDAs consisting of 12 ANDAs approved by the FDA and one ANDA under active review with the FDA, and all amendments there (the "Acquisition") for aggregate consideration of $10,000,000, inclusive of imputed interest payable pursuant to a non-interest bearing, secured convertible note due in August 2016 (the "*Mikah Note*"). The Mikah Note was amended on February 7, 2014 to make it convertible into shares of the Company's Series Convertible Preferred Stock.

The Mikah Note, as amended, was interest free and due and payable on the third anniversary of its issuance. Subject to certain limitations, the principal amount of the Mikah Note was convertible at the option of Mikah into shares of Common Stock at a rate of $0.07 (approximately 14,286 shares pe $1,000 in principal amount), the closing market price of the Company's Common Stock on the date that the asset purchase agreement and Note were executed and/or into shares of the Company's Series I Convertible Preferred Stock (the "*Series I Preferred Stock*") at the rate of 1 share of Series I Preferred Stock for each $100,000 of principal owed on the Mikah Note. The conversion rate was adjustable for customary corporate actions such as stock splits and, subject to certain exclusions, includes weighted average anti-dilution for common stock transactions at prices below the then applicable conversion rate. Pursuant to a security agreement, repayment of the Mikah Note was secured by the ANDAs acquired in the Acquisition.

On February 7, 2014, Mikah converted the principal amount of $10,000,000, representing the entire principal balance due under the Mikah Note, into 100 shares of the Company's Series I Preferred Stock.

On August 16, 2016, Mikah converted all 100 shares of Series I Preferred Stock for 142,857,143 shares of Common Stock.

On August 27, 2010, Elite executed an asset purchase with Mikah (the "*Naltrexone Agreement*"). Pursuant to the Naltrexone Agreement, Elite acquired from Mikah the Abbreviated New Drug Application number 75-274 (Naltrexone Hydrochloride Tablets USP, 50 mg), and all amendments thereto (the "*Naltrexone Hydrochloride ANDA*"), that have to date been filed with the FDA seeking authorization and approval to manufacture, package, ship and sell the products described in the Naltrexone Hydrochloride ANDA within the United States and its territories (including Puerto Rico) for aggregate consideration of $200,000. In lieu of cash, Mikah agreed to accept from Elite product development services to be performed by Elite and entered into a Development and License Agreement dated August 27, 2010 between the Company and Mikah (the "*Mikah Development Agreement").* A current report on form 8-K was filed on August 27, 2010 in relation to this announcement, such filing being incorporated herein by this reference. Please also refer to exhibit 10.5 of the Quarterly Report on Form 10-Q filed with SEC on November 15, 2010, such filing being incorporated herein by this reference.

The manufacturing of Naltrexone 50mg was successfully transferred to the Company's Northvale facility, and the first commercial shipment of this product was made in September 2013.

On January 28, 2015, the Mikah Development Agreement was terminated by mutual agreement of the parties thereto. Pursuant to the Mikah Development Agreement, Mikah made advance consideration payments to the Company totaling $200,000 in exchange for product development services to be provided at a future date. Subsequent to the execution of the Mikah Development Agreement, and before any development milestones were achieved, the sole owner of Mikah, Mr. Nasrat Hakim, became the President and Chief Executive Officer of the Company. Mikah has accordingly ceased operating and is in the process of liquidating its assets.

Any further development of the product related to the Mikah Development Agreement will belong to the Company, although there can be no assurances that such development will occur or be successful.

The Mikah Development Agreement required that the consideration paid in advance to the Company be refunded in the event of no milestones being achieved. Mr. Hakim, as owner of Mikah, has directed that the $200,000 refund due to Mikah not be paid currently, but rather be added to the amounts due under the Hakim Credit Line.

In October 2013, the Company entered into a bridge loan agreement (the "*Hakim Loan Agreement*") with Mr. Hakim. Under the terms of the Hakim Loan Agreement, the Company has the right, at its sole discretion, to a line of credit ("*Hakim Credit Line*") in the maximum principal amount of up to $1,000,000 at any one time. The purpose of the Hakim Credit Line was to support the acceleration of the Company's product development activities. The outstanding amount was evidenced by a promissory note, which matured on March 31, 2016. On March 31, 2016, the entire unpaid principal balance plus accrued interest thereon was due and payable in full. Prior to maturity or the occurrence of an Event of Default as defined in the Hakim Loan Agreement, the Company could borrow, repay, and re-borrow under the Hakim Credit Line through maturity. Amounts borrowed under the Hakim Credit Line bore interest at the rate of 10% per annum.

At March 31, 2016, a principal balance of $718,309 along with accrued interest of $70,784 was due and owing. The principal balance was paid in full on May 23, 2016. The accrued interest due as of March 31, 2016, plus $9,134 in additional interest accrued from April 1, 2016 through May 23, 2016 was paid in full on May 24, 2016. There are no amounts due and owing under the Hakim Loan Agreement or the Hakim Line of Credit, and both have expired.

On April 28, 2017, Elite entered into an exchange agreement with Nasrat Hakim, pursuant to which the Company issued to Mr. Hakim 24.0344 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 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 our common stock owned by Mr. Hakim.

The exchange was conducted pursuant to the exemption from registration provided by Section 3(a)(9) of the Securities Act.

Series J Preferred

Each share of Series J Preferred has a stated value of $1,000,000 (the "*Stated Value*"). Commencing on the earlier of three years from the date of issuance of the Series J Preferred or the date that shareholder approval of an increase in the authorized shares of common stock is obtained (the "*Shareholder Approval*") and the requisite corporate action has been effected, each share of Series J Preferred is convertible into shares of Company Common Stock at a rate calculated by dividing the Stated Value by $0.1521 (the "*Conversion Price*") (prior to any adjustment, 6,574,622 shares of Common Stock per whole share of Series J Preferred). At present, there is not a sufficient number of authorized but unissued or unreserved shares of Common Stock to permit full conversion of the Securities (the "*Authorized Share Deficiency*"). Accordingly, the Series J Preferred will not be convertible to the extent that there are not a sufficient number of shares available for issuance upon conversion unless and until Shareholder Approval has been obtained and the requisite corporate action has been effected. Subject to certain exceptions, the Conversion 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 Conversion Price. The Conversion price also is adjustable upon the happening of certain customary events such as stock dividends and splits, pro rata distributions and fundamental transactions.

Holders of Series J Preferred vote, along with the holders of Common Stock, on any matter presented to the shareholders. Each holder of Series J Preferred is 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 such holder are convertible regardless of whether an Authorized Share Deficiency Exists.

The Series J Preferred ranks senior to the Common Stock with respect to the payment of dividends. So long as any shares of Series J Preferred remain outstanding, the Company cannot declare, pay, or set aside any dividends on shares of any other of its capital stock, unless the holders receive, a dividend on each outstanding share of Series J Preferred in an amount equal to the dividend the holders would have been entitled to receive upon conversion, in full, of the shares of Series J Preferred regardless of whether an Authorized Share Deficiency Exists. In addition, solely during any period commencing four years after the issuance of the Series J Preferred, provided that the Authorized Share Deficiency still exists, until such time as the Authorized Share Deficiency no longer exists, holders of the Series J Preferred are entitled to receive dividends at the rate per share (as a percentage of the Stated Value per share) of 20% per annum, payable quarterly.

Upon liquidation, dissolution or winding up of the Company, holders of Series J Preferred are entitled to receive for each share of Series J Preferred Stock, pari passu and pro rata with the holders of Common Stock, out of the Company's assets, an amount equal to the amount distributable with regard to the number of whole shares of Common Stock into which the shares of Series J Preferred held by the holders are convertible as of the date of the Liquidation regardless of whether an Authorized Share Deficiency exists.

Series J Warrants

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 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. The Warrants provide for other standard adjustments upon the happening of certain customary events. The 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.

Trimipramine Acquisition

On May 16, 2017, we executed an asset purchase agreement with Mikah Pharma, and acquired from Mikah Pharma (the "*Trimipramine Acquisition*") an FDA approved ANDA for Trimipramine for aggregate consideration of $1,200,000, payable pursuant to a senior secured note due on December 31, 2020 (the "*Trimipramine Note*"). Mikah Pharma is owned by Nasrat Hakim, the Chairman of the Board of Directors, President and Chief Executive Officer (CEO) of the Company.

The Trimipramine Note bears interest at the rate of 10% per annum, payable quarterly. All principal and unpaid interest is due and payable on December 31, 2020. Pursuant to a security agreement, repayment of the Trimipramine Note is secured by the ANDA acquired in the Acquisition.

Distribution Agreement with Dr. Reddy's Laboratories, Inc.

On May 17, 2017, in conjunction with the Trimipramine Acquisition, the Company executed an assignment agreement with Mikah Pharma, pursuant to which the Company acquired all rights, interests, and obligations under a supply and distribution agreement (the "*Reddy's Trimipramine Distribution Agreement*") with Dr. Reddy's Laboratories, Inc. ("*Dr. Reddy's*") originally entered into by Mikah Pharma on May 7, 2017 and relating to the supply, sale and distribution of generic Trimipramine Maleate Capsules 25mg, 50mg and 100mg.

On May 22, 2017, the Company executed an assignment agreement with Mikah Pharma, pursuant to which the Company acquired all rights, interest and obligations under a manufacturing and supply agreement with Epic originally entered into by Mikah on June 30, 2015 and relating to the manufacture and supply of Trimipramine (the "*Trimipramine Manufacturing Agreement*").

Under the Trimipramine Manufacturing Agreement, Epic will manufacture Trimipramine under license from the Company pursuant to the FDA approved and currently marketed Abbreviated New Drug Application ("*ANDA*") that was acquired in conjunction with the Company's entry into these agreements.

Under the Reddy's Trimipramine Distribution Agreement, the Company will supply Trimipramine on an exclusive basis to Dr. Reddy's and Dr. Reddy's will be responsible for all marketing and distribution of Trimipramine in the United States, its territories, possessions, and commonwealth. The Trimipramine will be manufactured by Epic and transferred to Dr. Reddy's at cost, without markup.

Dr. Reddy's will pay to the Company a share of the profits, calculated without any deduction for cost of sales and marketing, derived from the sale of Trimipramine. The Company's share of these profits is in excess of 50%.

For information about our employment agreement with Mr. Hakim, please see "*Part II; Item 11 Executive Compensation-Agreements with Named Executive Officers*" above.

Strategic Alliance Agreement/Transactions with Epic Pharma LLC and Epic Investments LLC

On March 18, 2009, the Company entered into the Epic Strategic Alliance Agreement with Epic Pharma, LLC and Epic Investments, LLC, a subsidiary controlled by Epic Pharma LLC. For more information on the Epic Strategic Alliance Agreement please see our Current Reports on Form 8-K, filed with the SEC on March 23, 2009, May 6, 2009 and June 5, 2009, which disclosures are incorporated herein by reference. Ashok G. Nigalaye, Jeenarine Narine and Ram Potti, each were elected as members of our Board of Directors, effective June 24, 2009, as the three directors that Epic was entitled to designate for appointment to the Board pursuant to the terms of the Epic Strategic Alliance Agreement. Mr. Potti resigned from his position as Director of the Company on December 31, 2012, Dr. Nigalaye resigned as a Company Director on June 5, 2015 and Mr. Narine resigned from his position as Director of Company on April 7, 2016. Messrs. Nigalaye, Narine and Potti were also officers of Epic Pharma, LLC, in the following capacities:

- Mr. Nigalaye, Chairman and Chief Executive Officer of Epic Pharma, LLC;
- Mr. Narine, President and Chief Operating Officer of Epic Pharma, LLC; and,
- Mr. Potti, Vice President of Epic Pharma, LLC.

The Epic Strategic Alliance Agreement expired on June 4, 2012.

In May 2016, Humanwell Healthcare Group and PuraCap Pharmaceutical LLC announced that the companies have acquired 100% of the membership interests of Epic Pharma, LLC of Laurelton, NY.

The Epic Strategic Alliance included provisions entitling the Company to a Product Fee equal to 15% of profits derived from the sale of Oxy IR, as defined in the Epic Strategic Alliance Agreement. The Company is entitled to this product fee indefinitely.

Manufacturing and Licensing Agreement with Epic Pharma LLC

The Company has entered into two agreements with Epic which may constitute agreements with a related party due to the management of Epic including a member on our Board of Directors at the time such agreements were executed.

On June 4, 2015, the Company entered into the 2015 Epic License Agreement. Please see "*Item I Business; Licensing, Manufacturing and Development Agreements; Sales and Distribution Licensing Agreement with Epic Pharma LLC for SequestOx™*" in Item I above.

On October 2, 2013, Elite executed the Epic Pharma Manufacturing and License Agreement. Please see "*Item I Business; Licensing, Manufacturing and Development Agreements; Manufacturing and License Agreement with Epic Pharma LLC*" in Item I above.

Director Independence

All related person transactions are reviewed and, as appropriate, may be approved or ratified by the Board of Directors. If a Director is involved in the transaction, he or she may not participate in any review, approval, or ratification of such transaction. Related person transactions are approved by the Board of Directors only if, based on all of the facts and circumstances, they are in, or not inconsistent with, our best interests and the best interests of our stockholders, as the Board of Directors determines in good faith. The Board of Directors takes into account, among other factors it deems appropriate, whether the transaction is on terms generally available to an unaffiliated third-party under the same or similar circumstances and the extent of the related person's interest in the transaction. The Board of Directors may also impose such conditions as it deems necessary and appropriate on us or the related person in connection with the transaction.

In the case of a transaction presented to the Board of Directors for ratification, the Board of Directors may ratify the transaction or determine whether rescission of the transaction is appropriate.

ITEM 14 PRINCIPAL ACCOUNTANT FEES AND SERVICES

The Company's independent registered public accounting firm is Buchbinder Tunick & Company LLP ("*Buchbinder*").

The following table presents fees, including reimbursements for expenses, for professional audit services rendered by Buchbinder, for the audits of our financial statements and interim reviews of our quarterly financial statements.

	Fiscal 2018	Fiscal 2017	Fiscal 2016
Audit Fees	$ 128,800	$ 117,000	$ 110,500
Audit-Related Fees	1,850	-	7,000
Tax Fees	7,000	7,000	12,200

Audit Fees

Represents fees for professional services provided for the audit of our annual financial statements, services that are performed to comply with generally accepted auditing standards, and review of our financial statements included in our quarterly reports and services in connection with statutory and regulatory filings.

Audit-Related Fees

Represents the fees for assurance and related services that were reasonably related to the performance of the audit or review of our financial statements.

Tax Fees

Represents preparation of Federal, State and Local income tax returns.

The Audit Committee has determined that Buchbinder's rendering of these audit-related services was compatible with maintaining auditor's independence. The Board of Directors considered Buchbinder to be well qualified to serve as our independent public accountants. The Committee also pre approved the charges for services performed in Fiscal 2018.

The Audit Committee pre-approves all audit related and tax services and the terms thereof (which may include providing comfort letters in connection with securities underwriting) and non-audit services (other than non-audit services prohibited under Section 10A(g) of the Exchange Act or the applicable rules of the SEC or the Public Company Accounting Oversight Board) to be provided to us by the independent auditor; provided, however, the pre-approval requirement is waived with respect to the provisions of non-audit services for us if the "de minimus" provisions of Section 10A (i)(1)(B) of the Exchange Act are satisfied. This authority to pre-approve non-audit services may be delegated to one or more members of the Audit Committee, who shall present all decisions to pre-approve an activity to the full Audit Committee at its first meeting following such decision.

PART IV

ITEM 15 EXHIBITS, FINANCIAL STATEMENTS AND SCHEDULES

(a) The following are filed as part of this Annual Report on Form 10-K

(1) The financial statements and schedules required to be filed by Item 8 of this Annual Report on Form 10-K and listed in the Index to Consolidate Financial Statements.

(2) The Exhibits required by Item 601 of Regulation S-K and listed below in the "*Index to Exhibits required by Item 601 of Regulation S*-K."

(b) The Exhibits are filed with or incorporated by reference in this Annual Report on Form 10-K

(c) None

Index to Exhibits required by Item 601 of Regulation S-K.

Exhibit No.	Description
2.1	Agreement and Plan of Merger between Elite Pharmaceuticals, Inc., a Delaware corporation ("Elite-Delaware") and Elite Pharmaceuticals, Inc., a Nevada corporation ("Elite-Nevada"), incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed with th SEC on January 9, 2012.
3.1(a)	Articles of Incorporation of Elite-Nevada, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the SEC January 9, 2012.
3.1(b)	Certificate of Incorporation of Elite-Delaware, together with all other amendments thereto, as filed with the Secretary of State of the Stat of Delaware, incorporated by reference to (a) Exhibit 4.1 to the Registration Statement on Form S-4 (Reg. No. 333-101686), filed with th SEC on December 6, 2002 (the "Form S-4"), (b) Exhibit 3.1 to the Company's Current Report on Form 8-K dated July 28, 2004 and file with the SEC on July 29, 2004, (c) Exhibit 3.1 to the Company's Current Report on Form 8-K dated June 26, 2008 and filed with the SEC on July 2, 2008, and (d) Exhibit 3.1 to the Company's Current Report on Form 8-K dated December 19, 2008 and filed with the SEC December 23, 2008.*
3.1(c)	Certificate of Designations, Preferences and Rights of Series A Preferred Stock, as filed with the Secretary of the State of Delawar incorporated by reference to Exhibit 4.5 to the Current Report on Form 8-K dated October 6, 2004, and filed with the SEC on October 1 2004.*
3.1(d)	Certificate of Retirement with the Secretary of the State of the Delaware to retire 516,558 shares of the Series A Preferred Stock, as file with the Secretary of State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated March 10, 2006, and filed with the SEC on March 14, 2006.*
3.1(e)	Certificate of Designations, Preferences and Rights of Series B 8% Convertible Preferred Stock, as filed with the Secretary of the State Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated March 15, 2006, and filed with the SEC March 16, 2006.*
3.1(f)	Amended Certificate of Designations of Preferences, Rights and Limitations of Series B 8% Convertible Preferred Stock, as filed with th Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated April 2 2007, and filed with the SEC on April 25, 2007.*
3.1(g)	Certificate of Designations, Preferences and Rights of Series C 8% Convertible Preferred Stock, as filed with the Secretary of the State Delaware, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K dated April 24, 2007, and filed with the SEC on Apr 25, 2007.*
3.1(h)	Amended Certificate of Designations, Preferences and Rights of Series C 8% Convertible Preferred Stock, as filed with the Secretary the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated April 24, 2007, and filed with th SEC on April 25, 2007.*

3.1(i)	Amended Certificate of Designations of Preferences, Rights and Limitations of Series B 8% Convertible Preferred Stock, as filed with th Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated Septembe 15, 2008, and filed with the SEC on September 16, 2008.*
3.1(j)	Amended Certificate of Designations, Preferences and Rights of Series C 8% Convertible Preferred Stock, as filed with the Secretary the State of Delaware, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K dated September 15, 2008, and file with the SEC on September 16, 2008.*
3.1(k)	Amended Certificate of Designations of Preferences, Rights and Limitations of Series D 8% Convertible Preferred Stock, as filed with th Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.3 to the Current Report on Form 8-K dated Septembe 15, 2008, and filed with the SEC on September 16, 2008.*
3.1(l)	Certificate of Designation of Preferences, Rights and Limitations of Series E Convertible Preferred Stock, as filed with the Secretary State of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated June 1, 2009, and file with the SEC on June 5, 2009.*
3.1(m)	Amended Certificate of Designations of the Series D 8% Convertible Preferred Stock as filed with the Secretary of State of the State Delaware on June 29, 2010, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K, dated June 24, 2010 and filed wit the SEC on July 1, 2010.*
3.1(n)	Amended Certificate of Designations of the Series E Convertible Preferred Stock as filed with the Secretary of State of the State Delaware on June 29, 2010, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K, dated June 24, 2010 and filed wit the SEC on July 1, 2010.*
3.1(o)	Certificate of Designations of the Series G Convertible Preferred Stock as filed with the Secretary of State of the State of Nevada on Ap 18, 2013, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated April 18, 2013 and filed with the SEC on Apr 22, 2013 .
3.1(p)	Certificate of Designation of the Series H Junior Participating Preferred Stock, incorporated by reference to Exhibit 2 (contained in Exhib 1) to the Registration Statement on Form 8-A filed with the SEC on November 15, 2013.
3.1(q)	Certificate of Designations of the Series I Convertible Preferred Stock as filed with the Secretary of State of the State of Nevada February 6, 2014, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K, dated February 6, 2014 and filed with th SEC on February 7, 2014.
3.1(r)	Certificate of Designations of the Series J Convertible Preferred Stock as filed with the Secretary of State of the State of Nevada on Ma 3, 2017, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K, dated April 28, 2017 and filed with the SEC on Apr 28, 2017.
3.2(a)	Amended and Restated By-Laws of the Company, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K date March 17, 2014 and filed with the SEC on March 18, 2014.
3.2(b)	By-Laws of Elite-Delaware, as amended, incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form SB- (Reg. No. 333-90633) made effective on February 28, 2000 (the "Form SB-2").*
4.1	Form of specimen certificate for Common Stock of the Company, incorporated by reference to Exhibit 4.1 to the Form SB-2.*
4.2	Form of specimen certificate for Series B 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to th Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.*
4.3	Form of specimen certificate for Series C 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to th Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.*
4.4	Form of Warrant to purchase shares of Common Stock issued to purchasers in the private placement which closed on March 15, 2006 (the "Series B Financing"), incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated March 15, 2006 and filed with th SEC on March 16, 2006.*

4.5	Form of Warrant to purchase shares of Common Stock issued to purchasers in the Series B Financing, incorporated by reference to Exhib 4.3 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.*
4.6	Form of Warrant to purchase shares of Common Stock issued to the Placement Agent, in connection with the Series B Financing incorporated by reference to Exhibit 4.4 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 1 2006.*
4.7	Form of Warrant to purchase 600,000 shares of Common Stock issued to Indigo Ventures, LLC, incorporated by reference to Exhibit 4.1 t the Current Report on Form 8-K, dated July 12, 2006 and filed with the SEC on July 18, 2006.*
4.8	Form of Warrant to purchase up to 478,698 shares of Common Stock issued to VGS PHARMA, LLC, incorporated by reference Exhibit 3(a) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.*
4.9	Form of Non-Qualified Stock Option Agreement for 1,750,000 shares of Common Stock granted to Veerappan Subramanian, incorporate by reference as Exhibit 3(b) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.*
4.10	Form of Warrant to purchase shares of Common Stock issued to purchasers in the private placement which closed on April 24, 2007 (the "Series C Financing"), incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated April 24, 2007 and filed with th SEC on April 25, 2007.*
4.11	Form of Warrant to purchase shares of Common Stock issued to the placement agent in the Series C Financing, incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.*
4.12	Form of specimen certificate for Series D 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to th Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.*
4.13	Form of Warrant to purchase shares of Common Stock issued to purchasers in the private placement which closed on September 15, 2008 (the "Series D Financing"), incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated September 15, 2008 and file with the SEC on September 16, 2008.*
4.14	Form of Warrant to purchase shares of Common Stock issued to the placement agent in the Series D Financing, incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.*
4.15	Form of specimen certificate for Series E Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to th Current Report on Form 8-K, dated June 1, 2009, and filed with the SEC on June 5, 2009.*
4.16	Warrant to purchase shares of Common Stock issued to Epic Investments, LLC in the initial closing of the Strategic Alliance Agreemen dated as of March 18, 2009, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference Exhibit 4.2 to the Current Report on Form 8-K, dated June 1, 2009, and filed with the SEC on June 5, 2009.*
4.17	Form of specimen certificate for Series G Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.2 to th Current Report on Form 8-K, dated April 18, 2013 and filed with the SEC on April 22, 2013.
4.18	Form of specimen certificate for Series I Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.2 to th Current Report on Form 8-K, dated February 6, 2014 and filed with the SEC on February 7, 2014.
4.19	Rights Agreement, dated as of November 15, 2013, between the Company and American Stock Transfer & Trust Company, LLC incorporated by reference to Exhibit 1 to the Registration Statement on Form 8-A filed with the SEC on November 15, 2013.

4.20	Form of Series H Preferred Stock Certificate, incorporated by reference to Exhibit 1 to the Registration Statement on Form 8-A filed wi the SEC on November 15, 2013.
4.21	Warrant to purchase shares of Common Stock issued to Nasrat Hakim dated April 28, 2017 incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated April 28, 2017, and filed with the SEC on April 28, 2017.
10.1	Elite Pharmaceuticals, Inc. 2014 Equity Incentive Plan, incorporated by reference to Appendix B to the Company's Definitive Prox Statement for its Annual Meeting of Shareholders, filed with the SEC on April 3, 2014.
10.2	Form of Confidentiality Agreement (corporate), incorporated by reference to Exhibit 10.7 to the Form SB-2.
10.3	Form of Confidentiality Agreement (employee), incorporated by reference to Exhibit 10.8 to the Form SB-2.
10.4	Loan Agreement, dated as of August 15, 2005, between New Jersey Economic Development Authority ("NJEDA") and the Compan incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on Septembe 6, 2005.
10.5	Series A Note in the aggregate principal amount of $3,660,000.00 payable to the order of the NJEDA, incorporated by reference to Exhib 10.2 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
10.6	Series B Note in the aggregate principal amount of $495,000.00 payable to the order of the NJEDA, incorporated by reference to Exhib 10.3 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
10.7	Mortgage from the Company to the NJEDA, incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K, dated Augu 31, 2005 and filed with the SEC on September 6, 2005.
10.8	Indenture between NJEDA and the Bank of New York as Trustee, dated as of August 15, 2005, incorporated by reference to Exhibit 10. to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
10.9	Consulting Agreement, dated as of July 27, 2007, between the Registrant and Willstar Consultants, Inc., incorporated by reference a Exhibit 10.1 to the Quarterly Report on Form 10-Q for the period ending September 30, 2007 and filed with the SEC on November 14, 2007.
10.10	Compensation Agreement, dated as of December 1, 2008, by and between the Company and Jerry I. Treppel, incorporated by reference t Exhibit 10.1 to the Current Report on Form 8-K, dated December 1, 2008 and filed with the SEC on December 4, 2008.
10.11	Strategic Alliance Agreement, dated as of March 18, 2009, by and among the Company, Epic Pharma, LLC and Epic Investments, LL incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated March 18, 2009 and filed with the SEC on March 2 2009.
10.12	Amendment to Strategic Alliance Agreement, dated as of April 30, 2009, by and among the Company, Epic Pharma, LLC and Epi Investments, LLC, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated April 30, 2009 and filed with th SEC on May 6, 2009.
10.13	Second Amendment to Strategic Alliance Agreement, dated as of June 1, 2009, by and among the Company, Epic Pharma, LLC and Ep Investments, LLC, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated June 1, 2009, and filed with the SE on June 5, 2009.
10.14	Third Amendment to Strategic Alliance Agreement, dated as of Aug 18, 2009, by and among the Company, Epic Pharma LLC and Epi Investments, LLC, incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q, for the period ending June 30, 2009 ar filed with the SEC on August 19, 2009.
10.15	Employment Agreement, dated as of November 13, 2009, by and between the Company and Carter J. Ward, incorporated by reference t Exhibit 10.2 to the Quarterly Report on Form 10-Q, for the period ending September 30, 2009 and filed with the SEC on November 1 2009.

10.16	Elite Pharmaceuticals Inc. 2009 Equity Incentive Plan, as adopted November 24, 2009, incorporated by reference to Exhibit 10.1 to th Registration Statement Under the Securities Act of 1933 on Form S-8, dated December 18, 2009 and filed with the SEC on December 2 2009.
10.17	License Agreement, dated as of September 10, 2010, by and among Precision Dose Inc. and the Company, incorporated by reference t Exhibit 10.8 to the Quarterly Report on Form 10-Q, for the period ended September 30, 2010 and filed with the SEC on November 15, 201 (Confidential Treatment granted with respect to portions of the Agreement).
10.18	Manufacturing and Supply Agreement, dated as of September 10, 2010, by and among Precision Dose Inc. and the Company, incorporate by reference to Exhibit 10.9 to the Quarterly Report on Form 10-Q, for the period ended September 30, 2010 and filed with the SEC c November 15, 2010 (Confidential Treatment granted with respect to portions of the Agreement).
10.19	Product Development Agreement between the Company and Hi-Tech Pharmacal Co., Inc. dated as of January 4, 2011, incorporated b reference to Exhibit 10.1 to the Current Report on Form 8-K, dated January 4, 2011 and filed with the SEC on January 10, 201 (Confidential Treatment granted with respect to portions of the Agreement).
10.20	Manufacturing & Supply Agreement between the Company and ThePharmaNetwork, LLC, dated as of June 23, 2011, incorporated b reference to Exhibit 10.71 to the Annual Report on Form 10-K, for the period ended March 31, 2011 and filed with the SEC on June 2 2011 (Confidential Treatment granted with respect to portions of the Agreement).
10.21	Treppel $500,000 Bridge Loan Agreement dated June 12, 2012, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8 K filed with the SEC on June 13, 2012.
10.22	December 5, 2012 amendment to the Treppel Bridge Loan Agreement incorporated by reference to Exhibit 10.1 to the Current Report o Form 8-K filed with the SEC on December 10, 2012.
10.23	Letter Agreement between the Company and ThePharmaNetwork LLC, dated September 21, 2012 incorporated by reference to Exhib 10.6 to the Quarterly Report on Form 10-Q filed with the SEC on November 14, 2012 (Confidential Treatment granted with respect t portions of the Agreement).
10.24	Purchase Agreement between the Company and Lincoln Park Capital LLC dated April 19, 2013, incorporated by reference to Exhibit 10. to the Current Report on Form 8-K, dated April 18, 2013 and filed with the SEC on April 22, 2013.
10.25	Registration Rights Agreement between the Company and Lincoln Park Capital LLC dated April 19, 2013 , incorporated by reference t Exhibit 10.2 to the Current Report on Form 8-K, dated April 18, 2013 and filed with the SEC on April 22, 2013.
10.26	August 1, 2013 Employment Agreement with Nasrat Hakim, incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K dated August 1, 2013 and filed with the SEC on August 5, 2013.
10.27	August 1, 2013 Mikah LLC Asset Purchase Agreement, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K dated August 1, 2013 and filed with the SEC on August 5, 2013. (Confidential Treatment granted with respect to portions of the Agreement).
10.28	August 1, 2013 Secured Convertible Note from the Company to Mikah Pharma LLC., incorporated by reference to Exhibit 10.2 to th Current Report on Form 8-K, dated August 1, 2013 and filed with the SEC on August 5, 2013.
10.29	August 1, 2013 Security Agreement from the Company to Mikah Pharma LLC., incorporated by reference to Exhibit 10.3 to the Curre Report on Form 8-K, dated August 1, 2013 and filed with the SEC on August 5, 2013.
10.30	October 15, 2013 Hakim Credit Line Agreement, incorporated by reference to Exhibit 10.16 to the Quarterly Report on Form 10-Q for th period ended September 30, 2013.

10.31	October 2, 2013 Manufacturing and Licensing Agreement with Epic Pharma LLC, incorporated by reference to Exhibit 10.17 to th Amended Quarterly Report on Form 10-Q/A for the period ended September 30, 2013 and filed with the SEC on April 2 2014. Confidential Treatment granted with respect to portions of the Agreement.
10.33	November 21, 2013 Unsecured Convertible Note from the Company to Jerry Treppel, incorporated by reference to Exhibit 10.1 to th Current Report on Form 8-K, dated November 26, 2013 and filed with the SEC on November 26, 2013.
10.34	February 7, 2014 Amendment to Secured Convertible Note from the Company to Mikah, incorporated by reference to Exhibit 10.1 to th Current Report on Form 8-K, dated February 7, 2014 and filed with the SEC on February 7, 2014.
10.35	February 7, 2014 Amendment to Secured Convertible Note from the Company to Jerry Treppel, incorporated by reference to Exhibit 10.2 t the Current Report on Form 8-K, dated February 7, 2014 and filed with the SEC on February 7, 2014.
10.36	Purchase Agreement between the Company and Lincoln Park Capital LLC dated April 10, 2014 , incorporated by reference to Exhibit 10. to the Current Report on Form 8-K, dated April 10, 2014 and filed with the SEC on April 14, 2014.
10.37	Registration Rights Agreement between the Company and Lincoln Park Capital LLC dated April 10, 2014 , incorporated by reference t Exhibit 10.1 to the Current Report on Form 8-K, dated April 10, 2014 and filed with the SEC on April 14, 2014.
10.38	Employment Agreement with Dr. G. Kenneth Smith, dated October 20, 2014, incorporated by reference to Exhibit 10.82 to the Quarterl Report on Form 10-Q for the period ended September 30, 2014 and filed with the SEC on November 14, 2014.
10.39	January 19, 2015 Second Amendment to TPN-Elite Manufacturing and Supply Agreement dated June 23, 2011 and First Amendment to th TPN-Elite Manufacturing and Supply Agreement dated September 21, 2012, incorporated by reference to Exhibit 10.6 to the Quarter Report on Form 10-Q/A for the period ended September 30, 2012, and filed with the SEC on November 17, 2016. Confidential Treatmer granted with respect to portions of the Agreement.
10.40	January 28, 2015 First Amendment to the Loan Agreement between Nasrat Hakim and Elite Pharmaceuticals dated October 15, 201 incorporated by reference to Exhibit 10.83 to the Quarterly Report on Form 10-Q for the period ended December 31, 2014 and filed with the SEC on February 17, 2015.
10.41	January 28, 2015 Termination of Development and License Agreement for Mikah-001 between Elite Pharmaceuticals, Inc. and Mika Pharma LLC and Transfer of Payment, incorporated by reference to Exhibit 10.84 to the Quarterly Report on Form 10-Q for the perio ended December 31, 2014 and filed with the SEC on February 17, 2015 .
10.42	June 4, 2015 License Agreement with Epic Pharma LLC, incorporated by reference to Exhibit 10.85 to Amendment No. 1 to the Annu Report on Form 10-K for the fiscal year ended March 31, 2015 and filed with the SEC on July 11, 2016. (Confidential Treatment grante with respect to portions of the Agreement).
10.43	Amendment No. 1 to Hakim Employment Agreement, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K file with the SEC on January 29, 2016.
10.44	August 24, 2016 Master Development and License Agreement between Elite and SunGen Pharma LLC. incorporated by reference Exhibit 10.44 to the Quarterly Report on Form 10-Q for the period ended September 30, 2016 and filed with the SEC on November 9, 201 (Confidential Treatment granted with respect to portions of the Agreement).
10.45	August 9, 2016 Amendment to Manufacturing and Supply Agreement between the Company and ThePharmaNetwork, LLC, dated as June 23, 2011 incorporated by reference to Exhibit 10.45 to the Quarterly Report on Form 10-Q for the period ended September 30, 201 and filed with the SEC on November 9, 2016.
10.46	July 20, 2015 Third Amendment to TPN-Elite Manufacturing and Supply Agreement dated June 23, 2011 incorporated by reference t Exhibit 10.46 to the Quarterly Report on Form 10-Q for the period ended September 30, 2016 and filed with the SEC on November 9, 201 (Confidential Treatment granted with respect to portions of the Agreement).

10.47	Purchase Agreement between the Company and Lincoln Park Capital LLC dated May 1, 2017, incorporated by reference to Exhibit 10.1 the Current Report on Form 8-K, dated May 2, 2017 and filed with the SEC on May 2, 2017.
10.48	Registration Rights Agreement between the Company and Lincoln Park Capital LLC dated May 1, 2017, incorporated by reference Exhibit 10.2 to the Current Report on Form 8-K, dated May 2, 2017 and filed with the SEC on May 2, 2017.
10.49	April 28, 2017 Exchange Agreement between the Company and Nasrat Hakim, incorporated by reference to Exhibit 10.1 to the Curren Report on Form 8-K, dated April 28, 2017 and filed with the SEC on April 28. 2017.
10.50	May 2017 Trimipramine Acquisition Agreement from Mikah Pharma, incorporated by reference to Exhibit 10.50 to the Annual Report o Form 10-K, for the period ended March 31, 2017 and filed with the SEC on June 14, 2017.
10.51	May 2017 Secured Promissory Note from the Company to Mikah Pharma, incorporated by reference to Exhibit 10.51 to the Annual Repo on Form 10-K, for the period ended March 31, 2017 and filed with the SEC on June 14, 2017.
10.52	May 2017 Security Agreement between the Company to Mikah Pharma, incorporated by reference to Exhibit 10.52 to the Annual Repo on Form 10-K, for the period ended March 31, 2017 and filed with the SEC on June 14, 2017.
10.53	May 2017 Assignment of Supply and Distribution Agreement between Dr. Reddy's Laboratories and Mikah Pharma, incorporated b reference to Exhibit 10.53 to the Annual Report on Form 10-K, for the period ended March 31, 2017 and filed with the SEC on June 1 2017.
10.54	May 2017 Assignment of Manufacturing and Supply Agreement between Epic and Mikah Pharma, incorporated by reference to Exhib 10.54 to the Annual Report on Form 10-K, for the period ended March 31, 2017 and filed with the SEC on June 14, 2017.
10.55	Supply and Distribution Agreement between Dr. Reddy's Laboratories and Mikah Pharma, incorporated by reference to Exhibit 10.55 to th Annual Report on Form 10-K, for the period ended March 31, 2017 and filed with the SEC on June 14, 2017. (Confidential Treatme granted with respect to portions of the Agreement).
10.56	Manufacturing and Supply Agreement between Epic and Mikah Pharma, incorporated by reference to Exhibit 10.56 to the Annual Repo on Form 10-K, for the period ended March 31, 2017 and filed with the SEC on June 14, 2017. (Confidential Treatment granted with respe to portions of the Agreement).
10.57	Master Development And License Agreement For Products Between Elite Pharmaceuticals, Inc. And Sungen dated July 6, 201 incorporated by reference to Exhibit 10.57 to the Quarterly Report on Form 10-Q for the period ended June 30, 2017 and filed with the SE on August 9, 2017. (Confidential Treatment granted with respect to portions of the Agreement).
10.58	Second Amendment To Master Development And License Agreement For Products Between Elite Pharmaceuticals, Inc. And Sunge Pharma, LLC, incorporated by reference to Exhibit 10.58 to the Quarterly Report on Form 10-Q for the period ended June 30, 2017 ar filed with the SEC on August 9, 2017. (Confidential Treatment granted with respect to portions of the Agreement).
10.59	First Amendment To Master Development And License Agreement For Products Between Elite Pharmaceuticals, Inc. And Sunge Pharma, LLC, incorporated by reference to Exhibit 10.59 to the Quarterly Report on Form 10-Q for the period ended June 30, 2017 ar filed with the SEC on August 9, 2017. (Confidential Treatment granted with respect to portions of the Agreement).
10.60	May 29, 2018 License, Manufacturingand Supply Agreement with Glenmark Pharmaceuticals Inc. USA. Confidential portions of thi exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended
21	Subsidiaries of the Company**
23.1	Consent of Buchbinder Tunick & Company LLP, Independent Registered Public Accounting Firm**
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document

* On January 5, 2011, the Company changed its domicile from Delaware to Nevada. All corporate documents from Delaware have been superseded by Nevada corporate documents filed or incorporated by reference herein. All outstanding Delaware securities certificates are now outstanding Nevada securities certificates.

** Filed herewith.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

ELITE PHARMACEUTICALS, INC.

By: /s/ Nasrat Hakim
Nasrat Hakim
Chief Executive Officer

Dated: June 14, 2018

By: /s/ Carter J. Ward
Carter J. Ward
Chief Financial Officer

Dated: June 14, 2018

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Nasrat Hakim	Chief Executive Officer, President and Chairman of the Board of Directors	June 14, 2018
/s/ Carter J. Ward	Chief Financial Officer, Treasurer, Secretary	June 14, 2018
/s/ Barry Dash	Director	June 14, 2018
/s/ Jeffrey Whitnell	Director	June 14, 2018
/s/ Davis Caskey	Director	June 14, 2018

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEARS ENDED MARCH 31, 2018, 2017 AND 2016

CONTENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Shareholders of Elite Pharmaceuticals, Inc. and Subsidiary

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Elite Pharmaceuticals, Inc. and Subsidiary (the Company) as of March 31, 2018, and 2017 and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the years in the three year period ended March 31, 2018, 2017 and 2016, and the related notes (collectively referred to as the consolidated financial statements). We also have audited the Company's internal control over financial reporting as of March 31, 2018, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of March 31, 2018 and 2017, and the results of its operations and its cash flows for each of the years in the three-year period ended March 31, 2018, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of March 31, 2018, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by COSO.

Basis for Opinion

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express an opinion on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Buchbinder Tunick & Company LLP

Little Falls, New Jersey 07424
June 14, 2018

We have served as the Company's auditor since 2010

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS
(AUDITED)

	March 31, 2018	March 31, 2017
ASSETS		
Current assets:		
Cash	$ 7,179,237	$ 10,594,693
Accounts receivable, net of allowance for doubtful accounts of $-0-, respectively	675,879	934,059
Inventory	4,898,001	6,415,966
Prepaid expenses and other current assets	949,284	468,002
Total current assets	13,702,401	18,412,720
Property and equipment, net of accumulated depreciation of $8,408,979 and $7,426,752, respectively	8,993,708	9,039,404
Intangible assets, net of accumulated amortization of $-0-, respectively	7,713,001	6,419,091
Other assets:		
Restricted cash - debt service for NJEDA bonds	391,566	389,081
Security deposits	81,932	50,846
Total other assets	473,498	439,927
Total assets	**$ 30,882,608**	**$ 34,311,142**
LIABILITIES, MEZZANINE EQUITY AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,658,137	$ 1,049,815
Accrued expenses	1,788,571	794,628
Deferred revenue, current portion	1,013,333	1,013,333
Bonds payable, current portion, net of bond issuance costs	75,822	70,822
Loans payable, current portion	578,841	416,148
Total current liabilities	5,114,704	3,344,746
Long-term liabilities:		
Deferred revenue, net of current portion	1,252,223	2,265,557
Bonds payable, net of current portion and bond issuance costs	1,508,134	1,583,956
Senior secured promissory note - related party	1,200,000	-
Loans payable, net current portion	623,020	577,612
Derivative financial instruments – warrants	2,667,871	843,464
Other long-term liabilities	41,144	31,770
Total long-term liabilities	7,292,392	5,302,359
Total liabilities	**12,407,096**	**8,647,105**
Mezzanine equity		
Series J convertible preferred stock; par value $0.01; 50 shares authorized, 24.0344 issued and outstanding as of March 31, 2018; 0 shares authorized, 0 issued and outstanding as of March 31, 2017	13,903,960	-
Shareholders' equity:		
Common stock; par value $0.001; 995,000,000 shares authorized; 802,626,761 shares issued and 802,526,761 outstanding as of March 31, 2018; 928,031,448 shares issued and 927,931,448 outstanding as of March 31, 2017	802,629	928,034
Additional paid-in capital	146,602,502	163,896,410
Treasury stock; 100,000 shares as of March 31, 2018 and March 31, 2017; at cost	(306,841)	(306,841)
Accumulated deficit	(142,526,738)	(138,853,566)
Total shareholders' equity	**4,571,552**	**25,664,037**
Total liabilities, mezzanine equity and shareholders' equity	**$ 30,882,608**	**$ 34,311,142**

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENT OF OPERATIONS
(AUDITED)

	Years Ended March 31,		
	2018	**2017**	**2016**
Manufacturing fees	$ 5,199,006	$ 7,326,959	$ 8,002,866
Licensing fees	2,259,705	2,310,756	4,495,466
Total revenue	7,458,711	9,637,715	12,498,332
Cost of revenue	3,511,123	5,898,405	4,484,162
Gross profit	3,947,588	3,739,310	8,014,170
Operating expenses:			
Research and development	9,621,365	8,301,693	12,428,783
General and administrative	2,332,289	2,083,226	2,903,178
Non-cash compensation through issuance of stock options	244,753	357,955	333,362
Depreciation and amortization	800,460	352,369	665,647
Total operating expenses	12,998,867	11,095,243	16,330,970
Loss from operations	(9,051,279)	(7,355,933)	(8,316,800)
Other income (expense):			
Interest expense and amortization of debt issuance costs	(335,498)	(238,223)	(280,670)
Change in fair value of derivative instruments	4,650,266	9,525,103	7,394,006
Interest income	17,510	12,620	-
Other income, net	4,332,278	9,299,500	7,113,336
Income (loss) from operations before the benefit from sale of state net operating loss credits	(4,719,001)	1,943,567	(1,203,464)
Net benefit from sale of state net operating loss credits	1,045,829	1,867,614	520,452
Net (loss) income	(3,673,172)	3,811,181	(683,012)
Change in carrying value of convertible preferred share mezzanine equity	-	20,714,286	(9,285,715)
Net (loss) income attributable to common shareholders	$ (3,673,172)	$ 24,525,467	$ (9,968,727)
Basic (loss) income per share attributable to common shareholders	$ (0.00)	$ 0.03	$ (0.01)
Diluted loss per share attributable to common shareholders	$ (0.01)	$ (0.01)	$ (0.01)
Basic weighted average Common Stock outstanding	796,069,419	838,665,804	673,905,485
Diluted weighted average Common Stock outstanding	798,169,419	844,506,245	673,905,485

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)
(AUDITED)

	Common Stock			Treasury Stock			
	Shares	Amount	Additional Paid-In Capital	Shares	Amount	Accumulated Deficit	Total Shareholders' Equity (Deficit)
Balance at March 31, 2015	631,160,701	$ 631,162	$ 106,926,328	100,000	$ (306,841)	$ (141,981,735)	$ (34,731,086)
Net loss						(683,012)	(683,012)
Change in value of convertible preferred mezzanine equity			(9,285,715)				(9,285,715)
Issuance of Common Stock pursuant to the exercise of cash warrants	48,283,968	48,284	2,969,464				3,017,748
Issuance of Common Stock pursuant to the exercise of cash options	112,500	113	23,638				23,751
Common Stock issued in payment of employee salaries	4,236,555	4,237	1,034,763				1,039,000
Common Stock issued in payment of Directors' Fees	408,892	409	99,662				100,071
Common Stock issued in payment of consulting expenses	97,467	97	23,903				24,000
Common Stock issued as commitment shares pursuant to the Lincoln Park purchase agreement	298,923	299	83,803				84,102
Costs associated with raising capital			(84,102)				(84,102)
Common Stock sold pursuant to the Lincoln Park purchase agreement	23,945,346	23,945	6,175,698				6,199,643
Non-cash compensation through the issuance of employee stock options			333,363				333,363
Milestone shares issued pursuant to EPIC Strategic Alliance Agreement	3,000,000	3,000	837,000				840,000
Balance at March 31, 2016	711,544,352	$ 711,546	$ 109,137,805	100,000	$ (306,841)	$ (142,664,747)	$ (33,122,237)
Net income						3,811,181	3,811,181
Change in value of convertible preferred mezzanine equity			20,714,286				20,714,286
Issuance of Common Stock pursuant to the exercise of cash warrants	29,562,876	29,563	1,818,117				1,847,680
Issuance of Common Stock pursuant to the exercise of cash options	100,000	100	8,700				8,800
Common Stock issued in payment of employee salaries	3,633,397	3,634	819,117				822,751
Common Stock issued in payment of Directors' Fees	334,295	334	73,027				73,361
Common Stock issued in payment of consulting expenses	106,416	106	24,061				24,167
Common Stock issued as commitment shares pursuant to the Lincoln Park purchase agreement	366,118	366	82,595				82,961
Costs associated with raising capital			(121,587)				(121,587)
Common Stock sold pursuant to the Lincoln Park purchase agreement	39,526,851	39,527	7,553,762				7,593,289
Non-cash compensation through the issuance of employee stock options			357,955				357,955
Common Stock issued pursuant to the conversion of Series I Convertible Preferred Shares	142,857,143	142,858	23,428,572				23,571,430

Balance at March 31, 2017	928,031,448	$ 928,034	$ 163,896,410	100,000	$ (306,841)	$ (138,853,566)	$ 25,664,037
Net loss						(3,673,172)	(3,673,172)
Issuance of Common Stock pursuant to the exercise of cash warrants	5,658,295	5,658	347,985				353,643
Common Stock issued in payment of consulting expense	211,392	211	25,789				26,000
Common Stock issued in payment of employee salaries	2,460,941	2,461	302,539				305,000
Common Stock issued in payment of Directors' Fees	645,496	645	79,355				80,000
Common Stock issued as additional commitment shares pursuant to the LPC purchase agreement	277,009	277	34,927				35,204
Common Stock issued as commitment shares pursuant to the Lincoln Park purchase agreement	5,540,551	5,541	914,191				919,732
Costs associated with raising capital			(1,004,892)				(1,004,892)
Common Stock sold pursuant to the Lincoln Park purchase agreement	17,818,950	17,819	1,982,059				1,999,878
Non-cash compensation through the issuance of employee stock options			244,753				244,753
Retirement of Common Stock	(158,017,321)	(158,017)	(20,220,614)				(20,378,631)
Balance at March 31, 2018	802,626,761	$ 802,629	$ 146,602,502	100,000	$ (306,841)	$ (142,526,738)	$ 4,571,552

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

ELITE PHARMACEUITCALS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS
(AUDITED)

	Years Ended March 31,		
	2018	**2017**	**2016**
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net (loss) income	$ (3,673,172)	$ 3,811,181	$ (683,012)
Adjustments to reconcile net (loss) income to net cash used in operating activities:			
Depreciation and amortization	996,406	714,530	666,461
Change in fair value of derivative financial instruments - warrants	(4,650,266)	(9,525,103)	(7,394,006)
Non-cash compensation accrued	925,000	409,750	573,667
Salaries and Directors fees satisfied by the issuance of Common Stock	385,000	896,112	1,139,071
Consulting expenses paid via the issuance of Common Stock	26,000	24,167	24,000
Non-cash compensation from the issuance of Common Stock and options	244,753	357,955	333,363
Milestone shares issued pursuant to Epic Strategies Alliance Agreement	-	-	840,000
Non-cash rent expense	7,549	(17,374)	(22,996)
Non-cash lease accretion	1,828	1,721	1,621
Bad debt recovery	-	-	(117,095)
Change in operating assets and liabilities:			
Accounts receivable	258,180	596,237	33,240
Inventory	1,517,965	(3,122,237)	(261,727)
Prepaid expenses and other current assets	(512,368)	(92,382)	160,076
Accounts payable, accrued expenses and other current liabilities	677,268	(925,088)	(2,211,414)
Deferred revenue and customer deposits	(1,013,334)	(1,013,330)	4,153,330
Net cash used in operating activities	(4,809,191)	(7,883,861)	(2,765,421)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(180,937)	(1,097,562)	(1,918,804)
Intellectual property costs	(93,910)	(7,292)	(30,025)
Restricted cash	(2,485)	(122)	-
Net cash used in investing activities	(277,332)	(1,104,976)	(1,948,829)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from cash warrant and options exercises	353,643	1,856,480	3,041,499
Proceeds and repayments of line of credit, related party - net	-	(718,309)	135,238
Other loan payments	(547,496)	(401,485)	(404,131)
Costs associated with raising capital	(49,957)	(38,624)	-
Payment of NJEDA Bonds	(85,001)	(220,000)	(210,000)
Proceeds from sale of Common Stock to Lincoln Park Capital	1,999,878	7,593,289	6,199,643
Net cash provided by financing activities	1,671,067	8,071,351	8,762,249
Net change in cash	(3,415,456)	(917,486)	4,047,999
Cash, beginning of period	10,594,693	11,512,179	7,464,180
Cash, end of period	$ 7,179,237	$ 10,594,693	$ 11,512,179
Supplemental disclosure of cash and non-cash transactions:			
Cash paid for interest	$ 135,146	$ 142,351	$ 215,878
Cash paid for taxes	$ 5,500	$ 2,500	$ 4,048
Financing of equipment purchases and insurance renewal	$ 755,594	$ 308,834	$ 442,399
Issuance of Senior Promissory Note pursuant ANDA asset acquisition	$ 1,200,000	$ -	$ -
Conversion of Series I convertible preferred shares into Common Stock	$ -	$ 23,571,430	$ -
Commitment shares issued to Lincoln Park Capital	$ 954,936	$ 69,425	$ 84,102
Change in carrying value of convertible preferred mezzanine equity	$ -	$ 20,714,286	$ (9,285,715)
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 audited consolidated financial statements.

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 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"), an thereafter, commercially exploiting such products.

Principles of Consolidation

The accompanying audited consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP") and in conformity with the instructions on Form 10-K and Rule 8-03 of Regulation S-X and the related rules an regulations of the Securities and Exchange Commission ("SEC"). The 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 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.

Going Concern

In connection with the preparation of the financial statements for the year ended March 31, 2018, the Company conducted an evaluation as to whether there were conditions and events, considered in the aggregate, which raised substantial doubt as to the entity's ability to continue as a going concern within one year after the date of the issuance, or the date the financial statements were available for issuance, noting that there did not appear to be evidence of substantial doubt of the entity's ability to continue as a going concern.

Segment Information

Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 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 U.S. 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 audited consolidated financial statements. Please see note 17 for further details.

Revenue Recognition

The Company enters into licensing, manufacturing and development agreements, which may include multiple revenue generating activities, including, without limitation, milestones, licensing fees, product sales and services. These multiple elements are assessed in accordance with ASC 605-25, *Revenue Recognition – Multiple-Element Arrangements* in order to determine whether particular components of the arrangement represent separate units of accounting.

An arrangement component is considered to be a separate unit of accounting if the deliverable relating to the component has value to the customer on a standalone basis, and if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in control of the Company.

The Company recognizes payments received pursuant to a multiple revenue agreement as revenue, only if the related delivered item(s) have stand-alone value, with the arrangement being accordingly accounted for as a separate unit of accounting. If such delivered item(s) are considered to either not have stand-alone value, the arrangement is accounted for as a single unit of accounting, and the payments received are recognized as revenue over the estimated period of when performance obligations relating to the item(s) will be performed.

Whenever the Company determines that an arrangement should be accounted for as a single unit of accounting, it determines the period over which the performance obligations will be performed, and revenue will be recognized. If it cannot reasonably estimate the timing and the level of effort to complete its performance obligations under a multiple-element arrangement, revenues are then recognized on a straight-line basis over the period encompassing the expected completion of such obligations, with such period being reassessed at each subsequent reporting period.

Arrangement consideration is allocated at the inception of the arrangement to all deliverables on the basis of their relative selling price (the relative selling price method). When applying the relative selling price method, the selling price of each deliverable is determined using vendor-specific objective evidence of selling price, if such exists; otherwise, third-part evidence of selling price. If neither vendor-specific objective evidence nor third-party evidence of selling price exists for a deliverable, the Company uses its best estimate of the selling price for that deliverable when applying the relative selling price method. In deciding whether we can determine vendor-specific objective evidence or third-party evidence of selling price, the Company does not ignore information that is reasonably available without undue cost and effort.

When determining the selling price for significant deliverables under a multiple-element revenue arrangement, the Company considers any or all of the following, without limitation, depending on information available or information that could be reasonably available without undue cost and effort: vendor-specific objective evidence, third party evidence or best estimate of selling price. More specifically, factors considered can include, without limitation and as appropriate, size of market for a specific product, number of suppliers and other competitive market factors, forecast market shares and gross profits, barriers/time frames to market entry/launch, intellectual property rights and protections, exclusive or non-exclusive arrangements, costs of similar/identical deliverables from third parties, contractual terms, including, without limitation, length of contract, renewal rights, commercial terms, profit allocations, and other commercial, financial, tangible and intangible factors that may be relevant in the valuation of a specific deliverable.

Milestone payments are accounted for in accordance with ASC 605-28,*Revenue Recognition – Milestone Method* for any deliverables or units of accounting under which the Company must achieve a defined performance obligation which is contingent upon future events or circumstances that are uncertain as of the inception of the arrangement providing for such future milestone payment. Determination of the substantiveness of a milestone is a matter of subjective assessment performed at the inception of the arrangement, and with consideration earned from the achievement of a milestone meeting all of the following:

- It must be either commensurate with the Company's performance in achieving the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the Company's performance to achieve the milestone; and
- It relates solely to past performance; and
- It is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement.

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, 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.

Restricted Cash

As of March 31, 2018, and 2017, the Company had $391,566 and $389,081 of restricted cash, respectively, related to debt serve reserve in regard to the New Jersey Economic Development Authority ("*NJEDA*") bonds (see Note 6).

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

Research and Development

Research and development expenditures are charged to expense as incurred.

Leases

Lease agreements are evaluated to determine if they are capital leases meeting any of the following criteria at inception: (a) transfer of ownership; (b) bargain purchase option; (c) the lease term is equal to 75 percent or more of the estimated economic life of the leased property; or (d) the present value at the beginning of the lease term of the minimum lease payments, excluding that portion of the payments representing executory costs such as insurance, maintenance, and taxes to be paid by the lessor, including any profit thereon, equals or exceeds 90 percent of the excess of the fair value of the leased property to the lessor at lease inception over any related investment tax credit retained by the lessor and expected to be realized by the lessor.

If at its inception a lease meets any of the four lease criteria above, the lease is classified by the Company as a capital lease; and if none of the four criteria are met, the lease is classified by the Company as an operating lease.

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 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.

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.

The Company recognizes the benefit of an uncertain tax position that it has taken or expects to take on income tax returns it files if such tax position is more likely than not to be sustained on examination by the taxing authorities, based on the technical merits of the position. These tax benefits are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate resolution.

The Company operates in multiple tax jurisdictions within the United States of America. The Company remains subject to examination in all tax jurisdiction until the applicable statutes of limitation expire. As of March 31, 2018, a summary of the tax years that remain subject to examination in our major tax jurisdictions are: United States – Federal, 2014 and forward, and State, 2010 and forward. The Company did not record unrecognized tax positions for the years ended March 31, 2018, 2017, and 2016.

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 Topic 718,*Compensation-Stock Compensation*. Under the fair value recognition provisions of this topic, 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 simple 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 dilutive potential 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 Years Ended March 31,		
	2018	2017	2016
Numerator			
Net income (loss) attributable to common shareholders - basic	$ (3,673,172)	$ 24,525,467	$ (9,968,727)
Effect of dilutive instrument on net (loss) income	(4,650,266)	(30,239,389)	1,891,709
Net income (loss) attributable to common shareholders - diluted	$ (8,323,438)	$ (5,713,922)	$ (8,077,018)
Denominator			
Weighted average shares of common stock outstanding - basic	796,069,419	838,665,804	673,905,485
Dilutive effect of stock options, warrants and convertible securities	2,100,000	5,840,441	-
Weighted average shares of common stock outstanding - diluted	798,169,419	844,506,245	673,905,485
Net income (loss) per share			
Basic	$ (0.00)	$ 0.03	$ (0.01)
Diluted	$ (0.01)	$ (0.01)	$ (0.01)

Fair Value of Financial Instruments

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

ASC Topic 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 Topic 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 Topic 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 as of March 31, 2018 and March 31, 2017 aggregated by the level in the fair value hierarchy within which those measurements fell:

		Fair Value Measurement Using		
	Amount at Fair Value	Level 1	Level 2	Level 3
March 31, 2018				
Liabilities				
Derivative financial instruments - warrants	$ 2,667,871	$ -	$ -	$ 2,667,871
March 31, 2017				
Liabilities				
Derivative financial instruments - warrants	$ 843,464	$ -	$ -	$ 843,464

See Note 12, 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. Based upon current borrowing rates with similar maturities the carrying value of long-term debt approximates fair value.

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 (deficit).

Recently Adopted Accounting Standards

In January 2017, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") 2017-01, *Business Combinations: Clarifying the Definition of a Business*, which amends the current definition of a business. Under ASU 2017-01, to be considered a business an acquisition would have to include an input and a substantive process that together significantly contributes to the ability to create outputs. ASU 2017-01 further states that when substantially all of the fair value of gross assets acquired is concentrated in a single asset (or a group of similar assets), the assets acquired would not represent a business. The new guidance also narrows the definition of the term "outputs" to be consistent with how it is described in Topic 606, Revenue from Contracts with Customers. The changes to the definition of a business will likely result in more acquisitions being accounted for as asset acquisitions. The guidance is effective for the annual period beginning after December 15, 2017, with early adoption permitted. The Company has elected to early adopt ASU 2017-01 and to apply it to any transaction, which occurred prior to the issuance date that has not been reported in financial statements that have been issued or made available for issuance.

Recently Issued Accounting Pronouncements

In May 2014, the FASB issued ASU No. 2014-09 *Revenue from Contracts with Customers* ("ASU 2014-09"), which supersedes nearly all existing revenue recognition guidance under GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five-step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing GAAP. In addition, this guidance requires new or expanded disclosures related to the judgments made by companies when following this framework and additional quantitative disclosures regarding contract balances and remaining performance obligations. ASU No. 2014-09 may be applied using either a full retrospective approach, under which all years included in the financial statements will be presented under the revised guidance, or a modified retrospective approach, under which financial statements will be prepared under the revised guidance for the year of adoption, but not for prior years. Under the latter method, entities will recognize a cumulative catch-up adjustment to the opening balance of retained earnings at the effective date for contracts that still require performance by the entity.

On July 9, 2015, the FASB voted to defer the effective date by one year to December 15, 2017 for interim and annual reporting periods beginning after that date. ASU No. 2014-09 is effective for annual reporting periods beginning after December 15, 2017, including interim periods within those annual reporting periods. The Company developed an implementation plan to adopt this new guidance, which included an assessment of the impact of the new guidance on our financial position and results of operations. The Company has completed its assessment and has determined that this standard will have no material impact on its financial position or results of operations, except enhanced disclosure regarding revenue recognition, including disclosures of revenue streams, performance obligations, variable consideration and the related judgments and estimates necessary to apply the new standard. On April 1, 2018, the Company adopted the new accounting standard ASC 606, Revenue from Contracts with Customers and for all open contracts and related amendments as of April 1, 2018 using the modified retrospective method. Results for reporting periods beginning after April 1, 2018 will be presented under ASC 606, while the comparative information will not be restated and will continue to be reported under the accounting standards in effect for those periods.

From March 2016 through December 2017, the FASB issued ASU 2016-08 *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net),* ASU 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing,* ASU 2016-11, *Revenue Recognition (Topic 605) and Derivatives and Hedging (Topic 815): Rescission of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 EITF Meeting,* ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606):Narrow-Scope Improvements and Practical Expedients* and ASU No. 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers.* These amendments are intended to improve and clarify the implementation guidance of Topic 606. The effective date and transition requirements for the amendments are the same as the effective date and transition requirements of ASU No. 2014-09 and ASU No. 2015-14.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), 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. The Company is currently evaluating the effects of ASU 2016-02 on its audited consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, Statement *of Cash Flows (Topic 230) Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"). ASU 2016-15 eliminates the diversity in practice related to the classification of certain cash receipts and payments for debt prepayment or extinguishment costs, the maturing of a zero-coupon bond, the settlement of contingent liabilities arising from a business combination, proceeds from insurance settlements, distributions from certain equity method investees and beneficial interests obtained in a financial asset securitization. ASU 2016-15 designates the appropriate cash flow classification, including requirements to allocate certain components of these cash receipts and payments among operating, investing and financing activities. The guidance is effective for fiscal years beginning after December 15, 2017. The Company is currently evaluating the effects of ASU 2016-15 on its audited consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230) Restricted Cash a consensus of the FASB Emerging Issues Task Force* ("ASU 2016-18"). ASU 2016-18 requires restricted cash and cash equivalents to be included with cash and cash equivalents on the statement cash flows. The guidance is effective for fiscal years beginning after December 15, 2017. The Company is currently evaluating the effects of ASU 2016-18 on its audited consolidated financial statements.

In January 2017, the FASB issued ASU No 2017-04 *Intangibles-Goodwill and Other (Topic 350): Simplifying the Accounting for Goodwill Impairment* ("ASU 2017-04"). ASU 2017-04 simplifies the subsequent measurement of goodwill by eliminating Step 2 from the goodwill impairment test. In computing the implied fair value of goodwill under Step 2, an entity had to perform procedures to determine the fair value at the impairment testing date of its assets and liabilities (including unrecognized assets and liabilities) following the procedure that would be required in determining the fair value of assets acquired and liabilities assumed in a business combination. Instead, under ASU 2017-04, an entity should perform its annual or interim goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. Additionally, an entity should consider income tax effects from any tax-deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss, if applicable. ASU 2017-04 is effective for annual or any interim goodwill impairment tests for fiscal years beginning after December 15, 2019 and an entity should apply the amendments of ASU 2017-04 on a prospective basis. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company is currently evaluating the effects of ASU 2017-04 on its audited consolidated financial statements.

In May 2017, the FASB issued ASU No 2017-09 *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting* ("ASU 2017-09"). ASU 2017-09 provides clarity and reduces both (i) diversity in practice and (ii) cost and complexity when applying the guidance in Topic 718, Compensation-Stock Compensation, to a change to the terms or conditions of a share-based payment award. The amendments in ASU 2017-09 provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. An entity should account for the effects of a modification unless all three of the following are met: (1) The fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the modified award is the same as the fair value (or calculated value or intrinsic value, if such an alternative measurement is used) of the original award immediately before the original award is modified. If the modification does not affect any of the inputs to the valuation technique that the entity uses to value the award, the entity is not required to estimate the value immediately before and after the modification. (2) The vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified. (3) The classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified. Note that the current disclosure requirements in Topic 718 apply regardless of whether an entity is required to apply modification accounting under the amendments in ASU 2017-09. ASU 2017-09 is effective for all annual periods, and interim periods within those annual periods, beginning after December 15, 2017, with early adoption permitted. The Company is currently evaluating the effects of ASU 2017-09 on its audited consolidated financial statements.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features; II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception.* Part I of this update 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 this update 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. The amendments in Part II of this update do not have an accounting effect. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018. The Company is currently assessing the potential impact of adopting ASU 2017-11 on its audited consolidated 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. ASSET ACQUISITION

On May 15, 2017, Elite Laboratories, Inc., a wholly-owned subsidiary of the Company entered into an asset purchase agreement with Mikah Pharma LLC ("Mikah" and/or the "Seller"), a related party, to acquire the Abbreviated New Drug Applications for Trimipramine Maleate Capsules and testing data studies, and formulations created in connection therewith including but not limited to (i) the ANDA(s) (Trimipramine Maleate Capsules, 25, 50 and 100 mg (the "Product"), (ii) any correspondence with the United States Food and Drug Administration in Seller's files with respect to the ANDA(s), (iii) the right o reference to the Drug Master Files, as set forth in the ANDA(s); (iv) the ANDA(s) Technology and Scientific Materials; (v) all rights to manufacture, sell o otherwise exploit any products resulting therefrom including all rights to revenues generated therefrom; and (vi) a royalty free limited license to use any ANDA(s) Technology and Scientific Materials which is common to the Product and any other product of Seller, but only for Buyer's use in connection with the manufacture of any product (the "Purchased Assets"). Mikah is owned by Nasrat Hakim, the CEO, President and Chairman of the Board of the Compan For consideration of the purchased assets, the Company issued a Secured Promissory Note for the principal sum of $1,200,000 (see Note 8).

The Company evaluated the acquisition of the purchased assets under ASC 805,*Business Combinations* and ASU 2017-01 and concluded that as substantially all of the fair value of the gross assets acquired is concentrated in an identifiable group of similar assets, the transaction did not meet the requirements to be accounted for as a business combination and therefore was accounted for as an asset acquisition. Accordingly, the purchase price of the purchased assets was allocated entirely to an identifiable intangible asset as follows:

ANDA acquisition costs	$ 1,200,000
Total assets acquired	$ 1,200,000

NOTE 3. INVENTORY

Inventory consisted of the following:

	March 31,	
	2018	**2017**
Finished goods	$ 229,204	$ 221,657
Work-in-progress	297,350	283,086
Raw materials	4,371,447	5,911,223
	$ 4,898,001	$ 6,415,966

NOTE 4. PROPERTY AND EQUIPMENT, NET

Property and equipment consisted of the following:

	March 31,	
	2018	**2017**
Land, building and improvements	$ 7,675,317	$ 7,308,890
Laboratory, manufacturing and warehouse equipment	9,302,277	8,764,406
Office equipment and software	308,434	276,201
Furniture and fixtures	49,804	49,804
Transportation equipment	66,855	66,855
	17,402,687	16,466,156
Less: Accumulated depreciation	(8,408,979)	(7,426,752)
	$ 8,993,708	$ 9,039,404

Depreciation expense was $982,227, $700,351and $652,284 for the years ended March 31, 2018, 2017, and 2016, respectively.

NOTE 5. INTANGIBLE ASSETS

The following tables summarize the Company's intangible assets:

	March 31, 2018				
	Estimated Useful Life	Gross Carrying Amount	Additions	Accumulated Amortization	Net Book 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

	March 31, 2017				
	Estimated Useful Life	Gross Carrying Amount	Additions	Accumulated Amortization	Net Book Value
Patent application costs	*	$ 364,482	$ 7,292	$ -	$ 371,774
ANDA acquisition costs	Indefinite	6,047,317	-	-	6,047,317
		$ 6,411,799	$ 7,292	$ -	$ 6,419,091

* 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 6. 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 audited 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:

	March 31,	
	2018	2017
Gross bonds payable		
NJEDA Bonds - Series A Notes	$ 1,760,000	$ 1,845,000
Less: Current portion of bonds payable (prior to deduction of bond offering costs)	(90,000)	(85,000)
Long-term portion of bonds payable (prior to deduction of bond offering costs)	$ 1,670,000	$ 1,760,000
Bond offering costs	$ -	$ 354,453
Less: Accumulated amortization	(178,409)	(164,231)
Bond offering costs, net	$ (178,409)	$ 190,222
Current portion of bonds payable - net of bond offering costs		
Current portions of bonds payable	$ 90,000	$ 85,000
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	$ 75,822	$ 70,822
Long term portion of bonds payable - net of bond offering costs		
Long term portion of bonds payable	$ 1,670,000	$ 1,760,000
Less: Bond offering costs to be amortized subsequent to the next 12 months	(161,866)	(176,044)
Long term portion of bonds payable, net of bond offering costs	$ 1,508,134	$ 1,583,956

Amortization expense was $14,178 for the years ended March 31, 2018, 2017, and 2016, respectively.

Maturities of bonds for the next five years are as follows:

Years ending March 31,	Amount
2019	$ 90,000
2020	95,000
2021	105,000
2022	110,000
2023	115,000
Thereafter	1,245,000
	$ 1,760,000

NOTE 7. LOANS PAYABLE

Loans payable consisted of the following:

	March 31,	
	2018	2017
Equipment and insurance financing loans payable, between 3% and 13% interest and maturing between August 2018 and January 2023	$ 1,201,861	$ 993,760
Less: Current portion of loans payable	(578,841)	(416,148)
Long-term portion of loans payable	$ 623,020	$ 577,612

The interest expense associated with the loans payable was $119,890, $87,307 and $95,822 for the years ended March 31, 2018, 2017, and 2016, respectively.

Loan principal payments for the next five years are as follows:

Years ending March 31,	Amount
2019	$ 578,840
2020	309,836
2021	151,533
2022	122,339
2023	39,313
	$ 1,201,861

NOTE 8. 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 principa 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 b 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 $105,000 for the year ended March 31, 2018.

NOTE 9. DEFERRED REVENUE

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. Deferred revenues in the aggregate amount of $3,278,890 as of March 31, 2017, were comprised of a current component of $1,013,333 and a long-term component of $2,265,557. 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 10. 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 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*").

The 135 Ludlow Ave. modified lease includes an initial term, which expires 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. Additional renovations and construction to further expand the Company's manufacturing resources are in progress.

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 years ended March 31, 2018, 2017, and 2016 was $219,636, $190,550, and $180,854, respectively. Rent expense is recorded in general and administrative expense in the audited consolidated statements of operations. Deferred rent as of March 31, 2018 and 2017 was $9,702 and $2,152, respectively, and recorded as a component of other long-term liabilities. The tables below show the future minimum rental payments, exclusive of taxes, insurance and other costs, under the Ludlow Ave. lease:

Years ending March 31,	**Amount**
2019	$ 216,321
2020	220,650
2021	225,063
2022	229,563
2023	234,156
Thereafter	920,076
	$ 2,045,829

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 March 31, 2018 and 2017, the Company had a liability of $31,443 and $29,616, respectively and recorded as a component of other long-term liabilities.

NOTE 11. MEZZANINE EQUITY

Series I convertible preferred stock

On February 6, 2014, the Company created the Series I Convertible Preferred Stock (*Series I Preferred*"). A total of 495.758 shares of Series I Preferred were authorized, 100 shares are issued and outstanding, with a stated value of $100,000 per share and a par value of $0.01 as of March 31, 2016. On August 16, 2016, the 100 shares issued and outstanding were converted into 142,857,143 shares of common stock at the stated conversion price of $0.07 (See Note 13). In conjunction with the Certificate of Designations ("*COD*"), the shares converted were retired, cancelled, and returned to the status of authorized by unissued preferred stock, leaving a total of 395.758 shares of Series I Preferred authorized and 0 shares of Series I Preferred outstanding at March 31, 2018 and 2017, respectively.

The COD for the Series I Preferred contained the following features:

- Conversion feature - the Series I Preferred Shares may be converted, at the option of the Holder, into the Company's Common Stock at a state conversion price of $0.07.

- Subsequent dilutive issuances - if the Company issues options at a price below the Conversion Price, then the Conversion Price will be reduced.

- Subsequent dividend issuances - if the Company issues Common Stock in lieu of cash in satisfaction of its dividend obligation on its Series C Certificate, the applicable Conversion Price of the Series I Preferred is adjusted.

The Company has determined that the Series I Preferred host instrument was more akin to equity than debt and that the above financial instruments were clearly and closely related to the host instrument, with bifurcation and classification as a derivative liability being not required.

Based on the Company's review of the COD, the host instrument, the Series I Preferred Shares, was classified as mezzanine equity. The above identified embedded financial instruments: Conversion Feature, Subsequent Dilutive Issuances and Subsequent Dividend Issuances will not be bifurcated from the host and are therefore classified as mezzanine equity with the Series I Preferred. The Series I Preferred was carried at the maximum redemption value with changes in this value charged to retained earnings or to additional paid-in capital in the absence of retained earnings.

Changes in carrying value are also subtracted from net income (loss), (in a manner like the treatment of dividends paid on preferred stock), in arriving at net income (loss) available to common shareholders used in the calculation of earnings per share.

Authorized, issued and outstanding shares, along with carrying value and change in value as of the periods presented are as follows:

	March 31,	
	2018	2017
Shares authorized	395.758	395.758
Shares outstanding	-	-
Par value	$ 0.01	$ 0.01
Stated value	$ 100,000	$ 100,000
Conversion price	$ 0.07	$ 0.07
Common Stock to be issued upon redemption	-	-
Closing price on valuation date	$ 0.09	$ 0.15
Carrying value of Series I convertible preferred stock	$ -	$ -

	For the Years Ended March 31,		
	2018	2017	2016
Change in carrying value of convertible preferred share mezzanine equity – Series I	$ -	$ 20,714,286	$ (9,285,715)

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 March 31, 2018.

The issued shares were pursuant to an Exchange Agreement with Nasrat Hakim, ("*Hakim*") a related party and the Company's President, Chief Executive Officer 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 consolidated balance sheet as of March 31, 2018 (See Note 12).

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 shares of Common Stock 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 fo 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 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 March 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.

Solely during any period of time during which an Authorized Share Deficiency exists commencing on or after the fourth anniversary of the Origina 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 combinatio 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 o 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 Material* 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	90.00%
Shareholder approval threshold	$ 0.1521
Probability of approval if ending stock price is greater than threshold - midpoint	82.50%
Probability of approval if ending stock price is greater than threshold - midpoint	17.50%
Trials	200,000

Authorized, issued and outstanding shares, along with carrying value and change in value as of the periods presented are as follows:

	March 31, 2018	March 31, 2017
Shares authorized	50.000	-
Shares outstanding	24.0344	-
Par value	$ 0.01	$ -
Stated value	$ 1,000,000	$ -
Conversion price	$ 0.1521	$ -
Common Stock to be issued upon conversion	158,017,321	-
Carrying value of Series J convertible preferred stock	$ 13,903,960	$ -

NOTE 12. 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 seven to ten 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:

	March 31,					
	2018		2017		2016	
	Warrant Shares	Weighted Average Exercise Price	Warrant Shares	Weighted Average Exercise Price	Warrant Shares	Weighted Average Exercise Price
Balance at beginning of year	9,379,219	$ 0.0625	41,586,066	$ 0.0625	89,870,034	$ 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	(32,206,847)	$ 0.0625	(48,283,968)	$ 0.0625
Balance at end of year	79,008,661	$ 0.1521	9,379,219	$ 0.0625	41,586,066	$ 0.0625

Please note that all of the warrants issued prior to Fiscal 2018 were fully exercised, forfeited and/or expired on or before March 31, 2018. At March 31, 2018, the remaining warrants outstanding are held by Mr. Nasrat Hakim, the Company's Chief Executive Officer in conjunction with the Exchange Agreement described below.

The fair value of the warrants issued prior to Fiscal 2018, all was calculated using the Black-Scholes model and the following assumptions:

	March 31,	
	2017	2016
Fair value of the Company's common stock	$ 0.15	$ 0.31
Volatility (based on the Company's historical volatility)	72.5% - 73.1%	52% - 81%
Exercise price	$ 0.0625	$ 0.0625
Estimated life (in years)	1.0 - 1.1	0.2 - 2.1
Risk free interest rate (based on 1-year treasury rate)	1.02% - 1.03%	0.18% - 0.73%

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 24.0344 shares of its newly designated Series 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 11). As of March 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. Please also see Note 11.

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:

	March 31, 2018	April 28, 2017
Fair value of the Company's Common Stock	$ 0.1000	$ 0.1521
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	791,516,930	923,392,780
Warrant term (in years)	9.08	10.00
Risk-free rate	2.72%	2.30%
Volatility	90.00%	90.00%
Shareholder approval threshold	$ 0.1580	$ 0.1521
Probability of approval if ending stock price is greater than threshold - midpoint	82.50%	82.50%
Probability of approval if ending stock price is greater than threshold - midpoint	17.50%	17.50%
Trials	100,000	200,000
Fair value of derivative financial instruments - warrants	$ 2,667,871	$ 6,474,674

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

Balance as of March 31, 2016	$ 10,368,567
Change in fair value of derivative financial instruments - warrants	(9,525,103)
Balance as of March 31, 2017	843,464
Fair value of warrants granted pursuant to the issuance of Series J convertible preferred shares	6,474,674
Change in fair value of derivative financial instruments - warrants	(4,650,267)
Balance as of March 31, 2018	$ 2,667,871

NOTE 13. SHAREHOLDERS' EQUITY (DEFICIT)

Lincoln Park Capital – April 10, 2014 Purchase Agreement

On April 10, 2014, the Company entered into a Purchase Agreement (the "*Lincoln Park Purchase Agreement*" and/or "*Purchase Agreement*") and a Registration Rights Agreement (the "*Registration Rights Agreement*") with Lincoln Park Capital Fund, LLC ("*Lincoln Park*"). Pursuant to the terms of the Purchase Agreement, Lincoln Park has 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 ending June 1, 2017. Pursuant to the terms of the Registration Rights Agreement, the Company filed with the SEC registration statements to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the Purchase Agreement. The latest registration statement, which updates the prior registration statements, was declared effective by the SEC on July 13, 2016.

Upon execution of the Purchase Agreement, the Company issued 1,928,641 shares of common stock to Lincoln Park pursuant to the Purchase Agreement as consideration for its commitment to purchase additional shares of common stock under that agreement and the Company is obligated to issue up to an additional 1,928,641 commitment shares to Lincoln Park pro rata as up to $40.0 million of common stock 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.

In connection with the 2017 LPC Purchase Agreement, the Company issued to Lincoln Park 5,540,551 shares of common stock and are required t 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 Purchas 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, agreemen 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 Purchas 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 Par 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 $0.15, 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 contro 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 year ended March 31, 2018, a total of 17,818,950 shares were sold to Lincoln Park pursuant to the 2017 LPC Agreement fo net proceeds totaling $1,999,878. In addition, 5,540,551 shares were issued to Lincoln Park as initial commitment shares and 277,009 shares were issued to Lincoln Park as additional commitment shares, pursuant to the 2017 LPC Agreement.

Summary of Common Stock Activity

During the years ended March 2018, 2017, and 2016 the Company issued a total of 32,612,634, 216,487,096, and 80,383,651 shares of Common Stock respectively, with such issuances of Common Stock being summarized as follows:

	Years Ended March 31,		
	2018	**2017**	**2016**
Common Stock sold pursuant to the Lincoln Park Capital Purchase Agreements, with net proceeds of such shares totaling $1,999,878, $7,593,289 and $6,199,643 for the years ended March 31, 2018, 2017 and 2016, respectively.	17,818,950	39,526,851	23,945,346
Common Stock issued as initial and additional commitment shares pursuant to the Lincoln Park Capital Purchase Agreements	5,817,560	366,118	298,923
Common Stock issued pursuant to the conversion of Series I Convertible Preferred Share derivatives, with such derivative liabilities totaling $0, $23,571,430, and $0 for the years ended March 31, 2018, 2017 and 2016, respectively, at the time of their conversion.	-	142,857,143	-
Common Stock issued in payment of Director's fees totaling $80,000, $73,361, and $100,071 for the years ended March 31, 2018, 2017 and 2016, respectively.	645,496	334,295	408,892
Common Stock issued in payment of employee salaries totaling $305,000, $822,751, and $1,039,000 for the years ended March 31, 2018, 2017 and 2016, respectively.	2,460,941	3,633,397	4,236,555
Common Stock issued in payment of consulting expenses totaling $26,000, $24,167, and $24,000 for the years ended March 31, 2018, 2017 and 2016, respectively.	211,392	106,416	97,467
Common Stock issued pursuant to the exercise of cash warrants	5,658,295	29,562,876	48,283,968
Common Stock issued pursuant to the exercise of cash options	-	100,000	112,500
Milestone Common Stock issued pursuant to EPIC Strategic Alliance Agreement totaling $0, $0, and $840,000 for the years ended March 31, 2018, 2017 and 2016, respectively.		-	3,000,000
	32,612,634	216,487,096	80,383,651
Retirement of Common Stock	(158,017,321)	-	-
Common Stock issued	802,626,761	928,031,448	711,544,352

NOTE 14. 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 o 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 years ended March 31, 2018, 2017, and 2016 the Company issued 645,496, 334,295, and 408,892 shares of its common stock, respectively totaling $80,000, $73,361, and $100,071, respectively, in connection with director compensation.

Stock-based Employee Compensation

Employment contracts with the Company's President and Chief Executive Officer, Chief Financial Officer and certain other employees include provisions for a portion of each employee's salaries 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 year ended March 31, 2018, the Company issued 2,460,941 shares of common stock to certain employees, exclusive of the Company's Chief Executive Officer, in payment of salaries in the aggregate amount of $305,000, consisting of $228,750 of related employee salaries earned during the year ended March 31, 2018 and $76,250 in related employee salaries due and owing as of March 31, 2017, the end of the immediately prior fiscal year. An additional 4,329,135 shares of Common Stock are due and owing to the Company's Chief Executive Officer for salaries totaling $500,000 earned during the year ende March 31, 2018. Issuance of these shares of Common Stock have been deferred to an undetermined date.

As of March 31, 2018, the Company owes its President and Chief Executive Officer, Chief Financial Officer and certain other employees, a total o approximately 5.9 million shares of Common Stock in payment of salaries and fees totaling 1.3 million due and owing, inclusive of salaries earned by the Company's Chief Executive Officer, as described in the paragraph above. The Company anticipates that these shares of common stock will be issued during the fiscal year ended March 31, 2019.

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, 2015	7,642,167	$ 0.48	7.4	$ 635,996
Granted	360,000	0.38		
Forfeited and expired	(280,000)	0.60		
Exercised	(112,500)	0.21		
Outstanding at March 31, 2016	7,609,667	$ 0.48	6.5	$ 904,409
Granted	1,350,000	0.20		
Forfeited and expired	(2,122,000)	1.18		
Exercised	(100,000)	0.09		
Outstanding at March 31, 2017	6,737,667	$ 0.20	6.7	$ 258,747
Granted	640,000	0.16		
Forfeited and expired	-	-		
Exercised	(759,667)	0.56		
Outstanding at March 31, 2018	6,618,000	$ 0.16	6.1	$ 90,390
Exercisable at March 31, 2018	5,418,000	$ 0.15	5.6	$ 90,000

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 March 31, 2018, 2017, and 2016 was $0.10, $0.15, and $0.31, respectively.

The fair value of the options was calculated using the Black-Scholes model and the following assumptions:

	March 31,		
	2018	2017	2016
Volatility (based on the Company's historical volatility)	121% - 123%	120% - 121%	119% - 120%
Exercise price	$ 0.09 - 0.24	$ 0.13 - 0.33	$ 0.23 - 0.42
Estimated term (in years)	10	10	10
Risk free interest rate (based on 1-year treasury rate)	2.2% - 2.4%	1.5% - 2.5%	2.1% - 2.2%
Forfeiture rate	0.0% - 20.1%	2.3% - 4.6%	2.7%
Fair value of options granted	$ 79,215	$ 373,055	$ 129,913
Non-cash compensation through issuance of stock options	$ 244,753	$ 357,955	$ 333,362

NOTE 15. SALE OF NEW JERSEY STATE NET OPERATING LOSSES

During the year ended March 31, 2018, Elite Labs, a wholly owned subsidiary of Elite, received final approval from the New Jersey Economi Development Authority for the sale of net tax benefits of $439,313 relating to New Jersey net operating losses and net tax benefits of $606,516 relating to R&D tax credits. The Company sold the net tax benefits approved for sale at a transfer price equal to ninety-two cents for every benefit dollar for tota proceeds of $1,045,829.

NOTE 16. CONCENTRATIONS AND CREDIT RISK

Revenues

Four customers accounted for substantially all the Company's revenues for the year ended March 31, 2018. These four customers accounted for approximately 52%, 24%, 15% and 8% of revenues each, respectively.

Three customers accounted for substantially all the Company's revenues for the year ended March 31, 2017. These three customers accounted for approximately 46%, 29% and 19% of revenues each, respectively.

Three customers accounted for substantially all the Company's revenues for the year ended March 31, 2016. These three customers accounted for approximately 36%, 30% and 27% of revenues each, respectively.

Accounts Receivable

Four customers accounted for substantially all the Company's accounts receivable as of March 31, 2018. These four customers accounted for approximately 52%, 14%, 12%, and 11% of accounts receivable as of March 31, 2018.

Four customers accounted for substantially all the Company's accounts receivable as of March 31, 2017. These four customers accounted for approximately 53%, 17%, 14%, and 12% of accounts receivable as of March 31, 2017

Three customers accounted for substantially all the Company's accounts receivable as of March 31, 2016. These three customers accounted for approximately 54%, 30% and 8% of accounts receivable as of March 31, 2016.

Purchasing

Three suppliers accounted for more than 60% of the Company's purchases of raw materials for year ended March 31, 2018. These three suppliers accounted for approximately 29%, 27% and 5% of purchases each, respectively.

Three suppliers accounted for more than 65% of the Company's purchases of raw materials for year ended March 31, 2017. These three suppliers accounted for approximately 51%, 9% and 8% of purchases each, respectively.

For the year ended March 31, 2016, the same three suppliers accounted for more than 70% of the Company's purchases. These three suppliers accounted for approximately 42%, 23% and 10% of purchases each, respectively.

NOTE 17. SEGMENT RESULTS

FASB ASC 280-10-50 requires use of the "management approach" model for segment reporting. The management approach is based on the way a company's management organized segments within the company for making operating decisions and assessing performance. Reportable segments are based on products and services, geography, legal structure, management structure, or any other manner in which management disaggregates a company.

The Company has determined that its reportable segments are Abbreviated New Drug Applications ("ANDA") for generic products and New Dru Applications ("NDA") for branded products. The Company identified its reporting segments based on the marketing authorization relating to each and the financial information used by its chief operating decision maker to make decisions regarding the allocation of resources to and the financial performance of the reporting segments.

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 audited consolidated financial statements.

The following represents selected information for the Company's reportable segments:

	Years Ended March 31,		
	2018	2017	2016
Revenue by Segment			
ANDA	$ 6,458,711	$ 8,637,715	$ 9,164,999
NDA	1,000,000	1,000,000	3,333,333
	$ 7,458,711	$ 9,637,715	$ 12,498,332

	Years Ended March 31,		
	2018	2017	2016
Operating Income (Loss) by Segment			
ANDA	$ (1,827,943)	$ (522,160)	$ 4,940,515
NDA	(3,019,859)	(3,415,246)	(9,305,998)
	$ (4,847,802)	$ (3,937,406)	$ (4,365,483)

The table below reconciles the Company's operating income (loss) by segment to income from operations before provision for income taxes as reported in the Company's audited consolidated statements of operations.

	Years Ended March 31,		
	2018	2017	2016
Operating loss by segment	$ (4,847,802)	$ (3,937,406)	$ (4,365,483)
Corporate unallocated costs	(2,234,264)	(1,917,437)	(1,772,237)
Interest income	17,510	12,620	-
Interest expense and amortization of debt issuance costs	(335,498)	(238,223)	(280,670)
Depreciation and amortization expense	(800,460)	(352,369)	(665,647)
Significant non-cash items	(1,168,753)	(1,148,721)	(1,513,433)
Change in fair value of derivative instruments	4,650,266	9,525,103	7,394,006
Income (loss) from operations before the benefit from sale of state net operating loss credits	$ (4,719,001)	$ 1,943,567	$ (1,203,464)

NOTE 18. COLLABORATIVE AGREEMENT WITH EPIC PHARMA LLC

On June 4, 2015, the Company entered into the 2015 Epic License Agreement, which provides for the exclusive right to market, sell and distribute, by Epic Pharma LLC (*"Epic"*) of SequestOx™, an abuse deterrent opioid which employs the Company's proprietary pharmacological abuse-deterrent technology. Epic will be responsible for payment of product development and pharmacovigilance costs, sales, and marketing of SequestOx™, and Elite will be responsible for the manufacture of the product. Under the 2015 Epic License Agreement, Epic will pay Elite non-refundable payments totaling $15 million, with such amount representing the cost of an exclusive license to ELI-200, the cost of developing the product and certain filings and a royalty based on an amount equal to 50% of profits derived from net product sales as defined in the 2015 Epic License Agreement. The initial term of the exclusive right to product development sales and distribution is five years ("*Epic Exclusivity Period*"); the license is renewable upon mutual agreement at the end of the initial term.

In June 2015, Elite received non-refundable payments totaling $5.0 million from Epic for the exclusive right to product development sales and distribution of SequestOx™ pursuant to the Epic Collaborative Agreement, under which it agreed to not permit marketing or selling of SequestOx™ within the United States of America to any other party. Such exclusive rights are considered a significant deliverable element of the Epic Collaborative Agreement pursuant to ASC 605-25,*Revenue Recognition – Multiple Element Arrangements* These nonrefundable payments represent consideration for certain exclusive rights to ELI-200 and will be recognized ratably over the Epic Exclusivity Period.

In addition, in January 2016, a New Drug Application for SequestOx™ was filed, thereby earning the Company a non-refundable $2.5 million milestone, pursuant to the 2015 Epic License Agreement. The filing of this NDA represents a significant deliverable element as defined within the Epic Collaborative pursuant to ASC 605-25,*Revenue Recognition – Multiple Element Arrangements* Accordingly, the Company has recognized the $2.5 million milestone, which was paid by Epic and related to this deliverable as income during the year ended March 31, 2016.

To date, the Company received payments totaling $7.5 million pursuant to the 2015 Epic License Agreement, with all amounts being non-refundable. An additional $7.5 million is due upon approval by the FDA of the NDA filed for SequestOx™, and license fees based on commercial sales of SequestOx™ Revenues relating to these additional amounts due under the 2015 Epic License Agreement will be recognized as the defined elements are completed and collectability is reasonably assured.

Please note that on July 15, 2016, the FDA issued a Complete Response Letter, or CRL, regarding the NDA. The CRL stated that the review cyc for the SequestOx™ NDA is complete and the application is not ready for approval in its present form. Based on subsequent meetings and communications with the FDA, the Company believes that there is a clear path forward to address the issues cited in the CRL. The Company believes that the meeting minutes received from the FDA on January 23, 2017, supported a plan to address the issues cited by the FDA in the CRL by modifying the SequestOx™ formulation Such plan includes, without limitation, conducting bioequivalence and bioavailability fed and fasted studies, comparing the modified formulation to the original formulation. the Company modified the SequestOx™ formulation and, on January 30, 2018 reported positive topline results from a pilot study indicating the likelihood of achieving the required bioequivalence in a pivotal trial under fed conditions. The Company is reviewing these results with the FDA and discussing pharmacokinetic study requirements for a re-submission of the NDA.

The 2015 Epic License Agreement expires on June 4, 2020, and Epic has previously advised the Company of their desire to extend this agreement While discussions are ongoing, they are directly correlated to the regulatory status of SequestOx™. Furthermore, there can be no assurances that the parties will reach mutual agreement to extend the term of this agreement and no assurances that the terms and conditions of the agreement will be similar in all material aspects in the event that the agreement is extended by mutual consent of the parties. Non-receipt by the Company of the remaining $7.5 million milestone will have a material adverse effect on the Company's financial condition.

NOTE 19. COLLABORATIVE AGREEMENT WITH SUNGEN PHARMA LLC

On August 24, 2016, the Company entered into the SunGen Agreement. The SunGen Agreement provides that Elite and SunGen Pharma LLC v engage in the research, development, sales, and marketing of four generic pharmaceutical products. Two of the products are classified as CNS stimulants (the "*CNS Products*") and two of the products are classified as beta blockers (the "Beta Blocker Products").

Under the terms of the SunGen Agreement, Elite and SunGen will share in the responsibilities and costs in the development of these products and wi share in the profits from sales of the Products. Upon approval, the know-how and intellectual property rights to the products will be owned jointly by Elite and SunGen. SunGen shall have the exclusive right to market and sell the Beta Blocker Products using SunGen's label and Elite shall have the exclusive right t market and sell the CNS Products using Elite's label. Elite will manufacture and package all four products on a cost-plus basis.

On December 1, 2016 and July 24, 2017, Elite Labs and SunGen executed an amendment to the parties' 2016 Development and License Agreemer (the "*Amended Agreement*"), to undertake and engage in the research, development, sales and marketing of four additional generic pharmaceutical products bringing the total number of products under the amended agreement to eight. The product classes for the additional four products include antidepressants, antibiotics, and antispasmodics.

Under the terms of the Amended Agreement, Elite and SunGen will share in the responsibilities and costs in the development of these products and will share substantially in the profits from sales of the products. Upon approval, the know-how and intellectual property rights to the products will be owned jointly by Elite and SunGen. Three products will be owned jointly by Elite and SunGen; three shall be owned by SunGen while Elite shall have the marketin rights once the products are approved by the FDA; and two shall be owned by Elite while SunGen shall have the marketing rights once the products ar approved by the FDA. Elite will manufacture and package all eight products on a cost-plus basis.

On February 8, 2018, the Company filed an ANDA with the FDA for a generic version of an immediate release central nervous system (*CNS*") stimulant. The ANDA represents the first filing for a product co-developed with SunGen under the SunGen Agreement.

On May 24, 2018, the Company filed an ANDA with the FDA for a generic version of an extended release CNS stimulant. The ANDA represer the second filing for a product co-developed with SunGen under the SunGen Agreement.

There can be no assurances that any of these products, including the two products for which ANDAs have already been filed, will receive marketing authorization and achieve commercialization within a reasonable time period, or at all. In addition, even if marketing authorization is received, there can be no assurances that there will be future revenues of profits, or that any such future revenues or profits would be in amounts that provide adequate return on the significant investments made to secure these marketing authorizations.

NOTE 20. RELATED PARTY TRANSACTION AGREEMENTS WITH EPIC PHARMA LLC

The Company has entered into two agreements with Epic which constitute agreements with a related party due to the management of Epic including a member on our Board of Directors at the time such agreements were executed.

On June 4, 2015, the Company entered into the 2015 Epic License Agreement (please see Note 18 above). The 2015 Epic License Agreemer includes milestone payments totaling $10 million upon the filing with and approval of a New Drug Application ("NDA") with the FDA. The Company ha determined these milestones to be substantive, with such assessment being made at the inception of the 2015 Epic License Agreement, and based on the following:

- The Company's performance is required to achieve each milestone; and
- The milestones will relate to past performance, when achieved; and
- The milestones are reasonable relative to all of the deliverables and payment terms within the 2015 Epic License Agreement

After marketing authorization is received from the FDA, Elite will receive a license fee which is based on profits achieved from the commercial sale of ELI-200. On January 14, 2016, the Company filed an NDA with the FDA for SequestOx™, thereby earning a $2.5 million milestone pursuant to the 20 Epic License Agreement. The Company has received payment of this amount from Epic. An additional milestone payment of $7.5 million is due upon the FDA's approval of the SequestOx™ NDA. However, as described in Note 18 to these financial statements, collection of this milestone payment is unlikel without the parties to this agreement mutually agreeing to extend the existing term of the 2015 Epic License Agreement. There can be no assurances that the parties will reach mutual agreement to extend the term of this agreement and no assurances that the terms and conditions of the agreement will be similar in all material aspects in the event that the agreement is extended by mutual agreement of the parties. If the Company does not receive the milestone payment or license fees, it will materially and adversely affect our financial condition. In addition, even if marketing authorization is received, there can be no assurances that there will be future revenues of profits, or that any such future revenues or profits would be in amounts that provide adequate return on the significant investments made to secure this marketing authorization.

On October 2, 2013, Elite executed the Epic Pharma Manufacturing and License Agreement (the "*Epic Generic Agreement*"), which granted rights to Epic to manufacture twelve generic products whose ANDA's are owned by Elite, and to market, in the United States and Puerto Rico, six of these product on an exclusive basis, and the remaining six products on a non-exclusive basis. These products will be manufactured at Epic, with Epic being responsible for the manufacturing site transfer supplements that are a prerequisite to each product being approved for commercial sale. In addition, Epic is responsible for al regulatory and pharmacovigilance matters, as well as all marketing and distribution activities. Elite has no further obligations or deliverables under the Epic Generic Agreement.

Pursuant to the Epic Generic Agreement, Elite will receive $1.8 million, payable in increments that require the commercialization of all six exclusive products if the full amount is to be received, plus license fees equal to a percentage that is not less than 50% and not greater than 60% of profits achieved from commercial sales of the products, as defined in the Epic Generic Agreement. While Epic has launched four of the six exclusive products and Elite has collected $1.0 million of the $1.8 million total fee, collection of the remaining $800,000 is contingent upon Epic filing the required supplements with and receiving approval from the FDA for the remaining exclusive generic products. As the Epic Generic Agreement expires on October 2, 2018, it is unlikely that Epic will secure the required FDA approvals related to their payment to Elite of the remaining $800,000 milestones.

Both the 2015 Epic License Agreement and the Epic Generic Agreement contain license fees that will be earned and payable to the Company, after the FDA has issued marketing authorization(s) for the related product(s). License fees are based on commercial sales of the products achieved by Epic and calculated as a percentage of net sales dollars realized from such commercial sales. Net sales dollars consist of gross invoiced sales less those costs and deductions directly attributable to each invoiced sale, including, without limitation, cost of goods sold, cash discounts, Medicaid rebates, state program rebates, price adjustments, returns, short date adjustments, charge backs, promotions, and marketing costs. The rate applied to the net sales dollars to determine license fees due to the Company is equal to an amount negotiated and agreed to by the parties to each agreement, with the following significant factors, inputs, assumptions, and methods, without limitation, being considered by either or both parties:

- Assessment of the opportunity for each product in the market, including consideration of the following, without limitation: market size, number of competitors, the current and estimated future regulatory, legislative, and social environment for abuse deterrent opioids and the other generic products to which the underlying contracts are relevant;
- Assessment of various avenues for monetizing SequestOx™ and the twelve ANDA's owned by the Company, including the various combinations of sites of manufacture and marketing options;
- Elite's resources and capabilities with regards to the concurrent development of abuse deterrent opioids and expansion of its generic business segment, including financial and operational resources required to achieve manufacturing site transfers for twelve approved ANDA's;
- Capabilities of each party with regards to various factors, including, one or more of the following: manufacturing, marketing, regulatory and financial resources, distribution capabilities, ownership structure, personnel, assessments of operational efficiencies and entity stability, company culture and image;

- Stage of development of SequestOx™ and manufacturing site transfer and regulatory requirements relating to the commercialization of the generic products at the time of the discussions/negotiations, and an assessment of the risks, probability, and time frames for achieving marketing authorizations from the FDA for each product.

- Assessment of consideration offered; and

- Comparison of the above factors among the various entities with whom the Company was engaged in discussions relating to the commercialization of SequestOx™ and the manufacture/marketing of the twelve generics related to the Epic Generic Agreement.

This transaction is not to be considered as an arms-length transaction.

Please also note that, effective April 7, 2016, all Directors on the Company's Board of Directors that were also owners/managers of Epic had resigned as Directors of the Company and all current members of the Company's Board of Directors have no relationship to Epic. Accordingly, Epic no longer qualifies as a party that is related to the Company.

NOTE 21. MANUFACTURING, LICENSE AND DEVELOPMENT AGREEMENTS

The Company has entered into the following active agreements:

- License agreement with Precision Dose, dated September 10, 2010 (the "Precision Dose License Agreement"); and,
- Manufacturing and Supply Agreement with Ascend Laboratories Inc., dated June 23, 2011 and as amended on September 24, 2012, January 19, 2015 and July 20, 2015, and as extended on August 9, 2016 (the "Ascend Manufacturing Agreement"); and,
- Development and License Agreement with SunGen (the "July 2017 SunGen Agreement").

The Precision Dose Agreement provides for the marketing and distribution, by Precision Dose and its wholly owned subsidiary, TAGI Pharma, of Phentermine 37.5mg tablets (launched in April 2011), Phentermine 15mg capsules (launched in April 2013), Phentermine 30mg capsules (launched in April 2013), Hydromorphone 8mg tablets (launched in March 2012), Naltrexone 50mg tablets (launched in September 2013) and certain additional products that require approval from the FDA which has not been received. Precision Dose will have the exclusive right to market these products in the United States and Puerto Rico and a non-exclusive right to market the products in Canada. Pursuant to the Precision Dose License Agreement, Elite received $200k at signing and is receiving milestone payments and a license fee which is based on profits achieved from the commercial sale of the products included in the agreement.

Revenue from the $200k payment made upon signing of the Precision Dose Agreement is being recognized over the life of the Precision Dose Agreement.

The milestones, totaling $500k (with $405k already received), consist of amounts due upon the first shipment of each identified product, as follows: Phentermine 37.5mg tablets ($145k), Phentermine 15 & 30mg capsules ($45k), Hydromorphone 8mg ($125k), Naltrexone 50mg ($95k) and the balance of $95k due in relation to the first shipment of generic products which still require marketing authorizations from the FDA, and to which there can be no assurances of such marketing authorizations being granted and accordingly there can be no assurances that the Company will earn and receive these milestone amounts. These milestones have been determined to be substantive, with such determination being made by the Company after assessments based on the following:

- The Company's performance is required to achieve each milestone; and
- The milestones will relate to past performance, when achieved; and
- The milestones are reasonable relative to all of the deliverables and payment terms within the Precision Dose License Agreement.

The license fees provided for in the Precision Dose Agreement are calculated as a percentage of net sales dollars realized from commercial sales of the related products. Net sales dollars consist of gross invoiced sales less those costs and deductions directly attributable to each invoiced sale, including, without limitation, cost of goods sold, cash discounts, Medicaid rebates, state program rebates, price adjustments, returns, short date adjustments, charge backs, promotions, and marketing costs. The rate applied to the net sales dollars to determine license fees due to the Company is equal to an amount negotiated and agreed to by the parties to the Precision Dose License Agreement, with the following significant factors, inputs, assumptions, and methods, without limitation being considered by either or both parties:

- Assessment of the opportunity for each generic product in the market, including consideration of the following, without limitation: market size, number of competitors, the current and estimated future regulatory, legislative, and social environment for each generic product, and the maturity of the market;
- Assessment of various avenues for monetizing the generic products, including the various combinations of sites of manufacture and marketing options;
- Capabilities of each party with regards to various factors, including, one or more of the following: manufacturing resources, marketing resources, financial resources, distribution capabilities, ownership structure, personnel, assessment of operational efficiencies and stability, company culture and image;
- Stage of development of each generic product, all of which did not have FDA approval at the time of the discussions/negotiations and an assessment of the risks, probability, and time frame for achieving marketing authorizations from the FDA for the products;

- Assessment of consideration offered by Precision and other entities with whom discussions were conducted; and,
- Comparison of the above factors among the various entities with whom the Company was engaged in discussions relating to the commercialization of the generic products.

The Ascend Manufacturing Agreement provides for the manufacturing by Elite of Methadone 10mg for supply to Ascend Laboratories LLC ("Ascend"). Ascend is the owner of the approved ANDA for Methadone 10mg, and the Northvale Facility is an approved manufacturing site for this ANDA. There are no license fees or milestones relating to this agreement. All revenues earned are recognized as manufacturing revenues on the date of shipment of the product, when title for the goods is transferred, and for which the price is agreed to and it has been determined that collectability is reasonably assured. The initial shipment of Methadone 10mg pursuant to the Ascend Manufacturing Agreement occurred in January 2012 and expires on December 31, 2017. The Company is evaluating extension of this agreement and there have not been any formal negotiations of such with Ascend to date.

The Development and License Agreement with SunGen is to collaborate, develop and commercialize generic pharmaceutical products based upon a unique drug delivery platform used for extended release products. The Company and SunGen intend to begin with the development of five generic extended release products and to develop additional such products subsequently. More than a dozen products utilize this type of technology. This new co-development agreement will build upon the success of the first development agreement between the Company and SunGen and signed in 2016.

Under the terms of the July 2017 SunGen Agreement, the Company and SunGen will share the responsibilities and costs of the development and marketing of the products. Upon FDA approval, the products will be owned jointly by Elite and SunGen. Elite will manufacture and package all products on a cost-plus basis.

NOTE 22. RELATED PARTY AGREEMENTS WITH MIKAH PHARMA LLC

Pursuant to the asset acquisition as discussed in Note 2, on May 17, 2017, Elite Labs, executed an assignment agreement with Mikah, pursuant to which the Company acquired all rights, interests, and obligations under a supply and distribution agreement (the "Distribution Agreement") with Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's") originally entered into by Mikah on May 7, 2017 and relating to the supply, sale and distribution of generic Trimipramine Maleate Capsules 25mg, 50mg and 100mg ("Trimipramine").

On May 22, 2017, the Company executed an assignment agreement with Mikah, pursuant to which the Company acquired all rights, interests and obligations under a manufacturing and supply agreement with Epic Pharma LLC ("Epic") originally entered into by Mikah on June 30, 2015 and relating to the manufacture and supply of Trimipramine (the "Manufacturing Agreement").

Mikah is owned by Nasrat Hakim, the Chief Executive Officer, President and Chairman of the Board of the Company.

Under the Manufacturing Agreement, Epic will manufacture Trimipramine under license from the Company pursuant to the FDA approved and currently marketed ANDA that was acquired in conjunction with the Company's entry into these agreements (see Note 2).

Under the Distribution Agreement, the Company will supply Trimipramine on an exclusive basis to Dr. Reddy's and Dr. Reddy's will be responsible for all marketing and distribution of Trimipramine in the United States, its territories, possessions and commonwealth. The Trimipramine will be manufactured by Epic and transferred to Dr. Reddy's at cost, without markup.

Dr. Reddy's will pay to the Company a share of the profits, calculated without any deduction for cost of sales and marketing, derived from the sale of Trimipramine. The Company's share of these profits is in excess of 50%.

NOTE 23. INCOME TAXES

The components of the credit for income taxes are as follows:

	Years Ended March 31,		
	2018	2017	2016
Federal			
Current	$ -	$ -	$ -
Deferred	-	-	-
State			
Current	(5,500)	(2,500)	(4,048)
Deferred	-	-	-
Benefit from sale of state net operating loss credits	1,051,329	1,870,114	524,500
Net benefit from sale of state net operating loss credits	$ 1,045,829	$ 1,867,614	$ 520,452

The major components of deferred tax assets and liabilities at March 31, 2018, 2017, and 2016 are as follows (amounts in thousands of dollars):

	Years Ended March 31,		
	2018	2017	2016
Federal			
Net operating loss carry forward	$ 19,213	$ 29,915	$ 27,033
Valuation allowance	(19,213)	(29,915)	(27,033)
	$ -	$ -	$ -
State			
Net operating loss carry forward	$ 1,796	$ 1,930	$ 2,722
Valuation allowance	(1,796)	(1,930)	(2,722)
	$ -	**$ -**	**$ -**

At March 31, 2018, 2017, and 2016 a 100% valuation allowance is provided, as it is uncertain if the deferred tax assets will provide any future benefits because of the uncertainty about the Company's ability to generate the future taxable income necessary to use the net operating loss carryforwards.

The company believes that temporary timing differences between accrual and payment of income taxes are not material to the financial position of the Company.

As of March 31, 2018, Elite has a federal net operating loss carryforward of $92,516,164 and net operating loss carryforward in state tax jurisdictions of $20,991,389, some of which will begin to expire in 2019.

NOTE 24. QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

The Company's consolidated results of operations are shown below:

(In thousands, except per share data)	**Fourth Quarter**	**Third Quarter**	**Second Quarter**	**First Quarter**
Fiscal year ended March 31, 2018				
Total revenues	$ 1,597	$ 2,535	$ 1,624	$ 1,703
Costs of revenues	461	1,420	615	1,015
Gross profit	1,136	1,115	1,009	688
Operating expenses	3,759	3,175	3,139	2,926
Loss from operations	(2,623)	(2,060)	(2,130)	(2,238)
Other income (expense)	(203)	517	3,945	73
Income tax (credit) expense	3	-	-	(3)
Net (loss) income	(2,829)	(490)	1,815	(2,169)
Change in carrying value of convertible preferred mezzanine equity	-	-	-	-
Benefit from sale of state net operating loss credits	(5)	1,051	-	-
Net (loss) income attributable to common shareholders	(2,830)	(490)	1,815	(2,168)
Earnings per share – Basic	$ (0.00)	$ (0.00)	$ 0.00	$ (0.00)
Earnings per share – Diluted	$ (0.00)	$ (0.00)	$ 0.00	$ (0.00)

(In thousands, except per share data)	**Fourth Quarter**	**Third Quarter**	**Second Quarter**	**First Quarter**
Fiscal year ended March 31, 2017				
Total revenues	$ 1,350	$ 2,331	$ 2,686	$ 3,271
Costs of revenues	172	1,727	1,851	2,148
Gross profit	1,178	604	835	1,123
Operating expenses	4,368	2,326	2,040	2,361
Loss from operations	(3,190)	(1,722)	(1,205)	(1,238)
Other income (expense)	4	1,519	5,443	2,334
Income tax (credit) expense	-	1,870	-	(3)
Net (loss) income	(3,186)	1,667	4,238	1,099
Change in carrying value of convertible preferred mezzanine equity	-	-	22,857	(2,143)
Net (loss) income attributable to common shareholders	(3,186)	1,667	27,095	(1,044)
Earnings per share – Basic	$ 0.03	$ 0.00	$ 0.03	$ (0.00)
Earnings per share – Diluted	$ (0.01)	$ 0.00	$ (0.00)	$ (0.00)

(In thousands, except per share data)	Fourth Quarter	Third Quarter	Second Quarter	First Quarter
Fiscal year ended March 31, 2016				
Total revenues	$ 5,195	$ 2,194	$ 2,947	$ 2,163
Costs of revenues	1,036	836	1,415	1,197
Gross profit	4,159	1,358	1,532	966
Operating expenses	3,588	4,071	5,299	3,373
Income (loss) from operations	571	(2,713)	(3,767)	(2,407)
Other income (expense)	7,408	(9,520)	2,086	7,139
Income tax credit	(520)	-	-	-
Net income (loss)	8,499	(12,233)	(1,681)	4,732
Change in carrying value of convertible preferred mezzanine equity	14,142	(24,786)	(5,071)	6,429
Net income (loss) attributable to common shareholders	22,641	(37,019)	(6,753)	11,161
Earnings per share – Basic	$ 0.03	$ (0.05)	$ (0.01)	$ 0.02
Earnings per share – Diluted	$ 0.00	$ (0.05)	$ (0.01)	$ (0.00)

NOTE 25. SUBSEQUENT EVENTS

The Company has evaluated subsequent events from the balance sheet date through June 7, 2018. The following are material subsequent events:

Common Stock issued and sold pursuant to the Lincoln Park Purchase Agreement

Subsequent to March 31, 2018 and up to June 7, 2018 (the latest practicable date), a total of 1,011,856 shares of Common Stock were issued to Lincoln Park, with such shares consisting of 1,000,000 purchase shares and 11,856 additional commitment shares. Total proceeds from these transactions was $85,600.

Strategic Marketing Alliance with Glenmark Pharmaceuticals Inc. USA ("Glenmark")

On May 29, 2018 the Company signed a license, manufacturing and supply agreement with Glenmark (the "Glenmark Strategic Alliance") to market two of Elite's generic products in the United States, with an option to add products in the future. Through the Glenmark Strategic Alliance, Glenmark will sell and distribute the products and Elite will receive from Glenmark, manufacturing and license fees. Glenmark will have semi-exclusive marketing rights to the ANDA approved product, phendimetrazine 35mg tablets and exclusive marketing rights to an undisclosed pain product currently under review by the FDA with an expected approval date in the third quarter of this year. Collectively, the brand products and their generic equivalents had total annual sales of approximately $33.6 million in 2017, according to QuintilesIMS Health Data.

Filing of ANDA for Extended Release CNS Stimulant

On May 30, 2018, the Company filed an Abbreviated New Drug Application ("ANDA") with the US Food and Drug Administration ("FDA") for a generic version of an extended-release Central Nervous System ("CNS") stimulant. The ANDA represents the filing of a second product co-developed with SunGen Pharma LLC ("SunGen"). According to QuntilesIMS Health data, the branded product for the extended release CNS simulant and its generic equivalents had total U.S. sales of approximately $1.6 billion for the twelve months ended September 30, 2017.

Exhibit 10.60

LICENSE, SUPPLY AND DISTRIBUTION AGREEMENT

ELITE PHARMACEUTICALS, INC.,

ELITE LABORATORIES, INC.,

- and -

GLENMARK PHARMACEUTICALS INC., USA

Dated as of May 22, 2018

THIS LICENSE, SUPPLY AND DISTRIBUTION AGREEMENT made as of May 22, 2018 (the "**Effective Date**"), by and between ELITE PHARMACEUTICALS, INC. and ELITE LABORATORIES, INC., Nevada corporations located at 165 Ludlow Avenue, Northvale, New Jersey (collectively, "**ELITE**"), and GLENMARK PHARMACEUTICALS INC., USA, a Delaware corporation located at 750 Corporate Drive, Mahwah, Jersey 07430 ("**GLENMARK**").

WHEREAS:

A. ELITE has ownership rights to products and/or ANDAs specified on Schedule A (the "Products"), and GLENMARK wishes to license from ELI the semi-exclusive and/or exclusive rights, as the case may be, to market and sell the Products on the terms and conditions set forth in this Agreement.

B. ELITE has significant experience in developing, manufacturing and marketing finished dosage forms of pharmaceutical products, including the Products;

C. GLENMARK has significant experience in marketing pharmaceutical products; and

D. Subject to the terms and conditions of this Agreement, GLENMARK desires to engage ELITE on an exclusive basis to manufacture, supply, packa and label the Products and ELITE agrees to grant GLENMARK the right under this Agreement to commercialize the Products in the Territory or semi-exclusive and/or exclusive basis.

NOW, THEREFORE in consideration of the mutual covenants and obligations contained herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereto agree as follows:

ARTICLE 1 - DEFINITIONS

1.1 In addition to terms defined elsewhere in this Agreement, the terms set forth below shall be defined in this Agreement (including the recitals) as follows:

(a) "**Affiliate**" with respect to either Party means any Person who directly or indirectly through one or more intermediaries controls, is controlled by, or is under common control with such Party. The term "control" means the beneficial (direct or indirect) ownership of more than fifty-percent (50%) of the voting or equity interests of such Person or the power or right to direct the management and affairs of its business, whether through the ownership of voting securities, by contract, or otherwise.

(b) "**Agreement**" means this License, Supply and Distribution Agreement, together with all schedules hereto.

(c) "**ANDA**" means an Abbreviated New Drug Application pursuant to Section 505(j) of the FDCA.

(d) "**Bankruptcy Code**" has the meaning given in **Article 13.16**.

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

(e) "**Business Day**" in relation to each Party means any day other than a Saturday, a Sunday, or any statutory or public holiday on which banks are generally closed for regular business in New York, New York.

(f) "**Certificate of Analysis**" means a certificate of analysis that certifies that a given batch of Product meets the release Manufacturing Requirements.

(g) "**Claim**" means any claim, action, cause of action, or demand.

(h) "**Commercially Reasonable Efforts**" with respect to any activity means the efforts and resources that would be used in the performance of the relevant activity in compliance with Law by a Person (engaged in the manufacture and supply or distribution, sale and commercialization of pharmaceutical products, as applicable) of comparable size and resources as the applicable Party with regard to a product at a similar stage in its product life taking into account the following factors to the extent reasonable and relevant: issues of safety and efficacy, product profile, market potential, competitive market conditions, duration of exclusivity or other proprietary position of the product and the potential profitability and economic return of the product, all as measured by the facts and circumstances at the time such efforts are due.

(i) "**Confidential Information**" has the meaning given in **Article 12.2**.

(j) "**DEA**" shall mean the United States Drug Enforcement Administration or any successor entity.

(k) "**Debarred Entity**" has the meaning given in **Article 9.2(c).**

(l) "**Debarred Individual**" has the meaning given in **Article 9.2(c).**

(m) **"Distribution Fees"** means {***} percent ({***}%) of Net Sales for each Product that is DEA schedule II and {***} percent ({***}%) of Net Sales for all other Products.

(n) "**Effective Date**" has the meaning given in the preamble.

(o) "**Facility**" means the ELITE FDA-approved manufacturing site located at Ludlow Avenue, Northvale, New Jersey 07647.

(p) "**FDA**" means the United States Food and Drug Administration or any successor government agency.

(q) "**FDCA**" means the Federal Food, Drug, and Cosmetic Act.

(r) "**Force Majeure Event**" has the meaning given in **Article 13.5**.

(s) "**ELITE**" has the meaning given in the preamble.

(t) "**GLENMARK**" has the meaning given in the preamble.

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

(u) "**GMP**" means current good manufacturing practices for the manufacture of finished pharmaceutical products in effect within the Territory from time to time during the Term of this Agreement, which set minimum standards to ensure that pharmaceutical products meet established requirements for identity, strength, quality and purity, as established under the Laws of the Territory, including 21 C.F.R. Parts 210 and 211.

(v) "**Gross Profit**" means the Net Sales of a Product each calendar quarter less Transfer Price of Product, Distribution Fees and shipping cost from the Facility.

(w) **"Gross Sales"** means the gross amount invoiced by GLENMARK or its Affiliates or sublicensees for sales of the Product to Third Parti in the Territory.

(x) "**Indemnitee**" has the meaning given in **Article 11.3**.

(y) "**Indemnitor**" has the meaning given in **Article 11.3**.

(z) "**Intellectual Property Rights**" means any patent, trademark, copyright, trade secret, right in unpatented know-how, right of confidence and any other intellectual or industrial property right of any nature whatsoever in any part of the world, whether registered or unregistered.

(aa) "**Law**" means any federal, state, provincial and local laws, statutes, regulations, rules, guidelines, orders, ordinances, and any other requirements of any government or Regulatory Authority applicable to the development, registration, manufacturing, testing, packaging, storing, shipping, marketing, distribution and sale of pharmaceutical products or as otherwise applicable to the Parties respective obligations under this Agreement, including the FDCA.

(bb) "**Losses**" means any damages, liabilities, obligations, costs, expenses or losses, including reasonable legal fees and expenses, court costs, arbitration fees, penalties, fines, costs of investigation and amounts paid in settlement of claims.

(cc) "**Major Change**" shall mean a change that has the potential to adversely impact quality, identity, purity or stability of the Products or the compliance and validity of the Products Marketing Authorizations, as these factors may relate the safety or efficacy of the Product. For example: lowering the purity requirement for a starting material may adversely affect the quality of the Product and would be considered a Major Change. Tightening the purity requirement of a starting material cannot negatively affect the quality of the Product and may be considered a minor change.

(dd) "**Manufacturing Requirements**" has the meaning given in **Article 4.1(a)**.

(ee) "**Marketing Authorization**" means all approvals, licenses, registrations or authorizations of any Regulatory Authority, necessary for the manufacturing, use, storage, import, transport, marketing, promotion and sale of the Product in the Territory, together with pricing or reimbursement approval in countries where governmental approval is required for pricing or for the Product to be reimbursed by national health insurance.

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

(ff) **"Net Sales"** shall mean with respect to the Product, Gross Sales less the following items (whether or not separately stated on such invoice but only to the extent included in Gross Sales):

(i) Any and all promotional allowances, rebates, charge backs, quantity and cash discounts, and other usual and customary discounts to customers;

(ii) Amounts refunded, repaid or credited by reason of rejections, returns or recalls of goods;

(iii) Any sales, excise, turnover, inventory, value-added, and similar taxes and duties assessed on applicable sales;

(iv) Failure to supply penalties (in the case if Article 4.4 (i) and (ii), Non-affiliate third party administrative fees granted, Medicaid and state and/or governmental rebates, and shelf stock adjustments and retroactive price reductions.

Components of Net Sales shall be determined using the accrual method of accounting in accordance with US GAAP or an equivalent stipulated method of accounting in the Territory.

(gg) "**Non-Conforming Product**" has the meaning given in **Article 4.8(b)**.

(hh) "**Original Agreement**" has the meaning given in Recital A.

(ii) "**Packaging**" means all material used to prepare fully packaged Products, including labelling, containers, cartons, shipping cases, and inserts, as applicable.

(jj) "**Parties**" means the parties to this Agreement referred to collectively, and "**Party**" means either party to this Agreement referred to individually.

(kk) "**Person**" includes any individual, partnership, corporation, unincorporated organization or association, joint venture, limited liability company, trust or any other form of entity.

(ll) "**Pharmacovigilance Agreement**" means the pharmacovigilance agreement to be entered into by the Parties which shall set forth the safety data exchange procedures to be followed by the Parties for the collection, investigation, reporting and exchange of information concerning adverse events.

(mm) "**Products**" means the finished pharmaceutical products in commercially saleable form, as manufactured by ELITE and semi-exclusively and/or exclusively supplied to GLENMARK pursuant to this Agreement as set forth on Schedule A.

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

(nn) "**Purchase Order**" means a written, binding purchase order for a certain quantity of Product properly issued by GLENMARK accordance with the terms of this Agreement.

(oo) "**Quality Agreement**" means a quality agreement to be entered into by the Parties which will set forth certain obligations of the Parties in relation to the manufacture, packaging, quality control and testing of the Products in accordance with GMP.

(pp) "**Recall**" shall mean a recall, removal, market withdrawal, seizure, or field correction of Product.

(qq) "**Regulatory Authorities**" means any federal, state, local or international regulatory agency, department, bureau or other governmental entity responsible for regulating the manufacture, use, storage, importation, transportation, distribution marketing, promotion and sale of pharmaceutical products in the Territory, including the FDA and DEA.

(rr) **"Semi-exclusive"** means that ELITE may at its discretion manufacture and supply products for itself and for third parties

(ss) "**Specifications**" means the written methods, formulae, procedures, specifications, tests (and testing protocols) and standards pertaining to the Products as approved by FDA in the Product's ANDA and attached herein asSchedule B, which may be amended from time-to-time by the written agreement of the Parties.

(tt) "**Term**" has the meaning given in **Article 8.1**.

(uu) "**Territory**" means the United States of America and its possessions, territories, protectorates, military bases and commonwealths.

(vv) "**Third Party**" means any Person other than GLENMARK or ELITE, or any of their respective Affiliates.

(ww) "**Trademarks**" has the meaning given in **Article 4.3(a)**.

1.2 Interpretation of "Include". Where the words "include", "includes" or "including" are used in this Agreement, they shall mean, respectively, "include without limitation", "includes without limitation", "including but not limited to", or "including without limitation".

ARTICLE 2 - MARKETING AUTHORIZATIONS

2.1 Subject to the terms of this Agreement, ELITE shall exclusively and/or semi-exclusively, as the case may be, manufacture, supply, package and labe the Products for GLENMARK, and GLENMARK shall have the right to promote, market, store, distribute and sell the Products in the Territo ELITE hereby grants to GLENMARK and its Affiliates an exclusive and/or semi-exclusive right to fully commercialize the Products in the Territor GLENMARK agrees to exclusively purchase Products it requires from ELITE.

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

2.2 ELITE shall, at its expense, maintain and update the Marketing Authorizations for the Products as may be required for the Parties to perform the obligations hereunder. ELITE shall be solely responsible for all communications with the Regulatory Authorities in the Territory relating to any Marketing Authorizations for the Products. ELITE shall provide GLENMARK with timely notice of any communications from the Regulato Authorities which may affect ELITE's right or ability to supply GLENMARK with the Products.

ARTICLE 3 - PAYMENT TERMS

3.1 Transfer Price. ELITE shall sell each Product to GLENMARK at the prices set forth in Schedule A, which Transfer price shall be inclusive of all costs and expenses associated with the manufacture, supply, packaging, labeling of the Product to GLENMARK. ELITE shall not offer to sell t semi-exclusive Product to a Third Party at a lower price than that set forth in Schedule A without first offering to amend Schedule A and sell the Product at such lower price to GLENMARK.

3.2 Upon delivery of the Products to GLENMARK, ELITE shall submit invoices therefore to GLENMARK. GLENMARK shall pay each undis invoice in full within thirty one (31) days of its receipt in full of the Products reflected in the invoice and the Certificate of Analysis, which Certificate is in a form sufficient for release of the Products. A late payment fee of one percent (1%) per month may be imposed upon GLENMARK fo payments past due, unless Products therein are subject to a quality dispute. In the event of any inconsistency between an invoice and this Agreement, the terms of this Agreement shall control.

3.3 License Fees. Throughout the Initial Term and Renewal Term, GLENMARK shall pay to ELITE {***} percent ({***}%) of the Gross Profits received from sales of each Product within forty-five (45) days of the end of each calendar quarter ("License Fees"). Such payment shall additionally include a sales summary for each Product generally in the format as provided in Schedule C. In no case shall the License Fees for any calendar quarter be negative; provided, however in the event of a loss in any calendar quarter, the amount of that loss shall be carried forward to subsequent calendar quarters until the amount of such loss has been fully absorbed.

ARTICLE 4 - MANUFACTURING AND SUPPLY; COMMERCIALIZATION

4.1 Supply of Products.

(a) During the Term of this Agreement, ELITE shall use Commercially Reasonable Efforts to manufacture, timely supply, package and label fo delivery to GLENMARK the Products in accordance with any Purchase Orders issued by GLENMARK under the terms of this Agreeme ELITE shall manufacture, supply, package and label the Products in compliance with all Laws, including the GMPs, the Marketin Authorization, the Quality Agreement, and the Specifications ("**Manufacturing Requirements**").

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

(b) ELITE shall manufacture the Products in the Facility and use Commercially Reasonable Efforts to maintain access to sufficient supplies o raw materials, components and other required resources to perform its obligations under this Agreement, and meet GLENMARK's suppl requirements for the Products. ELITE shall not manufacture the Products at a site other than the Facility without first obtainin GLENMARK's prior written consent, which consent shall not be unreasonably withheld. ELITE shall be solely responsible for all costs a expenses incurred in connection with the manufacture of the Products hereunder, including without limitation costs and expenses of personnel, quality control, testing, manufacturing, facilities, equipment, materials, FDA product fees, FDA establishment fees and governmen sales, use, excise, property or similar taxes or excises.

(c) ELITE shall have procedures in place to ensure that the oldest approved inventory of the Products is distributed first. In addition, each Part shall maintain a tracking system by which the distribution of each lot of the Products may be readily determined to facilitate its Recall i necessary.

(d) Transfer Price Adjustments. The Transfer Prices for the Products under Schedule A are valid through *{***}*. After *{***}*, the Transfer Price for Products may be adjusted up or down for changes in the cost of active pharmaceutical ingredients, annual Generic Drug User Fee (GDUFA fees) proportional allocation, and material changes in serialization requirements. ELITE shall provide at least thirty (30) days written notice to GLENMARK for any such Transfer Price adjustments with justifications for any increase.

(e) The Parties shall enter into a Pharmacovigilance Agreement and Quality Agreement prior to the commencement of any manufacturing activities under this Agreement. The respective roles and responsibilities for quality assurance personnel of the Parties in carrying out the transactions pursuant to this Agreement shall be defined and stipulated in the Quality Agreement. The fully executed Pharmacovigilance Agreement and Quality Agreement are hereby incorporated and made a part of this Agreement by reference. In the event of any inconsistency between the provisions of the Pharmacovigilance Agreement and the provisions of this Agreement, the wording of the Pharmacovigilance Agreement shall govern any and all patient safety matters and this Agreement shall govern all other matters. The Parties hereby acknowledge and agree that in the event of any conflict between the terms of this Agreement and the terms of the Quality Agreement, this Agreement shall control with respect to all issues (other than with respect to the allocation of responsibility for quality assurance), and the Quality Agreement shall control with respect to the allocation of responsibility for quality assurance.

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

4.2 Master Production Plan and Purchase Orders. On or before fifteen (15)days prior to the end of each calendar quarter during the Term, GLENMARK shall deliver to ELITE a master production plan which covers a twelve (12) month period, which includes three (3) months binding purchase order, and nine (9) months non-binding forecast (the "**Master Production Plan**"). The first three months (beginning with the first month following the month in which the Master Production Plan is due) of each Master Production Plan shall be deemed to be a binding purchase order (the "**Binding Forecast**"). Months four (4) through twelve (12) of the Master Production Plan shall be GLENMARK's non-binding, good faith estimate of such requirement based on forecasted trade and GLENMARK shall have the ability to adjust the quantities forecast. Unless the Parties otherwise agree in writing, a firm orders for Product (the "**Purchase Order**") placed shall specify: (i) the type of Product being ordered; (ii) the amount of such Product being requested (which shall be in whole batch size quantities); and (iii) the requested delivery date which, unless otherwise agreed by ELITE in writing shall be not less than ninety (90) days after receipt of the Purchase Order. Each Master Production Plan and accompanying binding Purchase Order shall be deemed to be automatically accepted unless ELITE notifies GLENMARK of its rejection of the same within five (5) Business Days receipt. ELITE may only reject a Purchase Order if a Purchase Order is not consistent with the terms of this **Article 4.2** or is not timely delivered. Once a Purchase Order is accepted by ELITE, ELITE shall be obligated to timely manufacture, supply, package, label, and have ready for delivery the full quantities of Products set forth in the Purchase Order by the required delivery date at the Facility. In the event that the terms of any Purchase Order are not consistent with, or attempt to modify, the terms of this Agreement, the terms of this Agreement shall prevail. If GLENMARK requests changes to any Purchase Order after receipt thereof by ELITE, ELITE shall use Commercially Reasonable Efforts to comply with such changes.

4.3 Delivery Terms.

(a) GLENMARK shall provide ELITE packaging specifications and related materials that comply with FDA requirements and the Parties will finalize all packaging by the time of the first Purchase Order. If requested by GLENMARK, ELITE shall affix on the Product and/or on the label and/or the packages certain proprietary or registered marks, logos or insignia relating to the Product in accordance with the directions and specifications given by GLENMARK, along with any other marks, logos or insignia, as GLENMARK may stipulate from time to time (collectively, "**Trademark**"). Pursuant to the aforesaid, GLENMARK hereby grants to ELITE, a non-exclusive, non-transferable, non-assignable and non-sublicensable right to the Trademarks, solely for the purpose of affixing such Trademarks to the Product in accordance with GLENMARK's directions and specifications during the Term. GLENMARK shall have sole approval authority over all Product labeling and packaging specifications of the Products supplied to GLENMARK pursuant to this Agreement.

(b) ELITE shall deliver the full quantities of the Products set forth in each Purchase Order (Incoterms 2010 EXW) to GLENMARK or designee. All Products shall be packaged for shipment in accordance with the packaging specifications set forth in the Marketing Authorizations and packing instructions reasonably required by GLENMARK.

(c) Each Products shipment made by ELITE shall be accompanied by and shall include a Certificate of Analysis for each shipment of the Products manufactured and supplied hereunder. ELITE shall be responsible for all applicable release testing of the Products in accordance with the Manufacturing Requirements. ELITE shall perform all required in process quality control tests and quality assurance reviews on the Products, including without limitation, stability testing at its sole cost and expense. In addition, ELITE shall furnish GLENMARK, along with the first shipment of the Products, ELITE's Material Safety Data Sheets containing the relevant safety and health information and such other similar information as GLENMARK may reasonably from time-to-time request in connection therewith.

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

(d) All Products provided to GLENMARK shall have no less than eighty five percent (85%) remaining shelf-life remaining as per the Product ANDA.

(e) All orders containing at least ninety percent (90%) of the specified amount of Product in a given Purchase Order shall be deemed satisfied.

4.4 Failure to Supply. ELITE shall notify GLENMARK as promptly as possible, but in no event later than five (5) Business Days, after ELITE discov that it will not be able to supply the quantity of Products ordered by the delivery date specified in a Purchase Order. In such event: (i) ELITE sha cooperate with GLENMARK in taking all actions that GLENMARK deems reasonably necessary in order to remedy such inability to supply, ELITE's expense; and (ii) If ELITE's inability to supply continues past twenty (20) days from the required delivery date set forth in the Purchas Order at GLENMARK's election, any or all outstanding Purchase Orders relating to such Product may be cancelled and GLENMARK shall have obligations with respect to such Purchase Orders. Compliance by ELITE with this **Article 4.4** shall not relieve ELITE of any other obligation o liability under this Agreement. GLENMARK shall otherwise retain all of its rights under this Agreement and/or at law against ELITE for its failure deliver all or any portion of the quantity of Products ordered by GLENMARK. If ELITE's inability to supply continues past twenty (20) days from t required delivery date set forth in the Purchase Order, GLENMARK may, in its sole discretion, elect to terminate this Agreement immediately upo written notice to ELITE. With regards to a Binding Forecast or if ELITE accepted a Purchase Order from GLENMARK, pursuant to the procedu defined in Section 4.2 of this Agreement, then ELITE shall be responsible for the late charges and any penalties assessed against GLENMARK by Customers, unless the delay is attributable to (i) action or controls imposed by the DEA that do not result from ELITE's negligence; or (i demonstrable raw material shortages that are beyond ELITE's control. Late charges and any penalties assessed against ELITE by GLENMAI under this paragraph are due and payable within thirty (30) days of being invoiced by GLENMARK and, if not timely paid, may be deducted agains amounts owed by GLENMARK to ELITE.

4.5 Samples and Batch Records ELITE shall prepare and maintain batch records and file samples, properly stored, for each lot or batch of Product manufactured and shipped hereunder in compliance with all GMPs and Laws in the Territory.

4.6 Commercialization.

(a) GLENMARK shall use Commercially Reasonable Efforts to market and sell the Products in the Territory. All commercial matters regardir the marketing, promotion, sale, offer for sale, pricing or distribution of the Products in the Territory shall be under the exclusive control of GLENMARK.

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

4.7 Change of Specification. No alterations of the Specifications for the Products or other changes requiring prior approval by the FDA, or Major Changes to the manufacturing process or validated processes, can be made without the prior written approval of GLENMARK. ELITE shall noti GLENMARK in writing of any proposed alterations for the Specifications for the Products or any Major Changes to the manufacturing process validated processes. GLENMARK shall notify ELITE of GLENMARK's decision within sixty (60) days of receipt of such proposal from ELITI ELITE does not receive GLENMARK's decision in writing within sixty (60) days, the alteration of the Specifications or other Major Changes to t manufacturing process or validated process proposed by ELITE shall be deemed rejected by GLENMARK. In the event that the FDA or any otl governmental authority shall suggest or mandate any change or revision to the Product, such that the Specifications would no longer comply with such suggestion or mandate, the Parties shall work together in good faith to develop revised Specifications that meet all changes or revisions suggested or mandated by the FDA or other governmental authority and Schedule B shall be amended in writing to set forth the new agreed upon Specifications.

4.8 Acceptance of the Product.

(a) Following receipt of a shipment of Product at the final destination, GLENMARK, or its designee, shall conduct a visual inspection of th Product and all accompanying documents provided by ELITE, including without limitation, the Certificate of Analysis, in accordance with it customary procedures. GLENMARK shall advise ELITE, in writing, if it is rejecting a shipment of Product due to obvious physical dama or obvious packaging defect that are evident upon such visual inspection of the packaged Product as shipped by ELITE. GLENMARK (a its designees) shall have no obligation to inspect the Product beyond the visual inspection provided for in this **Article 4.8(a)**.

(b) In the case of defects other than those obvious defects described in **Article 4.8(a)**, including, by way of example, any failure of the Product, at the time of delivery, to meet the Manufacturing Requirements and the representations, warranties and covenants of **Article 9.2(f)**, GLENMARK shall promptly notify ELITE if it becomes aware of such non-obvious defect(s). Any defect in physical condition of Produc delivered by ELITE or Products that do not conform with the Manufacturing Requirements (as may be in effect from time to time) or th representations, warranties and covenants of **Article 9.2(f)** for any reason shall be deemed to be a non-conforming product ("**Non-Conforming Product**"). GLENMARK, or its designee, shall have the right to reject any Non-Conforming Product and no failure on the pa of GLENMARK, or its designee, or passage of time shall prejudice GLENMARK's right to reject or revoke acceptance of Non-Conform Product. All Non-Conforming Product shall be returned to ELITE at its sole cost and expense.

(c) If ELITE confirms the Non-Conforming Product or lab testing pursuant to **Article 4.8(d)** determines that the Product is Non-Conforming Product, ELITE shall, at GLENMARK's election, either replace such Non-Conforming Product with conforming Product or, refund GLENMARK, the price paid for such Non-Conforming Product plus any out-of-pocket expense GLENMARK may have incurred w respect thereto prior to its discovery of the defect, including without limitation shipping, insurance, recall, market withdrawal, regulatory compliance, returns, destruction, and packaging costs, and in any case, within forty-five (45) days of confirmation or determination of Non-Conforming Product.

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

(d) If the Parties cannot agree as to whether a delivered quantity of Product is Non-Conforming Product, then the Parties agree to have th batch in dispute tested and further analyzed by a recognized independent testing laboratory selected by the Parties. The appointment of such laboratory shall not be unreasonably withheld or delayed by either Party. The decision of the laboratory shall be in writing and, save for manifest error on the face of the decision, shall be binding on both Parties. Should said laboratory's testing determine that the Product is Non-Conforming Product then ELITE will bear the cost of such testing and comply with the terms of **Article 4.8(c)**. If said Product is determined to have been conforming, then GLENMARK shall bear all costs of the independent laboratory testing as well as accept the Product shipmen and pay for same within forty-five (45) days of such acceptance.

ARTICLE 5 - INSPECTIONS

5.1 Inspections. During the Term of this Agreement and thereafter in the event of a Claim against either Party regarding use of the Products is threatened or commenced, ELITE shall permit GLENMARK's representatives to enter ELITE's facilities, upon reasonable prior notice (except in the event o for-cause audit) and during normal business hours, for the purpose of inspecting the facility and quality control procedures and confirming compliance with all applicable GMPs and Laws in the Territory, the requirements of the Regulatory Authorities in the Territory, the Quality Agreement and this Agreement. If during any such inspection GLENMARK discovers any instances in which ELITE has not complied with the foregoing, then ELI shall promptly provide to GLENMARK a written plan for correcting such deficiencies, including a proposed timetable for implementing suc corrections, and shall ensure that such deficiencies are corrected, at ELITE's sole expense, as soon as reasonably practicable. ELITE agrees t provide GLENMARK with copies of all: (i) reasonably requested documentation in its possession relating to the manufacture of Produc Specifications, compliance with quality assurance standards, raw material vendors and manufacturing processes; and (ii) U.S. and internationa regulatory approvals, regulatory inspections of the manufacturing process, facilities and documentation, and other communications with Regulatory Authorities related to the Product; however ELITE shall not be required to provide copies to GLENMARK of ELITE's proprietary information a ELITE shall only be required to allow GLENMARK to inspect such proprietary information such as batch records at ELITE's site and under ELITE's supervision. Notwithstanding the provision of this **Article 5.1**, GLENMARK shall have no obligation or be deemed to have an obligation to inspec ELITE's facilities.

5.2 Regulatory Authority Inspections ELITE shall permit any Regulatory Authority to inspect the facility used to manufacture the Products and a associated records to the full extent permitted by applicable Law ("**Regulatory Inspection**"). ELITE shall notify GLENMARK within forty-eig (48) hours of becoming aware of any planned or actual Regulatory Inspection. ELITE agrees to reasonably cooperate with the applicable Regulator Authority in connection with such audits. ELITE shall notify GLENMARK prior to the commencement of any meetings with, or inspection activity b any Regulatory Authority, unless such inspection activity is an unannounced inspection. Further, ELITE shall provide a reasonable description t GLENMARK of any such governmental inquiries, notifications or inspections promptly (but in no event later than two (2) calendar days) after suc visit or inquiry. ELITE shall furnish to GLENMARK: (i) within two (2) calendar days after receipt, any report or correspondence issued by th Regulatory Authority in connection with such visit or inquiry, including but not limited to, any FDA Form 483, establishment inspection report, or warning letter; and (ii) copies of any and all responses or explanations to any Regulatory Authority relating to items set forth above prior to the submission of such responses or explanations to any Regulatory Authority by ELITE for comment, which comments shall be taken into consideratio by ELITE in good faith. ELITE shall also provide GLENMARK with a copy of all final responses.

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

ARTICLE 6 - RECORDS

6.1 Records. ELITE and GLENMARK shall maintain all records necessary to comply with all applicable Laws in the Territory relating to t performance of their respective obligations under this Agreement. ELITE shall also maintain, or cause to be maintained (i) all manufacturing records standard operating procedures, validation records, equipment log books, batch records, laboratory notebooks and all raw data relating to the manufacturing of the Products, and (ii) such other records as GLENMARK may reasonably require in order to ensure compliance by ELITE with t terms of this Agreement. All such records shall be maintained for such period as may be required pursuant to the applicable Laws.

6.2 Inspection of ELITE Books and Records. During the Term of this Agreement, and thereafter for the greater of (i) the period stipulated by the Laws in the Territory, and (ii) two (2) years from the expiration of the last Products manufactured, ELITE agrees that GLENMARK, at reasonable times upo reasonable prior notice, may inspect the research and development books and records of ELITE pertaining to ELITE's obligations under th Agreement for purposes of ensuring compliance with the terms of this Agreement.

6.3 Inspection of GLENMARK Books and RecordsGLENMARK shall keep, and shall require its Affiliates to maintain, in connection with the handlin sale, and distribution of the Product hereunder, books and records necessary to allow the accurate calculation, consistent with GAAP, of the amounts due to ELITE, the reporting obligations contemplated herein, and compliance with the terms of this Agreement, and GLENMARK shall maintain su books and records for a period of at least two (2) years after the end of the calendar year in which they were generated, or for such longer period as may be required by Applicable Law. Upon at least thirty (30) days prior written notice of each calendar year, ELITE, at its expense, shall have the right to have an independent public accounting or auditing firm, reasonably acceptable to GLENMARK, obtain access to such books and records a may be reasonably necessary to determine or verify the amount of payments due under this Agreement and compliance with the obligations hereof; provided, however, that this right may not be exercised more than once in any calendar year. Such accounting firm shall conduct such examination, and GLENMARK shall make such books and records available, during normal business hours at the facility(ies) where such books and records ar customarily maintained. Each such examination shall be limited to pertinent books and records for any year ending not more than twenty-four (24) months prior to the date of request, except that ELITE shall not be permitted to audit the same period of time more than once. The independen accounting firm will prepare and provide to each Party a written report stating whether the reports submitted and amounts paid are correct or incorrect and the amounts of any discrepancies. The conclusions of such accounting firm shall be final and binding on the Parties absent demonstrable error. If there was an underpayment by GLENMARK hereunder, GLENMARK shall promptly (but in no event later than thirty (30) days after receipt of the independent auditor's report so concluding) make payment to ELITE of any shortfall by wire transfer in U.S. dollars, plus interest on th amount of such shortfall calculated at the lesser of (a) five percent (5%) per annum, or (b) the maximum rate permitted by law from the date such payment should have been made to the date the shortfall is paid. If there was an overpayment by GLENMARK hereunder, ELITE shall promptly (b in no event later than thirty (30) days after ELITE's receipt of the independent auditor's report so concluding) refund to GLENMARK the exce amount by wire transfer in U.S. dollars. All costs of the audit, including the expenses of the independent accounting firm, shall be borne by ELITE unless the underpayment by GLENMARK results in a cumulative discrepancy during any calendar year in excess of the greater of (i) ten percen (10%) of the total amount reported to ELITE for that period or (ii) one hundred thousand dollars ($100,000.00), in which case all reasonable and documented costs of the audit, including the expenses of the independent accounting firm, shall be borne and promptly paid by GLENMARK. ELIT shall ensure that the independent public accountant or auditor maintains the confidentiality of GLENMARK's Confidential Information on terms n less restrictive than those set forth in this Agreement.

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

6.4 Annual Reports. ELITE shall provideGLENMARK in a timely manner copies of ELITE's annual reports to the FDA or any other Regulator Authority with respect to the Products.

ARTICLE 7 - RECALLS

7.1 Notification of Recall. If any Regulatory Authority or other governmental agency issues or requests a Recall or takes similar action in connection with a Product in the Territory, or if GLENMARK reasonably determines after consultation with ELITE that an event has occurred which may result the need for a Recall, the Party notified of or wishing to implement such Recall shall, within forty-eight (48) hours (regardless of weekday, weekend or holiday), advise the other Party thereof by telephone or facsimile, after which the Parties shall promptly discuss and work together to effect an appropriate course of action. ELITE shall be responsible for notifying the Regulatory Authorities in the Territory of any voluntary Recall and implementing any Recalls. GLENMARK shall fully cooperate with ELITE to fully implement any Recall. ELITE agrees to forward to GLENMARK a copy of any field communication associated with the Products that it plans to issue before such communication is issued or sent t any governmental agency. ELITE will maintain complete and accurate records of any activities conducted with respect to any Recall for such perio as may be required by Law. Following any Recall, ELITE will review all of its procedures as impacted by the identified root cause in the associate investigation, and will revise such procedures, as necessary, to correct the cause of such Recall subject to the change control requirements set forth in the Quality Agreement. ELITE will provide GLENMARK with such information regarding such review and revisions as GLENMARK may req and ELITE shall provide GLENMARK the right to approve, reject or request modifications to the proposed changes.

7.2 Recall Expenses. If a Recall results from the acts or omissions of one Party, then such Party shall bear the full expenses of both Parties incurred i the Recall. If a Recall is partially caused by the actions or omissions of both Parties, then each Party shall be responsible for its proportionate share o the Recall expenses based on its proportionate share of causation. Recall expenses include the expenses of notification, shipping, return, replacement (if possible), customer fees and penalties, and destruction of recalled Products (including Products which cannot be shipped due to the condition causing the Recall). The Parties shall discuss in good faith and agree on the scope and costs of Recall, if practicable, prior to enforcement of the Recall.

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

7.3 Notice of Failure to Meet Specifications. If ELITE discovers that there is a potential that any batch or lot of the Products already delivered t GLENMARK may fail to conform to the Specifications, then ELITE shall notify GLENMARK within twenty-four (24) hours (or one (1) busir day), of such determination of failure to meet the Specifications and of the nature thereof in detail, including, but not limited to, supplying GLENMARK with all investigatory reports, data and communications, out-of-specification reports and data and the results of all outside laboratory testing and conclusions, if any. ELITE shall investigate all such failures promptly, and at its sole expense, cooperate with GLENMARK in determining the caus for the failure and a corrective action to prevent future failures.

ARTICLE 8 - TERM & TERMINATION

8.1 Term. This Agreement shall commence upon the Effective Date, and, unless terminated earlier in accordance with the provisions hereof, shal continue for a period of three (3) years from the Effective Date ("**Initial Term**"). Unless earlier terminated pursuant to this Agreement, the Initia Term shall automatically be extended for successive one (1) year periods ("**Renewal Term**") unless at least one hundred eight (180) days before the expiration of the then current Term, a Party gives written notice to the other Party that it does not wish to extend the Agreement. The Initial Term and all Renewal Term (if any) are collectively referred to as the "Term."

8.2 Termination. If any one or more of the following events of default shall occur, then this Agreement may be terminated as set forth herein:

(a) if a Party files a petition in bankruptcy or is adjudged as bankrupt, or a petition in bankruptcy is filed against it and is not dismissed within sixty (60) days, or it becomes insolvent, takes advantage of legislation for creditor relief, has a receiver or receiver-manager appointed in relation to its assets, or discontinues its business, then the other Party may terminate this Agreement upon delivering written notice of termination;

(b) if a Party hereto violates or fails to perform any of its material undertakings, agreements, covenants or obligations under this Agreement (excluding matters otherwise specifically addressed with a termination right elsewhere in this Agreement) and the failure is not remedied within thirty (30) days after written notice from the non-defaulting Party, then the non-defaulting Party may terminate this Agreement upon delivering written notice of termination to the breaching Party; *provided* that if the breaching Party is diligently pursuing in good faith the remedy of the breach at the expiration of such thirty (30) day cure period, then such thirty (30) day cure period shall be extended as reasonably required to effect the cure;

(c) if a Party hereto willfully or fraudulently misrepresents any fact, information or report disclosed pursuant to this Agreement and such misrepresentation is not cured or remedied within thirty (30) days after the receipt of written notice thereof by the non-defaulting Party, then the other Party may terminate this Agreement upon delivering written notice of termination;

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

(d) if a court of competent jurisdiction makes a final determination that the marketing and sale of a Product in the Territory infringes the patent or other Intellectual Property Rights in the Territory of a third party and enjoins the marketing and sale of the Product in the Territory, and if all rights to appeal have been exhausted or expired, then GLENMARK may, upon delivering written notice to ELITE, terminate this Agreeme with respect to such Product;

(e) if GLENMARK decides to discontinue the marketing and selling of a Product for any reason, including its economic viability or changes market or regulatory conditions, then GLENMARK may terminate this Agreement with respect to such Product without penalty upo delivering written notice to ELITE not less than three (3) months prior to termination; and

(f) by ELITE, on a Product by Product basis, if any time after the first twelve (12) months from the first commercial sale, the average Licens Fee paid by Glenmark is less than *{***}* dollars (US$*{***}*) for a *{***}* six (*{***}*) month sales period for that Product.

8.3 Other Termination Rights. In addition to **Article 8.2**, (i) either Party may terminate this Agreement pursuant to **Articles 13.3** (Assignment without Consent) and **13.5** (Force Majeure), and (ii) GLENMARK may terminate this Agreement pursuant to **Article 4.4** (Failure to Supply) and **Article 9.2(c)** (Debarred), and (iii) ELITE may terminate this Agreement pursuant to **Article 9.3(c)** (Debarred).

8.4 Effect of Termination. Upon termination or expiration of this Agreement, the provisions of this Agreement shall continue to apply with respect to the Parties' respective rights and obligations in relation to any Purchase Order made prior to such termination, including without limitation ELITE' obligation to manufacture, release and deliver Products to GLENMARK, and GLENMARK's obligation to make payment for such Products. If t Agreement is terminated while GLENMARK is still in possession of Products ("**Remaining Products**"), ELITE hereby grants GLENMARK and Affiliates a license to promote, market, distribute and sell the Remaining Products in the Territory, subject to the License Fees in Article 3.3.

8.5 Survival. The expiration or earlier termination of this Agreement shall not relieve either Party hereto from any obligations which accrued prior to such expiration or earlier termination, and shall not destroy or diminish the binding force and effect of any of the terms and conditions of this Agreement that expressly or by implication come into or continue in effect on or after termination or expiration, including **ARTICLE 1 - , ARTICLE 5 - ARTICLE 6 - , ARTICLE 7 - ,** Section **8.4, ARTICLE 9 - , ARTICLE 11 - , ARTICLE 12 - ,** Sections **13.6**, and **13.7**. Further, the provisions from the Original Agreement that were deemed to survive the termination or expiration of that Agreement shall further survive.

ARTICLE 9 - REPRESENTATIONS & WARRANTIES

9.1 Representations and Warranties. Each Party represents and warrants to the other Party as follows, which representations and warranties shall be true as at the date hereof and throughout the Term of this Agreement:

(a) it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this Agreement; and

*{***}* *Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

(b) this Agreement is its legal, valid and binding obligation, enforceable in accordance with the terms and conditions hereof.

9.2 ELITE General and Supply Warranties. ELITE represents and warrants to GLENMARK as follows:

(a) No Other Agreements. No contracts, commitments or agreements of any nature exist, and none will be entered into during the Term of this Agreement, that impair or inhibit the ability of ELITE to perform its obligations hereunder.

(b) No Lawsuits. As of the date hereof there have not been any Claims, lawsuits, arbitrations, legal or administrative or regulatory proceedings, charges, or complaints or investigations, by any third party or government authority threatened, commenced, pending or proceeding against ELITE, and ELITE has not received any notice thereof, which could prevent ELITE from complying with its material obligations under t Agreement.

(c) Debarred. Neither ELITE nor any of its officers, directors, or employees or consultants performing services under this Agreement has bee or is: (1) an individual who has been debarred by the FDA pursuant to 21 U.S.C. § 335a(a) or (b) ("**Debarred Individual**") from providing services in any capacity to a person that has an approved or pending drug product application with FDA, or an employer, employee, o partner of such a Debarred Individual; or (2) a corporation, partnership or association that has been debarred by FDA pursuant to 21 U.S.C § 335a(a) or (b) ("**Debarred Entity**") from submitting or assisting in the submission of an NDA, or an employee, partner, shareholder, member, subsidiary, or affiliate of a Debarred Entity; or (3) an employer, employee or partner of an individual convicted within the last five years for crimes described in subsections (a) or (b) of Section 306 of the FDCA. If and when ELITE becomes aware of any fact that mak or gives rise to make this representation and warranty untrue, ELITE shall immediately notify GLENMARK in writing and any such brea may result in immediate termination of this Agreement by GLENMARK.

(d) Non-Infringement.

(i) ELITE's performance of its obligations hereunder does not and will not infringe any intellectual property rights of a third party.

(ii) No patents, patent applications if issued, or any other proprietary rights of any third party would be infringed by the manufacture, use or sale of the Product and ELITE shall indemnify, defend and hold harmless GLENMARK and its Affiliates against any and all su infringement claims, demands, actions, losses, damages, fines, penalties, costs and expenses (including reasonable attorneys' fees). The indemnification obligation of ELITE shall include Third Party patents issued after the Effective Date.

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

(e) Facility. The Facility is in compliance with all Laws, including without limitation GMP, and that there are no, nor have been any, citations or adverse conditions of a material nature noted in any inspection of the site which would cause the Product to be misbranded or adulterated. It has and shall maintain sufficient knowledge and experience and adequate production facility(s), equipment and processes to produce the Product and perform its obligations under this Agreement in compliance with all Laws.

(f) Products Supply. ELITE warrants, represents and covenants to GLENMARK that all Products delivered to GLENMARK hereunder shall:

(i) comply with the Specifications;

(ii) comply with the applicable Purchase Order;

(iii) be manufactured, tested, packaged, labeled, stored, handled and delivered by ELITE in accordance with (i) the terms of this Agreement, including the Specifications, and the Quality Agreement, (ii) the requirements of the Marketing Authorization, and (iii) all applicable GMPs and Laws in the Territory, including regulations set forth by the DEA;

(iv) be manufactured at the Facility approved by the Regulatory Authorities in the Territory;

(v) not be adulterated or misbranded under any applicable Laws in the Territory;

(vi) have at least eighty-five percent (85%) of the Product's shelf-life remaining at the time of delivery; and

(vii) be free of all liens, security interests, and other claims of any nature and free from defects in material, manufacturing and workmanship for the shelf-life of the Products.

(g) be manufactured, supplied, packaged, labeled and delivered in compliance with all serialization and aggregation requirements set forth in the Drug Supply Chain Security Act (DSCSA)Marketing Authorizations. ELITE warrants, represents and covenants to GLENMARK that (i) Marketing Authorizations have been obtained as necessary to permit GLENMARK to manufacture, use, store, import, transport and sell the Product in the Territory pursuant to the terms of this Agreement and (ii) ELITE shall maintain all necessary Marketing Authorizations in good standing to permit GLENMARK to manufacture, use, store, import, transport and sell the Product in the Territory pursuant to the terms of this Agreement.

(h) It is and shall at all times relevant to this Agreement be in full compliance with all applicable Laws relating or impacting in the performance of ELITE's duties and obligations under this Agreement, including but not limited to, those rules, regulations, and/or guidance promulgated or issued by the FDA, the Centers for Medicare & Medicaid Services, the U.S. Department of Health and Human Services Office of Inspector General the U.S. Drug Enforcement Agency, the U.S. Department of Justice, as well as any applicable environmental requirements and all serialization and aggregation requirements set forth in the Drug Supply Chain Security Act.

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

(i) Subject to DEA quotas, it has access to sufficient supplies of raw materials, components and other required resources to perform the services required under this Agreement, and shall exercise commercially reasonable and diligent efforts to maintain access to sufficient supplies without interruption during the Term.

9.3 GLENMARK General Warranties. GLENMARK represents and warrants to ELITE that:

(a) No Other Agreements. No contracts, commitments or agreements of any nature exist, and GLENMARK covenants that none will be entered into during the Term of this Agreement that impair or inhibit the ability of GLENMARK to perform its obligations hereunder.

(b) No Lawsuits. As of the date hereof there have not been any Claims, lawsuits, arbitrations, legal or administrative or regulatory proceedings, charges, or complaints or investigations by any third party or government authority threatened, commenced, pending or proceeding against GLENMARK, and GLENMARK has not received any notice thereof, which could prevent GLENMARK from complying with its mat obligations under this Agreement.

(c) Debarred. Neither GLENMARK nor any of its officers, directors, or employees or consultants performing services under this Agreement has been or is: (1) a Debarred Individual or an employer, employee, or partner of such a Debarred Individual; or (2) a Debarred Entity, or a employee, partner, shareholder, member, subsidiary, or affiliate of a Debarred Entity; or (3) an employer, employee or partner of an individual convicted within the last five years for crimes described in subsections (a) or (b) of Section 306 of the FDCA. If and when GLENMAR becomes aware of any fact that makes or gives rise to make this representation and warranty untrue, GLENMARK shall immediately notif ELITE in writing and any such breach may result in immediate termination of this Agreement by ELITE.

(d) It is and shall at all times relevant to this Agreement be in full compliance with all applicable Laws relating or impacting in the performance of GLENMARK's duties and obligations under this Agreement, including, to the extent applicable, but not limited to, those rules, regulations and/or guidance promulgated or issued by the FDA, the Centers for Medicare & Medicaid Services, the U.S. Department of Health a Human Services Office of Inspector General the U.S. Drug Enforcement Agency, the U.S. Department of Justice, as well as any applicab environmental requirements and all applicable requirements set forth in the Drug Supply Chain Security Act.

9.4 Disclaimer. EXCEPT FOR THE WARRANTIES AND REPRESENTATIONS PROVIDED OR REFERENCED IN THIS AGREEMI PARTIES MAKE NO OTHER WARRANTIES OR REPRESENTATIONS TO EACH OTHER, EXPRESS OR IMPLIED, IN(THOSE WITH RESPECT TO THE PRODUCTS, WHETHER STATUTORY OR OTHERWISE, AND EACH PARTY SPECI DISCLAIMS ALL OTHER WARRANTIES, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

ARTICLE 10 - COVENANTS

10.1 Compliance. Each Party shall perform its obligations under this Agreement in strict compliance with all applicable GMPs and Laws in the Territory and all applicable licenses, governmental permits or applications in the Territory.

10.2 Permits and Licenses. Each Party shall throughout the Term of this Agreement obtain and maintain any and all licenses, permits, orders, applications and consents (including facility licenses and permits) required by the Regulatory Authorities in the Territory, and all applicable Laws, regulations and GMPs necessary or required to perform its obligations under this Agreement.

ARTICLE 11 - INDEMNIFICATION & INSURANCE

11.1 Indemnification of ELITE. GLENMARK shall defend, indemnify and hold harmless ELITE, its Affiliates and their respective officers, directo employees, agents and representatives from and against all Losses from any Third-Party Claim directly resulting from:

(a) any breach of any obligations, actions, or representations made by GLENMARK under this Agreement; and

(b) any grossly negligent or intentionally wrongful act or omission of GLENMARK or of any person acting on GLENMARK's behalf, w authorization, when the wrongful act or omission occurred in performance of GLENMARK's obligations under this Agreement;

provided, however, that the foregoing indemnification obligations shall not apply to the extent such Losses are caused by an act or omission for which ELITE is contributorily negligent and/or otherwise required to indemnify GLENMARK under **Article 11.2**.

11.2 Indemnification of GLENMARK. ELITE shall defend, indemnify and hold harmless GLENMARK, its Affiliates and their respective office directors, employees, agents and representatives from and against all Losses from any Third-Party Claim directly resulting from:

(a) any breach of any obligations, actions, or representations made by ELITE under this Agreement;

(b) any infringement or claim of infringement of any patent, trademark or other intellectual property rights based on the manufacture and release of the Product furnished under the provisions of this Agreement;

(c) personal injury (including death) or property damage relating to or arising out of any use, distribution or sale of the Products by GLENMARI or its Affiliates to the extent that such Loss was the result of the Product not being manufactured to meet the Manufacturing Requirements and

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

(d) any grossly negligent or intentionally wrongful act or omission of ELITE or of any person acting on ELITE's behalf, with authorization, whe the wrongful act or omission occurred in performance of ELITE' obligations under this Agreement;

provided, however, that the foregoing indemnification obligations shall not apply to the extent such Losses are caused by an act or omission for which GLENMARK is required to indemnify ELITE unde**Article 11.1**. ELITE shall also indemnify GLENMARK for any damages arising from a interruption in supply of the Products to GLENMARK occasioned by ELITE's commitments, contractual or otherwise, with a Third Party subject **Article 4.4**.

11.3 Indemnification Procedure. Any Party entitled to indemnification hereunder (the "**Indemnitee**") shall notify the indemnifying Party (the "**Indemnitor**") promptly of any claim threatened or commenced against the Indemnitee. The Indemnitor shall assume control and direct the defense investigation and handling of the claim for and on behalf of the Indemnitee, *provided, however* that the Indemnitor shall not settle or consent to judgment without the Indemnitee's approval, which approval shall not to be unreasonably withheld. The Indemnitee shall cooperate with the Indemnitor, and may participate, at the Indemnitee's expense, in the defense of such claim. If the Indemnitor fails to assume control of the defense of any claim, or, having elected to assume control, thereafter fails to diligently defend the claim, the Indemnitee shall, without limitation to the Indemnitor's obligations hereunder, be entitled to contest, settle or pay the amount of the claim, and the Indemnitor shall be bound by the results obtained by the Indemnitee with respect to the claim.

11.4 Insurance. Each Party hereby represents to the other that it has, and during the Initial Term and any Renewal Term and for three (3) years after termination or expiration of this Agreement, will maintain, products liability insurance coverage of not less than US *{***}* dollars ($*{***}*) in the aggregate. For the sake of clarity, should ELITE increase its product liability insurance coverage beyond this amount, the new levels shal automatically apply to this Agreement. Upon the request of the other Party hereto, the insured Party shall furnish the other Party with a certificate o insurance evidencing such coverage and stating that such insurance shall not be cancelled, materially amended or allowed to lapse without at least thirty (30) days prior written notice to the other Party hereto. Each Party shall list the other Party as an additional insured on such Party's applicable insurance coverage. Each Party shall provide the certificate of insurance within ten (10) days of its receipt of a request for proof of insurance.

11.5 Survival. The obligations set forth in this **ARTICLE 11** shall survive the termination of this Agreement and remain in full force and effect for an indefinite period after termination in relation to any claim based on events which occur during the term hereof.

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

ARTICLE 12 - CONFIDENTIALITY

12.1 Confidentiality. During the Term of this Agreement and for five (5) years thereafter, each Party shall maintain in strict confidence the Confidential Information (as defined below) of the other Party. Each Party shall not use the Confidential Information of the other Party for any purpose other than the purposes expressly permitted by this Agreement, and shall not disclose such Confidential Information to any third party (including in connection with any publications, presentations or other disclosures) except to its employees, agents or advisors ("**Representatives**") who have a need to know such Confidential Information to perform such Party's obligations under this Agreement. Each Party shall ensure that any Representative to whom it discloses the other Party's Confidential Information is informed of the confidential nature of and duty not to disclose the information, and is obligated under written obligation to maintain the confidentiality thereof on terms at least as restrictive as those set forth herein. Each Party shall be responsible for any breach of this Agreement by its Representatives, which shall be considered a breach by such Party. Under no circumstances shall the receiving Party use the disclosing Party's Confidential Information for its own commercial advantage to the detriment of the disclosing Party. Each Party may disclose such of the Confidential Information of the other Party as may be required by the order of a court of competent jurisdiction or by any governmental authority having jurisdiction, *provided* that prior to any such disclosure the Party required to disclose shall, to the extent permitted by Law, notify the other Party prior to disclosing any Confidential Information and provide such other Party with a reasonable opportunity to contest or limit the scope of the required disclosure and obtain any protective orders as may be appropriate. In the event the disclosure is nonetheless compelled, the Party making the disclosure shall only disclose the information to the extent required to comply with the Law. Upon termination or expiration of this Agreement, or upon request, a Party shall destroy or return all Confidential Information of the other Party and certify in writing that such return (or destruction) has been completed; provided, however, that each Party shall be entitled to retain one archival copy of such Confidential Information solely for purposes of monitoring such Party's compliance with its obligations under this **ARTICLE 12 -** .

12.2 Definition. "**Confidential Information**" means all proprietary technical information, marketing, business and financial information, scientific data, information, whether or not labeled "Confidential", and all tangible and intangible embodiments and oral disclosures thereof of any kind whatsoever, and all other materials which a disclosing Party treats confidentially that relates to a Product or the business of a Party and is disclosed or developed under or in connection with this Agreement. Confidential Information shall not include any information which the receiving Party can show by competent proof:

(a) was known to or in the possession of the receiving Party prior to the date of its actual receipt from the disclosing Party;

(b) is readily available to the public other than through the fault of the receiving Party;

(c) was disclosed by a third party not under an obligation of confidentiality to the disclosing Party; or

(d) is subsequently independently developed by the receiving Party without use of the Confidential Information as demonstrated by competent written records.

12.3 Injunctive Relief. The Parties acknowledge that any breach of this **ARTICLE 12 -** may constitute irreparable harm, and that the non-breaching Party shall be entitled to seek specific performance or injunctive relief to enforce this **ARTICLE 12 -** in addition to whatever remedies such Party may otherwise be entitled to at law or in equity, without the necessity of posting bond or any other security.

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

12.4 No Publicity. Except as required by law, neither Party shall originate any publicity, news release or other public announcements, written or oral, whether to the public press, to stockholders, or otherwise, relating to this Agreement, any amendment hereto, performance hereunder or the existence of an arrangement between the Parties without the prior written approval of the other Party, which approval shall not be unreasonably withheld. Nothing in the provision shall be deemed to prevent a Party from making such disclosures or announcements that are legally required of such Party, *provided* that in any event the non-disclosing Party shall have the right to review any such disclosure and revise such disclosure to the extent it relates to the use of the non-disclosing Party's name or Confidential Information. No Party shall, without the prior written consent of the affected Party, use in advertising, publicity, or otherwise, the name, trademark, logo, symbol, or other image of the affected Party without the other Party's prior written consent.

ARTICLE 13 - MISCELLANEOUS

13.1 Notices. Any notice or other document required or permitted to be given pursuant to this Agreement shall be in writing and shall be delivered by personally by hand; by courier; by prepaid certified mail, return receipt requested; or by email, in each case addressed to the Party to whom it is to be given at the address set forth below or at such other address as the Party to whom such notice is to be given shall have last notified the other Party in accordance with the provisions of this section:

In the case of ELITE at:	Glenmark Pharmaceuticals, Inc., USA 750 Corporate Drive Mahwah, NJ 07430 Attention: President
And in the case of GLENMARK at:	Elite Pharmaceuticals Inc. 165 Ludlow Avenue Northvale, NJ 07647 Attention: CEO

Any such notice or other document shall:

(i) if delivered by hand, courier, or email be deemed to have been given and received at the place of receipt on the date of delivery, *provided* that if delivery is other than during business hours (9:00 a.m. to 5:00 p.m., local time) on a Business Day in the place of receipt, such notice shall be deemed to have been given and received at the place of receipt on the first Business Day thereafter; and

(ii) if mailed, be deemed to have been given and received at the place of receipt on the earlier of the date of actual receipt and three (3) Business Days after the date of mailing. In the event of postal disruption, such notices or documents must be delivered by means other than by mail.

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

13.2 Relationship of the Parties. The relationship of the Parties is that of independent contractors. Nothing in this Agreement shall be deemed or construed to constitute or create between the Parties hereto a partnership, joint venture, agency, or other relationship other than as expressly set forth herein. This Agreement does not constitute any one Party hereto as the agent or legal representative of the other Party for any purpose whatsoever. Neither of the Parties grants to the other any right or authority to assume or create any obligation or responsibility, express or implied, on behalf of it or in its name in any manner whatsoever, unless otherwise agreed to in writing by the other Party.

13.3 Inurement & Assignment. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns. Except as otherwise expressly provided herein, neither Party may assign or transfer it rights or obligations under this Agreement, in whole or in part, without the prior written consent of the other Party. Notwithstanding the foregoing, both GLENMARK and ELITE shall be entitled assign its rights and performance of its obligations under this Agreement to any Affiliate or to the acquirer of all or substantially all of the business or assets to which this Agreement relates (whether by stock sale, asset sale, merger, consolidation or otherwise), provided that the assigning Party remains fully responsible for the performance of the obligations of its Affiliates under this Agreement. Any assignment or transfer by a Party other than in accordance with the terms hereof shall be void and shall entitle the other Party to terminate this Agreement.

13.4 No Waiver; Remedies. No Party to this Agreement shall be deemed or taken to have waived any provision of this Agreement unless such waiver is in writing, and then such waiver shall be limited to the circumstances set forth in such written waiver. No failure or delay on the part of a Party in exercising any right, power or remedy shall operate as a waiver thereof, nor shall any single or partial exercise of any such right, power or remedy preclude any other or further exercise thereof or the exercise of any other right, power or remedy. All remedies provided for hereunder shall be cumulative of and in addition to any and all other remedies, at law or in equity, which any Party may have, and the exercise of any one or more of such remedies shall not preclude the exercise of any others.

13.5 Force Majeure. If either Party is prevented from complying, either totally or in part, with any of the terms or provisions of this Agreement by reason of force majeure, including fire, flood, earthquake, storm, general strike, lockout, riot, war, terrorism, rebellion, accident, acts of God and/or any other cause or externally induced similar casualty beyond its reasonable control and without the fault or negligence of either Party(a "**Force Majeure Event**"), then, upon written notice by the Party liable to perform to the other Party, the requirements of this Agreement or such of its provisions as may be affected, and to the extent so affected, shall be suspended during the period of such disability, *provided* that the Party asserting force majeure shall bear the burden of establishing the existence of such Force Majeure Event by clear and convincing evidence, and*provided further* that the Party prevented from complying shall use its best efforts to remove such disability, and shall continue performance with the utmost dispatch whenever such causes are removed, and shall notify the other Party of the Force Majeure Event not more than five (5) Business Days from the time of the event and state the nature of the Force Majeure Event, its anticipated duration and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is reasonably required. When such circumstances arise, the Parties shall discuss what, if any, modification of the terms of this Agreement may be required in order to arrive at an equitable solution. Notwithstanding the foregoing, if a Force Majeure Event shall continue for a period of longer than three (3) consecutive months or one hundred and twenty (120) days in any twelve (12) month period, then the Party unaffected by such event may terminate this Agreement immediately upon giving written notice of termination to the other Party. Notwithstanding any provision contained herein, any action taken by a Regulatory Authority as a result of a Party's negligence or willful misconduct shall not constitute a Force Majeure Event under this **Article 13.5**.

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

13.6 Dispute Resolution. The Parties recognize that disputes as to certain matters may from time to time arise which relate to a Party's rights and/or obligations under this Agreement. It is the objective of the Parties to establish procedures to facilitate the resolution of such disputes in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this **Article 13.6** if and when such a dispute arises between the Parties arises. Notwithstanding the provisions of this **Article 13.6** however, nothing herein contained shall preclude a Party from seeking equitable remedies in any court of competent jurisdiction as set forth in **Article 13.7** hereof. If any controversy, dispute or claim arises between the Parties relating to the interpretation, breach, performance, enforcement, termination or validity of this Agreement and the Parties cannot resolve the dispute within thirty (30) days of a written request by one Party to any other Party, the Parties agree to hold a meeting, attended by the Chief Executive Officer or President, or a Vice President designated by him/her, of each Party, to attempt in good faith to negotiate a resolution of the dispute prior to pursuing other available remedies. If, within thirty (30) days after such written request, the Parties have not succeeded in negotiating a resolution of the dispute, the Party may seek any other remedies available to it in at law or in equity.

13.7 Governing Law & Venue. This Agreement shall be governed by, and construed in accordance with, the laws of the State of New York, without giving effect to any choice of law or conflict of law rules or provisions that would cause the application of the laws of any jurisdiction other than the State of New York. Each Party hereby irrevocably submits to the exclusive jurisdiction of any federal or state court in New York, NY for the purposes of any suit, action or other proceeding arising out of this Agreement or any transaction contemplated hereby. Each Party further agrees that service of any process, summons, notice or document by certified or registered mail to such Party's address set forth in **Article 13.1** or such other address or to the attention of such other person as the recipient Party has specified by prior written notice to the sending Party shall be effective service of process in any action, suit or proceeding in New York with respect to any matters to which it has submitted to jurisdiction as set forth above in the immediately preceding sentence. Each Party irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of this Agreement or the transactions contemplated hereby in the federal or the state courts in New York, NY and hereby irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such action, suit or proceeding brought in such court has been brought in an inconvenient forum.

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

13.8 Waiver of Trial by Jury. TO THE FULLEST EXTENT PERMITTED BY LAW, THE PARTIES HEREBY WAIVE THEIR RESPE RIGHTS TO A JURY TRIAL OF ANY PROCEEDING BASED UPON, ARISING OUT OF, OR RELATED TO THIS AGRE INCLUDING ANY DISPUTE ARISING OUT OF OR RELATING TO THE PERFORMANCE THEREOF, OR ANY TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT. THE SCOPE OF THIS WAIVER IS INTENDED TO ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT AND THAT RELATE TO THE SU MATTER OF THIS AGREEMENT, INCLUDING CONTRACT CLAIMS, TORT CLAIMS, BREACH OF DUTY CLAIMS AND AL COMMON LAW AND STATUTORY CLAIMS.

13.9 Severability. If any provision in this Agreement is held to be invalid, void or unenforceable, then the remainder of this Agreement, or the application of such provision to the Parties or to the circumstances other than those as to which it is held invalid or unenforceable, shall not be affected thereby and shall be enforced to the fullest extent permitted by law. The Parties agree to renegotiate any such invalid, void or unenforceable provision in good faith in order to provide a reasonably acceptable alternative consistent with the basic purposes of this Agreement.

13.10 Entire Agreement. This Agreement (including the Schedules attached hereto and the Pharmacovigilance Agreement and Quality Agreement) constitutes the entire agreement between the Parties with respect to the subject matter hereof, and all prior or agreements, whether written or oral, are superseded hereby. This Agreement may be amended only in writing executed by the Parties.

13.11 Sub-contracting. ELITE shall not sub-contract any of the work to be performed under this Agreement without the prior written consent o GLENMARK. No such sub-contracting shall relieve ELITE of any of its obligations hereunder.

13.12 Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed shall be deemed to be an original and all of which when taken together shall constitute this Agreement.

13.13 Headings. The captions and headings contained herein are for convenience of the Parties and in no way define, limit or describe the scope of this Agreement.

13.14 Language. The language of this Agreement and all proceedings taken in relation thereto shall be English.

13.15 Currency. Unless otherwise specifically provided, all references to money amounts are expressed in terms of United States Dollars (USD) and a payments made pursuant to this Agreement shall be made in that currency.

13.16 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any Section of this Agreement are and shall otherwise be deemed to be for purposes of Section 365(n) of Title 11, of the United States Code (the "**Bankruptcy Code**") licenses of rights to "intellectual property" as defined in Section 101(35A) of the Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights an elections under the Bankruptcy Code. Upon the bankruptcy of any Party, the non-bankrupt Party shall use its best efforts to transfer its Produc responsibilities to a third party, unless the bankrupt Party elects to continue, and continues, to perform all of its obligations under this Agreement.

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

13.17 Construction of Agreement. The terms and provisions of this Agreement represent the results of negotiations between the Parties and their representatives, each of which has been represented by counsel of its own choosing, and neither of which has acted under duress or compulsion, whether legal, economic or otherwise. Accordingly, the terms and provisions of this Agreement shall be interpreted and construed in accordance with their usual and customary meanings, and each of the Parties hereto hereby waives the application in connection with the interpretation and construction of this Agreement of any rule of law to the effect that ambiguous or conflicting terms or provisions contained in this Agreement shall be interpreted or construed against the Party whose attorney prepared the executed draft or any earlier draft of this Agreement.

[SIGNATURE PAGE FOLLOWS]

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the date first written above.

ELITE PHARMACEUTICALS, INC.

By: \\s\Nasrat Hakim

Name: _____

Title: _____

GLENMARK PHARMACEUTICALS INC., USA

By: \\s\Robert Matsuk

Name: _____

Title: _____

ELITE LABORATORIES, INC.

By: \\s\Nasrat Hakim

Name: _____

Title: _____

Schedule A: Products

Schedule B: Product Specifications

Schedule C Quarterly Report for Calculation of Gross Profit

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

SCHEDULE A

Products and Prices

Product List

Generic Name	**ANDA #**	**Reference Listed Drug**	**Market exclusivity grant from ELITE**
Phendimetrazine 35 mg tablets	40762	Bontil® (Phendimetrazine Tartrate) Tablets, mfg by Valeant Pharm.	Semi-exclusive
*{***}* tablets	TBD	*{***}*	Exclusive

Transfer Prices ($/bottle)

Name	**Full Batch Qty.**	**Bottle Size**	**Cost per bottle**
Phendimetrazine 35 mg tablet	800,000 tablets	100 count	$*{***}*
Phendimetrazine 35 mg tablet	800,000 tablets	1000 count	$*{***}*
*{***}*	1,440,000	100 count	$*{***}*
*{***}*	720,000	100 count	$*{***}*

Pricing includes all Product manufacturing and packaging costs, quality assurance, batch quality control testing and stability testing, and is subject pricing adjustments in Section 4.1(d).

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

SCHEDULE B

PRODUCT SPECIFICATIONS
Elite Pharmaceuticals Inc.
FINISHED PRODUCT ANALYSIS

{***}			{***}
Manufacturer: Elite Laboratories, Inc	{***}	{***}	{***}
QC#:	{***}	{***}	

Test / Method	Specification	Results	Notebook Reference
{***}	{***}		
{***}	{***}		
{***}	{***}		
{***}	{***}		
{***}	{***}		
{***}	{***}		
{***}	{***}	{***}	
{***}	{***}	{***}	

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

SCHEDULE B

PRODUCT SPECIFICATIONS
Elite Pharmaceuticals Inc.
FINISHED PRODUCT ANALYSIS

{***}			{***}
Manufacturer: Elite Laboratories, Inc	{***}	{***}	{***}
QC#:	{***}	{***}	

Test / Method	Specification	Results	Notebook Reference
{***}	{***}		
{***}	{***}		
{***}	{***}		
{***}	{***}		
{***}	{***}		
{***}	{***}		
{***}	{***}	{***}	
{***}	{***}	{***}	

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

SCHEDULE B

PRODUCT SPECIFICATIONS
Elite Pharmaceuticals Inc.
FINISHED PRODUCT ANALYSIS

Phendimetrazine Tartrate Tablets USP 35 mg			*{***}*
Manufacturer: Elite Laboratories, Inc	Department: Analytics and QC	Version 0	*{***}*
QC#:	Batch#:	*{***}*	

Test / Method	Specification	Results	Notebook Reference
*{***}*	*{***}*		
*{***}*	*{***}*		
*{***}*	*{***}*		
*{***}*	*{***}*		
*{***}*	*{***}*		
*{***}*	*{***}*		
*{***}*	*{***}*		
*{***}*	*{***}*		
*{***}*	*{***}*		
*{***}*	*{***}*		
*{***}*	*{***}*	*{***}*	*{***}*

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

SCHEDULE C

QUARTERLY REPORT FOR CALCULATION OF GROSS PROFIT

PRODUCT NAME:_____

QUANTITY SOLD BY SKU	**XXXX UNITS**
GROSS SALES	**$**
DEDUCTIONS:	
CHARGEBACKS	
REBATES	
ADMINISTRATIVE FEES	
BILLBACKS	
RETURNS	
SHELF STOCK ADJUSTMENTS	
OTHER DEDUCTIONS	
CASH DISCOUNTS	
MEDICAID	
NET SALES	**$**
TRANSFER PRICE	
SELLING AND DISTRIBUTION EXPENSES	
SHIPPING COSTS	
GROSS PROFIT	
MATERIAL WRITE OFFS	
NET PROFIT	
PROFIT SHARE PAYMENT TO ELITE AT *{*}*%**	

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

Exhibit 21

Subsidiary of the Company

Elite Laboratories, Inc., a Delaware corporation.

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following documents of our reports dated June 14, 2018, relating to the consolidated financial statements of Elite Pharmaceuticals, Inc. and Subsidiary, and the effectiveness of internal control over financial reporting of Elite Pharmaceuticals, Inc. and Subsidiary included in the Annual Report on Form 10-K of the Company for the year ended March 31, 2018.

Registration Statement No. 333-217866 on Form S-3
Registration Statement No. 333-197694 on Form S-8
Registration Statement No. 333-163907 on Form S-8
Registration Statement No. 333-132140 on Form S-8
Registration Statement No. 333-118524 on Form S-8

Buchbinder Tunick & Company LLP

Wayne, New Jersey
June 14, 2018

Exhibit 31.1

CERTIFICATION BY PRINCIPAL EXECUTIVE OFFICER

I, Nasrat Hakim, certify that:

1) I have reviewed this annual report on Form 10-K for the year ended March 31, 2018 of Elite Pharmaceuticals, Inc. (the "Registrant")
2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4) The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting.
5) The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: June 14, 2018

/s/ Nasrat Hakim
Nasrat Hakim, Chief Executive Officer

Exhibit 31.2

CERTIFICATION BY PRINCIPAL FINANCIAL OFFICER

I, Carter J. Ward certify that:

1) I have reviewed this annual report on Form 10-K for the year ended March 31, 2018 of Elite Pharmaceuticals, Inc. (the "Registrant")
2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4) The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting.
5) The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: June 14, 2018

/s/ Carter J. Ward
Carter J. Ward, Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Elite Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended March 31, 2018 filed with Securitie and Exchange Commission (the "Report"), I, Nasrat Hakim, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopte pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the consolidated financial condition of the Company as of the dates presented and the consolidated result of operations of the Company for the periods presented.

Date: June 14, 2018

/s/ Nasrat Hakim
Nasrat Hakim, Chief Executive Officer

This certification has been furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

A signed original of this written statement required by Section 906 has been provided to Elite Pharmaceuticals, Inc. and will be retained by Elite Pharmaceuticals Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Elite Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended March 31, 2018 filed with Securitie and Exchange Commission (the "Report"), I, Carter J. Ward, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopte pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the consolidated financial condition of the Company as of the dates presented and the consolidated result of operations of the Company for the periods presented.

Date: June 14, 2018

/s/ Carter Ward
Carter J. Ward, Chief Financial Officer

This certification has been furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

A signed original of this written statement required by Section 906 has been provided to Elite Pharmaceuticals, Inc. and will be retained by Elite Pharmaceuticals Inc. and furnished to the Securities and Exchange Commission or its staff upon request.