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, 2017

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, 2016, 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).C

Title of Class	Aggregate Market Value	As of Close of Business on
Common Stock - $0.001 par value	$ 157,268,326	September 30, 2016

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	Share Outstanding	As of Close of Business on
Common Stock - $0.001 par value	775,554,678	June 7, 2017

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") was incorporated on October 1, 1997 under the laws of the State of Delaware, and its wholly-owned subsidiary, Elite Laboratories, Inc. ("Elite Labs"), was incorporated on August 23, 1990 under the laws of the State of Delaware. On January 5, 2012, Elite Pharmaceuticals was reincorporated under the laws of the State of Nevada.

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 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 Applications ("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.

Commercial Products

We own, license or contract manufacture the following products current 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 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.

There have been several mergers relating to ECR and successor entities and transfer of brand name ownership since this product was originally launched. Lodrane D® is accordingly currently promoted and distributed in the U.S. by Valeant Pharmaceuticals International Inc. ("Valeant"). Lodrane D® is available over-the-counter but also has physician promotion. Lodrane D® is the one of the only adult brompheniramine containing products available to the consumer at this time.

Elite is manufacturing the product for Valeant and will receive manufacturing revenues for this product.

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 performs manufacturing and packaging of Methadone 10mg for Ascend.

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.

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 ANDA Purchase.

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

The first shipment of Hydroxyzine 10mg, Hydroxyzine 25mg and Hydroxyzine 50mg were made by Epic, pursuant to the Epic Manufacturing and License Agreement, in April 2015. Hydroxyzine 10mg, Hydroxyzine 25mg and Hydroxyzine 50mg are currently being manufactured and distributed by Epic 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 IR Product in the Epic Strategic Alliance Agreement Dated March 18, 2009 (the "Epic Strategic Alliance"). Oxy IR was developed at the Northvale Facility 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 first 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 Trimipramine products and Epic Pharma will manufacture the products. The Epic Pharma agreement insures the uninterrupted supply of generic Trimipramine. Trimipramine is a generic version of Surmontil®, a tricyclic antidepressant. Surmontil® and generic Trimipramine have total US sales of approximately $2 million in 2016 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, 20mg 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 fee 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 review 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 the 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 obtain 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. 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 fed study is in progress. The Company plans on initiating the fasted study after successful completion of the fed study. Resubmission of the SequestOx™ application requires successful completion of all required studies, including these fed and fasted studies.

Please note, however, that there can be no assurances of successful completion of any required studies. Furthermore, in the event of such successful completion of all required studies, there can be no assurances that the Company's intended future resubmission of the NDA product filing will be accepted by or receive marketing approval from the FDA. In addition, even if the Company receives marketing approval, there can be no assurances of future revenues or profits relating 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.

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 Company has not received a response from the FDA regarding this ANDA filing.

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 Company has not received a response from the FDA regarding this ANDA 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.

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 rights (depending on the ANDA) to Epic. Commercial manufacturing of these products is expected to be transferred to either Epic or the Northvale Facility, with the 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 License 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 consideration 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 Dose 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 amendments 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 to 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 License 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 twelve 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 transfers 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-200 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 a 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 note that there was a change in management of Epic that occurred in May 2016, concurrent with a change in ownership of Epic. The new management of Epic has advised us of their desire to renegotiate the 2015 SequestOx™ License Agreement. While the 2015 SequestOx™ License Agreement is still in effect, as a prudent business practice, we are currently cooperating with Epic and are engaged in such negotiations with Epic, which are ongoing, as well as pursuing other options relating to the license and/or distribution of SequestOx™. We believe that if agreement is reached with Epic on revised terms and conditions and amendment is made to the 2015 SequestOx™ License Agreement, such amendment may materially differ from the current 2015 SequestOx™ License Agreement.

In addition, on July 15, 2016, the FDA issued a Complete Response Letter, or CRL, regarding the NDA. The CRL stated that the review cycle for the 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 obtain 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. 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 fed study is in progress. The Company plans on initiating the fasted study after successful completion of the fed study. Resubmission of the SequestOx™ application requires successful completion of all required studies, including these fed and fasted studies.

There can be no assurances of successful completion of any required studies. Furthermore, in the event of such successful completion of all required studies, there can be no assurances that the Company's intended future resubmission of the NDA product filing will be accepted by or receive marketing approval from the FDA. In addition, even if the Company receives marketing approval, there can be no assurances of future revenues or profits relating 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.

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 us pursuant to the Mikah Thirteen ANDA Acquisition. Of the twelve approved ANDAs, Epic will have the exclusive right to market six products as listed in 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 Epic 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 be 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 defined by the Epic Manufacturing and License Agreement. The term of the Epic Manufacturing and License Agreement is five years and may be extended for an 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.

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 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, interests 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 in 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 manufacture 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.

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, we entered into an agreement with SunGen Pharma LLC ("SunGen") (the "SunGen Agreement") to undertake and 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 will share 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. 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 to market and sell the CNS Products using Elite's label. Elite will manufacture and package all four products on a cost-plus basis.

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. On July 15, 2016, the FDA issued a Complete Response Letter, or CRL, regarding the NDA. The CRL stated that the review cycle for the 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 can take to obtain approval of SequestOx™. Based on the FDA response, the Company believes there is a clear path forward to address the issues cited in the CRL. 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 fed study is in progress. The Company plans on initiating the fasted study after successful completion of the fed study. Resubmission of the SequestOx™ application requires successful completion of all required studies, including these fed and fasted studies. Please note that there can be no assurances of the Company receiving marketing authorization for SequestOx™, and accordingly, there can be no assurances that the Company will earn and receive the additional $7.5 million or future license fees. If the Company does not receive these payments or fees, it will materially and adversely affect our financial condition.

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"). Percocet® is a combination medication, with abuse deterrence, and is used to help relieve moderate to severe pain. The Company has not received a response from the FDA regarding this application. 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 acetaminophen tablets USP CII) 2.5mg/325mg, 5mg/325mg, 7.5mg/325mg and 10mg/325mg tablets ("Generic Hydrocodone/APAP"). Norco is a combination medication and is used to help relieve moderate to moderately severe pain. The Company has not received a response from the FDA regarding this application. 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.

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 result, costs incurred in relation to the development of these 10 products have not been material.

Research and development costs were $8.3 million, $12.4 million and $14.7 million for years ended March 31, 2017, 2016 and 2015, respectively. Costs incurred during the prior fiscal years relate almost entirely to the development of the abuse deterrent opioid product, SequestOx™, and costs incurred during the current fiscal year relate almost entirely 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.

On June 4, 2015, the Company entered into a sales and distribution licensing agreement which included a non-refundable payment of $5 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-refundable milestone is due upon the FDA's approval of Elite's NDA. Please note, as further detailed above, there can be no assurances of the Company receiving marketing authorization for SequestOx™, and accordingly, there can be no assurances that the Company will earn and receive the additional $7.5 million or future license fees. 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 6,635,284 (assigned to Celgene Corporation)	March 2018
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 two additional U.S. patents and two foreign patents. 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 to compensate the patent holder for the time required for FDA regulatory review of the product. Such benefits under the Drug Price Competition Act are 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 December 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 (the "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. Mikah 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 and 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, filed 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 prescription 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 has 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 product (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.

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 has 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.

Please note that, as discussed in "Discontinued Products" above, in March 2011, the FDA announced its intention to remove approximately 500 cough/cold and allergy related products from the U.S. market, with such list of 500 products including the Lodrane Extended Release Products. After this announcement by the FDA, the Company's customer for the Lodrane Products cancelled all outstanding orders and manufacturing of the Lodrane Products ceased. This cancellation of outstanding orders and the cessation of manufacturing of Lodrane Products had a material adverse effect on revenues for periods beginning subsequent to March 31, 2011.

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 drug 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 the 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. If, 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 complicated 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 market 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 general 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 a NDA in that the FDA waives the requirement of conducting complete 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 on individuals and companies that commit certain illegal acts relating to the generic drug approval process. In some situations, the Generic Drug Enforcement Act 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 provides 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., and 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 Acura 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. If 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 a NDA. ANDA products are referred to as generic pharmaceuticals and NDA products are referred to as branded pharmaceuticals. In the years ended March 31, 2017, 2016 and 2015 revenue from our ANDA segment was $8.6 million, $9.2 million and $5.0 million, respectively. In the years ended March 31, 2017, 2016 and 2015 revenue from our NDA segment was $1.0 million, $3.3 million and $0, respectively.

Segment information is consistent with the financial information regularly 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, 2017, we had 46 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 the 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 Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information 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 at http://www.Elitepharma.com under the Investor Relations tab for SEC Filings or by 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, 2017, 2016 and 2015, we incurred net losses from operations of approximately $7.4 million, $8.3 million, and $16.5 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, 2017 to support the anticipated commercial launch of SequestOx™ and also ensure operations through March 31, 2018, 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, 2017, we had cash on hand of approximately $10.6 million and a working capital surplus of $15.1 million, and, for the fiscal year ended March 31, 2017, we had losses from operations totaling $7.4 million, net other income totaling $9.3 million and net income of $3.8 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, methadone, phendimetrazine, isradipine, hydroxyzine and immediate release Lodrane D®, combined with the successful transfer of manufacturing site and commercial launch of the six remaining approved generic products licensed to Epic Pharma LLC which have not yet been commercialized, 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 and License Agreement, milestones, revenues and profit splits pursuant to the 2015 SequestOX™ License Agreement, profit splits earned from the commercial sale of Trimipramine pursuant to the Reddy's Trimipramine Distribution Agreement, revenues and profits earned pursuant to the SunGen Agreement and other opportunities in our pipeline, Elite eventually could be profitable. However, there can be no assurances that we will be able to timely raise additional funds, if needed, on acceptable terms through the 2017 LPC Purchase Agreement or otherwise, that the sales of the current generic product line will continue, that the 12 approved generic products licensed to Epic Pharma LLC will be successfully commercialization and generate future revenues or that the other opportunities in our pipeline will be successfully commercialized. There can also be no assurances of Elite becoming 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 will 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 be 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 of 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 a 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 postmarketing 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 Postmarketing 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 of 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 repackagers 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 regulations 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. The Affordable Care Act and any further changes to health care laws or regulatory framework that reduce our revenues or increase our costs 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 our 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 of 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. Our revenue and future profitability could be negatively affected by the passage of these laws or similar federal or state legislation. 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 opioids 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, 2017, intangible assets were approximately $6.4 million, or approximately 19% 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 Obama administration 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.

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.

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 risk 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.

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 additional 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 effect 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 present 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 SequestOx 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 meeting 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 issues 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. If 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 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. 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 received a Warning Letter from the U.S. Food and Drug Administration ("FDA") regarding Postmarketing 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.

On August 26, 2016, Elite received a Warning Letter from the FDA regarding Postmarketing Adverse Drug Experience (PADE) reporting. The Warning Letter relates to certain observations that the FDA believes 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 cites that Elite's Standard Operating Procedures (SOPs) do not adequately address how to monitor and receive adverse drug experiences (ADEs). While Elite has a contract with an external service provider for follow-up to ADEs, Elite remains responsible for ensuring the ADEs are appropriately investigated and that follow-up information is submitted in a timely manner to the FDA. The FDA believes that Elite does not have adequate SOPS for ADEs, and failed to investigate, evaluate, and timely report ADEs.

Elite takes the matters identified in the Warning Letter seriously and is currently addressing the deficiencies cited in the letter. The Company has been cooperating with the FDA to resolve any outstanding issues. The Warning Letter does not restrict the production or shipment of any of the Elite's products, or the sale or marketing of the Company's products, however unless and until the Company is able to correct outstanding issues 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. Please note that there can be no assurances that the Company will correct outstanding issues to the FDA's satisfaction, nor can there be any assurances of the FDA granting approval of pending drug applications in the event of the Company's successful resolution, to the satisfaction of the FDA of the issues identified in the Warning Letter.

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.

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, 2017, the closing sale price on the OTC Bulletin Board ("OTC-BB") of our Common Stock fluctuated from a high of $0.38 per share to a low of $0.13 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 5,540,550 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 5,540,550 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 June 7, 2017, there were outstanding shares of preferred stock convertible into approximately 158 million shares of Common Stock and warrants to purchase an aggregate of approximately 88.4 million shares of Common Stock at exercise prices of $0.0625 to $0.1521 per share, vested options to purchase an aggregate of approximately 4.9 million shares at a weighted average exercise price of $0.19. 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 of 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 Directors 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 making 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.

The restatement of our previously issued unaudited quarterly financial statements has been time-consuming and expensive and could expose us to additional risks that could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our common shares to decline.

We have restated our previously issued unaudited financial statements for the three months ended June 30, 2015 included in the Quarterly Report on Form 10-Q for the quarter ended June 30, 2015 and the unaudited financial statements for the three and six months ended September 30, 2015 included in the Quarterly Report on Form 10-Q for the quarter ended September 30, 2015. In addition, these restated financial statements include corrections of errors in accounting that were made in previously issued audited annual and unaudited interim periods, that we did not consider material pursuant to guidance provided by SEC Staff Accounting Bulletin 99, Materiality ("SAB 99") and SEC Staff Accounting Bulletin 108, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements ("SAB 108"), and accordingly reflected on the restated financial statements on a prospective basis.

This restatement (including the review of the errors in accounting that made such restatement necessary) has been time consuming and expensive, requiring the incurrence of substantial and unanticipated expenses and costs, including, without limitation, audit, legal, consulting, research and other professional fees in connection to the identification and correction of errors in accounting, restatement of previously issued financial statements and the remediation of material weaknesses in our system of internal controls over financial reporting. In an event of and to the extent that the actions taken to remediate the weaknesses in our system controls over financial reporting are not successful, we could be forced to incur additional time and expense. Furthermore, there is generally an increased risk of shareholder, governmental, or other actions in connection with the restatement of financial statements, with any such proceedings, regardless of outcome, usually consuming a significant amount of management's time and attention as well as related legal, accounting and other costs. In situations of a company not prevailing in any such proceedings, there is the possibility of substantial damages or settlement costs being required of the company that did not prevail.

We have previously identified material weaknesses in our internal control over financial reporting which could adversely affect our ability to report our financial condition, cash flows and results of operations in a timely and accurate manner and/or increase the risk of future misstatements, which could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our common shares and/or debt securities to decline.

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. Based on reviews conducted by management, our Independent Auditors and specific guidance from subject matter experts engaged by us, we have concluded that material weaknesses in our internal controls over financial reporting existed that contributed to the errors in accounting that necessitated the restatement of previously issued financial statements. A material weakness is a deficiency, or a combination of deficiencies, in internal controls over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

Management determined that we did not maintain effective internal controls over financial reporting as of the fiscal year ended March 31, 2016 due to the existence of the following material weaknesses identified by management: We did not maintain adequate segregation of duties in our accounting and financial reporting process. We have not appropriately restricted access to our accounting applications to appropriate users and we do not have processes in place that ensure that appropriate segregation of duties is maintained. Certain personnel have access to financial applications, programs, and data beyond that needed to perform their individual job responsibilities and without independent monitoring. This allows for the creation, review and processing of certain financial data without independent review and authorization. There are also certain financial personnel that have incompatible duties, including in the areas of cash disbursements, payroll, and journal entry reviews. We have not yet completed the process of assigning different people the responsibilities of authorizing transactions, recording transactions, and maintaining custody of assets to sufficiently reduce the opportunities to allow any person to be in a position to both perpetrate and conceal errors or fraud in the normal course of the person's duties. Particularly in the areas of purchases, cash disbursements, journal entry review and payroll, certain individuals have incompatible duties that limit our ability to identify and detect errors or fraud that may occur.

We identified and implemented remediation actions. The Company's management assessed the effectiveness of the Company's internal control over financial reporting as of March 31, 2017, 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, 2017, the Company's internal control over financial reporting is effective.

We regularly review and evaluate internal controls systems to allow management to report on the effectiveness of our internal controls over financial reporting, and there can be no assurances of Management's continued assertion of effective internal controls over financial reporting. We may discover additional weaknesses in our internal controls over financial reporting or disclosure controls and procedures, or may determine that existing controls are no longer effective. The next time we evaluate our internal controls over financial reporting and disclosure controls and procedures, if we identify one or more new material weaknesses or have been unable to timely remediate our existing material weaknesses, we would be unable to conclude that our internal controls over financial reporting or disclosure controls and procedures are effective. If we are unable to conclude that our internal controls over financial reporting or our disclosure controls and procedures are effective, or if our independent registered public accounting firm expresses an opinion that our internal controls over financial reporting is ineffective, we may not be able to report our financial condition and results of operations in a timely and accurate manner, which could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our common shares to decline. In addition, any potential future restatements could subject us to additional adverse consequences, including sanctions by the SEC, shareholder litigation and other adverse actions. Moreover, we may be the subject of further negative publicity focusing on such financial statement adjustments and resulting restatement and negative reactions from our shareholders, creditors, or others with whom we do business. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our common shares to decline.

Our Common Stock is considered a "penny stock". The application of the "penny stock" rules to our Common Stock could limit the trading and liquidity of our Common Stock, adversely affect the market price of our Common Stock, and increase the transaction costs to sell shares of 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 an 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 volume limitations in over-the-counter securities. Because trades and quotations on the OTCBB involve a manual process, the market information for such securities 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 to 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 or 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 the manual order processing involved in handling OTCBB trades, order processing and reporting may be delayed, and an individual may not be able to cancel or 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 the 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 foregoing, 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 23.0344 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. Except as discussed below, 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.

Arbitration with Precision Dose, Inc.

On May 9, 2014, Precision Dose Inc., the parent company of TAGI Pharmaceuticals, Inc., commenced an arbitration against the Company alleging that the Company failed to properly supply, price and satisfy gross profit minimums regarding Phentermine 37.5mg tablets, as required by the parties' agreements. Elite denied Precision Dose's allegations and has counterclaimed that Precision Dose is no longer entitled to exclusivity rights with respect to Phentermine 37.5mg tablets, and is responsible for certain costs, expenses, price increases and lost profits relating to Phentermine 37.5mg tablets and the parties' agreements. The parties have reached agreement in settlement of these issues, with Precision Dose agreeing to pay certain amounts to the Company in exchange for Elite agreeing to restore exclusivity rights with respect to Phentermine 37.5mg tablets, subject to certain defined conditions. Both parties have been complying with the agreed settlement terms and the Company has notified the Arbitrator of this settlement, requesting the issuance of proceeding termination documents.

Due to the agreements reached and adhered to with regards to this issue, the Company has determined that no contingency loss needs to be recorded.

Please see the risk factor in Item 1A titled “We have been dependent on one or a few major customers. If we are unable to develop more customers our business most likely will be adversely affected.”

ITEM 4 MINE SAFETY DISCLOSURES

Not Applicable.

PART II

ITEM 5 MARKET FOR COMPANY'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF 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 periods 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-dealer 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, 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
Fiscal Year Ending March 31, 2016		
March 31, 2016	$ 0.42	$ 0.29
December 31, 2015	$ 0.44	$ 0.21
September 30, 2015	$ 0.25	$ 0.20
June 30, 2015	$ 0.27	$ 0.20

As of June 7, 2017, the last reported sale price of our Common Stock, as reported by the OTCBB, was $0.20.

Holders

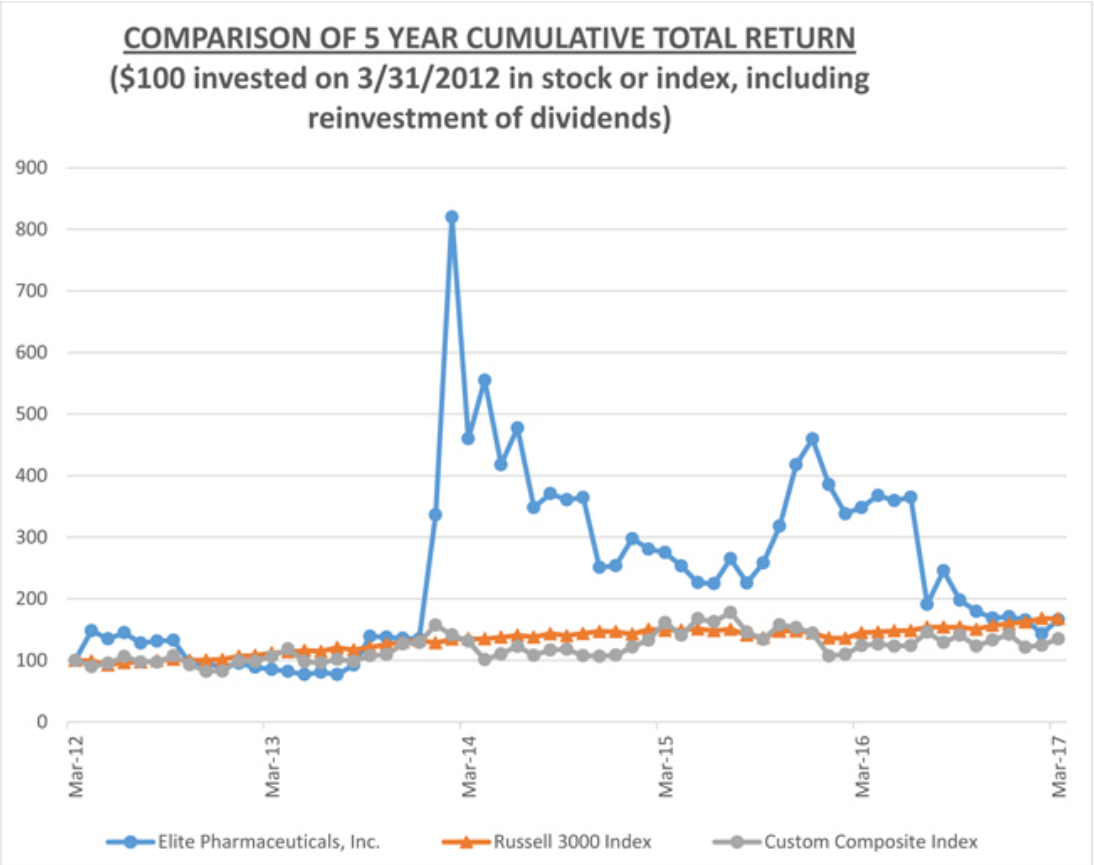
As of June 7, 2017, there were, respectively, approximately 130 and 1 holders of record of our Common Stock and Series J Preferred Stock.

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.



(performance data provided by Factset)

	Value of $100 Invested on March 31, 2012 March 31,					
	2012	2013	2014	2015	2016	2017
Elite Pharmaceuticals Inc.	$ 100.00	$ 85.51	$ 460.11	$ 275.28	$ 348.31	$ 168.18
Russell 3000 Index	$ 100.00	$ 112.16	$ 134.87	$ 148.70	$ 145.21	$ 168.03
Custom Composite Index	$ 100.00	$ 106.12	$ 112.12	$ 161.51	$ 124.16	$ 135.22

(source: Factset)

Recent Sales of Unregistered Securities

During the year ended March 31, 2017, the Company issued an aggregate of 176.4 million shares of Common Stock, with such shares constituting unregistered securities, consisting of 3.9 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, 29.6 million shares of Common Stock issued pursuant to the exercise of warrants, and 142.9 million shares of Common Stock issued pursuant to the conversion of Series I Convertible Preferred Shares. 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, 2017.

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	—	—	1,407,812(2)
Total	**—**	**—**	**4,407,812**

(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 common shares are reserved for grant and issuance pursuant to the 2014 Plan. The 2014 Plan is administered and interpreted by our Compensation Committee (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 appreciation 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 granted 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 unrestricted 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 persons 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 common shares are reserved for grant and issuance pursuant to the 2009 Equity Incentive Plan. The 2009 Equity Incentive Plan is administered and interpreted by our 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 do 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 that 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 to 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. Please see Note 1 to the audited financial statements "Summary of Significant Accounting Policies", for further discussion on prospective restatement of financial information to reflect corrections in accounting error.

	Years Ended March 31,				
	2017	2016	2015	2014	2013
	(dollars in thousands, except per share amounts)				
Consolidated Statement of Operations Data:					
Total revenue	$ 9,638	$ 12,498	$ 5,015	$ 4,601	$ 3,404
Loss from operations	(7,356)	(8,317)	(16,507)	(5,284)	(1,563)
Other income (expense), net	9,300	7,113	21,724	(36,270)	3,259
Benefit from sale of state net operating loss credits	1,868	520	3	293	354
Net income (loss)	3,811	(683)	5,221	(41,261)	2,050
Change in carrying value of convertible preferred share mezzanine equity	20,714	(9,286)	23,709	(55,314)	(562)
Net income (loss) attributable to common shareholders	24,525	(9,969)	28,930	(96,575)	1,488
Basic income (loss) per share attributable to common shareholders	0.03	(0.01)	0.05	(0.21)	(0.00)
Diluted income (loss) per share attributable to common shareholders	(0.01)	(0.01)	(0.02)	(0.21)	(0.00)
Consolidated Balance Sheet Data:					
Cash	$ 10,595	$ 11,512	$ 7,464	$ 6,942	$ 369
Current assets	18,413	16,714	12,331	9,925	2,543
Total assets	34,311	31,674	25,920	24,318	11,125
Current liabilities	3,345	4,640	5,069	6,161	5,357
Working capital	15,068	12,074	7,262	3,764	(2,814)
Long-term liabilities	5,302	15,870	20,583	38,373	8,107
Convertible preferred share mezzanine equity	-	44,286	35,000	60,982	6,335
Total shareholders' equity (deficit)	25,664	(33,122)	(34,731)	(81,198)	(8,673)
Other Financial Data:					
Cash used in operating activities	$ (7,884)	$ (2,765)	$ (15,103)	$ (4,217)	$ (1,693)
Cash (used in) provided by investing activities	(1,105)	(1,949)	2,879	(558)	(192)
Cash provided by financing activities	8,071	8,762	12,746	11,347	1,585

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 Fiscal 2015. Prior to Fiscal 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 Fiscal 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 our 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 the FDA. In March 2016, we received notification of the FDA's acceptance of this filing and that such filing has been granted priority review 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 the SequestOx™ 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 meeting to discuss steps that we could take to obtain approval of SequestOx™. Based on the FDA response, we believe that there is a clear path forward to address the issues cited in the CRL. We believe 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 fed study is in progress. The Company plans on initiating the fasted study after successful completion of the fed study. Resubmission of the SequestOx™ application requires successful completion of all required studies, including these fed and fasted studies. Please note, however, that there can be no assurances that our intended future resubmission of the NDA product filing will be accepted by or receive marketing approval from the FDA. In addition, even if we receive marketing approval, there can be no assurances of future revenues or profits relating 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.

On August 9, 2016, we 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 Company has not received a response from the FDA regarding this ANDA filing.

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 Company has not received a response from the FDA regarding this ANDA 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.

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, 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 offset 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 million milestone in January 2016 related to the filing of a New Drug Application for SequestOx™. This milestone payment was offset by increases in license fees 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 in 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 for 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 $0.36 million, an increase of $0.03 million or 7% from $0.33 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 (expense), net	$ 9,299,500	$ 7,113,336	$ 2,186,164	31%

Other income (expense), 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 Economic Development Authority for the sale of net tax benefits. The Company sold the net tax benefits approved for total proceeds of $1,870,114.

Change in value of Series I convertible preferred stock:

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.

Years Ended March 31, 2016 and 2015

Revenue, Cost of revenue and Gross profit:

	Years Ended March 31,		Change	
	2016	2015	Dollars	Percentage
Manufacturing fees	$ 8,002,866	$ 3,870,457	$ 4,132,409	107%
Licensing fees	4,495,466	1,139,789	3,355,677	294%
Lab fee revenues	-	5,000	(5,000)	-100%
Total revenue	12,498,332	5,015,246	7,483,086	149%
Cost of revenue	4,484,162	3,013,592	1,470,570	49%
Gross profit	$ 8,014,170	$ 2,001,654	$ 6,012,516	300%
Gross profit - percentage	64%	40%		

Total revenues for the year ended March 31, 2016 increased by $7.5 million, or 149%, to $12.5 million, as compared to $5.0 million, for the corresponding year due to continued growth in the Company's generic product lines.

Manufacturing fees increased by $4.1 million, or 107%, due to continued growth in the Company's generic product sales.

Licensing fees increased by $3.4 million, or 294%. This increase 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 for SequestOx™ in addition to increased profit splits from product sales relating to TAGI and Epic.

Costs of revenue consists of manufacturing and assembly costs. Our costs of revenue increased by $1.5 million or 49%, to $4.5 million, as compared to $3.0 million for the year ended March 31, 2015. This increase is due to the increase in manufacturing volumes.

Our gross profit margin was 64% during the year ended March 31, 2016 as compared to 40% during the year ended March 31, 2015. This increase is due in large part to the Company earning a one-time, non-refundable $2.5 million milestone in January 2016 related to the filing of an NDA for SequestOx™.

Operating expenses:

	Years Ended March 31,		Change	
	2016	2015	Dollars	Percentage
Operating expenses:				
Research and development	$ 12,428,783	$ 14,727,472	$ (2,298,689)	-16%
General and administrative	2,903,178	2,904,114	(936)	0%
Non-cash compensation	333,362	260,045	73,317	28%
Depreciation and amortization	665,647	616,995	48,652	8%
Total operating expenses	$ 16,330,970	$ 18,508,626	$ (2,177,656)	-12%

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, 2016 decreased by $2.2 million, or 12%, to $16.3 million, as compared to $18.5 million for the year ended March 31, 2015.

Research and development costs for the year ended March 31, 2016 were $12.4 million, a decrease of $2.3 million or 16% from $14.7 million of such costs for the year ended March 31, 2015. The decrease was due to the timing and composition of ongoing development of our abuse deterrent opioid and other products.

General and administrative expenses for the year ended March 31, 2016 and 2015 were $2.9 million. We have continued to increase the utilization of our manufacturing facilities resulting in lower unallocated overheads.

Non-cash compensation expense for the year ended March 31, 2016 and 2015 was $0.33 million, an increase of $0.07 million, or approximately 28% from $0.26 million for the comparable period of the prior year. The increase was due to the issuance of options to purchase an aggregate of 4,334,000 shares of Common Stock to various employees during the year ended March 31, 2016, primarily pursuant to employment agreements, and the timing of the amortization schedule established at the time of issuance of the related stock options

Depreciation and amortization expense for the year ended March 31, 2016 was $0.67 million, an increase of $0.05 million, or 8% from $0.62 million of such costs for the year ended March 31, 2015. The increase was primarily due to the expansion and upgrading of the Northvale Facility, which has required substantial investments in property, plant and equipment.

As a result of the foregoing, our loss from operations for the year ended March 31, 2016 was $8.3 million, compared to a loss from operations of $16.5 million for the year ended March 31, 2015.

Other income (expense):

	Years Ended March 31,		Change	
	2016	2015	Dollars	Percentage
Other income (expense):				
Interest expense and amortization of debt issuance costs	$ (280,670)	$ (287,231)	$ 6,561	2%
Change in fair value of derivative instruments	7,394,006	20,340,874	(12,946,868)	-64%
Gain on sale of investment	-	1,670,685	(1,670,685)	-100%
Other income (expense), net	$ 7,113,336	$ 21,724,328	$ (14,610,992)	-67%

Other income for the year ended March 31, 2016 totaled a net other income of $7.1 million, a decrease in net other income of $14.6 million from the net other income of $21.7 million for the year ended March 31, 2015. 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, 2016 totaling $7.4 million, as compared to a net derivative income of $20.3 million and gain on sale of investment totaling $1.7 for the year ended March 31, 2015, a $14.6 million overall decrease in other income. 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, 2016, including credits for income taxes totaling $0.5 million was $1.2 million, compared to a net income of $5.2 million, inclusive of credit for income taxes totaling $0.003 million for the year ended March 31, 2015.

Net benefit from sale of state net operating loss credits

During the year ended March 31, 2016, Elite Labs, a wholly owned subsidiary of Elite, received final approval from the New Jersey Economic Development Authority for the sale of net tax benefits. The Company sold the net tax benefits approved for total proceeds of $520,452.

Change in value of Series I convertible preferred stock:

Changes in the value in our Series I convertible preferred stock, which is included in the calculation of net loss attributable to common shareholders resulted in the net loss being increased by $9.3 million for the year ended March 31, 2016, as compared to an increase in net income attributable to common shareholders of $23.7 million for the year ended March 31, 2015. Accordingly, net income (loss) attributable to common shareholders for the year ended March 31, 2016 was net loss of $10.0 million, compared to net income attributable to common shareholders of $28.9 million for the year ended March 31, 2015.

Liquidity and Capital Resources

Capital Resources

	March 31,		
	2017	2016	Change
Current assets	$ 18,412,720	$ 16,713,956	$ 1,698,764
Current liabilities	3,344,746	4,640,189	(1,295,443)
Working capital	15,067,974	12,073,767	2,994,207

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, 2017, the Company had cash on hand of $10.6 million and a working capital surplus of $15.1 million. The Company believes that such resources, combined with the Company's access to the new equity line with Lincoln Park Capital (see below), are sufficient to fund operations through the current operating cycle. For the year ended March 31, 2017, the Company had losses from operations totaling $7.4 million, net other income totaling $9.3 million and net income of $3.8 million. In addition, changes in the carrying value of preferred share mezzanine equity for the year ended March 31, 2017 were an increase of $20.7 million, with such amount being charged to net income available to common shareholders. Please note that the Company's other income/(expenses) and net income available to common shareholders are significantly influenced by the fluctuations in the fair value of outstanding preferred share and warrant derivatives, and that 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) increased by $3.0 million from $12.1 million as of March 31, 2016 to $15.1 million as of March 31, 2017, with such increase being primarily related to capital financings that included $7.6 million in proceeds from the sale of Common Stock pursuant to the 2014 Purchase Agreement with Lincoln Park and $1.9 million in proceeds from the exercise of cash warrants and options, offset in large part by purchases of fixed assets and leasehold improvements totaling $1.1 million and payment on principal of $0.2 million in NJEDA Bonds and other loans. Please note that capital financings provide cash to the Company without a corresponding current liability and accordingly have an accretive effect on working capital.

The Company does not anticipate being profitable for the fiscal year ending March 31, 2018, 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 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,		
	2017	2016	2015
Net cash used in operating activities	$ (7,883,861)	$ (2,765,421)	$ (15,103,233)
Net cash (used in) provided by investing activities	(1,104,976)	(1,948,829)	2,879,213
Net cash provided by financing activities	8,071,351	8,762,249	12,746,424

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 issuance of common stock to Lincoln Park Capital of $7.6 million, proceeds from the exercise of cash warrants and option 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 Fiscal 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 issuance of common stock to Lincoln Park Capital of $6.2 million, proceeds from the exercise of cash warrants 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 million during Fiscal 2016.

Year Ended March 31, 2015

Net cash used in operating activities for the year ended March 31, 2015 was $15.1 million, which included net income of $5.2 million, and changes in operating assets and liabilities of $0.8 million. The changes in the balance of assets and liabilities include an increase in account receivables, inventory and prepaid expenses and other current assets totaling $2.0 million, and offset by an increase in deferred revenues and customer deposits of $1.2 million. These instances of decreases in cash are offset by change in non-cash compensation accrued of $0.7 million, non-cash change in fair value of derivative financial instruments – warrants of $20.3 million, non-cash compensation from the issuance of common stock of $0.3 million and gain on sale of investment of $1.7 million.

Net cash provided by investing activities for the year ended March 31, 2015 was $2.9 million. This consisted in $2.0 million of cash expenditures related to purchases of property and equipment, offset by $5.0 million from proceeds related to the sale of investment in Novel.

Net cash provided by financing activities for the year ended March 31, 2015 was $12.7 million. This consisted of proceeds from the issuance of common stock to Lincoln Park Capital of $13.2 million, proceeds from the exercise of cash warrants and option exercises of $0.8 million; offset by $0.2 million in other loan principal payments and $1.1 million related to payment of NJEDA bonds.

Overall, as a result of the foregoing, the Company had a net increase in cash of $0.5 million during Fiscal 2015.

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 110.6 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 ("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 5,540,550 shares of Common Stock and we are required to issue up to 5,540,550 additional shares of Common Stock pro rata as we require Lincoln Park to purchase our shares under the Purchase Agreement over the term of 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 Regulation 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 from registration requirements.

The 2017 LPC Purchase Agreement and the 2017 LPC Registration Rights Agreement contain customary representations, warranties, agreements and conditions to completing future sale transactions, indemnification rights and obligations of the parties. 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 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 Purchase Agreement. Lincoln Park has no right to require any sales by us, but is obligated to 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 our 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 used 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.

Hakim $1,000,000 Bridge Revolving Credit Line

On October 15, 2013 (the "Hakim Credit Line Effective Date"), and as amended on January 4, 2015, we entered into a bridge loan agreement (the "Hakim Loan Agreement") with Nasrat Hakim, our Chairman of the Board of Directors, President and CEO. Under the terms of the Hakim Loan Agreement, we have the right, in our 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. Mr. Hakim provided the Credit Line for the purpose of supporting the acceleration of our product development activities. The outstanding amount matured on March 31, 2016. Amounts borrowed under the Hakim Credit Line bear interest at the rate of ten percent (10%) per annum. As of March 31, 2016, the principal balance owed under the Credit Line was $718k with an additional $71k in accrued interest being also owed, in accordance with the terms and conditions of the Credit Line. The entire principal amount due under the Hakim Credit Line, which expired on March 31, 2016, was paid on May 24, 2016. An additional $9k in interest, accrued at an annual rate of 10%, was incurred on the principal balance outstanding during the period beginning on April 1, 2016 and ending on May 24, 2016, the date on which the principal balance was paid. All interest amounts owed in relation to principal balances outstanding on the Hakim Credit Line and consisting of interest amounts due and owing as of March 31, 2016 and interest amounts incurred subsequent to March 31, 2016 and up to the date of principal repayment, were paid on May 24, 2016.

Convertible Note Payable to Mikah Pharma LLC

On August 1, 2013, Elite Labs, a wholly owned subsidiary of the Company, executed an asset purchase agreement (the "Mikah Purchase Agreement") with Mikah Pharma LLC ("Mikah"), an entity that is wholly owned by Mr. Nasrat Hakim, who, in conjunction with this transaction, was appointed as Elite's CEO, President and a Director on August 2, 2012, and acquired from Mikah a total of 13 Abbreviated New Drug Applications ("ANDAs") consisting of 12 ANDAs approved by the FDA and one ANDA under active review with the FDA, and all amendments thereto (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"). Please see "Thirteen Abbreviated New Drug Applications ("ANDAs")" in Part I, Item 1 Business, above for more information on the Acquisition. The Mikah Note was amended on February 7, 2014 to make it convertible into shares of the Company's Series I 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 per $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 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 (the "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, and was retired.

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 Fund 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, 2017.

The NJEDA Bonds require the Company to make an annual principal payment on September 1st of varying amounts as specified in the loan 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, at par in July 2014.

Contractual Obligations

The following table lists our enforceable and legally binding non-cancellable obligations as of March 31, 2017:

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Long term debt	$ 2,537,808	$ 289,048	$ 570,778	$ 317,982	$ 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	1,075,965	173,623	270,055	197,762	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, 2017, 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, 2017, 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 April 2015, the FASB issued ASU 2015-3, *Simplifying the Presentation of Debt Issuance Costs* ("ASU 2015-3"). ASU 2015-3 revises previous guidance to require that debt issuance costs be reported in the audited consolidated financial statements as a direct deduction from the face amount of the related liability, consistent with the presentation of debt discounts. Prior to the amendments, debt issuance costs were presented as a deferred charge (i.e. an asset) on the audited consolidated financial statements. This new guidance is effective for the annual period ending after December 15, 2015, and for annual periods and interim periods thereafter. The amendments must be applied retrospectively. The Company has adopted the provisions of ASU 2015-03. Refer to Note 2 Change in Accounting Principle for the effect of adopting ASU 2015-03 on the consolidated balance sheet as of March 31, 2016.

Recently Issued Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The core principle of ASU 2014-09 is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and services. This standard is effective for fiscal years and interim reporting periods beginning after December 15, 2016. In August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date.* The amendments in this update deferred the effective date for implementation of ASU 2014-09 by one year and is now effective for annual reporting periods beginning after December 15, 2017. Early application is permitted only as of annual reporting periods beginning after December 15, 2016 including interim reporting periods within that period. Topic 606 is effective for the Company in the first quarter of fiscal 2019. The Company is currently evaluating the effects of ASU 2014-09 and related ASUs noted below on its audited consolidated financial statements.

From March through December 2016, 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 July 2015, the FASB issued ASU 2015-11, *Simplifying the Measurement of Inventory (Topic 330)* ("ASU 2015-11"). The amendments in ASU 2015-11 clarify the determination of net realizable value of inventory, applicable to measurement of inventory asset value on the balance sheet. The amendments do not change the core principal of the guidance provided in Topic 330, specifically the valuation of inventory at the lower of cost or market value, with market value being determined by the net realizable value of the inventory item(s). The amendments clarify, however, that net realizable value is to be measured as the estimated selling price in the ordinary course of business, less reasonably predicable costs of completion, disposal, and transportation. The guidance is effective for the annual period beginning after December 15, 2016, and for annual periods and interim periods thereafter, with early adoption being optional and permitted as of the beginning of an interim or annual reporting period. The Company is currently evaluating the effects of ASU 2015-11 on its audited consolidated financial statements.

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 March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting (Topic 718)* ("ASU 2016-09"). The amendments in ASU 2016-09 provide revised guidance in relation to the following with regards to share based payments: i) Accounting for forfeitures, ii) Income tax effects, and iii) classification of excess tax benefits. The guidance is effective for the annual period beginning after December 15, 2016, and for annual periods and interim periods thereafter, with early adoption being optional and permitted as of the beginning of an interim or annual reporting period. The Company is currently evaluating the effects of ASU 2016-09 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 the Company beginning after December 15, 2017, although early adoption is permitted. 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 new standard is expected to be effective for fiscal years, and interim periods within those years, beginning after December 15, 2017, with early adoption permitted. 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. 2017-01 "*Business Combinations (Topic 805) – Clarifying the Definition of a Business"* (ASU 2017-01). ASU 2017-01 clarifies the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The amendments in this update provide a screen to determine when an integrated set of assets and activities (collectively referred to as a "set"), is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. This screen reduces the number of transactions that need to be further evaluated. ASU 2017-01 is effective for annual periods beginning after December 15, 2017, including interim periods within those periods, with early adoption permitted. The amendments in this update should be applied prospectively on or after the effective date. The Company is currently evaluating the effects of ASU 2017-01 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.

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 QUANITTATIVE 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 three 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 the 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, 2017. Based on that evaluation, the Company's Chief Executive Officer and the Company's Chief Financial Officer have concluded that the Company's disclosure controls and procedures were effective as of March 31, 2017 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, 2017, 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, 2017, 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, 2017. This report appears on page 75 of this Annual Report on Form 10-K.

Changes in internal control over financial reporting

During Fiscal 2017, the Company has taken significant actions to remediate the material weaknesses relating to inadequate segregation of duties and controls over the financial reporting of complex accounting issues as described in our Annual Report on Form 10-K filed with the SEC on June 15, 2016. Independent, third party subject matter experts were engaged to assist with the documentation and evaluation of the existing control environment, identification of gaps and weaknesses in controls, as well as advise on the formulation and implementation of improved controls and remediation of weaknesses identified.

Changes in controls relating to the remediation of segregation of duties:

In connection with the current year assessment, an evaluation was performed by the subject matter experts which led to a shift in certain roles and responsibilities in order to enhance the segregation of duties in certain key transaction processes. More specifically:

- Workflow enhancements were implemented to ensure review and approval responsibilities for payroll, cash disbursements and journal entries were well documented and reassigned to other members of management.
- New software was implemented to require separate initiation and approval roles for disbursements,
- Financial reporting experts were engaged to provide further segregation within our financial reporting process, providing enhancements and separation between the reconciliation process, the preparation of the financial statements and the review and approval process.
- Key systems are regularly monitored to ensure that user access is appropriate in the enhanced environment.

Changes in controls relating to the remediation of financial reporting of complex accounting issues:

Management engaged the subject matter experts to assist in the identification, evaluation, documentation and reporting of unusual or complex transactions that could have an accounting implication under GAAP. In connection with this enhancement, Management also implemented additional review and reconciliation steps were added to the financial reporting process to ensure that transactions and contracts are appropriately recognized in the proper period.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited Elite Pharmaceuticals, Inc. and Subsidiary's (the "Company") internal control over financial reporting as of March 31, 2017, based on criteria established in *Internal Control—Integrated Framework (2013 edition)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. 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 audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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.

In our opinion, Elite Pharmaceuticals, Inc. and Subsidiary maintained, in all material respects, effective internal control over financial reporting as of March 31, 2017, based on criteria established in *Internal Control—Integrated Framework (2013 edition)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows of the Company, and our report dated June 14, 2017, expressed a(n) unqualified opinion.

/s/ Buchbinder Tunick & Company LLP
Wayne, New Jersey
June 14, 2017

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	56	Chairman of the Board, President, and Chief Executive Officer	August 1, 2013	III
Barry Dash, Ph. D.	86	Director	April 2005	II
Jeffrey Whitnell	61	Director	October 2009	III
Eugene Pfeifer	77	Director	April 2016	I
Davis Caskey	69	Director	April 2016	I
Carter J. Ward	53	Chief Financial Officer, Secretary and Treasurer	July 2009	
Douglas Plassche	53	Executive Vice President of Operations	August 2013	

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 Director of Quality Unit at TheraTech, overseeing manufacturing and research and development. In 2009, Mr. Hakim founded Mikah Pharma, LLC, a virtual, fully functional pharmaceutical company. Mr. Hakim holds a Bachelor in Chemistry/Bio-Chemistry and Masters of Science in Chemistry from California State University at Sacramento, Sacramento, CA; a Masters in Law with Graduate Certification in U.S. and International Taxation from St. Thomas University, School of Law, Miami, FL.; and a Graduate Certification in Regulatory Affairs (RAC) from California State University at San Diego, San Diego, CA. Mr. 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, and 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 Company (Nabisco Brands, Inc.) from 1978 to 1982. From 1976 to 1978 he was Vice President and Director of Laboratories of the Consumer Products Division of 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 was Assistant Professor at the College of Pharmaceutical Sciences from 1956 to 1960. He is a member of the American Pharmaceutical Association, the American Association for the Advancement of Science and the Society of Cosmetic Chemist, American Association of Pharmaceutical Scientists, Drug Information Association, American Foundation for Pharmaceutical Education, and Diplomate American Board of Forensic Examiners. He is the author of 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 since October 2009, member of the Nominating Committee since September 2016 and designated by the Board as an "audit committee financial expert" as defined under applicable rules under the Exchange Act. Since April 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 medical device company. From June 2009 to June 2010, Mr. Whitnell provided financial advisory services to various healthcare companies, including ReliefBand Medical Technologies. From June 2004 to June 2009, Mr. Whitnell was Chief Financial Officer and Senior Vice President of Finance at Akorn, Inc. From June 2002 to June 2004, Mr. Whitnell was Vice President of Finance and Treasurer for Ovation Pharmaceuticals. From 1997 to 2001, Mr. Whitnell was Vice President of Finance and Treasurer for MediChem Research. Prior to 1997, Mr. Whitnell held various finance positions at Akzo Nobel and Motorola. Mr. 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 of 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 expert provide specific experience to serve as a director for the Company.

Eugene Pfeifer

Eugene Pfeifer has served as a Director since April 2016 and a member of the Nominating Committee and Compensation Committee since September 2016. Mr. Pfeifer brings 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 from 1980 to 1985. Since retiring from legal practice in 2009, Mr. Pfeifer has 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 Competition 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 issues, 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 Trade Commission, where he represented the FTC in Federal Court to enjoin violations of the Federal Trade Commission Act, and served ten years in the Chief 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 Supreme Court. Mr. Pfeifer is a graduate of Brown University and the Georgetown University Law Center. Mr. Pfeifer's qualifications and extensive experience in the 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 Board of Directors.

Davis Caskey

Davis Caskey has served as a Director since April 2016, and a member of the Audit Committee, the nominating Committee and the Compensation 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 to 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 and 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 brings 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.

Jeenarine Narine

Jeenarine Narine served as a Director from June 2009 to April 2016. Mr. Narine was elected as a member of Elite's Board in June 2009 as one of three directors designated by Epic pursuant to the terms of the Epic Strategic Alliance Agreement (see Item 13: "Certain Relationships and Related Transactions and Director Independence; Certain Related Person Transactions; Strategic Alliance Agreement/Transactions With Epic Pharma LLC And Epic Investments LLC" below). Since December 2010, Mr. Narine has been the President and Chief Operating Officer of Epic Pharma, LLC, a manufacturer of generic pharmaceuticals and Elite's strategic partner pursuant to the Epic Strategic Alliance Agreement, in which capacity he oversees all manufacturing operations. From July 2008 to December 2010, Mr. Narine served as Epic Pharma's Executive Vice President of Manufacturing and Operations. Mr. Narine is also the current President of Eniran Manufacturing Inc., a contract manufacturer of dietary and nutritional supplements, and has held such office since 2000. In addition, Mr. Narine has been since 1989 the President of A&J Machine Inc., a company owned by Mr. Narine that is engaged in the sales of new and used pharmaceutical manufacturing equipment. In addition to this professional experience, Mr. Narine graduated from the Guyana Industrial Institute, where he studied Metalology and Welding. Mr. Narine's experience as President and Chief Operating Officer and, previously, as Executive Vice President of Manufacturing and Operations of Epic Pharma LLC and his knowledge of pharmaceutical manufacturing equipment led to the conclusion that he is qualified to serve as a director.

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 generic pharmaceuticals and nutraceuticals in India. Mr. Ward began his career as a certified public accountant in the audit department of KPMG and is a Certified 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 more than 100 products. From 2007 to 2009, Mr. Plassche was the Senior Director of Manufacturing for PAR Pharmaceuticals, overseeing 200 employees and the 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. Based solely on a review of the copies of such Forms received by us, we found that, during the fiscal year ended March 31, 2017, Eugene Pfeifer filed a Form 3 late.

Committees of the Board

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

Audit Committee

During Fiscal 2017, the members of the Audit Committee were Jeffrey Whitnell (Chairman of the Audit Committee), Dr. Barry Dash. Davis Caskey 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 the 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 NYSE MKT LLCE or any other national exchange).

Nominating Committee

During Fiscal 2017, the members of the Nominating Committee were Nasrat Hakim (Chairman of the Nominating Committee), Dr. Barry Dash, Eugene Pfeifer, Davis Caskey and Jeenarine Narine (for the period of April 1, 2016 through Mr. Narine's resignation from the Board on April 7, 2016). There were no material changes to the procedures by which security holders may recommend nominees to our Board of Directors since the filing of our last Annual Report on Form 10-K.

Compensation Committee

During Fiscal 2017, the members of the Compensation Committee were Dr. Barry Dash (Chairman of the Compensation Committee), Jeffrey Whitnell, Eugene Pfeifer, Davis Caskey and Nasrat Hakim.

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. As of September 2016, the members of the Compensation Committee are Dr. Barry Dash (Chairman of the Compensation Committee), Jeffrey Whitnell, Eugene Pfeiffer, Davis Caskey and Nasrat Hakim. 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, 2017 were:

- Nasrat Hakim, Chairman of the Board, President, and Chief Executive Officer, 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 two key employees during the fiscal year ended March 31, 2017- George Kenneth Smith and Barbara Ellison (Barbara Ellison retired from the Company, effective June 1, 2016 and is no longer an employee of the Company).

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 Chairman of the Board, President, and CEO, 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's 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 an 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 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.

Barbara Ellison

On March 3, 2014, the Company entered into an employment agreement with Ms. Barbara Ellison (the "Ellison Employment Agreement"). Pursuant to the Ellison Employment Agreement, Ms. Ellison serves as an at-will employee, in the position of Vice President of Quality Operations and Regulatory Affairs, commencing on March 24, 2014. The Ellison Employment Agreement includes a total base compensation of $190,000, consisting of $165,000 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. Ms. Ellison is also eligible for an annual bonus in cash and/or equity based awards for up to an equivalent of 25% of base salary, with such annual bonus being granted based upon the achievement of agreed milestones in the discretion of the Company and its Chief Executive Officer. In addition, pursuant to the Ellison Employment Agreement, Ms. Ellison was granted options to purchase 600,000 shares of Common Stock, at a price of $ 0.33 per share, (the closing price of the Common Stock on the date of the Ellison Employment Agreement). The options were issued pursuant to the 2009 Employee Stock Option Plan and vest over a period of three years with the vesting period commencing one year from the date of issuance.

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

On March 1, 2015, Ms. Ellison 's compensation was adjusted to include a total base compensation of $193,800, consisting of $168,800 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.

The Common Stock component of Ms. Ellison'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.

Ms. Ellison retired from the Company, effective June 1, 2016 and is no longer an employee of the Company. As of the date of Ms. Ellison's retirement, the options issued to Ms. Ellison were not fully vested, with 400,000 shares being vested and 200,000 shares being non-vested. Pursuant to the 2009 Employee Stock Option Plan, vesting of options require that the employee holder of such options be employed by the Company on each vesting date. Accordingly, future vesting of the non-vested option to purchase 200,000 held by Ms. Ellison at the time of her retirement's retirement is prohibited. The vested options to purchase up to 400,000 shares at a price of $0.33 per share expired without being exercised 90 days from the date of termination of Ms. Ellison's employment with the Company, pursuant to the 2009 Employee Stock Option Plan.

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 Employment 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 Common 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 of 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 effect 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.

Jerry Treppel

On December 1, 2008, Elite entered into a compensation agreement with Mr. Treppel (the "First Treppel Agreement") providing for the terms under which Mr. Treppel will serve as the non-executive Chairman of the Board. Pursuant to the First Treppel Agreement, Mr. Treppel will serve as the non-executive Chairman of the Board until immediately prior to the next annual meeting of the Company's stockholders; provided, however, that following such annual meeting, and each subsequent annual meeting of the Company's stockholders, if the Board elects Mr. Treppel as the non-executive Chairman of the Board, the term of the First Treppel Agreement will be extended through the earlier of (a) the date of the next subsequent annual meeting of the Company's stockholders and (b) the date upon which Mr. Treppel no longer serves as the non-executive Chairman.

During the term of the First Treppel Agreement, including any applicable extensions thereof, Mr. Treppel is entitled to cash compensation of $2,083.33 on a monthly basis in lieu of, and not in addition to, any cash directors' fees and other compensation paid to other non-employee members of the Board. Mr. Treppel is also entitled to reimbursement of any expenses reasonably incurred in the performance of his duties under the First Treppel Agreement upon presentation of proper written evidence of such expenditures.

In addition, pursuant to the terms of the First Treppel Agreement, Elite granted to Mr. Treppel under its 2004 Stock Option Plan non-qualified stock options to purchase 180,000 shares of Common Stock of Elite, par value $0.001 per share, exercisable for a period of 10 years at an exercise price per share of $0.06, subject to the terms and conditions of the related option agreement.

Under the First Treppel Agreement, Elite has also agreed to indemnify Mr. Treppel to the fullest extent permitted by law in accordance with the By-Laws of Elite against (a) reasonable expenses, including attorneys' fees, incurred by him in connection with any threatened, pending, or completed civil, criminal, administrative, investigative, or arbitrative action, suit, or proceeding (and any appeal therein) seeking to hold him liable for actions taken in his capacity as Chairman of the Board, and (b) reasonable payments made by him in satisfaction of any judgment, money decree, fine (including assessment of excise tax with respect to an employee benefit plan), penalty or settlement for which he may have become liable in any such action, suit or proceeding, provided that any such expenses or payments are not the result of Mr. Treppel's gross negligence, willful misconduct or reckless actions.

Either party may terminate the First Treppel Agreement, effective immediately upon the giving of written notice to the other party. If no such written notice is given, then the term of the First Treppel Agreement shall end immediately prior to the next annual meeting of the Company's stockholders (the "Treppel Term"), provided however, that following such annual meeting, and each subsequent meeting of the Company's stockholders, if the Board elects Mr. Treppel to continue to serve as the non-executive Chairman of the Board, the Treppel Term shall be extended through the earlier of (a) the date of the next subsequent annual meeting of the Company's stockholders and (b) the date upon which Mr. Treppel shall no longer serve as the non-executive Chairman of the Board.

On September 15, 2009, Mr. Treppel was appointed Chief Executive Officer of the Company and he served in that capacity until his resignation in August 2013. He continues to also serve as Chairman of the Board and he has agreed to forego any additional compensation related to his activities and Chief Executive Officer. Accordingly, Mr. Treppel's compensation as Chief Executive Officer and Chairman of the Board remains unchanged from the First Treppel Agreement.

On October 23, 2009, at the meeting of the Board held immediately after the annual stockholders meeting, Mr. Treppel's compensation as Chairman of the Board was revised to an annual amount of $30,000, payable in common shares of the Company. The amount of common shares to be issued to Mr. Treppel in payment of compensation due to him as Chairman of the Board is calculated on a quarterly basis, and is 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.

Mr. Treppel agreed to forego any additional compensation for his services as Chief Executive Officer of the Company.

Mr. Treppel stepped down from his position as Chief Executive Officer and was replaced by Mr. Nasrat Hakim in this position in August 2013. Mr. Treppel resigned from the Board of Directors in January 2016.

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 Exercises and Stock Vested

No options have been exercised by our Named Executive Officers during the 2017 Fiscal Year.

Options to purchase an aggregate of 1,700,000 shares of Common Stock and issued to Named Executive Officers in prior fiscal years vested during Fiscal 2017.

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 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

Summary Compensation Table

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						
	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
	2015(1)	350,000(2)	350,000(3)	—	18,000(4)	718,000
Carter J. Ward, Chief Financial Officer						
	2017(1)	192,816(5)	—	—	—	192,816
	2016(1)	187,668(5)	30,000(6)	—	—	217,668
	2015(1)	180,600(5)	36,000(6)	—	—	216,600
Douglas Plassche, Executive Vice President (12)						
	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
	2015(1)	231,150(7)	69,000(8)	—	6,000(4)	306,150
Barbara Ellison, Vice President (12)						
	2017(1)	38,550(9)	—	—	—	38,550
	2016(1)	193,800(9)	—	—	—	193,800
	2015(1)	190,317(9)	10,000(10)	188,356(11)	—	388,673
George Kenneth Smith, Vice President						
	2017(1)	412,000(13)	—	—	—	412,000
	2016(1)	401,000(13)	—	—	—	401,000
	2015(1)	178,707(13)	—	412,360(14)	—	591,067
Jerry Treppel, Chief Executive Officer and Chairman of the Board of Directors (15)						
	2017(1)	—	—	—	—	—
	2016(1)	—	—	—	23,404(16)	23,404
	2015(1)	—	—	—	30,000(16)	30,000

(1) Represents amounts paid or accrued for the fiscal years ended March 31, 2017, 2016, and 2015, 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 Shares in lieu of cash.

A total of 1,832,626 Common Shares have been issued and an additional 845,004 Common Shares are due and owing to Mr. Hakim in relation to salaries earned by Mr. Hakim during Fiscal 2017. A total of 1,445,445 Common Shares have been issued to Mr. Hakim in full payment of salaries earned by Mr. Hakim during Fiscal 2016. A total of 1,168,806 Common Shares were issued to Mr. Hakim in full payment of salaries earned by Mr. Hakim during Fiscal 2015.

(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 Shares 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.

A total of 1,061,079 Common Shares 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. A total of 1,168,806 Common Shares were issued to Mr. Hakim in full payment of bonuses earned by Mr. Hakim during Fiscal 2015.

(4) Represents amounts paid for auto allowances

(5) Represents salaries earned by Mr. Ward pursuant to the Ward Employment Agreement.

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 109,958 shares of Common Stock in lieu of cash with an additional 50,700 shares of Common Stock being owed. 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. Fiscal 2015 salaries consist of $150,600 being paid in accordance with the Company's payroll practices and $30,000 being paid via the issuance of 100,183 shares of Common Stock in lieu of cash.

(6) Discretionary cash bonuses awarded by the Chief Executive Officer

(7) Represents salaries earned by Mr. Plassche pursuant to the Plassche Employment Agreement.

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 91,631 shares of Common Stock in lieu of cash with an additional 42,250 shares of Common Stock being owed. 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. Fiscal 2015 salaries consist of $206,150 being paid in accordance with the Company's payroll practices and $25,000 being paid via the issuance of 83,486 shares of Common Stock in lieu of cash.

(8) Cash bonuses paid pursuant to the Plassche Employment Agreement.

(9) Represents salaries earned by Ms. Ellison pursuant to the Ellison Employment Agreement.

Fiscal 2017 salaries consist of $34,383 being paid in accordance with the Company's payroll practices and $4,167 being paid via the issuance of 13,026 shares of Common Stock in lieu of cash.
Fiscal 2016 salaries consist of $168,800 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.
Fiscal 2015 salaries consist of $165,317 being paid in accordance with the Company's payroll practices and $25,000 being paid via the issuance of 83,541 shares of Common Stock in lieu of cash.

(10) Cash bonuses paid pursuant to the Ellison Employment Agreement.

(11) Options to purchase 600,000 shares of Common Stock granted pursuant to the Ellison Employment Agreement.
The options include a purchase price equal to the closing price of the Company's Common Stock as of the date of the Ellison Employment Agreement and vest in 3 equal, annual increments, beginning on the date that is one year after the date of the Ellison Employment Agreement. Value of the options granted was determined by applying the Black Scholes model for the valuation of options.

These options expired, without being exercised 90 days from the date of termination of Ms. Ellison's employment with the Company, pursuant to the 2009 Employee Stock Option Plan.

(12) Ms. Ellison retired on June 1, 2016 and is no longer an employee of the Company

(13) Represents salaries earned by Mr. Smith pursuant to the Smith Employment Agreement

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 916,313 shares of Common Stock in lieu of cash with an additional 422,502 shares of Common Stock being owed. 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. Fiscal 2015 salaries consist of $67,596 being paid in accordance with the Company's payroll practices and $111,111 being paid via the issuance of 440,512 shares of Common Stock in lieu of cash.

(14) Options to purchase 1,500,000 shares of Common Stock granted pursuant to the Smith Employment Agreement.

The options include a purchase price equal to the closing price of the Company's Common Stock as of the date of the Smith Employment Agreement and vest in 3 equal, annual increments, beginning on the date that is one year after the date of the Smith Employment Agreement. Value of the options granted was determined by applying the Black Scholes model for the valuation of options.

(15) Mr. Treppel stepped down from his position as Chief Executive Officer in August 2013 and resigned from the Board of Directors in January 2016.

(16) Represents compensation due to Mr. Treppel for his service as Chairman of the Board of Directors. Mr. Treppel received no salary or additional compensation for his service as Chief Executive Officer. Compensation due to Mr. Treppel was paid via the issuance of Common Stock in lieu of cash, pursuant to the Company's Director compensation policy.

A total of 93,271 shares of Common Stock were issued to Mr. Treppel for Chairman fees earned during Fiscal 2016. A total of 100,184 shares of Common Stock were issued to Mr. Treppel for Chairman fees earned during Fiscal 2015.

Outstanding Equity Awards at March 31, 2017

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	1,000,000	—	500,000(1)	0.29	10/20/2024

(1) Options vest in October 2017.

DIRECTOR COMPENSATION

The following table sets forth information concerning director compensation for the year ended March 31, 2017:

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(6)	20,000(9)	—	—	—	—	30,000
Jeffrey Whitnell(2)	10,000(6)	20,000(9)	—	—	—	—	30,000
Eugene Pfeifer(3)	9,806(7)	19,590(10)	—	—	—	—	29,396
Davis Caskey(4)	9,222(8)	18,443(11)	—	—	—	—	27,665
Jeenarine Narine(5)	—	328(12)	—	—	—	—	328

(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, 2017.

(3) Mr. Pfeifer has served as a Director since April 7, 2016. Amounts represent Director compensation earned during the period April 7, 2016 through March 31, 2017.

(4) Mr. Caskey has served as a Director since April 28, 2016. Amounts represent Director compensation earned during the period April 7, 2016 through March 31, 2017.

(5) Mr. Narine resigned from the Board on April 7, 2016. Amounts represent Director compensation earned during the period April 1, 2016 through April 7, 2016.

(6) $7,500 of this amount was paid in March 2017 and $2,500 is owed and expected to be paid on or before March 31, 2018.

(7) $7,306 of this amount was paid in March 2017 and $2,500 is owed and expected to be paid on or before March 31, 2018.

(8) $6,722 of this amount was paid in March 2017 and $2,500 is owed and expected to be paid on or before March 31, 2018.

(9) A total of 73,305 shares of Common Stock were issued and 33,800 shares of Common Stock are due and owing to Dr. Dash and Mr. Whitnell for Director's fees that are paid via the issuance of Common Stock and earned during Fiscal 2017.

(10) A total of 72,039 shares of Common Stock were issued and 33,800 shares of Common Stock are due and owing to Mr. Pfeifer for Director's fees that are paid via the issuance of Common Stock and earned during the period April 7, 2016 through March 31, 2017.

(11) A total of 68,519 shares of Common Stock were issued and 33,800 shares of Common Stock are due and owing to Mr. Caskey for Director's fees that are paid via the issuance of Common Stock and earned during the period April 28, 2016 through March 31, 2017.

(12) A total of 1,008 shares of Common Stock were issued to Mr. Narine for Director's fees that are paid via the issuance of Common Stock and earned during the period April 1, 2016 through April 7, 2016.

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, 2017 and March 31, 2016 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 and Chairman 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, 2017 (except as otherwise indicated), regarding beneficial ownership of our Common Stock and our Series I 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, 2017, we had 775.5 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, 2017. 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 Common Stock	Series J Preferred Stock	Percent (%) of Voting Securities Beneficially Owned
Nasrat Hakim, President, Chief Executive Officer and Chairman of the Board of Directors*	12,642,565(1)	24.0344(2)	18.1%
Barry Dash, Director*	1,378,257(3)	-	**
Jeffrey Whitnell, Director*	1,239,902(4)	-	**
Eugene Pfeifer, Director*	105,840(5)	-	**
Davis Caskey, Director*	102,318(6)	-	**
Carter J. Ward, Chief Financial Officer *	3,641,018(7)	-	**
Douglas Plassche, Executive Vice President *	3,328,129(8)	-	**
Jeenarine Narine, Former Director	22,605,292(9)	-	2.4%
Ashok Nigalaye, Former Director	50,115,539(10)	-	5.3%
All Directors and Officers as a group	22,438,029(11)	24.0344(2)	19.1%

* 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 845,004 shares of Common Stock due and owing to Mr. Hakim as of March 31, 2017 (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 1,254,457 shares of Common Stock held as per the most recent Form 4 filing and 33,800 shares of Common Stock due and owing to Dr. Dash as of March 31, 2017 (the latest practicable date) for Directors fees accrued as of such date and vested options to purchase 90,000 shares of Common Stock.

(4) Includes 1,206,102 shares of Common Stock held as per the most recent Form 4 filing and 33,800 shares of Common Stock due and owing to Mr. Whitnell as of March 31, 2017 (the latest practicable date) for Directors fees accrued as of such date.

(5) Includes 72,040 shares of Common Stock held as per the most recent Form 4 filing and 33,800 shares of Common Stock due and owing to Mr. Pfeifer as of March 31, 2017 (the latest practicable date) for Directors fees accrued as of such date.

(6) Includes 68,518 shares of Common Stock held as per the most recent Form 4 filing and 33,800 shares of Common Stock due and owing to Mr. Caskey as of March 31, 2017 (the latest practicable date) for Directors fees accrued as of such date.

(7) Includes 3,240,318 shares of Common Stock held as per the most recent Form 4 filing, and 50,700 shares of Common Stock due and owing to Mr. Ward as of March 31, 2017 (the latest 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 285,879 shares of Common Stock held as per the most recent Form 4 filing, 42,250 shares of Common Stock due and owing to Mr. Plassche 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) Mr. Narine resigned on April 7, 2017. Address is c/o Epic Pharma LLC, 227-15 N. Conduit Ave, Laurelton, NY 11413. Includes warrants to purchase 2,910,532 shares of Common Stock and 19,694,760 shares of Common Stock held with the Company's transfer agent in account(s) that is (are) beneficially owned by Mr. Narine.

(10) Dr. Nigalaye resigned on June 5, 2015. Address is c/o Epic Pharma LLC, 227-15 N. Conduit Ave, Laurelton, NY 11413. Includes warrants to purchase 2,000,000 shares of Common Stock and 48,115,539 shares of Common Stock held with the Company's transfer agent in account(s) that is (are) beneficially owned by Dr. Nigalaye.

(11) Relates only to current directors and officers. Includes 17,924,875 shares of Common Stock held, as per the applicable most recent Form 3 or Form 4 filings, 1,073,155 shares of Common Stock due and owing as of March 31, 2017 (the latest practicable date) for director's fees and salaries accrued as of such date, and vested options to purchase 3,440,000 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.

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 Abbreviated New Drug Applications ("ANDAs") consisting of 12 ANDAs approved by the FDA and one ANDA under active review with the FDA, and all amendments thereto (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 I 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 per $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 "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 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") 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, President, and 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 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, interests 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;
- 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 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 18 to the audited financial statements, "Collaborative Agreement with Epic Pharma LLC"). The 2015 Epic License Agreement includes milestone payments totaling $10 million upon the filing with and approval of a New Drug Application ("NDA") with the FDA. The Company has 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 sales 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 2015 Epic License Agreement. The Company has received payment of this amount from Epic. 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 cycle for the 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 can take to obtain approval of SequestOx™. Based on the FDA response, the Company believes there is a clear path forward to address the issues cited in the CRL. 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 fed study is in progress. The Company plans on initiating the fasted study after successful completion of the fed study. Resubmission of the SequestOx™ application requires successful completion of all required studies, including these fed and fasted studies. Please note that there can be no assurances of the Company receiving marketing authorization for SequestOx™, and accordingly, there can be no assurances that the Company will earn and receive the additional $7.5 million or future license fees. If the Company does not receive these payments or fees, it will materially and adversely affect our financial condition.

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 products 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 all 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 $800k is contingent upon Epic filing the required supplements with and receiving approval from the FDA for the remaining exclusive generic products. There can be no assurances of Epic filing these supplements, or getting approval of any supplements filed. Accordingly, there can be no assurances of Elite receiving the remaining $800k due under the Epic Generic Agreement, or future license fees related thereto. Please also note that all commercialization, regulatory, manufacturing, marketing and distribution activities are being conducted solely by Epic, without Elite's participation.

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.

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 and Berkower LLC, for the audits of our financial statements and interim reviews of our quarterly financial statements.

	Fiscal 2017	Fiscal 2016	Fiscal 2015
Audit fees	$ 117,000	$ 110,500	$ 103,600
Audit-related fees	—	7,000	4,000
Tax fees	7,000	12,200	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 2017.

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 Consolidated 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 the 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 on 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 State of Delaware, incorporated by reference to (a) Exhibit 4.1 to the Registration Statement on Form S-4 (Reg. No. 333-101686), filed with the 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 filed 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 on 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 Delaware, 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 12, 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 filed 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 of 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 on 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 the 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 24, 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 of 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 April 25, 2007.*
3.1(h)	Amended Certificate of Designations, Preferences and Rights of Series C 8% Convertible Preferred Stock, as filed with the Secretary of 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 the 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 the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated September 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 of the State of Delaware, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K dated September 15, 2008, and filed 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 the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.3 to the Current Report on Form 8-K dated September 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 of 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 filed 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 of 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 with 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 of 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 with 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 April 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 April 22, 2013 .
3.1(p)	Certificate of Designation of the Series H Junior Participating Preferred Stock, incorporated by reference to Exhibit 2 (contained in Exhibit 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 on 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 the 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 May 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 April 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 dated 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-2 (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 the 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 the 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 the 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 Exhibit 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 16, 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 to 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 as 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, incorporated 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 the 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 the 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 filed 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 the 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 Agreement, dated as of March 18, 2009, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to 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 the 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 the 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 with 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 Proxy 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 Company, 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 September 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 Exhibit 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 Exhibit 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 August 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 10.5 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 as 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 to 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, LLC, 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 23, 2009.
10.12	Amendment to Strategic Alliance Agreement, dated as of April 30, 2009, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated April 30, 2009 and filed with the 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 Epic 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 SEC 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 Epic Investments, LLC, incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q, for the period ending June 30, 2009 and 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 to 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 16, 2009.
10.16	Elite Pharmaceuticals Inc. 2009 Equity Incentive Plan, as adopted November 24, 2009, incorporated by reference to Exhibit 10.1 to the Registration Statement Under the Securities Act of 1933 on Form S-8, dated December 18, 2009 and filed with the SEC on December 22, 2009.
10.17	License Agreement, dated as of September 10, 2010, by and among Precision Dose Inc. and the Company, incorporated by reference to 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, 2010 (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, incorporated 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 on 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 by 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, 2011 (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 by 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 29, 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 on 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 Exhibit 10.6 to the Quarterly Report on Form 10-Q filed with the SEC on November 14,2012 (Confidential Treatment granted with respect to 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 10.1 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 to 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 the 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 Current 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 the 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 the Amended Quarterly Report on Form 10-Q/A for the period ended September 30, 2013 and filed with the SEC on April 25, 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 the 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 the 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 to 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 10.1 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 to 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 Quarterly 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 the TPN-Elite Manufacturing and Supply Agreement dated September 21, 2012, incorporated by reference to Exhibit 10.6 to the Quarterly Report on Form 10-Q/A for the period ended September 30, 2012, and filed with the SEC on November 17, 2016. Confidential Treatment 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, 2013, 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 Mikah Pharma LLC and Transfer of Payment, incorporated by reference to Exhibit 10.84 to the Quarterly Report on Form 10-Q for the period ended December 31, 2014 and filed with the SEC on February 17, 2015 .
10.42	June 4, 2015 License Agreement with Epic Pharma LLC, incorporated by reference to Exhibit 10.85 to Amendment No. 1 to the Annual Report on Form 10-K for the fiscal year ended March 31, 2015 and filed with the SEC on July 11, 2016. (Confidential Treatment granted 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 filed 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 to 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, 2016. (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 of June 23, 2011 incorporated by reference to Exhibit 10.45 to the Quarterly Report on Form 10-Q for the period ended September 30, 2016 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 to 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, 2016. (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 to 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 to 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 Current 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.**
10.51	May 2017 Secured Promissory Note from the Company to Mikah Pharma.**
10.52	May 2017 Security Agreement between the Company to Mikah Pharma.**
10.53	May 2017 Assignment of Supply and Distribution Agreement between Dr. Reddy's Laboratories and Mikah Pharma.**
10.54	May 2017 Assignment of Manufacturing and Supply Agreement between Epic and Mikah Pharma. **
10.55	Supply and Distribution Agreement between Dr. Reddy's Laboratories and Mikah Pharma. 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.**

10.56	Manufacturing and Supply Agreement between Epic and Mikah Pharma. 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.**
21	Subsidiaries of the Company**
23.1	Consent of Buchbinder Tunick and Company LLP, Independent Registered Public Accounting Firm**
23.2	Consent of Berkower LLC, 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, 2017

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

Dated: June 14, 2017

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, 2017
/s/ Carter J. Ward	Chief Financial Officer, Treasurer, Secretary	June 14, 2017
/s/ Barry Dash	Director	June 14, 2017
/s/ Jeffrey Whitnell	Director	June 14, 2017
/s/ Eugene Pfeifer	Director	June 14, 2017
/s/ Davis Caskey	Director	June 14, 2017

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEARS ENDED MARCH 31, 2017, 2016 AND 2015

CONTENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of Elite Pharmaceuticals, Inc. and Subsidiary (the "Company") as of March 31, 2017 and 2016, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for the periods ended March 31, 2017 and 2016. The Company's management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Elite Pharmaceuticals, Inc. and Subsidiary as of March 31, 2017 and 2016, and the results of its operations and its cash flows for each of the two years in the period ended March 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Elite Pharmaceuticals, Inc. and Subsidiary's internal control over financial reporting as of March 31, 2017, based on criteria established in *Internal Control—Integrated Framework (2013 edition)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated June 14, 2017, expressed an unqualified opinion.

We have also audited the adjustments described in Note 1 that were applied to restate the March 31, 2015, consolidated statement of operations, stockholders' equity, and cash flow. In our opinion, such adjustments are appropriate and have been properly applied.

/s/ Buchbinder Tunick & Company LLP
Wayne, New Jersey
June 14, 2017

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited, before the effects of the adjustments related to the restatement described in Note 1, the accompanying consolidated statements of operations, changes in stockholders' deficit and cash flows of Elite Pharmaceuticals, Inc. and Subsidiary (the "Company"), for the year ended March 31, 2015. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, except for the effects of the adjustments related to the restatement described in Note 1, the consolidated financial statements referred to above present fairly, in all material respects, the results of operations and cash flows of Elite Pharmaceuticals, Inc. and Subsidiary for the year ended March 31, 2015 in conformity with accounting principles generally accepted in the United States of America.

We were not engaged to audit, review, or apply any procedures to the adjustments related to the restatement described in Note 1 and, accordingly, we do not express an opinion or any other form of assurance about whether such adjustments are appropriate and have been properly applied. Those adjustments were audited by Buchbinder Tunick & Company LLP.

/s/ Berkower LLC

Iselin, New Jersey
June 15, 2015

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

	March 31,	
	2017	**2016**
ASSETS		
Current assets:		
Cash	$ 10,594,693	$ 11,512,179
Accounts receivable, net of allowance for doubtful accounts of $-0-, respectively	934,059	1,530,296
Inventory	6,415,966	3,293,729
Prepaid expenses and other current assets	468,002	377,752
Total current assets	18,412,720	16,713,956
Property and equipment, net of accumulated depreciation of $7,426,752 and $6,726,401, respectively	9,039,404	8,110,721
Intangible assets, net of accumulated amortization of $-0-, respectively	6,419,091	6,411,799
Other assets:		
Restricted cash - debt service for NJEDA bonds	389,081	388,959
Security deposits	50,846	48,714
Total other assets	439,927	437,673
Total assets	**$ 34,311,142**	**$ 31,674,149**

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

	March 31,	
	2017	2016
LIABILITIES, MEZZANINE EQUITY AND SHAREHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 1,049,815	$ 1,804,429
Accrued expenses	794,628	555,352
Deferred revenue, current portion	1,013,333	1,013,333
Bonds payable, current portion (net of bond issuance costs)	70,822	205,822
Line of credit, related party	-	718,309
Loans payable, current portion	416,148	342,944
Total current liabilities	3,344,746	4,640,189
Long-term liabilities:		
Deferred revenue, net of current portion	2,265,557	3,278,887
Bonds payable, net of current portion and bond issuance costs	1,583,956	1,654,777
Loans payable, net current portion	577,612	520,829
Derivative financial instruments - warrants	843,464	10,368,567
Other long-term liabilities	31,770	47,422
Total long-term liabilities	5,302,359	15,870,482
Total liabilities	**8,647,105**	**20,510,671**
Mezzanine equity		
Series I convertible preferred stock; par value $0.01; 395.758 shares authorized, 0 issued and outstanding as of March 31, 2017; 495.758 shares authorized, 100 shares issued and outstanding as of March 31, 2016	-	44,285,715
Shareholders' equity (deficit):		
Common stock; par value $0.001; 995,000,000 shares authorized; 928,031,448 shares issued and 927,931,448 outstanding as of March 31, 2017; 711,544,352 shares issued and 711,444,352 outstanding as of March 31, 2016	928,034	711,546
Additional paid-in capital	163,896,410	109,137,805
Treasury stock; 100,000 shares as of March 31, 2017 and March 31, 2016; at cost	(306,841)	(306,841)
Accumulated deficit	(138,853,566)	(142,664,747)
Total shareholders' equity (deficit)	**25,664,037**	**(33,122,237)**
Total liabilities, mezzanine equity and shareholders' equity (deficit)	**$ 34,311,142**	**$ 31,674,149**

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended March 31,		
	2017 (Audited)	2016 (Audited)	2015 (Audited and Restated)
Manufacturing fees	$ 7,326,959	$ 8,002,866	$ 3,870,457
Licensing fees	2,310,756	4,495,466	1,139,789
Lab fee revenues	-	-	5,000
Total revenue	9,637,715	12,498,332	5,015,246
Cost of revenue	5,898,405	4,484,162	3,013,592
Gross profit	3,739,310	8,014,170	2,001,654
Operating expenses:			
Research and development	8,301,693	12,428,783	14,727,472
General and administrative	2,083,226	2,903,178	2,904,114
Non-cash compensation through issuance of stock options	357,955	333,362	260,045
Depreciation and amortization	352,369	665,647	616,995
Total operating expenses	11,095,243	16,330,970	18,508,626
Loss from operations	(7,355,933)	(8,316,800)	(16,506,972)
Other income (expense):			
Interest expense and amortization of debt issuance costs	(238,223)	(280,670)	(287,231)
Change in fair value of derivative instruments	9,525,103	7,394,006	20,340,874
Interest income	12,620	-	-
Gain on sale of investment	-	-	1,670,685
Other income (expense), net	9,299,500	7,113,336	21,724,328
Income (loss) from operations before the benefit from sale of state net operating loss credits	1,943,567	(1,203,464)	5,217,356
Net benefit from sale of state net operating loss credits	1,867,614	520,452	3,249
Net income (loss)	3,811,181	(683,012)	5,220,605
Change in carrying value of convertible preferred share mezzanine equity	20,714,286	(9,285,715)	23,709,069
Net income (loss) attributable to common shareholders	$ 24,525,467	$ (9,968,727)	$ 28,929,674
Basic income (loss) per share attributable to common shareholders	$ 0.03	$ (0.01)	$ 0.05
Diluted loss per share attributable to common shareholders	$ (0.01)	$ (0.01)	$ (0.02)
Basic weighted average common shares outstanding	838,665,804	673,905,485	591,214,959
Diluted weighted average common shares outstanding	844,506,245	673,905,485	757,579,151

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

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

	Common Stock			Treasury Stock			
	Shares	Amount	Additional Paid-In Capital	Shares	Amount	Accumulated Deficit	Total Shareholders' Equity (Deficit)
Balance at March 31, 2014	560,242,430	$560,244	$ 65,750,782	100,000	$(306,841)	$(147,202,340)	$ (81,198,155)
Net income						5,220,605	5,220,605
Change in value of convertible preferred mezzanine equity			23,709,069				23,709,069
Issuance of common shares pursuant to the exercise of cash warrants	11,985,388	11,985	762,868				774,853
Issuance of common shares pursuant to the exercise of cash options	223,334	223	25,777				26,000
Common shares issued in payment of employee salaries	2,518,668	2,519	847,218				849,737
Common shares issued in payment of Directors' Fees	321,611	322	109,678				110,000
Common shares issued in payment of consulting expenses	70,169	70	23,929				23,999
Common shares issued as commitment shares pursuant to the Lincoln Park purchase agreement	2,566,861	2,567	(2,567)				-
Costs associated with raising capital			(16,365)				(16,365)
Common shares sold pursuant to the Lincoln Park purchase agreement	47,172,240	47,172	13,189,452				13,236,624
Non-cash compensation through the issuance of employee stock options			260,047				260,047
Conversion of Series I convertible preferred stock into common shares	6,060,000	6,060	2,266,440				2,272,500
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 shares pursuant to the exercise of cash warrants	48,283,968	48,284	2,969,464				3,017,748
Issuance of common shares pursuant to the exercise of cash options	112,500	113	23,638				23,751
Common shares issued in payment of employee salaries	4,236,555	4,237	1,034,763				1,039,000
Common shares issued in payment of Directors' Fees	408,892	409	99,662				100,071
Common shares issued in payment of consulting expenses	97,467	97	23,903				24,000
Common shares 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 shares 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 shares pursuant to the exercise of cash warrants	29,562,876	29,563	1,818,117				1,847,680
Issuance of common shares pursuant to the exercise of cash options	100,000	100	8,700				8,800
Common shares issued in payment of employee salaries	3,633,397	3,634	819,117				822,751
Common shares issued in payment of Directors' Fees	334,295	334	73,027				73,361
Common shares issued in							

payment of consulting expenses	106,416	106	24,061				24,167
Common shares 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 shares 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 shares 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

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended March 31,		
	2017 (Audited)	2016 (Audited)	2015 (Audited and Restated)
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income (loss)	$ 3,811,181	$ (683,012)	$ 5,220,605
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Depreciation and amortization	714,530	666,461	581,855
Change in fair value of derivative financial instruments - warrants	(9,525,103)	(7,394,006)	(20,340,874)
Non-cash compensation accrued	409,750	573,667	679,771
Salaries and directors fees satisfied by the issuance of common stock	896,112	1,139,071	959,737
Consulting expenses paid via the issuance of common stock	24,167	24,000	23,999
Non-cash compensation from the issuance of common stock and options	357,955	333,363	260,047
Milestone shares issued pursuant to Epic Strategies Alliance Agreement	-	840,000	-
Non-cash rent expense	(17,374)	(22,996)	23,703
Non-cash lease accretion	1,721	1,621	1,526
Bad debt recovery	-	(117,095)	-
Gain on sale of investment	-	-	(1,670,685)
Change in operating assets and liabilities:			
Accounts receivable	596,237	33,240	(714,355)
Inventory	(3,122,237)	(261,727)	(1,099,518)
Prepaid expenses and other current assets	(92,382)	160,076	(147,188)
Accounts payable, accrued expenses and other current liabilities	(925,088)	(2,211,414)	1,131,477
Deferred revenue and customer deposits	(1,013,330)	4,153,330	(13,333)
Net cash used in operating activities	(7,883,861)	(2,765,421)	(15,103,233)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(1,097,562)	(1,918,804)	(1,965,018)
Intellectual property costs	(7,292)	(30,025)	(31,853)
Withdrawals from restricted cash, net	(122)	-	(123,916)
Proceeds from sale of investment in Novel	-	-	5,000,000
Net cash (used in) provided by investing activities	(1,104,976)	(1,948,829)	2,879,213
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from cash warrant and options exercises	1,856,480	3,041,499	800,853
Proceeds and repayments of line of credit, related party - net	(718,309)	135,238	54,322
Other loan payments	(401,485)	(404,131)	(219,010)
Costs associated with raising capital	(38,624)	-	(16,365)
Payment of NJEDA Bonds	(220,000)	(210,000)	(1,110,000)
Proceeds from sale of common stock to Lincoln Park Capital	7,593,289	6,199,643	13,236,624
Net cash provided by financing activities	8,071,351	8,762,249	12,746,424
Net change in cash	(917,486)	4,047,999	522,404
Cash, beginning of period	11,512,179	7,464,180	6,941,776
Cash, end of period	$ 10,594,693	$ 11,512,179	$ 7,464,180
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:			
Cash paid for interest	$ 142,351	$ 215,878	$ 89,336
Cash paid for taxes	$ 2,500	$ 4,048	$ 2,500
SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:			
Financing of equipment purchases and insurance renewal	$ 308,834	$ 442,399	$ 804,861
Commitment shares issued to Lincoln Park Capital	$ 69,425	$ 84,102	$ 830,521
Change in carrying value of convertible preferred mezzanine equity	$ 20,714,286	$ (9,285,715)	$ 23,709,069
Conversion of Series I convertible preferred stock into common shares	$ 23,571,430	$ -	$ 2,272,500

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY
NOTES TO 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 5, 2012, Elite Pharmaceuticals was reincorporated under the laws of the State of Nevada. Elite Labs engages primarily in researching, developing and licensing proprietary orally administered, controlled-release drug delivery systems and products with abuse deterrent capabilities and the manufacture of generic, oral dose pharmaceuticals. The Company is equipped to manufacture controlled-release products on a contract basis for third parties and itself, if and when the products are approved. These products include drugs that cover therapeutic areas for pain, allergy, bariatric and infection. Research and development activities are done so with an objective of developing products that will secure marketing approvals from the United States Food and Drug Administration ("FDA"), and thereafter, commercially exploiting such products.

Principles of Consolidation

The accompanying 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 and 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, 2017, 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.

Restatement of Previously Issued Consolidated Financial Statements

As disclosed in the Company's Annual Report on Form 10-K for the year ended March 31, 2016, the Company has restated the consolidated financial statements as of and for the years ended March 31, 2015 and 2014 and unaudited quarterly financial information for the first two quarters in the year ended March 31, 2016 and the first three quarters in the year ended March 31, 2015, to correct prior periods primarily related to (i) an error in accounting treatment for license agreement with Epic, in which the Company determined that revenue relating to a $5,000,000 non-refundable payment, which was originally recognized in full during the quarterly period ended June 30, 2015, should have been recognized, on a straight line basis, over the exclusivity period, coinciding with the five year term of the Epic Collaborative Agreement, as this payment is attributed to the exclusive license and other rights granted to Epic in the Epic Collaborative Agreement; and (ii) a determination that the Series I convertible preferred stock, which had originally been classified as a derivative liability prior to the quarter ended December 31, 2015, should have been recorded as mezzanine equity at the maximum redemption amount each reporting period with changes recorded in additional paid in capital.

These audited consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements for the year ended March 31, 2016 included in the Company's Fiscal 2016 Annual Report on Form 10-K, filed with the SEC on June 15, 2016. In addition, the Company's future Quarterly Reports on Form 10-Q for subsequent quarterly periods during the current fiscal year will reflect the impact of the restatement in the comparative prior quarter and year-to-date periods.

Reclassifications

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

Segment Information

Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 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, 2017, and March 31, 2016, the Company had $389,081 and $388,959 of restricted cash, respectively, related to debt serve reserve in regards 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, 2017, 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, 2017, a summary of the tax years that remain subject to examination in our major tax jurisdictions are: United States – Federal, 2013 and forward, and State, 2009 and forward. The Company did not record unrecognized tax positions for the years ended March 31, 2017, 2016, and 2015.

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,		
	2017	**2016**	**2015**
Numerator			
Net income (loss) attributable to common shareholders - basic	$ 24,525,467	$ (9,968,727)	$ 28,929,674
Effect of dilutive instrument on net (loss) income	(30,239,389)	1,891,709	(44,049,943)
Net loss attributable to common shareholders - diluted	$ (5,713,922)	$ (8,077,018)	$ (15,120,269)
Denominator			
Weighted average shares of common stock outstanding - basic	838,665,804	673,905,485	591,214,959
Dilutive effect of stock options, warrants and convertible securities	5,840,441	-	166,364,192
Weighted average shares of common stock outstanding - diluted	844,506,245	673,905,485	757,579,151
Net income (loss) per share			
Basic	$ 0.03	$ (0.01)	$ 0.05
Diluted	$ (0.01)	$ (0.01)	$ (0.02)

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, 2017 and March 31, 2016, 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, 2017				
Liabilities				
Derivative financial instruments - warrants	$ 843,464	$ -	$ -	$ 843,464
March 31, 2016				
Liabilities				
Derivative financial instruments - warrants	$ 10,368,567	$ -	$ -	$ 10,368,567

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 April 2015, the FASB issued ASU 2015-3, *Simplifying the Presentation of Debt Issuance Costs* ("ASU 2015-3"). ASU 2015-3 revises previous guidance to require that debt issuance costs be reported in the audited consolidated financial statements as a direct deduction from the face amount of the related liability, consistent with the presentation of debt discounts. Prior to the amendments, debt issuance costs were presented as a deferred charge (i.e. an asset) on the audited consolidated financial statements. This new guidance is effective for the annual period ending after December 15, 2015, and for annual periods and interim periods thereafter. The amendments must be applied retrospectively. The Company has adopted the provisions of ASU 2015-03. Refer to Note 2 Change in Accounting Principle for the effect of adopting ASU 2015-03 on the consolidated balance sheet as of March 31, 2016.

Recently Issued Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The core principle of ASU 2014-09 is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and services. This standard is effective for fiscal years and interim reporting periods beginning after December 15, 2016. In August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date.* The amendments in this update deferred the effective date for implementation of ASU 2014-09 by one year and is now effective for annual reporting periods beginning after December 15, 2017. Early application is permitted only as of annual reporting periods beginning after December 15, 2016 including interim reporting periods within that period. Topic 606 is effective for the Company in the first quarter of fiscal 2019. The Company is currently evaluating the effects of ASU 2014-09 and related ASUs noted below on its audited consolidated financial statements.

From March through December 2016, 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 July 2015, the FASB issued ASU 2015-11, *Simplifying the Measurement of Inventory (Topic 330)* ("ASU 2015-11"). The amendments in ASU 2015-11 clarify the determination of net realizable value of inventory, applicable to measurement of inventory asset value on the balance sheet. The amendments do not change the core principal of the guidance provided in Topic 330, specifically the valuation of inventory at the lower of cost or market value, with market value being determined by the net realizable value of the inventory item(s). The amendments clarify, however, that net realizable value is to be measured as the estimated selling price in the ordinary course of business, less reasonably predicable costs of completion, disposal, and transportation. The guidance is effective for the annual period beginning after December 15, 2016, and for annual periods and interim periods thereafter, with early adoption being optional and permitted as of the beginning of an interim or annual reporting period. The Company is currently evaluating the effects of ASU 2015-11 on its audited consolidated financial statements.

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 March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting (Topic 718)* ("ASU 2016-09"). The amendments in ASU 2016-09 provide revised guidance in relation to the following with regards to share based payments: i) Accounting for forfeitures, ii) Income tax effects, and iii) classification of excess tax benefits. The guidance is effective for the annual period beginning after December 15, 2016, and for annual periods and interim periods thereafter, with early adoption being optional and permitted as of the beginning of an interim or annual reporting period. The Company is currently evaluating the effects of ASU 2016-09 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 the Company beginning after December 15, 2017, although early adoption is permitted. 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 new standard is expected to be effective for fiscal years, and interim periods within those years, beginning after December 15, 2017, with early adoption permitted. 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. 2017-01 "*Business Combinations (Topic 805) – Clarifying the Definition of a Business"* (ASU 2017-01). ASU 2017-01 clarifies the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The amendments in this update provide a screen to determine when an integrated set of assets and activities (collectively referred to as a "set"), is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. This screen reduces the number of transactions that need to be further evaluated. ASU 2017-01 is effective for annual periods beginning after December 15, 2017, including interim periods within those periods, with early adoption permitted. The amendments in this update should be applied prospectively on or after the effective date. The Company is currently evaluating the effects of ASU 2017-01 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.

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. CHANGE IN ACCOUNTING PRINCIPLE

As noted in Note 1 Summary of Significant Accounting Policies, the Company adopted the provisions of ASU 2015-03 and has retroactively reclassified its consolidated balance sheet for the year ended March 31, 2016. During the fiscal year ended March 31, 2016, the Company had accounted for bond offering costs associated with its NJEDA Bonds as an other asset within the Company's consolidated balance sheet.

The following table is a summary of the effect of the reclassification on the consolidated balance sheet:

	As of March 31, 2016		
	As previously filed	Adjustments	As reclassified
Other assets:			
EDA bond offering costs	$ 204,401	$ (204,401)	$ -
Current liabilities:			
Current portion of EDA bonds payable	$ 220,000	$ (14,178)	$ 205,822
Long term liabilities:			
EDA bonds payable - non-current	$ 1,845,000	$ (190,223)	$ 1,654,777

NOTE 3. INVENTORY

Inventory consisted of the following:

	March 31,	
	2017	2016
Finished goods	$ 221,657	$ 225,699
Work-in-progress	283,086	222,784
Raw materials	5,911,223	2,845,246
	6,415,966	3,293,729
Less: Inventory reserve	-	-
	$ 6,415,966	$ 3,293,729

NOTE 4. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	March 31,	
	2017	2016
Land, building and improvements	$ 7,308,890	$ 6,230,543
Laboratory, manufacturing and warehouse equipment	8,764,406	8,255,286
Office equipment and software	276,201	234,634
Furniture and fixtures	49,804	49,804
Transportation equipment	66,855	66,855
	16,466,156	14,837,122
Less: Accumulated depreciation	(7,426,752)	(6,726,401)
	$ 9,039,404	$ 8,110,721

Depreciation expense was $700,351, $652,284 and $566,028 for the years ended March 31, 2017, 2016, and 2015, respectively.

NOTE 5. INTANGIBLE ASSETS

The following tables summarize the Company's intangible assets:

	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

	March 31, 2016				
	Estimated Useful Life	Gross Carrying Amount	Additions	Accumulated Amortization	Net Book Value
Patent application costs	*	$ 334,457	$ 30,025	$ -	$ 364,482
ANDA acquisition costs	Indefinite	6,047,317	-	-	6,047,317
		$ 6,381,774	$ 30,025	$ -	$ 6,411,799

* 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, 2017	March 31, 2016
Gross bonds payable		
NJEDA Bonds - Series A Notes	$ 1,845,000	$ 2,065,000
Less: Current portion of bonds payable (prior to deduction of bond offering costs)	(85,000)	(220,000)
Long-term portion of bonds payable (prior to deduction of bond offering costs)	$ 1,760,000	$ 1,845,000
Bond offering costs	$ 354,453	$ 354,453
Less: Accumulated amortization	(164,231)	(150,052)
Bond offering costs, net	$ 190,222	$ 204,401
Current portion of bonds payable - net of bond offering costs		
Current portions of bonds payable	$ 85,000	$ 220,000
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	$ 70,822	$ 205,822
Long term portion of bonds payable - net of bond offering costs		
Long term portion of bonds payable	$ 1,760,000	$ 1,845,000
Less: Bond offering costs to be amortized subsequent to the next 12 months	(176,044)	(190,223)
Long term portion of bonds payable, net of bond offering costs	$ 1,583,956	$ 1,654,777

Amortization expense was $14,178, $14,178 and $14,177 for years ended March 31, 2017, 2016, and 2015, respectively.

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

Year ending March 31,	Amount
2018	$ 85,000
2019	90,000
2020	95,000
2021	105,000
2022	110,000
Thereafter	1,360,000
	$ 1,845,000

NOTE 7. LOANS PAYABLE

Loans payable consisted of the following:

	March 31, 2017	March 31, 2016
Equipment and insurance financing loans payable, between 3% and 13% interest and maturing between May 2017 and March 2022	$ 993,760	$ 863,773
Less: Current portion of loans payable	(416,148)	(342,944)
Long-term portion of loans payable	$ 577,612	$ 520,829

The interest expense associated with the loans payable was $87,307, $95,822 and $47,828 for the years ended March 31, 2017, 2016, and 2015, respectively.

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

Year ending March 31	Amount
2018	$ 416,148
2019	234,577
2020	195,129
2021	89,442
2022	58,464
	$ 993,760

NOTE 8. LINE OF CREDIT – RELATED PARTY

In October 2013, the Company entered into a bridge loan agreement (the "Hakim Loan Agreement") with Mr. Nasrat Hakim, the Company's Chairman of the Board, President, and Chief Executive Officer. 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 is to support the acceleration of the Company's product development activities. The outstanding amount is evidenced by a promissory note, which matured on March 31, 2016, as amended. On March 31, 2016, the entire unpaid principal balance plus accrued interest thereon was due and payable in full. The Company could have prepaid any amounts owed without penalty. Any such prepayments shall first be attributable to interest due and owing and then to principal. Interest only shall be payable quarterly on January 1, April 1, July 1, and October 1 of each year. Prior to maturity or the occurrence of an Event of Default as defined in the Hakim Loan Agreement, the Company may 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.

As of March 31, 2016, the principal balance owed under the Hakim Credit Line was $718,309, with an additional $70,784 in accrued interest being also owed, in accordance with the terms and conditions of the Hakim Credit Line. This principal balance was paid in full on May 23, 2016. Accrued interest consisting of $70,784 due and owed on March 31, 2016, plus $9,134 in interest due, owed and expensed during the period April 1, 2016 through May 23, 2016 was paid on May 24, 2016. Accordingly, as of March 31, 2017, there are no amounts due and owing under the Hakim Loan Agreement or the Hakim Line of Credit and both have expired.

NOTE 9. DEFERRED REVENUE

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. Deferred revenues in the aggregate amount of $4,292,220 as of March 31, 2016, were comprised of a current component of $1,013,333 and a long-term component of $3,278,887. 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.

Legal Proceedings

Arbitration with Precision Dose, Inc.

On May 9, 2014, Precision Dose Inc., the parent company of TAGI Pharmaceuticals, Inc., commenced an arbitration against the Company alleging that the Company failed to properly supply, price and satisfy gross profit minimums regarding Phentermine 37.5mg tablets, as required by the parties' agreements. Elite denied Precision Dose's allegations and has counterclaimed that Precision Dose is no longer entitled to exclusivity rights with respect to Phentermine 37.5mg tablets, and is responsible for certain costs, expenses, price increases and lost profits relating to Phentermine 37.5mg tablets and the parties' agreements. The parties have reached agreement in settlement of these issues, with Precision Dose agreeing to pay certain amounts to the Company in exchange for Elite agreeing to restore exclusivity rights with respect to Phentermine 37.5mg tablets, subject to certain defined conditions. Both parties have been complying with the agreed settlement terms and the Company has notified the Arbitrator of this settlement, requesting the issuance of proceeding termination documents.

Due to the agreements reached and adhered to with regards to this issue, the Company has determined that no contingency loss needs to be recorded.

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, 2017, 2016, and 2015 was $190,550, $180,854, and $153,430, respectively. Rent expense is recorded in general and administrative expense in the audited consolidated statements of operations. Deferred rent as of March 31, 2017 and March 31, 2016 was $2,152 and $19,528, respectively and recorded as a component of other long-term liabilities. The tables below shows the future minimum rental payments, exclusive of taxes, insurance and other costs, under the Ludlow Ave. lease:

Year ending March 31,	**Amount**
2018	$ 212,085
2019	216,321
2020	220,650
2021	225,063
2022	229,563
Thereafter	1,154,232
	$ 2,257,914

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, 2017, and March 31, 2016, the Company had a liability of $29,616 and $27,895, 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, 2017.

The COD for the Series I Preferred contained the following features:

Background

- Conversion feature - the Series I Preferred Shares may be converted, at the option of the Holder, into the Company's Common Stock at a stated 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,	
	2017	2016
Shares authorized	395.758	495.758
Shares outstanding	-	100
Par value	$ 0.01	$ 0.01
Stated value	$ 100,000	$ 100,000
Conversion price	$ 0.07	$ 0.07
Common shares to be issued upon redemption	-	142,857,143
Closing price on valuation date	$ 0.15	$ 0.31
Carrying value of Series I convertible preferred stock	$ -	$ 44,285,715

	For the Years Ended March 31,		
	2017	2016	2015
Change in carrying value of convertible preferred share mezzanine equity	$ 20,714,286	$ (9,285,715)	$ 23,709,069

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

A summary of warrant activity is as follows:

	March 31,					
	2017		2016		2015	
	Warrant Shares	Weighted Average Exercise Price	Warrant Shares	Weighted Average Exercise Price	Warrant Shares	Weighted Average Exercise Price
Balance at beginning of year	41,586,066	$ 0.0625	89,870,034	$ 0.0625	102,143,091	$ 0.0625
Warrants exercised, forfeited and/or expired, net	(32,206,847)		(48,283,968)		(12,273,057)	
Balance at end of year	9,379,219	$ 0.0625	41,586,066	$ 0.0625	89,870,034	$ 0.0625

The fair value of the warrants was calculated using the Black-Scholes model and the following assumptions:

	March 31,		
	2017	2016	2015
Fair value of the Company's common stock	$ 0.15	$ 0.31	$ 0.25
Volatility (based on the Company's historical volatility)	72.5% - 73.1%	52% - 81%	93% - 113%
Exercise price	$ 0.0625	$ 0.0625	$ 0.0625 - 0.25
Estimated life (in years)	1.0 - 1.1	0.2 - 2.1	1.2 - 3.1
Risk free interest rate (based on 1-year treasury rate)	1.02% - 1.03%	0.18% - 0.73%	0.05% - 0.89%

The changes in warrants (Level 3 financial instruments) measured at fair value on a recurring basis for the year ended March 31, 2017 were as follows:

Balance as of March 31, 2014	$ 38,103,447
Change in fair value of derivative financial instruments - warrants	(20,340,874)
Balance as of March 31, 2015	17,762,573
Change in fair value of derivative financial instruments - warrants	(7,394,006)
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

NOTE 13. SHAREHOLDERS' EQUITY (DEFICIT)

Lincoln Park Capital

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 million of common stock purchased by Lincoln Park. Through March 31, 2017, the Company sold to Lincoln Park an aggregate of 110.6 million shares under the Purchase Agreement for aggregate gross proceeds of approximately $27.0 million. The Company also issued an additional 1.3 million Commitment Shares.

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 control the timing and amount of any sales of the Company's common stock to Lincoln Park.

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

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

The net proceeds under the Purchase Agreement to the Company will depend on the frequency and prices at which the Company sells shares of its stock to Lincoln Park.

Summary of Common Stock Activity

During Fiscal Years 2017, 2016, and 2015 the Company issued a total of 216,487,096, 80,383,651, and 70,918,271 shares of Common Stock, respectively, with such issuances of Common Stock being summarized as follows:

Description	Fiscal Year 2017	Fiscal Year 2016	Fiscal Year 2015
Common shares sold pursuant to the Lincoln Park Capital Purchase Agreements, with net proceeds of such shares totaling $7,593,289 and $6,199,643, $13,236,624 in Fiscal 2017, Fiscal 2016, and Fiscal 2015, respectively.	39,526,851	23,945,346	47,172,240
Common shares issued as commitment shares pursuant to the Lincoln Park Capital Purchase Agreements	366,118	298,923	2,566,861
Common Shares issued pursuant to the conversion of Series I Convertible Preferred Share derivatives, with such derivative liabilities totaling $23,571,430, $0, and $2,272,500 for Fiscal 2017, Fiscal 2016, and Fiscal 2015, respectively, at the time of their conversion.	142,857,143	—	6,060,000
Common Shares issued in payment of Director's fees totaling $73,361, $100,071, and $110,000 for Fiscal 2017, Fiscal 2016, and Fiscal 2015, respectively.	334,295	408,892	321,611
Common shares issued in payment of employee salaries totaling $822,751, $1,039,000, and $849,737 for Fiscal 2017, Fiscal 2016, and Fiscal 2015, respectively.	3,633,397	4,236,555	2,518,668
Common shares issued in payment of consulting expenses totaling $24,167, $24,000, and $23,999 for Fiscal 2017, Fiscal 2016, and Fiscal 2015, respectively.	106,416	97,467	70,169
Common shares issued pursuant to warrants exercised	29,562,876	48,283,968	11,985,388
Common shares issued pursuant to options exercised	100,000	112,500	223,334
Milestone shares issued pursuant to EPIC Strategic Alliance Agreement totaling $0, $840,000, and $0 for Fiscal 2017, Fiscal 2016, and Fiscal 2015, respectively.	—	3,000,000	—
Total common shares issued	216,487,096	80,383,651	70,918,271
Common shares issued at March 31,	928,031,448	711,544,352	631,160,701

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 of director's fees are to be paid via the issuance of shares of the Company's common stock, in lieu of cash, with the valuation of such shares being calculated on quarterly basis and equal to the average closing price of the Company's common stock.

During the years ended March 31, 2017, 2016, and 2015 the Company issued 334,295, 408,892, and 321,611 shares of its common stock, respectively, totaling $73,361, $100,071, and $110,000, 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 includes 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, 2017, the Company issued 3,633,397 shares of common stock to certain employees in payment of salaries in the aggregate amount of $822,751, consisting of $815,251 of related employee salaries earned during the year ended March 31, 2017 and $7,500 in related employee salaries due and owing as of March 31, 2016, the end of the immediately prior fiscal year. Please note that these shares were issued to employees that resigned from their positions with the Company and represented those shares due and owing as of the date of such resignations.

As of March 31, 2017, the Company owes its President and Chief Executive Officer, Chief Financial Officer and certain other employees and consultants, a total of 1.3 million shares of Common Stock in payment of salaries and fees totaling $0.2 million due and owing. The Company anticipates that these shares of common stock will be issued during the fiscal year ended March 31, 2018.

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, 2014	5,435,667	$ 0.54	7.4	$ 1,376,430
Granted	2,590,000	0.31		
Forfeited and expired	(160,166)	0.18		
Exercised	(223,334)	0.12		
Outstanding at March 31, 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
Exercisable at March 31, 2017	4,937,667	$ 0.19	6.2	$ 256,566

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, 2017, 2016, and 2015 was $0.15, $0.31, and $0.25 respectively.

The fair value of the options was calculated using the Black-Scholes model and the following assumptions:

	March 31,		
	2017	**2016**	**2015**
Volatility (based on the Company's historical volatility)	120% - 121%	119% - 120%	120% - 121%
Exercise price	$ 0.13 - 0.33	$ 0.23 - 0.42	$ 0.27 - 0.46
Estimated term (in years)	10	10	10
Risk free interest rate (based on 1-year treasury rate)	1.5% - 2.5%	2.1% - 2.2%	2.2% - 2.8%
Forfeiture rate	2.3% - 4.6%	2.7%	0.0%
Fair value of options granted	$ 373,055	$ 129,913	$ 769,421
Non-cash compensation through issuance of stock options	$ 357,955	$ 333,363	$ 260,047

NOTE 15. SALE OF NEW JERSEY STATE NET OPERATING LOSSES

During the year ended March 31, 2017, Elite Labs, a wholly owned subsidiary of Elite, received final approval from the New Jersey Economic Development Authority for the sale of net tax benefits of $1,286,842 relating to New Jersey net operating losses and net tax benefits of $745,891 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 total proceeds of $1,867,614.

NOTE 16. CONCENTRATIONS AND CREDIT RISK

Revenues

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.

Three customers accounted for substantially all the Company's revenues for the year ended March 31, 2015. These three customers accounted for approximately 55%, 24% and 11% of revenues each, respectively.

Accounts Receivable

Four customers accounted for 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 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.

Seven suppliers accounted for more than 80% of the Company's purchases of raw materials for year ended March 31, 2015. Included in these seven suppliers are four suppliers that accounted for approximately 38%, 11%, 10% 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 Drug 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,		
	2017	2016	2015
Revenue by Segment			
ANDA	$ 8,637,715	$ 9,164,999	$ 5,015,246
NDA	1,000,000	3,333,333	-
	$ 9,637,715	$ 12,498,332	$ 5,015,246

	Years Ended March 31,		
	2017	2016	2015
Operating (Loss) Income by Segment			
ANDA	$ (522,160)	$ 4,940,515	$ 1,650,128
NDA	(3,415,246)	(9,305,998)	(14,939,115)
	$ (3,937,406)	$ (4,365,483)	$ (13,288,987)

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,		
	2017	2016	2015
Operating loss by segment	$ (3,937,406)	$ (4,365,483)	$ (13,288,987)
Corporate unallocated costs	(1,917,437)	(1,772,237)	(1,319,938)
Interest income	12,620	-	-
Interest expense and amortization of debt issuance costs	(238,223)	(280,670)	(287,231)
Depreciation and amortization expense	(352,369)	(665,647)	(616,995)
Significant non-cash items	(1,148,721)	(1,513,433)	(1,281,052)
Change in fair value of derivative instruments	9,525,103	7,394,006	20,340,874
Gain on sale of investment	-	-	1,670,685
Income (loss) from operations before the benefit from sale of state net operating loss credits	$ 1,943,567	$ (1,203,464)	$ 5,217,356

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 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 cycle for the 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 it could take to obtain 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. It 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 fed study is in progress. The Company plans on initiating the fasted study after successful completion of the fed study. Resubmission of the SequestOx™ application requires successful completion of all required studies, including these fed and fasted studies. There can be no assurances that our intended future resubmission of the NDA product filing 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. 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 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.

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 will 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 will 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 to market and sell the CNS Products using Elite’s label. Elite will manufacture and package all four products on a cost-plus basis.

As of and for the year ended March 31, 2017; no revenues and expense have been incurred or recognized under the SunGen agreement.

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 Agreement includes milestone payments totaling $10 million upon the filing with and approval of a New Drug Application ("NDA") with the FDA. The Company has 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 sales 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 2015 Epic License Agreement. The Company has received payment of this amount from Epic. On December 21, 2016, the Company met with the FDA for an end-of-review meeting to discuss steps that the Company can take to obtain approval of SequestOx™. Based on the FDA response, the Company believes there is a clear path forward to address the issues cited in the CRL. 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 fed study is in progress. The Company plans on initiating the fasted study after successful completion of the fed study. Resubmission of the SequestOx™ application requires successful completion of all required studies, including these fed and fasted studies. Please note that there can be no assurances of the Company receiving marketing authorization for SequestOx™, and accordingly, there can be no assurances that the Company will earn and receive the additional $7.5 million or future license fees. 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 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 products 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 all 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 $800k is contingent upon Epic filing the required supplements with and receiving approval from the FDA for the remaining exclusive generic products. There can be no assurances of Epic filing these supplements, or getting approval of any supplements filed. Accordingly, there can be no assurances of Elite receiving the remaining $800k due under the Epic Generic Agreement, or future license fees related thereto. Please also note that all commercialization, regulatory, manufacturing, marketing and distribution activities are being conducted solely by Epic, without Elite's participation.

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 as extended on August 9, 2016 (the "Ascend Manufacturing 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.

NOTE 22. INCOME TAXES

The components of the credit for income taxes are as follows:

	Years Ended March 31,		
	2017	**2016**	**2015**
Federal			
Current	$ -	$ -	$ -
Deferred	-	-	-
State			
Current	(2,500)	(4,048)	3,249
Deferred	-	-	-
Benefit from sale of state net operating loss credits	1,870,114	524,500	-
Net benefit from sale of state net operating loss credits	$ 1,867,614	$ 520,452	$ 3,249

The major components of deferred tax assets and liabilities at March 31, 2017, 2016, and 2015 are as follows *(amounts in thousands of dollars)*:

	Years Ended March 31,		
	2017	**2016**	**2015**
Federal			
Net operating loss carry forward	$ 29,915	$ 27,033	$ 24,547
Valuation allowance	(29,915)	(27,033)	(24,547)
	$ -	$ -	$ -
State			
Net operating loss carry forward	$ 1,930	$ 2,722	$ 2,602
Valuation allowance	(1,930)	(2,722)	(2,602)
	$ -	$ -	$ -

At March 31, 2017, 2016, and 2015 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, 2017, Elite has a federal net operating loss carryforward of $29,915,546 and net operating loss carryforward in state tax jurisdictions of $1,929,616, which will begin to expire in 2019.

NOTE 23. 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, 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)

(In thousands, except per share data)	Fourth Quarter	Third Quarter	Second Quarter	First Quarter
Fiscal year ended March 31, 2015				
Total revenues	$ 1,234	$ 1,363	$ 1,256	$ 1,162
Costs of revenues	904	700	682	729
Gross profit	331	663	575	433
Operating expenses	5,788	3,221	4,636	4,864
Loss from operations	(5,457)	(2,557)	(4,061)	(4,431)
Other income (expense)	(898)	9,974	10,310	2,338
Income tax credit	(3)	—	—	—
Net (loss) income	(6,350)	7,417	6,248	(2,094)
Change in carrying value of convertible preferred mezzanine equity	(2,715)	13,600	15,132	(2,308)
Net (loss) income attributable to common shareholders	(9,065)	21,017	21,380	(4,402)
Earnings per share – Basic	$ (0.01)	$ 0.03	$ 0.04	$ (0.01)
Earnings per share – Diluted	$ (0.01)	$ (0.01)	$ (0.01)	$ (0.01)

NOTE 24. SUBSEQUENT EVENTS

The Company has evaluated subsequent events from the balance sheet date through June 7, 2017, the date the accompanying financial statements were issued. The following are material subsequent events.

Exchange Agreement with Nasrat Hakim

On April 28, 2017, the Company entered into an exchange agreement (the "Exchange Agreement") with Nasrat Hakim, the Chairman of the Board, President, and Chief Executive Officer of the Company, pursuant to which the Company issued to Mr. Hakim 23.0344 shares of its newly designated Series J Convertible Preferred Stock ("Series J Preferred") and Warrants to purchase an aggregate of 79,008,661 shares of its Common Stock (the "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 exchange was conducted pursuant to the exemption from registration provided by Section 3(a)(9) of the Securities Act of 1933, as amended (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 authorized shares is obtained 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.

Lincoln Park Transaction

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

Under the terms and subject to the conditions of the Purchase Agreement, the Company has the right to sell to and Lincoln Park is obligated to purchase up to $40 million in shares of the Company's 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. 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 4.99% of the then outstanding shares of Common Stock.

In connection with the Purchase Agreement, the Company issued to Lincoln Park 5,540,550 shares of Common Stock and the Company is required to issue up to 5,540,550 additional shares of Common Stock pro rata as the Company requires Lincoln Park to purchase its shares under the Purchase Agreement over the term of the agreement. Lincoln Park has represented to the Company, among other things, that it is an "accredited investor" (as such term is defined in Rule 501(a) of Regulation D under the Securities Act of 1933, as amended (the "Securities Act")). The Company sold the securities in reliance upon an exemption from registration contained in Section 4(a)(2) under the Securities Act. The securities sold may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements.

Trimipramine Acquisition

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

The 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.

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, 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.

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").

Under the 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 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%.

Common Stock issued and sold pursuant to the Lincoln Park Purchase Agreement

Subsequent to March 31, 2016 and up to June 7, 2017 (the latest practicable date), a total of 5,540,550 shares of Common Stock were issued to Lincoln Park Capital, with such shares representing initial commitment shares issued pursuant to the 2017 Lincoln Park Purchase Agreement. No shares of Common Stock were sold, no additional commitment shares were issued, and no proceeds were received pursuant to the 2017 Lincoln Park Purchase Agreement.

Exhibit 10.50
May 15, 2017

ASSET PURCHASE AGREEMENT

ASSET PURCHASE AGREEMENT ("Agreement"), dated May 15, 2017 (the "Effective Date"), between **Mikah Pharma LLC** a limited liability company organized under the laws of the State of Delaware ("Seller") and **Elite Laboratories, Inc.**, a corporation incorporated under the laws of the State of Delaware ("Buyer"). Buyer and Seller are each "Party" to this Agreement and together constitute the "Parties".

Background

Seller owns ANDA(s) that it acquired from Actavis, Inc. that was operating under a Consent Decree, a copy of which was provided to Buyer, which may subject the ANDA(s) (as defined below) to additional scrutiny before FDA permits the Products (as defined below) to be manufactured elsewhere. Nevertheless, on the terms and conditions set forth in this Agreement and the Consent Decree, Buyer wishes to purchase from Seller and Seller wishes to sell to Buyer, the ANDA(s).

NOW, THEREFORE, in consideration of the mutual covenants herein contained and for other good and valuable consideration the receipt and adequacy of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE 1

DEFINITIONS

Section 1.1 Definitions

All terms not defined below are defined elsewhere in this Agreement.

"Affiliate" means any Person that directly or indirectly Controls, is Controlled by or is under common Control with another Person. A Person will be deemed to "Control" another Person if it has the power to direct or cause the direction of the other Person, whether through ownership of securities, by contract or otherwise.

"Agency" means any governmental regulatory authority or authorities in the United States responsible for granting approval(s), clearance(s), qualification(s), license(s) or permit(s) for any aspect of the research, development, manufacture, marketing, distribution or sale of a Product. The term "Agency" includes, but is not limited to, the FDA and the United States Drug Enforcement Administration.

"ANDA(s)" means Abbreviated New Drug Applications listed in Schedule 1 and all amendments thereto, that have to-date been filed with the FDA seeking authorization and approval to manufacture, package, ship and sell, as more fully defined in 21 C.F.R. Part 314, the Products.

"ANDA(s) Technology and Scientific Materials" means any technological, scientific, chemical or biological materials, trade secrets, know-how, Intellectual Property, techniques, data, inventions, practices, methods and all other confidential and proprietary technical, research, development and other applicable business information (whether patented, patentable or otherwise) related to the manufacture, validation, packaging, release testing, stability and shelf life of the Product, including all Product formulations, in existence and in the possession of Seller as of the Closing Date.

"Assumed Liabilities" has the meaning set forth in Section 2.3.

"Bill of Sale" means a bill of sale to be delivered by Seller to Buyer effective on the Closing Date, substantially in the form of Exhibit A.

"Business Day" means any day other than a Saturday, Sunday or other day on which banks in New York, New York are permitted or required to close by law or regulation.

"Buyer" has the meaning set forth in the preamble.

"Buyer Indemnified Parties" has the meaning set forth in Section 8.2.

Calendar Quarter" means the three month period ending on the last day of each of March, June, September and December.

"Closing" and "Closing Date" have the meanings given such terms in Section 3.1.

"Development" means all preclinical and clinical drug development activities, including test method development and stability testing, toxicology, bioequivalency, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting clinical trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing and sale of the Products, Product approval and registration, and regulatory affairs related to the foregoing. "Develop" means to engage in Development.

"Effective Date" has the meaning set forth in the preamble.

"Encumbrance" means any mortgage, charge, lien, security interest, easement, right of way, pledge or encumbrance of any nature whatsoever.

"Excluded Liabilities" has the meaning set forth in Section 2.3.

"FDA" means the United States Food and Drug Administration.

"Governmental Entity" means any court, administrative agency, department or commission or other governmental authority or instrumentality, whether U.S. or non-U.S.

"Governmental Rule" means any law, judgment, order, decree, statute, ordinance, rule or regulation issued or promulgated by any Governmental Entity or Agency.

"Intellectual Property**"** has the meaning set forth in Section 4.7.

"Liabilities" means any and all debts, liabilities and obligations, whether accrued or fixed, absolute or contingent, matured or unmatured, or determined or determinable, including those arising under any law, action or governmental order and those arising under any contract, agreement, arrangement, commitment or undertaking, or otherwise.

"Losses" means, collectively, any and all damages, losses, taxes, Liabilities, claims, judgments, penalties, costs and expenses (including reasonable legal fees and expenses).

"Material Adverse Effect" means an effect which is material and adverse to the Purchased Assets taken as a whole, but does not include: (i) any adverse effect due to changes in conditions generally affecting (A) the healthcare industry or (B) the United States economy as whole, (ii) any change or adverse effect caused by, or relating to, the announcement of this Agreement and the transactions contemplated by this Agreement or (iii) any adverse effect due to legal or regulatory changes.

"Mutual Confidential Disclosure Agreement" means the Mutual Confidential Disclosure Agreement entered into by the parties dated May 18, 2010.

"Person" means any individual, corporation, partnership, limited liability company, joint venture, trust, business association, organization, Governmental Entity or other entity.

"Product(s)" means the pharmaceutical or products now or hereafter described in the ANDA(s).

"Purchase Note" has the meaning set forth in Section 2.1.

"Purchase Price" has the meaning set forth in Section 2.1.

"Purchased Assets" has the meaning set forth in Section 2.2.

"Security Agreement" has the meaning set forth in Section 2.1.

"Territory" means the United States and its territories, possessions, and commonwealths, including Puerto Rico.

"United States" or "U.S." or "U.S.A." means the United States of America.

Section 1.2 Interpretation

When used in this Agreement the words "include", "includes" and "including" will be deemed to be followed by the words "without limitation." Any terms defined in the singular will have a comparable meaning when used in the plural, and vice-versa.

Section 1.3 Currency

All currency amounts referred to in this Agreement are in United States Dollars, unless otherwise specified.

ARTICLE 2

SALE AND PURCHASE OF ASSETS

Section 2.1 Purchase and Sale

Upon the terms and subject to the conditions of this Agreement, on the Closing Date, upon payment of the $1,200,000 purchase price (the "Purchase Price") in the form of a Senior Secured Promissory Note (the "Purchase Note"), a copy of the form of which is attached hereto as Exhibit B, payment and performance of which by Buyer is secured in accordance with an ANDA(s) Security Agreement in the form attached hereto as Exhibit C (the "Security Agreement"), and by this reference incorporated herein, Seller will sell, assign, transfer, convey and deliver to Buyer, and Buyer will purchase, acquire and accept, all right, title and interest, within the Territory, of Seller in, to and under the Purchased Assets.

Section 2.2 Purchased Assets

The term "Purchased Assets" means the following properties, assets and rights of whatever kind and nature, tangible or intangible, of Seller existing on the Closing Date that relate solely and exclusively to the ANDA(s) and any testing, data, studies, and formulations created in connection therewith including but not limited to: (i) the ANDA(s), (ii) any correspondence with the FDA in Seller's files with respect to the ANDA(s), (iii) the right of 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 or 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.

Section 2.3 Assumption of Certain Liabilities and Obligations

From and after the Closing, Buyer will assume, be responsible for and pay, perform and discharge when due only those Liabilities in connection with the Purchased Assets, the use thereof and the later sale of any Product by Buyer arising from and after the Closing Date and only with respect to events, conditions, actions or circumstances first arising after the Closing Date, including but not limited to (i) Liabilities arising from any patent or trademark infringement claim or lawsuit brought by any Third Party, (ii) any product liability claim, and (iii) Liabilities arising from FDA or any other Governmental Entity action or notification after the Closing Date (collectively, the "Assumed Liabilities"). Notwithstanding the foregoing, Buyer will not assume or be liable for any Liabilities arising in connection with the Product and the Purchased Assets manufactured prior to the Closing Date, including Liabilities resulting from Third Party agreements of Seller or its Affiliates and Third Party claims arising out of acts or omissions of Seller prior to Closing Date (collectively, the "Excluded Liabilities").

ARTICLE 3

CLOSING

Section 3.1 Closing Date

The closing of the sale and transfer of the Purchased Assets (the "Closing") will take place at the offices of either Buyer or Seller or by fax, electronic delivery or mail, or other place as mutually agreed to by the Parties. The Closing shall take place on the Effective Date or first Business Day following the execution of this Agreement; provided, however, all of the conditions to each Party's obligations under this Article have been satisfied or waived, or at such other time and date as will be mutually agreed to by the Parties hereto (such date of the Closing being hereinafter referred to as the "Closing Date").

Section 3.2 Intentionally left blank.

Section 3.3 Conditions to Obligations of Buyer

The obligation of Buyer to purchase the Purchased Assets from Seller is subject to the satisfaction on and as of the Closing of each of the following conditions, unless waived by Buyer:

(a) Representations. The representations and warranties of Seller set forth in this Agreement will be true and correct as of the Closing as though made on and as of the Closing, except to the extent such representations and warranties relate to an earlier date (in which case such representation and warranties will be true and correct as of such earlier date).

(b) Performance of Obligations of Seller. Seller will have performed or complied in all material respects with all obligations, conditions and covenants required to be performed by it under this Agreement at or prior to the Closing.

(c) Closing Deliveries. Seller will have executed and delivered to Buyer, dated as of the Closing Date, the (i) Bill of Sale, and (ii) a "Transfer of Ownership" letter to the FDA, relating to each of the ANDA(s), as prescribed in 21 CFR 314.72, and shall deliver to Buyer a certificate of the Secretary of State or other applicable Governmental Authority certifying the good standing of Seller in its jurisdiction of organization as of a date within seven days of the Closing Date.

(d) ANDA(s). As further described in Section 6.2, Seller will deliver the ANDA(s) to Buyer.

(e) No Government Rule enacted, entered, promulgated, enforced or issued by any Governmental Entity, Agency, or other legal restraint or prohibition shall be pending, threatened or in effect, which would (i) prevent consummation of any of the transactions contemplated by this Agreement, (ii) cause any of the transactions contemplated by this Agreement to be rescinded following consummation or (iii) affect adversely the right of Purchaser to own or exploit the Purchased Assets.

Section 3.4 Conditions to the Obligations of Seller

The obligations of Seller to sell, assign, convey, and deliver the Purchased Assets, or to cause the Purchased Assets to be sold, assigned, conveyed or delivered, as applicable, to Buyer are subject to the satisfaction on and as of the Closing of each of the following conditions, unless waived by the Seller:

(a) Representations and Warranties. The representations and warranties of Buyer set forth in this Agreement will be true and correct in all material respects as of the Closing as though made on and as of the Closing, except: (i) to the extent such representations and warranties expressly relate to an earlier date (in which case such representations and warranties will be true and correct as of such earlier date) and (ii) for breaches of representations and warranties as to matters that individually or in the aggregate would not materially interfere with Buyer's performance of its obligations hereunder; and

(b) Closing Deliveries. Buyer shall have delivered to Seller, (i) an original executed copy of the Purchase Note and Security Agreement, and (ii) a certificate of the Secretary of State or other applicable Governmental Authority certifying the good standing of Buyer in its jurisdiction of organization as of a date within seven days of the Closing Date.

ARTICLE 4

REPRESENTATIONS AND WARRANTIES OF SELLER

As of each of the Effective Date and Closing Date, Seller hereby represents and warrants to Buyer as follows:

Section 4.1 Seller Organization; Good Standing; Business

Seller is a limited liability company, duly organized, validity existing and in good standing under the laws of the State of Delaware. Seller has the requisite power and authority to own the Purchased Assets and to carry on its business as currently conducted. Seller is duly qualified to conduct business as a foreign limited liability company and is in good standing in each jurisdiction where the nature of the business conducted by it makes such qualification necessary, except where the failure to do so qualify or be in good standing would not have a Material Adverse Effect. Seller, in the ordinary course of its business, regularly acquires and sells ANDAs.

Section 4.2 Authority; Execution and Delivery

Seller has the requisite limited liability company power and authority to enter into this Agreement and to consummate the transaction contemplated. The execution and delivery of this Agreement by Seller and the consummation of the transactions contemplated have been validly authorized. This Agreement has been executed and delivered by Seller and, assuming the due authorization, execution and delivery of this Agreement by Buyer, will constitute the legal and binding obligation of Seller, enforceable against it in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent transfer and other similar laws affecting creditors' rights generally from time to time in effect and to general principles of equity (including concepts of materiality, reasonableness, good faith and fair dealing) regardless of whether considered in a proceeding in equity or at law.

Section 4.3 Consents; No Violation, Etc.

The execution and delivery of this Agreement do not, and the consummation of the transactions contemplated hereby and the compliance with the terms hereof will not: (i) violate any Governmental Rule applicable to Seller, (ii) conflict with any provision of the certificate of incorporation or by-laws or certificate of formation or operating agreement (or similar organizational document) of Seller, (iii) result in a violation or breach of, or constitute (with or without due notice or lapse of time or both) a default (or give rise to any right of termination, cancellation or acceleration) under, or result in the creation of any Encumbrance upon any of the Purchased Assets (other than those imposed by the Security Agreement) under any of the terms, conditions or provisions of, any contract, agreement, plan, understanding, undertaking, commitment or arrangement, whether written or oral, any note, bond, mortgage, indenture, lease, license, deed of trust, loan, or other agreement, instrument or obligation to which Seller is a party or by which Seller or any of the Purchased Assets may be bound, (iv) to the knowledge of Seller, violate any rights of any non-party, or (v) require any approval, authorization, consent, license, exemption, filing or registration with any court, arbitrator or Governmental Entity, except, with respect to the foregoing clauses (i) and (iii), for such violations or conflicts which would not have a Material Adverse Effect or materially interfere with Seller's performance of its obligations hereunder or, with respect to the foregoing clause (v), for such approvals, authorizations, consents, licenses, exemptions, filings or registrations which have been obtained or made or which, if not obtained or made, would not have a Material Adverse Effect or interfere with Seller's performance of its obligations hereunder.

Section 4.4 Litigation

To the knowledge of Seller, there are no claims, suits, actions or other proceedings pending or threatened in writing against Seller at law or in equity before or by any Governmental Entity or Agency, including but not limited to federal, state, municipal or other governmental department, commission, board bureau, agency or instrumentality, domestic or foreign, which may in any way materially adversely affect the performance of Seller's obligations under this Agreement or the transactions contemplated hereby. There are no outstanding claims, suits, actions, judgments, orders, injunctions, decrees or awards against Seller in connection with the Purchased Assets, this Agreement or the transactions contemplated hereby that have not been satisfied in all material respects.

Section 4.5 Title to Purchased Assets; AS IS

Seller has good and valid title to all of the Purchased Assets, as the case may be, free and clear of all Encumbrances. Buyer agrees that it is purchasing and will take possession of the Purchased Assets in their **AS IS** condition and that Buyer has been given the opportunity to conduct such investigations and inspections of the Purchased Assets as it deems necessary or appropriate.

Section 4.6 Purchased Assets AS IS

SELLER DOES NOT MAKE ANY REPRESENTATIONS OR WARRANTIES THAT THE FDA WILL APPROVE ANY FILINGS FOR OR RELATED TO THE ANDA(s) TRANSFERRED HEREUNDER OR THAT BUYER WILL EVER BE ABLE TO PRODUCE A COMMERICALLY SALEABLE PRODUCT AS TO THE ANDA(s). SELLER FURTHER MAKES NO REPRESENTATIONS AS TO THE ADEQUACY OR COMPLETENESS OF THE FORMULATION OR OTHER DATA UNDERLYING THE ANDA(s) AND FURTHER MAKES NO REPRESENTATION AS TO THE REGULATORY SUFFICIENCY OF THE ANDA(s).

Section 4.7 Intellectual Property.

Seller owns or possesses adequate and enforceable licenses or other rights to use all "Intellectual Property" as defined below, is not in default under any such licensing or similar agreement and has not received any notice or has knowledge of conflict with or infringement (or alleged infringement) of any rights of others. Seller has no notice or knowledge that any of the Intellectual Property is being infringed upon or appropriated by any third party. The use of any Intellectual Property and other technical or proprietary data related to the Purchased Assets has not required and does not require the payment of any royalty or similar payment to any person, firm or corporation, and, immediately following the Closing, Buyer will have good and marketable title thereto, free and clear of any Encumbrances. "Intellectual Property" means all inventions, improvements, patents, utility models, designs, trade names, trade dress, trade secrets, trademarks, service marks, copyrights, know-how and other proprietary rights (including all grants, registrations or applications therefor), and all goodwill associated therewith, relating to the Purchased Assets or necessary for exploitation of the Purchased Assets, including, without limitation, any trade name, trademark or service mark.

Section 4.8 Full Disclosure

No representation or warranty of Seller in this Agreement (including the Schedules attached hereto) and no statement of Seller contained in any document or certificate contemplated by this Agreement, considered as a whole with all other representations, warranties and statements, contains or will contain any untrue statement of material fact or omits or will omit to state any material fact necessary, in light of the circumstances under which it was made, in order to make the statements herein or therein not misleading.

Section 4.9 Exclusive Representations and Warranties

Other than the representations and warranties set forth in this Article 4, Seller is not making any other representations or warranties, express or implied, with respect to the Purchased Assets.

ARTICLE 5

REPRESENTATIONS OF BUYER

As of each of the Effective Date and Closing Date, Buyer hereby represents and warrants to Seller as follows:

Section 5.1 Buyer's Organization; Good Standing

Buyer is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. Buyer is not in arrears of any taxes and is not under investigation by any Governmental Entity. Buyer has requisite corporate power and authority to carry on its business as it is currently being conducted. Buyer is qualified to conduct business as a foreign corporation and is in good standing in every jurisdiction where the nature of the business conducted by it makes such qualification necessary, except where the failure to so qualify or be in good standing would not prevent or materially delay the consummation of the transactions contemplated hereby.

Section 5.2 **Authority; Execution and Delivery**

Buyer has the corporate power and authority to enter into this Agreement and to consummate the transactions contemplated hereby. The execution and delivery of this Agreement by Buyer and the consummation of the transactions contemplated hereby have been authorized. This Agreement has been executed and delivered by Buyer and, assuming the due authorization, execution and delivery of this Agreement by Seller, constitutes the legal and binding obligation of Buyer, enforceable against Buyer in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent transfer and other similar laws affecting creditors' rights generally from time to time in effect and to general principles of equity (including concepts of materiality, reasonableness, good faith and fair dealing regardless) of whether considered in a proceeding in equity or at law.

Section 5.3 **Consents; Notices; No Violations, Etc.**

The execution and delivery of this Agreement do not, and the consummation of the transactions contemplated hereby and the compliance with the terms hereof will not: (i) violate any Governmental Rule, (ii) conflict with any provision of the certificate of incorporation or by-laws of Buyer, (iii) result in a violation or breach of, or constitute (with or without due notice or lapse of time or both) a default (or give rise to any right of termination, cancellation or acceleration) under, or result in the creation of any Encumbrance upon any of the Purchased Assets (other than those imposed by the Security Agreement) under any of the terms, conditions or provisions of, any contract, agreement, plan, understanding, undertaking, commitment or arrangement, whether written or oral, any, note, bond, mortgage, indenture, lease, license, deed of trust, loan, or other agreement, instrument or obligation to which Buyer is a party or (iv) require any approval, authorization, consent, license, exemption, filing or registration with any court, arbitrator or Governmental Entity, except with respect to the foregoing clauses (i) and (iii), for such violations or conflicts which would not materially interfere with Buyer's performance of its obligations hereunder or, with respect to the foregoing clause (iv), for such approvals, authorizations, consents, licenses, exemptions, filings or registrations which have been obtained or made or which, if not obtained or made, would not materially interfere with Buyer's performance of its obligations hereunder.

Section 5.4 **Litigation**

As of the date hereof, there is no suit, claim, action, investigation or proceeding pending or, to the knowledge of Buyer, threatened against Buyer or any of its Affiliates which if adversely determined would delay the ability of Buyer to perform any of its obligations hereunder.

Section 5.5 **Status of ANDA(s)**

Buyer has reviewed each of the ANDA(s), recognizes that they may be subject to additional scrutiny by the FDA as a result of the Consent Decree, and recognizes and assumes all risks and costs directly or indirectly associated with the ANDA(s), obtaining FDA approval to transfer the manufacturing site for the ANDA(s) and the Products.

Section 5.6 **Assumption of Regulatory Commitments**

From and after the Closing Date, Buyer will assume control of and responsibility for all costs, obligations and Liabilities arising from or related to, any commitments or obligations to any Governmental Entity involving the ANDA(s) and any of the other Purchased Assets.

ARTICLE 6

OTHER AGREEMENTS

Section 6.1 Confidentiality

The parties agree that the exchange of confidential information and materials relating to the Purchased Assets and the terms and conditions contained in this Agreement shall be governed by the Mutual Confidential Disclosure Agreement, which is hereby incorporated herein by reference in its entirety. The term of the Mutual Confidential Disclosure Agreement is hereby extended by the parties for five (5) years beyond the term of the Agreement.

Section 6.2 Transfer of ANDA(s) and Technology Transfer Assistance

For a period of 30 days from and after the Closing Date, Seller will cooperate with Buyer in disclosing and copying any relevant records and reports which are required to be made, maintained and reported pursuant to Governmental Rules in the Territory with respect to the ANDA(s) that is a part of the Purchased Assets, including ANDA(s) documents, marketing and regulatory authorizations and a tech-transfer package containing analytical methods, master batch records, validation reports, Annual Product Reports, finished product and raw material specifications, and retain samples, in each case to the extent they are available. The Parties will make reasonable efforts to recover any missing regulatory documents (original ANDA(s) and any amendments or supplements thereto) from FDA and to take any other actions required by the FDA to effect the transactions contemplated herein.

Section 6.3 Intentionally left blank.

Section 6.4 Further Action; Consents; Filings

Upon the terms and subject to the conditions hereof, Seller and Buyer will use their respective reasonable efforts to: (i) take, or cause to be taken, all actions necessary and proper under applicable Governmental Rules or otherwise to satisfy the conditions to Closing and consummate and make effective the transactions contemplated by this Agreement, (ii) obtain from the requisite Governmental Entities any consents, licenses, permits, waivers, approvals, authorizations or orders required to be obtained or made in connection with the authorization, execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement, and (iii) make all necessary filings, and thereafter make any other advisable submissions, with respect to this Agreement and the transactions contemplated by this Agreement required under any applicable Governmental Rules. The parties will cooperate with each other in connection with the making of all filings, including by providing all such non-confidential documents to the other party hereto and its advisors prior to filing and, if requested, by accepting all reasonable additions, deletions or changes suggested in connection therewith. Seller and Buyer will furnish all information required for any application or other filing to be made pursuant to the rules and regulations of any applicable Governmental Rules in connection with the transactions contemplated by this Agreement.

ARTICLE 7

TERMINATION AMENDMENT AND WAIVER

Section 7.1 Termination

(a) This Agreement may be terminated and the transactions contemplated hereby abandoned at any time prior to the Closing:

(i) by mutual written consent of Seller and Buyer; or

(ii) by Buyer if any of the conditions set forth in Section 3.3 will have become incapable of fulfillment and will not have been waived by Buyer; or

(iii) by Seller if any of the conditions set forth in Section 3.4 will have become incapable of fulfillment and will not have been waived by Seller,

provided, the party seeking termination pursuant to clause (ii) or (iii) is not in breach of any of its representations, warranties, covenants or agreements contained in this Agreement.

(b) In the event of termination of this Agreement by either party pursuant to this Section, written notice thereof will be given to the other party and the transactions contemplated by this Agreement will be terminated, without further action by either party. If this Agreement is terminated as provided herein:

(i) Buyer will return the Purchased Assets and all documents and other material received from Seller relating to the Purchased Assets and to the transactions contemplated hereby, whether so obtained before or after the execution hereof, to Seller; and

(ii) All confidential information received by Buyer with respect to Seller, the Purchased Assets will be continued to be treated confidential in accordance with the Mutual Confidential Disclosure Agreement.

Section 7.2 Amendments and Waivers

This Agreement may not be amended except by an instrument in writing signed by both parties hereto. By an instrument in writing, Buyer, on the one hand, or Seller, on the other hand, may waive compliance by the other party with any term or provision of this Agreement that such other party was or is obligated to comply with perform.

ARTICLE 8

INDEMNIFICATION

Section 8.1 Survival

All representations and warranties of Seller and Buyer contained herein or made pursuant hereto will survive the Closing Date for an indefinite period or until such time as Buyer and Seller shall mutually agree in writing. The covenants and agreements of the parties hereto contained in this Agreement will survive and remain in full force for the applicable periods described herein or, if no such period is specified, indefinitely. Any right of indemnification pursuant to this Article with respect to a claimed breach of a representation, warranty, covenant, agreement or obligation shall expire only upon written release by the party whom such representation, warranty, covenant, agreement or obligation is owed. The provisions of this Section 8.1 will survive for so long as any other Section of this Agreement will survive.

Section 8.2 Indemnification

(a) Seller Indemnification. Seller hereby agrees to indemnify and defend Buyer and its Affiliates, and their respective officers, directors and employees (the "Buyer Indemnified Parties") against, and agrees to hold them harmless from, any Losses to the extent such Losses arise from or in connection with the following:

(i) breach or alleged breach by Seller and/or any of its Affiliates or successors in interest thereto of any representation or warranty made by it contained in this Agreement;

(ii) any breach or alleged breach by Seller and/or any of its Affiliates or successors in interest thereto of any of its covenants, agreements or obligations contained in this Agreement; or

(iii) events, conditions actions or circumstances arising prior to the Closing;

provided, that Seller's aggregate liability in respect of all Losses suffered or incurred by Buyer Indemnified Parties shall not exceed, and Seller will have no obligation to compensate any Buyer Indemnified Party for Losses in excess of, an aggregate amount equal to the Purchase Price. Seller may satisfy any obligation hereunder to compensate Buyer Indemnified Parties by a reduction in the unpaid balance of the Purchase Note; and, if the amount of such Losses exceeds the unpaid portion of the Purchase Note, then, to the extent that any portion of the Purchase Price or the payments due on the Purchase Note have been paid in the form of shares of stock in Buyer, Seller may pay such excess Losses with shares of common stock in Buyer. If Seller elects to use common stock in Buyer to compensate the excess Losses suffered or incurred by the Buyer Indemnified Parties, then the value of each share shall be the average closing price of a share of Buyer's common stock on the principal trading market on which such shares are then trading for the 10 trading days immediately preceding the date on which the shares are delivered in payment.

(b) Buyer Indemnification. Buyer hereby agrees to indemnify and defend Seller and its Affiliates and related companies, and their respective officers, directors and employees (the "Seller Indemnified Parties") against, and agrees to hold them harmless from, any Losses to the extent such Losses arise from or in connection with the following:

(i) any breach or alleged breach by Buyer and/or any of its Affiliates or successors in interest of any representation or warranty made by it contained in this Agreement;

(ii) any breach or alleged breach by Buyer and/or any of its Affiliates or successors in interest of any of its covenants, agreements or obligations contained in this Agreement; or

(iii) any and all liability in connection with the use and sale of the Product(s) by Buyer or the ANDA(s)

provided, that Buyer's aggregate liability in respect of all Losses suffered or incurred by Seller Indemnified Parties shall not exceed, and Buyer will have no obligation to compensate any Seller Indemnified Party for Losses in excess of, an aggregate amount equal to the Purchase Price.

Section 8.3 Procedure

(a) In order for an Indemnified Party under this Article 8 (an "Indemnified Party") to be entitled to any indemnification provided for under this Agreement, the Indemnified Party will, within a reasonable period of time following the discovery of the matters giving rise to any Losses, notify its applicable insurer and the indemnifying party under this Article 8 (the "Indemnifying Party") in writing of its claim for indemnification for such Losses, specifying in reasonable detail the nature of the Losses and the amount of the liability estimated to accrue therefrom; provided, however, that failure to give notification will not affect the indemnification provided hereunder, except to the extent the Indemnifying Party will have been actually prejudiced as a result of the failure. Thereafter, the Indemnified Party will deliver to the Indemnifying Party, within a reasonable period of time after the Indemnified Party's receipt of such request, all information, records and documentation reasonably requested by the Indemnifying Party with respect to such Losses. The Indemnifying Party shall control all litigation reflecting to the indemnification. Without limiting the foregoing, the Indemnified Party shall control choice of counsel, staffing, and all decisions to be made with the litigation.

(b) If the indemnification sought pursuant hereto involves a claim made by a non-party against the Indemnified Party (a "Non-Party Claim"), the Indemnifying Party will be entitled to participate in the defense of such Non-Party Claim and, if it so chooses, to assume the defense of such Non-Party Claim with counsel selected by the Indemnifying Party. Should the Indemnifying Party so elect to assume the defense of a Non-Party Claim, the Indemnifying Party will not be liable to the Indemnified Party for any legal expenses subsequently incurred by the Indemnified Party in connection with the defense thereof. If the Indemnifying Party assumes such defense, the Indemnifying Party will control such defense. The Indemnifying Party will be liable for the reasonable fees and expenses of counsel employed by the Indemnified Party for any period during which the Indemnifying Party has not assumed the defense thereof (other than during any period in which the Indemnified Party will have failed to give notice of the Non-Party Claim as provided above). If the Indemnifying Party chooses to defend or prosecute a Non-Party Claim, all of the parties hereto will cooperate in the defense or prosecution thereof. Such cooperation will include the retention and (upon the Indemnifying Party's request) the provision to the Indemnifying Party of records and information, which are reasonably relevant to such Non-Party Claim, and making employees available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder. If the Indemnifying Party chooses to defend or prosecute any Non-Party Claim, the Indemnifying Party will seek the approval of the Indemnified Party (not to be unreasonably withheld) to any settlement, compromise or discharge of such Non-Party Claim the Indemnifying Party may recommend and which by its terms obligates the Indemnifying Party to pay the full amount of the liability in connection with such Non-Party Claim. Whether or not the Indemnifying Party will have assumed the defense of a Non-Party Claim, the Indemnified Party will not admit any liability with respect to, or settle, compromise or discharge, such Non-Party Claim without the Indemnifying Party's prior written consent. The Indemnifying Party shall reimburse upon demand, all reasonable costs and expenses incurred by the Indemnified Party in cooperation with the defense or prosecution of the Non-Party Claim.

Section 8.4 Exclusive Remedy.

The indemnification rights provided in this Article 8 shall constitute the sole and exclusive remedy with respect to all claims of any kind or nature related to, or arising out of, or in connection with, any breach of or inaccuracy in any representation, warranty or covenant contained in this Agreement (other than claims arising from fraud or intentional misrepresentation on the part of a party in connection with the transactions contemplated by this Agreement). Nothing in this Section 8.4 shall limit any party's right to seek and obtain any equitable relief, including specific performance, to which any party shall be entitled or to seek any remedy on account of any party's fraudulent or intentional misrepresentation.

ARTICLE 9

GENERAL PROVISIONS

Section 9.1 Expenses

Except as otherwise specified in this Agreement, all costs and expenses, including fees and disbursements of counsel, financial advisors and accountants, incurred in connection with this Agreement and the transactions contemplated hereby will be paid by the party incurring such costs and expenses, whether or not the Closing will have occurred.

Section 9.2 Further Assurances and Actions

Each of the parties hereto, upon the request of the other party hereto, whether before or after the Closing and without further consideration, will do, execute, acknowledge and deliver or cause to be done, executed, acknowledged or delivered all such further acts, deeds, documents, assignments, transfers, conveyances, powers of attorney and assurances as may be reasonably necessary to effect complete consummation of the transactions contemplated by this Agreement. Seller and Buyer agree to execute and deliver such other documents, certificates, agreements and other writings and to take such other actions as may be reasonably necessary in order to consummate or implement expeditiously the transactions contemplated by this Agreement.

Section 9.3 Notices

All notices and other communications required or permitted to be given or made pursuant to this Agreement shall be in writing signed by the sender and shall be deemed duly given: (a) on the date delivered, if personally delivered, (b) on the date sent by facsimile with automatic confirmation by the transmitting machine showing the proper number of pages were transmitted without error, (c) on the Business Day after being sent by Federal Express or another recognized overnight mail service which utilizes a written form of receipt for next day or next business day delivery, or (d) upon receipt after mailing, if mailed by United States postage-prepaid certified or registered mail, return receipt requested, in each case addressed to the applicable party at the address set forth below: provided that a party may change its address for receiving notice by the proper giving of notice hereunder:

(a) **if to Seller, to:**

Mikah Pharma LLC

(b) **if to Buyer, to**:

Elite Laboratories, Inc.
165 Ludlow Avenue
Northvale, New Jersey 07647

Attn: Carter Ward, Chief Financial Officer
Fax No.: (201) 750-2755

With a courtesy copy, which shall not constitute notice hereunder, sent to:

Richard Feiner, Esq.
Wall Street Plaza
88 Pine Street
22nd floor
New York, NY 10005
Attn: Richard Feiner
Fax No.: (917) 720-0863

Section 9.4 Headings

The table of contents and headings contained in this Agreement are for reference purposes only and will not affect in any way the meaning or interpretation of this Agreement.

Section 9.5 Severability

If any term or other provision of this Agreement is invalid, illegal or incapable of being enforced under any law or public policy, all other terms and provisions of this Agreement will nevertheless remain in full force and effect so long as the economic or legal substance of the transactions contemplated hereby is not affected in any manner materially adverse to any party. Upon such determination that any term or other provision is invalid, illegal or incapable of being enforced, the parties hereto will negotiate in good faith to modify this Agreement so as to effect the original intent of the parties hereto as closely as possible in an acceptable manner in order that the transactions contemplated hereby are consummated as originally contemplated to the greatest extent possible.

Section 9.6 Counterparts

This Agreement may be executed in one (1) or more counterparts, all of which will be considered one and the same agreement and will become effective when one or more counterparts have been signed by each of the Parties hereto and delivered to the other parties hereto. This Agreement, once executed by a Party, may be delivered to the other Party hereto by facsimile or electronic transmission of a copy of this Agreement bearing the signature of the Party so delivering this Agreement. A faxed or electronically delivered signature shall have the same legally binding effect as an original signature.

Section 9.7 Entire Agreement: No Non-Party Beneficiaries

This Agreement and the Exhibits and Schedules hereto constitute the entire agreement and supersede all prior agreements and understandings both written and oral (including any letter or intent, memorandum of understanding electronic communicators, e-mail or term sheet), between or among the parties hereto with respect to the subject matter hereof. Except as specifically provided herein or therein, such agreements are not intended to confer upon any non-party other than the parties hereto any rights or remedies hereunder or thereunder.

Section 9.8 Governing Law

This Agreement and any and all matters arising directly or indirectly herefrom shall be governed by and construed and enforced in accordance with the laws of the State of New Jersey, U.S.A. applicable to agreements made and to be performed entirely in such state, without giving effect to the conflict of law principles thereof.

Section 9.9 Jurisdiction, Venue, Service of Process

Buyer and Seller agree to irrevocably submit to the sole and exclusive jurisdiction of the state or federal courts in the state of New Jersey for any suit, action or other proceeding arising out of this Agreement or any transaction contemplated hereby. Notwithstanding the foregoing, only if such suit, action or other proceeding may not be brought in New Jersey, it may instead be brought in a Delaware court of appropriate jurisdiction. Each party agrees that service of any process, summons, notice or document by U.S. registered mail or recognized international courier service to such party's address set forth in this Agreement shall be effective service of process.

Section 9.10 Specific Performance

The parties hereto agree that irreparable damage would occur in the event any provision of this Agreement were not performed in accordance with the terms hereof and that the parties will be entitled to specific performance of the terms hereof, in addition to any other remedy at law or in equity, without the necessity of demonstrating the inadequacy of monetary damages and without the posting of a bond.

Section 9.11 Force Majeure

Neither party will be in default of this Agreement to the extent that performance of its obligations (other than obligations to pay amounts owed under this Agreement) is delayed or prevented by reason of events or circumstances beyond its reasonable control, including without limitation, earthquake, flood or other acts of God, fire, explosion, terrorism, war, compliance with laws, regulations or governmental or judicial orders, labor disputes, unavailability of transportation ("Force Majeure"). Should either party be delayed in or prevented from performing any of its obligations under this Agreement by reason of Force Majeure, such party shall give prompt notice thereof to the other party and shall be obligated to perform the affected obligations within sixty (60) days after the Force Majeure ceases to delay or prevent performance thereof.

Section 9.12 Publicity

Neither party will make any public announcement concerning, or otherwise publicly disclose, any information with respect to the transactions contemplated by this Agreement or any of the terms and conditions hereof without the prior written consent of the other parties hereto. Notwithstanding the foregoing, either party may make any public disclosure concerning the transactions contemplated hereby that in the opinion of such party's counsel may be required by law or the rules of any stock exchange on which such party's or its Affiliates' securities trade; provided, however, the party making such disclosure will provide the non-disclosing party with a copy of the intended disclosure reasonably, and to the extent practicable, prior to public dissemination, and the parties hereto will coordinate with one another regarding the timing, form and content of such disclosure. Notwithstanding the foregoing, after the Closing, Buyer may publicize its ability to market and sell the Product(s) without approval from Seller.

Section 9.13 Schedules and Exhibits.

The Schedules and all Exhibits attached hereto are hereby incorporated by reference into, and made a part of, this Agreement.

Section 9.14 Ambiguities.

Each Party and its counsel have participated fully in the review and revision of this Agreement. Any rule of construction to the effect that ambiguities are to be resolved against the drafting party shall not apply in interpreting this Agreement. The language in this Agreement shall be interpreted as to its fair meaning and not strictly for or against any Party.

Section 9.15 Assignment

Neither party may assign its rights or obligations under this Agreement without the prior written consent of the other party; provided, however, that either party may assign its rights and obligations under this Agreement, without the prior written consent of the other party, to an Affiliate or to a successor of the assignment party by reason of merger, sale of all or substantially all of its assets or any similar transaction. Any permitted assignee or successor-in-interest will assume all obligations of its assignor under this Agreement. No assignment will relieve either party of its responsibility for the performance of any obligation. This Agreement will be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns.

[signature page follows]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be signed by their respective representatives thereunto duly authorized, all as of the date first written above.

MIKAH PHARMA LLC	**ELITE LABORATORIES, INC.**
By: /s/ Nasrat Hakim Nasrat Hakim, President and CEO	By: /s/ Carter Ward Carter Ward, Chief Financial Officer

Exhibit 10.50
May 15, 2017

SCHEDULE 1

ABBREVIATED NEW DRUG APPLICATIONS

Number	Description	Status
077361	Trimipramine Maleate Capsules, 25, 50 and 100 mg	Approved ANDA

EXHIBIT A

BILL OF SALE

THIS BILL OF SALE, dated May 15, 2017, is executed by Mikah Pharma LLC ("Seller"), a limited liability company organized under the laws of Delaware in favor of Elite Laboratories, Inc. ("Buyer"), a corporation incorporated under the laws of Delaware, pursuant to the Asset Purchase Agreement, dated May 15, 2017 (the "Agreement"), by and between Seller and Buyer. Capitalized terms used but not defined herein have the meanings given to them in the Agreement.

i. The Agreement provides for, among other things, the sale of the Purchased Assets by Seller to Buyer.

ii. In consideration of the payment of the amounts set forth in the Agreement, Seller by this Bill of Sale does hereby, sell, transfer, assign and deliver to Buyer, all of its rights, title and interest in and to the Purchased Assets.

iii. Seller hereby represents that from time to time after the delivery of this instrument, at Buyer's request and without further consideration, Seller will do, execute, acknowledge and deliver, or will cause to be done, executed, acknowledged and delivered, all such further acts, deeds, conveyances, transfers, assignments, powers of attorney and assurances as reasonably may be required more effectively to convey, transfer to and vest in Buyer, and to put Buyer in possession of, the Purchased Assets.

iv. This instrument is executed by, and will be binding upon, Seller and its successors and assigns for the uses and purposes set forth herein.

v. This Bill of Sale shall be construed and enforced in accordance with the laws of the State of New Jersey.

IN WITNESS WHEREOF, this Bill of Sale has been duly executed and delivered by Seller as of the date and year first written above.

MIKAH PHARMA LLC

By: _____
Nasrat Hakim, President and CEO

EXHIBIT B

FORM OF SECURED PROMISSORY NOTE

[See Exhibit 10.51]

EXHIBIT C

FORM OF ANDA SECURITY AGREEMENT

[See Exhibit 10.52]

Exhibit 10.51

THIS SECURED PROMISSORY NOTE (THE "NOTE") HAS NOT BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS AS EVIDENCED BY A LEGAL OPINION OF COUNSEL, THE SUBSTANCE OF WHICH SHALL BE REASONABLY ACCEPTABLE TO THE COMPANY.

Issue Date: May 15, 2017 Principal Amount: $1,200,000.00

ELITE PHARMACEUTICALS, INC. AND ELITE LABORATORIES, INC.
SECURED NOTE DUE 2020

FOR VALUE RECEIVED, pursuant to the Purchase Agreement (as defined below), ELITE PHARMACEUTICALS, INC., a Nevada corporation (the "**Company**") and its wholly-owned subsidiary, ELITE LABORATORIES, INC., a Delaware corporation ("**Elite**" and, together with the Company, the "**Debtors**"), jointly and severally, promise to pay to the order of MIKAH PHARMA LLC, a limited liability company organized under the laws of the State of Delaware (the "**Holder**"), the principal sum of Million Dollars Two Hundred Thousand and no cents ($1,200,000), plus all accrued but unpaid interest thereon, on the Maturity Date (as defined below), or such earlier date as the Note is required or permitted to be repaid as provided hereunder. Interest shall accrue and be payable as set forth below in Section 2(b).

Payments of principal shall be made in lawful money of the United States of America to the Holder at its address as provided in Section 9 or by wire transfer to such account specified from time to time by the Holder hereof for such purpose by notice as provided in Section 9.

1 . Definitions. In addition to the terms defined elsewhere in this Note, (a) capitalized terms that are not otherwise defined herein have the meanings given to such terms in the Asset Purchase Agreement by and between Holder and Elite of even date (the "**Purchase Agreement**"), and (b) the following terms have the meanings indicated:

"**Bankruptcy Event**" means any of the following events: (a) any of the Debtors commences a case or other proceeding under any bankruptcy, reorganization, arrangement, adjustment of debt, relief of debtors, dissolution, insolvency or liquidation or similar law of any jurisdiction relating to such Debtor; (b) there is commenced against any of the Debtors any such case or proceeding that is not dismissed within 60 days after commencement; (c) any of the Debtors is adjudicated insolvent or bankrupt or any order of relief or other order approving any such case or proceeding is entered; (d) any of the Debtors suffers any appointment of any custodian or the like for it or any substantial part of its property that is not discharged or stayed within 60 days; (e) any of the Debtors makes a general assignment for the benefit of creditors; (f) any of the Debtors calls a meeting of its creditors with a view to arranging a composition, adjustment or restructuring of its debts; or (g) any of the Debtors, by any act or failure to act, expressly indicates its consent to, approval of or acquiescence in any of the foregoing or takes any corporate or other action for the purpose of effecting any of the foregoing.

"**Maturity Date**" means December 31, 2020.

"**Original Issue Date**" means the date of the first issuance of this Note.

"**Person**" means any individual, corporation, partnership, limited liability company, joint venture, trust, business association, organization, Governmental Entity or other entity.

"**Security Agreement**" means the Security Agreement of even date between the Holder as Secured Party and the Debtors as Debtors.

"**Transaction Documents**" means, collectively, this Note, the Purchase Agreement, the Security Agreement, and the schedules and exhibits hereto and thereto.

2. Payment of Principal and Interest.

(a) Principal Payment at Maturity. The Company shall pay the outstanding principal balance of this Note to the Holder on the Maturity Date.

(b) Interest Payments. Interest shall be computed on the unpaid principal amount at the per annum rate of ten percent (10%); provided, upon the occurrence of an Event of Default as defined hereunder, 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

3. Registration of Notes. The Debtors shall register the Note upon records to be maintained by the Debtors for that purpose (the "**Note Register**") in the name of the record holder thereof from time to time. The Debtors may deem and treat the registered Holder of this Note as the absolute owner hereof for the purpose of any payment of principal hereon, and for all other purposes, absent actual notice to the contrary.

4. Transfers; Registration thereof.

(a) The Holder is not permitted to transfer this Note or any of its rights thereunder; except to its sole member or any other entity wholly-owned by its sole member; provided that the transferee of any such permitted transfer agrees to be bound by this and any other restrictions of Holder under the Note.

(b) The Debtors shall register the transfer of any portion of this Note in the Note Register upon surrender of this Note to the Debtors at its address for notice set forth herein. Upon any such registration or transfer, a new Note, in substantially the form of this Note (any such new Note, a "**New Note**"), evidencing the portion of this Note so transferred shall be issued to the transferee and a New Note evidencing the remaining portion of this Note not so transferred, if any, shall be issued to the transferring Holder. The acceptance of the New Note by the transferee thereof shall be deemed the acceptance by such transferee of all of the rights and obligations of a holder of a Note. No service charge or other fee will be imposed in connection with any such registration of transfer or exchange.

5. Events of Default.

(a) "**Event of Default**" means any one of the following events (whatever the reason and whether it shall be voluntary or involuntary or effected by operation of law or pursuant to any judgment, decree or order of any court, or any order, rule or regulation of any administrative or governmental body):

(i) any default in the payment of principal in respect of the Note, as and when the same becomes due and payable (whether on the date on which the obligations under the Note mature or by acceleration, redemption, prepayment or otherwise) and such default continues for a period of fifteen (15) Business Days;

(ii) a material breach by any of the Debtors of its covenants, representations or warranties hereunder or in any other Transaction Document that remains uncured for a period of thirty (30) days following receipt by the Debtors of written notice of such breach;

(iii) any Debtor, which is a partnership, limited liability company, limited partnership or a corporation, dissolves, suspends or discontinues doing business (other than a consolidation or similar transaction between the Debtors); or

(iv) the occurrence of a Bankruptcy Event.

(b) At any time or times following the occurrence of an Event of Default, all amounts due and owing under this Note shall become immediately due and payable.

(c) Upon the occurrence of any Bankruptcy Event, all amounts due and owing under this Note shall immediately become due and payable in full in cash, without any further action by the Holder.

(d) In connection with any Event of Default, the Holder need not provide and the Debtors hereby waive any presentment, demand, protest or other notice of any kind, and the Holder may immediately and without expiration of any grace period enforce any and all of its rights and remedies hereunder, under any of the Transaction Documents and all other remedies available to it under applicable law. Any such declaration may be rescinded and annulled by the Holder at any time prior to payment hereunder. No such rescission or annulment shall affect any subsequent Event of Default or impair any right consequent thereto. The remedies under this Note and any other Transaction Document or available under applicable law shall be cumulative.

6 . Charges, Taxes and Expenses. The Holder shall be responsible for all tax liability that may arise as a result of holding or transferring this Note.

7. Grant of Security Interest. This Note and payments of principal and all other obligations with respect to this Note are hereby secured by all of the Purchased Assets. Elite hereby conveys to Holder a first priority security interest in all Purchased Assets as set forth in the Security Agreement.

8 . Notices. Any and all notices or other communications or deliveries hereunder shall be in writing and shall be deemed given and effective on the earliest of (i) the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number specified in this Section 9 prior to 5:30 p.m. (New York City time) on a Business Day, (ii) the next Business Day after the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number specified in this Section 9 on a day that is not a Business Day or later than 5:30 p.m. (New York City time) on any Business Day, (iii) the Business Day following the date of mailing, if sent by nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given. The addresses for such communications shall be: (i) if to any of the Debtors, care of Elite as set forth in the Purchase Agreement, or (ii) if to the Holder, as set forth in the Purchase Agreement.

9. Miscellaneous.

(a) This Note shall be binding on and inure to the benefit of the parties hereto and their respective successors and permitted assigns. The Debtors shall not be permitted to assign this Note and the Holder shall not be permitted to assign this Note other than pursuant to Section 4.

(b) Subject to Section 9(a), nothing in this Note shall be construed to give to any person or corporation other than the Debtors and the Holder any legal or equitable right, remedy or cause under this Note.

(c) Governing Law; Venue; Waiver Of Jury Trial . ALL QUESTIONS CONCERNING THE CONSTRUCTION, VALIDITY, ENFORCEMENT AND INTERPRETATION OF THIS NOTE SHALL BE GOVERNED BY AND CONSTRUED AND ENFORCED IN ACCORDANCE WITH THE INTERNAL LAWS OF THE STATE OF NEW JERSEY, WITHOUT REGARD TO THE PRINCIPLES OF CONFLICTS OF LAW THEREOF. EACH PARTY HEREBY IRREVOCABLY SUBMITS TO THE EXCLUSIVE JURISDICTION OF THE FEDERAL COURTS SITTING IN THE COUNTY OF ESSEX, CITY OF NEWARK AND OF THE STATE COURTS SITTING IN THE COUNTY OF BERGEN, CITY OF HACKENSACK, FOR THE ADJUDICATION OF ANY DISPUTE HEREUNDER OR IN CONNECTION HEREWITH OR WITH ANY TRANSACTION CONTEMPLATED HEREBY OR DISCUSSED HEREIN (INCLUDING WITH RESPECT TO THE ENFORCEMENT OF ANY OF THE TRANSACTION DOCUMENTS), AND HEREBY IRREVOCABLY WAIVES, AND AGREES NOT TO ASSERT IN ANY SUIT, ACTION OR PROCEEDING, ANY CLAIM THAT IT IS NOT PERSONALLY SUBJECT TO THE JURISDICTION OF ANY SUCH COURT, THAT SUCH SUIT, ACTION OR PROCEEDING IS IMPROPER. EACH PARTY HEREBY IRREVOCABLY WAIVES PERSONAL SERVICE OF PROCESS AND CONSENTS TO PROCESS BEING SERVED IN ANY SUCH SUIT, ACTION OR PROCEEDING BY MAILING A COPY THEREOF VIA REGISTERED OR CERTIFIED MAIL OR OVERNIGHT DELIVERY (WITH EVIDENCE OF DELIVERY) TO SUCH PARTY AT THE ADDRESS IN EFFECT FOR NOTICES TO IT UNDER THIS AGREEMENT AND AGREES THAT SUCH SERVICE SHALL CONSTITUTE GOOD AND SUFFICIENT SERVICE OF PROCESS AND NOTICE THEREOF. NOTHING CONTAINED HEREIN SHALL BE DEEMED TO LIMIT IN ANY WAY ANY RIGHT TO SERVE PROCESS IN ANY MANNER PERMITTED BY LAW. THE BORROWERS HEREBY WAIVES ALL RIGHTS TO A TRIAL BY JURY.

(d) The headings herein are for convenience only, do not constitute a part of this Note and shall not be deemed to limit or affect any of the provisions hereof.

(e) In case any one or more of the provisions of this Note shall be invalid or unenforceable in any respect, the validity and enforceability of the remaining terms and provisions of this Note shall not in any way be affected or impaired thereby and the parties will attempt in good faith to agree upon a valid and enforceable provision which shall be a commercially reasonable substitute therefor, and upon so agreeing, shall incorporate such substitute provision in this Note.

(f) No provision of this Note may be waived or amended except in a written instrument signed, in the case of an amendment, by the Debtors and the Holder or, or, in the case of a waiver, by the Holder. No waiver of any default with respect to any provision, condition or requirement of this Note shall be deemed to be a continuing waiver in the future or a waiver of any subsequent default or a waiver of any other provision, condition or requirement hereof, nor shall any delay or omission of either party to exercise any right hereunder in any manner impair the exercise of any such right.

(g) Each Party and its counsel have participated fully in the review and revision of this Note and the Transaction Documents. Any rule of construction to the effect that ambiguities are to be resolved against the drafting party shall not apply in interpreting this Agreement. The language in this Note and the Transaction Documents shall be interpreted as to its fair meaning and not strictly for or against any Party.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK
SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Debtors have caused this Note to be duly executed by a duly authorized officer as of the date first above indicated.

ELITE PHARMACEUTICALS, INC

By /s/ Carter Ward
Name: Carter Ward
Title: CFO

ELITE LABORATORIES, INC.

By /s/ Carter Ward
Name: Carter Ward
Title: CFO

Exhibit 10.52

ANDA SECURITY AGREEMENT

THIS ABBREVIATED NEW DRUG APPLICATION SECURITY AGREEMENT (the "**Agreement**"), dated as of May 15, 2017, between Elite Laboratories, Inc., a Delaware corporation ("**Elite**") and its parent, Elite Pharmaceuticals, Inc., a Nevada corporation (collectively, "**Debtors**"), and Mikah Pharma LLC, a limited liability company organized under the laws of the State of Delaware ("**Secured Party**");

WHEREAS, Debtors and Secured Party are parties to that certain Secured Note Due 2020 of even date herewith (herein, as at any time amended, extended, restated, renewed or modified, the "**Note**"); and

WHEREAS, it is a condition to the willingness of Secured Party to enter into the Asset Purchase Agreement by and between Secured Party and Elite of even date (the "**Purchase Agreement**"), to sell the Purchased Assets (as defined in the Purchase Agreement) to Elite and to accept the Note as consideration under the Purchase Agreement for the Purchased Assets that Debtors enter into this ANDA Security Agreement and grant to Secured Party the security interest provided for herein; and

WHEREAS, in order to induce Secured Party to accept the Note and the debt evidenced thereby as consideration for the Purchased Assets under the Purchase Agreement, Debtors have agreed to grant to Secured Party a security interest in and to and mortgage on the Abbreviated New Drug Applications included in the Purchased Assets (collectively, the "**ANDAs**"). This Agreement is being executed contemporaneous with the Purchase Agreement and the Note under which Secured Party is granted a lien on and security interest in and to, the ANDAs, whereby Secured Party shall have the right to foreclose on the ANDAs in the event Secured Party alleges the occurrence of an Event of Default under the Note. Terms not defined herein shall have the meaning set forth in the Note and terms not defined herein or in the Note shall have the meaning set forth in the Purchase Agreement.

NOW, THEREFORE, in consideration of the premises, and other good and valuable consideration the sufficiency of which is hereby acknowledged, Debtors hereby agree with Secured Party as follows:

1. To secure any and all obligations of Debtors to Secured Party under the Note and Transaction Documents, including but not limited to, repayment of the obligations of Debtors under the Note, Debtors hereby convey, grant, assign, pledge, transfer, mortgage, and create in favor of Secured Party a security interest in and to and mortgage on all of Debtors' right, title and interest in and to the Purchased Assets (as that term is defined in the Purchase Agreement), including without limitation any and all rights under any notices or agreements related thereto (collectively, the "**Collateral**").

2. Debtors represent, covenant and warrant that, subject to the representations of the Secured Party in the Purchase Agreement:

(a) the ANDAs are subsisting;

(b) Elite is the sole and exclusive owner of the entire and unencumbered right, title and interest in and to the Collateral, free and clear of any liens, charges and encumbrances, including without limitation pledges, assignments, registered user agreements and covenants by Debtors not to sue third persons;

(c) Debtors have the unqualified right to enter into this Agreement and perform its terms; and

(d) All ANDAs on file with the Food and Drug Administration (the "FDA") were prepared in accordance with applicable law.

3. Debtors agree that, until all of the obligations under the Note shall have been satisfied in full, Debtors will not, without Secured Party's prior written consent, which consent will not be unreasonably withheld, enter into any agreement to transfer or sell any of the Collateral.

3A. Perfection of Secured Party's Interests.

(a) Debtors agree to cooperate and join, at their expense, with Secured Party in taking such steps as are reasonably necessary, in Secured Party's judgment, to perfect or continue the perfected status of the security interests granted hereunder, including, without limitation, the execution and delivery of any financing statements, amendments thereto and continuation statements, the delivery of chattel paper, documents or instruments to the Secured Party, the obtaining of landlords' and mortgagees' waivers required by Secured Party, the notation of encumbrances in favor of Secured Party on certificates of title, and the execution and filing of any collateral assignments and any other instruments reasonably requested by Secured Party to perfect its security interest in any and all of the Collateral.

(b) Secured Party may at any time and from time to time, file financing statements, continuation statements, filings with the FDA or other federal agencies, and amendments thereto, that describe the Collateral and which contain any other information required by the Uniform Commercial Code or federal law for the sufficiency or filing office acceptance of any financing statement, continuation statement, other filing, or amendment, including whether a Debtor is an organization, the type of organization and any organization identification number issued to the Debtor. Debtors agree to furnish any such information to the Secured Party promptly upon request. Any such financing statements, continuation statements, other filing or amendments may be signed by Secured Party on behalf of Debtors, and may be filed at any time in any jurisdiction, whether or not Revised Article 9 of the Uniform Commercial Code is then in effect in that jurisdiction. The foregoing grant of authority to sign and file such documents on behalf of Debtors is a power of attorney coupled with an interest and shall be irrevocable for the life of this Agreement. Secured Party, or its designee, as attorney-in-fact, will not be liable for any acts or omissions, or for any error of judgment or mistake of fact or law, except for gross negligence, or willful misconduct. This power, being coupled with an interest, is irrevocable until all obligations of Debtors to Secured Party under the Note and Transaction Documents have been indefeasibly paid in full and performed and satisfied.

(c) Debtors shall, at any time and from time to time, take such steps as Secured Party may reasonably require for Secured Party, (i) to obtain an acknowledgment, in form and substance satisfactory to the Secured Party, of any third party having possession of any of the Collateral that the third party holds such Collateral for the benefit of the Secured Party, and (ii) otherwise to insure the continued perfection and priority of Secured Party's security interest in any of the Collateral and of the preservation of its rights therein.

4. If any Event of Default under the Note or this Agreement shall have occurred, Secured Party shall have, in addition to all other rights and remedies given it by this Agreement, those allowed by law and the rights and remedies of a Secured Party under the Uniform Commercial Code as enacted in any jurisdiction in which the ANDAs may be deemed located and, without limiting the generality of the foregoing, Secured Party may immediately, without demand of performance and without notice or demand whatsoever to Debtor, all of which are hereby expressly waived, and without advertisement, sell at public or private sale or otherwise realize upon, assign, transfer, license or otherwise dispose of, including but not limited to, transferring the ANDAs in New Jersey or elsewhere, all or from time to time any of the ANDAs, or any interest which Debtors may have therein, and after deducting from the proceeds of sale or other disposition of any and all of the ANDAs all expenses (including all expenses for broker's fees and legal services), apply the residue of such proceeds to Debtors' obligations to Secured Party under the Note. Any remainder of the proceeds after payment in full of Debtors' obligations owing to Secured Party under the Note and Transaction Documents including but not limited to the repayment in full of Debtors' obligations to Secured Party under the Note shall be paid over to Debtor. Notice of any sale or other disposition of the ANDAs shall be given to Debtors at least ten (10) days before the time of any intended public or private sale or other disposition of the ANDAs is to be made, which Debtors hereby agree shall be reasonable notice of such sale or other disposition. At any such sale or other disposition, Secured Party or any holder of the Note may, to the extent permissible under applicable law, purchase the whole or any part of the ANDAs free from any right of redemption on the part of Debtors, which right is hereby waived and released. Debtors waive the benefit of any marshalling doctrine with respect to Secured Party's exercise of its rights hereunder. Debtors grant a royalty-free license to Secured Party for all patents, service marks, trademarks, trade names, copyrights, computer programs and other intellectual property and proprietary rights sufficient to permit Secured Party to exercise all rights granted to Secured Party under this Agreement.

5. At such time as Debtors shall completely satisfy all of Debtors' obligations to Secured Party under the Note and Transaction Documents including but not limited to repayment of the obligations of Debtors under the Note, this Agreement and the Note shall terminate and Secured Party shall execute and deliver to Debtors all documents and other instruments as may be necessary or proper to terminate this Agreement and re-vest in Elite the ANDAs, subject to any disposition thereof which may have been made by Secured Party pursuant hereto.

6. Any and all fees, costs and expenses, of whatever kind or nature, including reasonable attorney's fees and legal expenses incurred by Secured Party in connection with the consummation of this transaction, the filing or recording of any documents (including all taxes in connection therewith) in public offices, the payment or discharge of any taxes, counsel fees, maintenance fees, encumbrances or otherwise protecting, maintaining or preserving the ANDAs, or in defending or prosecuting any actions or proceedings arising out of or related to the ANDAs, shall be borne and paid by Debtors on demand by Secured Party and until so paid shall become part of Debtors' obligations under the Note. Debtors hereby agree to execute and deliver to Secured Party any and all additional documents requested by Secured Party regarding the ANDAs at any time and from time to time in its discretion to carry out and enforce the terms and conditions of this Agreement.

7. Debtors shall have the duty, through counsel acceptable to Secured Party, to complete the approval process of the ANDAs, pending as of the date of this Agreement or thereafter until all of Debtors' obligations under the Note shall have been paid in full, to file and provide further information and documentation and to do any and all acts which are necessary or desirable to seek approval of the ANDAs and to preserve and maintain all rights to the ANDAs. Any expenses incurred in connection with the ANDAs shall be borne by Debtors. Debtors shall not abandon any ANDAs without the consent of Secured Party, which consent shall not be unreasonably withheld.

8. If Debtors breach or fail to comply with any of the terms and conditions of this Agreement or upon the occurrence of an Event of Default under the Note or any of the Transaction Documents, Debtors hereby authorize and empower Secured Party to make, constitute and appoint any officer or agent of Secured Party as Secured Party may select, in its exclusive discretion, as Debtors' true and lawful attorney-in-fact, with the power to endorse Debtors' name on all applications, documents, papers and instruments of every kind and nature necessary or desirable, including without limitation, for Secured Party to approve, use, own, transfer, assign, license or dispose of the ANDAs, or necessary or desirable for Secured Party to assign, pledge, convey or otherwise transfer title in or dispose of the ANDAs to Secured Party or anyone else, including without limitation any and all Forms 356H, and/or such other forms as the FDA shall require. Debtors hereby ratify all that such attorney shall lawfully do or cause to be done by virtue hereof. This power of attorney shall be irrevocable for the life of this Agreement. Secured Party, or its designee, as attorney-in-fact, will not be liable for any acts or omissions, or for any error of judgment or mistake of fact or law, except for gross negligence, or willful misconduct. This power, being coupled with an interest, is irrevocable until all obligations of Debtors to Secured Party under the Note and Transaction Documents have been indefeasibly paid in full and performed and satisfied.

9. If Debtors fail to comply with any of their obligations hereunder, Secured Party may do so in Debtors' name or in Secured Party's name, but at Debtors' expense, and Debtors hereby agree to reimburse Secured Party in full for all expenses, including reasonable attorney's fees, incurred by Secured Party in approving, protecting, defending and maintaining the ANDAs.

10. No course of dealing between Debtors and Secured Party, nor any failure to exercise, nor any delay in exercising, on the part of Secured Party, any right power or privilege hereunder or under the Note shall operate as a waiver thereof; nor shall any single or partial exercise of any right, power or privilege hereunder or thereunder preclude any other or further exercise thereof or the exercise of any other right, power or privilege.

11. All of Secured Party's rights and remedies with respect to the ANDAs, whether established hereby or by the Note or the other Transaction Documents, or by any other agreements or by law shall be cumulative and may be exercised singularly or concurrently.

12. The provisions of this Agreement are severable, and if any clause or provision shall be held invalid and unenforceable in whole or in part in any jurisdiction, then such invalidity or unenforceability shall affect only such clause or provision, or part thereof, in such jurisdiction, and shall not in any manner affect such clause or provision in any other jurisdiction, or any other clause or provision of this Agreement in any jurisdiction.

13. This Agreement is subject to modification only by a writing signed by the parties.

14. The benefits and burdens of this Agreement shall inure to the benefit of and be binding upon the respective successors and permitted assigns of the parties.

15. The validity and interpretation of this Agreement and the rights and obligations of the parties shall be governed by the laws of the State of New Jersey.

16. The provisions of Sections 13 and 14 of the Note are hereby incorporated by reference into this Agreement. To the extent that there is a conflict between the provisions of this Agreement and Sections 13 and 14 of the Note, the provisions of this Agreement shall govern.

[Signature Page follows]

IN WITNESS WHEREOF, this ANDA Security Agreement is execution hereof as of the day and year first above written.

Debtors:

ELITE LABORATORIES, INC.

By: /s/ Carter Ward
Name: Carter Ward
Title: CFO

ELITE PHARMACEUTICALS, INC.

By: /s/ Carter Ward
Name: Carter Ward
Title: CFO

Secured Party:

MIKAH PHARMA LLC

By: /s/ Nasrat Hakim
Nasrat Hakim
Title: CEO

STATE OF NEW JERSEY)
) ss.:
COUNTY OF _____)

On the _____ day of May, in the year 2017, before me personally came _____, to me known, who, being by me duly sworn, did depose and say that he resides in _____; that he is the _____ of Elite Laboratories, Inc., the corporation described in and which executed the above instrument; and that he signed his name thereto by authority of the board of directors of said corporation.

_____
Notary Public

STATE OF NEW JERSEY)
) ss.:
COUNTY OF _____)

On the _____ day of May, in the year 2017, before me personally came _____, to me known, who, being by me duly sworn, did depose and say that he resides in _____; that he is the _____ of Elite Pharmaceuticals, Inc., the corporation described in and which executed the above instrument; and that he signed his name thereto by authority of the board of directors of said corporation.

_____
Notary Public

STATE OF NEW JERSEY)
) ss.:
COUNTY OF _____)

On the _____day of May, in the year 2017, before me personally came Nasrat Hakim, to me known, who, being by me duly sworn, did depose and say that he resides in _____; that he is the _____ of Mikah Pharma LLC., the limited liability company described in and which executed the above instrument; and that he signed his name thereto upon his authority as manager of said company.

_____
Notary Public

SPECIAL POWER OF ATTORNEY

STATE OF NEW JERSEY)
) ss.:
COUNTY OF _____)

KNOW ALL MEN BY THESE PRESENTS, that Elite Laboratories, Inc., a Delaware corporation, having an address at 165 Ludlow Avenue, Northvale, New Jersey 07647 ("**Debtor**"), pursuant and subject to the terms and conditions contained in an Abbreviated New Drug Application Security Agreement dated as of the date hereof (as amended, modified, restated or supplemented from time to time, the "**Security Agreement**"), hereby appoints and constitutes Mikah Pharma LLC with an address at 20 Kilmer Drive, Hillsborough, New Jersey, 08844 ("**Secured Party**"), its true and lawful attorney, with full power of substitution, and with full power and authority to perform the following acts on behalf of Debtor:

1. Assigning, selling, transferring, or otherwise disposing of all right, title and interest of Debtor in and to all Abbreviated New Drug Applications ("ANDA") of Debtor specified in the Security Agreement, and all registrations and recordings thereof, and all pending applications therefor, and for the purpose of the recording, registering and filing of, or accomplishing any other formality with respect to, the foregoing, and to execute and deliver any and all agreements, documents, instruments of assignment or other writings necessary or advisable to effect such purpose;

2. To execute any and all documents, statements, certificates or other writings necessary or advisable in order to effect the purposes described above as Secured Party may in its sole discretion determine including without limitation any and all Forms 356H and/or such other forms as the FDA may require.

This power of attorney is made pursuant to the Security Agreement, dated the date hereof, between Debtor and Secured Party and may not be revoked until the payment in full of all Debtors' obligations under the Security Agreement.

ELITE LABORATORIES, INC.

ATTEST:

By: _____
Name:
Title:

_____
Name:
Title:

STATE OF NEW JERSEY)
) ss.:
COUNTY OF _____)

On the _____ day of May, in the year 2017, before me personally came _____, to me known, who, being by me duly sworn, did depose and say that he resides in _____; that he is the _____ of Elite Laboratories, Inc., the corporation described in and which executed the above instrument; and that he signed his name thereto by authority of the board of directors of said corporation.

_____
Notary Public

Exhibit 10.53

ASSIGNMENT AGREEMENT

This assignment agreement ("Assignment Agreement") is entered into as of May 17, 2017, by and between Mikah Pharma LLC ("Mikah") organized and existing under the laws of Delaware having an office at 20 Kilmer Drive, Hillsborough, NJ 08844 (the "Mikah"), and Elite Laboratories, Inc. ("Elite") organized and existing under the laws of Delaware having an office at 165 Ludlow Avenue, Northvale, NJ 07647. Capitalized terms used but not defined herein shall have the meanings ascribed to them in that certain Supply and Distribution Agreement between Mikah Pharma LLC and Dr. Reddy's Laboratories, Inc. at 107 College Road East, Princeton, NJ 08540 dated as of May 4, 2017 (the "Distribution Agreement").

WHEREAS, Dr. Reddy and Mikah Mikah entered into the Distribution Agreement for sales and distribution of the Product;

WHEREAS, on May 16, 2017, Mikah sold all of its rights, interests and obligations to Elite for the Product in the Distribution Agreement.

WHEREAS, under Section 13.8 of the Distribution Agreement, the Mikah wishes to transfer and assign to the Elite all of the Mikah's rights and interests in and to, and obligations under the Distribution Agreement, and the Elite wishes to be the Elite and transferee of such rights, interests and obligations;

NOW, THEREFORE, the parties hereto, intending to be legally bound, do hereby agree as follows:

1. Assignment and Assumption. The Mikah hereby transfers and assigns to the Elite, and the Elite hereby acquires from the Mikah all of the Mikah's rights, and interests in and to the Distribution Agreement, of whatever kind or nature, and the Elite hereby assumes and agrees to perform all obligations, duties, liabilities and commitments of the Mikah under the Distribution Agreement, of whatever kind or nature.

3. Effectiveness. This Assignment Agreement shall be effective as of the date set first set forth above.

4. Governing Law; Binding Effect. This Assignment Agreement shall be governed in accordance with the substantive laws of the State of New Jersey, United States without giving effect to that State's rules on conflicts of law, and any litigation that may arise herefrom shall be instituted in any U.S. Federal Court that has jurisdiction.

5. Counterparts. This Assignment Agreement may be executed in one or more counterparts, including facsimile counterparts, each of which shall be deemed to be an original copy of this Assignment Agreement, and all of which, when taken together, shall be deemed to constitute one and the same agreement. Delivery of such counterparts by facsimile or electronic mail (in PDF or .tiff format) shall be deemed effective as manual delivery.

IN WITNESS WHEREOF, the Elite and Mikah have executed this Assignment Agreement as of the date first set forth above.

:
ELITE LABORATORIES, INC.
By: /s/ Carter Ward

Name: Carter Ward

Title: CFO

:
MIKAH PHARMA LLC
By: /s/ Nasrat Hakim

Name: Nasrat Hakim

Title: CEO

Exhibit 10.54

ASSIGNMENT AGREEMENT

This assignment agreement ("Assignment Agreement") is entered into as of May 22, 2017, by and between Mikah Pharma LLC ("Mikah") organized and existing under the laws of Delaware having an office at 20 Kilmer Drive, Hillsborough, NJ 08844 (the "Mikah"), and Elite Laboratories, Inc. ("Elite") organized and existing under the laws of Delaware having an office at 165 Ludlow Avenue, Northvale, NJ 07647. Capitalized terms used but not defined herein shall have the meanings ascribed to them in that certain Manufacturing and Supply Agreement between Mikah Pharma LLC and Epic Pharma, LLC at 227-15 N. Conduit Avenue, Laurelton, NY 11413 dated as of May 11, 2011 (the "Manufacturing Agreement").

WHEREAS, Epic Pharma and Mikah entered into the Manufacturing Agreement for manufacturing and supply of the Product;

WHEREAS, on May 16, 2017, Mikah sold all of its rights, interests and obligations to Elite for the Product in the Manufacturing Agreement.

WHEREAS, under Section 17.8 of the Manufacturing Agreement, Mikah wishes to transfer and assign to the Elite all of the Mikah's rights and interests in and to, and obligations under the Manufacturing Agreement, and the Elite wishes to be the assignee and transferee of such rights, interests and obligations;

NOW, THEREFORE, the parties hereto, intending to be legally bound, do hereby agree as follows:

1. Assignment and Assumption. Mikah hereby transfers and assigns to Elite, and Elite hereby acquires from Mikah all Mikah's rights, and interests in and to the Manufacturing Agreement, of whatever kind or nature, and the Elite hereby assumes and agrees to perform all obligations, duties, liabilities and commitments of Mikah under the Manufacturing Agreement, of whatever kind or nature.

3. Effectiveness. This Assignment Agreement shall be effective as of the date first set forth above.

4. Governing Law; Binding Effect. This Assignment Agreement shall be governed in accordance with the substantive laws of the State of New Jersey, United States without giving effect to that State's rules on conflicts of law, and any litigation that may arise here from shall be instituted in any U.S. Federal Court that has jurisdiction.

5. Counterparts. This Assignment Agreement may be executed in one or more counterparts, including facsimile counterparts, each of which shall be deemed to be an original copy of this Assignment Agreement, and all of which, when taken together, shall be deemed to constitute one and the same agreement. Delivery of such counterparts by facsimile or electronic mail (in PDF or .tiff format) shall be deemed effective as manual delivery.

IN WITNESS WHEREOF, Elite and Mikah have executed this Assignment Agreement as of the date first set forth above.

ELITE LABORATORIES, INC.
By: /s/ Carter Ward

Name: Carter Ward

Title: CFO

MIKAH PHARMA LLC
By: /s/ Nasrat Hakim

Name: Nasrat Hakim

Title: CEO

Exhibit 10.55

SUPPLY AND DISTRIBUTION AGREEMENT

This **SUPPLY AND DISTRIBUTION AGREEMENT** (the "Agreement"), dated May 4, 2017 (the "Effective Date"), is by and between Dr. Reddy's Laboratories Inc., organized and existing under the laws of New Jersey having an office at 107 College Road East, Princeton, New Jersey 08540 ("DRL") and Mikah Pharma, LLC, organized and existing under the laws of the State of Delaware, having an office at 20 Kilmer Drive, Hillsborough, New Jersey 08844 ("Mikah"). DRL and Mikah are each a "Party" and together constitute the "Parties" under this Agreement.

RECITALS

WHEREAS, Mikah owns a certain abbreviated new drug application ("ANDA") for Product that Actavis LLC has the exclusive rights to market and sell. Due to a potential merger between Actavis LLC ("Actavis") and Teva Pharmaceutical Industries Ltd., Actavis wishes to terminate the agreement with Mikah under the terms outlined in Attachment 1;

WHEREAS, DRL possesses expertise relating to the marketing, distribution and sale of pharmaceutical products; and

WHEREAS, Mikah and DRL wish to enter into an agreement whereby DRL will have exclusive marketing, distribution and sales rights to Product.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, the sufficiency and satisfaction of which are hereby acknowledged, DRL and Mikah hereby agree as follows:

ARTICLE 1
DEFINITIONS

The following bold terms have the meanings set forth in this Agreement:

"**Affiliate(s)**" means any corporation, firm, partnership or other entity that controls, is controlled by or is under common control with a Party. For purposes of this definition, "control" shall mean the ownership of at least fifty percent (50%) of the voting share capital of such entity or any other comparable equity or ownership interest.

"**Agreement**" has the meaning set forth in the initial paragraph of this agreement.

"**ANDA(s)**" has the meaning given to it in the Recitals.

"**API"** means the active pharmaceutical ingredient for the 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.*

"**Applicable Laws**" means all laws, ordinances, codes, rules and regulations within the Territory applicable to the Manufacture of the Product or any aspect thereof and the obligations of either Party, as the context requires under this Agreement, including, without limitation, (a) all applicable federal, state and local laws and regulations (including Environmental Laws); (b) the U.S. Federal Food, Drug and Cosmetic Act (the "**FD&C Act**"), and (c) the regulations promulgated under the FD&C Act including without limitation those regarding Good Manufacturing Practices ("**cGMPs**")), each as amended from time to time; and (d) all laws, ordinances, codes, rules and regulations relating to Mikah and DRL as they apply to the manufacture, shipping, storage and distribution of the Product.

"**Application**" means the ANDA for Trimipramine submitted to the FDA under section 505(j) of the FD&C Act and any amendments or supplements thereto.

"**Calendar Quarter**" means each consecutive three-month period beginning on January 1, April 1, July 1 or October 1 of any given year.

"**Commercialization**" means the marketing, promotion, distribution and sale of the Product by DRL.

"Components" means all labels, bottles, caps, seals, cardboard packaging, inserts, inactive ingredients and other materials (excluding API) used to Label and package a Unit for shipment to DRL.

"**Confidential Information**" has the meaning given to it in Section 7.2.

"**Contract Manufacturer**" means Epic Pharma LLC and its respective successors and permitted assigns.

"**Defective Product"** means any Product having a Latent Defect or Patent Defect.

"**DRL Commercial Expenses**" means *{***}*% of Net Sales to reimburse DRL for its costs and expenses for marketing, advertisement, promoting, and selling (including costs and expenses for launch, sales force training and materials, samples, conventions, symposia, marketing, direct mailing, marketing research, public relations, printed materials, medical information, regulatory activities and distribution of Product).

"**DRL Finished Dosage Manufacturing Cost**" means the sum of the following:

(a) A = All amounts paid to Supplier for manufacture of the finished dosage of Product with Supplier supplying the finished packaged product at the Transfer Price to DRL;

(b) B = All amounts paid by DRL, if any, to a Third Party finish packager if applicable; 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.*

(c) C = An amount equal to all taxes, duties, insurance and transportation costs incurred and paid by DRL to deliver the finished Product from the contract manufacturer to its warehouse.

DRL Finished Dosage Manufacturing Cost (N) shall be calculated as: N = A+B+C.

If the manufacture of any component of the finished dosage is performed for DRL by a Third Party and not accounted for in the Transfer Price, then such amounts paid to such Third Party in connection with the manufacturing of the component thereof shall be included in DRL Finished Dosage Manufacturing Cost when applicable. The DRL Finished Dosage Manufacturing Cost shall be at actual cost incurred and shall not include any mark-ups by DRL.

"**Effective Date**" means the date this Agreement was fully executed.

"**Facility**" means the Contract Manufacturer's manufacturing facility of Epic Pharma LLC at Laurelton, NY. Mikah is responsible for identifying and transferring the Product to a different facility, if needed and only to the extent the different facility consents to inspections and audits by DRL under Section 5.7 of this Agreement

"**Failure to Supply Charges**" means any reasonable monetary charge, assessment, debit, deduction, penalty, cost or expense imposed against DRL by a customer, or paid, or required to be paid by DRL, to a customer, pursuant to an arm's length contract or agreement between DRL for the sale of the Product to said customer resulting solely from the failure to ship the Product in the quantities ordered by said customer, where such failure is due solely to Supplier's failure to deliver such quantities of the Product to DRL on or before the delivery date indicated on DRL's Purchase Order submitted in compliance with the terms and conditions of this Agreement to which such Product quantities correspond, and Supplier's failure is attributable to causes within Supplier's reasonable control.

"**FDA**" means the United States Food and Drug Administration and any successor bodies.

"**Intellectual Property**" means any and all of the following, and rights in, arising out of, or associated therewith: U.S. and non-U.S. (a) trade secrets, know-how, proprietary information, inventions, discoveries, improvements, technology, technical data, and research and development, whether or not patentable, (b) trademarks, service marks, trade dress, trade names, and equivalents thereof, and (c) copyrights, mask works, registrations and applications thereof, and any equivalents thereof.

"**Form 483**" means the written notice of objectionable practices or deviations from the regulations that is prepared by the FDA investigator at the end of an inspection.

"**Latent Defect**" means any instance where Product fails to conform to the Specifications or fails to conform to the representations, warranties and indemnifications given by Mikah herein, and such failure is not or was not discoverable even upon reasonable physical inspection or standard testing procedures upon receipt by DRL in accordance with DRL's standard operating procedures.

"**Manufacture(d)**" or "**Manufacturing**" means the compounding, filling, producing, testing and packaging of the Raw Materials into a finished dosage form in accordance with the Specifications and the terms and conditions set forth in this Agreement.

"**Material Provisions**" means Sections 2.1, 2.9.2, 3.1 and 3.2 of this Agreement.

"Net Profit" means, for each Calendar Quarter, the Net Sales derived from the sale of such Product in the Territory during such Calendar Quarter, less the sum of:

(a) DRL Finished Dosage Manufacturing Costs

(b) DRL Commercial Expenses; and

(c) all reasonable costs and expenses (including settlements and damage awards) in connection with product liability claims or patent infringement claims arising from the sales of the Product under this Agreement and that are not subject to indemnification or insurance.

In no case shall the Net Profit 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 by future Net Profits. DRL shall not deduct any cost for sales and marketing.

"**Net Sales**" means, with respect to any Calendar Quarter, the actual gross amounts invoiced by DRL, its Affiliates or permitted sublicensees on all of their sales of the Product (including hospital sales, mail orders, retail sales, and sales to governmental entities, wholesalers and medical institutions) in the Territory to Third Parties less deductions actually allowed or accrued by using GAAP for the following:

(a) sales and excise taxes, value added taxes, and duties which fall due and are paid by the purchaser as a direct consequence of such sales and any other governmental charges imposed upon the importation, use or sale of the Product, but only to the extent that such taxes and duties are (i) actually included and itemized in the gross sales amounts invoiced to and specifically paid by the purchaser over and above the usual selling price of the Product, (ii) customarily included and itemized in the gross sales amounts invoiced to and specifically paid by the purchaser over and above the usual selling price of all comparable products in the relevant market, and (iii) are not recovered or recoverable;

(b) trade, quantity and cash discounts that are customary in the generic pharmaceutical industry in the Territory and that are actually allowed or accrued on the Product;

(c) allowances or credits to customers on account of shelf adjustments, failure to supply (other than Failure to Supply Charges which are separately paid by Mikah), rejection, withdrawal, recall or return of the Product or on account of retroactive price reductions affecting the Product, to the extent that such allowances or credits are customary in the generic pharmaceutical industry in the Territory and are actually allowed or accrued on the Product, any adjustments in the ordinary course of business for short-dated Product; and

(d) rebates, discounts, and/or chargebacks specifically related to the Product on an actual credited, paid or accrued basis, including those granted to government agencies, if any.

Net Sales with respect to sales of the Product that are not made on an arm's length basis or that are made for consideration other than cash shall be calculated based on the average per-unit Net Sales of the Product without regard to such non-arm's length or non-cash sales.

"**Patent Defect**" means any instance where Product fails to conform to the Specifications or fails to conform to the representations, warranties and indemnifications given by Mikah herein, and such failure is or was discoverable upon reasonable physical inspection or standard testing procedures upon receipt by DRL in accordance with DRL' standard operating procedures.

"**Penalties**" means fees, penalties and other amounts payable to DRL customers as a result of a supply failure with respect to such Product.

"**Product**" means Trimipramine.

"**Purchase Order**" shall have the meaning set forth in Section 2.4.

"**Raw Materials**" means all raw materials, including API, supplies, components and packaging necessary to manufacture and ship the Product in accordance with the Specifications.

"**Recall(ed)**" and "**Recall Costs**" each has the meaning set forth in Section 5.6.

"**RLD**" or "**Reference Listed Drug**" means Surmontil®.

"**Regulatory Agent**" means Epic Pharma LLC and its respective successors and permitted assigns.

"**Regulatory Authority**" means any governmental regulatory authority within a Territory involved in regulating any aspect of the manufacture, sale, distribution, packaging or use of the Product(s).

"**Rolling Forecast**" has the meaning set forth in Section 2.3.

"**Specifications**" means the specifications for the Product contained in Application, which are hereby incorporated herein by reference as if set forth in this Agreement including, without limitation, such specifications as may from time to time be established, amended or modified by applicable Regulatory Authorities or the Parties hereto, subject to the terms and conditions set forth in Article 5.

"**Supplier**" means, with respect to Product, Mikah and the Contract Manufacturer, jointly and severally. For the avoidance of doubt, the use of Supplier in this Agreement shall be interpreted to mean that Mikah shall or shall not perform and Mikah shall ensure that Contract Manufacturer shall or shall not perform the duties and obligations referenced herein.

"**Term**" has the meaning set forth in Section 10.1.

"**Third Party**" means any Person or entity other than a Party or any of its Affiliates.

"**Territory**" means the United States of America, its territories, possessions, commonwealths and any other country, which the Parties agree in writing to add to this definition of Territory in an amendment to this Agreement.

"Transfer Price" means the supply price of each Product.

"Unsalable" means Product that DRL has determined is unable to sell to its customers, whether as a result of short dating, damage or otherwise.

ARTICLE 2
MANUFACTURE, SUPPLY AND COMMERCIALIZATION

2.1 Supply and Purchase of Product. Each Product shall be manufactured at the Facility in accordance with the Specifications, Applicable Laws, and the terms and conditions of this Agreement. Supplier shall not implement any change in the Specifications that may be noticeable by the consumer until the Parties have agreed in writing to such change, the implementation date for such change, and any increase or decrease in costs, expenses or fees associated with such change. Supplier shall respond promptly to any request made by DRL for a change in the Specifications, and both Parties shall use commercially reasonable, good faith efforts to agree to the terms of such change in a timely manner.

2.2 Labelling. Supplier shall label the Product with the DRL trademark and such other labeling as may be requested by DRL. No other trademarks, logos or trade names shall be displayed on the Product labels, except as may be required by law or regulation. DRL shall provide Supplier with proposed label and labeling specifications for the Product as soon as practicable after the execution of this Agreement. DRL shall provide Supplier with reasonable notice of all labeling or packaging changes or requests for additional labels or packaging.

2.3 Forecasts. DRL shall provide Mikah and the Contract Manufacturer with non-binding rolling twelve (12) month forecasts of its Product requirements by delivery date. The forecasts will be updated at least quarterly ("**Rolling Forecasts**"), and shall be used by Supplier to order and maintain the Raw Materials necessary to fulfill DRL's forecasted Product requirements, taking into account the vendors' lead times, minimum order quantities, and Supplier's lead time. The Rolling Forecasts will become binding only upon issuance of a Purchase Order by DRL.

*{***} 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 . 4 Purchase Orders. DRL shall submit purchase orders for Product to Contract Manufacture, with a copy to Mikah, specifying: (a) the number of units of Product to be purchased, (b) the Transfer Price, (c) the expected delivery date, and (c) such other special terms and conditions that may be applicable to such order ("**Purchase Orders**"). DRL shall order based on batch size as provided in Exhibit A. For every delivery, per Product, a firm binding order must be made at least three (3) months in advance of delivery date or such lesser period of time that the Parties may agree to, in writing. Supplier shall confirm the order and projected date of shipment within seven (7) calendar days after having received a Purchase Order. All Purchase Orders received and not rejected by Supplier within seven (7) days of Supplier's receipt shall be deemed to have been confirmed by Supplier in accordance with its reflected terms. Supplier shall not be obligated to fulfill any order received less than three (3) months prior to a requested shipment date for any Product, however Supplier shall use commercially reasonable efforts to accommodate any requested shipment date.

2 . 5 Terms of Sale. DRL's orders for Product shall be made pursuant to its standard form of Purchase Order. To the extent such Purchase Order contains terms or conditions that are in conflict with the terms and conditions of this Agreement, the conflicting terms or conditions of the Purchase Order will have no effect, unless Supplier agrees, in writing, to such terms or conditions or that such terms and conditions will supersede the terms of this Agreement.

2 . 6 Order Cancellation or Modification. DRL may cancel a Purchase Order or modify the date of shipment or the quantity of Product specified in a Purchase Order, by submitting a written change order request to Supplier and Supplier shall use commercially reasonable efforts to approve the cancellation or modification requested by DRL, or such other modifications that might be mutually acceptable, and shall advise DRL of its determination within five (5) business days of the submission of DRL's proposed change order.

2.7 Delivery and Shipment.

2 . 7 . 1 Shipment. All Product shall be delivered Ex works (Incoterms 2010), Contract Manufacturer's loading dock. Upon Supplier's delivery of the Product, DRL will bear all risk of loss, delay, or damage in transit as well as all costs of further shipment and appropriate insurance. All Product delivered hereunder shall be suitably packed for shipment by Supplier in accordance with good commercial practice, and instructions provided to Supplier by DRL, with respect to protection of such Product during transportation, marked for shipment to DRL. Such shipment shall also include a certificate of analysis and a certificate of compliance in accordance with the terms of the Quality Agreement. Supplier shall choose a commercially reasonable carrier, acceptable to DRL for each shipment of Product, unless DRL or its Affiliates have specified a particular carrier in its Purchase Order.

2.7.2 Performance Standards**.**

(a) Specifications and Characteristics. Supplier shall provide to DRL Product in finished packaged form and produced in accordance with the Specifications and in compliance with the FD&C Act.

(b) Failure to Supply. If Supplier is unable to manufacture or deliver the Product to DRL in the quantities set forth in the Rolling Forecasts, Supplier shall promptly notify DRL in writing of the period of such inability and/or anticipated inability to manufacture or deliver Product. Failure to Supply Charges will be charged back to Mikah. Mikah shall pay DRL any Failure to Supply Charges within sixty (60) days after receipt of written notice by DRL of any such Failure to Supply Charges.

*{***} 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.*

2.7.3 Shelf Life. Unless DRL requests a delay of shipment, all Product delivered to DRL shall have at least seventy-five percent (75%) of shelf life remaining upon delivery of Product. Supplier will make reasonable best efforts to ship Product that has at least ninety percent (90%) of shelf life remaining upon delivery of Product. In case the Supplier is not able to supply the product with more than or equal to 90% shelf life, the Supplier shall seek DRL written approval before shipping the product.

2.7.4 Delivery Conditions. All delivered Product shall be in full cases, and shall be on heat treated pallets. For the avoidance of doubt, DRL will not accept Product delivered in partial cases or on chemically treated pallets.

2.8 Competitive Product. Supplier shall not, directly or indirectly, without DRL's prior written consent, develop, manufacture, market or supply the Product and/or any generic (submitted or intended for submission in an ANDA filed under section 505(j) of the FD&C Act or in a new drug application ("NDA") filed under section 505(b)(2) of the FD&C Act) product containing API as the sole active ingredient in any strength which is AB rated and substitutable for the RLD product, and shall work exclusively with DRL with respect to products containing API as the sole active ingredient for marketing and sale to any person or entity other than DRL.

2.9 Commercialization.

2.9.1 Manufacturing. Mikah shall ensure that the Contract Manufacturer maintains FDA-compliant manufacturing facilities for commercial production and packaging that can supply DRL with Product in the Territory in full batch increments packaged in saleable forms similar to RLD as defined in the Application and in DRL's trade dress under DRL's NDC number and labeler code. In fulfillment of DRL's Purchase Orders, Mikah shall ensure that Contract Manufacturer manufactures quantities of Product for Commercialization by DRL in the Territory in accordance with FDA requirements and all Applicable Laws.

2.9.2 Permits and Licenses. Mikah shall ensure (at its own cost and expense) that the Contract Manufacturer obtains all permits and licenses required to import/export Raw Materials, if applicable, including API for the development and manufacture of pilot batches, pivotal batches and commercial batches of Product. Mikah shall be responsible for any and all facility licenses or finished dosage form manufacturing site fees established under GDUFA and shall comply with GDUFA requirements including self-identification.

2.9.3 Commercialization. Upon receipt of the quantities of the respective Product from Supplier in fulfillment of DRL's Purchase Order for launch quantities, DRL will be responsible for the Commercialization of Product in the Territory, provided that no litigation is then pending against DRL or Supplier with regard to patent infringement with respect to the manufacture, use or sale of such Product. DRL's obligations with respect to Commercialization include customer service, inventory management, complaint processing, chargebacks and rebate calculations, returns, billing and warehousing. All activities related to Commercialization shall be performed by DRL in accordance with FDA requirements and all Applicable Laws.

*{***} 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.*

2.9.4 Pharmacovigilance. Mikah, shall be ensure that the Regulatory Agent manages all pharmacovigilance activities related to Product, including but not limited to: Individual Case Safety Reporting, Periodic Aggregate Event Reporting and Serious Signal detection as required by 21 C.F.R. §314.80 or other applicable C.F.R., maintenance of Serious Adverse Event or Adverse Drug Experience records required by Applicable Laws and REMS requirements. Mikah shall be responsible for responding to all adverse drug event reports received from lay persons and/or health care professionals respecting a Product. Prior to the first commercial sale of a Product, the Parties shall enter into a pharmacovigilance agreement allocating responsibilities for pharmacovigilance consistent with this Section (the "**Pharmacovigilance Agreement**"). Mikah shall ensure that a pharmacovigilance infrastructure is maintained as required to fulfill its responsibilities under this Agreement and the Pharmacovigilance Agreement. All out of pocket cost shall be shared equally by the Parties.

2.9.5 Quality Agreement. Mikah and DRL agree to enter into a quality agreement for the Product, which will specify each Party's responsibility for quality, compliance and regulatory matters. If there is inconsistency between the terms of such quality agreement and this Agreement, the terms of this Agreement shall control.

2.9.6 Label Information. All Product sold by DRL shall bear the DRL trademark, DRL trade dress, the applicable DRL NDC number and labeler code, and the required information to identify the manufacturing site as per regulatory requirements.

ARTICLE 3
PRICE, PROFIT SHARING AND PAYMENTS

3.1 Transfer Price. Mikah shall cause the Product to be supplied to DRL at the agreed upon Transfer Price. The Transfer Price as of the Effective Date, based on the expected commercial batch size, is indicated in Attachment 2. The Transfer Price is the price per Unit paid by DRL to Mikah for the purchase of a Product, which price shall be the total of all actual direct and indirect manufacturing costs including the cost of:

(i) procuring API;

(ii) procuring all inactive Raw Materials used in the formulation of the Product and necessary for the manufacture of the Product in its finished form;

(iii) procuring all Components such as containers, closures, labels (DRL only to review and approve label content), labeling, artwork, inserts and other primary and secondary packaging components necessary for the manufacture of the Product as finished goods;

(iv) all analytical and stability testing to release the Product;

(v) all packaging expenses;

*{***} 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.*

(vi) other direct and indirect costs associated with manufacturing the Product (including direct labor and benefits, overhead for manufacturing, stability, quality control and other allocated corporate and facility overhead) all determined in accordance and consistent with GAAP; and

(vii) all other expenses attributable to the Product or its manufacturing if incurred, for example (but not limitation) all expenses for testing, release, stability and regulatory fees.

For the avoidance of doubt, the Transfer Price includes all costs related to the procurement, manufacturing, testing, release, stability, and regulatory activities for the Product. The Transfer Price shall be based on the "commercial conversion cost", which shall be inclusive of any manufacturing efficiencies. The "commercial conversion costs" shall not include idle capacity variances. Mikah shall transfer the Product at the same price they bought from the Contract Manufacturer and shall not add any markup over and above the Contract Manufacturer's supply price.

3 . 2 Transfer Price Adjustment. Mikah shall consult with DRL prior to agreeing to any adjustment in the Contract Manufacturer's Product supply price.

3 . 3 Supply Payment Terms. All amounts payable with respect to the delivery of Product (as opposed to the profit share payment described in Section 3.6) shall be expressed in United States Dollars and shall be due and payable by DRL to Supplier within thirty (30) days from the delivery of the Product pursuant to the Purchase Order or such lesser period that DRL may agree to, in writing, with respect to any particular Product. All invoices will be sent to the address specified in the applicable purchase order, and each invoice will state the aggregate and unit price for Product in a given shipment.

3 . 4 Price Improvement and Adjustments. The Parties agree to pursue a continuous improvement strategy to seek ways to improve their overall business practices and manufacturing performance and reduce both of their costs.

3 . 5 Profit Sharing. Mikah shall be entitled to *{***}* percent (*{***}*%) of the Net Profit derived from sales of the Product in the Territory.

3.6 Profit Share Reporting and Payments.

3.6.1 Within forty-five (45) days following the end of each Calendar Quarter during the Term, DRL shall submit to Mikah a written report setting forth in reasonable detail the quantity of Product sold in the Territory (as measured in saleable units of Product), the gross invoiced sales of Product in the Territory and its Net Sales calculations, the cost of goods sold and its Net Profit calculations, in each case, for such period. Such report shall be accompanied by payment of Mikah's share of the Net Profit amount described therein. Any adjustments to be made in respect of payments previously made to Mikah due to rebates, returns and the like, shall be factored into the calculation of subsequent payments.

*{***} 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.*

3.6.2 If the Net Profit for Product in any Calendar Quarter is a negative figure (a "**Net Loss**"), then for purposes of calculating Net Profit and the corresponding payment of Mikah's profit sharing percentage of such Net Profits, such Net Loss for Product shall be carried forward and offset against a subsequent Calendar Quarter's profit for Product.

3.7 Records and Financial Audit. Mikah shall maintain records and documents documenting the Transfer Price of each of Product and DRL shall maintain all records documenting Net Sales to the sale of Product for a time period equal to the period required by Applicable Laws. Each Party shall have the right, not more often than once in any two immediately preceding calendar years, upon not less than ten (10) business days' prior written notice, to have an independent Third Party auditor examine the books and records of the other Party to verify the other Party's obligations hereunder (for example DRL may audit the Transfer Price and Mikah may audit the Profit Sharing Percentage calculation, including all underlying sales data, and Net Sales and Net Profits calculations). Such auditor, prior to any review hereunder, shall have entered into an appropriate confidentiality agreement with each Party on mutually acceptable terms and shall have been instructed not to reveal to the Party who requests the audit the details of its review, except for (i) such information as is required to be disclosed under this Agreement, and (ii) such information presented in a summary fashion as is necessary to report the accountant's conclusions to both parties. The audited Party shall cooperate in any audit by allowing the auditor access to all records necessary for the auditor to conduct such audit. The cost of such examination shall be borne by the auditing Party unless the audit reveals an error of at least ten percent (10%) in the auditing Party's favor, in which case the audited Party shall bear such cost and expense of the audit. Mikah and DRL agree to work together with the auditor in good faith to resolve any disputes arising out of any audit in a timely, professional and non-adversarial manner. All such audits shall be performed during regular business hours and under reasonable confidentiality provisions which shall include that such auditor shall be bound by the confidentiality provisions contained in this Agreement.

3.8 Taxes. All taxes and duties assessed on the Product, prior to or upon sale to DRL are the responsibility of Mikah. If any payment under this Agreement is subject to a local withholding tax, the Party that is paying the relevant sum shall withhold the appropriate tax amount and shall timely provide the other Party with a certificate evidencing its actual payment of the withholding tax to the local tax authorities. The Parties shall use reasonable commercial efforts to collectively address any withholding tax requirements prior to the date such payments are to be made.

ARTICLE 4
PRODUCT CONFORMITY TO SPECIFICATIONS

4.1 Notification of Defective Product. DRL shall notify Mikah within thirty (30) days after receiving the Product at DRL if DRL has determined that such shipment contains Defective Product. Mikah shall, at its own cost and expense, supply DRL with any missing quantities of Product as soon as reasonably possible after receipt of such notice. Notice of any Patent Defect shall be provided by DRL to Mikah within thirty (30) days of inspection of Product in such shipment. Notice of a Latent Defect shall be provided within thirty (30) days of DRL becoming aware of the Latent Defect. DRL shall provide Mikah a sample of such Latent or Patent Defective Product. Subject to the foregoing, DRL shall have the right to reject any batch of Defective Product prior to the expiry of such batch of Product. A Product that is not rejected within the applicable period of time shall be deemed accepted by DRL.

*{***} 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 Resolution of Defective Product. If Mikah agrees that a batch constitutes Defective Product, Mikah shall, at its option, replace the Defective Product or repay the full amount of any payments, including shipping costs, made by DRL for such Product. If Mikah does not agree with DRL's determination that such Product is Defective Product, then after reasonable efforts to resolve the disagreement, either Party may submit a sample, batch record, and associated documentation of such Product to a mutually agreed upon independent third party who is an expert or is familiar with the industry to determine whether the Product meets the Specifications or is otherwise Defective Product. The independent party's results shall be final and binding on both Parties. If such results indicate that the Product was Defective Product, Mikah shall replace the Defective Product or repay the full amount of any payments, including shipping costs, made by DRL for such Product. Unless otherwise agreed to by the Parties in writing, the costs associated with such testing and review shall be borne by the non-prevailing Party.

ARTICLE 5
REGULATORY MATTERS

5.1 Recordkeeping. Supplier shall maintain true and accurate books, records, test and laboratory data, reports and all other information relating to Manufacturing under this Agreement, including all information required to be maintained by all Applicable Laws. Such information shall be maintained in forms, notebooks and records for a period of at least two (2) years from the relevant finished Product expiration date or longer if required under Applicable Laws.

5.2 Regulatory Compliance. DRL shall be solely responsible for all permits and licenses required by any Regulatory Authority with respect to the distribution of the Product, including any product licenses, applications and amendments in connection therewith. Mikah, as the Party owning Application, shall have responsibility for monitoring and ensuring the compliance with all statutes, regulations, guidelines and other requirements of the Regulatory Authority pertaining to the Product and the applicable Regulatory Approval including permits and licenses with respect to Application, and ensuring that the Facility and its equipment, and the Manufacture of the Product are in compliance with Application and the Specifications. Each Party intends and commits to cooperate to satisfy all Applicable Laws, regulations and practices within the scope of its respective responsibilities under this Agreement.

5.3 Regulatory Correspondence. Mikah shall notify DRL immediately of any correspondence, any inspections, and the result of any inspection(s) with the FDA or any Regulatory Authority directly related to the Product. Mikah shall send a draft to DRL of all correspondence Mikah intends to send to any Regulatory Authority directly related to the Product. For all correspondence with a Regulatory Authority directly related to the Product that is not in response to a regulatory deficiency or problem, DRL shall have seven (7) business days to approve the draft correspondence, and if DRL is silent after seven (7) business days, it is understood DRL gives its constructive consent to the correspondence. For all correspondence with a Regulatory Authority directly related to the Product that is in response to a regulatory deficiency or problem, DRL shall have the absolute right to approve the draft correspondence before such correspondence is sent to the Regulatory Authorities. In such a case, DRL will make every effort to act expediently in approving the draft correspondence.

5.4 Track and Trace. With respect to Product, each Party shall comply with the national system for tracing pharmaceutical products through the supply chain, as set forth in the Drug Quality and Security Act (H.R. 3204), as such may be supplemented, amended or modified.

5.5 Governmental Inspections and Requests. Each Party shall promptly inform the other, in writing, of any inspection, application for inspection, and other regulatory action, by any regulatory agency relating to the Product or the Manufacture of Product or, in the case of the Supplier, the Facility at which Supplier Manufactures, packages, tests or stores the Product. Each Party will permit the other's representatives to be present during any such inspection related directly to the Product. Each Party will provide the other with the results of all regulatory inspection or audits directly related to the Product with fourteen (14) business days after such Party's receipt of such results.

5.6 Recall.

5.6.1 Consultation. If any Regulatory Authority seizes any Product or requests or requires a Party to recall or withdraw any quantity of the Product (a "**Recall**"), or if a Party reasonably deems it necessary to initiate a voluntary recall, field correction, market withdrawal, stock recovery or other similar action (a "**Product Action**"), then the Parties shall promptly consult with each other in good faith regarding the timely compliance with all Applicable Laws pertaining thereto, it being understood and agreed that no Party shall be prohibited hereunder from taking any action that it is required to take by Applicable Laws.

5.6.2 Records. In the case of a Recall or Product Action, each Party shall make a complete and accurate record of all out-of-pocket costs incurred by it in connection with the Recall or Product Action, a copy of which shall be delivered to the other Party upon request as soon after the completion of such Recall or Product Action as may be practicable. DRL and Mikah shall each have the right, in their sole discretion and at their sole cost, to use a Third Party to assist with its obligations relating to a Recall or Product Action. All out of pocket costs and expenses incurred in connection with such Recall or Product Action (including the cost of goods sold, distribution expenses and Third-Party recall expenses) are collectively the "**Recall Costs**".

5.6.3 Costs of Recall. To the extent and in the proportion the cause or reason of any such recall, withdrawal, field correction or seizure of Product is directly attributable to activities performed by Supplier in the manufacture of the Product, Mikah shall be responsible for the Recall Costs and replacement of the Product (at its own cost). To the extent and in the proportion the cause or reason of any such recall, withdrawal, field correction or seizure of Product is directly attributable to activities performed by DRL with respect to distribution of the Product, DRL shall be responsible for the Recall Costs and replacement of the Product (at its own cost). To the extent the cause or reason of any such recall, withdrawal, field correction or seizure of Product cannot be determined, the Parties shall be responsible for the recall expenses and replacement of the Product in the ratio of their profit sharing percentage.

5 . 7 Inspections and Audits by DRL. Representatives of DRL shall have access to the Facility for the purpose of: (a) conducting inspections of such facility and Supplier's maintenance and usage of the equipment utilized in the Manufacture of the Product, (b) performing quality control audits or (c) witnessing the Manufacture, storage or transportation of the Product or the materials related to or used in the Manufacture of the Product. DRL shall have access to the results of any tests performed by Supplier relating to Product and the processes or materials used in their Manufacture. Mikah shall use its best efforts to ensure that DRL has similar access to the facilities, data and records of Contract Manufacturer and its agents. Such inspections do not relieve Supplier of any of its obligations under this Agreement or create new obligations on the part of DRL. This right of inspection can be exercised at least once a year, provided written notice is given to Mikah at least two weeks prior to the inspection, or at any time for cause. Mikah shall permit such inspection during normal business hours at reasonable and mutually acceptable times, accompanied at all times by a Supplier representative.

ARTICLE 6
REPRESENTATIONS, WARRANTIES & COVENANTS

6.1 Mikah. Mikah hereby represents, warrants and covenants to DRL that:

6.1.1 At the time of each delivery of the Product, such Product and its corresponding Raw Materials will conform to the Specifications, and shall be manufactured in accordance with all Applicable Laws, and shall be free of any Defective Product.

6.1.2 The Product shall not, at the time of delivery to DRL, contain any material or be manufactured, handled or stored in any way that would cause the Product to be adulterated in any way within the meaning of Section 501, or misbranded within the meaning of Section 502, of the FD&C Act, as amended from time to time.

6.1.3 As of the Effective Date and at all times during the Term, Supplier and the Facility and all equipment utilized in the Manufacture of the Product is and will be in compliance with all Applicable Laws;

6.1.4 Neither Mikah, nor to its' best knowledge, information and belief, Contract Manufacturer, nor any of their employees has ever been: (a) debarred; (b) convicted of a crime for which a person can be disbarred under Section 306 (a) or (b) of the Generic Drug Enforcement Act of 1992 (Article 306(a) or (b)); (c) threatened to be debarred; or (d) indicted for a crime or otherwise engaged in conduct for which a person can be debarred under Section 306 (a) or (b). Mikah agrees to immediately notify DRL should any Regulatory Authority threaten any action that could possibly result in a breach of this Section;

6.1.5 The Manufacture of the Product shall be in accordance with the Specifications and will be made, stored, packaged, labeled and controlled by Supplier in accordance with all Applicable Laws;

6.1.6 Supplier has reviewed and approved all applicable in-process and finished Product test results to ensure conformity of such results with the Specifications, regardless of which Party is responsible for finished Product release;

6.1.7 The certificate of analysis and certificate of compliance that will accompany each shipment of Product shall be accurate, truthful and made in good faith;

6.1.8 Mikah is the sole and exclusive owner of, and has the valid right to use, assign, transfer and license others to use, to the full extent contemplated under this Agreement, the Mikah IP (as defined in Section 7.2), free and clear of all liens, restrictions and any other Third Party rights or interest (including rights or interest of academic entities or governmental authorities);

6.2 DRL. DRL hereby represents, warrants and covenants to Mikah that:

6.2.1 All artwork and the content thereof provided to Mikah shall comply with all Applicable Laws;

6.2.2 All Product received by DRL from Mikah or the Contract Manufacturer will be shipped, stored, distributed, used and/or disposed of by DRL in accordance with all Applicable Laws; and

6.2.3 DRL will comply with all Applicable Laws applicable to DRL's performance under this Agreement and its use of any Product provided by Supplier under this Agreement.

6.3 Mutual. Each Party hereby represents, warrants and covenants to the other Party that:

6.3.1. Existence and Power. Such Party: (a) is duly organized, validly existing and in good standing under the laws of the state or province in which it is organized, (b) has the power and authority and the full legal right, power and authority to own and operate its property and assets, and to carry on its business as it is now being conducted, and (c) is in compliance with all requirements of Applicable Laws.

6.3.2 Authorization and Enforcement of Obligations. Such Party: (a) has the power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder and (b) has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;

6.3.3 Execution and Delivery. This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms;

6.3.4 No Consents. All necessary consents, approvals and authorizations of all Regulatory Authorities and other persons required to be obtained by such Party in connection with the Agreement have been obtained; and

6.3.5 No Conflict. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder: (a) do not conflict with or violate any requirement of Applicable Laws; and (b) do not materially conflict with, or constitute a material default or require any consent under, any current contractual obligation of such Party except as recited in Attachment 1.

6.3.6 Legal or Equitable Action. Such Party is not a party to, nor as of the Effective Date, to each Party's knowledge, is it threatened with, any legal or equitable action or proceeding before any court, arbitrator, administrative agency or other tribunal which is reasonably likely to adversely affect its ability to execute and deliver this Agreement or fully and timely perform its covenants, duties and obligations described in this Agreement.

6.4 Disclaimer. EXCEPT AS PROVIDED IN THIS ARTICLE 6, NEITHER PARTY MAKES ANY REPRESENTATIONS, WARRANTIES OR CONDITIONS (EXPRESS, IMPLIED, STATUTORY OR OTHERWISE) WITH RESPECT TO THE SUBJECT MATTER HEREOF AND EACH PARTY EXPRESSLY DISCLAIMS ANY SUCH ADDITIONAL WARRANTIES.

ARTICLE 7
CONFIDENTIAL INFORMATION AND INTELLECTUAL PROPERTY

7.1 **Confidentiality.** The Parties acknowledge that the Confidentiality Agreement between the Parties dated 26 April 2016 (the "**Confidentiality Agreement**") shall continue to govern the Parties' respective obligations to one another with regard to the "Confidential Information" (as defined in the Confidentiality Agreement) each has disclosed to the other and shall continue to disclose to the other in connection with this Agreement; provided that the Parties' respective obligations with regard to any such Confidential Information disclosed prior to or after the date of this Agreement shall survive the termination of this Agreement for a period of seven (7) years from the date of such termination, in accordance with the terms of the Confidentiality Agreement.

7.2 **Intellectual Property**. All Intellectual Property owned by or licensed to Mikah as of the date of signing of this Agreement or developed by Mikah in connection with the development of the Product shall be owned by Mikah (the "**Mikah IP**"). Mikah hereby grants to DRL an exclusive license under the Mikah IP to use, import, export, sell, offer for sale, have sold and otherwise Commercialize the Product in the Territory during the Term.

7.3 **Patent Litigation**. All claims, expenses or damages (including attorneys' fees) in connection with any litigation instituted by a Third Party relating to a claim or claims of infringement of patents against either of the Parties, relating to or arising from the filing of Application, and/or the manufacturing, marketing, use or offer to sell of Product in the Territory shall be shared by the Parties in the ratio of the Profit Sharing Percentage. Each Party will support any such litigation with supportive materials and direct participation in any deposition as requested or required by the other Party.

*{***} 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 8
INDEMNIFICATION

8.1 Indemnification by Mikah. Mikah shall defend, indemnify and hold harmless DRL, its Affiliates, and their respective directors, officers, employees and agents ("DRL Indemnitees") from and against any and all suits, claims, losses, demands, liabilities, damages, costs and expenses (including reasonable attorneys' fees) in connection with any suit, demand or action by any third party ("Losses") arising out of or resulting from: (a) any intellectual property matters relating to the Product, (b) any breach of its representations, warranties or obligations set forth in this Agreement or resulting from the breach of its obligations to deliver Product in full conformity to the Specifications and in conformity with all Applicable Laws or (c) any negligence or willful misconduct by Mikah or Contract Manufacturer, except in each case to the extent that such Losses are within the scope of the indemnification obligations of DRL under Section 8.2.

8.2 Indemnification by DRL. DRL shall defend, indemnify and hold harmless Mikah, its Affiliates, and their respective directors, officers, employees and agents ("Mikah Indemnitees") from and against all Losses arising out of or resulting from: (a) any breach of its representations, warranties or obligations set forth in this Agreement; or (b) any negligence or willful misconduct by DRL, except to the extent that any of the foregoing arises out of or results from any Mikah Indemnitees' obligations set forth in Section 8.1.

8.3 Indemnification Procedures. All indemnification obligations in this Agreement are conditioned upon the Party seeking indemnification (the "Indemnified Party"): (a) promptly notifying the other Party (the "Indemnifying Party") of any claim or liability of which the Party seeking indemnification becomes aware (including a copy of any related complaint, summons, notice or other instrument); provided, however, that failure to provide such notice within a reasonable period of time shall not relieve the Indemnifying Party of any of its obligations hereunder except to the extent the Indemnifying Party is prejudiced by such failure; (b) cooperating with the Indemnifying Party in the defense of any such claim or liability; and (c) not compromising or settling any claim or liability without prior written consent of the Indemnifying Party. The Indemnifying Party shall have the sole and exclusive right to select counsel to defend any such claim and final decision-making authority regarding all aspects of the defense of such claim. Notwithstanding the foregoing, (1) the Indemnified Party shall have the right to retain its own separate counsel in connection with any such claim at its own expense, (2) no admission of liability and no settlement of any claim in a manner adverse to the Indemnified Party shall be made without the approval of the Indemnified Party, acting reasonably, and (3) no admission of liability shall be made by the Indemnified Party without the approval of the Indemnifying Party, acting reasonably, and the Indemnifying Party shall not be liable for any settlement of any claim made without such approval.

*{***} 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 9
INSURANCE

9.1 Supplier Insurance. Product Supplier shall, at its own cost and expense, obtain and maintain in full force and effect the following insurance during the term of this Agreement: (i) Commercial General Liability insurance with per-occurrence and general aggregate limits of not less than $5,000,000; (ii) Products and Completed Operations Liability Insurance with per-occurrence and general aggregate limits of not less than $5,000,000; (iii) Statutory Workers' Compensation and Employer's Liability Insurance as per applicable law with an amount not less than $500,000 including excess liability coverage. In the event that any of the required policies of insurance are written on a claims made basis, then such policies shall be maintained during the entire term of this Agreement and for a period of not less than three (3) years following the termination or expiration of this Agreement. Supplier shall waive subrogation rights against DRL for workers' compensation benefits and shall obtain a waiver from any insurance carriers with which Supplier carries workers' compensation insurance releasing their subrogation rights against DRL. DRL shall be named as an additional insured under the Commercial General Liability and Products and Completed Operations Liability insurance policies as respects the manufacturing services outlined in this Agreement. Supplier shall furnish certificates of insurance for all of the above noted policies and required additional insured status to DRL within ten (10) days after the Effective Date of the Agreement and upon renewal of any such policies.

9.2 DRL Insurance. DRL shall, at its own cost and expense, obtain and maintain in full force and effect the following insurance during the term of this Agreement: (i) Products and Completed Operations Liability Insurance with per-occurrence and general aggregate limits of not less than $5,000,000; (ii) Statutory Workers' Compensation and Employer's Liability Insurance as per applicable law with an amount not less than $500,000 including excess liability coverage. In the event that any of the required policies of insurance are written on a claims made basis, then such policies shall be maintained during the entire term of this Agreement and for a period of not less than three (3) years following the termination or expiration of this Agreement. DRL shall waive subrogation rights against Mikah for workers' compensation benefits and shall obtain a waiver from any insurance carriers with which DRL carries workers' compensation insurance releasing their subrogation rights against Mikah. Mikah shall be named as an additional insured under the Products and Completed Operations Liability insurance policies as respects the Product and completed operations outlined in this Agreement. DRL shall furnish certificates of insurance for all of the above noted policies and required additional insured status to Mikah within ten (10) days after the Effective Date of the Agreement and upon renewal of any such policies.

*{***} 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
TERM AND TERMINATION

10.1 Term of Agreement. The Term of this Agreement, with respect to Product, shall commence as of the first commercial sale of the Product by DRL in the Territory and shall continue for three (3) years (the "Initial Term"), and thereafter, shall automatically renew for additional one (1)-year terms (each, a "Renewal Term") (the Initial Term and all Renewal Terms are collectively, the "Term"). This Agreement may be terminated at the conclusion of the Initial Term or at any time thereafter by either Party upon six (6) months written notice.

10.2 Default. If either Party at any time breaches any of the Material Provisions of this Agreement, the other Party shall have the right to terminate this Agreement with respect to a Product to which the breach relates upon sixty (60) days written notice, whereupon this Agreement shall terminate with respect to such Product, unless the breach complained of is corrected within the said notice period. In addition, either Party shall have the right to terminate the entire Agreement if it chooses upon a material breach of any term that is not corrected as set forth herein.

10.3 Material Breach. Either Party shall be entitled to terminate this Agreement upon thirty (30) days' prior written notice to the other Party in the event of a material breach of any provision of this Agreement by the other Party if the notifying Party requires cure and such breach is not cured within thirty (30) days after the breaching Party's receipt of notice of such breach (however, if the breach is capable of being cured and such breaching Party is working diligently to cure such breach the period for cure shall be extended for an additional 45 days).

10.4 Termination by DRL.

10.4.1 DRL shall have the right on thirty (30) days' written notice to terminate this Agreement, without penalty, in the event, in its sole discretion, (i) the sale of such Product becomes commercially non-viable, (ii) there is an unacceptable risk from a product liability perspective, (iii) the Product becomes non-viable as a result of an acquisition or merger involving DRL, (iv) a Third Party asserts that any activities carried out pursuant to this Agreement infringe its Intellectual Property rights (including patent rights) and DRL reasonably concludes that it is not in its commercial interests to continue the sale of the Product, as a result of the infringement claim, (v) Contract Manufacturer fails to maintain cGMP compliant status of Facility with the FDA; or (vi) any Regulatory Authority requires the cessation of the manufacture or marketing of the Product.

10.4.2 Notwithstanding any other provision of this Agreement, DRL may terminate the supply provisions of this Agreement, related to Product by notice in writing to Mikah given within sixty (60) days after Mikah or Contract Manufacturer receives a Form 483 report with respect to a Product or the manufacturing facility therefor and it has not complied with such Form 483 within a reasonable time thereafter and is not diligently pursuing corrective action in response thereto.

10.5 Termination for Bankruptcy. Either Party may immediately terminate this Agreement upon the filing or institution of bankruptcy, reorganization (in connection with any insolvency), liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party, or in the event a receiver or custodian is appointed for such other Party's business, or if a substantial portion of such other Party's business is subject to attachment or similar process; provided, however, that in the case of any involuntary bankruptcy proceeding or the attachment of a substantial portion of a Party's assets, such right to terminate shall only become effective if the proceeding or attachment is not dismissed within sixty (60) days after the filing thereof.

10.6 Consequences of Termination. Except as necessary to permit DRL to sell any Product remaining in the distribution chain, upon any expiration or termination of this Agreement, except as the Parties may otherwise agree in the event and at the time of termination, any and all license rights granted by Mikah to DRL shall automatically and immediately terminate and revert to Mikah free of charge, and free and clear of any liens, security interest or encumbrance. Mikah shall pay DRL, within sixty (60) days of the effective date of termination, the amount of outstanding Net Loss in proportion to the profit share percentage to which Mikah is entitled.

10.7 Survival. The provisions of this Agreement which by their terms are to be performed or complied with subsequent to the termination or expiration of this Agreement shall survive such termination or expiration and shall continue in full force and effect in accordance with their respective terms. Except as set forth below or elsewhere in this Agreement, the following provisions of this Agreement shall survive expiration or termination of this Agreement (whether terminated pursuant to Article 10 or any other section providing for termination): Sections 3.7, 5.1, 5.4, 5.6, 7.1, 7.2, 10.6, 10.7 and 10.8 and Articles 6, 8 and 13.

10.8 Force Majeure. Except as to payments required under this Agreement, if any default or delay occurs which prevents or materially impairs a Party's performance and is due to a cause beyond the Party's reasonable control, and provided that the default or delay is not caused by or the fault of such Party, including but not limited to an act of God, flood, fire, explosion, earthquake, casualty, accident, war, revolution, civil commotion, blockade, terrorism or embargo and available supply of material, the affected Party shall promptly notify the other Party in writing of such cause and shall exercise diligent efforts to resume performance under this Agreement as soon as possible. Neither Party will be liable to the other Party for any loss or damage due to such cause.

ARTICLE 11
LIMITATIONS OF LIABILITY

EXCEPT FOR THOSE INDEMINITY OBLIGATIONS ARISING OUT OF ARTICLE 8 HEREIN, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES OF SUCH OTHER PARTY ARISING OUT OF PERFORMANCE UNDER THIS AGREEMENT, INCLUDING WITHOUT LIMITATION, LOSS OF REVENUES, PROFITS OR DATA, WHETHER IN CONTRACT OR TORT, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

*{***} 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
NOTICE

All notices and other communications hereunder ("Notices") shall be in writing and shall be deemed given: (a) when delivered personally; (b) when delivered by facsimile transmission or e-mail of a Portable Document Format (PDF) (receipt verified); (c) when received or refused, if mailed by registered or certified mail (return receipt requested), postage prepaid; or (d) when delivered if sent by reliable express courier service with a confirmation, to the Parties at the following addresses (or at such other address for a Party as shall be specified by like notice; provided, that notices of a change of address shall be effective only upon receipt thereof):

To DRL:	Dr. Reddy's Laboratories, Inc. 107 College Road East Princeton, NJ 08540 Attention: Head of North America Generics
With a copy to:	Dr. Reddy's Laboratories, Inc. 107 College Road East Princeton, NJ 08540 Attention: Head of North America Legal Fax: (908) 450 1264
To Mikah:	Mikah Pharma LLC 20 Kilmer Drive Hillsborough, New Jersey, 08844 Attn: Nasrat Hakim, President

ARTICLE 13
MISCELLANEOUS

13.1 Entire Agreement; Amendments. This Agreement, the exhibits, attachments, and any amendments hereto or thereto, constitute the entire understanding and supersedes all prior agreements and understandings, both written and oral, among or between the Parties with respect to the specific subject matter hereof. Neither Party shall be liable or bound to the other Party in any manner by any representations, warranties or covenants relating to such subject matter except as specifically set forth herein. No term of this Agreement may be amended except upon written agreement of both Parties, unless otherwise provided in this Agreement.

13.2 Recitals. The recitals are hereby incorporated by reference and made part of this Agreement.

13.3 Captions. The captions in this Agreement are for convenience only and are not to be interpreted or construed as a substantive part of this Agreement. The terms "Article" and "Section" shall be used interchangeably.

*{***} 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.*

13.4 Further Assurances. The Parties agree to execute, acknowledge and deliver such further instruments and to take all such other incidental acts as may be reasonably necessary or appropriate to carry out the purpose and intent of this Agreement.

13.5 No Waiver. Failure by either Party to insist upon strict compliance with any term of this Agreement in any one or more instances will not be deemed to be a waiver of its rights to insist upon such strict compliance with respect to any subsequent failure.

13.6 Severability. If any term of this Agreement is declared invalid or unenforceable by a court or other body of competent jurisdiction, the remaining terms of this Agreement will continue in full force and effect.

13.7 Independent Contractors. The relationship of the Parties is that of independent contractors, and neither Party will incur any debts or make any commitments for the other Party except to the extent expressly provided in this Agreement. Nothing in this Agreement is intended to create or will be construed as creating between the Parties the relationship of joint ventures, co-partners, employer/employee or principal and agent.

13.8 Successors and Assigns. This Agreement will be binding upon and inure to the benefit of the Parties, their successors and permitted assigns. Neither Party may assign this Agreement, in whole or in part, without the prior written consent of the other Party, except that either Party may, without the other Party's consent, assign this Agreement to an Affiliate or to a successor to substantially all of the business or assets of the assigning Party. Any assignment or transfer in contravention of this Agreement shall be null and void.

13.10 Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument. Any photocopy, facsimile or electronic reproduction of the executed Agreement shall constitute an original.

13.11 Publicity. Neither Party will make any press release or other public disclosure regarding this Agreement or the transactions contemplated hereby without the other Party's express prior written consent, except as required under applicable law or by any governmental agency, in which case the Party required to make the press release or public disclosure shall use commercially reasonable efforts to obtain the approval of the other Party as to the form, nature and extent of the press release or public disclosure prior to issuing the press release or making the public disclosure.

13.12 Conflicting Terms. To the extent this Agreement and the Quality Agreement have directly conflicting terms, this Agreement shall govern.

13.13 Currency. Wherever a currency is indicated throughout this Agreement, that currency shall be United States Dollars, unless otherwise clearly indicated.

13.14 Days. Wherever reference is made to days, working days or any measurement of time in days, calendar days shall be used regardless of weekends and holidays.

*{***} 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.*

13.15 Sophisticated Parties. Each Party to this Agreement is a sophisticated business Party negotiating in good faith with the advice of legal counsel. Each Party is hereby advised to seek the advice of legal counsel prior to executing this Agreement.

13.16 English Language. This Agreement has been negotiated and is written in the English language, and while some of the Parties may not speak English as their first language, they have sought the use of translators, if necessary and understand the meaning of this entire Agreement.

13.17 Dispute Resolution. In the event of any dispute, prior to filing any legal action in court, except in the event of any breach or threatened breach of this Agreement by either Party that the other Party believes will cause irreparable harm and damage to it, the Parties shall follow the following procedure, in good faith, in an effort to avoid litigation:

(a) Executives of the Parties will meet or speak informally within fifteen (15) days of the request of either Party to discuss the areas of disagreement and to negotiate in good faith regarding possible solutions. As part of this dispute resolution process, either Party will, at the request of the other Party, promptly provide to the other Party a short and plain written statement setting forth that Party's position regarding the dispute and that Party's suggested resolution.

(b) Within fifteen (15) days after receipt of the statement referenced in the preceding paragraph, the receiving Party will provide to the sending Party a short and plain written response setting forth the receiving Party's position regarding the claim and the receiving Party's suggested resolution

(c) For a period of fifteen (15) days following the sending of the response referenced in the preceding paragraph, the Parties will negotiate in an effort to resolve the controversy. The foregoing written statements of the Parties shall be deemed to be confidential settlement communications under federal and state rules of evidence.

13.18 Governing Law and Venue. This Agreement shall be governed in accordance with the substantive laws of the State of New Jersey, United States, without giving effect to that State's rules on conflict of laws, and any litigation that may arise herefrom shall be instituted in any U.S. Federal Court that has jurisdiction.

[Remainder of page intentionally left blank; 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 have caused their duly authorized representative to execute this Agreement effective as of the date set forth above.

DR. REDDY'S LABORATORIES INC.		**MIKAH PHARMA, LLC**	
By:	/s/Alok Sonic	By:	/s/Nasrat Hakim
Name:	Alok Sonic	Name:	Nasrat Hakim
Its:		Its:	CEO

*{***} 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 A

PRODUCT INFORMATION

Product	Batch Size	Price Per Bottle without API
Trimipramine 25mg, 30ct bottle	*{***}*	See Product pricing given in Attachment 2
Trimipramine 50mg, 30ct bottle	*{***}*	See Product pricing given in Attachment 2
Trimipramine 100mg, 30ct bottle	*{***}*	See Product pricing given in Attachment 2

*{***} 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.*

Attachment 1

Termination of the Asset Purchase Agreement and Master Supply Agreement dated as of May 25, 2016 by and between Actavis LLC and Mikah Pharma LLC

*{***} 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.*

Attachment 2

Amendment to Epic-Mikah Manufacturing and Supply Agreement dated as of June 30, 2015 by and between Mikah Pharma LLC and Epic Pharma LLC

*{***} 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 10.56

MANUFACTURING AND SUPPLY AGREEMENT

This MANUFACTURING AND SUPPLY AGREEMENT (this "Agreement") is made as of May _, 2011, (the "Effective Date") by and between Mikah Pharma, LLC, organized and existing under the laws of the State of Delaware, having offices at 20 Kilmer Drive, Hillsborough, New Jersey 08844, (referred to herein as "Mikah") and Epic Pharma, LLC, a company organized under the laws of Delaware having offices at 227-15 N. Conduit Avenue, Laurelton, NY 11413 (referred to herein as "Epic" or "Manufacturer"). Mikah and Epic are each a "Party" and together constitute the "Parties" to this agreement

A. WHEREAS Mikah desires that Epic performs certain services relating to the Product(s) (as defined below), including (a) developing and preparing the documentation required for the transfer of the manufacturing process to Epic's facility and the filing of a CBE30 for the ANDA, and (b) manufacturing finished dosage forms appropriate for commercial sale, marketing and distribution in the Territory (as defined below) in accordance with the requirements of this Agreement; and

B. WHEREAS Epic desires to perform such technology transfer, manufacturing and supply services to enable Mikah or its designees to commercially market, sell and distribute the Product(s) upon the terms and conditions of this Agreement entered into between the Parties and incorporated herein by reference.

NOW, THEREFORE in consideration of the mutual covenants and agreements contained herein, the sufficiency and satisfaction of which are hereby acknowledged, Mikah and Epic hereby agree as follows:

ARTICLE 1
DEFINITIONS

The following capitalized terms have the meanings set forth in this Agreement

"Affiliate(s)" shall mean any person or entity which, directly or indirectly, controls, is controlled by, or is under common control with, a party or its assignee. Control shall be determined based upon either their legal right to control or de facto control of the entity.

"ANDA" means Abbreviated New Drug Application and all amendments thereto, that have to date been filed with the FDA seeking authorization and approval to manufacture, package, ship and sell, as more fully defined in 21 C.F.R. Part 314, the Products, as well as the Abbreviated New Drug Application for any other Product hereafter added to the terms of this Agreement.

"API" means the active pharmaceutical ingredient required for the Products.

"Applicable Laws" means all laws, ordinances, codes, rules and regulations within the Territory applicable to the Manufacturing of the Product or in any territory applicable to any aspect thereof and the obligations of Epic or Mikah, as the context requires under this Agreement, including, without limitation: (a) all applicable federal, state and local laws and regulations of the Territory (including Environmental Laws) relating to the Manufacture of the Products; (b) the United States Federal Food, Drug and Cosmetic Act, and (c) the regulations promulgated under the FD&C Act including without limitation those regarding the Good Manufacturing Practices ("cGMP") each as amended from time to time.

*{***} 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.*

"Confidential Information" is as defined in Section 10.2.

"Data" shall refer to all data, materials, plans, reports, test results and other information developed solely by or for Mikah in connection with the Technology Transfer and/or the Manufacturing of the Products.

"Defective Product" means any Product that fails to conform to the Specifications or Applicable Laws.

"Effective Date" means the date this Agreement was fully executed.

"Facility" means Epic's manufacturing facility located at 227-15 N. Conduit Avenue, Laurelton, NY 11413.

“FDA" means the United States of America Food and Drug Administration.

"Intellectual Property" means without limitation, patents, patent applications, knowhow, trade secrets, copyrights, trademarks, designs, concepts, technical information, manuals, standard operating procedures, instructions or specifications.

"Latent Defect" means a defect: (a) which could not reasonably have been discovered upon receipt and careful inspection of the Product and (b) for which the assignable cause has been attributed to the actions or omissions of Epic prior to delivery of the Product.

"Manufacture(d)" or "Manufacturing" means the compounding, filling, producing, testing and/or packaging of the API and Raw Materials into a finished dosage form in accordance with the Specifications and the terms and conditions set forth in this Agreement.

"Mikah Technology" means any and all data, Specifications, formulations, analytical methods, reports, studies, or other information in whatever form, relating to the Products that are owned or controlled by Mikah as of the Effective Date and/or during the Term of this agreement.

"Patent Defect" shall mean any instance where a Product, fails to conform to the Specifications or fails to conform to the indemnifications given by Epic herein, and such failure is discoverable upon reasonable physical inspection or standard testing procedures upon receipt by Mikah or its affiliates in accordance with applicable standard operating procedures.

"Product" means each of the pharmaceutical products now or hereafter listed on Exhibit A, as it may be amended by the Parties from time to time.

"Purchase Order" shall have the meaning set forth in Section 3.4.

"Raw Materials" means all raw materials (including APIs), supplies, components and packaging necessary to manufacture and ship the Product in accordance with the Specifications.

"Regulatory Authority" means any governmental regulatory authority within a Territory involved in regulating any aspect of the development, manufacture, testing, market approval, sale, distribution, packaging or use of the Product.

"Rolling Forecast" shall have the meaning set forth in Section 3.2.

"Specifications" means with respect to each Product, the procedures, requirements, standards, quality control testing and other data and the scope of services as set forth or referenced in the ANDA, the relevant portions of which shall be supplied to Epic, and are hereby incorporated by reference into this Agreement, along with any amendments or modifications thereto, subject to the terms and conditions set forth in Article 7.

"Technology Transfer" shall mean transfer of the ANDA's manufacturing process and analytical methods developed or owned by Mikah to Epic, including but not limited to: the transfer of the formulation; range finding; the manufacture of a confirmation batch and an exhibit batch at the Facility; methods transfers and improvements; updating USP and regulatory requirements as they relate to the methods; selection of suitable API, excipients and specifications; the manufacturing of pivotal submission batches at the Facility and the preparation of all documentation required for Mikah's filing and approval of a CBE30 with FDA.

"Term" shall have the meaning set forth in Article 14.1.

"Territory" means the United States of America, its territories, possessions, commonwealths and any other country, which the Parties agree in writing to add to this definition of Territory in an amendment to this Agreement.

ARTICLE 2
TECHNOLOGY TRANSFER, VALIDATION & RELATED SERVICES

2 . 1 Services. Epic shall perform, at its sole cost and expense, all Technology Transfer, validation and qualification services (including: equipment, methods and facility qualification), validation and stability services required by Applicable Laws to commence manufacturing the Product for commercial sale by Mikah or its designees in accordance with the terms of this Agreement.

2 . 2 Supply of API, Excipients and Packaging Material. Epic shall provide the API, excipients, capsules bottles, labels and chemicals needed for the manufacture of the Product pursuant to this Agreement Epic will be responsible for the testing and conforming release of the API, excipients and packaging materials and maintaining the required storage conditions directed by the Specifications.

2.3 Labeling. Mikah shall provide Epic with all artwork copy or other material templates developed or produced by Mikah or its Affiliates for the Product labels, printed packaging materials and Product inserts. Epic shall purchase the labels and printed materials. Epic shall not make any changes to the artwork, copy or other materials submitted by Mikah without the prior written approval of Mikah or its Affiliates. Epic will submit to Mikah, for Mikah's approval, a proof of all Product labels, printed packaging materials and Product inserts prior to printing.

ARTICLE 3
MANUFACTURE AND SUPPLY

3.1 Supply and Purchase of Product. During the Term of this Agreement and subject to the provisions herein, Mikah shall purchase from Epic and Epic agrees to manufacture and supply solely and exclusively to Mikah, such Product as Mikah may order from time to time pursuant to this Agreement. Mikah hereby grants to Epic a nonexclusive, royalty-free license, under which Epic has no right to grant sublicenses, and to use Mikah Technology and the Work Product to Manufacture and supply Product solely for and to Mikah. Epic shall manufacture the Product at its Facility in accordance with the ANDA, the Specifications. Applicable Laws, and the terms and conditions of this Agreement. During the Term of this Agreement and subject to Mikah receiving final approval of the Product ANDAs from FDA, Mikah shall purchase the Product, in finished packaged form, from Epic in accordance with the terms and conditions of this Agreement. Epic shall not manufacture the Product or any derivative thereof, whether for itself or for any other company, broker, or distributor whatsoever.

3.2 Forecasts. Commencing three months before the anticipated commercial launch of each Product, Mikah or Actavis, Mikah's designee, shall provide Epic with non-binding rolling twelve (12) month forecasts of its Product requirements by delivery date. These forecasts will become binding only upon issuance of a Purchase Order by Mikah. The forecasts will be updated monthly during the first business week of each calendar month ("Rolling Forecasts"). The Parties agree to discuss the forecasts and the status of the business for the Product quarterly. The Parties further agree that all such forecasts are for planning purposes only and Mikah shall have no obligation to purchase Product consistent with such forecasts hereunder except as may be set forth in a Purchase Order (defined below). Epic agrees to keep at least that amount of inventory of Raw Materials on hand or with Epic to meet Mikah's forecasted Product requirements. It is understood between the Parties that all forecast information must be kept completely confidential.

3.3 Reliance on Forecasts. Epic shall use the forecasts to order and maintain the Raw Materials necessary to fulfil the forecasted Product requirements, taking into account the Raw Material vendor's lead times, minimum order quantities, and Epic's lead time. In no case will Epic maintain more than a three (3) month supply of Raw Materials without Mikah's prior written consent.

3 . 4 Purchase Orders. Mikah or Actavis, Mikah's designee, shall submit Purchase Orders for Product ("Purchase Orders") specifying: (a) the number of units of Product to be purchased, (b) the Price, (c) the expected delivery date, and (d) such other special terms and conditions that may be applicable to such order. For every delivery, per Product, a firm binding order must be made at least two (2) months in advance of delivery date or such lesser period of time that the Parties may agree to, in writing. Epic shall confirm the order and projected date of shipment within seven (7) calendar days after having received a Purchase Order. All Purchase Orders received and not rejected by Epic within 7 days of Epic's receipt shall be deemed to have been confirmed by Epic in accordance with its reflected terms. Epic shall accept all Mikah Purchase Orders (whether submitted by Mikah or Actavis), as described herein. Though Epic shall not be obligated to fulfill any order received less than two (2) months prior to a requested shipment date for any Product, Epic shall use commercially reasonable efforts to accommodate any requested shipment date.

3 . 5 Capacity. Epic shall, at all times during the term hereof, maintain the Manufacturing capacity to supply at least 125% of the quantities forecasted by Mikah.

3 . 6 Terms of Sale. Mikah orders for Product shall be made pursuant to its (or Actavis's) standard form of Purchase Order. To the extent such Purchase Order contains terms or conditions that are in conflict with the terms and conditions of this Agreement, the conflicting terms or conditions of the Purchase Order will have no effect, unless Epic agrees, in writing, to such terms or conditions or that such terms and conditions will supersede the terms of this Agreement.

3 . 7 Order Cancellation or Changes. Mikah may cancel a Purchase Order or modify the date of shipment or the quantity of Product specified in a Purchase Order, by submitting a written change order to Epic at least thirty (30) days in advance of the previously requested date of shipment. All such change orders shall be binding and effective upon receipt by Epic. If Mikah requests a cancellation or modification of a Purchase Order less than 30 days in advance of the previously requested delivery date, such change order shall be binding and effective only upon the written approval by Epic. Epic shall use commercially reasonable efforts to approve the cancellation or modification requested by Mikah, or such other modifications that might be mutually acceptable, and shall advise Mikah of its determination within 3 business days of the submission of Mikah's proposed change order. In the case of partial acceptance, Epic shall specify the quantities and date of shipment of the portion of the Order it can accept, and Mikah shall be entitled to fill any additional amounts not Manufactured by Epic from a Second Source.

3 . 8 Timeliness of Delivery. It is of essence to this Agreement that Epic delivers the Product at the date of shipment stated in the order confirmation. If for any reason Epic believes that delivery of any Purchase Order will be delayed, Epic shall promptly advise Mikah as well as the new anticipated delivery date. If Epic fails to deliver the full quantity of Product on or before the delivery date specified in the applicable confirmed Purchase Order, for any reason other than Force Majeure, Epic shall compensate Mikah for any losses or fines imposed by its direct or indirect customer, and Mikah shall have the right to find or use a second source for the supply of the Product.

3.9 Shipment. All Product shall be delivered EXW, Epic's loading dock. Upon Epic's delivery of the Product EXW, Mikah will bear all risk of loss, delay, or damage in transit as well as all costs of further shipment and appropriate insurance. All Product delivered hereunder shall be suitably packed for shipment by Epic in accordance with good commercial practice, and instructions provided to Epic by Mikah, with respect to protection of such Product during transportation and marked for shipment to Mikah. Such shipment shall also include a Certificate of Analysis ("C of A") and a Certificate of Compliance ("C of C") in accordance with the terms of the Quality Agreement.

3.10 Residual Materials. If Mikah (i) cancels or modifies its Purchase Orders pursuant to Section 3.7, or (ii) requests that Epic purchase any Raw Materials prior to the placement of the related Purchase Order, which creates residual inventory of the API or other Raw Materials that Epic has purchased in accordance with the terms of this Agreement, Mikah shall purchase any APJ and other Raw Materials that Epic purchased in accordance with Section 3.3 of this Agreement which Epic cannot return or use elsewhere, as reasonably determined by Epic. Mikah shall purchase such API or other Raw Materials from Epic for an amount equal to Epic's actual cost therefore, within sixty (60) days of Epic's written request and delivery of such Raw Materials, provided Epic certifies to Mikah that the API and other Raw Materials purchased by Mikah have been stored and otherwise maintained by Epic under cGMP conditions.

3.11 First Priority. Epic hereby agrees that it shall not Manufacture or process goods for itself or for a third party where to do so will, as a consequence, delay delivery of Mikah's firm Purchase Order requirements of Product under this Agreement or cause Epic to refuse or fail to accept a Purchase Order in the manner set forth herein.

3.12 Second Source. At any time during the term of this Agreement, Mikah may seek to establish a second source for the Manufacture of any or all of the Products. Upon notice of such intention, and in compliance with all applicable confidentiality obligations set forth herein or elsewhere, Epic shall cooperate in any way reasonably necessary to permit such second source to be validated as a Manufacturing site of the Product under the ANDA.

3.13 Facility Transfer. In the event that Epic breaches any of its obligations or requirements under this Agreement and fails to cure any such breach within 60 days of notice thereof by Mikah (or if earlier, on the date such breach results in the inability of Mikah to sell and market the Products or any of them under the provisions of the FD&C Act or applicable Laws), Mikah shall have the right to take all actions necessary to accomplish a Technology Transfer to a different manufacturing facility for the Product so effected (a "Facility Transfer").The Facility Transfer shall be at the cost and expense of Epic. Upon and after a Facility Transfer made pursuant to this Section, Mikah shall not be obligated to make any payments to Epic with respect to Product that is not manufactured at Epic's Facility. Any facility Transfer shall be effective until the Product Termination Date for each individual Product. The rights of Mikah under this Section shall be in addition to its other rights under this Agreement.

ARTICLE 4
PRICE AND PAYMENT

4.1 Supply Price and Other Payments. Attached hereto as Exhibit B is the pricing for the Product and certain additional payments that shall be made by Mikah to Epic in connection with this Agreement.

4.2 Audit Right. Mikah reserves the right, upon advance written notice to audit Epic's documentation related to any charges submitted to Mikah. In the event that such an audit results in a calculation, which differs, from the audited party's calculations, the Parties agree to negotiate in good faith to reach agreement as to the amount of the Price adjustment. In the event that the Parties cannot reach agreement, the Parties agree to hire an independent third party auditor, and share the costs of such audit, whose determination shall be binding on both Parties.

4 . 3 Payment Terms. All amounts payable under this Section shall be expressed in United States Dollars and shall be due and payable by Mikah to Epic within 60 of delivery of the finished packaged lots. All payments shall be made by wire transfer in accordance with written instructions given by Epic from time to time.

ARTICLE 5
PRODUCT CONFORMITY TO SPECIFICATIONS

5 . 1 Notification of Defective Product. Mikah shall notify Epic within sixty (60) days after receiving the Product if Mikah has determined that such shipment contains a quantitative defect such that Epic has delivered a quantity of Product that is less than the quantity stated in any invoice or bill of landing. Epic shall, at its own cost and expense, supply Mikah with any missing quantities of Product as soon as practical after receipt of such Notice (as defined herein). Notice of Patent Defect shall be provided by Mikah to Epic within sixty (60) days of inspection of Product in such shipment Mikah shall provide Epic a sample of such Defective Product Notice of a Latent Defect shall be provided within thirty (30) days after Mikah notices the Latent Defect.

5 . 2 Resolution of Defective Product. Notwithstanding the foregoing, Mikah shall have the right to reject any batch of Product having Latent Defects prior to the expiry of such batch of Product. If Epic agrees that the batch is Defective Product, Epic shall, at its option, replace the Defective Product or repay the full amount of any payments, including shipping and recall costs and cost of API, made by Mikah for such Product. If Epic does not agree with Mikah's determination that such Product is Defective Product, then after reasonable efforts to resolve the disagreement, either Party may submit a sample of such Product to a mutually agreed upon independent third party who is an expert or is familiar with the industry to determine whether the Product meets the Specifications. The independent party's results shall be final and binding and if such results indicate that the Product was a Defective Product, Epic shall, at its option, replace the Defective Product or repay the full amount of any payments, including shipping costs and cost of API, made by Mikah for such Product. Unless otherwise agreed to by the Parties in writing. the costs associated with such testing and review shall be borne by the non-prevailing Party.

ARTICLE 6
DELIVERY

6 . 1 Delivery. Epic shall segregate and store all Product until its shipment on the dates reasonably meeting the delivery dates specified by Epic's commitments issued in connection with Mikah's Purchase Orders. Epic shall tender the Product for delivery to the destination specified by Mikah. Mikah shall be responsible for all costs associated with the Product after delivery by Epic to the specified destination in accordance with the terms of this Agreement.

6.2 Shelf Life. All Product shipped to Mikah shall have at least twenty-one (21) months of saleable shelf life remaining upon receipt of Product at destination in accordance with Section 6.1 except for the exhibit and validation lots.

ARTICLE 7
CHANGES TO SPECIFICATIONS

All Specifications and any changes thereto agreed to by the Parties from time to time shall be in writing, dated and signed by the Parties. No change in the Specifications shall be implemented by Epic without the prior written approval of Mikah. Epic shall respond promptly to any request made by FDA or Mikah for a change in the Specifications or the Facility, and both Parties shall use commercially reasonable, good faith efforts to agree to the terms of any requested change in the Specifications or the Facility that affects the Manufacture of the Product in a timely manner.

ARTICLE 8
RECORDS AND REGULATORY MATTERS

8.1 Batch Records and Data. Within a reasonable period of time following the completion of Manufacturing of the first batch of each Product, and on the anniversary of the signing of this Agreement thereafter, Epic shall provide Mikah with properly completed copies of batch records prepared in accordance with the Specifications; provided, however, that if testing reveals an out-of-Specification result, Epic shall provide such batch records within 14 days following resolution of the out-of-Specification result. In addition, for all shipments of Product, Epic shall provide Mikah with an accurate COA and Mikah shall accept such COA given in good faith, regardless of whether or not Mikah shall accept the Product.

8.2 Recordkeeping. Epic shall maintain true and accurate books, records, test and laboratory data, reports and all other information relating to Manufacturing under this Agreement, including all information required to be maintained by all Applicable Laws. Such information shall be maintained in original forms, notebooks and records for a period of at least three (3) years from the relevant finished Product expiration date or longer if required under Applicable Laws.

8.3 Regulatory Compliance. Epic shall act as Mikah's regulatory agent and shall be responsible for the correspondence with the Regulatory Authority with respect to the Product and the Specifications, including any product licenses, applications and amendments in connection therewith. Epic will be responsible to maintain all permits and licenses required by any Regulatory Authority with respect to the Facility and its equipment and the manufacture and distribution of the Product Each Party intends and commits to cooperate to satisfy all Applicable Laws within the scope of its respective responsibilities under this Agreement.

8 . 4 Regulatory Correspondence. Mikah shall be the sole owner of the ANDA. Epic shall notify Mikah immediately of any correspondence, any inspections, and the result of any inspection(s) with the FDA or any Regulatory Authority. Epic shall immediately send a draft to Mikah of all correspondence Epic intends to send to any Regulatory Authority, related to the Product For all correspondence with a Regulatory Authority, related to the Product that is not in response to a regulatory deficiency or problem, Mikah shall have fourteen (14) business days to approve the draft correspondence, and if Mikah is silent after fourteen (14) business days, it is understood Mikah gives its constructive consent to the correspondence. For all correspondence with a Regulatory Authority, related to the Product that is in response to a regulatory deficiency or problem, Mikah shall have the absolute right to approve the draft correspondence before such correspondence is sent to the Regulatory Authorities. In such a case, Mikah will make every effort to act expediently in approving the draft correspondence.

8 . 5 Governmental Inspections and Requests. Epic shall immediately advise Mikah if an authorized agent of any Regulatory Authority visits the Facility or any portion thereof, which may affect the Manufacturing of the Product. Epic shall furnish to Mikah a copy of the report by such Regulatory Authority, if any, within ten (10) days of Epic's receipt of such report. Further, upon receipt of a Regulatory Authority request to inspect the Facility or audit Epic's books and records and such inspection would affect the Manufacturing under this Agreement, Epic shall immediately notify Mikah, and shall provide Mikah with a copy of any written document received from such Regulatory Authority.

8 . 6 Recall. In the event Epic believes a recall, field alert, Product withdrawal or field correction may be necessary with respect to any Product provided under this Agreement, Epic shall immediately notify Mikah in writing (for the sake of clarification "immediately" as used in this section shall mean no more than two (2) days). Epic will not act to initiate a recall, field alert, Product withdrawal or field correction without the express prior written approval of Mikah, unless otherwise required by Applicable Laws. In the event Mikah believes a recall, field alert, Product withdrawal or field correction may be necessary with respect to any Product provided under this Agreement, Mikah shall immediately notify Epic in writing and Epic shall provide all necessary cooperation and assistance to Mikah. The cost of any recall, field alert, Product withdrawal or field correction shall be borne by Mikah except that Epic shall be obligated to reimburse Mikah for recall, field alert, Product withdrawal or field correction costs incurred by Mikah to the extent such recall, field alert, Product withdrawal or field correction is caused by Epic's breach of its representations, warranties, or obligations under this Agreement, Applicable Laws or its negligence or willful misconduct. For purposes hereof, recall costs shall be limited to reasonable, actual and documented administrative costs incurred by Mikah or third party customers directly in connection with such recall, withdrawal or correction, replacement and disposal of the Defective Product to be recalled, in accordance with Article 5.

8 . 7 Inspections and Audits by Mikah. Representatives of Mikah shall have access to the Facility for the purpose of: (a) conducting inspections of such facility and Epic's maintenance and usage of the equipment utilized in the development and manufacture of Product, (b) performing quality control audits or (c) witnessing the development, manufacturing, storage or transportation of the Product or the materials related to or used in the manufacture of Product including API. Mikah shall have access to the results of any tests performed by Epic relating to Product and the API or the processes or materials used in the development and manufacture. Epic shall use its best efforts to ensure that Mikah has similar access to the facilities, data and records of Epic's Epics or agents. Such inspections do not relieve Epic of any of its obligations under this Agreement or create new obligations on the part of Mikah. Such visits by Mikah's representatives shall be conducted during normal business hours.

ARTICLE 9
REPRESENTATIONS AND WARRANTIES

9.1 **Epic**. Epic hereby represents, warrants and covenants to Mikah that:

9.1.1 At the time of each delivery of the Product as provided under this Agreement, such Product and its corresponding Raw Materials will conform to and will have been manufactured, stored and transported in full conformance with the Specifications, cGMPs and all Applicable Laws;

9.1.2 The Product shall not, at the time of delivery to Mikah, contain any material or be manufactured, handled or stored in any way that would cause the Product to be adulterated in any way within the meaning of Section 501 or misbranded within the meaning of Section 502 of the Food, Drug and Cosmetic Act, as amended;

9.1.3 As of the Effective Date and at all times during the Term, Epic and the Facility and all equipment utilized in the manufacture of the Product is and will be in compliance with all Applicable Laws, including all applicable workplace safety regulations under OSHA (or the equivalent local governmental entity), all tax regulations and Environmental Laws;

9.1.4 At all times during the Term, Epic shall obtain Mikah's written approval for the use of any third party contract laboratory intended for the testing and release of API, excipients and/or finished Product if such laboratory is not filed in said ANDA.

9.1.5 At all times during the Term, Epic shall continue to hold all licenses, approvals, permits and similar authorizations of Regulatory Authorities necessary or required to operate the Facility and its equipment;

9.1.6 Neither Epic nor any of its employees has ever been: (a) debarred. or (b) convicted of a crime for which a person can be disbarred under Section 306 (a) or (b) of the Generic Drug Enforcement Act of 1992 as amended from time to time, or (c) been convicted of any crime in the country where the Product is manufactured. Epic agrees to immediately notify Mikah should any Regulatory Authority threaten any action that could possibly result in a breach of this Section;

9.1.7 The Manufacture, storage, packaging and labeling of the Product shall be in complete accordance with all Applicable Laws, the ANDA and the Specifications and will be made, stored. packaged, labeled and controlled by Epic in accordance with any other applicable manufacturing information, or regulatory requirements;

9.1.8 Unless otherwise agreed by the Parties in writing. Epic has: (a) reviewed and approved all Specifications, (b) if applicable, reviewed and approved all in-process and finished Product test results to ensure conformity of such results with the Specifications, regardless of which Party is responsible for finished Product release;

9.1.9 The COA which will accompany each shipment of Product shall be accurate, truthful and made in good faith such that Mikah shall be able to legally rely on each COA;

9.1.10 During the Term of this Agreement, and subject to the provisions herein, including but not limited to Section 3.2, Epic shall not develop, manufacture, market or sell any product competitive with the Product, nor shall it offer any assistance, or permit any of its employees to offer any assistance to any third party (including for this purpose any Affiliate of Epic in the world) to take any action which Epic would be prohibited from engaging in pursuant to this Article;

9.1.11 Neither Epic nor any of its Affiliates is manufacturing the Product or any derivative thereof for any other person, entity or company whatsoever. Following the execution of this Agreement, neither Epic nor any of its Affiliates shall develop or manufacture the Products with or for any third party.

9.1.12 Neither Epic nor any of its Affiliates shall manufacture, market or distribute any of the Products. whether for their own benefit or for the benefit of a third party, for a period of five years following the termination of this Agreement.

9.2 **Mikah**. Mikah hereby represents, warrants and covenants to Epic that:

9.2.1 All artwork templates and the content thereof provided to Epic shall comply with all Applicable Laws;

9.2.2 All Product delivered to Mikah by Epic will be held, used and/or disposed of by Mikah in accordance with all Applicable Laws; and

9.2.3 Mikah will comply with all Applicable Laws applicable to Mikah's performance under this Agreement and its use of any materials or Product provided by Epic under this Agreement; and

9.3 **Mutual**. Each Party hereby represents, warrants and covenants to the other Party that:

9.3.1 Existence and Power. Such Party: (a) is duly organized, validly existing and in good standing under the laws of the state in which it is organized, (b) has the power and authority and the legal right to own and operate its property and assets, and to carry on its business as it is now being conducted, and (c) is in compliance with all requirements of Applicable Laws.

9.3.2 Authorization and Enforcement of Obligations. Each Party: (a) bas the power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder and (b) has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;

9.3.3 Execution and Delivery. This Agreement has been duly executed and delivered on behalf of each Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms;

9.3.4 No Consents. All necessary consents, approvals and authorizations of all Regulatory Authorities and other persons required to be obtained by such Party in connection with the Agreement have been obtained; and

9.3.5 No Conflict. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder: {a) do not conflict with or violate any requirement of Applicable Laws; and (b) do not materially conflict with, or constitute a material default or require any consent under any current contractual obligation of such Party.

9.4 Survival. The obligations of this Article 9 will terminate five (5) years from the expiration or termination of this Agreement.

9.5 Limitations. THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS ARTICLE ARE THE SOLE AND EXCLUSIVE REPRESENTATIONS AND WARRANTIES MADE BY EACH PARTY TO THE OTHER AND NEITHER PARTY MAKES ANY OTHER REPRESENTATIONS. WARRANTIES OR GUARANTEES OF ANY KIND WHATSOEVER INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 10
CONFIDENTIAL INFORMATION

10.1 Mutual Obligation. Epic and Mikah agree that they will not disclose the other Party's Confidential Information (defined below) to any third party without the prior written consent of the other Party except as required by law, regulation or court or administrative order; provided. However, that prior to making any such legally required disclosure, the Party making such disclosure shall give the other Party as much prior notice of the requirement for and contents of such disclosure as is practicable under the circumstances. Notwithstanding the foregoing, each Party may disclose the other Party's Confidential Information to any of its Affiliates that: (a) need to know such Confidential Information for the purpose of performing under this Agreement (b) are advised of the contents of this Article, and (c) agree to be bound by the terms of this Article.

10.2 Definition. As used in this Agreement, the term "Confidential Information" includes all such information rotated to the Product furnished by Epic or Mikah, or any of their respective representatives or Affiliates.to the other or its representatives or Affiliates, whether furnished before, on, or, after the date of this Agreement and furnished in any form, including but not limited to written. Verbal, visual, electronic or in any other media or manner. Confidential Information includes all proprietary technologies, Intellectual Property, analyses, compilations, business or technical information and other materials prepared by either Party, or any of their respective representatives, containing or based in whole or in part on any such information furnished by the other Party or its representatives. Confidential Information also includes the existence of this Agreement and its terms as well as the Confidentiality Agreement signed as of March __, 2011 which is hereby made a part of this Agreement and is attached hereto as Exhibit 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.*

10.3 Exclusions. Notwithstanding Section 10.2. Confidential Information does not include information that: (a) is or becomes generally available to the public or within the industry to which such information rotates other than as a result of a breach of this Agreement. or (b) is already known by the receiving Party at the time of disclosure as evidenced by the receiving Party's written records, or (c) becomes available to the receiving Party on a non-confidential basis from a source that is entitled to disclose it on a non-confidential basis, or (d) was or is independently developed or discovered by or for the receiving Party without reference to the Confidential Information, as evidenced by the receiving Party's written records.

10.4 Return of Confidential Information. Upon termination of this Agreement, the receiving Party shall, upon request, promptly return within thirty (30) days all such Confidential Information, including any copies thereof, and cease its use or, at the request of the disclosing Party, shall promptly destroy the same and certify such destruction to the disclosing Party; except for a single copy thereof, which may be retained for the sole purpose of complying with the scope of the obligations incurred under this Agreement.

10.5 Survival. The obligations of this Article 10 will terminate five (5) years from the expiration of this Agreement.

ARTICLE 11
INTELLECTUAL PROPERTY

11.1 Notice of Infringement Claim. In the event that a third party at any time provides written notice of a claim to, or brings an action, suit or proceeding against, any Party, any of their respective Affiliates, in each case claiming infringement of third party patent rights based upon an assertion or claim arising out of the filing of an ANDA for the Product, or development, manufacture, marketing, distribution, sale, import or use of the Products in the Territory by Mikah ("Infringement Claim"), such Party shall promptly notify the other Party of the claim or the commencement of such action, suit or proceeding, enclosing a copy of the claim and all papers served.

11.2 Exclusive Right to Defend. Mikah shall have the sole and exclusive right, but not the obligation, to defend and/or settle any such Infringement Claim. If an Infringement Claim is brought against Epic ("Epic Infringement Claim"), then Epic shall so notify Mikah in writing within fifteen (15) days of receipt. Upon proper notification of the Epic Infringement Claim,

(i) Mikah shall have the sole and exclusive right to select counsel for such claim and final decision making authority regarding all aspects of the defense and settlement of such claim,

(ii) Epic shall be entitled to participate in the defense of an Epic Infringement Claim and to employ counsel at its expense to assist therein, and

(iii) Epic shall provide Mikah with such information and assistance as Mikah may reasonably request.

11.3 Epic Assistance. Upon written request from Mikah, Epic shall promptly provide Mikah and/or its counsel with such access to information about, and personnel knowledgeable of, the Products and their formulation, use and process of manufacture to enable Mikah to:

(i) ascertain whether the manufacture, marketing, distribution, sale, import or use of the Products in and for the Territory will infringe any existing patent of a third party;

(ii) determine its conduct in relation to any proceedings alleging infringement of a third party's patent in the Territory;

(iii) provide witnesses or documentation from Epic in any proceedings alleging infringement of a third party's patent in the Territory; and

(iv) if deemed advisable, the Parties shall enter into a joint defense agreement containing customary terms and conditions for the purpose of, inter alia, preserving confidentiality and any applicable privilege attaching to information and data exchanged by the parties under and pursuant to this Agreement

ARTICLE 12
INDEMNIFICATION

12.1 Indemnification by Epic. Epic shall defend, indemnify and hold harmless Mikah, and its directors. officers, employees and agents ("Mikah Indemnitees") from and against any and all suits, claims, losses, demands, liabilities, damages, costs and expenses (including reasonable attorneys' fees) in connection with any suit, demand or action by any third party ("Losses") arising out of or resulting from: (a) any breach of its representations, warranties or obligations set forth in this Agreement or resulting from the breach of its obligations to deliver Product in full conformity to the Specifications, or for Product to remain in full conformity through its expiration date and in conformity with all Applicable Laws or (b) any negligence or willful misconduct by Epic, except to the extent that any of the foregoing arises out of or results from any Mikah Indemnitee's obligations set forth in Section 12.2 below.

12.2 Indemnification by Mikah. Mikah shall defend, indemnify and hold harmless Epic, its Affiliates, and their respective directors, officers, employees and agents ("Epic Indemnitees") from and against all Losses arising out of or resulting from: (a) any breach of its representations, warranties or obligations set forth in this Agreement; or (b) any negligence or willful misconduct by Mikah, except to the extent that any of the foregoing arises out of or results from any Epic Indemnitee's obligations set forth in Section 12.1 above.

12.3 Indemnification Procedures. All indemnification obligations in this Agreement are conditioned upon the Party seeking indemnification: (a) promptly notifying the indemnifying Party of any claim or liability of which the Party seeking indemnification becomes aware (including a copy of any related complaint, summons, notice or other instrument); provided, however, that failure to provide such notice within a reasonable period of time shall not relieve the indemnifying Party of any of its obligations hereunder except to the extent the indemnifying Party is prejudiced by such failure; (b) cooperating with the indemnifying Party in the defense of any such claim or liability; and (c) not compromising or settling any claim or liability without prior written consent of the indemnifying Party.

ARTICLE 13
INSURANCE

1 3 . 1 Epic Insurance. Epic shall, at its own cost and expense. obtain and maintain in full force and effect the following insurance during the term of this Agreement: (i) Commercial General Liability insurance with per-occurrence and general aggregate limits of not less than $1,000,000; (ii) Products and Completed Operations Liability Insurance with per-occurrence and general aggregate limits of not less than $5,000,000; (iii) Statutory Workers' Compensation and Employer's Liability Insurance with an amount not less than $500,000 including excess liability coverage. In the event that any of the required policies of insurance arc written on a claims made basis, then such policies shall be maintained during the entire term of this Agreement and for a period of not less than three (3) years following the termination or expiration of this Agreement Epic shall waive subrogation rights against Mikah for workers' compensation benefits and shall obtain a waiver from any insurance carriers with which Epic carries workers' compensation insurance releasing their subrogation rights against Mikah. Mikah shall be named as an additional insured under the Commercial General Liability and Products and Completed Operations Liability insurance policies as respects the manufacturing services outlined in this Agreement. Epic shall furnish certificates of insurance for all of the above noted policies and required additional insured status to Mikah within 10 days after the Effective Date of the Agreement and upon renewal of any such policies.

13.2 Mikah Insurance. Mikah or its affiliate shall, at its own cost and expense, obtain and maintain in full force and effect the following insurance during the term of this Agreement: (i) Products and Completed Operations Liability Insurance with per-occurrence and general aggregate limits of not less than $5,000,000; (ii) Statutory Workers' Compensation and Employer's Liability Insurance with an amount not less than $500,000 including excess liability coverage. In the event that any of the required policies of insurance are written on claims made basis, then such policies shall be maintained during the entire term of this Agreement and for a period of not less than three (3) years following the termination or expiration of this Agreement. Mikah shall waive subrogation rights against Epic for workers' compensation benefits and shall obtain a waiver from any insurance carriers with which Mikah carries workers' compensation insurance releasing their subrogation rights against Epic. Epic shall be named as an additional insured under the Products and Completed Operations Liability insurance policies as respects the Product and completed operations outlined in this Agreement. Mikah shall furnish certificates of insurance for all of the above noted policies and required additional insured status to Epic within 10 days after the Effective Date of the Agreement and upon renewal of any such policies.

ARTICLE 14
TERM AND TERMINATION

1 4 . 1 Term. This Agreement shall commence on the Effective Date and shall continue for a period of five (5) years after commercial launch of Product, on a Product-by-Product basis, unless earlier terminated under this section (the "Term"). The Term shall automatically renew for additional periods of one (1) year each ("Renewal Term") unless Mikah provides written notice of termination to Epic at least six (6) months prior to the expiration of the Term or any Renewal Tenn. Epic agrees to continue to supply Product to Mikah under the terms of this Agreement until Mikah has satisfactorily qualified a Second Source of Product.

14.2 Termination by Either Party.

14.2.1 Material Breach. Either Party may terminate this Agreement effective upon sixty (60) days prior written notice to the other Party, if the other Party commits a material breach of this Agreement and fails to cure such breach by the end of such sixty (60) day period;

14.2.2 Bankruptcy. Either Party may terminate this Agreement effective upon written notice to the other Party, if the other Party becomes insolvent or admits in writing its inability to pay its debts as they become due, files a petition for bankruptcy, makes an assignment for the benefit of its creditors or has a receiver, trustee or other court officer appointed for its properties or assets, and shall comply with Section 2 herein.

14.3 Termination by Mikah.

14.3.1 Mikah shall have the right on sixty (60) days' written notice to terminate this Agreement, or a single Product under this Agreement, without penalty, in the event: (a) in Mikah's sole opinion, the sale of Product manufactured pursuant to this Agreement become commercially non-viable, (b) if, in Mikah's sole opinion, any Intellectual Property rights of any third party may be infringed, misappropriated, or otherwise violated by the manufacture, use, importation, sale or distribution of the Product in the Territory or if there is an unacceptable risk from a product liability perspective, (c) if Mikah acquires or merges with a company which render the Product no longer viable, (d) any Regulatory Authority requires Mikah to cease production of Product, or (e) Mikah decides to manufacture the Product hereunder in any of its own manufacturing facilities.

14.3.2 In the event of a termination pursuant to Section 14.3.1 above, other than for intellectual property or safety reasons, the Parties shall coordinate to sell off all in process inventory (and/or Safety Stock) that may remain in Epic's Facility upon receipt of the Notice. In order that Epic get the benefit of absorption and Mikah have the ability to retain its customer base until such post-notification inventory is processed and Safety Stock sold, the post notification inventory shall be manufactured into finished dosage Product by Epic as well as the Safety Stock sold to Mikah at cost or the Parties can split the costs of the components which were purchased by Epic to fill a Purchase Order at the time of termination or to manufacture the Safety Stock.

14.3.3 In the event of a termination under Section 14.3.1(e), Epic shall provide Mikah all reasonable assistance in transferring the Product(s) to Mikah's manufacturing facility(ies).

14.4 Force Majeure. Except as to payments required under this Agreement, if any default or delay occurs which prevents or materially impairs a Party's performance and is due to a cause beyond the Party's reasonable contra and provided that the default or delay is not caused by or the fault of such Party, including but not limited to an act of God, flood, fire, explosion, earthquake, casualty, accident, terrorism, war, revolution, civil commotion, blockade, terrorism or embargo, injunction, law, proclamation, order, regulation or governmental demand, the affected Party shall promptly notify the other Party in writing of such cause and shall exercise diligent efforts to resume performance under this Agreement as soon as possible. Neither Party will be liable to the other Party for any loss or damage due to such cause; nor will the Term be extended thereby. Neither Party may terminate this Agreement because of such default or delay except upon thirty (30) days' prior written notice to the other Party if the default or delay has existed for five (5) months and is continuing at the end of the thirty (30) day notice period.

14.5 Effect of Termination. Expiration or termination of this Agreement shall be without prejudice to any rights or obligations that accrued to the benefit of either Party prior to such expiration or termination. In the event that this Agreement is terminated by either Party, Epic shall assist Mikah in effecting a smooth transition to an alternate contractor of the Product at Mikah's sole cost and expense. The rights and obligations of the Parties shall continue under Articles 4, 6, 8, 9, 10, 11, 12, 13, 14, 15, and 16 notwithstanding expiration or termination of this Agreement.

ARTICLE 15
LIMITATIONS OF LIABILITY

NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL (EXCEPT FOR TIIOSE INDEMNITY OBLIGATIONS UNDER ARTICLE 12 THAT ARE DEFINED AS CONSEQUENTIAL DAMAGES) DAMAGES ARISING OUT OF PERFORMANCE UNDER THIS AGREEMENT, INCLUDING WITHOUT LIMITATION, LOSS OF REVENUES, PROFITSOR DAT WHETHER IN CONTRACT OR TORT, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

ARTICLE 16
NOTICE

All notices and other communications hereunder ("Notice(s)") shall be in writing and shall be deemed given: (a) when delivered personally; (b) when delivered by facsimile transmission (receipt verified); (c) when received or refused, if mailed by registered or certified mail (return receipt requested),postage prepaid; or (d) when delivered if sent by reliable express courier service with a confirmation, to the Parties at the following addresses (or at such other address for a Party as shall be specified by like notice; provided, that notices of a change of address shall be effective only upon receipt thereof):

To Mikah: Mikah Pharma LLC

Attn: Nasrat Hakim, President
Email: nasrathakim@mikahpharma.com

To Epic: Epic Pharma LLC
227-15N. Conduit Avenue Laurelton, NY 11413
Attn: Jai Narine, President and Ashok Nigalaye, CEO
Email: J.Narine@epic-pharma.com
Email: A.Nigalaye@epic-pharma.com

ARTICLE 17
MISCELLANEOUS

17.1 Entire Agreement Amendments. This Agreement, the exhibits, attachments, and any amendments hereto or thereto, including the Quality Agreement and the Confidentiality Agreement, constitute the entire understanding between the Parties with respect to the specific subject matter hereof. No term of this Agreement may be amended except upon written agreement of both Parties, unless otherwise provided in this Agreement.

17.2 Recitals. The recitals are hereby incorporated by reference and made part of this Agreement.

17.3 Captions. The captions in this Agreement are for convenience only and are not to be interpreted or construed as a substantive part of this Agreement. The terms "Article" and "Section" shall be used interchangeably.

17.4 Further Assurances. The Parties agree to execute, acknowledge and deliver such further instruments and to take all such other incidental acts as may be reasonably necessary or appropriate to carry out the purpose and intent of this Agreement.

17.5 No Waiver. Failure by either Party to insist upon strict compliance with any term of this Agreement in any one or more instances will not be deemed a waiver of its rights to insist upon such strict compliance with respect to any subsequent failure.

17.6 Severability. If any term of this Agreement is declared invalid or unenforceable by a court or other body of competent jurisdiction, the remaining terms of this Agreement will continue in full force and effect.

17.7 Independent Contractors. The relationship of the Parties is that of independent contractors, and neither Party will incur any debts or make any commitments for the other Party except to the extent expressly provided in this Agreement. Nothing in this Agreement is intended to create or wilt be construed as creating between the Parties the relationship of joint ventures, co-partners, employer/employee or principal and agent.

17.8 Successors and Assigns. This Agreement will be binding upon and inure to the benefit of the Parties, their successors and permitted assigns. Neither Party may assign this Agreement, in whole or in part, without the prior written consent of the other Party, except that either Party may, without the other Party's consent, assign this Agreement to an Affiliate or to a successor to substantially all of the business or assets of the assigning company.

17.9 Governing Law. This Agreement shall be governed by and construed under the laws of the State of Delaware, United States of America, excluding its conflicts of law provisions.

17.10 Alternative Dispute Resolution. If any dispute arises between the Parties ("Dispute"), such Dispute shall be presented to the respective presidents or senior executives of the Parties for their consideration and resolution. Each Party shall endeavor to amicably resolve the dispute in good faith as a first step, prior to taking any other action.

17.11 Prevailing Party. In any dispute resolution proceeding between the Parties in connection with this Agreement, the prevailing Party will be entitled to its reasonable attorney's fees and costs in such proceeding.

17.12 Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument. Any photocopy, facsimile or electronic reproduction of the executed Agreement shall constitute an original.

17.13 Publicity. Neither Party will make any press release or other public disclosure regarding this Agreement or the transactions contemplated hereby without the other Party's express prior written consent, except as required under applicable law or by any governmental agency, in which case the Party required to make the press release or public disclosure shall use commercially reasonable efforts to obtain the approval of the other Party as to the form, nature and extent of the press release or public disclosure prior to issuing the press release or making the public disclosure.

17.14 Conflicting Terms. To the extent this Agreement and the ANDA Development Agreement have directly conflicting terms, this Agreement shall govern.

17.15 Currency. Wherever a currency is indicated throughout this Agreement, that currency shall be United States Dollars, unless otherwise clearly indicated.

17.16 Days. Wherever reference is made to days, working days or any measurement of time in days, calendar days shall be used regardless of weekends and holidays.

17.17 Sophisticated Parties. Each Party to this Agreement is a sophisticated business party negotiating in good faith with the advice of legal counsel. Each Party is hereby advised to seek the advice of legal counsel prior to executing this Agreement.

17.16 English Language. This Agreement has been negotiated and is written in the English language, and while some of the Parties may not speak English as their first language, they have sought the use of translators, if necessary and understand the meaning of this entire Agreement.

IN WITNESS WHEREOF, the Parties have caused their duly authorized representative to execute this Agreement effective as of the Effective Date.

MIKAH PHARMA LLC

/s/ Nasrat Hakim
Name: Nasrat Hakim
Title: President & CEO

EPIC PHARMA LLC

/s/ Ashok G. Nigalaye
Name: Ashok Nigalaye
Title: CEO

/s/ Jeenarine Narine
Name: Jai Narine
Title: President

EXHIBIT A
PRODUCTS

ANDA 77-361 (Trimipramine Maleate Capsules, 25mg, 50mg and l00mg) and all amendments thereto

Trimipramine Maleate Capsules, 25mg, 50mg and 100 mg	Bottle of 30's	Bottle of 90's	Bottle of 100's	Bottle of 500’s

(Specifications)
As set forth by each product's ANDA, United States Pharmacopeia, applicable GMP and FDA.

*{***} 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.*

June 30, 2015

Ashok Nigalye, PhD CEO
Epic Pharma LLC
227-15 North Conduit Avenue Laurelton, NY 11413

Re: Amendment to Epic-Mikah Manufacturing and Supply Agreement dated May 11, 2011 ("Amendment")

Dr. Nigalye,

Epic Pharma LLC, a Delaware limited liability company ("Epic"), and Mikah Pharma LLC, Inc., a Delaware corporation Manufacturing and Supply Agreement effective as of May 11, 20 (the "Agreement"). All capitalized terms used without definition in this letter agreement have the respective meanings provided in the Agreement.

Effective as of the date of this letter agreement, the parties agree that Exhibit B of the Agreement shall be deleted and replaced in its entirety with a new Exhibit B that shall read as follows:

EXHIBIT B
SUPPLY PRICE AND OTHER PAYMENTS

Pricing: Epic shall manufacture Trimipramine Capsules in 30 count bottles for Mikah, in finished packaged form for the following Transfer Price:

25 mg	${***}
50 mg	${***}
100 mg	${***}

Calculations of cost per 30 count bottle: The transfer price for the 25 mg and 100 mg is ${***} per bottle excluding API cost. The price for the 50 mg 30 count bottle is ${***} excluding API cost.

The API cost for a 30 count bottle of 25, 50 and 100 mg of Trimipramine is ${***}, ${***} and ${***} respectively. It is calculated as 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.*

1) 25mg/tablet*30 tablets/bottle * *{***}*
2) 50mg/tablet*30 tablets/bottle * *{***}*
3) 100mg/tablet*30 tablets/bottle * *{***}*

Duration: The Transfer Price is fixed for three years beginning on the effective date of the Amendment. However, price adjustments may occur, (i) upon mutual agreement of the Parties or (ii) in the event there are special increases or decreases in the cost of Raw Materials that impact the total cost of goods for that SKU by more than 10%.

Batch size: Epic may increase the 25 mg and 100 mg batch size from *{***}* to *{***}* Capsules; and the 50 mg batch size from *{***}* to *{***}* Capsules.

MIKAH PHARMA LLC

By: /s/ Nasrat Haim
Name: Nasrat Hakim
Title: President and CEO

Accepted and agreed as of this June 30, 2015

EPIC PHARMA LLC

By: /s/ Ashok Nigalye
Name: Ashok Nigalye, PhD
Title: CEO

*{***} 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, 2017, relating to the consolidated financial statements 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, 2017.

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

/s/ Buchbinder Tunick & Company LLP

Wayne, New Jersey
June 14, 2017

EXHIBIT 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following documents of our report dated June 15, 2015 relating to the consolidated financial statements of Elite Pharmaceuticals, Inc. and Subsidiary included in the Annual Report on Form 10-K of the Company for the year ended March 31, 2017.

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

/s/ Berkower LLC

Iselin, New Jersey
June 14, 2017

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, 2017 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, 2017

/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, 2017 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, 2017

/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, 2017 filed with Securities and Exchange Commission (the "Report"), I, Nasrat Hakim, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted 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, 2017

/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, 2017 filed with Securities 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 adopted 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, 2017

/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.
