

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

FORM 10-K

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

FOR THE ANNUAL PERIOD ENDED MARCH 31, 2019

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

(State or other jurisdiction of
incorporation or organization)

22-3542636

(I.R.S. Employer
Identification No.)

165 LUDLOW AVENUE
NORTHVALE, NEW JERSEY

(Address of principal executive offices)

07647

(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:

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

Title of each class

Trading Symbol

Name of each exchange on which registered

Common Stock, par value \$0.001 per share

ELTP

OTCQB

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

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 X

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 X No

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	X
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	X
		Emerging growth company	<input type="checkbox"/>

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 X

The aggregate market value of Common Stock held by non-affiliates at September 30, 2018, the last business day of the registrant's most recently completed second fiscal quarter was \$73,517,602.

The number of shares of the registrant's Common Stock outstanding as of June 7, 2019 was 828,388,501.

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, our ability to fund all of our activities 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.

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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 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 currently being sold commercially:

Product	Branded Product Equivalent	Therapeutic Category	Launch Date
Phentermine HCl 37.5mg tablets (“Phentermine 37.5mg”)	Adipex-P [®]	Bariatric	April 2011
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
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
Methadone HCl 5mg and 10mg tablets (“Methadone 5mg” and “Methadone 10mg”)	Dolophine [®]	Pain	November 2018
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, Amphetamine Sulfate Immediate Release 5mg, 7.5mg, 10mg, 12.5mg, 15mg, 20mg and 30mg tablets (“Amphetamine IR 5mg”, “Amphetamine IR 7.5mg”, “Amphetamine IR 10mg”, “Amphetamine IR 12.5mg”, “Amphetamine IR 15mg”, “Amphetamine IR 20mg” and “Amphetamine IR 30mg”)	Adderall [®]	Central Nervous System (“CNS”) Stimulant	April 2019

Note: Phentermine 37.5mg is also referred to as "Phentermine Tablets". Phentermine 15mg and Phentermine 30mg are collectively and individually referred to as "Phentermine Capsules". Hydromorphone 8mg is also referred to as "Hydromorphone Tablets". Phendimetrazine 35mg is also referred to as "Phendimetrazine Tablets". Naltrexone 50mg is also referred to as "Naltrexone Tablets". Isradipine 2.5mg and Isradipine 5mg are collectively and individually referred to as "Isradipine Capsules". 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 Capsules". Methadone 5mg and Methadone 10mg are collectively and individually referred to as "Methadone Tablets". Amphetamine IR 5mg, Amphetamine IR 7.5mg, Amphetamine IR 10mg, Amphetamine IR 12.5mg, Amphetamine IR 15mg, Amphetamine IR 20mg and Amphetamine IR 30mg are collectively and individually referred to as "Amphetamine IR Tablets".

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.

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 "2013 ANDA Purchase Agreement" 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 2011.

Phendimetrazine 35mg is currently a commercial product being manufactured by Elite and distributed by Glenmark Pharmaceuticals Inc., US/ ("Glenmark") on a non-exclusive basis, and by Elite.

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

Phentermine 15mg and Phentermine 30mg

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

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

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

Naltrexone 50mg

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

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

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

Isradipine 2.5mg and Isradipine 5mg

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

Isradipine 2.5mg and Isradipine 5mg are currently a commercial product being manufactured by Elite and distributed by Glenmark, on an exclusive basis.

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 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.

Trimipramine 25mg, Trimipramine 50mg and Trimipramine 100mg are currently a commercial product being manufactured by Elite and distributed by Glenmark, on an exclusive basis.

Amphetamine IR Tablets

On December 10, 2018, the Company received approval from the FDA for Amphetamine IR Tablets, a generic version of Adderall[®], an immediate-release mixed salt of a single entity Amphetamine product (Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate Amphetamine Sulfate) with strengths of 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 20 mg, and 30 mg tablets. The product is a central nervous system stimulant and is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) and Narcolepsy. According to QVIA (formerly QuintilesIMS Health) data the branded product and its equivalents had total U.S. sales of \$365 million for the twelve months ending September 30, 2018. This is the first product approval for our Elite and SunGen Pharma LLC (“SunGen”) collaboration. The product is jointly owned. Elite will manufacture and package the product on a cost-plus basis and the parties are negotiating an agreement for sales of the product. Amphetamine IR Tablets are currently sold pursuant to the Lannett Alliance, with first commercial shipment of this product occurring in April 2019. Please see the section below titled “Strategic Marketing Alliance with Lannett Company Inc.” for further details on the Lannett Alliance.

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 July 7, 2017, the Company reported topline results from a pivotal bioequivalence fed study for SequestOx™. The mean Tmax (the amount of time that a drug is present at the maximum concentration in serum) of SequestOx™ was 4.6 hr. with a range of 0.5 hr. to 12 hr. and the mean Tmax of the comparator, Roxicodone®, was 3.4 hr. with a range of 0.5 hr. to 12 hr. A key objective for the study was to determine if the reformulated SequestOx™ had a similar Tmax to the comparator when taken with a high fat meal. Based on these results, the Company paused clinical trials for this formulation of SequestOx™. On January 30, 2018, the Company reported positive topline results from a pilot study conducted for a modified SequestOx™ wherein, based on the results of this pilot study, the modified SequestOx™ formulation is expected to achieve bioequivalence with a Tmax range equivalent to the reference product when conducted in a pivotal trial under fed conditions. The Company has provided the pilot data to the FDA, requesting clarification as to the requirements for resubmission of the NDA. The FDA has provided guidance for repeated bio-equivalence studies in order to bridge the new formulation to the original SequestOx studies and also extended our filing fee waiver until July 2020. Due to the prohibitive cost of such repeated bio-equivalence studies, the Company has paused development of this product.

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

Oxycodone Hydrochloride extended release (generic version of Oxycontin®)

On September 20, 2017, the Company filed an ANDA with the FDA for generic version of Oxycontin® (extended release Oxycodone Hydrochloride). OxyContin® is approved for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. IMS reported approximately \$2.3 billion in revenue for OxyContin® and its equivalents in 2016. The FDA requested additional information relating to this filing, compliance with which would require significant resources. Development of this product is currently paused, with the Company evaluating the feasibility of the continued development of this product.

Generic version of extended release Central Nervous System stimulant

On May 24, 2018, the Company filed an ANDA with the FDA for a generic version of an extended release CNS stimulant. The ANDA represents the second filing for a product co-developed with SunGen under the SunGen Agreement. According to IMS Health data, the branded product and its equivalents had total U.S. sales of approximately \$1.6 billion for the twelve months ended September 30, 2017. The Company received a request from the FDA for additional information to which the Company has responded. The response is under review by the FDA.

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

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

Acetaminophen and Codeine Phosphate

On September 18, 2018, the Company filed an ANDA with the FDA for a generic version of Tylenol® with Codeine (acetaminophen and codeine phosphate) 300mg/7.5mg, 300mg/15mg, 300mg/30mg and 300mg/60mg tablets. Acetaminophen with codeine is a combination medication indicated for the management of mild to moderate pain, where treatment with an opioid is appropriate and for which alternative treatments are inadequate. Acetaminophen with codeine products have annual U.S. sales of approximately \$45 million according to IQVIA (formerly QuintilesIMS Health Data).

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 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 these marketing authorizations.

Approved Products Not Yet Commercialized

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 received approval of this ANDA in July 2018. Elite has not yet launched this product and is seeking a partner for this product.

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

In December 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. The Company received approval of this ANDA in November 2018. Norco is 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. .. Elite has not yet launched this product and is seeking a partner for the product.

Dantrolene Sodium Capsules

In March 2019, the Company’s prior approval supplement (“PAS”) filed with the FDA was approved, thereby successfully transferring manufacture of Dantrolene Sodium 25mg, 50mg and 100mg capsules (“Dantrolene Capsules”) to the Northvale Facility. The approved ANDAs for Dantrolene Capsules were acquired as part of the 2013 ANDA acquisition between the Company and Mikah Pharma. Please see the section below titled “Asset Acquisition Agreements” for further details on the 2013 ANDA acquisition agreement. Dantrolene Capsules will be marketed by Lannett Company, pursuant to the marketing alliance agreement between the Company and Lannett. Please see the section below titled “*Strategic Marketing Alliances with Lannett Company, Inc.*” for further details on this marketing alliance. The Company expects commercial launch of Dantrolene Capsules during this year.

Loxapine 5mg, 10mg, 25mg and 50mg capsules (“Loxapine Capsules”)

A PAS has been filed with the FDA for transfer of manufacturing of this product to the Northvale Facility, with such PAS being under review by the FDA. The approved ANDAs for Loxapine Capsules were acquired as part of the 2013 ANDA acquisition between the Company and Mikah Pharma. Please see the section below titled “Asset Acquisition Agreements” for further details on the 2013 ANDA acquisition agreement.

Discontinued and Transferred Products

The FDA's Generic Drug User Fee Amendment ("GDUFA") fee structure includes fee brackets that are based on the number of ANDAs owned as of the April 1st annual measurement date. As of the measurement date in 2018, The Company qualified as a medium sized company, which is defined as an entity that owns between 6 and 19 ANDAs. During the fiscal year ending March 31, 2019, the Company received approval for several ANDAs, which, when added to those approved in prior periods resulted in the Company owning in excess of 19 ANDAs and would have required classification as a large sized company as of the 2019 measurement date. Based on the latest fee schedule published by the FDA in August 2018, the annual fee for a large company is \$1.1 million higher than the fee we paid as a qualified medium company. Qualifying as a large sized company would accordingly result in a significant increase in annual regulatory fees.

Prior to the April 1, 2019 measurement date, the Company conducted an evaluation of all ANDAs owned to determine the feasibility of incurring such increased annual fees in relation to the value and place of each ANDA in the company's current and future operations and strategic plans. Based on this study, the Company identified the following ANDAs for sale and, if sale was not possible prior to the measurement date, discontinuance, so as to ensure that total ANDAs owned at the measurement date were not greater than 19, allowing the Company to qualify as a medium sized entity, as opposed to a large sized entity, which would have resulted in increased regulatory costs in excess of \$1 million annually.

Hydroxyzine HCl

Approved ANDAs for Hydroxyzine HCl 10mg, 25mg and 50mg tablets ("Hydroxyzine Tablets") were sold to Epic Pharma LLC for cash consideration totaling \$450,000. The three related approved ANDAs had an aggregate carrying value of \$787,000, with such sale resulting in a recognized loss of \$337,000 during the fiscal year ended March 31, 2019.

Phentermine Capsules

Approved ANDAs for Phentermine 30mg and 15mg capsules and Phentermine 30mg seeded capsules were discontinued in March 2019. These three ANDAs had an aggregate carrying value of \$291,000, which was recognized as a loss during the fiscal year ended March 31, 2019.

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 amendment thereto, that have to date been filed with the FDA seeking authorization and approval to manufacture, package, ship and sell the products described in this ANDA within the United States and its territories (including Puerto Rico) for aggregate consideration of \$200,000. In lieu of cash, Mikah Pharma agreed 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.

2013 ANDA Purchase Agreement

On August 1, 2013, Elite executed a purchase agreement with Mikah (the “2013 ANDA Purchase Agreement”) pursuant to which, Elite acquired, for an aggregate consideration of \$10,000,000, inclusive of imputed interest, approved ANDAs for the following products: Hydroxyzine HCl 10mg, 25mg and 50mg tablets (“Hydroxyzine Tablets”), Phentermine Capsules, Phentermine Tablets, Phendimetrazine Tablets, Isradipine Capsules, Dantrolene Capsules and Loxapine 5mg, 10mg, 25mg and 50mg capsules (“Loxapine Capsules”). In addition, Elite acquired one ANDA under review by the FDA, which is not expected to be approved and for which no value was assigned.

The Company issued a secured, non interest bearing, convertible note for the aggregate consideration, with such note being due in August 2016. This note was amended on February 7, 2014 to make it convertible into shares of the Company’s Series I Convertible Preferred Stock. On February 7, 2014, the note was converted into 100 shares of the Company’s Series I Preferred Stock, and retired.

On August 16, 2016, these 100 shares of Series I Preferred Stock were converted into 142,857,143 shares of Common Stock, with such shares being included in the exchange agreement dated April 28, 2017 pursuant to which shares were returned to the company, in exchange for shares of Series J Preferred Stock and Warrants, both of which are still outstanding. Please see “*Certain Relationships And Related Transactions, And Director Independence*,” below for further details of these transactions.

The following is a summary of the status of the ANDAs acquired pursuant to the 2013 ANDA Purchase Agreement:

Product	Status
Hydroxyzine Tablets	Transferred to Epic Pharma
Phentermine Capsules	Discontinued
Phentermine Tablets	Commercial
Phendimetrazine Tablets	Commercial
Isradipine Capsules	Commercial
Dantrolene Capsules	Manufacturing transferred to Northvale facility; Commercial launch expected this year
Loxapine Capsules	Manufacturing site transfer in progress

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. Trimipramine is currently manufactured by Elite and marketed by Glenmark pursuant to the Glenmark Strategic Alliance. 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.

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

Licensing, Manufacturing and Development Agreements

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

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

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

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

Manufacturing and License Agreement with Epic Pharma LLC

On October 2, 2013, we executed the Epic Pharma Manufacturing and License Agreement (the “Epic Manufacturing and License Agreement”). This agreement, which expired on October 2, 2018, 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 2013 ANDA Purchase Agreement. Of the twelve approved ANDAs, Epic had an 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. Pursuant to the Epic Manufacturing and License Agreement, we received a license fee and milestone payments. The license fee was computed as a percentage of the gross profit, as defined in the Epic Manufacturing and License Agreement, earned by Epic from the sale of the products. The manufacturing cost used for the calculation of the license fee was a predetermined amount per unit plus the cost of the active pharmaceutical ingredient (“API”) and the sales cost for the calculation was predetermined based on net sales.

The Epic Manufacturing and License Agreement expired on October 2, 2018, in accordance with terms and conditions therein.

Trimipramine Acquisition

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

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

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

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

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

Under the Trimipramine Manufacturing Agreement, Epic manufactured 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 supplied Trimipramine on an exclusive basis to Dr. Reddy’s and Dr. Reddy’s was responsible for all marketing and distribution of Trimipramine in the United States, its territories, possessions, and commonwealth. The Trimipramine was manufactured by Epic and transferred to Dr. Reddy’s at cost, without markup.

Dr. Reddy’s paid 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 was in excess of 50%.

The Reddy’s Trimipramine Distribution Agreement was terminated by mutual consent of the parties on August 1, 2018.

Ascend 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 tablets (the “*Ascend Methadone*”) to ThePharmaNetwork LLC (the “*Ascend Methadone Manufacturing and Supply Agreement*”). ThePharmaNetwork LLC was subsequently acquired by Alkem Laboratories Ltd (*Alkem*) and now goes by the name Ascend Laboratories LLC (“*Ascend*”) and is a wholly owned subsidiary of Alkem.

Ascend is the owner of the approved ANDA for Ascend Methadone, and the Northvale Facility is an approved manufacturing site for this ANDA. The Ascend Methadone Manufacturing and Supply Agreement provides for the manufacturing and packaging by the Company of Ascend Methadone.

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

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

Subsequent to the expiration of the Ascend Methadone Manufacturing and Supply Agreement, the Company honored purchase orders from Ascend to manufacture Ascend Methadone. The commercial terms on those purchase orders honored were similar to those included in the expired agreement. The last shipment of Ascend Methadone pursuant to purchase orders honored subsequent to the expiration of the Ascend Methadone Manufacturing and Supply Agreement occurred in April 2018 and there will be no further manufacture or shipments of Ascend Methadone.

Precision Dose License Agreement

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

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

Master Development and License Agreement with SunGen Pharma LLC

On August 24, 2016, as amended we entered into an agreement with SunGen Pharma LLC (“SunGen”) (the “SunGen Agreement”) to undertake an engage in the research, development, sales and marketing of eight generic pharmaceutical products. Two of the products are classified as CNS stimulants (the “CNS Products”), two of the products are classified as beta blockers and the remaining four products consist of antidepressants, antibiotics and antispasmodics. To date, the Company has received approval from the FDA for Amphetamine IR Tablets (the first of the two CNS Products) and has file ANDA’s for the second CNS Product as well as ANDA filed for an antibiotic product.

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

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

On May 24, 2018, the Company filed an ANDA with the FDA for a generic version of an extended release CNS stimulant. The ANDA represents the second filing for a product co-developed with SunGen under the SunGen Agreement. According to IMS Health data, the branded product and its equivalents had total U.S. sales of approximately \$1.6 billion for the twelve months ended September 30, 2017. The Company received a request from the FDA for additional information to which the Company has responded. The filing is under review by the FDA.

On December 10, 2018, the Company received approval from the FDA for Amphetamine IR Tablets, a generic version of Adderall[®], an immediate-release mixed salt of a single entity Amphetamine product (Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate Amphetamine Sulfate) with strengths of 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 20 mg, and 30 mg tablets. The product is a central nervous system stimulant and is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) and Narcolepsy. According to QVIA (formerly QuintilesIMS Health) data the branded product and its equivalents had total U.S. sales of \$365 million for the twelve months ending September 30, 2018. This is the first product approval for our Elite and SunGen Pharma LLC (“SunGen”) collaboration. The product is jointly owned. Elite will manufacture and package the product on cost-plus basis and the parties are negotiating an agreement for sales of the product. Amphetamine IR Tablets is currently sold pursuant to the Lannett Alliance, with first commercial shipment of this product occurring in April 2019. Please see the section below titled “Strategic Marketing Alliance with Lannett Company Inc.” for further details on the Lannett Alliance.

On January 3, 2019, the Company filed an ANDA with the FDA for a generic version of an antibiotic product. According to QVIA (formerly QuintilesIMS Health) data, the branded product for this antibiotic and its equivalents had total annual U.S. sales of approximately \$94 million for the twelve months ending September 30, 2018. The product is jointly owned by Elite and SunGen. Upon approval by the FDA of this ANDA, Elite will manufacture and package the product on a cost-plus basis. The ANDA is currently under review by the FDA.

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, and even for those products for which marketing authorization has already been received, there can be no assurances that there will be future revenues or profits, or that any such future revenues or profits would be in amounts that provide adequate return on the significant investments made to secure these marketing authorizations or provide sufficient financial contributions to support costs of operations and overheads.

Strategic Marketing Alliance with Glenmark Pharmaceuticals, Inc. USA

On May 29, 2018, and as amended on August 1, 2018, we entered into a license, manufacturing and supply agreement with Glenmark Pharmaceuticals Inc. USA (“Glenmark”) to market the two Elite generic products described below in the United States with the option to add products in the future (the “Glenmark Alliance”).

Pursuant to the Glenmark Alliance, Glenmark will purchase the products from Elite and then sell and distribute them. In addition to the purchase price for the products, Elite will receive license fees well in excess of 50% of gross profits. Gross profits is defined as net sales less the price paid to Elite for the products, distribution fees (less than 10%) and shipping costs. Glenmark will have semi-exclusive marketing rights to the ANDA approved generic product phendimetrazine 35mg tablets, and exclusive marketing rights to the following ANDA approved generic products: Methadone 10mg, Methadone 5mg, Trimipramine 25mg, Trimipramine 50mg, Trimipramine 100mg, and effective October 2, 2018, upon expiration of the Epic Manufacturing and License Agreement, exclusive marketing rights to the following ANDA approved generic products: Isradipine 2.5mg and Isradipine 5mg. The Glenmark Alliance has an initial term of three years and automatically renews for one year periods absent prior written notice of non-renewal. In addition to customary termination provisions, the Agreement permits Glenmark to terminate with regard to a product on at least three months’ prior written notice if it determines to stop marketing and selling such product, and it permits Elite to terminate with regard to a product if at anytime after the first twelve months from the first commercial sale, the average license fee paid by Glenmark for such product is less than \$100,000 for a six month sales period.

The first commercial shipment of Methadone Tablets pursuant to the Glenmark Alliance occurred in November 2018. The first commercial shipment of Isradipine Capsules pursuant to the Glenmark Alliance occurred in March 2019. The first commercial shipment of Trimipramine Capsules occurred in April 2019.

There can be no assurances that there will be future revenues or profits, earned pursuant to the Glenmark Alliance, 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 authorizations for products included in the Glenmark Alliance or provide sufficient financial contributions to support costs of operations and overheads.

Strategic Marketing Alliances with Lannett Company Inc.

The Company has entered into two separate license, supply and distribution agreements with Lannett Company Inc. (“Lannett”). The first agreement dated March 6, 2019 relates to products that were co-developed with SunGen (the “Lannett-SunGen Product Alliance”). The second agreement, dated April 1, 2019 relates to products that were solely developed by Elite (the “Lannett-Elite Product Alliance”). Both agreements are collectively and individually referred to as the “Lannett Alliance”)

Pursuant to Lannett-SunGen Product Alliance with Lannett, Lannett will be the exclusive U.S. marketer and distributor for two generic products co-developed and co-owned by Elite and SunGen – Amphetamine IR Tablets and a second product which is an extended release CNS stimulant that is currently under review by the FDA. Elite will manufacture and Lannett will purchase the products from Elite and then sell and distribute them. In addition to the purchase prices for the products, Elite will receive license fees in excess of 50% of net profits, which will be shared equally with SunGen, pursuant to the SunGen Agreement. The Lannett-SunGen Product Alliance has an initial term of three years and automatically renews for one year periods absent prior written notice of non-renewal. In addition to customary termination provisions, the Agreement permits Lannett to terminate with regard to a product on at least six months’ prior written notice, and it permits Elite or Lannett to terminate with regard to a product if at anytime after the first twelve months from the first commercial sale, the average license fee paid by Lannett for such product is less than \$300,000 for a six month sales period. In addition to manufacturing fees and license fees, Lannett will also pay a milestone, of \$750,000 upon commercial launch of the extended release CNS stimulant product that is currently under review by the FDA. This milestone payment will be shared equally by Elite and SunGen, pursuant to the SunGen Agreement.

The first commercial shipment of Amphetamine IR Tablets, a generic version of Adderall[®], with strengths of 5mg, 7.5mg, 10mg, 12.5mg, 15mg, 20mg and 30mg, pursuant to the Lannett-SunGen Product Alliance occurred in April 2019.

Pursuant to the Lannett-Elite Product Alliance, Lannett will be the exclusive U.S. marketer and distributor for Dantrolene Capsules. Elite will manufacture and Lannett will purchase Dantrolene Capsules from Elite and then sell and distribute them. In addition to the purchase prices for the products Elite will receive license fees in excess of 50% of net profits. Net profits is defined as net sales less the price paid to Elite for the products, distribution fees (less than 10%) and shipping costs. The Lannett-Elite Product Alliance has an initial term of three years and automatically renews for one year periods absent prior written notice of non-renewal. In addition to customary termination provisions, the Agreement permits Lannett to terminate with regard to a product on at least six months’ prior written notice and it permits Elite or Lannett to terminate with regard to a product if at anytime after the first twelve months from the first commercial sale, the average license fee paid by Lannett for such product is less than \$300,000 for a six month sales period.

Products Under Development

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

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

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

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

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

On September 18, 2018, the Company filed an Abbreviated New Drug Application with the US Food and Drug Administration (the "FDA") for generic version of Tylenol® with Codeine (acetaminophen and codeine phosphate) 300mg/7.5mg, 300mg/15mg, 300mg/30mg and 300mg/60mg tablets. Please see "*Filed products under FDA review*" above. Please note that there can be no assurances of this product receiving marketing authorization or achieving commercialization. In addition, even if marketing authorization is received and the product is commercialized, there can be no assurances of future revenues or profits in such amounts that would provide adequate return on the significant investments made to secure marketing authorization for this product.

On January 3, 2019, the Company filed an Abbreviated New Drug Application with the US Food and Drug Administration for a generic version of an antibiotic product. Please see "*Filed products under FDA review*" above. Please note that there can be no assurances of this product receiving marketing authorization or achieving commercialization. In addition, even if marketing authorization is received and the product is commercialized, there can be no assurances of future revenues or profits in such amounts that would provide adequate return on the significant investments made to secure marketing authorization for this product. Please also see the section below titled "*Master Development and License Agreement with SunGen Pharma LLC*".

The Company believes that the abuse deterrent technology can be applied to and incorporated into a wide range of opioids used today for pain management and has, to date, identified 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, cost incurred in relation to the development of these products have not been material.

Research and development costs were \$7.6 million and \$9.6 million for years ended March 31, 2019 and 2018, respectively. Costs incurred relate to the development of the abuse deterrent opioid product, *SequestOx™*, the ongoing development of our abuse deterrent opioid and other products in addition to a focus on clinical trials for generic products.

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. 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 6,620,439	October 2020
U.S. patent 6,926,909	April 2023
U.S. patent 8,182,836	April 2024
U.S. patent 8,425,933	April 2024
U.S. patent 8,703,186	April 2024
Canadian patent 2,521,655	April 2024
Canadian patent 2,541,371	September 2024
U.S. patent 9,056,054	June 2030
E.P. patent 1615623	April 2024
U.S. patent 10213388	April 2030

We also have pending applications for two additional U.S. patents non-provisional patents and one provisional patent application and one foreign patent application. 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, for which United States trademark registration is being sought.

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 – Methadone Manufacturing and Supply Agreement

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

Other Business Factors and Details

Government Regulation and Approval

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

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 an 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) Mylan Laboratories, Inc., Endo Pharmaceuticals, Inc., Teva Pharmaceuticals Industries Ltd., Amneal Laboratories, Inc., Mallinckrodt, and Aurobindo. 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., Collegium Pharmaceuticals, Inc., and Purdue Pharma LP

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 an NDA. ANDA products are referred to as generic pharmaceuticals and NDA products are referred to as brande pharmaceuticals. For the years ended March 31, 2019 and 2018 revenue from our ANDA segment was \$6.6 million and \$6.5 million respectively. For the years ended March 31, 2019 and 2018 revenue from our NDA segment was \$1.0 million and \$1.0 million, respectively.

Segment information is consistent with the financial information regularly reviewed by our chief operating decision maker, who we have determined to be the chief executive office, for the purposes of making decisions about allocating resources and assessing performance of the Company. There are currently no intersegment revenues. Asset information by operating segment is not presented below since the chief operating decision maker does not review this information by segment.

Employees

As of June 14, 2019, we had 35 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 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 amendment 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 may 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 avoid infringing the intellectual property of others;
- The ability to protect our intellectual property from being acquired by other entities;
- Our ability to manage growth and integrate acquired products and assets successfully; and
- The addition or loss of customers.

A negative variation in one, many or all of the above factors could, may or will have a material adverse effect on Elite's business, results of operations, financial condition, and cash flow and ability to operate in the future, depending on the nature of the variation(s).

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, resulting in a material adverse effect on Elite's business, results of operations, financial condition, and cash flow and ability to operate in the future.

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, 2019 and 2018, we incurred net losses from operations of approximately \$9.2 million and \$9.1 million, respectively. In addition, as noted below, the auditor's opinion on the financial statements for the year ended March 31, 2019 is qualified with respect to there being substantial doubt as to the Company's ability to continue as a going concern and we expect to continue to incur losses until we are able to generate sufficient revenues to support our operations and offset operating costs. Failure to generate such sufficient revenues will have a material adverse effect on our business, results of operations, financial condition, cash flow and ability to operate in the future.

We most likely will require additional financing to meet our business objectives.

We most likely will need additional funding to accomplish our plans to conduct the clinical development and commercialization of a range of multiple abuse resistant opioids or initiate, continue or complete the development of additional generic products already identified for development or currently in development.

As of March 31, 2019, we had cash on hand of approximately \$2.3 million and a working capital surplus of \$2.0 million, and, for the fiscal year ended March 31, 2019, we had losses from operations totaling \$9.2 million, net other expenses totaling \$0.8 million and net loss of \$9.3 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, which has decreased from \$0.166 on May 1, 2017 to \$0.099 on March 31, 2019, 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 "Management's Discussion and Analysis of Financial Condition and Results of Operations; Liquidity and Capital Resources; Lincoln Park Capital".

While growth in our current generic product line, consisting of Phentermine Tablets, Phentermine Capsules, Phendimetrazine Tablets, Naltrexone Tablets, Isradipine Capsules, Oxy IR, Trimipramine Capsules, Methadone Tablets and Amphetamine IR Tablets, combined with manufacturing, profit split and royalty revenues earned pursuant to the Lannett Alliance, the Glenmark Alliance, the Precision Dose License Agreement, from sales of Oxy IR by Epic, and successful commercialization of other products in our product development pipeline, may lead to eventual profitability, there can be no assurances of Elite becoming profitable. Furthermore, there can be no assurances of the continuation revenues being earned from the current generic product line, no assurances of Elite's successful commercialization of other products in our development pipeline, and no assurances of Elite's ability to continue as a going concern. In addition, there can be no assurances of Elite being able to raise additional funds in a timely manner, on acceptable terms, if needed to support commercial operations, whether from the 2017 LPC Purchase Agreement or otherwise, resulting in a material detrimental effect on Elite's ability to become profitable and accordingly being a material factor to the detriment of Elite's ability to continue as a going concern as well as having a material adverse effect on our business, results of operations, financial condition, and cash flow and ability to operate in the future.

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.

As noted in the next risk factor, we will need to increase our authorized shares of Common Stock.

If we are unable to increase our authorized shares of common stock, our ability to raise additional funds most likely will be materially adversely affected. Our inability to increase our authorized shares also will result in a requirement to pay significant annual dividends pursuant to our outstanding shares of Series J Preferred Stock.

As of June 14, 2019, all of our 995,000,000 authorized shares of Common Stock were issued or reserved for issuance upon conversion of our outstanding shares of Series J Preferred Stock, exercise of outstanding option and warrants, as well as issuance pursuant to the Purchase Agreement with Lincoln Park Capital. To meet our obligations under the foregoing instruments and to raise additional funding through the sale of our common stock, we need to increase the number of authorized shares of our common stock.

Pursuant to the terms of the Series J Preferred Stock we are obligated to use our best efforts to obtain shareholder approval to increase the number of authorized shares to an amount that is sufficient to allow the issuance of Common Stock pursuant to conversion of all of the outstanding shares of Series J Preferred Stock by April 28, 2021. Furthermore, if such shareholder approval is not timely obtained and our authorized shares of Common Stock are not sufficiently increased by April 28, 2021, Nasrat Hakim, the holder of the Series J Preferred Stock, is entitled to an annual dividend equal to twenty percent of the stated value (\$1,000 per share) of Series J Preferred Stock commencing on such date. We plan on holding an annual meeting of shareholders during the calendar year 2021, at which time we will seek an increase in our authorized shares of Common Stock (the "Proposal").

If our shareholders do not approve the Proposal, our ability to raise additional funds most likely will be materially adversely affected and we will be required to pay the dividend on the outstanding shares of Series J Preferred Stock.

Our independent auditors have expressed substantial doubt about our ability to continue as a going concern.

As of March 31, 2019, we had cash on hand of approximately \$2.3 million and a working capital surplus of \$2.0 million, and, for the fiscal year ended March 31, 2019, we had losses from operations totaling \$9.2 million, net other expenses totaling \$0.8 million and net loss of \$9.3 million. Because of the foregoing, in their report on our financial statements for the year ended March 31, 2019, our independent auditors included an explanatory paragraph regarding their substantial doubt about our ability to continue as a going concern. We will continue to experience net operating losses in the foreseeable future. Our ability to continue as a going concern is subject to our ability to generate a profit and/or obtain necessary funding from outside sources, including obtaining additional funding from the sale of our securities, increasing sales, reducing overhead or obtaining loan from various financial institutions where possible.

We have identified material weaknesses in our internal control over financial reporting which could, if not remediated, 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, the Company's Independent Auditors and specific guidance from subject matter experts engaged by the Company, we have concluded that material weaknesses in the Company's internal controls over financial report existed. 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.

The Company has identified certain remediation actions and is in the process of implementing them, but such efforts are not complete, most likely require the retention of additional personnel or consultants (which is subject to the Company's financial condition). Although no material misstatement of our historical financial statements was identified, if we are unable to complete our remediation in a timely manner or if our remedial measures are insufficient to address the material weaknesses, or if additional material weaknesses in our internal controls are discovered or occur in the future, it may materially adversely affect our ability to report our financial condition and results of operations in a timely and accurate manner and there will continue to be an increased risk of future misstatements. In our periodic review and evaluation of internal controls systems to allow management to report on the effectiveness of our internal controls over financial reporting, we may discover additional weaknesses in our internal controls over financial reporting or disclosure controls and procedures. 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. Please see Item 9A "Controls And Procedures" in Part II.

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 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 2005. There can be no assurances of Elite making principal and interest payments in the amounts and on the dates specified in the NJEDA Bond agreement. The failure by Elite to make principal and/or interest payments required by the NJEDA Bonds, could result in the increased possibility of an acceleration of amount due pursuant to such notice of default previously issued, with such an acceleration having a material adverse effect on Elite's business, results of operations, financial condition, cash flow and ability to operate in the future.

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 one approved generic product for which a PAS for transfer of manufacturing site has been filed with the FDA. 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. Failure to bring to commercialization any of the products already in development by Elite will have a material adverse effect on Elite's ability to operate in the future.

The failure to successfully identify and develop additional generic products or to introduce these generic products on a timely basis most likely will result in a material adverse effect on our ability to operate in the future.

We may not be successful in our efforts to continue to create a pipeline of product candidates or develop commercially successful products. Identifying, developing and obtaining regulatory approval and commercializing additional product candidates is prone to all direct, indirect, known and unknown risks inherent in the development of pharmaceuticals, including, without limitation, products which initially show promise in preliminary pharmacological or marketing studies, but fail to yield the positive results initially expected. No assurances can be given that we will be able to successfully identify additional product candidates, advance any additional product candidates through the development process or successfully commercialize any such additional product candidates. The inability or failure of Elite to successfully identify, develop and commercialize additional product candidates, most likely will have a material adverse effect on our business, results of operations, financial condition, cash flow and ability to operate in the future.

The failure to successfully develop, commercialize and market new products most likely will result in a material adverse effect on our ability to operate in the future.

To sustain current operations, engender business growth, achieve current and future revenues and profitability, we significantly depend on our ability to successfully develop, commercialize and market new pharmaceutical products, including, without limitation, our own products as well as those developed with SunGen. As a result, we must continually develop, test and manufacture new products, which must meet regulatory standards to receive requisite marketing authorizations.

The process of developing and obtaining regulatory approvals for new products is time-consuming, costly and inherently unpredictable. Products we are currently developing may not receive the regulatory approvals or clearances necessary for us to market them and, if approved, we may be unable to successfully commercialize them on a timely basis or at all, or if commercialized, revenues and profits achieved from the sale of such products might not reach levels that provide sufficient return on those costs incurred during the commercialization process.

The successful commercialization of a product is subject to a number of factors, including:

- The timely filing of any NDA, ANDA or other regulatory submission applicable to our product candidates;
- Any adverse development or perceived adverse development with respect to the applicable regulatory agency's review of such regulatory submission and approval for the indication sought;
- The effectiveness, ease of use and safety of our products as compared to existing products;
- Customer demand and the willingness of physicians and customers to adopt our products over products with which they may have more loyalty or familiarity and overcoming any biases towards our products;
- The cost of our product compared to alternative products and the pricing and commercialization strategies of our competitors;
- The success of our launch and marketing efforts;
- Adverse publicity about us, our products, our competitors and their products or the industry as a whole or favorable publicity about competitors;
- The advent of new and innovative alternative products; and
- Any unforeseen issues or adverse developments in connection with a product and any resulting litigation or regulatory scrutiny and harm to our reputation or the reputation or acceptance of the product in the market.

In addition, there are many risks associated with developing, commercializing and marketing new products that are beyond our control. For example, without limitation, our collaboration partner(s) may decide to make substantial changes to a product's formulation or design, may experience financial difficulties or may have limited financial resources. Any of the foregoing may delay the development, commercialization and/or marketing of new products. In addition, if a codeveloper on a new product terminates our collaboration agreement or does not perform under the agreement, we may experience delays and additional costs in developing and marketing that product, with no assurances of us having the resources that may be required to overcome such delays or additional costs that were beyond our control.

We conduct research and development to enable us to manufacture and market pharmaceutical products in accordance with specific government regulations. Our drug development efforts relating to SequestOx and certain generics are focused on technically difficult-to-formulate products and/or products that require advanced manufacturing technology. Typically, expenses related to research, development and regulatory approval of compounds for SequestOx, which is a branded pharmaceutical product are significantly greater than those expenses associated with generic products. Expanded research and development efforts are required, resulting in increased research expenses. Because of the inherent risk associated with research and development efforts in the healthcare industry, particularly with respect to new drugs, our research and development expenditures may not result in the successful regulatory approval and introduction of new pharmaceutical products and failure in the development of any new product can occur at any point in the process, including late in the process after substantial investment. Also, after we submit a regulatory application, the relevant governmental health authority may require that we conduct additional studies, including, for example, studies to assess the product's interaction with alcohol. As a result, we may be unable to reasonably predict the total research and development costs to develop a particular product and there is a significant risk that the funds we invest in research and development will not generate financial returns. In addition, our operating results and financial condition may fluctuate as the amount we spend to research and develop, commercialize, acquire or license new products, technologies and businesses changes. Much of the preceding occurred with the development of SequestOx which has not yet received marketing approval from the FDA, with material adverse effects on our business, results of operations, financial condition, cash flows and ability to operate resulting in the past, as well as the risk remaining for the future.

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 our manufacturing facility or the facilities of any of our suppliers fail to comply with regulatory requirements or encounter other manufacturing difficulties, it could adversely affect our ability to manufacture and supply products. All facilities and manufacturing processes used for the manufacture of pharmaceutical products are subject to inspection by regulatory agencies at any time and must be operated in conformity with current good manufacturing practice (“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, recordkeeping, quality assurance and quality control so that their products meet applicable specifications and other requirements for product safety, efficacy and quality. Failure to comply with applicable legal requirements subjects us, our manufacturing facilities and the facilities of our third party suppliers to possible legal or regulatory action, including, without limitation, shutdown, which may adversely affect our ability to supply the product. Additionally, our manufacturing facilities, and those of our third party suppliers may face other significant disruptions due to labor strikes, failure to reach acceptable agreement with labor unions, infringement of intellectual property rights, vandalism, natural disaster, storm or other environmental damage, civil or political unrest, export or import restrictions or other events. Were we not able to manufacture products at our manufacturing facilities, or were our third party suppliers unable to manufacture products at their facilities because of regulatory, business or any other reasons, the manufacture and marketing of these products would be interrupted. This could have a material adverse impact on our business, results of operation, financial condition, cash flows, competitive position and ability to operate.

We may decide to sell or withdraw approved ANDAs, which could result in a material adverse effect on our ability to operate in the future.

We may, from time to time, sell and/or withdraw approved ANDAs if we determine that the costs of maintaining such ANDAs is excessive when compared to their actual current value and their perceived value and place in our strategic plans. For example, and without limitation, during the twelve months ended March 31, 2019, we received new product approvals that would have resulted in us owning a number of ANDAs that would have required us to self identify as a large size ANDA holder, on the measurement date, as per the FDA’s Generic Drug User Fee Amendment (“GDUFA”) program fee structure, as opposed to the medium size ANDA classification in effect prior to these new ANDA approvals. Based on the GDUFA program fees in effect for the period October 1, 2018 through September 30, 2019, the annual fee for large sized ANDA holders was approximately \$1.1 million greater than the fee for medium sized ANDA holders. After conducting a study of ANDAs held, we identified three ANDAs relating to Hydroxyzine Tablets and three ANDAs relating to Phentermine Capsules for sale or if we were not able to sell them, withdrawal, which, after such disposal, qualified us to once again self identify as a medium sized ANDA holder on the measurement date, thereby qualifying for an annual fee that was \$1.1m lower, based on the latest published fee schedule.

Although our expectations are to engage only in the sale or withdrawal of ANDAs if they advance or otherwise support our overall strategy, any such ANDA sale by definition reduces the size and scope of our business, with a direct correlation to opportunities with respect to certain markets, products or therapeutic categories, resulting in the potential for any such ANDA sale or withdrawal having a material adverse effect on our business, results of operations, financial condition, cash flow and ability to operate in the future.

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 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 FDCA 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 and ability to operate in the future.

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

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

Many of our products contain controlled substances. The stringent DEA regulations on our use of controlled substances include restrictions on their use in research, manufacture, distribution, and storage. A breach of these regulations could result in imposition of civil penalties, refusal to renew or action to revoke necessary registrations, or other restrictions on operations involving controlled substances. In addition, failure to comply with applicable legal requirements subjects the manufacturing facilities of our subsidiaries and manufacturing partners to possible legal or regulatory action, including shutdown. Any such shutdown may adversely affect their ability to supply us with product and thus, our ability to market affected products. This could have a negative impact on our business, results of operations, financial condition, cash flows and competitive position. See also the risk described under the caption *“The DEA limits the availability of the active ingredients used in many of our current products and products in development, as well as the production of these products, and, as a result, our procurement and production quotas may not be sufficient to meet commercial demand or complete clinical trials.”* In addition, we are subject to the Federal Drug Supply Chain Security Act (DSCSA). The U.S. government has enacted DSCSA which requires development 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 repackages of certain prescription drugs are required to provide and capture certain product tracing information under the Drug Quality and Security Act (*“DQSA”*). Title II of the DQSA, referred to as the Drug Supply Chain Security Act, requires companies in certain prescription drugs’ chain of distribution to build electronic, interoperable systems to identify and trace the products as they are distributed in the United States. Compliance with the DQSA or any future federal or state electronic pedigree requirements may increase the Company’s operational expenses and impose significant administrative burdens.

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

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

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

If pharmaceutical companies are successful in limiting the use of generics through their legislative, regulatory and other efforts, our sales of generic products may suffer.

Many pharmaceutical companies increasingly have used state and federal legislative and regulatory means to delay generic competition. These efforts have included:

- Pursuing new patents for existing products which may be granted just before the expiration of earlier patents, which could extend patent protection for additional years;
- Using the Citizen Petition process (for example, under 21 C.F.R. s. 10.30) to request amendments to FDA standards;
- Attempting to use the legislative and regulatory process to have drugs reclassified or rescheduled or to set definitions of abuse-deterrent formulations to protect patents and profits; and
- Engaging in state-by-state initiatives to enact legislation that restricts the substitution of some generic drugs.

If pharmaceutical companies or other third parties are successful in limiting the use of generic products through these or other means, our sales of generic products and our growth prospects may decline. A material decline in generic product sales will have a material adverse effect on our results of operations, financial condition, cash flows and our ability to operate.

The availability of third party reimbursement for our products is uncertain, and thus we may find it difficult to maintain current price levels. Additionally, the market may not accept those products for which third party reimbursement is not adequately provided.

Our ability to commercialize and generate revenues and profit splits relating to the sale of our products depends, in part, on the extent to which reimbursement for the costs of these products is available from government healthcare programs, such as Medicaid and Medicare, private health insurers and others. We cannot be certain that, over time, third party reimbursements for our products will be adequate for us to maintain price levels sufficient for realization of an appropriate return on our investment. Government payers, private insurers and other third party payers are increasingly attempting to contain healthcare costs by: (i) limiting both coverage and the level of reimbursement (including adjusting co-pays) for drugs, (ii) refusing, in some cases, to provide any coverage for off-label uses for drugs and (iii) requiring or encouraging, through more favorable reimbursement levels or otherwise, the substitution of generic alternatives to branded drugs. The Trump Administration also has been targeting drug prices in ways that could affect reimbursement for our products. For example, beginning in January 2019, Medicare Advantage Plans will be permitted to apply "step therapy" to products covered under Part B, which could impact our ability to negotiate for favorable product access in this sector. Additionally, in October 2018, President Trump announced a new initiative to contain drug costs by establishing an "international pricing index" that would be used as a benchmark in deciding how much to pay for Medicare Part B drugs. The Centers for Medicare and Medicaid Services (CMS) issued an Advance Notice of Proposed Rulemaking for the Medicare Program that would reduce Part drug spending and reimbursement in part based on the prices that manufacturers charge to customers in foreign countries (also referred to as reference pricing). This proposal targets physician-administered drugs, and it is therefore possible that any final rule could adversely affect reimbursement for certain products that we sell, and we cannot anticipate the adverse impact of this or similar developments on our business. Additionally, the new Congress is considering multiple proposals impacting healthcare. There can be no assurance as to which proposals, if any, will be adopted, the final terms of any such proposals and the ultimate impact that such proposals would have on our business, but there can be no assurances given that any such impact will not be materially detrimental to our business, results of operations, financial condition, cash flows and ability to operate in the future.

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 ten patents and we have three 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.

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. While this proposed legislation has not been enacted into law to date, our revenue and future profitability could be negatively affected by the passage of this law or similar federal or state legislation. Furthermore, pressure from social activist groups and future government regulations may also put downward pressure on the price of drugs, which could result in downward pressure on the prices of our products in the future.

New tariffs and evolving trade policy between the United States and other countries, including China and Mexico, may have an adverse effect on our sourcing of critical raw materials from suppliers located outside of the United States and corresponding adverse effects on our business and results of operations.

Some of our suppliers, including those of critical active pharmaceutical ingredients are located outside of the United States. There is currently significant uncertainty about the future relationship between the U.S. and various other countries, including China and Mexico, with respect to trade policies, treaties, government regulations and tariffs. The Trump Administration has called for substantial changes to U.S. foreign trade policy, including the possibility of imposing greater restrictions on international trade and significant increases in tariffs on goods imported into the U.S. In September 2018, the U.S. Trade Representative (USTR) enacted a tariff on the import of certain Chinese products with a combined import value of approximately \$200 billion, including non U.S. sourced APIs and starting materials used in our products. The tariff became effective on September 24, 2018, with an initial rate of 10%, and the Trump Administration has expressed a willingness to potentially increase tariffs to 25%. These tariffs could potentially disrupt our existing supply chains and impose additional costs on our business, including, without limitation, costs with respect to raw materials upon which our business depends. Furthermore, if tariffs, trade restrictions or trade barriers are placed on products such as ours by foreign governments, especially China, it could cause us to raise prices for our products, which may result in the loss of customers with a corresponding detrimental impact on our business, financial condition, results of operations, cash flow and ability to operate. If we are unable to pass along increased costs to our customers, our margins could be adversely affected, with a corresponding detrimental impact on our business, financial condition, results of operations, cash flow and ability to operate. Additionally, it is possible further tariffs may be imposed that could affect imports of active pharmaceutical ingredients and excipients used in our products, or our business may be adversely impacted by retaliatory trade measures taken by China or other countries, including restricted access to such raw materials used in our products, causing us to raise prices or make changes to our products, which could require significant resources and time for regulatory compliance. This would have a corresponding detrimental impact on our business, financial condition, results of operations, cash flow and ability to operate. Furthermore, the continued threats of tariffs, trade restrictions and trade barriers could have a generally disruptive impact on the global economy and, therefore, negatively impact our sales profit margins, profit splits, raw material costs and ability to source raw materials. Given the unpredictable regulatory environment in China and the U.S. and uncertainty regarding how the U.S. or foreign governments will act with respect to tariffs, international trade agreements and policies, further governmental action related to tariffs, additional taxes, regulatory changes or other retaliatory trade measures in the future could occur with a corresponding detrimental impact on our business, financial condition, results of operations, cash flow and ability to operate.

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 2011.

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.

In March 2011, the FDA issued a directive removing from the market approximately 500 cough/cold and allergy products, including our Lodrane® extended release product line. At that time, the Lodrane® extended release products constituted approximately 97% of our revenues.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Intangible assets represent a significant portion of our assets. As of March 31, 2019, intangible assets were approximately \$6.6 million, or approximately 27% 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 harm. The FDA and/or the DEA may impose new regulations concerning the manufacture, storage, transportation, distribution, and sale of prescription narcotics. Such regulations may include new labeling requirements, the development and implementation of a formal REMS, restrictions on prescription and sale of such products and mandatory reformulation in order to make abuse of such products more difficult. In 2007, Congress passed legislation authorizing the FDA to require companies to undertake post-approval studies in order to assess known or signaled potential serious safety risks and to make any labeling changes necessary to address safety risks. Congress also empowered the FDA to require companies to formulate REMS to confirm a drug's benefits exceed its risks. In 2011, the FDA issued letters to manufacturers of long-acting and extended-release opioids requiring them to develop and submit to the FDA a post-market REMS plan to require that training is provided to prescribers of these products and that information is provided to prescribers that they can use in counseling patients on the risks and benefits of opioid drug use. Elite does not currently own a product that requires a REMS plan, but some of the products in our pipeline may require a REMS plan. The federal government has also released a comprehensive action plan to reduce prescription drug abuse, which may include proposed legislation to amend existing controlled substances laws to require healthcare practitioners who request DEA registration to prescribe controlled substances to receive training on opioid prescribing practices as a condition of registration. In addition, state health departments and boards of pharmacy have authority to regulate distribution and may modify their regulations with respect to prescription narcotics in an attempt to curb abuse.

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

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

Included in our commercial products and development pipeline are medications containing opioids. Certain governmental and regulatory agencies, as well as state and local jurisdictions, are focused on the abuse of opioid medications in the United States. State and local governmental agencies may investigate us as a manufacturer and/or distributor of medicines containing opioids or in conjunction with their investigation of other pharmaceutical wholesale distributors, and others in the supply chain that have a direct or indirect connection to our operations in relation to the distribution of opioid medications. In addition, multiple lawsuits have been filed against other pharmaceutical manufacturers and distributors alleging, among other claims, that they failed to provide effective controls and procedures to guard against the diversion of controlled substances, acted negligently by distributing controlled substances to pharmacies that serve individuals who abuse controlled substances, and failed to report suspicious orders of controlled substances in accordance with regulations. Additional governmental entities have indicated an intent to sue these other manufacturers and distributors. While no such actions have been taken against us, the immediate effect on the Company has been an inability to commercialize and market two opioid products approved during the twelve months ended March 31, 2019 and a cessation of orders for another opioid that had been marketed by one of our marketing partners. Further, defense against any such opioid related lawsuits could be prohibitive with regards to cost resulting in an adverse material effect on our business, financial condition, results of operations, cash flows and stock price. Similar allegations made against us, even without litigation, could also negatively affect our business in various ways, including through increased costs and harm to our reputation. In addition, an adverse resolution of any lawsuit or investigation could also have a material adverse effect on our business, results of operations, cash flows and stock price.

Our business and financial condition may be adversely affected by legislation or regulatory reform of the healthcare system in the United States.

In April 2018, New York enacted a statute called the Opioid Stewardship Act (the Stewardship Act), which, among other things, provided for certain sellers and distributors of certain opioids in the state of New York (the Contributing Parties) to make payments to a newly created Opioid Stewardship Fund (the Fund). By its terms, the Stewardship Act required Contributing Parties to pay a total of up to \$100 million annually into the Fund, with each Contributing Party's share based on the total amount of morphine milligram equivalents of certain opioids sold or distributed by the Contributing Party in the state of New York during the preceding calendar year, subject to potential adjustments by the New York State Department of Health. Failure of a Contributing Party to make required reports or pay its ratable share, or a Contributing Party passing on the cost of its ratable share to a purchaser, could subject the Contributing Party to penalties. In December 2018, the U.S. District Court for the Southern District of New York held the Stewardship Act unconstitutional. This ruling is on appeal. If the decision is reversed, we may be deemed to be a Contributing Party under the Stewardship Act and even if we are not considered to be a Contributing Party, or such a determination is never made, other entities may attempt to seek reimbursement from Endo for payments made related to products manufactured by Endo and distributed in New York. Furthermore, the application of the Stewardship Act may require additional regulatory guidance, which could be substantially delayed, increasing the uncertainty as to the ultimate effect of the Stewardship Act on us. If we are ultimately deemed to be a Contributing Party under the Stewardship Act, or similar legislation that could be enacted by New York or other jurisdictions, compliance with those laws could have an adverse effect on our business, results of operations, financial condition and cash flows. Additionally, in October 2018, the U.S. Congress enacted the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (H.R. 6). Intended to achieve sweeping reform to combat the opioid epidemic, H.R. 6, among other provisions, amends related laws administered by the FDA, DEA and CMS. Among other things, the law: amends requirements related to the FDA's authority to include packaging requirements in REMS requirements; increases civil and criminal penalties for drug manufacturers and distributors for failing to maintain effective controls against diversion of opioids or for failing to report suspicious opioid orders; requires the DEA to estimate the amount of opioid diversion when establishing manufacturing and procurement quotas; implements expanded anti-kickback and financial disclosure provisions; and authorizes the Department of Health and Human Services to implement a demonstration program which would award grants to hospitals and emergency departments to develop, implement, enhance or study alternative pain management protocols and treatments that limit the use and prescription of opioids in emergency departments. While the effect of this legislation is still uncertain, it is likely that our products will be affected by enforcement of the legislation, including through related policies and implementing regulations. There can be no assurances that the effects of this legislation will not be determinant to our business, results of operations, financial condition, cash flow or ability to operate.

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

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

Please also see the above risk factor titled “The availability of third party reimbursement for our products is uncertain, and thus we may find it difficult to maintain current price levels. Additionally, the market may not accept those products for which third party reimbursement is not adequately provided”.

Legislative or regulatory programs that may influence prices of prescription drugs or decrease the degree to which individuals are covered by healthcare insurance 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.

Furthermore, employers may seek to reduce costs by reducing or eliminating employer group healthcare plans or transferring a greater portion of healthcare costs to their employees. Job losses or other economic hardships may also result in reduced levels of coverage for some individuals, potentially resulting in lower levels of healthcare coverage for themselves or their families. Further, in addition to the fact that the Tax Cuts and Jobs Act of 2017 (“TCJA”) eliminated the Patient Protection and Affordable Care Act (“PPACA”) requirement that individuals maintain insurance or face a penalty, additional steps by the Trump Administration or other parties to limit or end cost-sharing subsidies to lower income Americans may increase instability in the insurance marketplace and the number of uninsured Americans. These economic conditions may affect patients’ ability to afford healthcare as a result of increased co-pay or deductible obligations, greater cost sensitivity to existing co-pay or deductible obligations and lost healthcare insurance coverage or for other reasons. We believe such conditions could lead to changes in patient behavior and spending patterns that negatively affect usage of certain of our products, including some patients delaying treatment, rationing prescription medications, leaving prescriptions unfilled, reducing the frequency of visits to healthcare facilities, utilizing alternative therapies or foregoing healthcare insurance coverage. Such changes may result in reduced demand for our products, with no assurances given that such would result in an impact which is not detrimental to our business, results of operations, financial condition, cash flows or ability to operate.

In December 2018, the U.S. District Court for the Northern District of Texas held in *Texas v. Azar* that, because the provisions of the PPACA requiring certain individuals to either obtain health insurance or pay a shared responsibility payment are no longer permissible under the U.S. Congress’ taxing power, the entire PPACA is no longer constitutional. While this decision is appealable to the U.S. Court of Appeals, changes in law resulting from this ongoing lawsuit or other court challenges to the PPACA could materially and adversely affect the sales of our products, our business, results of operations, financial position, cash flows and ability to operate.

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.

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

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

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

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

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

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

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

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

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

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

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

Our business is dependent on market perceptions of us and the safety and efficacy of 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 of 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 *GDUFA* 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 affect prospective future sales made directly by Company.

Under these arrangements, from time to time, customers are given credits on our generic products that are held by them in inventory after there is a decrease in the market prices of the same generic products due to competitive pricing. Therefore, if new competitors enter the marketplace and significantly lower the prices of any of their competing products, the price of our products would also likely be reduced. As a result, we, or our 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 issue cited in the CRL, with such path forward including modification of the SequestOx formulation, and the successful completion of in vitro and in vivo studies. 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. The Company has currently paused further development of SequestOx due to the prohibitive cost of such and attendant risks related thereto.

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

On August 26, 2016, Elite received a Warning Letter from the FDA regarding Postmarketing Adverse Drug Experience (PADE) reporting. The Warning Letter related to certain observations that the FDA believed were inadequately addressed by the Company's response to a Form 483 issued by the FDA from a recent inspection at its facility. The Warning Letter cited that Elite's Standard Operating Procedures (SOPs) did not adequately address how 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 did not have adequate SOPs for ADEs, and failed to investigate, evaluate, and timely report ADEs. Elite successfully addressed the deficiencies cited in the letter and, on December 15, 2017, the FDA issued a closeout letter, removing any restrictions placed on us by the warning letter.

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

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

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

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

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

Impact of New Tax Legislation

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

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

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

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

Risk Related to Our Common Stock

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

The market price for the publicly traded stock of pharmaceutical companies is generally characterized by high volatility. There has been significant volatility in the market prices for our Common Stock. For the twelve months ended March 31, 2019, the closing sale price on the OTC Bulletin Board (“OTC-BB”) of our Common Stock fluctuated from a high of \$0.1167 per share to a low of \$0.0735 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 March 31, 2019, there were outstanding shares of preferred stock convertible into approximately 158 million shares of Common Stock and warrants to purchase an aggregate of approximately 79 million shares of Common Stock at an exercise price of \$0.1521 per share, vested options to purchase an aggregate of approximately 5.6 million shares at a weighted average exercise price of \$0.14. 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, 2/3 of 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 of 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 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 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.

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 (the “Exchange Act”). 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 foregone demand for securities that are traded through the OTCBB may be decreased or eliminated.

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

The Company issued 24,034,444 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, two 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 four 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. Please see the risk factor “If we are unable to increase our authorized shares of common stock, our ability to raise additional funds most likely will be materially adversely affected. Our inability to increase our authorized shares also will result in a requirement to pay significant annual dividends pursuant to our outstanding shares of Series J Preferred Stock”.

The requirements of the Sarbanes-Oxley Act of 2002 and other U.S. securities laws impose substantial costs, and may drain our resources and distract our management

We are subject to certain of the requirements of the Sarbanes-Oxley Act of 2002, as well as the reporting requirements under the Exchange Act. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting. In prior years, we have incurred significant costs and expended resources in creating, implementing and maintaining such effective disclosure controls and procedures and internal controls. During the most current fiscal year reporting period, however, we identified material weaknesses in internal controls. As a company with limited resources and staff, it is challenging to maintain effective controls, especially in regards to achieving adequate segregation of duties. Control weaknesses, such as those identified, can require significant financial and other resources to remediate and the existence of unremediated control weaknesses raise the risk of future material errors in the Company's financial statements. In addition, ongoing weaknesses can subject the Company to SEC enforcement action, which might include monetary fines or other equitable remedies that could have a material adverse effect on our business, operations, financial condition, results of operations and cash flows. Please see Item 9A "Controls And Procedures" in Part II.

We have no plans to pay regular dividends on our ordinary shares or to conduct ordinary share repurchases.

We do not intend to pay any cash dividends either currently or in the foreseeable future on our ordinary shares. Additionally, we do not intend to conduct ordinary share repurchases either currently or in the foreseeable future.

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. While manufacturing, packaging, warehousing and regulatory activities are currently conducted at this location, additional renovations and construction continue to occur as required by operations.

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

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

ITEM 3 LEGAL PROCEEDINGS

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

ITEM 4 MINE SAFETY DISCLOSURES

Not Applicable.

PART II

ITEM 5 MARKET FOR COMPANY'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER 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 period 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, 2019		
March 31, 2019	\$ 0.11	\$ 0.07
December 31, 2018	\$ 0.11	\$ 0.07
September 30, 2018	\$ 0.13	\$ 0.08
June 30, 2018	\$ 0.10	\$ 0.08
Fiscal Year Ending March 31, 2018		
March 31, 2018	\$ 0.14	\$ 0.10
December 31, 2017	\$ 0.10	\$ 0.08
September 30, 2017	\$ 0.19	\$ 0.09
June 30, 2017	\$ 0.24	\$ 0.14

As of June 10, 2019, the last reported sale price of our Common Stock, as reported by the OTCBB, was \$0.767.

Holders

As of June 7, 2019, there were, respectively, approximately 122 and 1 holders of record of our Common Stock and Series J Preferred Stock.

Dividends

Pursuant to our Series J Preferred Stock, if our shareholders do not approve the proposal to increase the number of authorized shares of Common Stock at its next meeting, Nasrat Hakim, the holder of the Series J Preferred Stock, is entitled to an annual dividend equal to twenty percent of the stated value (\$1,000 per share) of Series J Preferred Stock commencing on April 28, 2021.

We have never paid cash dividends on our Common Stock. Unless required to pay dividends on our Series J Preferred Stock, we currently anticipate that we will retain all available funds for use in the operation and expansion of our business.

Recent Sales of Unregistered Securities

None.

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, 2019:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average 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)) (a)
Equity compensation plans approved by security holders ⁽¹⁾	—	—	3,000,000
Equity compensation plans not approved by security holders	—	—	2,336,420 ⁽²⁾
Total	—	—	5,336,420

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

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

2014 Equity Incentive Plan

Our 2014 Equity Incentive Plan (the "2014 Plan") was adopted by the Board on March 17, 2014, to attract, motivate and retain officers, employees, consultants, and directors by issuing common stock-based incentives to directors, officers, employees, and consultants who are selected for participation. By relating incentive compensation to increases in shareholder value, it is hoped that these individuals will both continue in the long-term service of the Company and be motivated to experience a heightened interest and participate in the future success of Company operations. An aggregate of 3,000,000 shares of Common Stock are reserved for grant and issuance pursuant to the 2014 Plan. The 2014 Plan is administered and interpreted by our Compensation 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 person whose present and potential contributions are important to the success of Elite and its subsidiaries, by offering them an opportunity to participate in our future performance through awards of Options, the right to purchase Common Stock and Stock Bonuses. An aggregate of 8,000,000 shares of Common Stock 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 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

Not applicable.

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.

The independent auditor’s reports on our financial statements for the years ended March 31, 2019, and 2018, includes a “going concern” explanatory paragraph that describes substantial doubt about our ability to continue as a going concern. Management’s plans in regard to the factors prompting the explanatory paragraph are discussed below and also in Note 1. Summary Of Significant Accounting Policies-Going Concern, to the consolidated financial statements filed herein. In addition, our independent auditors report on Internal Control over Financial Reporting contains an adverse opinion in its report on the effectiveness of our internal control over financial reporting as of March 31, 2019. Please see Item 9A “Controls And Procedures” in Part II and the related risk factors in *Item 1A-“Risk Factors”*.

While our financial statements are presented on the basis that we are a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business over a reasonable length of time, our auditors have raised a substantial doubt about our ability to continue as a going concern.

Results of Operations:

Years Ended March 31, 2019 and 2018

Revenue, Cost of revenue and Gross profit:

	Years Ended March 31,		Change	
	2019	2018	Dollars	Percentage
Manufacturing fees	\$ 5,387,696	\$ 5,199,006	\$ 188,690	4%
Licensing fees	2,180,812	2,259,705	(78,893)	-3%
Total revenue	7,568,508	7,458,711	109,797	1%
Cost of revenue	4,700,978	3,511,123	1,189,855	34%
Gross profit	\$ 2,867,530	\$ 3,947,588	\$ (1,080,058)	-27%
Gross profit - percentage	38%	53%		

Total revenues for the year ended March 31, 2019 increased by \$0.1 million or 1%, to \$7.6 million, as compared to \$7.5 million, for the corresponding period of the prior year.

Manufacturing fees increase by \$0.2 million, or 4%, due to the launch of Methadone Tablets during the last part of the fiscal year ended March 31, 2019.

Licensing fees decreased by \$0.1 million, or 3% due to increased in-market sales costs, especially with regards to opioid taxes imposed in New York State, resulting in lower profit margins achieved by our marketing partners and corresponding decreases in profit splits being paid to the Company.

Costs of revenue consists of manufacturing and assembly costs. Our costs of revenue increased by \$1.2 million or 34%, to \$4.7 million as compared to \$3.5 million for the corresponding period of the prior year. The increase in costs of revenue is due to a product mix that included higher cost materials and increased overhead costs due in large part to increased costs of regulatory compliance.

Our gross profit margin was 38% during the year ended March 31, 2019 as compared to 53% during the year ended March 31, 2018. The decrease in profit margin percentage is due to difference in manufacturing product mix on a year on year basis, combined with increased overhead costs due in large part to increased costs of regulatory compliance.

Operating expenses:

	Years Ended March 31,		Change	
	2019	2018	Dollars	Percentage
Operating expenses:				
Research and development	\$ 7,599,820	\$ 9,621,365	\$ (2,021,545)	-21%
General and administrative	3,083,546	2,332,289	751,256	32%
Non-cash compensation	136,369	244,753	(108,384)	-44%
Depreciation and amortization	1,206,495	800,460	406,035	51%
Total operating expenses	\$ 12,026,230	\$ 12,998,867	\$ (972,638)	-7%

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, 2019 decreased by \$1.0 million, or 7%, to \$12.0 million, as compared to \$13.0 million for the prior year.

Research and development costs for the year ended March 31, 2019 were \$7.6 million, a decrease of \$2.0 million or 21% from \$9.6 million of such costs for the prior year. The decrease was due to the timing and composition of ongoing development of our generic product pipeline, combined with limited development activities relating to our abuse deterrent opioid resulting in a product development cost profile that is more heavily weighted towards lower cost activities.

General and administrative expenses for the year ended March 31, 2019 were \$3.1 million, an increase of \$0.8 million or 32% from \$2.3 million of such costs for the prior year. The increase was due to increased regulatory compliance and health and commercial insurance costs, combined with lower manufacturing facility utilization as compared to the prior year.

Non-cash compensation expense for the year ended March 31, 2019 was \$0.1 million, a decrease of \$0.1 million or 44% from \$0.2 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, 2019 was \$1.2 million, an increase of \$0.4 million, or 51% from \$0.8 million of such costs for the comparable period of the prior year. The increase was due to acquisitions of additional fixed assets as well as higher depreciation absorption rates as compared to the prior year.

As a result of the foregoing, our loss from operations for the year ended March 31, 2019 was \$9.2 million, compared to a loss from operations of \$9.1 million for the year ended March 31, 2018.

Other income (expense):

	Years Ended March, 31		Change	
	2019	2018	Dollars	Percentage
Other income (expense):				
Interest expense and amortization of debt issuance costs	\$ (369,174)	\$ (335,498)	\$ (33,676)	10%
Change in fair value of derivative instruments	180,042	4,650,266	(4,470,224)	-96%
Interest income	21,461	17,510	3,951	23%
(Loss) realized from transfer / discontinuance of intangible assets	(628,966)	-	(628,966)	n/a
Other income, net	\$ (796,637)	\$ 4,332,278	\$ (4,499,949)	-104%

Other income (expense), net for the year ended March 31, 2019 was net other expense of \$0.2 million, an increase in net other expenses of \$4.5 million from the net other income of \$4.3 million for the comparable period of the prior year. The increase in other expense was due to the change in the fair value of our outstanding warrants (derivative instruments) during the year ended March 31, 2019 totaling other income of \$0.2 million, as compared to \$4.7 million for the prior year, combined with a loss realized from the transfer/discontinuance of intangible assets of \$0.6 million being recorded in the year ended March 31, 2019, as compared to there being no corresponding loss realized in the comparable period of the prior year. Please note that the change in fair value of derivative instruments is determined in large part by the number of warrants outstanding and the change in the closing price of our Common Stock as of the end of the year, as compared to the closing price at the beginning of the year, with a strong inverse relationship between derivative revenues and increases in the closing price of our Common Stock.

As a result of the foregoing, our net loss from operations before the net benefit from sale of state net operating loss credits for the year ended March 31, 2019 was \$10.0 million, compared to net loss of \$4.7 million for the comparable period of the prior year.

Net benefit from sale of state net operating loss credits

During the year ended March 31, 2019, 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 net proceeds of \$0.7 million, compared to \$1.0 million for the prior year.

Change in value of convertible preferred share mezzanine equity:

There was no change in the value of our convertible preferred stock, which is included in the calculation of net income (loss) attributable to common shareholders for the years ended March 31, 2019 and March 31, 2018.

Liquidity and Capital Resources

Capital Resources

	March 31, 2019	March 31, 2018	Change
Current assets	\$ 8,856,542	\$ 13,702,401	\$ (4,845,859)
Current liabilities	6,906,132	5,114,704	1,791,430
Working capital	1,950,410	8,587,697	(6,637,289)

The Company's consolidated financial statements are prepared using generally accepted accounting principles in the United States applicable to a going concern, which contemplated the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred net losses and negative cash flows since inception. For the twelve months ended March 31, 2019 and 2018, the Company recorded a net loss from operations of approximately \$9.2 million and \$9.1 million, respectively. For the twelve months ended March 31, 2019 and 2018, the Company recorded net decreases in cash of approximately \$4.9 million and \$3.4 million, respectively. Furthermore, during the twelve months ended March 31, 2019, the Company realized a net decrease in working capital, defined as current assets less current liabilities, of approximately \$6.6 million. The Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and allow it to continue as a going concern.

In connection with the preparation of the financial statements for the year ended March 31, 2019, the Company conducted an evaluation as to whether there were conditions and events, considered in the aggregate, which raised substantial doubt as to its 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 appear to be evidence of substantial doubt of its ability to continue as a going concern. To continue as a going concern, the Company will need to do some or all of the following, without limitation: obtainment additional financing, increase sales of existing products, bring additional products in the pipe line to market and/or reduce expenses. the successful development of the Company's contemplated plan of operations, and its transition, ultimately, to the attainment of profitable operations are necessary for the Company to continue operations.

The accompanying financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should we be unable to continue as a going concern. In addition, the auditor's opinion on the financial statements for the year ended March 31, 2019 contains an explanatory paragraph with respect to there being substantial doubt as to the Company's ability to continue as a going concern.

Please also note that while the equity line available under the 2017 LPC Purchase Agreement had approximately \$36 million available for purchase of shares of Common Stock, the ability of the Company to access these funds is strongly and directly correlated to the trading price of Common Stock in the OTM Market. Accordingly, absent an increase in the such trading price of Common Stock, to a price that is significantly above the closing price of \$0.099 on March 31, 2019, the Company will be unable to realize a significant portion of the remaining equity line through sales of Common Stock to Lincoln Park pursuant to the 2017 LPC Purchase Agreement, resulting in substantial doubt as to the availability of adequate financial resources required for continued operations on a going concern basis.

Our working capital (total current assets less total current liabilities) decreased by \$6.6 million from \$8.6 million as of March 31, 2018 to \$2.0 million as of March 31, 2019, with such decrease being primarily related to the loss from operations of \$9.2 million, combined with a \$1.8 million increase in current liabilities.

The Company does not anticipate being profitable for the fiscal year ending March 31, 2020, due in large part to manufacture revenues and license fees not being at volumes and contributions sufficient to fund increased operating and product development costs. In order to finance these significant costs, the Company entered into the 2017 LPC Purchase Agreement. Due to the factors described above, the Company's ability to access funds available under the 2017 LPC Purchase Agreement may be limited, resulting in an adverse effect on the Company's liquidity and ability to operate. Please see below for further detail 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 del 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:

	Year ended March 31,	
	2019	2018
Net cash used in operating activities	\$ (6,792,760)	\$ (4,809,191)
Net cash provided by (used in) investing activities	330,870	(277,332)
Net cash provided by financing activities	1,566,855	1,671,067

Year Ended March 31, 2019

Net cash used in operating activities for the year ended March 31, 2019 was \$6.8 million, which included a net loss of \$9.3 million, and net use of cash resulting from changes in operating assets and liabilities of \$0.9 million. The changes in the balance of assets and liabilities include increases in account receivables of \$0.5 million and decrease in deferred revenues of \$1.0 million, which result in a net decrease in cash offset by decreases in inventory of \$0.4 million, which results in a net increase in operating cash flow. The net loss of \$9.3 million is offset by non cash expenses which include, without limitation, depreciation and amortization of \$1.3 million, non cash compensation of \$1.7 million and non cash loss realized on the sale and discontinuance of intangible assets of \$0.6 million.

Net cash provided by investing activities for the year ended March 31, 2019 was \$0.3 million, which primarily resulted from cash proceeds realized from the sale of intangible assets.

Net cash provided by financing activities for the year ended March 31, 2018 was \$1.6 million. This consisted of proceeds from the sale of common stock to Lincoln Park Capital of \$2.1 million, offset by \$0.5 million in loan principal payments, including repayment of an NJEDA Bonds of \$0.1 million.

Overall, as a result of the foregoing, the Company had a net decrease in cash of \$4.9 million during the year ended March 31, 2019.

Year Ended March 31, 2018

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

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

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

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

Lincoln Park Capital

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

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

In connection with the 2017 LPC Purchase Agreement, we issued to Lincoln Park 5,540,551 shares of Common Stock and we are required to issue up to 5,540,551 additional shares of Common Stock pro rata as we require Lincoln Park to purchase our shares under the Purchase Agreement over the term 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.

During the fiscal year ended March 31, 2019, the Company issued 285,831 shares of its common stock as additional commitment shares and sold 22,033,967 shares of its common stock for proceeds totaling \$2,063,541.

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, 2019.

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, in full, in July 2014.

Exchange Agreement

On April 28, 2017, we entered into an exchange agreement (the "*Exchange Agreement*") with Nasrat Hakim, our Chief Executive Officer, pursuant to which we issued to Mr. Hakim 24,034 shares of our newly designated Series J Convertible Preferred Stock and Warrants to purchase an aggregate of 79,008,661 shares of our Common Stock in exchange for 158,017,321 shares of our common stock owned by Mr. Hakim. Please see *Item 13 Certain Relationships And Related Transactions, And Director Independence; Certain Related Person Transactions; Transactions with Nasrat Hakim and Mikah Pharma LLC* in Part III.

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, 2019, 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.

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

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

Nature of goods and services

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

a) Manufacturing Fees

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

The Company recognizes revenue when the customer obtains control of the Company's product based on the contractual shipping terms of the contract. Revenue on product are presented gross because the Company is primarily responsible for fulfilling the promise to provide the product, is responsible to ensure that the product is produced in accordance with the related supply agreement and bears risk of loss while the inventory is in-transit to the commercial partner. Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products to a customer.

b) License Fees

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

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

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

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

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

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

Collaborative Arrangements

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

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

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

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

Cash

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

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 specific identification by lot number 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.

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.

Please also see the section titled “Recently Issued Accounting Pronouncements” regarding accounting standards relating to leases that will be implemented effective as of April 1, 2019.

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 jurisdictions until the applicable statutes of limitation expire. As of March 31, 2019, a summary of the tax years that remain subject to examination in our major tax jurisdictions are: United States – Federal, 2014 and forward, and State, 2010 and forward. The Company did not record unrecognized tax positions for the years ended March 31, 2019 and 2018.

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.

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.

The carrying amounts of the Company's financial assets and liabilities, such as cash, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued expenses, approximate their fair values because of the short maturity of these instruments. Based upon current borrowing rates with similar maturities the carrying value of long-term debt approximates fair value.

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

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

Treasury Stock

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

Recently Adopted Accounting Standards

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

In May 2014, the FASB issued ASU No. 2014-09 *Revenue from Contracts with Customers* (“ASU 2014-09”), which was subsequently amended and supplemented by several additional ASUs, including, without limitation:

- ASU No. 2015-14, “*Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*”, issued in August 2015, which deferred the effective date of ASU 2014-09 to annual and interim periods beginning after December 15, 2017.
- ASU 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*, issued in March 2016;
- ASU 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*, issued in April 2016
- 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*, issued in May 2016; and
- ASU No. 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers*, issued in December 2016.

These ASUs have generally been codified in *Accounting Standards Codification Topic 606, “Revenue from Contracts with Customers”*, and are collectively referred herein as “ASC 606”. ASC 606 supersedes the revenue recognition requirements in *Accounting Standards Codification Topic 605, “Revenue Recognition”* (“ASC 605”), and requires entities to recognize revenue when control of promised goods or services is transferred to customers at an amount that reflects the consideration to which entities expect to be entitled in exchange for those goods or services.

The Company adopted ASC 606 on April 1, 2018 for all open contracts and related amendments as of such date, using the modified retrospective method. Under the modified retrospective method, results beginning on April 1, 2018 are presented under ASC 606, while the comparative prior period(s) results continue to be presented under ASC 605, based on the accounting standards originally in effect for such periods. As a result of adopting ASC 606, the Company recorded no change in its accumulated deficit at April 1, 2018, representing the cumulative impact of adopting ASC 606.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230) Classification of Certain Cash Receipts and Cash Payments* (“ASU 2016-15”). ASU 2016-15 eliminates the diversity in practice related to the classification of certain cash receipts and payments for debt prepayment or extinguishment costs, the maturing of a zero-coupon bond, the settlement of contingent liabilities arising from a business combination, proceeds from insurance settlements, distributions from certain equity method investees and beneficial interests obtained in a financial asset securitization. ASU 2016-15 designates the appropriate cash flow classification, including requirements to allocate certain components of these cash receipts and payments among operating, investing and financing activities. The guidance is effective for fiscal years beginning after December 15, 2017. The Company’s adoption of this standard as of April 1, 2018 had no impact to the Company’s consolidated financial statements for the twelve months ended March 31, 2019.

In November 2016, the FASB issued ASU No. 2016-18 *Restricted Cash (ASC 230): Statement of Cash Flows* (“ASU No. 2016-18”) ASU No. 2016-18 requires that a statement of cash flows explain the change during the period in the total of cash and amounts generally described as restricted cash. Restricted cash will be included with cash and cash equivalents when reconciling the beginning of period and end of period balances on the statement of cash flows upon adoption of this standard. As a result of the adoption of the new guidance, the Company increased the beginning of year total amount shown on the consolidated statement of cash flows by \$391,566 and \$389,081 for the fiscal years ended March 31, 2019 and 2018, respectively. These amounts represent the balance of restricted cash included in the consolidated balance sheets as of March 31, 2019 and 2018, respectively. Restricted cash is related to debt service reserve in regard to the NJEDA bonds.

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 adopted ASU 2017-09 on April 1, 2018. The adoption of this standard did not materially impact the Company’s stock-based compensation expense as no awards were modified during the twelve months ended March 31, 2019.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02 *Leases (ASC 842)*, which is effective for public entities for annual reporting periods beginning after December 15, 2018. Under ASU 2016-02, lessees will be required to recognize the following for all leases (with the exception of short-term leases) at the commencement date: 1) a lease liability, which is a lessee’s obligation to make lease payments arising from a lease, measured on a discounted basis, and 2) a right-of-use asset, which is an asset that represents the lessee’s right to use, or control the use of, a specified asset for the lease term. In July 2018, the FASB issued ASU 2018-10, *Codification Improvements to ASC 842 (Leases)*, and ASU 2018-11, *Leases (ASC 842), Targeted Improvements*, which provide narrow amendments to clarify how to apply certain aspects of the new lease standard, (ii) entities with an additional transition method to adopt the new standard, and (ii) lessors with a practical expedient for separating components of a contract. All ASUs are effective for annual periods and interim periods within those annual periods beginning after December 15, 2018 and is effective for the Company for the year ending March 31, 2020. The Company has evaluated the effects of ASU 2016-02 and determined that a right-of-use asset, lease liability and increase in accumulated deficit due to cumulative effect of change in accounting principal valued at approximately \$1.1 million, \$1.5 million and \$0.3 million, respectively will be recorded as of April 1, 2019.

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 consolidated financial statements.

In July 2017, the FASB issued ASU 2017-11 *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features; II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. Part I of this update addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of the pricing of future equity offerings. Current accounting guidance creates cost and complexity for entities that issue financial instruments (such as warrants and convertible instruments) with down round features that require fair value measurement of the entire instrument or conversion option. Part II of this update addresses the difficulty of navigating Topic 480, *Distinguishing Liabilities from Equity*, because of the existence of extensive pending content in the FASB Accounting Standards Codification. This pending content is the result of the indefinite deferral of accounting requirements about mandatorily redeemable financial instruments of certain nonpublic entities and certain mandatorily redeemable noncontrolling interests. The amendments in Part II of this update do not have an accounting effect. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018. The Company is currently assessing the potential impact of adopting ASU 2017-11 on its consolidated financial statements and related disclosures.

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

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

In August 2018, the FASB issued ASU 2018-15, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40) Customer Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* (“ASU 2018-15”), to help entities evaluate the accounting for fees paid by a customer in a cloud computing arrangement (hosting arrangement) by providing guidance for determining when the arrangement includes a software license. The guidance provided generally means that an intangible asset is recognized for the software license and, to the extent that the payments attributable to the software license are made over time, a liability also is recognized. If a cloud computing arrangement does not include a software license, the entity should account for the arrangement as a service contract. This generally means that the fees associated with the hosting element (service) of the arrangement are expensed as incurred. ASU 2018-15 is effective for fiscal years beginning subsequent to December 15, 2019. The Company is currently assessing the potential impact of adopting ASU 2018-15 on its consolidated financial statements and related disclosures.

In March 2019, the FASB issued ASU 2019-1, *Leases (Topic 842) Codification Improvements* (“ASU 2019-1”), to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing essential information about leasing transactions. The amendments ASU 2019-1 include the following items:

- Determining the fair value of the underlying asset by lessors that are not manufacturers or dealers (Issue 1);
- Presentation on the statement of cash flows—sales-type and direct financing leases (Issue 2), and
- Transition disclosures related to Topic 250, Accounting Changes and Error Corrections (Issue 3).

The amendments in ASU 2019-1 amend Topic 842 and are effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The Company is evaluating the effect that this update will have on its consolidated financial statements and related disclosures.

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

ITEM 7A QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

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

ITEM 8 FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

None

ITEM 9A CONTROLS AND PROCEDURES

The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, have evaluated 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, 2019, based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control ("COSO"). Based on that evaluation, and as disclosed in *Management's Annual Report on Internal Control over Financial Reporting* below, the Company's Chief Executive Officer and the Company's Chief Financial Officer have concluded that the Company's disclosure controls and procedures were not effective as of March 31, 2019 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.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. As of March 31, 2019, we identified the following control deficiencies that we believe constituted individually, and in the aggregate, material weaknesses in the design and operation components of our internal controls within the COSO framework:

- We were unable to revise, formalize and implement revised controls, policies and procedure documentation to evidence a system of internal controls, including testing of such revised controls that is consistent with our current personnel and available resources.
- We failed to maintain effective control activities over our control environment, risk assessment, information technology and monitoring components.
- We had insufficient segregation of duties, oversight of work performed and lack of compensating controls in our finance and accounting functions due to limited personnel and resources. Management's conclusion regarding insufficient segregation of duties is founded on the loss, without replacement, of key personnel and resources that had previously achieved adequate segregation of duties, combined with excessive reliance on our Chief Financial Officer to assume most of those activities that were previously performed by personnel that left us without replacement.

Management's Annual Report on Internal Control over Financial Reporting

Our 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 Exchange Act. Our 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.

Our management assessed the effectiveness of our internal control over financial reporting as of March 31, 2019, with such assessment being pursuant to the criteria set forth by COSO in *Internal Control-Integrated Framework (2013)*. Based on our assessment, utilizing those criteria, we determined that, as of March 31, 2019, there were material weaknesses in both the design and operation of our internal control over financial reporting.

The deficiencies in our internal controls over financial reporting and disclosure controls and procedures are described above and our efforts to remediate these deficiencies are described below.

Our independent registered public accounting firm, in its report on the effectiveness of our internal control over financial reporting, contains an adverse opinion on the effectiveness of our internal control over financial reporting as of March 31, 2019. This report is included in this Annual Report on Form 10-K. Please see Item 1A-*Risk Factors; We have identified material weaknesses in our internal control over financial reporting which could, if not remediated, 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*".

Changes in internal control over financial reporting

Subsequent to the quarter ended December 31, 2018, due to loss of key personnel and constraints on resources, material weaknesses in internal control over financial reporting were identified, as further detailed above. The Company's remediation efforts are detailed below, with such activities expected to result in further changes in internal control over financial reporting as necessary to remediate the identified material weaknesses.

Remediation Efforts to Address Material Weaknesses

We intend to revise the existing control environment documentation, designing and implementing controls, policies and procedure documentation that is consistent with our current personnel, resources and capabilities. Please note that these material weaknesses cannot be considered remediated until the applicable remedial controls operate for a sufficient period of time, allowing management, through testing, to reach a conclusion on such controls design and operational efficacy. There is also a strong direct correlation between resources and our ability to remediate, in accordance with COSO criteria, the above referenced material weaknesses in internal controls. Accordingly, improvement in our financial position is a critical component of our ability to achieve effective disclosure controls and procedures.

ITEM 9B OTHER INFORMATION

Annual Shareholders' Meeting The Company will be holding an annual shareholders' meeting on or about September 25, 2019 (the "2019 Annual Meeting"). Shareholders may submit written proposals to the Company on matters appropriate for shareholder action at the 2019 Annual Meetings by following the rules of the SEC and the requirements of the Company's Amended and Restated Bylaws. The Company must receive proposals intended for inclusion in its proxy statement and proxy card for the 2019 Annual Meeting no later than June 25, 2019. Any such proposal when submitted must be in full compliance with applicable law, including Rule 14a-8 of the Exchange Act, and the Company's Amended and Restated Bylaws. Additionally, the Company's Amended and Restated By-Laws permit shareholders to propose business to be considered and to nominate Directors for election by the shareholders at future annual meetings. To propose business or to nominate a Director for the September 2019 Annual Meeting not for inclusion in the proxy statement and proxy card for that meeting, the Shareholder must deliver written notice to the Company on or before June 24, 2019 setting forth the information required to be included in such notice under the Company's Amended and Restated Bylaws. Any such proposal or nomination when submitted must be in full compliance with the Company's Amended and Restated Bylaws.

If a Shareholder gives notice of a proposal or a nomination after the applicable deadline specified above, the notice will not be considered timely, and the Shareholder will not be permitted to present the proposal or the nomination to the Shareholders for a vote at the meeting.

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	58	President, Chief Executive Officer and Director	August 2013	III
Barry Dash, Ph. D.	88	Director	April 2005	II
Jeffrey Whitnell	63	Director	October 2009	III
Eugene Pfeifer ⁽¹⁾	-	Director	April 2016	I
Davis Caskey	71	Director	April 2016	I
Carter J. Ward	55	Chief Financial Officer, Secretary and Treasurer	July 2009	
Douglas Plassche	56	Executive Vice President of Operations	August 2013	

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

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

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

Nasrat Hakim

Nasrat Hakim has served as a Director, President, and Chief Executive officer since August 2013. He has been a member of the Audit Committee member and chairman of the nominating Committee and member of the Compensation Committee since September 2016. Mr. Hakim has more than 30 year 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 Alharma 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 Alharma, 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, full 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 Chemists, 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 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 June 2010 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 served as a Director from April 2016 and a member of the Nominating Committee and Compensation Committee from September 2016, until his passing on June 10, 2018. Mr. Pfeifer brought with him more than 45 years of regulatory and trade experience, most recently having served as a law partner at King & Spalding in Washington DC from 1986 to 2009 and prior to that as a law partner at the Burditt, Bowles & Radius from 1980 to 1985. After retiring from legal practice in 2009, Mr. Pfeifer worked as a consultant to companies, including consultation for the Company, by providing his expertise regarding FDA and FTC issues. Among his many accomplishments, he was a major participant in the development of the Drug Price Competition and Patent Term Restoration Act of 1984 and provided strategic counseling to companies affected by that statute. In addition, he 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 Radius, 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 Chicago 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 was 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 was qualified to be a member of the Company’s Board of Directors.

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

Davis Caskey

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

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 supply chain, 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 December 31, 2018, all of our Officers and Directors had complied with all applicable Section 16(a) filing requirements on a timely basis with regard to transactions occurring in 2018.

Committees of the Board

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

Audit Committee

During Fiscal 2019, 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 American LLC Company Guide (although our securities are not listed on the NYSE American LLC or any other national exchange).

Nominating Committee

During Fiscal 2019, the members of the Nominating Committee were Nasrat Hakim (Chairman of the Nominating Committee), Dr. Barry Dash and Davis Caskey. 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 2019, the members of the Compensation Committee were Dr. Barry Dash (Chairman of the Compensation Committee), Jeffrey Whitnell, 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 executive compensation are determined by the Compensation Committee, which currently is comprised of four independent non-employee directors, and one director who is also the Company's Chief Scientific Officer. However, the Compensation Committee's decisions concerning the compensation of the Company's Chief Executive Officer are subject to ratification by the independent directors of the Board of Directors. From September 2016 to June 2018, the members of the Compensation Committee were Dr. Barry Dash (Chairman of the Compensation Committee), Jeffrey Whitnell, Eugene Pfeiffer, Davis Caskey and Nasrat Hakim. Mr. Pfeiffer passed away on June 10, 2018 and the Company has not yet nominated a replacement. The Committee operates pursuant to a charter. Under the Compensation Committee charter, the Compensation Committee has authority to retain compensation consultants, outside counsel, and other advisors that the committee deems appropriate, in its sole discretion, to assist it in discharging its duties, and to approve the terms of retention and fees to be paid to such consultants. The Compensation Committee did not engage any advisors.

Named Executive Officers

The named executive officers for the fiscal year ended March 31, 2019 were:

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

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

We also had one key employee during the fiscal year ended March 31, 2019 - George Kenneth Smith.

Our executive compensation program

Overview

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

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

Elements of our executive compensation program

Base Salary

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

Bonuses

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

Stock Options

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

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

Retirement and Deferred Compensation Benefits

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

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

Post-Termination/Change of Control Compensation

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

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

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

Perquisites

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

Agreements with Named Executive Officers

Nasrat Hakim

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

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

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

Carter J. Ward

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

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

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

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

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

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

Douglas Plassche

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

Mr. Plassche's employment is terminable by either party. If the Company terminates Mr. Plassche without cause, Mr. Plassche is entitled to 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.

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.

Hedging Policy

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

Options Exercised and Stock Vested

No options have been exercised by our Named Executive Officers during the 2019 Fiscal Year.

There was no vesting during Fiscal 2019 of options to purchase Common Stock that were issued to Named Executive Officers in prior periods.

Pension Benefits

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

Nonqualified Deferred Compensation

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

Potential Payments Upon Termination or Change of Control

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

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

Compensation of named executive officers:

Name and Principal Position	Fiscal Year	Salary ⁽¹⁾ (\$)	Bonus ⁽¹⁾ (\$)	Option Awards ⁽¹⁾ (\$)	All Other Compensation ⁽¹⁾ (\$)	Total (\$)
<u>Nasrat Hakim, President, Chief Executive Officer and Chairman of the Board of Directors</u>						
	2019(1)	500,000(2)	500,000(3)	—	48,000(4)	1,048,000
	2018(1)	500,000(2)	500,000(3)	—	18,000(4)	1,018,000
<u>Carter J. Ward, Chief Financial Officer</u>						
	2019(1)	192,816(5)	-	—	—	192,816
	2018(1)	192,816(5)	25,000(6)	—	—	217,816
<u>Douglas Plassche, Executive Vice President</u>						
	2019(1)	253,552(7)	75,000(8)	—	6,000(9)	259,552
	2018(1)	253,552(7)	75,000(8)	—	6,000(9)	334,552
<u>George Kenneth Smith, Vice President</u>						
	2018(1)	412,000(10)	—	—	—	412,000
	2018(1)	412,000(10)	—	—	—	412,000

- (1) Represents amounts paid or accrued for the fiscal years ended March 31, 2019 and 2018, respectively.
- (2) Represents total salaries paid or accrued to Mr. Hakim pursuant to the Hakim Employment Agreement, with such amounts to be paid via the issuance of Common Stock in lieu of cash.
No shares of Common Stock have been issued to Mr. Hakim in payment of salaries due for Fiscal 2019. A total of 5,473,559 shares of Common Stock are due and owing to Mr. Hakim in payment of salaries earned by Mr. Hakim during Fiscal 2019.
No Common Stock have been issued to Mr. Hakim in payment of salaries due for Fiscal 2018. A total of 4,329,135 shares of Common Stock are due and owing to Mr. Hakim in relation to salaries earned by Mr. Hakim during Fiscal 2018.
In aggregate, a total of \$1,125,000 is accrued, due and owing to Mr. Hakim for salaries earned during Fiscal 2019, Fiscal 2018 and the twelve months ended March 31, 2017, but not paid. This amount is to be paid via the issuance of 10,648,303 shares of Common Stock, with the date of such issuance of shares of Common Stock being undetermined.
- (3) Represents bonuses paid or accrued to Mr. Hakim pursuant to the Hakim Employment Agreement.
Bonus earned by Mr. Hakim during Fiscal 2019 was accrued and is owing to Mr. Hakim.
Bonus earned by Mr. Hakim during Fiscal 2018 was accrued and is owing to Mr. Hakim.
In aggregate, bonuses totaling \$1,125,000 earned by Mr. Hakim during Fiscal 2019, Fiscal 2018 and the twelve months ended March 31, 2017 are accrued and owing.
Pursuant to the Hakim Employment Agreement, these bonuses are to be paid in accordance with the Company's payroll practices.
- (4) Represents amounts paid for auto and housing allowances in Fiscal 2019 and amounts paid for auto allowances only in Fiscal 2018
- (5) Represents salaries earned by Mr. Ward pursuant to the Ward Employment Agreement.
Fiscal 2019 salaries consist of \$162,816 being paid in accordance with the Company's payroll practices and \$30,000 being accrued, due and owing to be paid via the issuance of 328,414 shares of Common Stock.
Fiscal 2018 salaries consist of \$162,816 being paid in accordance with the Company's payroll practices and \$30,000 being paid via the issuance of 191,360 shares of Common Stock in lieu of cash with an additional 68,389 shares of Common Stock being owed.
In aggregate, salaries totaling \$37,500 are accrued, due and owing to Mr. Ward for salaries earned and not paid during Fiscal 2019 and Fiscal 2018, with such accrued amount to be paid via the issuance of 396,808 shares of Common Stock, with the date of such issuance of shares of Common Stock being undetermined.
- (6) Discretionary cash bonuses awarded by the Chief Executive Officer.
Bonus awarded during Fiscal 2018 was accrued as of March 31, 2018 and paid in April 2018 in accordance with the Company's payroll practices.
- (7) Represents salaries earned by Mr. Plassche pursuant to the Plassche Employment Agreement.
Fiscal 2019 salaries consist of \$228,552 being paid in accordance with the Company's payroll practices and \$25,000 being accrued, due and owing and to be paid via the issuance of 276,678 shares of Common Stock.
Fiscal 2018 salaries consist of \$228,552 being paid in accordance with the Company's payroll practices and \$25,000 being paid via the issuance of 159,467 shares of Common Stock in lieu of cash, with an additional 56,991 shares of Common Stock being owed.
In aggregate, salaries totaling \$31,250 are accrued, due and owing to Mr. Plassche for salaries earned and not paid during Fiscal 2019 and Fiscal 2018, with such accrued amount to be paid via the issuance of 330,674 shares of Common Stock, with the date of such issuance of shares of Common Stock being undetermined.
- (8) Cash bonuses paid pursuant to the Plassche Employment Agreement
Bonus awarded during Fiscal 2018 was accrued as of March 31, 2018 and paid in April 2018 in accordance with the Company's payroll practices.
Bonus awarded during Fiscal 2019 was accrued as of March 31, 2019 and paid in May 2018 in accordance with the Company's payroll practices.
- (9) Represents amounts paid for auto allowances
- (10) Represents salaries earned by Mr. Smith pursuant to the Smith Employment Agreement.
Fiscal 2019 salaries consist of \$162,000 being paid in accordance with the Company's payroll practices and \$250,000 being accrued, due and owing and to be paid via the issuance of 2,736,780 shares of Common Stock.
Fiscal 2018 salaries consist of \$162,000 being paid in accordance with the Company's payroll practices and \$250,000 being paid via the issuance of 1,594,661 shares of Common Stock in lieu of cash with an additional 569,905 shares of Common stock being owed.
In aggregate, salaries totaling \$312,500 are accrued, due and owing to Mr. Smith for salaries earned and not paid during Fiscal 2019 and Fiscal 2018, with such accrued amount to be paid via the issuance of 3,306,685 shares of Common Stock, with the date of such issuance of shares of Common Stock being undetermined.

Outstanding Equity Awards at March 31, 2018

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

The following table sets forth information concerning director compensation for the year ended March 31, 2019:

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	10,000(2)	20,000(3)	-	-	-	-	30,000
Jeffrey Whitnell	10,000(2)	20,000(3)	-	-	-	-	30,000
Eugene Pfeifer ⁽⁴⁾	5,651(5)	-	-	-	-	-	5,651
Davis Caskey	10,000(2)	20,000(3)	-	-	-	-	30,000

- (1) Please refer to the section below titled “*Director Fee Compensation*” for details on the Company’s director fee compensation policy.
- (2) Amounts represent Director fees earned during the fiscal year ended March 31, 2019 which are to be paid in cash. These fees were accrued and unpaid as of March 31, 2019, with a payment date being undetermined.
- (3) Director fees earned during the fiscal year ended March 31, 2019 which are to be paid via the issuance of an aggregate of 656,826 shares of Common Stock, with Dr. Dash, Mr. Whitnell and Mr. Caskey each receiving 218,942 shares of Common Stock. These shares were not issued as of March 31, 2019, and the amount due was accrued. Payment of this amount due via share issuance will be made at an undetermined date.
- (4) Mr. Pfeifer passed away on June 10, 2018.
- (5) Represents director fees earned by Mr. Pfeifer from April 1, 2018 through June 10, 2018. After Mr. Pfeifer’s passing, the Board directed that all directors fees due and owing to Mr. Pfeifer be paid to his estate in cash.

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, 2019 and March 31, 2018 did not receive any options or equity compensation for serving as directors other than shares of Common Stock earned in lieu of cash in relation to Director fees due.

Other

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

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

The following table sets forth certain information, as of June 7, 2019 (except as otherwise indicated), regarding beneficial ownership of our Common Stock and our Series J Preferred Stock by (i) each person who is known by us to own beneficially more than 5% of each such class, (ii) each of our directors (iii) each of our executive officers and (iv) all our directors and executive officers as a group. As of June 7, 2019, we had 828.4 million shares of Common Stock outstanding (exclusive of 0.1 million treasury shares) and 24,034,444 shares of Series J Preferred Stock outstanding. On any matter presented to the holder 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, 2019. Except as otherwise indicated, the Shareholders listed in the table have sole voting and investment powers with respect to the shares indicated.

Name and Address Of Beneficial Owner of Common Stock	Amount and Nature of Beneficial Ownership		Percent (%) of Voting Securities Beneficially Owned (11)
	Common Stock	Series J Preferred Stock	
Nasrat Hakim, President, Chief Executive Officer and Chairman of the Board of Directors*	22,445,864(1)	24.0344(2)	18.0%
Barry Dash, Director*	1,680,550(3)		**0%
Jeffrey Whitnell, Director*	1,632,015(4)		**0%
Eugene Pfeifer, Director*	233,414(5)		**0%
Davis Caskey, Director*	494,431(6)		**0%
Carter J. Ward, Chief Financial Officer *	4,518,727(7)		**0%
Douglas Plassche, Executive Vice President *	3,818,270(8)		**0%
Ashok Nigalaye, Former Director	50,265,539(9)		5.1%
All Directors and Officers as a group	34,589,857(10)	24.0344(2)	19.22%

* 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 10,648,303 shares of Common Stock due and owing to Mr. Hakim as of March 31, 2019 (the latest practicable date) for compensation earned pursuant to Mr. Hakim's employment agreement with the Company. Excludes warrants to purchase 79,008,661 shares of Common Stock which are not currently exercisable.
- (2) Series J Preferred Stock has an aggregate of 158,017,321 voting rights.
- (3) Includes 1,416,011 shares of Common Stock held as per the most recent Form 4 filing and 264,539 shares of Common Stock due and owing to Dr. Dash as of March 31, 2019 (the latest practicable date) for Directors fees accrued as of such date.
- (4) Includes 1,367,476 shares of Common Stock held as per the most recent Form 4 filing and 264,539 shares of Common Stock due and owing to Mr. Whitnell as of March 31, 2018 (the latest practicable date) for Directors fees accrued as of such date.
- (5) Mr. Pfeifer passed away on June 10, 2018. Includes 233,414 shares still held in Mr. Pfeifer's account with the Company's transfer agent.
- (6) Includes 229,892 shares of Common Stock held as per the most recent Form 4 filing and 264,539 shares of Common Stock due and owing to Mr. Caskey as of March 31, 2019 (the latest practicable date) for Directors fees accrued as of such date.
- (7) Includes 3,771,919 shares of Common Stock held and 396,808 shares of Common Stock due and owing to Mr. Ward as of March 31, 2019 (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 487,596 shares of Common Stock held as per the most recent Form 4 filing, 330,674 shares of Common Stock due and owing to Mr. Plassche as of March 31, 2019 (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.
Dr. Nigalaye resigned on June 5, 2015. Address is c/o Granulation Technology Inc. 12 Industrial Road, Fairfield, NJ 07004. Includes 50,265,539 shares of Common Stock held with the Company's transfer agent in account(s) that is (are) beneficially owned by Dr. Nigalaye.
- (10) Relates only to current directors and officers. Includes 19,070,455 shares of Common Stock held, as per the applicable most recent Form 3 or Form 4 filings, 12,169,402 shares of Common Stock due and owing as of March 31, 2019 (the latest practicable date) for director's fees and salaries accrued as of such date, and vested options to purchase 3,350,000 shares of Common Stock. Excludes warrants to purchase 79,008,661 shares of Common Stock which are not currently exercisable and 24,0344 Series J Preferred Convertible Shares.
- (11) The denominator includes 158,017,321 votes attributable to the outstanding Series J Preferred Stock. Accordingly, the percentage of Common Stock beneficially owned by each Owner listed in the table other than Mr. Hakim is slightly greater than the percentage listed in this column.

ITEM 13 CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Certain Related Person Transactions

Transactions with Nasrat Hakim and Mikah Pharma LLC

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

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 “*Naltrexone Hydrochloride ANDA*”), that have to date been filed with the FDA seeking authorization and approval to manufacture, package, ship and sell the products described in the Naltrexone Hydrochloride ANDA within the United States and its territories (including Puerto Rico) for aggregate consideration of \$200,000. In lieu of cash, Mikah agreed to accept from Elite product development services to be performed by Elite and entered into a Development and License Agreement dated August 27, 2010 between the Company and Mikah (the “*Mikah Development Agreement*”). A current report on [form 8-K](#) was filed on September 1, 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.

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 share of its newly designated Series J Convertible Preferred Stock (“*Series J Preferred*”) and Warrants to purchase an aggregate of 79,008,661 shares of Common Stock (the “*Series J Warrants*”) and, along with the Series J Preferred issued to Mr. Hakim, the “*Securities*”) in exchange for 158,017,321 shares of our common stock owned by Mr. Hakim.

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

On December 3, 2018, Elite entered into a Development Agreement for products with Mikah Pharma. The agreement provides for the Company and Mikah to collaborate on the development and commercialization of generic products. Mikah will provide, at its sole cost and expense, including API costs and bioequivalence studies, an approvable generic bioequivalent formulation. The Company and Mikah will collaborate to transfer the formulation and methods to Elite’s facility and to file the product(s) with the FDA. Mikah shall pay Elite for services rendered on a cost-plus basis. Mikah shall own any ANDA produced by the collaboration. The Company and Mikah will negotiate in good faith a manufacturing and supply agreement to produce the products on a cost-plus basis. Either party may terminate the agreement with 30 days written notice. As of March 31st 2019, Mikah had prepaid for an API with the intent to develop a generic product, but had not yet received the API and no service work by the Company had been completed.

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 four 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 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, in full, of the shares of Series J Preferred in an amount equal to the dividend the holders would have been entitled to receive upon conversion, if 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. As discussed above, in the risk factor “If we are unable to increase our authorized shares of common stock, our ability to raise additional funds most likely will be materially adversely affected. Our inability to increase our authorized shares also will result in a requirement to pay significant annual dividends pursuant to our outstanding shares of Series J Preferred Stock” we plan on holding an annual meeting of shareholders on a date during the calendar year 2019 which has not yet been determined, at which time the Company will seek an increase in our authorized shares of Common Stock (the “Proposal”).

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

Series J Warrants

The Series J Warrants are exercisable for a period of 10 years from the date of issuance, commencing on the earlier of (i) the date that Shareholder Approval is obtained, and the requisite corporate action has been effected; or (ii) April 28, 2020. The initial exercise price is \$0.1521 per share and the Warrants can be exercised for cash or on a cashless basis. The exercise price is subject to adjustment for any issuances or deemed issuances of common stock or common stock equivalents at an effective price below the then exercise price. The Warrants provide for other standard adjustments upon the happening of certain customary events. The Warrants are not exercisable during any period when an Authorized Share Deficiency exists and will expire on the expiry date, without regards to the existence of an Authorized Shares Deficiency.

Trimipramine Acquisition

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Manufacturing and Licensing Agreement with Epic Pharma LLC

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

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

On October 2, 2013, Elite executed the Epic Pharma Manufacturing and License Agreement. Please see *Item I Business; Licensing, Manufacturing and Development Agreements; Manufacturing and License Agreement with Epic Pharma LLC* in Item I above. This agreement expired on October 2, 2018.

Director Independence

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

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

ITEM 14 PRINCIPAL ACCOUNTANT FEES AND SERVICES

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

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

	Fiscal 2019	Fiscal 2018
Audit Fees	\$ 122,000	\$ 128,800
Audit-Related Fees	1,850	1,850
Tax Fees	7,000	7,000

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 2019.

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
3.1(a)	<u>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.</u>
3.1(b)	<u>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.</u>
3.1(c)	<u>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.</u>
3.1(d)	<u>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.</u>
3.1(e)	<u>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.</u>
3.2(a)	<u>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.</u>
4.1	<u>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.</u>
4.2	<u>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.</u>
4.3	<u>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.</u>
4.4	<u>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.</u>
4.5	<u>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.</u>
10.1	<u>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.</u>

- 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 [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.](#)
- 10.10 [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.](#)
- 10.11 [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.](#)
- 10.12 [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.](#)
- 10.13 [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.](#)
- 10.14 [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.](#)
- 10.15 [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 \(Confidential Treatment granted with respect to portions of the Agreement\).](#)

- 10.16 [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 \(Confidential Treatment granted with respect to portions of the Agreement\).](#)
- 10.17 [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 \(Confidential Treatment granted with respect to portions of the Agreement\).](#)
- 10.18 [Letter Agreement between the Company and ThePharmaNetwork LLC, dated September 21, 2012 incorporated by reference to Exhibit 10.10 to the Quarterly Report on Form 10-Q filed with the SEC on November 14, 2012 \(Confidential Treatment granted with respect to portions of the Agreement\).](#)
- 10.19 [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.](#)
- 10.20 [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. \(Confidential Treatment granted with respect to portions of the Agreement\).](#)
- 10.21 [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.](#)
- 10.22 [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.](#)
- 10.23 [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.](#)
- 10.24 [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.](#)
- 10.25 [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.](#)
- 10.26 [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.](#)
- 10.27 [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.](#)

- 10.28 [January 28, 2015 First Amendment to the Loan Agreement between Nasrat Hakim and Elite Pharmaceuticals dated October 15, 2014, 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.](#)
- 10.29 [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.](#)
- 10.30 [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. \(Confidential Treatment granted with respect to portions of the Agreement\).](#)
- 10.31 [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.](#)
- 10.32 [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. \(Confidential Treatment granted with respect to portions of the Agreement\).](#)
- 10.33 [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.](#)
- 10.34 [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. \(Confidential Treatment granted with respect to portions of the Agreement\).](#)
- 10.35 [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.](#)
- 10.36 [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.](#)
- 10.37 [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.](#)
- 10.38 [May 2017 Trimipramine Acquisition Agreement from Mikah Pharma, incorporated by reference to Exhibit 10.50 to the Annual Report on Form 10-K, for the period ended March 31, 2017 and filed with the SEC on June 14, 2017.](#)
- 10.39 [May 2017 Secured Promissory Note from the Company to Mikah Pharma, incorporated by reference to Exhibit 10.51 to the Annual Report on Form 10-K, for the period ended March 31, 2017 and filed with the SEC on June 14, 2017.](#)
- 10.40 [May 2017 Security Agreement between the Company to Mikah Pharma, incorporated by reference to Exhibit 10.52 to the Annual Report on Form 10-K, for the period ended March 31, 2017 and filed with the SEC on June 14, 2017.](#)
- 10.41 [May 2017 Assignment of Supply and Distribution Agreement between Dr. Reddy's Laboratories and Mikah Pharma, incorporated by reference to Exhibit 10.53 to the Annual Report on Form 10-K, for the period ended March 31, 2017 and filed with the SEC on June 14, 2017.](#)

10.42	May 2017 Assignment of Manufacturing and Supply Agreement between Epic and Mikah Pharma, incorporated by reference to Exhibit 10.54 to the Annual Report on Form 10-K, for the period ended March 31, 2017 and filed with the SEC on June 14, 2017.
10.43	Supply and Distribution Agreement between Dr. Reddy's Laboratories and Mikah Pharma, incorporated by reference to Exhibit 10.55 to the Annual Report on Form 10-K, for the period ended March 31, 2017 and filed with the SEC on June 14, 2017. (Confidential Treatment granted with respect to portions of the Agreement).
10.44	Manufacturing and Supply Agreement between Epic and Mikah Pharma, incorporated by reference to Exhibit 10.56 to the Annual Report on Form 10-K, for the period ended March 31, 2017 and filed with the SEC on June 14, 2017. (Confidential Treatment granted with respect to portions of the Agreement).
10.45	Master Development And License Agreement For Products Between Elite Pharmaceuticals, Inc. And SunGen dated July 6, 2017, incorporated by reference to Exhibit 10.57 to the Quarterly Report on Form 10-Q for the period ended June 30, 2017 and filed with the SEC on August 9, 2017. (Confidential Treatment granted with respect to portions of the Agreement).
10.46	Second Amendment To Master Development And License Agreement For Products Between Elite Pharmaceuticals, Inc. and SunGen Pharma, LLC, incorporated by reference to Exhibit 10.58 to the Quarterly Report on Form 10-Q for the period ended June 30, 2017 and filed with the SEC on August 9, 2017. (Confidential Treatment granted with respect to portions of the Agreement).
10.47	First Amendment To Master Development And License Agreement For Products Between Elite Pharmaceuticals, Inc. and SunGen Pharma LLC, incorporated by reference to Exhibit 10.59 to the Quarterly Report on Form 10-Q for the period ended June 30, 2017 and filed with the SEC on August 9, 2017. (Confidential Treatment granted with respect to portions of the Agreement).
10.48	May 29, 2018 License, Manufacturing and Supply Agreement with Glenmark Pharmaceuticals Inc.USA, incorporated by reference to Exhibit 10.60 to the Annual Report on Form 10-K for the fiscal year ended March 31, 2018 and filed with the SEC on June 14, 2018. (Confidential treatment granted with respect to portions of the Agreement).
10.49	License, Supply And Distribution Agreement effective April 9, 2019 by and between Elite Pharmaceuticals, Inc., and Elite Laboratories, Inc. and Lannett Company, Inc., USA (portions of this Agreement have been redacted in compliance with Regulation S-K Item 601(b)(10))*
10.50	License, Supply And Distribution Agreement effective March 6, 2019 by and between Elite Pharmaceuticals, Inc., and Elite Laboratories, Inc. and Lannett Company, Inc., USA (portions of this Agreement have been redacted in compliance with Regulation S-K Item 601(b)(10))*
10.51	Development Agreement effective December 3, 2018 by and between Mikah Pharma LLC and Elite Laboratories, Inc. (portions of this Agreement have been redacted in compliance with Regulation S-K Item 601(b)(10))*
21	Subsidiaries of the Company***
23.1	Consent of Buchbinder Tunick & Company LLP, Independent Registered Public Accounting Firm**
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**
101.INS***	XBRL Instance Document
101.SCH***	XBRL Taxonomy Schema Document
101.CAL***	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF***	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB***	XBRL Taxonomy Extension Label Linkbase Document
101.PRE***	XBRL Taxonomy Extension Presentation Linkbase Document

* 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 21, 2019

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

Dated: June 21, 2019

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
/s/ Nasrat Hakim	Chief Executive Officer, President and Chairman of the Board of Directors	June 21, 2019
/s/ Carter J. Ward	Chief Financial Officer, Treasurer, Secretary	June 21, 2019
/s/ Barry Dash	Director	June 21, 2019
/s/ Jeffrey Whitnell	Director	June 21, 2019
/s/ Davis Caskey	Director	June 21, 2019

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED FINANCIAL STATEMENTS
FOR THE YEARS ENDED MARCH 31, 2019 AND 2018

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Elite Pharmaceuticals, Inc. and Subsidiary (the Company) as of March 31, 2019 and 2018 and the related statements of operations, stockholders' equity (deficit), and cash flows for each of the years in the two-year period ended March 31, 2019 and 2018, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of March 31, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the two-year period ended March 31, 2019, 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) (PCAOB), the Company internal control over financial reporting as of March 31, 2019, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated June 21, 2019, expressed an adverse opinion.

Substantial Doubt about the Company's Ability to Continue as a Going Concern

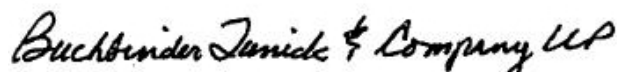
The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred recurring losses from operations, negative cash flows from operations and has an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Buchbinder Tunick & Company LLP



Little Falls, New Jersey 07424

June 21, 2019

We have served as the Company's auditor since 2010

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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Adverse Opinion on Internal Control over Financial Reporting

We have audited Elite Pharmaceuticals, Inc. and Subsidiary's (the Company's) internal control over financial reporting as of March 31, 2019, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, because of the effect of the material weaknesses described in the following paragraph on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of March, 31, 2019, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by COSO.

A material weakness is a control deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weaknesses have been identified and included in management's assessment.

- The Company did not revise, formalize and implement revised controls, policies and procedure documentation to evidence a system of internal controls, including testing of such revised controls that is consistent with their current personnel and available resources.
- The Company failed to maintain effective control activities over their control environment, risk assessment, information technology and monitoring components.
- The Company had insufficient segregation of duties, oversight of work performed and lack of compensating controls in their finance and accounting functions due to limited personnel and resources. Management's conclusion regarding insufficient segregation of duties is founded on the loss, without replacement, of key accounting personnel and resources that had previously achieved adequate segregation of duties, combined with excessive reliance on our Chief Financial Officer to assume most of those activities that were previously performed by personnel that left us without replacement.

These material weaknesses were considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2019 financial statements, and this report does not affect our report dated June 21, 2019, on those financial statements.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets and the related consolidated statements of operations, changes in stockholders' equity (deficit), and cash flows for each of the two years in the period ended March 31, 2019 of the Company, and our report dated June 21, 2019, expressed an unqualified opinion on those financial statements.

Basis for Opinion

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 Controls over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rule and regulations of the Securities and Exchange Commission and the PCAOB.

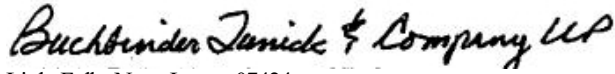
We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over 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.

Definition and Limitations of Internal Control over Financial Reporting

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

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

Buchbinder Tunick & Company LLP



Little Falls, New Jersey 07424

We have served as the Company's auditor since 2010

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

	<u>March 31,</u> <u>2019</u>	<u>March 31,</u> <u>2018</u>
ASSETS		
Current assets:		
Cash	\$ 2,277,643	\$ 7,179,237
Accounts Receivable, net of allowance for doubtful accounts of \$-0-, respectively	1,321,805	675,879
Inventory	4,515,723	4,898,001
Prepaid expenses and other current assets	741,371	949,284
Total current assets	<u>8,856,542</u>	<u>13,702,401</u>
Property and equipment, net of accumulated depreciation of \$9,651,718 and \$8,408,979, respectively	<u>8,443,849</u>	<u>8,993,708</u>
Intangible assets, net of accumulated amortization of \$-0-, respectively	<u>6,634,035</u>	<u>7,713,001</u>
Other assets:		
Restricted cash - debt service for NJEDA bonds	398,125	391,566
Security deposits	69,383	81,932
Total other assets	<u>467,508</u>	<u>473,498</u>
Total assets	<u>\$ 24,401,934</u>	<u>\$ 30,882,608</u>
LIABILITIES, MEZZANINE EQUITY AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts Payable	\$ 1,375,347	\$ 1,658,137
Accrued expenses	3,713,601	1,788,571
Deferred revenue, current portion	1,013,333	1,013,333
Bonds payable, current portion, net of bond issuance costs	80,822	75,822
Loans payable, current portion	573,029	578,841
Customer Deposits	150,000	-
Total current liabilities	<u>6,906,132</u>	<u>5,114,704</u>
Long-term liabilities:		
Deferred revenue, net of current portion	238,890	1,252,223
Bonds payable, net of current portion and bond issuance costs	1,427,315	1,508,134
Senior secured promissory note - related party	1,200,000	1,200,000
Loans payable, net current portion	699,269	623,020
Derivative financial instruments - warrants	2,487,830	2,667,871
Other long-term liabilities	46,402	41,144
Total long-term liabilities	<u>6,099,706</u>	<u>7,292,392</u>
Total liabilities	<u>13,005,838</u>	<u>12,407,096</u>

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

	March 31, 2019	March 31, 2018
Mezzanine equity		
Series J convertible preferred stock; par value \$0.01; 50 shares authorized, 24.0344 issued and outstanding as of March 31, 2019; 50 shares authorized, 24.0344 issued and outstanding as of March 31, 2018	13,903,960	13,903,960
Shareholders' equity:		
Common stock; par value \$0.001; 995,000,000 shares authorized; 824,946,559 shares issued and 824,846,559 outstanding as of March 31, 2019; 802,626,761 shares issued and 802,526,761 shares outstanding as of March 31, 2018	824,949	802,629
Additional paid-in capital	148,780,087	146,602,502
Treasury stock; 100,000 shares as of March 31, 2019 and March 31, 2018; at cost	(306,841)	(306,841)
Accumulated deficit	(151,806,059)	(142,526,738)
Total shareholders' equity	(2,507,864)	4,571,552
Total liabilities, mezzanine equity and shareholders' equity	\$ 24,401,934	\$ 30,882,608

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

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

	Years ended March 31,	
	2019	2018
Manufacturing Fees	\$ 5,387,696	\$ 5,199,006
Licensing Fees	2,180,812	2,259,705
Total revenue	<u>7,568,508</u>	<u>7,458,711</u>
Cost of revenue	4,700,978	3,511,123
Gross Profit	<u>2,867,530</u>	<u>3,947,588</u>
Operating expenses:		
Research and development	7,599,820	9,621,365
General and administrative	3,083,546	2,332,289
Non-cash compensation through issuance of stock options	136,369	244,753
Depreciation and amortization	1,206,495	800,460
Total operating expenses	<u>12,026,230</u>	<u>12,998,867</u>
Loss from operations	(9,158,700)	(9,051,279)
Other income (expense):		
Interest expense and amortization of debt issuance costs	(369,173)	(335,498)
Change in fair value of derivative instruments	180,041	4,650,266
Interest income	21,461	17,510
(Loss) realized from transfer/discontinuance of intangible assets	(628,966)	
Other (expense) income, net	<u>(796,637)</u>	<u>4,332,278</u>
(Loss) from operations before net benefit from sale of state net operating loss credits	(9,955,337)	(4,719,001)
Net benefit from sale of state net operating loss credits	676,016	1,045,829
Net (loss) attributable to common shareholders	<u>\$ (9,279,321)</u>	<u>\$ (3,673,172)</u>
Basic loss per share attributable to common shareholders	<u>\$ (0.01)</u>	<u>\$ (0.00)</u>
Diluted loss per share attributable to common shareholders	<u>\$ (0.01)</u>	<u>\$ (0.01)</u>
Basic weighted average Common Stock outstanding	<u>814,172,891</u>	<u>796,069,419</u>
Diluted weighted average Common Stock outstanding	<u>816,312,992</u>	<u>798,169,419</u>

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

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

	<u>Common Stock</u>		<u>Additional</u>	<u>Treasury Stock</u>		<u>Accumulated</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Paid-In</u>	<u>Shares</u>	<u>Amount</u>		
			<u>Capital</u>				<u>Equity</u>
							<u>Deficit)</u>
Balance at March 31, 2017	928,031,448	\$ 928,034	\$163,896,410	100,000	\$ (306,841)	\$ (138,853,566)	\$ 25,664,037
Net loss						(3,673,172)	(3,673,172)
Issuance of Common Stock pursuant to the exercise of cash warrants	5,658,295	5,658	347,985				353,643
Common Stock issued in payment of consulting expense	211,392	211	25,789				26,000
Common Stock issued in payment of employee salaries	2,460,941	2,461	302,539				305,000
Common Stock issued in payment of Directors' Fees	645,496	645	79,355				80,000
Common Stock issued as additional commitment shares pursuant to the LPC purchase agreement	277,009	277	34,927				35,204
Common Stock issued as commitment shares pursuant to the Lincoln Park purchase agreement	5,540,551	5,541	914,191				919,732
Costs associated with raising capital			(1,004,892)				(1,004,892)
Common Stock sold pursuant to the Lincoln Park purchase agreement	17,818,950	17,819	1,982,059				1,999,878
Non-cash compensation through the issuance of employee stock options			244,753				244,753
Retirement of Common Stock	(158,017,321)	(158,017)	(20,220,614)				(20,378,631)
Balance at March 31, 2018	802,626,761	\$ 802,629	\$146,602,502	100,000	\$ (306,841)	\$ (142,526,738)	\$ 4,571,552
Net loss						(9,279,321)	(9,279,321)
Common Stock sold pursuant to the Lincoln Park purchase agreement	22,033,967	22,034	2,041,502				2,063,536
Common Stock issued as commitment shares pursuant to the Lincoln Park purchase agreement	285,831	286	28,444				28,730
Costs associated with raising capital			(28,730)				(28,730)
Non-cash compensation through the issuance of employee stock options			136,369				136,369
Balance at March 31, 2019	824,946,559	\$ 824,949	\$148,780,087	100,000	\$ (306,841)	\$ (151,806,059)	\$ (2,507,864)

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

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

	Years ended March 31,	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (9,279,321)	\$ (3,673,172)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,256,917	996,406
Change in fair value of derivative financial instruments - warrants	(180,042)	(4,650,266)
Non-cash compensation accrued	1,581,250	925,000
Salaries & Directors fees satisfied by the issuance of Common Stock	-	385,000
Consulting expenses paid via the issuance of Common Stock	-	26,000
Non-cash compensation from the issuance of Common Stock and options	136,369	244,753
Non-cash rent expense and lease accretion	5,254	9,377
Non-cash Loss on sale and discontinuance of intangible assets	628,966	-
Change in operating assets and liabilities:		
Accounts receivable	(545,926)	258,180
Inventory	382,278	1,517,965
Prepaid expenses and other current assets	23,826	(512,368)
Accounts payable, accrued expenses and other current liabilities	61,002	677,268
Deferred revenue and customer deposits	(863,333)	(1,013,334)
Net cash used in operating activities	<u>(6,792,760)</u>	<u>(4,809,191)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(19,130)	(180,937)
Intellectual property costs	-	(93,910)
Proceeds from sale of intangible assets	350,000	-
Net cash from (used in) investing activities	<u>330,870</u>	<u>(274,847)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sale of Common Stock to Lincoln Park Capital	2,092,265	1,999,878
Proceeds from cash warrant and options exercises	-	353,643
Payment of bond principal	(90,000)	(85,001)
Other loan proceeds (payments), net	(406,681)	(547,496)
Costs associated with raising capital	(28,729)	(49,957)
Net cash provided by financing activities	<u>1,566,855</u>	<u>1,671,067</u>
Net change in cash and restricted cash	(4,895,035)	(3,412,971)
Cash and restricted cash, beginning of period	<u>7,570,803</u>	<u>10,983,774</u>
Cash and restricted cash, end of period	<u>\$ 2,675,768</u>	<u>\$ 7,570,803</u>
Supplemental disclosure of cash and non-cash transactions:		
Cash paid for interest	\$ 226,455	\$ 135,146
Cash paid for taxes	\$ -	\$ 5,500
Financing of equipment purchases and insurance renewal	\$ 686,968	\$ 755,594
Issuance of Senior Secured Promissory Note pursuant ANDA asset acquisition	\$ -	\$ 1,200,000
Commitment shares issued to Lincoln Park Capital	\$ 28,729	\$ 954,936
Retirement of Common Stock pursuant to the issuance of Series J convertible preferred shares	\$ -	\$ 20,378,631

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

**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 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.

Going Concern

At March 31, 2019, the Company had unrestricted cash balances totaling \$2.3 million. The Company has incurred losses and negative cash flows from operations every year since its inception, including operating losses and negative overall cash flows of \$9.1 million and \$4.9 million for the year ended March 31, 2019, respectively. In addition, overall working capital, defined as current assets minus current liabilities decreased by approximately \$6.6 million during the year ended March 31, 2019.

Based on the foregoing, the Company has determined that there did appear to be evidence of substantial doubt of its ability to continue as a going concern. To continue as a going concern, the Company will need to do some or all of the following, without limitation: obtainment additional financing, increase sales of existing products, bring additional products in the pipe line to market and/or reduce expenses. the successful development of the Company's contemplated plan of operations, and its transition, ultimately, to the attainment of profitable operations are necessary for the Company to continue operations.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The financial statements included herein do not reflect any adjustments relating to the recoverability and reclassification of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

Segment Information

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

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

There are currently no intersegment revenues. Asset information by operating segment is not presented below since the chief operating decision maker does not review this information by segment. The reporting segments follow the same accounting policies used in the preparation of the Company's audited consolidated financial statements. Please see note 17 for further details.

Revenue Recognition

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

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

Nature of goods and services

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

a) Manufacturing Fees

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

The Company recognizes revenue when the customer obtains control of the Company’s product based on the contractual shipping terms of the contract. Revenue on product are presented gross because the Company is primarily responsible for fulfilling the promise to provide the product, is responsible to ensure that the product is produced in accordance with the related supply agreement and bears risk of loss while the inventory is in-transit to the commercial partner. Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products to a customer.

b) License Fees

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

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

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

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

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

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

Disaggregation of revenue

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

	For the year ended March 31,	
	2019	2018
NDA:		
Licensing fees	\$ 1,000,000	\$ 1,000,000
Total NDA revenue	<u>1,000,000</u>	<u>1,000,000</u>
ANDA:		
Manufacturing fees	\$ 5,387,696	\$ 5,199,006
Licensing fees	1,180,812	1,259,705
Total ANDA revenue	<u>6,568,508</u>	<u>6,458,711</u>
Total revenue	<u>\$ 7,568,508</u>	<u>\$ 7,458,711</u>

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, 2019, and 2018, the Company had \$398,125 and \$391,566 of restricted cash, respectively, related to debt service reserve in regard to the New Jersey Economic Development Authority ("*NJEDA*") bonds (see Note 6).

Accounts Receivable

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

Inventory

Inventory is recorded at the lower of cost or market on a specific identification by lot number 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, 2019, the Company did not identify any indicators of impairment.

Please also see Note 5 for further details on intangible assets.

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.

Please also see the section titled "Recently Issued Accounting Pronouncements" regarding accounting standards relating to leases that will be implemented effective as of April 1, 2019.

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 jurisdictions until the applicable statutes of limitation expire. As of March 31, 2019, a summary of the tax years that remain subject to examination in our major tax jurisdictions are: United States – Federal, 2014 and forward, and State, 2010 and forward. The Company did not record unrecognized tax positions for the years ended March 31, 2019 and 2018.

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 instrument 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:

	Years ended March 31,	
	2019	2018
Numerator		
Net loss attributable to common shareholders - basic	\$ (9,279,320)	\$ (3,673,172)
Effect of dilutive instrument on net loss	(180,042)	(4,650,266)
Net loss attributable to common shareholders - diluted	<u>\$ (9,459,362)</u>	<u>\$ (8,323,438)</u>
Denominator		
Weighted average shares of common stock outstanding - basic	814,172,891	796,069,419
Dilutive effect of stock options, warrants and convertible securities	2,140,101	2,100,000
Weighted average shares of common stock outstanding - diluted	<u>816,312,992</u>	<u>798,169,419</u>
Net income (loss) per share		
Basic	<u>\$ (0.01)</u>	<u>\$ (0.00)</u>
Diluted	<u>\$ (0.01)</u>	<u>\$ (0.01)</u>

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, 2019 and March 31, 2018 aggregated by the level in the fair value hierarchy within which those measurements fell:

	Amount at Fair Value	Fair Value Measurement Using		
		Level 1	Level 2	Level 3
March 31, 2019				
Liabilities				
Derivative financial instruments - warrants	<u>\$ 2,487,830</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 2,487,830</u>
March 31, 2018				
Liabilities				
Derivative financial instruments - warrants	<u>\$ 2,667,871</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 2,667,871</u>

See Note 12, for specific inputs used in determining fair value.

The carrying amounts of the Company's financial assets and liabilities, such as cash, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued expenses, approximate their fair values because of the short maturity of these instruments. Based upon current borrowing rates with similar maturities the carrying value of long-term debt approximates fair value.

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

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

Treasury Stock

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

Recently Adopted Accounting Standards

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

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), which was subsequently amended and supplemented by several additional ASUs, including, without limitation:

- ASU No. 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, issued in August 2015, which deferred the effective date of ASU 2014-09 to annual and interim periods beginning after December 15, 2017.
- ASU 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*, issued in March 2016;
- ASU 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*, issued in April 2016
- 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* issued in May 2016; and
- ASU No. 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers*, issued in December 2016.

These ASUs have generally been codified in *Accounting Standards Codification Topic 606, "Revenue from Contracts with Customers"*; and are collectively referred herein as "ASC 606". ASC 606 supersedes the revenue recognition requirements in *Accounting Standards Codification Topic 605, "Revenue Recognition"* ("ASC 605"), and requires entities to recognize revenue when control of promised goods or services is transferred to customers at an amount that reflects the consideration to which entities expect to be entitled in exchange for those goods or services.

The Company adopted ASC 606 on April 1, 2018 for all open contracts and related amendments as of such date, using the modified retrospective method. Under the modified retrospective method, results beginning on April 1, 2018 are presented under ASC 606, while the comparative prior period(s) results continue to be presented under ASC 605, based on the accounting standards originally in effect for such periods. As a result of adopting ASC 606, the Company recorded no change in its accumulated deficit at April 1, 2018, representing the cumulative impact of adopting ASC 606.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230) Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"). ASU 2016-15 eliminates the diversity in practice related to the classification of certain cash receipts and payments for debt prepayment or extinguishment costs, the maturing of a zero-coupon bond, the settlement of contingent liabilities arising from a business combination, proceeds from insurance settlements, distributions from certain equity method investees and beneficial interests obtained in a financial asset securitization. ASU 2016-15 designates the appropriate cash flow classification, including requirements to allocate certain components of these cash receipts and payments among operating, investing and financing activities. The guidance is effective for fiscal years beginning after December 15, 2017. The Company's adoption of this standard as of April 1, 2018 had no impact to the Company's consolidated financial statements for the twelve months ended March 31, 2019.

In November 2016, the FASB issued ASU No. 2016-18 *Restricted Cash (ASC 230): Statement of Cash Flows* (“ASU No. 2016-18”). ASU No. 2016-18 requires that a statement of cash flows explain the change during the period in the total of cash and amounts generally described as restricted cash. Restricted cash will be included with cash and cash equivalents when reconciling the beginning of period and end of period balances on the statement of cash flows upon adoption of this standard. As a result of the adoption of the new guidance, the Company increased the beginning of year total amount shown on the consolidated statement of cash flows by \$391,566 and \$389,081 for the fiscal years ended March 31, 2019 and 2018, respectively. These amounts represent the balance of restricted cash included in the consolidated balance sheets as of March 31, 2019 and 2018, respectively. Restricted cash is related to debt service reserve in regard to the NJEDA bonds (see Note 6).

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 adopted ASU 2017-09 on April 1, 2018. The adoption of this standard did not materially impact the Company’s stock-based compensation expense as no awards were modified during the twelve months ended March 31, 2019.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02 *Leases (ASC 842)*, which is effective for public entities for annual reporting periods beginning after December 15, 2018. Under ASU 2016-02, lessees will be required to recognize the following for all leases (with the exception of short-term leases) at the commencement date: 1) a lease liability, which is a lessee’s obligation to make lease payments arising from a lease, measured on a discounted basis, and 2) a right-of-use asset, which is an asset that represents the lessee’s right to use, or control the use of, a specified asset for the lease term. In July 2018, the FASB issued ASU 2018-10, Codification Improvements to ASC 842 (Leases), and ASU 2018-11, Leases (ASC 842), Targeted Improvements, which provide narrow amendments to clarify how to apply certain aspects of the new lease standard, (i) entities with an additional transition method to adopt the new standard, and (ii) lessors with a practical expedient for separating components of a contract. All ASUs are effective for annual periods and interim periods within those annual periods beginning after December 15, 2018 and is effective for the Company for the year ending March 31, 2020. The Company has evaluated the effects of ASU 2016-02 and determined that a right-of-use asset, lease liability and increase in accumulated deficit due to cumulative effect of change in accounting principal valued at approximately \$1.1 million, \$1.5 million and \$0.3 million, respectively will be recorded as of April 1, 2019.

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 consolidated financial statements.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features; II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. Part I of this update addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of the pricing of future equity offerings. Current accounting guidance creates cost and complexity for entities that issue financial instruments (such as warrants and convertible instruments) with down round features that require fair value measurement of the entire instrument or conversion option. Part II of this update addresses the difficulty of navigating Topic 480, Distinguishing Liabilities from Equity, because of the existence of extensive pending content in the FASB Accounting Standards Codification. This pending content is the result of the indefinite deferral of accounting requirements about mandatorily redeemable financial instruments of certain nonpublic entities and certain mandatorily redeemable noncontrolling interests. The amendments in Part II of this update do not have an accounting effect. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018. The Company is currently assessing the potential impact of adopting ASU 2017-11 on its consolidated financial statements and related disclosures.

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

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

In August 2018, the FASB issued ASU 2018-15, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40) Customer Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* ("ASU 2018-15"), to help entities evaluate the accounting for fees paid by a customer in a cloud computing arrangement (hosting arrangement) by providing guidance for determining when the arrangement includes a software license. The guidance provided generally means that an intangible asset is recognized for the software license and, to the extent that the payments attributable to the software license are made over time, a liability also is recognized. If a cloud computing arrangement does not include a software license, the entity should account for the arrangement as a service contract. This generally means that the fees associated with the hosting element (service) of the arrangement are expensed as incurred. ASU 2018-15 is effective for fiscal years beginning subsequent to December 15, 2019. The Company is currently assessing the potential impact of adopting ASU 2018-15 on its consolidated financial statements and related disclosures.

In March 2019, the FASB issued ASU 2019-1, *Leases (Topic 842) Codification Improvements* ("ASU 2019-1"), to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing essential information about leasing transactions. The amendments ASU 2019-1 include the following items:

- Determining the fair value of the underlying asset by lessors that are not manufacturers or dealers (Issue 1);
- Presentation on the statement of cash flows—sales-type and direct financing leases (Issue 2), and
- Transition disclosures related to Topic 250, Accounting Changes and Error Corrections (Issue 3).

The amendments in ASU 2019-1 amend Topic 842 and are effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The Company is evaluating the effect that this update will have on its consolidated financial statements and related disclosures.

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

NOTE 2. ASSET ACQUISITION

On May 15, 2017, Elite Laboratories, Inc., a wholly-owned subsidiary of the Company entered into an asset purchase agreement with Mikah Pharma LLC (“Mikah” and/or the “Seller”), a related party, to acquire the Abbreviated New Drug Applications for Trimipramine Maleate Capsules and testing data studies, and formulations created in connection therewith including but not limited to (i) the ANDA(s) (Trimipramine Maleate Capsules, 25, 50 and 100 mg (the “Product”), (ii) any correspondence with the United States Food and Drug Administration in Seller’s files with respect to the ANDA(s), (iii) the right 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 (the “Purchased Assets”). Mikah is owned by Nasrat Hakim, the CEO, President and Chairman of the Board of the Company. For consideration of the purchased assets, the Company issued a Secured Promissory Note for the principal sum of \$1,200,000 (see Note 8).

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

ANDA acquisition costs	\$ 1,200,000
Total assets acquired	<u>\$ 1,200,000</u>

NOTE 3. INVENTORY

Inventory consisted of the following:

	March 31, 2019	March 31, 2018
Finished goods	\$ 575,699	\$ 229,204
Work-in-progress	189,069	297,350
Raw materials	3,750,955	4,371,447
	<u>4,515,723</u>	<u>4,898,001</u>
Less: Inventory reserve	-	-
	<u>\$ 4,515,723</u>	<u>\$ 4,898,001</u>

NOTE 4. PROPERTY AND EQUIPMENT, NET

Property and equipment consisted of the following:

	March 31,	
	2019	2018
Land, building and improvements	\$ 5,260,523	\$ 5,260,524
Laboratory, manufacturing, warehouse and transportation equipment	12,078,340	11,715,805
Office equipment and software	373,601	176,965
Furniture and fixtures	383,103	249,393
	<u>18,095,567</u>	<u>17,402,687</u>
Less: Accumulated depreciation	(9,651,718)	(8,408,979)
	<u>\$ 8,443,849</u>	<u>\$ 8,993,708</u>

Depreciation expense was \$1,242,739 and \$982,227 for the years ended March 31, 2019 and 2018, respectively.

NOTE 5. INTANGIBLE ASSETS

The following tables summarize the Company’s intangible assets:

	March 31, 2019					
	Estimated Useful Life	Gross Carrying Amount	Additions	Reductions	Accumulated Amortization	Net Book Value
Patent application costs	*	\$ 465,684	\$ -	\$ -	\$ -	\$ 465,684
ANDA acquisition costs	Indefinite	7,247,317	-	(1,078,966)	-	6,168,351
		<u>\$ 7,713,001</u>	<u>\$ -</u>	<u>\$ (1,078,966)</u>	<u>\$ -</u>	<u>\$ 6,634,035</u>

March 31, 2018

	Estimated Useful Life	Gross Carrying Amount	Additions	Reductions	Accumulated Amortization	Net Book Value
Patent application costs	*	\$ 371,774	\$ 93,910	\$ -	\$ -	\$ 465,684
ANDA acquisition costs	Indefinite	6,047,317	1,200,000	-	-	7,247,317
		<u>\$ 6,419,091</u>	<u>\$ 1,293,910</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 7,713,001</u>

* 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).

The following ANDA's, with an aggregate carrying amount of \$291,491 were discontinued during Fiscal 2019:

- 40227 – *Phentermine 30mg capsules*
- 40448 – *Phentermine 30mg capsules*
- 40460 – *Phentermine 15mg capsules*

The following ANDA's, with an aggregate carrying amount of \$787,475 were transferred to Epic Pharma for cash consideration totaling \$450,000:

- 40600 – *Hydroxyzine 10mg*
- 40602 – *Hydroxyzine 25mg*
- 40604 – *Hydroxyzine 50mg*

The primary catalyst for the discontinuance and transfer of the above referenced ANDA's was the FDA's Generic Drug User Fee Amendment ("GDUFA") fee structure, which provides for additional annual fees in excess of \$1.1 million (as per the most current fee schedule published in August 2018) for entities that own in excess of 19 ANDA's as of the annual April 15 measurement date.

The ANDA's approved by the FDA subsequent to the prior year's measurement date, when added to those previously approved and owned by the Company, would have resulted in the Company owning more than 19 ANDA's. Management conducted an evaluation of all ANDA's held and the feasibility of incurring the additional GDUFA fees and identified the above ANDA's as being not significant to the Company's plans. The ANDA's that were discontinued were duplicates of ANDA's currently in commercial production and the ANDA's sold to Epic Pharma were related to products that were not qualified for manufacture at the Northvale Facility.

The aggregate carrying amount of the six ANDAs discontinued or transferred was \$1,078,966 and the aggregate cash consideration received in relation to the transfer of ANDAs was \$450,000, resulting in a realized loss on transfer/discontinuance of intangible assets of \$628,966.

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 service 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, 2019	March 31, 2018
Gross bonds payable		
NJEDA Bonds - Series A Notes	\$ 1,670,000	\$ 1,760,000
Less: Current portion of bonds payable (prior to deduction of bond offering costs)	(95,000)	(90,000)
Long-term portion of bonds payable (prior to deduction of bond offering costs)	<u>\$ 1,575,000</u>	<u>\$ 1,670,000</u>
Bond offering costs		
Bond offering costs	\$ 354,453	\$ 354,453
Less: Accumulated amortization	(192,591)	(178,409)
Bond offering costs, net	<u>\$ 161,862</u>	<u>\$ 176,044</u>
Current portion of bonds payable - net of bond offering costs		
Current portions of bonds payable	95,000	\$ 90,000
Less: Bonds offering costs to be amortized in the next 12 months	(14,178)	(14,178)
Current portion of bonds payable, net of bond offering costs	<u>\$ 80,822</u>	<u>\$ 75,822</u>
Long term portion of bonds payable - net of bond offering costs		
Long term portion of bonds payable	1,575,000	\$ 1,670,000
Less: Bond offering costs to be amortized subsequent to the next 12 months	(147,685)	(161,866)
Long term portion of bonds payable, net of bond offering costs	<u>\$ 1,427,315</u>	<u>\$ 1,508,134</u>

Amortization expense was \$14,178 for the years ended March 31, 2019 and 2018, respectively.

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

Years ending March 31,	Amount
2020	\$ 95,000
2021	105,000
2022	110,000
2023	115,000
2024	125,000
Thereafter	1,120,000
	<u>\$ 1,670,000</u>

NOTE 7. LOANS PAYABLE

Loans payable consisted of the following:

	March 31, 2019	March 31, 2018
Equipment and insurance financing loans payable, between 3.5% and 12.73% interest and maturing between July 2019 and December 2023	\$ 1,272,298	\$ 1,201,861
Less: Current portion of loans payable	(573,029)	(578,841)
Long-term portion of loans payable	<u>\$ 699,269</u>	<u>\$ 623,020</u>

The interest expense associated with the loans payable was \$114,980 and \$119,890 for the years ended March 31, 2019 and 2018, respectively.

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

Years ending March 31,	Amount
2020	\$ 573,029
2021	260,358
2022	239,802
2023	162,111
2024	36,998
	<u>\$ 1,272,298</u>

NOTE 8. RELATED PARTY SECURED PROMISSORY NOTE WITH MIKAH PHARMA LLC

For consideration of the assets acquired on May 15, 2017, the Company issued a Secured Promissory Note (the "Note") to Mikah for the principal sum of \$1,200,000. The Note matures on December 31, 2020 in which the Company shall pay the outstanding principal balance of the Note. Interest shall be computed on the unpaid principal amount at the per annum rate of ten percent (10%); provided, upon the occurrence of an Event of Default as defined within the Note, the principal balance shall bear interest from the date of such occurrence until the date of actual payment at the per annum rate of fifteen percent (15%). All interest payable hereunder shall be computed on the basis of actual days elapsed and a year of 360 days. Installment payments of interest on the outstanding principal shall be paid as follows: quarterly commencing August 1, 2017 and on November 1, February 1, May 1 and August 1 of each year thereafter. No principal or interest payments have been made on the Note since its issuance. All unpaid principal and accrued but unpaid interest shall be due and payable in full on the maturity date. The interest expense associated with the Note was \$120,000 for the year ended March 31, 2019 and total accrued interest due and owing as of March 31, 2019 is \$225,000.

NOTE 9. DEFERRED REVENUE

Deferred revenues in the aggregate amount of \$1,252,223 as of March 31, 2019, were comprised of a current component of \$1,013,333 and a long-term component of \$238,890. Deferred revenues in the aggregate amount of \$2,265,557 as of March 31, 2018, were comprised of a current component of \$1,013,333 and a long-term component of \$1,252,223. These line items represent the unamortized amounts of a \$200,000 advance payment received for a TAGI licensing agreement with a fifteen-year term beginning in September 2010 and ending in August 2025 and the \$5,000,000 advance payment Epic Collaborative Agreement with a five-year term beginning in June 2015 and ending in May 2020. These advance payments were recorded as deferred revenue when received and are earned, on a straight-line basis over the life of the licenses. The current component is equal to the amount of revenue to be earned during the 12-month period immediately subsequent to the balance date and the long-term component is equal to the amount of revenue to be earned thereafter.

NOTE 10. COMMITMENTS AND CONTINGENCIES

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

Operating Leases – 135 Ludlow Ave.

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

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

The 135 Ludlow Ave. property required significant leasehold improvements and qualifications, as a prerequisite, for its intended future use. Manufacturing, packaging, warehousing and regulatory activities are currently conducted at this location. Additional renovations and construction to further expand the Company's manufacturing resources are in progress.

Rent expense is recorded on the straight-line basis. Rents paid in excess is recognized as deferred rent. Rent expense under the 135 Ludlow Ave. modified lease for the years ended March 31, 2019 and 2018 was \$219,638 and \$219,636, respectively. Rent expense is recorded in general and administrative expense in the audited consolidated statements of operations. Deferred rent as of March 31, 2019 and 2018 was \$13,022 and \$9,702, respectively, and recorded as a component of other long-term liabilities. The tables below show the future minimum rental payments, exclusive of taxes, insurance and other costs, under the Ludlow Ave. lease:

Years ending March 31,	Amount
2020	\$ 220,650
2021	225,063
2022	229,563
2023	234,156
2024	238,836
Thereafter	681,240
	<u>\$ 1,829,508</u>

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, 2019 and 2018, the Company had a liability of \$33,383 and \$31,443, 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, 2019 and 2018, respectively.

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

- Conversion feature - the Series I Preferred Shares may be converted, at the option of the Holder, into the Company’s Common Stock at a 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 instrument 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,	
	2019	2018
Shares authorized	395,758	395,758
Shares outstanding	-	-
Par value	\$ 0.01	\$ 0.01
Stated value	\$ 100,000	\$ 100,000
Conversion price	\$ 0.07	\$ 0.07
Common Stock to be issued upon redemption	-	-
Closing price on valuation date	\$ 0.10	\$ 0.09
Carrying value of Series I convertible preferred stock	\$ -	\$ -

Series J convertible preferred stock

On April 28, 2017, the Company created the Series J Convertible Preferred Stock (*Series J Preferred*) in conjunction with the Certificate of Designations ("*Series J COD*"). A total of 50 shares of Series J Preferred were authorized, 24.0344 shares are issued and outstanding, with a stated value of \$1,000,000 per share and a par value of \$0.01 as of March 31, 2019.

The issued shares were pursuant to an Exchange Agreement with Nasrat Hakim, (*Hakim*) a related party and the Company's President, Chief Executive Officer and Chairman of the Board of Directors. Pursuant to the Exchange Agreement the Company exchanged 158,017,321 shares of Common Stock for 24.0344 shares of Series J Preferred and warrants to purchase 79,008,661 shares of common stock at \$0.1521 per share. The aggregate stated value of the Series J Preferred issued was equal to the aggregate value of the shares of common stock exchanged, with such value of each share of Common Stock exchanged being equal to the closing price of the Common Stock on April 27, 2017. In connection with the Exchange Agreement, the Company also issued warrants to purchase 79,008,661 shares of common stock at \$0.1521 per share, and such warrants are classified as liabilities on the accompanying consolidated balance sheet as of March 31, 2019 (See Note 12).

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

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

If upon any Conversion Date there is not a sufficient number of authorized shares of Common Stock (that are not issued, outstanding or reserved for issuance) available to effect the entire conversion of the then outstanding shares of Series J Preferred Stock and the then outstanding common stock purchase warrants issued in conjunction therewith (an "*Authorized Share Deficiency*"), such conversion shall not exceed the Issuable Maximum (as defined in the Series J COD); however, the Company shall use its best efforts to obtain shareholder approval within two (2) years of the date of first issuance of Series Preferred Stock to permit the balance of the conversion. If shareholder approval is not obtained due to an insufficient number of shareholder votes for passage the Company shall continue to solicit for shareholder approval annually thereafter. As of March 31, 2019, the Company does not have a sufficient number of unreserved authorized shares to effect the entire conversion, notwithstanding that the earliest possible Conversion Date is April 28, 2020.

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

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

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

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

	April 28, 2017
Fair value of the Company's Common Stock	\$ 0.1521
Conversion price	\$ 0.1521
Number of Series J Preferred issued	24.0344
Fully diluted shares outstanding as of measurement date	923,392,780
Risk-free rate	2.30%
Volatility	90.00%
Shareholder approval threshold	\$ 0.1521
Probability of approval if ending stock price is greater than threshold - midpoint	82.50%
Probability of approval if ending stock price is greater than threshold - midpoint	17.50%
Trials	200,000

Authorized, issued and outstanding shares, along with carrying value and change in value as of the periods presented are as follows:

	March 31, 2019	March 31, 2018
Shares authorized	50.000	50.000
Shares outstanding	24.0344	24.0344
Par value	\$ 0.01	\$ 0.01
Stated value	\$ 1,000,000	\$ 1,000,000
Conversion price	\$ 0.1521	\$ 0.1521
Common Stock to be issued upon conversion	158,017,321	158,017,321
Carrying value of Series J convertible preferred stock	\$ 13,903,960	\$ 13,903,960

NOTE 12. DERIVATIVE FINANCIAL INSTRUMENTS – WARRANTS

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

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

A summary of warrant activity is as follows:

	Year ended March 31,			
	2019		2018	
	Warrant Shares	Weighted Average Exercise Price	Warrant Shares	Weighted Average Exercise Price
Balance at beginning of year	79,008,661	\$ 0.1521	9,379,219	\$ 0.0625
Warrants granted pursuant to the issuance of Series J convertible preferred shares	-	\$ -	79,008,661	\$ 0.1521
Warrants exercised, forfeited and/or expired, net	-	\$ -	(9,379,219)	\$ 0.0625
Balance at end of year	79,008,661	\$ 0.1521	79,008,661	\$ 0.1521

Please note that all of the warrants issued prior to Fiscal 2018 were fully exercised, forfeited and/or expired on or before March 31, 2018. At March 31, 2018, the remaining warrants outstanding are held by Mr. Nasrat Hakim, the Company's Chief Executive Officer in conjunction with the Exchange Agreement described below.

The fair value of the warrants issued prior to Fiscal 2018, all was calculated using the Black-Scholes model and the following assumptions:

	March 31 2017
Fair value of the Company's common stock	\$ 0.15
Volatility (based on the Company's historical volatility)	72.5% - 73.1%
Exercise price	\$ 0.0625
Estimated life (in years)	1.0 - 1.1
Risk free interest rate (based on 1-year treasury rate)	1.02% - 1.03%

On April 28, 2017, the Company entered into an exchange agreement (the "Exchange Agreement") with Nasrat Hakim, the Chairman of the Board President, and Chief Executive Officer of the Company, pursuant to which the Company issued to Mr. Hakim 24,034 shares of its newly designated Series Convertible Preferred Stock ("Series J Preferred") and Warrants to purchase an aggregate of 79,008,661 shares of its Common Stock (the "Series J Warrants" and, along with the Series J Preferred issued to Mr. Hakim, the "Securities") in exchange for 158,017,321 shares of Common Stock owned by Mr. Hakim. The fair value of the Series J Warrants was determined to be \$6,474,674 upon issuance at April 28, 2017.

The Series J Warrants are exercisable for a period of 10 years from the date of issuance, commencing on the earlier of (i) the date that Shareholder Approval is obtained, and the requisite corporate action has been effected; or (ii) April 28, 2020. The initial exercise price is \$0.1521 per share and the Series J Warrants can be exercised for cash or on a cashless basis. The exercise price is subject to adjustment for any issuances or deemed issuances of common stock or common stock equivalents at an effective price below the then exercise price. Such exercise price adjustment feature prohibits the Company from being able to conclude the warrants are indexed to its own stock and thus such warrants are classified as liabilities and measured initially and subsequently at fair value. The Series J Warrants also provide for other standard adjustments upon the happening of certain customary events. The Series J Warrants are not exercisable during any period when an Authorized Share Deficiency exists and will expire on the expiry date, without regards to the existence of an Authorized Shares Deficiency (see Note 11). As of March 31, 2019, the Company does not have a sufficient number of unreserved authorized shares to effect the entire conversion of the Series J Preferred, therefore the Series J Warrants are not currently exercisable. Please also see Note 11.

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

	March 31, 2019	March 31, 2018
Fair value of the Company's Common Stock	\$ 0.990	\$ 0.100
Initial exercise price	\$ 0.1521	\$ 0.1521
Number of common warrants	79,008,661	79,008,661
Fully diluted shares outstanding as of measurement date	824,946,559	791,516,930
Warrant term (in years)	8.08	9.08
Risk-free rate	2.35%	2.72%
Volatility	90.00%	90.00%
Shareholder approval threshold	\$ 0.1580	\$ 0.1580
Probability of approval if ending stock price is greater than threshold - midpoint	82.50%	82.50%
Probability of approval if ending stock price is greater than threshold - midpoint	17.50%	17.50%
Trials	100,000	100,000
Fair value of derivative financial instruments - warrants	\$ 2,487,830	\$ 2,667,871

The changes in warrants (Level 3 financial instruments) measured at fair value on a recurring basis for the year ended March 31, 2019 were as follows:

Balance as of March 31, 2017	843,464
Fair value of warrants granted pursuant to the issuance of Series J convertible preferred shares	6,474,674
Change in fair value of derivative financial instruments - warrants	(4,650,267)
Balance as of March 31, 2018	\$ 2,667,871
Change in fair value of derivative financial instruments - warrants	(180,041)
Balance as of March 31, 2019	<u>\$ 2,487,830</u>

NOTE 13. SHAREHOLDERS' EQUITY (DEFICIT)

Lincoln Park Capital – April 10, 2014 Purchase Agreement

On April 10, 2014, the Company entered into a Purchase Agreement (the “*Lincoln Park Purchase Agreement*” and/or “*Purchase Agreement*”) and a Registration Rights Agreement (the “*Registration Rights Agreement*”) with Lincoln Park Capital Fund, LLC (“*Lincoln Park*”). Pursuant to the terms of the Purchase Agreement, Lincoln Park has agreed to purchase from the Company up to \$40 million of common stock (subject to certain limitations) from time to time over a 36-month period ending June 1, 2017. Pursuant to the terms of the Registration Rights Agreement, the Company filed with the SEC registration statements to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the Purchase Agreement. The latest registration statement, which updates the prior registration statements, was declared effective by the SEC on July 13, 2016.

Upon execution of the Purchase Agreement, the Company issued 1,928,641 shares of common stock to Lincoln Park pursuant to the Purchase Agreement as consideration for its commitment to purchase additional shares of common stock under that agreement and the Company is obligated to issue up to an additional 1,928,641 commitment shares to Lincoln Park pro rata as up to \$40.0 million of common stock purchased by Lincoln Park.

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

Lincoln Park Capital – May 1, 2017 Purchase Agreement

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

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

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

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

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

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

In addition to Regular Purchases, on any business day on which the Company has properly submitted a Regular Purchase notice and the closing sale price is not below \$0.15, 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. During the year ended March 31, 2019, a total of 22,033,967 shares were sold to Lincoln Park pursuant to the 2017 LPC Agreement for net proceeds totaling \$2,063,541. In addition, 285,831 shares were issued to Lincoln Park as additional commitment shares, pursuant to the 2017 LPC Agreement. During the year ended March 31, 2018, a total of 17,818,950 shares were sold to Lincoln Park pursuant to the 2017 LPC Agreement for net proceeds totaling \$1,999,878. In addition, 5,540,551 shares were issued to Lincoln Park as initial commitment shares and 277,009 shares were issued to Lincoln Park as additional commitment shares, pursuant to the 2017 LPC Agreement.

Summary of Common Stock Activity

During the years ended March 2019 and 2018, the Company issued a total of 32,612,634 and 216,487,096 shares of Common Stock, respectively, with such issuances of Common Stock being summarized as follows:

	Years ended March 31,	
	2019	2018
Common Stock sold pursuant to the Lincoln Park Capital Purchase Agreements, with net proceeds of such shares totaling \$2,063,541 and \$1,999,878 for the years ended March 31, 2019 and 2018, respectively.	22,033,967	17,818,950
Common Stock issued as initial and additional commitment shares pursuant to the Lincoln Park Capital Purchase Agreements	285,831	5,817,560
Common Stock issued in payment of Director’s fees totaling \$0 and \$80,000 for the years ended March 31, 2019 and 2018, respectively.	-	645,496
Common Stock issued in payment of employee salaries totaling \$0 and \$305,000 for the years ended March 31, 2019 and 2018, respectively.	-	2,460,941
Common Stock issued in payment of consulting expenses totaling \$0 and \$26,000 for the years ended March 31, 2019 and 2018, respectively.	-	211,392
Common Stock issued pursuant to the exercise of cash warrants	-	5,658,295
Common Stock Issued during the fiscal year	<u>22,319,798</u>	<u>32,612,634</u>
Retirement of Common Stock during the fiscal year	-	(158,017,321)
Common Stock issued as of March 31, 2019 and 2018, respectively	<u>824,946,559</u>	<u>802,626,761</u>

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 a quarterly basis and equal to the average closing price of the Company's common stock.

During the year ended March 31, 2019, the Company accrued a total of 793,617 shares of Common Stock as being due and owing in relation to director compensation totaling \$75,000 earned and accrued during the period January 1, 2018 through March 31, 2019, and consisting of 656,827 shares accrued for director compensation totaling \$60,000 for the 12 months ended March 31, 2019 and 136,790 shares accrued for director compensation totaling \$15,000 for the 3 months ended March 31, 2018. Issuance of these shares has been deferred to an undetermined date.

During the years ended March 31, 2019 and 2018, the Company issued 645,496 and 334,295 shares of its Common Stock, respectively, relating to director compensation totaling \$80,000 and \$73,361, for each year, respectively.

Stock-based Employee Compensation

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

During the year ended March 31, 2019, the Company accrued a total of 4,034,219 shares of common stock as being due and owing to certain employees, exclusive of the Company's Chief Executive Officer and relating to accrued salaries in the aggregate amount of \$381,250 earned but not paid during the period January 1, 2018 through March 31, 2019 and consisting of 3,338,871 shares accrued for salaries totaling \$305,000 for the 12 months ended March 31, 2019 and 695,348 shares accrued for salaries totaling \$76,250 for the 3 months ended March 31, 2018. Issuance of these shares has been deferred to an undetermined date.

During the year ended March 31, 2019, the Company accrued a total of 10,648,343 shares of common stock as being due and owing to its Chief Executive Officer and relating to accrued salaries in the aggregate amount of \$1,125,000 earned, but not paid during the period January 1, 2017 through March 31, 2019. Of this amount, 5,473,559 shares was accrued for salaries totaling \$500,000 for the 12 months ended March 31, 2019, 4,329,661 shares was accrued for salaries totaling \$500,000 for the 12 months ended March 31, 2018 and 845,083 shares was accrued for salaries totaling \$125,000 for the 3 month period ended March 31, 2017. Issuance of these shares has been deferred to an undetermined date.

As of March 31, 2019, the Company owes its President and Chief Executive Officer, Chief Financial Officer and certain other employees, a total of approximately 14.7 million shares of Common Stock in payment of salaries and fees totaling 1.5 million due and owing, inclusive of salaries earned by the Company's Chief Executive Officer, as described in the paragraph above. Issuance of these shares of common stock has been deferred to an undetermined date.

Options

Under its 2014 Stock Option Plan and prior options plans, the Company may grant stock options to officers, selected employees, as well as member 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 March 31, 2017	6,737,667	\$ 0.20	6.7	\$ 258,747
Granted	640,000	0.16		
Forfeited and expired	-	-		
Exercised	(759,667)	0.56		
Outstanding at March 31, 2018	6,618,000	\$ 0.16	6.1	\$ 90,390
Granted	-			
Forfeited and expired	(460,000)			
Exercised	-			
Outstanding at March 31, 2019	6,158,000	\$ 0.15	5.0	\$ 87,330
Exercisable at March 31, 2019	5,635,002	\$ 0.14	4.7	87,330

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, 2019 and 2018 was \$0.10 and \$0.10.

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

	March 31,	
	2019	2018
Volatility (based on the Company's historical volatility)	n/a	121% - 123%
Exercise price	n/a	\$ 0.09 - 0.24
Estimated term (in years)	n/a	10
Risk free interest rate (based on 1-year treasury rate)	n/a	2.2% - 2.4%
Forfeiture rate	n/a	0.0% - 20.1%
Fair value of options granted	n/a	\$ 79,215
Non-cash compensation through issuance of stock options	n/a	\$ 244,753

NOTE 15. SALE OF NEW JERSEY STATE NET OPERATING LOSSES

During the year ended March 31, 2019, 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 \$296,883 relating to New Jersey net operating losses and net tax benefits of \$376,133 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 \$619,175.

During the year ended March 31, 2018, 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 \$439,313 relating to New Jersey net operating losses and net tax benefits of \$606,516 relating to R&D tax credits. The Company sold the net tax benefits approved for sale at a transfer price equal to ninety-two cents for every benefit dollar for total proceeds of \$1,045,829.

NOTE 16. CONCENTRATIONS AND CREDIT RISK

Revenues

Four customers accounted for substantially all the Company's revenues for the year ended March 31, 2019. These four customers accounted for approximately 57%, 22%, 9% and 8% of revenues each, respectively.

Four customers accounted for substantially all the Company's revenues for the year ended March 31, 2018. These four customers accounted for approximately 52%, 24%, 15% and 8% of revenues each, respectively.

Accounts Receivable

Four customers accounted for substantially all the Company's accounts receivable as of March 31, 2019. These four customers accounted for approximately 38%, 34%, 19%, and 4% of accounts receivable as of March 31, 2019.

Four customers accounted for substantially all the Company's accounts receivable as of March 31, 2018. These four customers accounted for approximately 52%, 14%, 12%, and 11% of accounts receivable as of March 31, 2018.

Purchasing

Three suppliers accounted for more than 60% of the Company's purchases of raw materials for year ended March 31, 2019. These three suppliers accounted for approximately 35%, 17% and 11% of purchases each, respectively.

Three suppliers accounted for more than 60% of the Company's purchases of raw materials for year ended March 31, 2018. These three suppliers accounted for approximately 29%, 27% and 5% of purchases each, respectively.

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,	
	2019	2018
Revenue by Segment		
ANDA	\$ 6,568,508	\$ 6,458,711
NDA	1,000,000	1,000,000
	<u>\$ 7,568,508</u>	<u>\$ 7,458,711</u>
	Years ended March 31,	
	2019	2018
Operating Income (Loss) by Segment		
ANDA	\$ (4,361,649)	\$ (1,827,943)
NDA	122,961	(3,019,859)
	<u>\$ (4,238,688)</u>	<u>\$ (4,847,802)</u>

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,	
	2019	2018
Operating loss by segment	\$ (4,238,688)	\$ (4,847,802)
Corporate unallocated costs	(2,683,720)	(2,234,264)
Interest income	8,448	17,510
Interest expense and amortization of debt issuance costs	(369,174)	(335,498)
Depreciation and amortization expense	(1,206,495)	(800,460)
Significant non-cash items	(1,645,750)	(1,168,753)
Change in fair value of derivative instruments	180,042	4,650,266
Income (loss) from operations before the benefit from sale of state net operating loss credits	<u>\$ (9,955,337)</u>	<u>\$ (4,719,001)</u>

NOTE 18. COLLABORATIVE AGREEMENT WITH EPIC PHARMA LLC

On June 4, 2015, the Company entered into the 2015 Epic License Agreement, which provides for the exclusive right to market, sell and distribute, by Epic Pharma LLC (*Epic*) of SequestOx™, an abuse deterrent opioid which employs the Company's proprietary pharmacological abuse-deterrent technology. Epic will be responsible for payment of product development and pharmacovigilance costs, sales, and marketing of SequestOx™, and Elite will be responsible for the manufacture of the product. Under the 2015 Epic License Agreement, Epic will pay Elite non-refundable payments totaling \$15 million, with such amount representing the cost of an exclusive license to ELI-200, the cost of developing the product and certain filings and a royalty based on an amount equal to 50% of profits derived from net product sales as defined in the 2015 Epic License Agreement. The initial term of the exclusive right to product development sales and distribution is five years ("*Epic Exclusivity Period*"); the license is renewable upon mutual agreement at the end of the initial term.

In June 2015, Elite received non-refundable payments totaling \$5.0 million from Epic for the exclusive right to product development sales and distribution of SequestOx™ pursuant to the Epic Collaborative Agreement, under which it agreed to not permit marketing or selling of SequestOx™ within the United States of America to any other party. Such exclusive rights are considered a significant deliverable element of the Epic Collaborative Agreement pursuant to ASC 605-25, *Revenue Recognition – Multiple Element Arrangements*. These nonrefundable payments represent consideration for certain exclusive rights to ELI-200 and will be recognized ratably over the Epic Exclusivity Period.

In addition, in January 2016, a New Drug Application for SequestOx™ was filed, thereby earning the Company a non-refundable \$2.5 million milestone, pursuant to the 2015 Epic License Agreement. The filing of this NDA represents a significant deliverable element as defined within the Epic Collaborative Agreement 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 July 7, 2017, the Company reported topline results from a pivotal bioequivalence fed study for SequestOx™. The mean Tmax (the amount of time that a drug is present at the maximum concentration in serum) of SequestOx™ was 4.6 hr. with a range of 0.5 hr. to 12 hr. and the mean Tmax of the comparator, Roxicodone®, was 3.4 hr. with a range of 0.5 hr. to 12 hr. A key objective for the study was to determine if the reformulated SequestOx™ had a similar Tmax to the comparator when taken with a high fat meal. Based on these results, the Company paused clinical trials for this formulation of SequestOx™. On January 30, 2018, the Company reported positive topline results from a pilot study conducted for a modified SequestOx™ wherein, based on the results of this pilot study, the modified SequestOx™ formulation is expected to achieve bioequivalence with a Tmax range equivalent to the reference product when conducted in a pivotal trial under fed conditions. The Company has provided the pilot data to the FDA, requesting clarification as to the requirements for resubmission of the NDA. The FDA has provided guidance for repeated bio-equivalence studies in order to bridge the new formulation to the original SequestOx studies and also extended our filing fee waiver until July 2020. Due to the prohibitive cost of such repeated bio-equivalence studies, the Company has paused development of this product.

The 2015 Epic License Agreement expires on June 4, 2020, and Epic has previously advised the Company of their desire to extend this agreement. While discussions are ongoing, they are directly correlated to the regulatory status of SequestOx™. Furthermore, there can be no assurances that the parties will reach mutual agreement to extend the term of this agreement and no assurances that the terms and conditions of the agreement will be similar in all material aspects in the event that the agreement is extended by mutual consent of the parties. Non-receipt by the Company of the remaining \$7.5 million milestone will have a material adverse effect on the Company's financial condition.

NOTE 19. COLLABORATIVE AGREEMENT WITH SUNGEN PHARMA LLC

On August 24, 2016, the Company entered into the SunGen Agreement. The SunGen Agreement provides that Elite and SunGen Pharma LLC v engage in the research, development, sales, and marketing of four generic pharmaceutical products. Two of the products are classified as CNS stimulants (the “CNS Products”) and two of the products are classified as beta blockers (the “Beta Blocker Products”).

Under the terms of the SunGen Agreement, Elite and SunGen will share in the responsibilities and costs in the development of these products and 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.

On December 1, 2016 and July 24, 2017, Elite Labs and SunGen executed an amendment to the parties’ 2016 Development and License Agreement (the “Amended Agreement”), to undertake and engage in the research, development, sales and marketing of four additional generic pharmaceutical products bringing the total number of products under the amended agreement to eight. The product classes for the additional four products include antidepressants, antibiotics, and antispasmodics.

Under the terms of the Amended Agreement, Elite and SunGen will share in the responsibilities and costs in the development of these products and will share substantially in the profits from sales of the products. Upon approval, the know-how and intellectual property rights to the products will be owned jointly by Elite and SunGen. Three products will be owned jointly by Elite and SunGen; three shall be owned by SunGen while Elite shall have the marketing rights once the products are approved by the FDA; and two shall be owned by Elite while SunGen shall have the marketing rights once the products are approved by the FDA. Elite will manufacture and package all eight products on a cost-plus basis.

On December 10, 2018, the Company received approval from the FDA for an ANDA filed for a generic version of Adderall®, an immediate-release mixed salt of a single entity amphetamine product (Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, Amphetamine Sulfate), with strengths of 5mg, 7.5mg, 10mg, 12.5mg, 15mg, 20mg, and 30mg tablets. The product is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) and Narcolepsy. This approval represents the first FDA approval received for a product co-developed with SunGen under the SunGen Agreement. The first commercial shipment of this product occurred in April 2019. The product is currently marketed by Lannett Company Inc (“Lannett”) under license granted pursuant a strategic marketing alliance dated March 11, 2019 (“the Lannett Alliance”).

On May 24, 2018, the Company filed an ANDA with the FDA for a generic version of an extended release CNS stimulant. The ANDA represents the second filing for a product co-developed with SunGen under the SunGen Agreement. This product will also be marketed by Lannett pursuant to the Lannett Alliance.

On January 3, 2019, the Company filed an ANDA with the FDA for a generic version of an antibiotic product. The ANDA represents the third filing for a product co-developed with SunGen under the SunGen Agreement.

There can be no assurances that any of these products, even those for which ANDAs have been filed, will receive marketing authorization and achieve commercialization within a reasonable time period, or at all. In addition, even if marketing authorization is received, including the product for which such marketing authorization has already been received, there can be no assurances that there will be future revenues or profits, or that any such future revenues or profits would be in amounts that provide adequate return on the significant investments made to secure these marketing authorizations.

NOTE 20. RELATED PARTY TRANSACTION AGREEMENTS WITH EPIC PHARMA LLC

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

On June 4, 2015, the Company entered into the 2015 Epic License Agreement (please see Note 18 above). The 2015 Epic License 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 sale of ELI-200. On January 14, 2016, the Company filed an NDA with the FDA for SequestOx™, thereby earning a \$2.5 million milestone pursuant to the 2015 Epic License Agreement. The Company has received payment of this amount from Epic. An additional \$7.5 million is due upon approval by the FDA of the NDA filed for SequestOx™. Please note that on July 15, 2016, the FDA issued a Complete Response Letter, or CRL, regarding the NDA. The CRL states 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 this and the meeting minutes received from the FDA on January 23, 2017, the Company formulated a plan to address the issues cited by the FDA in the CRL, with such plan including, without limitation, modifying the SequestOx™ formulation, conducting bioequivalence and bioavailability fed and fasted studies, comparing the modified formulation to the original formulation. On July 7, 2017, the Company reported topline results from a pivotal bioequivalence fed study for SequestOx™. This study resulted in a mean Tmax of 4.6 hours, with a range of 0.5 hour to 12 hours and a mean Tmax of the comparator, Roxicodone® of 3.4 hours with a range of 0.5 hour to 12 hours. A key objective of this study was to determine if the reformulated SequestOx™ had a similar Tmax to the comparator when taken with a high fat meal. Based on these results, the Company will pause, not proceed, with the rest of the clinical trials, and seek clarity from the FDA before deciding on the next steps for immediate release SequestOx™. There can be no assurances of the success of any future clinical trials, or if such trials are successful, there can be no assurances that an intended future resubmission of the NDA product filing, if made, will be accepted by or receive marketing approval from the FDA, and accordingly, there can be no assurances that the Company will earn and receive the additional \$7.5 million or future license fees. 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”). The Epic Generic Agreement, which expired on October 2, 2018 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 were to 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 was to be 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 was to 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. The Epic Generic Agreement expired on October 2, 2018 with Epic launching four of the six exclusive products and Elite collecting \$1.0 million of the total \$1.8 million fee.

The 2015 Epic License Agreement contains 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 have 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");
- Development and License Agreement with SunGen (the "SunGen Agreement");
- Strategic Marketing Alliance with Glenmark Pharmaceuticals, Inc. USA dated May 29, 2018 (the "Glenmark Alliance");
- Strategic Marketing Alliance with Lannett Company, Inc. dated March 11, 2019 (the "Lannett-SunGen Product Alliance")
- Strategic Marketing Alliance with Lannett Company, Inc. dated April 9, 2019 (the "Lannett-Elite Product Alliance")

The Precision Dose Agreement provides for the marketing and distribution, by Precision Dose and its wholly owned subsidiary, TAGI Pharma, c 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 SunGen Agreement provides for the research, development, sales and marketing of eight generic pharmaceutical products. Two of the products are classified as CNS stimulants (the “CNS Products”), two of the products are classified as beta blockers and the remaining four products consist of antidepressants, antibiotics and antispasmodics. To date, the Company has filed ANDAs with the FDA for the two CNS Products and one antibiotic identified in the SunGen Agreement. The Company received FDA approval of the ANDA filed for the first CNS Product in December 2018 and achieved commercial launch in April 2019, with such product being marketed pursuant to the Lannett Alliance.

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

The Glenmark Alliance, provides for the manufacture by Elite and marketing by Glenmark of identified generic products under license from Elite. In addition to the purchase prices for the products, Elite will receive license fees well in excess of 50% of gross profits. Gross profit is defined as net sales less the price paid to Elite for the products, distribution fees (less than 10%) and shipping costs. Glenmark will have semi-exclusive marketing rights to the ANDA approved generic product, phendimetrazine 35mg tablets, and exclusive marketing rights to generic Methadone HCl. Collectively, the brand products and their generic equivalents had total annual sales of approximately \$33.6 million in 2017, according to Quintiles IMS Health data. The Agreement has an initial term of three years and automatically renews for one-year periods absent prior written notice of non-renewal. In addition to customary termination provisions, the Agreement permits Glenmark to terminate with regard to a product on at least three months’ prior written notice if it determines to stop marketing and selling such product, and it permits Elite to terminate with regard to a product if at any time after the first twelve months from the first commercial sale, the average license fee paid by Glenmark for such product is less than \$100,000 for a six-month sales period.

Pursuant to Lannett-SunGen Product Alliance with Lannett Company Inc. (“Lannett”), Lannett will be the exclusive U.S. marketer and distributor of two generic products co-developed and co-owned by Elite and SunGen – Amphetamine IR Tablets and a second product which is an extended release CNS stimulant that is currently under review by the FDA. Elite will manufacture and Lannett will purchase the products from Elite and then sell and distribute them. In addition to the purchase prices for the products, Elite will receive license fees in excess of 50% of net profits, which will be shared equally with SunGen pursuant to the SunGen Agreement. The Lannett-SunGen Product Alliance has an initial term of three years and automatically renews for one year period absent prior written notice of non-renewal. In addition to customary termination provisions, the Agreement permits Lannett to terminate with regard to a product on at least six months’ prior written notice, and it permits Elite or Lannett to terminate with regard to a product if at anytime after the first twelve months from the first commercial sale, the average license fee paid by Lannett for such product is less than \$300,000 for a six month sales period. In addition to manufacturing fees and license fees, Lannett will also pay a milestone, of \$750,000 upon commercial launch of the extended release CNS stimulant product that is currently under review by the FDA. This milestone payment will be shared equally by Elite and SunGen, pursuant to the SunGen Agreement.

The first commercial shipment of Amphetamine IR Tablets, a generic version of Adderall[®], with strengths of 5mg, 7.5mg, 10mg, 12.5mg, 15mg, 20mg and 30mg, pursuant to the Lannett-SunGen Product Alliance occurred in April 2019.

Pursuant to the Lannett-Elite Product Alliance, Lannett will be the exclusive U.S. marketer and distributor for Dantrolene Capsules. Elite will manufacture and Lannett will purchase Dantrolene Capsules from Elite and then sell and distribute them. In addition to the purchase prices for the products Elite will receive license fees in excess of 50% of net profits. Net profits is defined as net sales less the price paid to Elite for the products, distribution fees (less than 10%) and shipping costs. The Lannett-Elite Product Alliance has an initial term of three years and automatically renews for one year periods absent prior written notice of non-renewal. In addition to customary termination provisions, the Agreement permits Lannett to terminate with regard to a product on at least six months' prior written notice and it permits Elite or Lannett to terminate with regard to a product if at anytime after the first twelve months from the first commercial sale, the average license fee paid by Lannett for such product is less than \$300,000 for a six month sales period.

NOTE 22. RELATED PARTY AGREEMENTS WITH MIKAH PHARMA LLC

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

On May 22, 2017, the Company executed an assignment agreement with Mikah, pursuant to which the Company acquired all rights, interests and obligations under a manufacturing and supply agreement with Epic originally entered into by Mikah on June 30, 2015 and relating to the manufacture and supply of Trimipramine (the "Epic Trimipramine Manufacturing Agreement"). Pursuant to this agreement, Epic manufactured Trimipramine under license from Elite. In September 2018, Elite successfully transferred manufacturing of Trimipramine to the Northvale Facility, resulting in the irrelevance of the Epic Trimipramine Manufacturing Agreement. Trimipramine is currently manufactured by Elite.

Mikah is owned by Nasrat Hakim, the CEO, President and Chairman of the Board of the Company.

The Reddy's Distribution Agreement was concluded by mutual consent in August 2018.

Trimipramine is one of the products included in the Glenmark Strategic Alliance and is currently marketed and distributed by Glenmark.

NOTE 23. INCOME TAXES

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

	Years ended March 31,	
	2019	2018
Federal		
Current	\$ -	\$ -
Deferred	-	-
State		
Current	3,000	(5,500)
Deferred	-	-
Benefit from sale of state net operating loss credits	673,016	1,051,329
Net benefit from sale of state net operating loss credits	<u>\$ 676,016</u>	<u>\$ 1,045,829</u>

The major components of deferred tax assets and liabilities at March 31, 2019 and 2018 are as follows (amounts in thousands of dollars):

	Years ended March 31,	
	2019	2018
Federal		
Net operating loss carry forward	\$ 21,005	\$ 19,213
Valuation allowance	(21,005)	(19,213)
	<u>\$ -</u>	<u>\$ -</u>
State		
Net operating loss carry forward	\$ 2,239	\$ 1,796
Valuation allowance	(2,239)	(1,796)
	<u>\$ -</u>	<u>\$ -</u>

At March 31, 2019 and 2018 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, 2019, Elite has a federal net operating loss carryforward of \$100,024,740 and net operating loss carryforward in state tax jurisdictions of \$24,873,437 some of which will begin to expire in 2020.

NOTE 24. SUBSEQUENT EVENTS

The Company has evaluated subsequent events from the balance sheet date through June 21, 2019. The following are material subsequent events:

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

Subsequent to March 31, 2019 and up to June 7, 2019 (the latest practicable date), a total of 3,541,942 shares of Common Stock were issued to Lincoln Park, with such shares consisting of 3,500,000 purchase shares and 41,942 additional commitment shares. Total proceeds from these transactions was \$302,800.

EXPLANATORY NOTE: [] INDICATES THE PORTION OF THIS EXHIBIT THAT HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IN PUBLICLY DISCLOSED.**

**LICENSE, SUPPLY
AND DISTRIBUTION AGREEMENT**

FOR DANTROLENE CAPSULES

ELITE PHARMACEUTICALS, INC.,

ELITE LABORATORIES, INC.,

- and -

LANNETT COMPANY, INC.

Dated as of April 9, 2019

EXPLANATORY NOTE: [] INDICATES THE PORTION OF THIS EXHIBIT THAT HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IN PUBLICLY DISCLOSED.**

THIS LICENSE, SUPPLY AND DISTRIBUTION AGREEMENT made as of April 9, 2019 (the “**Effective Date**”), by and between ELITE PHARMACEUTICALS, INC. a Nevada corporation and ELITE LABORATORIES, INC., Delaware corporation located at 165 Ludlow Avenue, Norwood, New Jersey 07647 (collectively, “**ELITE**”), and LANNETT COMPANY, INC., USA, a Delaware corporation located at 9000 State Road, Philadelphia, Pennsylvania 19136 and/or its Affiliates (“**LANNETT**”).

WHEREAS:

- A. ELITE has ownership rights to Products and/or ANDAs specified in Schedule A (the “Products”) and LANNETT wishes to license from ELITE the exclusive rights to market and sell the Products on the terms and conditions set forth in this Agreement.
- B. ELITE has significant experience in developing, manufacturing and marketing finished dosage forms of pharmaceutical products, including the Products;
- C. LANNETT has significant experience in marketing pharmaceutical products; and
- D. Subject to the terms and conditions of this Agreement, LANNETT desires to engage ELITE on an exclusive basis to manufacture, supply, package and label the Products and ELITE agrees to grant LANNETT the right under this Agreement to commercialize the Products in the Territory on an exclusive basis.

NOW, THEREFORE in consideration of the mutual covenants and obligations contained herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereto agree as follows:

ARTICLE 1 - DEFINITIONS

- 1.1 In addition to terms defined elsewhere in this Agreement, the terms set forth below shall be defined in this Agreement (including the recitals) as follows:
 - (a) “**Affiliate**” with respect to either Party means any Person who directly or indirectly through one or more intermediaries controls, is controlled by, or is under common control with such Party. The term “control” means the beneficial (direct or indirect) ownership of more than fifty-percent (50%) of the voting or equity interests of such Person or the power or right to direct the management and affairs of its business, whether through the ownership of voting securities, by contract, or otherwise.
 - (b) “**Agreement**” means this License, Supply and Distribution Agreement, together with all schedules hereto.
 - (c) “**Analytical Specifications**” has the meaning given in **Article 4.1(a)**.
 - (d) “**ANDA**” means an Abbreviated New Drug Application pursuant to Section 505(j) of the FDCA.
 - (e) “**Bankruptcy Code**” has the meaning given in **Article 14.16**.

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- (f) “**Business Day**” in relation to each Party means any day other than a Saturday, a Sunday, or any statutory or public holiday on which banks are generally closed for regular business in New York, New York.
- (g) “**Certificate of Analysis**” means a certificate of analysis that certifies that a given batch of Product meets the release Product Specifications.
- (h) “**Claim**” means any claim, action, cause of action, or demand.
- (i) “**Commercially Reasonable Efforts**” with respect to any activity means the efforts and resources that would be used in the performance of the relevant activity in compliance with Law by a Person (engaged in the manufacture and supply or distribution, sale and commercialization of pharmaceutical products, as applicable) of comparable size and resources as the applicable Party with regard to a product at a similar stage in its product life taking into account the following factors to the extent reasonable and relevant: issues of safety and efficacy, product profile, market potential, competitive market conditions, duration of exclusivity or other proprietary position of the product and the potential profitability and economic return of the product, all as measured by the facts and circumstances at the time such efforts are due.
- (j) “**Confidential Information**” has the meaning given in **Article 12.2**.
- (k) “**DEA**” shall mean the United States Drug Enforcement Administration or any successor entity.
- (l) “**Debarred Entity**” has the meaning given in **Article 9.2(c)**.
- (m) “**Debarred Individual**” has the meaning given in **Article 9.2(c)**.
- (n) “**Distribution Fees**” means [**] percent ([**]%) of Net Sales for all Products.
- (o) “**Effective Date**” has the meaning given in the preamble.
- (p) “**Facility**” means the ELITE FDA-approved manufacturing site located at 135/165 Ludlow Avenue, Northvale, NJ, USA 07647.
- (q) “**FDA**” means the United States Food and Drug Administration or any successor government agency.
- (r) “**FDCA**” means the Federal Food, Drug, and Cosmetic Act.
- (s) “**Force Majeure Event**” has the meaning given in **Article 14.5**.
- (t) “**ELITE**” has the meaning given in the preamble.
- (u) “**GMP**” means current good manufacturing practices for the manufacture of finished pharmaceutical products in effect within the Territory from time to time during the Term of this Agreement, which set minimum standards to ensure that pharmaceutical products meet established requirements for identity, strength, quality and purity, as established under the Laws of the Territory, including 21 C.F.R. Parts 210 and 211.

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- (v) “**Gross Sales**” means the gross amount invoiced by LANNETT or its Affiliates or sublicensees for sales of the Product to Third Parties in the Territory.
- (w) “**Indemnitee**” has the meaning given in **Article 11.3**.
- (x) “**Indemnitor**” has the meaning given in **Article 11.3**.
- (y) “**Intellectual Property Rights**” means any patent, trademark, copyright, trade secret, right in unpatented know-how, right of confidence and any other intellectual or industrial property right of any nature whatsoever in any part of the world, whether registered or unregistered.
- (z) “**LANNETT**” has the meaning given in the preamble.
- (aa) “**Law**” means any federal, state, provincial and local laws, statutes, regulations, rules, guidelines, orders, ordinances, and any other requirements of any government or Regulatory Authority in the Territory applicable to the development, registration, manufacturing, testing, packaging, storing, shipping, marketing, distribution and sale of pharmaceutical products or as otherwise applicable to the Parties respective obligations under this Agreement, including the FDCA.
- (bb) “**Losses**” means any damages, liabilities, obligations, costs, expenses or losses, including reasonable legal fees and expenses, court costs, penalties, fines, costs of investigation and amounts paid in settlement of claims.
- (cc) “**Major Change**” shall mean a change that has the potential to adversely impact quality, identity, purity or stability of the Products or the compliance and validity of the Products Marketing Authorizations, as these factors may relate the safety or efficacy of the Product and as defined in the FDA regulations and guidance.
- (dd) “**Marketing Authorization**” means all approvals, licenses, registrations or authorizations of any Regulatory Authority, necessary for the manufacturing, use, storage, import, transport, marketing, promotion and sale of the Product in the Territory, together with pricing or reimbursement approval in countries where governmental approval is required for pricing or for the Product to be reimbursed by national health insurance.
- (ee) “**Net Sales**” shall mean with respect to the Product, Gross Sales less the following items (whether or not separately stated on such invoice but only to the extent included in Gross Sales):
 - (i) Any and all promotional allowances, rebates, charge backs, quantity and cash discounts, and other usual and customary discounts to customers;

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- (ii) Amounts refunded, repaid or credited by reason of rejections, returns or recalls of goods;
- (iii) Any sales, excise, turnover, inventory, value-added, and similar taxes and duties assessed on applicable sales;
- (iv) Failure to Supply penalties (in the case if Article 4.4 (i) and (ii)), Non-affiliate third party administrative fees granted, Medicaid and state and/or governmental rebates, and shelf stock adjustments and retroactive price reductions.

Components of Net Sales shall be determined using the accrual method of accounting in accordance with US GAAP or an equivalent stipulated method of accounting in the Territory.

- (ff) “**Net Profits**” is calculated as listed in Schedule C and means the Net Sales of a Product, minus the sum of (i) the Distribution Fee, (ii) Transfer Price of Product and (iii) shipping costs from the Facility.
- (gg) “**Non-Conforming Product**” has the meaning given in **Article 4.8(b)**.
- (hh) “**Original Agreement**” has the meaning given in Recital A.
- (ii) “**Packaging**” means all material used to prepare fully packaged Products, including labeling, containers, closures, cartons, and shipping cases, as applicable.
- (ij) “**Parties**” means the parties to this Agreement referred to collectively, and “**Party**” means either party to this Agreement referred to individually.
- (kk) “**Person**” includes any individual, partnership, corporation, unincorporated organization or association, joint venture, limited liability company, trust or any other form of entity.
- (ll) “**Safety Data Exchange Agreement or SDEA**” means the pharmacovigilance agreement to be entered into by the Parties which shall set forth the safety data exchange procedures to be followed by the Parties for the collection, investigation, reporting and exchange of information concerning adverse events.
- (mm) “**Products**” means the finished pharmaceutical products in commercially saleable form, as manufactured by ELITE exclusively supplied to LANNETT pursuant to this Agreement as set forth on Schedule A.
- (nn) “**Purchase Order**” means a written, binding purchase order for a certain quantity of Product properly issued by LANNETT in accordance with the terms of this Agreement.
- (oo) “**Quality Agreement**” means a quality agreement to be entered into by the Parties which will set forth certain obligations of the Parties in relation to the manufacture, packaging, quality control and testing of the Products in accordance with GMP.

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- (pp) “**Recall**” shall mean a recall, removal, market withdrawal, seizure, or field correction of Product.
- (qq) “**Regulatory Authorities**” means any federal, state, local or international regulatory agency, department, bureau or other governmental entity responsible for regulating the manufacture, use, storage, importation, transportation, distribution marketing, promotion and sale of pharmaceutical products in the Territory, including the FDA and DEA.
- (rr) “**Regulatory Approval**” means all approvals or authorizations granted by the FDA for marketing the Products in the Territory.
- (ss) “**Specifications**” means the written methods, formulae, procedures, specifications, tests (and testing protocols) and standards pertaining to the Products as approved by FDA in the Product’s ANDA and attached herein as Schedule B, which may be amended from time-to-time by the written agreement of the Parties.
- (tt) “**Term**” has the meaning given in **Article 8.1**.
- (uu) “**Territory**” means the United States of America and its possessions, territories, protectorates, military bases and commonwealths.
- (vv) “**Third Party**” means any Person other than LANNETT or ELITE, or any of their respective Affiliates.
- (ww) “**Trademarks**” has the meaning given in **Article 4.3(a)**.
- (xx) “**Transfer Price**” is listed and defined in Schedule A.

1.2 Interpretation of “Include”: Where the words “include”, “includes” or “including” are used in this Agreement, they shall mean, respectively, “include without limitation”, “includes without limitation”, “including but not limited to”, or “including without limitation”.

ARTICLE 2 - MARKETING AUTHORIZATIONS

- 2.1 Subject to the terms of this Agreement, ELITE shall exclusively manufacture, supply, package and label the Products for LANNETT, and LANNETT shall have the right to promote, market, store, distribute and sell the Products in the Territory. ELITE hereby grants to LANNETT and its Affiliates an exclusive right to fully commercialize the Products in the Territory. LANNETT agrees to exclusively purchase Products it requires from ELITE.
- 2.2 ELITE shall, at their expense, maintain and update the Marketing Authorizations for the Products as may be required for the Parties to perform their obligations hereunder. ELITE shall be solely responsible for all communications with the Regulatory Authorities in the Territory relating to any Marketing Authorizations for the Products. ELITE shall provide LANNETT with timely notice of any communications from the Regulatory Authorities which may affect ELITE’s right or ability to supply LANNETT with the Products.

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ARTICLE 3 - PAYMENT TERMS

- 3.1 Transfer Price. ELITE shall sell each Product to LANNETT at the prices set forth in Schedule A, which Transfer price shall be inclusive of all costs and expenses associated with the manufacture, supply, packaging, labeling of the Product to LANNETT.
- 3.2 Upon delivery of the Products to LANNETT, ELITE shall submit invoices therefore to LANNETT. LANNETT shall pay each undisputed invoice in full within thirty (30) days of its receipt in full of the Products reflected in the invoice and the Certificate of Analysis, which Certificate is in a form sufficient for release of the Products. A late payment fee of one percent (1%) per month may be imposed upon LANNETT for payments past due unless Products therein are subject to a quality dispute. In the event of any inconsistency between an invoice and this Agreement, the terms of this Agreement shall control.
- 3.3 License Fees. Within forty-five (45) days of the end of each calendar quarter, LANNETT shall pay to ELITE a License Fee from the date of commercialization of the Products through June 30, 2020, of [**] percent ([**]%) of the Net Profits received from sales of each Product. For the year July 1, 2020 through June 30, 2021 and each year thereafter, LANNETT shall pay to ELITE a License Fee of either (a) [**] percent ([**]%) of the Net Profits received from sales of each Product; or (b) if LANNETT receives [**] dollars (\$[**]) or more in Net Profits during such year, [**] percent ([**]%) of the Net Profits received from sales of each Product, with such higher percentage being paid on only such amount exceeding the [**] dollars (\$[**]). Such payment shall additionally include a sales summary for each Product generally in the format as provided in Schedule C. In no case shall the License Fee for any calendar quarter be negative; provided, however in the event of a loss in any calendar quarter, subject to ELITE's written approval of any Product pricing by LANNETT that leads to quarterly losses and subject to the loss carryover clause that follows, the amount of that loss shall be carried forward to subsequent calendar quarters until the amount of such loss has been fully absorbed. In the event that Net Profits for calendar quarter are negative, LANNETT shall carry over the applicable License Fee percentage set forth above multiplied by the value by which the Net Profits are negative in such calendar quarter and deduct this amount from the calculation of Net Sales for the following calendar quarter. If Net Profits are negative in two (2) or more consecutive calendar quarters, LANNETT shall invoice ELITE the applicable License Fee percentage set forth above multiplied by the value by which the Net Profits are negative for the previous calendar quarter and carry over the applicable License Fee percentage set forth above multiplied by the value by which Net Profits are negative for the current calendar quarter and deduct this amount from the calculation of Net Sales for the following calendar quarter. For the avoidance of doubt, if Net Profits are negative in subsequent calendar quarters, the amounts will be similarly carried over or reimbursed as per the terms set forth in this Section 3.3 until Net Profits are positive. Reimbursement of negative Net Profits owed by ELITE in this Section 3.3 shall be payable to LANNETT within forty-five (45) days after receipt of an invoice from LANNETT.

ARTICLE 4 - MANUFACTURING AND SUPPLY; COMMERCIALIZATION

- 4.1 Supply of Products.
- (a) During the Term of this Agreement, ELITE shall use Commercially Reasonable Efforts to manufacture, timely supply, package and label for delivery to LANNETT the Products in accordance with any Purchase Orders issued by LANNETT under the terms of this Agreement. Purchase Orders shall include the shipping instructions in accordance with Schedule D hereto. ELITE shall manufacture, supply, package and label the Products in compliance with all Laws, including the GMPs, the Marketing Authorization, the Quality Agreement, and the Specifications ("**Analytical Specifications**").

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- (b) ELITE shall manufacture the Products in the Facility and use Commercially Reasonable Effortsto maintain access to sufficient supplies of raw materials, components and other required resources to perform its obligations under this Agreement, and meet LANNETT's supplyrequirements for the Products. ELITE shall not manufacture the Products at a site otherthan the Facility without first obtaining LANNETT's prior written consent, whichconsent shall not be unreasonably withheld. ELITE shall be solely responsible for all costs and expenses incurred in connection with the manufacture of the Products hereunder, including without limitation costs and expenses of personnel, quality control, testing, manufacturing, facilities, equipment, materials, FDA product fees, FDA establishment fees and government sales, use, excise, property or similar taxes or excises.
- (c) ELITEshall have procedures in place to ensure that the oldest approved inventory of the Products is distributed first. In addition, each Party shall maintain a tracking system by whichthe distribution of each lot of the Products may be readily determined to facilitate its Recall if necessary.
- (d) Transfer Price Adjustments. The Transfer Prices for the Products underSchedule A are valid through December 31, 2019. After December 31, 2019, the Transfer Price for Products maybe adjusted for any increase in the cost of active pharmaceutical ingredients, annual Generic Drug User Fees (GDUFA fees) proportional allocation, and other materiae government mandated requirements. ELITE shall provide at least thirty (30) days written notice toLANNETT for any such Transfer Price adjustments with justifications for any increase. ELITE shall use commercially reasonable efforts to reduce its manufacturing expenses for the Products. At either Party's written request, the Parties will discuss ingood faith the revision of the Transfer Price (and any subsequently agreed prices) to take into account adverse market conditions resulting in unsatisfactory returns for LANNETT or changes in the manufacturing costs for the Products. The revised Transfer Price shall be laid down in writing and inserted as an amended Schedule A to this Agreement. Confirmed orders are excluded from Transfer Price negotiations. If, after good faith negotiations, the Parties are unable to reach agreement on an adjustment to the Transfer Pricing for the Products, then LANNETT shall be entitled to terminate this Agreementeffective upon at least sixty (60) days' prior written notice to ELITE.
- (e) The Parties shall enter into a Safety Data Exchange Agreement and Quality Agreement. Therespective roles and responsibilities for quality assurance personnel of the Parties in carrying out the transactions pursuant to this Agreement shall be defined and stipulated in the Quality Agreement. The fully executed SDEA (SDEA) and Quality Agreement are heret incorporated and made a part of this Agreement by reference. In the event of any inconsistency between the provisions of the SDEA and the provisions of this Agreement, the wordingof the SDEA shall govern any and all patient safety matters and this Agreement shall govern all other matters. The Parties hereby acknowledge and agree that in the event of any conflict between the terms of this Agreement and the terms of the Quality Agreement, this Agreement shall control with respect to all issues (other than with respect to all quality matters), and the Quality Agreement shall control with respect to all quality matters.

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4.2 Master Production Plan and Purchase Orders On or before fifteen (15) days prior to the end of each calendar quarter during the Term, LANNETT shall deliver to ELITE a master production plan which covers a twelve (12) month period, which includes three (3) months binding purchase order, and nine (9) months non-binding forecast (the “**Master Production Plan**”). The first three months (beginning with the first month following the month in which the Master Production Plan is due) of each Master Production Plan shall be deemed to be a binding purchase order (the “**Binding Forecast**”). Months four (4) through twelve (12) of the Master Production Plan shall be LANNETT’s non-binding, good faith estimate of such requirements based on forecasted trade and LANNETT shall have the ability to adjust the quantities forecast. Unless the Parties otherwise agree in writing, all firm orders for Product (the “**Purchase Order**”) placed shall specify: (i) the type of Product being ordered; (ii) the amount of such Product being requested (which shall be in whole batch size quantities); and (iii) the requested delivery date which, unless otherwise agreed by ELITE in writing, shall be not less than ninety (90) days after receipt of the Purchase Order. Each Master Production Plan and accompanying binding Purchase Order shall be deemed to be automatically accepted unless ELITE notifies LANNETT of its rejection of the same within four (4) Business Days of receipt. ELITE may only reject a Purchase Order if a Purchase Order is not consistent with the terms of this **Article 4.2** or is not timely delivered. Once a Purchase Order is accepted by ELITE, ELITE shall be obligated to timely manufacture, supply, package, label, and have ready for delivery the full quantities of Products set forth in the Purchase Order by the required delivery date at the Facility. In the event that the terms of any Purchase Order are not consistent with, or attempt to modify, the terms of this Agreement, the terms of this Agreement shall prevail. If LANNETT requests changes to a Purchase Order after receipt thereof by ELITE, ELITE shall use Commercially Reasonable Efforts to comply with such changes. ELITE shall use commercially reasonable efforts to supply up to one hundred twenty-five percent (125%) of LANNETT’S requirement forecast of Products for the applicable period.

4.3 Delivery Terms.

- (a) LANNETT shall provide ELITE packaging specifications and related materials that comply with FDA requirements and the Parties will finalize all packaging by the time of the first Purchase Order. If requested by LANNETT, ELITE shall affix on the Product and/or on the label and/or the packages certain proprietary or registered marks, logos or insignia relating to the Product in accordance with the directions and specifications given by LANNETT along with any other marks, logos or insignia, as LANNETT may stipulate from time to time (collectively, “**Trademark**”). Pursuant to the aforesaid, LANNETT hereby grants to ELITE, a non-exclusive, non-transferable, non-assignable and non-sublicensable right to the Trademarks, solely for the purpose of affixing such Trademarks to the Product in accordance with LANNETT’S directions and specifications during the Term. LANNETT shall have sole approval authority over all Product labeling and packaging specifications of the Products supplied to LANNETT pursuant to this Agreement.

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- (b) ELITE shall deliver the full quantities of the Products set forth in each Purchase Order (Incoterms2010 EXW) to LANNETT or its designee. All Products shall be packaged for shipment in accordance with the packaging specifications set forth in the Marketing Authorizations and packing instructions reasonably required by LANNETT.
- (c) Each Products shipment made by ELITE shall be accompanied by and shall include a Certificate of Analysis for each shipment of the Products manufactured and supplied hereunder. ELITE shall be responsible for all applicable release testing of the Products in accordance with the Analytical Specifications. ELITE shall perform all required in-process quality control tests and quality assurance reviews on the Products, including without limitation, stability testing at its sole cost and expense. In addition, ELITE shall furnish LANNETT, along with the first shipment of the Products, ELITE's Material Safety Data Sheets containing the relevant safety and health information and such other similar information as LANNETT may reasonably request in connection therewith.
- (d) All Products provided to LANNETT shall have no less than eighty five percent (85%) remaining shelf-life remaining as per the Product's ANDA.
- (e) All orders containing at least ninety percent (90%) of the specified amount of Product in a given Purchase Order shall be deemed satisfied.

4.4 Failure to Supply. ELITE shall notify LANNETT as promptly as possible, but in no event later than five (5) Business Days, after ELITE discovers that it will not be able to supply the quantity of Products ordered by the delivery date specified in a Purchase Order. In such event: (i) ELITE shall cooperate with LANNETT in taking all actions that LANNETT deems reasonably necessary in order to remedy such inability to supply, at ELITE's expense; and (ii) If ELITE's inability to supply continues past twenty (20) days from the required delivery date set forth in the Purchase Order at LANNETT's election any or all outstanding Purchase Orders relating to such Product may be cancelled and LANNETT shall have no obligation with respect to such Purchase Orders; provided, however, ELITE must cover any Failure to Supply (as defined below) obligations set forth in this Section. Compliance by ELITE with this **Article 4.4** shall not relieve ELITE of any other obligation or liability under this Agreement. LANNETT shall otherwise retain all of its rights under this Agreement and/or at law against ELITE for its failure to deliver all or any portion of the quantity of Products ordered by LANNETT. With regard to a Binding Forecast or if ELITE accepted a Purchase Order from LANNETT, pursuant to the procedures defined in Section 4.2 of this Agreement, then ELITE shall be responsible for the late charges and any penalties assessed against LANNETT by its Customers or any other third party or any costs, fees, charges, or penalties incurred by Lannett ("Failure to Supply"), unless the delay is attributable to (i) action or controls imposed by the DEA that do not result from ELITE's negligence, gross negligence or willful misconduct or (ii) demonstrable raw material shortages that are beyond ELITE's control, but ELITE will use commercially reasonable efforts to keep three (3) to six (6) months of raw materials inventory on hand at all times. Late charges and any penalties assessed against ELITE by LANNETT under this paragraph are due and payable within thirty (30) days of being invoiced by LANNETT and, if not timely paid, may be deducted against amounts owed by LANNETT to ELITE.

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- 4.5 Samples and Batch Records. ELITE shall prepare and maintain batch records and file samples, properly stored, for each lot or batch of Products manufactured and shipped hereunder in compliance with all GMPs and Laws in the Territory.
- 4.6 Commercialization. LANNETT shall use Commercially Reasonable Efforts to market and sell the Products in the Territory. All commercial matters regarding the marketing, promotion, sale, offer for sale, pricing or distribution of the Products in the Territory shall be under the exclusive control of LANNETT.
- 4.7 Change of Specification. No alterations of the Specifications for the Products or other changes requiring prior approval by the FDA, or material changes to the manufacturing process or validated processes, can be made without the prior written approval of LANNETT. ELITE shall notify LANNETT in writing of any proposed alterations for the Specifications for the Products or any Major Changes to the manufacturing process or validated processes. LANNETT shall notify ELITE of LANNETT's decision within thirty (30) days of receipt of such proposal from ELITE. If ELITE does not receive LANNETT's decision in writing within thirty (30) days, the alteration of the Specifications or other Major Changes to the manufacturing process or validated process proposed by ELITE shall be deemed rejected by LANNETT. In the event that the FDA or any other governmental authority shall suggest or mandate any change or revision to the Product, such that the Specifications would no longer comply with such suggestion or mandate, the Parties shall work together in good faith to develop revised Specifications that meet all changes or revisions suggested or mandated by the FDA or other governmental authority and Schedule B shall be amended in writing to set forth the new agreed upon Specifications.
- 4.8 Acceptance of the Product.
- (a) Following receipt of a shipment of Product at the final destination, LANNETT, or its designee, shall conduct a visual inspection of the Product and all accompanying documents provided by ELITE, including without limitation, the Certificate of Analysis, in accordance with its customary procedures. LANNETT shall advise ELITE, in writing, if it is rejecting shipment of Product due to obvious physical damage or obvious packaging defect that are evident upon such visual inspection of the packaged Product as shipped by ELITE. LANNETT (and its designees) shall have no obligation to inspect the Product beyond the visual inspection provided for in this **Article 4.8(a)**.
 - (b) In the case of defects other than those obvious defects described in **Article 4.8(a)**, including, by way of example, any failure of the Product, at the time of delivery, to meet the Analytical Specifications and the representations, warranties and covenants of **Article 9.2(f)**, LANNETT shall promptly notify ELITE if it becomes aware of such non-obvious defect(s). Any defect in physical condition of Products delivered by ELITE or Products that do not conform with the Analytical Specifications (as may be in effect from time to time) or the representations, warranties and covenants of **Article 9.2(f)** for any reason shall be deemed to be a non-conforming product ("**Non-Conforming Product**"). LANNETT, or its designee, shall have the right to reject any Non-Conforming Product and no failure on the part of LANNETT, or its designee, or passage of time shall prejudice LANNETT's right to reject or revoke acceptance of Non-Conforming Product. All Non-Conforming Product shall be returned to ELITE at its sole cost and expense.

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- (c) If ELITE confirms the Non-Conforming Product or lab testing pursuant to **Article 4.8(d)** determines that the Product is Non-Conforming Product, ELITE shall, at LANNETT's election, either replace such Non-Conforming Product with conforming Product or, refund to LANNETT, the price paid for such Non-Conforming Product.
- (d) If the Parties cannot agree as to whether a delivered quantity of Product is Non-Conforming Product, then the Parties agree to have the batch in dispute tested and further analyzed by a recognized independent testing laboratory selected by the Parties or a quality consultant (if not a laboratory analysis issue). The appointment of such laboratory or quality consultant shall not be unreasonably withheld or delayed by either Party. The decision of the laboratory or quality consultant shall be in writing and, save for manifest error on the face of the decision, shall be binding on both Parties. Should said laboratory's testing or quality consultant determine that the Product is Non-Conforming Product then ELITE will bear the cost of such testing or quality consultant and comply with the terms of **Article 4.8(c)**. If said Product is determined to have been conforming, then LANNETT shall bear all costs of the independent laboratory testing or quality consultant as well as accept the Product shipment and pay for same within forty-five (45) days of such acceptance.

ARTICLE 5 - INSPECTIONS

- 5.1 Inspections. During the Term of this Agreement and thereafter in the event of a Claim against either Party regarding use of the Products is threatened or commenced, ELITE shall permit LANNETT's representatives to enter ELITE's facilities, upon reasonable prior notice (except in the event of a for-cause audit) and during normal business hours, for the purpose of inspecting the facility and quality control procedures and confirming compliance with all applicable GMPs and Laws in the Territory, the requirements of the Regulatory Authorities in the Territory, the Quality Agreement and this Agreement. If during any such inspection LANNETT discovers any instances in which ELITE has not complied with the foregoing, then ELITE shall promptly provide to LANNETT a written plan for correcting such deficiencies, including a proposed timetable for implementing such corrections, and shall ensure that such deficiencies are corrected, at ELITE's sole expense, as soon as reasonably practicable. ELITE agrees to provide LANNETT with copies of all: (i) reasonably requested documentation in its possession relating to the manufacture of Product, Specifications, compliance with quality assurance standards, raw material vendors and manufacturing processes; and (ii) U.S. and international regulatory approvals, regulatory inspections of the manufacturing process, facilities and documentation, and other communications with Regulatory Authorities related to the Product; however ELITE shall not be required to provide copies to LANNETT of ELITE's proprietary information and ELITE shall only be required to allow LANNETT to inspect such proprietary information such as batch records at ELITE's site and under ELITE's supervision. Notwithstanding the provision of this **Article 5.1**, LANNETT shall have no obligation or be deemed to have an obligation to inspect ELITE's facilities.
- 5.2 Regulatory Authority Inspections. ELITE shall permit any Regulatory Authority to inspect the facility used to manufacture the Products and all associated records to the full extent permitted by applicable Law ("**Regulatory Inspection**"). ELITE shall notify LANNETT within forty-eight (48) hours of becoming aware of any planned or actual Regulatory Inspection. ELITE agrees to reasonably cooperate with the applicable Regulatory Authority in connection with such audits. ELITE shall notify LANNETT prior to the commencement of any meetings with, or inspection activity by, any Regulatory Authority, unless such inspection activity is an unannounced inspection. Further, ELITE shall provide a reasonable description to LANNETT of any such governmental inquiries, notifications or inspections related to Products promptly (but in no event later than five (5) calendar days) after such visit or inquiry. ELITE shall furnish to LANNETT: (i) within five (5) calendar days after receipt, any report or correspondence issued by the Regulatory Authority in connection with such visit or inquiry, including but not limited to, any FDA Form 483, establishment inspection report, or warning letter; and (ii) copies of any and all responses or explanations to any Regulatory Authority relating to items set forth above prior to the submission of such responses or explanations to any Regulatory Authority by ELITE for comment, which comments shall be taken into consideration by ELITE in good faith. ELITE shall also provide LANNETT with a copy of all final responses.

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ARTICLE 6 - RECORDS

- 6.1 Records. ELITE and LANNETT shall maintain all records necessary to comply with all applicable Laws in the Territory relating to the performance of their respective obligations under this Agreement. ELITE shall also maintain, or cause to be maintained (i) all manufacturing records, standard operating procedures, validation records, equipment log books, batch records, laboratory notebooks and all raw data relating to the manufacturing of the Products, and (ii) such other records as LANNETT may reasonably require in order to ensure compliance by ELITE with the terms of this Agreement. All such records shall be maintained for such period as may be required pursuant to the applicable Laws.
- 6.2 Inspection of ELITE Books and Records. During the Term of this Agreement, and thereafter for the greater of (i) the period stipulated by the Laws in the Territory, and (ii) two (2) years from the expiration of the last Products manufactured, ELITE agrees that LANNETT at reasonable times upon reasonable prior notice, may inspect the research and development books and records of ELITE pertaining to ELITE's obligations under this Agreement for purposes of ensuring compliance with the terms of this Agreement.
- 6.3 Inspection of LANNETT Books and Records LANNETT shall keep, and shall require its Affiliate to maintain, in connection with the handling, sale, and distribution of the Product hereunder, books and records necessary to allow the accurate calculation, consistent with GAAP, of the amounts due to ELITE, the reporting obligations contemplated herein, and compliance with the terms of this Agreement, and LANNETT shall maintain such book and records for a period of at least two (2) years after the end of the calendar year in which they were generated, or for such longer period as may be required by Applicable Law. Upon at least thirty (30) days prior written notice, ELITE, at its expense, shall have the right to have an independent public accounting or auditing firm, reasonably acceptable to LANNETT, obtain access to such books and records as may be reasonably necessary to determine or verify the amount of payments due under this Agreement and compliance with the obligations hereof; provided, however, that this right may not be exercised more than once in any calendar year. Such accounting firm shall conduct such examination, and LANNETT shall make such books and records available, during normal business hours at the facility(ies) where such books and records are customarily maintained. Each such examination shall be limited to pertinent books and records for any year ending not more than twenty-four (24) months prior to the date of request, except that ELITE shall not be permitted to audit the same period of time more than once. The independent accounting firm will prepare and provide to each Party a written report stating whether the reports submitted and amounts paid are correct or incorrect and the amounts of any discrepancies. The conclusions of such accounting firm shall be final and binding on the Parties absent demonstrable error. If there was an underpayment by LANNETT hereunder, LANNETT shall promptly (but no event later than thirty (30) days after its receipt of the independent auditor's report so concluding) make payment to ELITE of any shortfall by wire transfer in U.S. dollars, plus interest on the amount of such shortfall calculated at the lesser of (a) five percent (5%) per annum, or (b) the maximum rate permitted by law from the date such payment should have been made to the date the shortfall is paid. If there was an overpayment by LANNETT hereunder, ELITE shall promptly (but in no event later than thirty (30) days after ELITE's receipt of the independent auditor's report so concluding) refund to LANNETT the excess amount by wire transfer in U.S. dollars. All cost of the audit, including the expenses of the independent accounting firm, shall be borne by ELITE unless the underpayment by LANNETT results in a cumulative discrepancy during any calendar year in excess of the greater of (i) ten percent (10%) of the total amount reported to ELITE for the period or (ii) one hundred thousand dollars (\$100,000.00), in which case all reasonable and documented costs of the audit, including the expenses of the independent accounting firm, shall be borne and promptly paid by LANNETT. ELITE shall ensure that the independent public accountant or auditor maintains the confidentiality of LANNETT's Confidential Information on terms no less restrictive than those set forth in this Agreement.
- 6.4 Annual Reports. ELITE shall provide LANNETT in a timely manner copies of ELITE's annual reports to the FDA or any other Regulatory Authority with respect to the Products.

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ARTICLE 7 - RECALLS

- 7.1 Notification of Recall. If any Regulatory Authority or other governmental agency issues or requests a Recall or takes similar action in connection with a Product in the Territory, or if LANNETT reasonably determines after consultation with ELITE that an event has occurred which may result in the need for a Recall, the Party notified of or wishing to implement such Recall shall, within forty-eight (48) hours (regardless of weekday, weekend or holiday), advise the other Party thereof by telephone or facsimile, after which the Parties shall promptly discuss and work together to effect an appropriate course of action. ELITE shall be responsible for notifying the Regulatory Authorities in the Territory of any voluntary Recall and implementing any Recalls. LANNETT shall fully cooperate with ELITE to fully implement any Recall. ELITE agrees to forward to LANNETT copy of any field communication associated with the Products that it plans to issue before such communication is issued or sent to any governmental agency. ELITE will maintain complete and accurate records of any activities conducted with respect to any Recall for such period as may be required by Law. Following any Recall, ELITE will review all of its procedures as impacted by the identified root cause in the associated investigation, and will revise such procedures, as necessary, to correct the cause of such Recall subject to the change control requirements set forth in the Quality Agreement. ELITE will provide LANNETT with such information regarding such review and revisions as LANNETT may request and ELITE shall provide LANNETT the right to approve, reject or request modifications to the proposed changes.
- 7.2 Recall Expenses. If a Recall results from the acts or omissions of one Party, then such Party shall bear the full expenses of both Parties incurred in the Recall. For clarity, if a Recall is due to a defect during the manufacture, processing, packaging or labelling of the Product prior to delivery, the cost and expense shall be borne solely by ELITE. If a Recall is partially caused by the actions or omissions of both Parties, then each Party shall be responsible for its proportionate share of the Recall expenses based on its proportionate share of causation. Recall expenses include the expenses of notification, shipping, return, replacement (if possible), customer fees and penalties, and destruction of recalled Products (including Products which cannot be shipped due to the condition causing the Recall). The Parties shall discuss in good faith and agree on the scope and costs of Recall, if practicable, prior to enforcement of the Recall.
- 7.3 Notice of Failure to Meet Specifications. If ELITE discovers that there is a potential that any batch or lot of the Products already delivered to LANNETT may fail to conform to the Specifications, then ELITE shall notify LANNETT within twenty-four (24) hours (one (1) business day), of such determination of failure to meet the Specifications and of the nature thereof in detail, including, but not limited to, supplying LANNETT with all investigatory reports, data and communications, out-of-specification reports and data and the results of all outside laboratory testing and conclusions, if any. ELITE shall investigate all such failures promptly, and at its sole expense, cooperate with LANNETT in determining the cause for the failure and a corrective action to prevent future failures.

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ARTICLE 8 - TERM & TERMINATION

- 8.1 Term. This Agreement shall commence upon the Effective Date, and, unless terminated earlier in accordance with the provisions hereof, shall continue for a period of three (3) years from the Effective Date (“**Initial Term**”). Unless earlier terminated pursuant to this Agreement, the Initial Term may be extended for successive one (1) year periods (“**Renewal Term**”) upon mutual agreement of the Parties in writing. The Initial Term and all Renewal Term (if any) are collectively referred to as the “Term.”
- 8.2 Termination. If any one or more of the following events of default shall occur, then this Agreement may be terminated as set forth herein:
- (a) if a Party files a petition in bankruptcy or is adjudged as bankrupt, or a petition in bankruptcy is filed against it and is not dismissed within sixty (60) days, or it becomes insolvent, takes advantage of legislation for creditor relief, has a receiver or receiver-manager appointed in relation to its assets, or discontinues its business, then the other Party may terminate this Agreement upon delivering written notice of termination;
 - (b) if a Party hereto violates or fails to perform any of its material undertakings, agreements, covenants or obligations under this Agreement (excluding matters otherwise specifically addressed with a termination right elsewhere in this Agreement) and the failure is not remedied within thirty (30) days after written notice from the non-defaulting Party, then the non-defaulting Party may terminate this Agreement upon delivering written notice of termination to the breaching Party; *provided* that if the breaching Party is diligently pursuing in good faith the remedy of the breach at the expiration of such thirty (30) day cure period, then such thirty (30) day cure period may be extended as reasonably required to effect the cure if agreed to by the non-defaulting Party;
 - (c) if a Party hereto willfully or fraudulently misrepresents any fact, information or report disclosed pursuant to this Agreement and such misrepresentation is not cured or remedied within thirty (30) days after the receipt of written notice thereof by the non-defaulting Party, then the other Party may terminate this Agreement upon delivering written notice of termination;
 - (d) if a court of competent jurisdiction makes a final determination that the marketing and sale of a Product in the Territory infringes the patent or other Intellectual Property Rights in the Territory of a third party and enjoins the marketing and sale of the Product in the Territory, and if all rights to appeal have been exhausted or expired, then LANNETT may, upon delivering written notice to ELITE, terminate this Agreement with respect to such Product;

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- (e) by ELITE or LANNETT, on a Product by Product basis, if any time after the first twelve (12) months from the first commercial sale, the average License Fee paid by Lannett is less than three hundred thousand dollars (US\$300,000) for a six (6) month sales period for that Product; and
- (f) Lannett will also have the right to suspend further performance under this Agreement and/or terminate this Agreement in its entirety, without liability except for unpaid previously delivered Products, if: (i) ELITE loses any approval(s) from the FDA required to perform its obligations under this Agreement; (ii) ELITE or its principals are involved in felonious or fraudulent activities related to Elite's business; or (iii) ELITE is unable to successfully address material deficiencies identified by the FDA that prevent Elite from manufacturing Product as a result of an inspection of ELITE'S facility within sixty (60) days after ELITE'S receipt of a deficiency notice from the FDA; or (iv) more than three (3) late shipments of the Products occur during any 12-month period during the Term. In any such event, LANNETT may terminate this Agreement immediately by written notice to ELITE. For purposes of this Section, a late shipment shall mean failure by ELITE to deliver to LANNETT ninety (90) percent (90%) of the Products ordered by LANNETT for delivery within twenty (20) days of the date specified for such delivery in the applicable Purchase Order.

8.3 Other Termination Rights. In addition to **Article 8.2**, (i) either Party may terminate this Agreement pursuant to **Articles 14.3** (Assignment without Consent) and **14.5** (Force Majeure), and (ii) LANNETT may terminate this Agreement pursuant to **Article 4.4** (Failure to Supply) and **Article 9.2(c)** (Debarred), and (iii) ELITE may terminate this Agreement pursuant to **Article 9.3(c)** (Debarred). LANNETT may terminate this Agreement for any reason upon providing ELITE with six (6) months written notice.

8.4 Effect of Termination. Upon termination or expiration of this Agreement, the provisions of this Agreement shall continue to apply with respect to the Parties' respective rights and obligations in relation to any Purchase Order made prior to such termination, including without limitation ELITE's obligation to manufacture, release and deliver Products to LANNETT, and LANNETT's obligation to make payment for such Products. If this Agreement is terminated while LANNETT is still in possession of Products (**Remaining Products**"), ELITE hereby grants LANNETT and its Affiliates a license to promote, market, distribute and sell the Remaining Products in the Territory, subject to the License Fees in Article 3.3.

8.5 Survival. The expiration or earlier termination of this Agreement shall not relieve either Party hereto from any obligations which accrued prior to such expiration or earlier termination, and shall not destroy or diminish the binding force and effect of any of the terms and conditions of this Agreement that expressly or by implication come into or continue in effect on or after termination or expiration, including **ARTICLE 1 - , ARTICLE 5 , ARTICLE 6 - , ARTICLE 7 - , Section 8.4, ARTICLE 9 - , ARTICLE 11 - , ARTICLE 12 - , Sections 14.6, and 14.7**. Further, the provisions from the Original Agreement that were deemed to survive the termination or expiration of that Agreement shall further survive.

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ARTICLE 9 - REPRESENTATIONS & WARRANTIES

9.1 Representations and Warranties. Each Party represents and warrants to the other Party as follows, which representations and warranties shall be true as at the date hereof and throughout the Term of this Agreement:

- (a) it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this Agreement; and
- (b) this Agreement is its legal, valid and binding obligation, enforceable in accordance with the terms and conditions hereof.

9.2 ELITE General and Supply Warranties. ELITE represents and warrants to LANNETT as follows:

- (a) No Other Agreements. No contracts, commitments or agreements of any nature exist, and none will be entered into during the Term of this Agreement, that impair or inhibit the ability of ELITE to perform its obligations hereunder.
- (b) No Lawsuits. As of the date hereof there have not been any Claims, lawsuits, arbitrations, legal or administrative or regulatory proceedings, charges, or complaints or investigations, by any third party or government authority threatened, commenced, pending or proceeding against ELITE, and ELITE has not received any notice thereof, which could prevent ELITE from complying with its material obligations under this Agreement.
- (c) Debarred. Neither ELITE nor any of its officers, directors, or employees or consultants performing services under this Agreement has been or is: (1) an individual who has been debarred by the FDA pursuant to 21 U.S.C. § 335a(a) or (b) (“**Debarred Individual**”) from providing services in any capacity to a person that has an approved or pending drug product application with FDA, or an employer, employee, or partner of such a Debarred Individual; or (2) a corporation, partnership or association that has been debarred by FDA pursuant to 21 U.S.C. § 335a(a) or (b) (“**Debarred Entity**”) from submitting or assisting in the submission of an ANDA, or an employee, partner, shareholder, member, subsidiary, or affiliate of a Debarred Entity; or (3) an employer, employee or partner of an individual convicted within the last five years for crimes described in subsections (a) or (b) of Section 306 of the FDCA. If and when ELITE becomes aware of any fact that makes or gives rise to make this representation and warranty untrue, ELITE shall immediately notify LANNETT in writing and any such breach may result in immediate termination of this Agreement by LANNETT.
- (d) Non-Infringement.
- (i) ELITE’s performance of its obligations hereunder to the best of ELITE’s knowledge does not and will not infringe any intellectual property rights of a third party.

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- (ii) To the best of ELITE's knowledge no patents, patent applications if issued, or any other proprietary rights of any third party would be infringed by the manufacture, use or sale of the Product and ELITE shall indemnify, defend and hold harmless LANNETT at its Affiliates against any and all such infringement claims, demands, actions, losses, damages, fines, penalties, costs and expenses (including reasonable attorneys' fees). The indemnification obligation of ELITE shall include Third Party patents issued after the Effective Date.
- (e) Facility. The Facility is in compliance with all Laws, including without limitation GMP, and that there are no, nor have been any, citations or adverse conditions of a material nature noted in any inspection of the site which would cause the Product to be misbranded or adulterated. It has and shall maintain sufficient knowledge and experience and adequate production facility(s), equipment and processes to produce the Product and perform its obligations under this Agreement in compliance with all Laws.
- (f) Products Supply. ELITE warrants, represents and covenants to LANNETT that all Products delivered to LANNETT hereunder shall:
 - (i) comply with the Specifications;
 - (ii) comply with the applicable Purchase Order;
 - (iii) be manufactured, tested, packaged, labeled, stored, handled and delivered by ELITE in accordance with (i) the terms of this Agreement, including the Specifications, and the Quality Agreement, (ii) the requirements of the Marketing Authorization, (iii) all applicable GMPs and Laws in the Territory, including regulations set forth by the DEA, (iv) all of ELITE's quality control procedures and associated test methods for the Products;
 - (iv) be manufactured at the Facility approved by the Regulatory Authorities in the Territory;
 - (v) not be adulterated or misbranded under any applicable Laws in the Territory;
 - (vi) have at least eighty-five percent (85%) of the Product's shelf-life remaining at the time of delivery; and
 - (vii) be free of all liens, security interests, and other claims of any nature and free from defects in material, manufacturing and workmanship for the shelf-life of the Products.
- (g) be manufactured, supplied, packaged, labeled and delivered in compliance with all serialization and aggregation requirements set forth in the Drug Supply Chain Security Act (DSCSA) Marketing Authorizations. The serialization requirements include, but are not limited to, the addition of Product identifiers imprinted on each sellable unit, on each homogenous case and on each pallet intended to be introduced in the Territory. Unique Product identifiers will include a national drug code, serial identifier (provided by LANNETT), lot number and expiration date. Serial numbers must be aggregated from item to case and case to pallet. ELITE warrants, represents and covenants to LANNETT that (i) all Marketing Authorizations have been obtained as necessary to permit LANNETT to manufacture, use, store, import, transport and sell the Product in the Territory pursuant to the terms of this Agreement and (ii) ELITE shall maintain all necessary Marketing Authorizations in good standing to permit LANNETT to manufacture, use, store, import, transport and sell the Product in the Territory pursuant to the terms of this Agreement.

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- (h) It is and shall at all times relevant to this Agreement be in full compliance with all applicable Laws relating or impacting in the performance of ELITE's duties and obligations under this Agreement, including but not limited to, those rules, regulations, and/or guidance promulgated or issued by the FDA, the Centers for Medicare & Medicaid Services, the U.S. Department of Health and Human Services, Office of Inspector General, the U.S. Drug Enforcement Agency, the U.S. Department of Justice, as well as any applicable environmental requirements and all serialization and aggregation requirements set forth in the Drug Supply Chain Security Act.
- (i) Subject to DEA quotas, it has access to sufficient supplies of raw materials, components and other required resources to perform the services required under this Agreement, and shall exercise commercially reasonable and diligent efforts to maintain access to sufficient supplies without interruption during the Term.

9.3 LANNETT General Warranties. LANNETT represents and warrants to ELITE that:

- (a) No Other Agreements. No contracts, commitments or agreements of any nature exist, and LANNETT covenants that none will be entered into during the Term of this Agreement that impair or inhibit the ability of LANNETT to perform its obligation hereunder.
- (b) No Lawsuits. As of the date hereof there have not been any Claims, lawsuits, arbitrations, legal or administrative or regulatory proceedings, charges, or complaints or investigations by any third party or government authority threatened, commenced, pending or proceeding against LANNETT, and LANNETT has not received any notice thereof, which could prevent LANNETT from complying with its material obligations under this Agreement.
- (c) Debarred. Neither LANNETT nor any of its officers, directors, or employees or consultants performing services under this Agreement has been or is: (1) a Debarred Individual or an employer, employee, or partner of such a Debarred Individual; or (2) a Debarred Entity, or an employee, partner, shareholder, member, subsidiary, or affiliate of a Debarred Entity; or (3) an employer, employee or partner of an individual convicted within the last five years for crimes described in subsections (a) or (b) of Section 306 of the FDCA. If and when LANNETT becomes aware of any fact that makes or gives rise to make this representation and warranty untrue, LANNETT shall immediately notify ELITE in writing and any such breach may result in immediate termination of this Agreement by ELITE.

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- (d) It is and shall at all times relevant to this Agreement be in full compliance with all applicable Laws relating or impacting in the performance of LANNETT's duties and obligations under this Agreement, including, to the extent applicable, but not limited to, those rules, regulations, and/or guidance promulgated or issued by the FDA, the Centers for Medicare & Medicaid Services, the U.S. Department of Health and Human Services Office of Inspector General the U.S. Drug Enforcement Agency, the U.S. Department of Justice, as well as any applicable environmental requirements and all applicable requirements set forth in the Drug Supply Chain Security Act.

- 9.4 Disclaimer. EXCEPT FOR THE WARRANTIES AND REPRESENTATIONS PROVIDED OR REFERENCED IN THIS AGREEMENT, THE PARTIES MAKE NO OTHER WARRANTIES OR REPRESENTATIONS TO EACH OTHER, EXPRESS OR IMPLIED, INCLUDING THOSE WITH RESPECT TO THE PRODUCTS, WHETHER STATUTORY OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ALL OTHER WARRANTIES, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 10 - COVENANTS

- 10.1 Compliance. Each Party shall perform its obligations under this Agreement in strict compliance with all applicable GMPs and Laws in the Territory, and all applicable licenses, governmental permits or applications in the Territory.
- 10.2 Permits and Licenses. Each Party shall throughout the Term of this Agreement obtain and maintain any and all licenses, permits, orders, applications and consents (including facility licenses and permits) required by the Regulatory Authorities in the Territory, and all applicable Laws, regulations and GMPs necessary or required to perform its obligations under this Agreement.

ARTICLE 11 - INDEMNIFICATION & INSURANCE

- 11.1 Indemnification of ELITE LANNETT shall defend, indemnify and hold harmless ELITE, its Affiliates and their respective officers, directors, employees, agents and representatives from and against all Losses from any Third-Party Claim directly resulting from:
- (a) any breach of any obligations, actions, or representations made by LANNETT under this Agreement; and
 - (b) any negligent, grossly negligent or intentionally wrongful act or omission of LANNETT or of any person acting on LANNETT's behalf, with authorization, when the wrongful act or omission occurred in performance of LANNETT's obligations under this Agreement;

provided, however, that the foregoing indemnification obligations shall not apply to the extent such Losses are caused by an act or omission for which ELITE is contributorily negligent and/or otherwise required to indemnify LANNETT under **Article 11.2**.

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11.2 Indemnification of LANNETT ELITE shall defend, indemnify and hold harmless LANNETT, its Affiliate and their respective officers, directors, employees, agents and representatives from and against all Losses from any Third-Party Claim directly resulting from:

- (a) any breach of any obligations, actions, or representations made by ELITE under this Agreement;
- (b) any infringement or claim of infringement of any patent, trademark or other intellectual property rights based on the manufacture and release of the Product furnished under the provisions of this Agreement;
- (c) personal injury (including death) or property damage relating to or arising out of any use, distribution or sale of the Products by LANNETT or its Affiliates to the extent that such Loss was the result of the Product not being manufactured to meet the Analytical Specifications;
- (d) any negligent, grossly negligent or intentionally wrongful act or omission of ELITE or of any person acting on ELITE's behalf with authorization, when the wrongful act or omission occurred in performance of ELITE's obligations under this Agreement;
- (e) the condition of any Products sold, supplied or delivered to LANNETT under this Agreement including any defect in material, workmanship, design, manufacturing or formula;
- (f) any warnings and instructions, or lack thereof, for any Product;
- (g) the possession, distribution, sale and/or use of, or by reason of the seizure of, any Product; and
- (h) any actual or asserted violation(s) of the FDCA or any applicable Law by virtue of which any Product sold, supplied or delivered to Lannett under this Agreement is alleged or determined to be adulterated, misbranded, mislabeled or otherwise not in full compliance with, or in contravention of, any applicable Law.

provided, however, that the foregoing indemnification obligations shall not apply to the extent such Losses are caused by an act or omission for which LANNETT is contributorily negligent or is required to indemnify ELITE under **Article 11.1**. ELITE shall also indemnify LANNETT for any damages arising from any interruption in supply of the Products to LANNETT occasioned by ELITE's commitments, contractual or otherwise, with Third Party subject to **Article 4.4**.

11.3 Indemnification Procedure. Any Party entitled to indemnification hereunder (the "**Indemnitee**") shall notify the indemnifying Party (the "**Indemnitor**") promptly of any claim threatened or commenced against the Indemnitee. The Indemnitor shall assume control and direct the defense, investigation and handling of the claim for and on behalf of the Indemnitee, *provided, however* that the Indemnitor shall not settle or consent to judgment without the Indemnitee's approval, which approval shall not to be unreasonably withheld. The Indemnitee shall cooperate with the Indemnitor, and may participate, at the Indemnitee's expense, in the defense of such claim. If the Indemnitor fails to assume control of the defense of any claim, or, having elected to assume control, thereafter fails to diligently defend the claim, the Indemnitee shall, without limitation to the Indemnitor's obligations hereunder, be entitled to contest, settle or pay the amount of the claim, and the Indemnitor shall be bound by the results obtained by the Indemnitee with respect to the claim.

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- 11.4 Insurance. Each Party hereby represents to the other that it has, and during the Initial Term and any Renewal Term and for three (3) years after termination or expiration of this Agreement, will maintain, products liability insurance coverage of not less than US five million dollars (\$5,000,000.00) per occurrence and five million dollars (\$5,000,000) in the aggregate. For the sake of clarity, should ELITE increase its product liability insurance coverage beyond this amount, the new levels shall automatically apply to this Agreement. Upon the request of the other Party hereto, the insured Party shall furnish the other Party with a certificate of insurance evidencing such coverage and each Party shall endeavor to provide notice to the other Party if there is a material change or cancellation of the policy. Each Party shall list the other Party as an additional insured on such Party's applicable insurance coverage. Each Party shall provide the certificate of insurance within ten (10) days of its receipt of a request for proof of insurance.
- 11.5 Survival. The obligations set forth in this **ARTICLE 11** shall survive the termination of this Agreement and remain in full force and effect for an indefinite period after termination in relation to any claim based on events which occur during the term hereof.

ARTICLE 12 - CONFIDENTIALITY

- 12.1 Confidentiality. During the Term of this Agreement and for five (5) years thereafter, each Party shall maintain in strict confidence the Confidential Information (as defined below) of the other Party. Each Party shall not use the Confidential Information of the other Party for any purpose other than the purposes expressly permitted by this Agreement, and shall not disclose such Confidential Information to any third party (including in connection with any publications, presentations or other disclosures) except to its employees, agents or advisors ("**Representatives**") who have a need to know such Confidential Information to perform such Party's obligations under this Agreement. Each Party shall ensure that any Representative to whom it discloses the other Party's Confidential Information is informed of the confidential nature of and duty not to disclose the information, and is obligated under written obligation to maintain the confidentiality thereof on terms at least as restrictive as those set forth herein. Each Party shall be responsible for any breach of this Agreement by its Representatives, which shall be considered a breach by such Party. Under no circumstances shall the receiving Party use the disclosing Party's Confidential Information for its own commercial advantage to the detriment of the disclosing Party. Each Party may disclose such of the Confidential Information of the other Party as may be required by the order of a court of competent jurisdiction or by any governmental authority having jurisdiction, *provided* that prior to any such disclosure the Party required to disclose shall, to the extent permitted by Law, notify the other Party prior to disclosing any Confidential Information and provide such other Party with a reasonable opportunity to contest or limit the scope of the required disclosure and obtain any protective orders as may be appropriate. In the event the disclosure is nonetheless compelled, the Party making the disclosure shall only disclose the information to the extent required to comply with the Law. Upon termination or expiration of this Agreement, or upon request, a Party shall destroy or return all Confidential Information of the other Party and certify in writing that such return (or destruction) has been completed; provided, however, that each Party shall be entitled to retain one archival copy of such Confidential Information solely for purposes of monitoring such Party's compliance with its obligations under this **ARTICLE 12** - .

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- 12.2 Definition. “**Confidential Information**” means all proprietary technical information, marketing, business and financial information, scientific data, information, whether or not labeled “Confidential”, and all tangible and intangible embodiments and oral disclosures thereof of any kind whatsoever, and all other materials which a disclosing Party treats confidentially that relates to a Product or the business of a Party and is disclosed or developed under or in connection with this Agreement. Confidential Information shall not include any information which the receiving Party can show by competent proof:
- (a) was known to or in the possession of the receiving Party prior to the date of its actual receipt from the disclosing Party;
 - (b) is readily available to the public other than through the fault of the receiving Party;
 - (c) was disclosed by a third party not under an obligation of confidentiality to the disclosing Party; or
 - (d) is subsequently independently developed by the receiving Party without use of the Confidential Information as demonstrated by competent written records.
- 12.3 Injunctive Relief. The Parties acknowledge that any breach of this **ARTICLE 12** - may constitute irreparable harm, and that the non-breaching Party shall be entitled to seek specific performance or injunctive relief to enforce this **ARTICLE 12** - in addition to whatever remedies such Party may otherwise be entitled to at law or in equity, without the necessity of posting bond or any other security.
- 12.4 Separate Confidentiality Agreement. LANNETT and ELITE have entered into a separate Mutual Confidential Disclosure Agreement dated January 7, 2019 (“**Confidentiality Agreement**”). Such Confidentiality Agreement will be and remain in full force and effect as provided therein. In the event of any conflict between the terms of this Agreement and the terms of any such Confidentiality Agreement, the terms of such Confidentiality Agreement will control.
- 12.5 No Publicity. Except as required by law, neither Party shall originate any publicity, news release or other public announcements, written or oral, whether to the public press, to stockholders, or otherwise, relating to this Agreement, any amendment hereto, performance hereunder or the existence of an arrangement between the Parties without the prior written approval of the other Party, which approval shall not be unreasonably withheld. Nothing in the provision shall be deemed to prevent a Party from making such disclosures or announcements that are legally required of such Party; *provided* that in any event the non-disclosing Party shall have the right to review any such disclosure and revise such disclosure to the extent it relates to the use of the non-disclosing Party’s name or Confidential Information. No Party shall, without the prior written consent of the affected Party, use in advertising, publicity, or otherwise, the name, trademark, logo, symbol, or other image of the affected Party without the other Party’s prior written consent.

ARTICLE 13 - REGULATORY MATTERS

- 13.1 Regulatory Responsibilities. ELITE will, at its own cost and expense, continue to own and maintain the applicable Regulatory Approvals necessary to market the Products in the Territory. ELITE shall be responsible for all regulatory and safety reporting requirements associated with ownership of the Regulatory Approval, including, without limitation, adverse event reports, annual reports mandated by the applicable Laws in the Territory. Additionally, ELITE shall be responsible for complying with applicable Laws to appropriately categorize and report changes to the FDA, including without limitation, amendments, supplements, and annual reports. All communications by ELITE with the FDA relating to the Products as marketed in the Territory shall be promptly provided in writing to LANNETT, and ELITE shall promptly provide to LANNETT copies of all documents sent to or received from the FDA regarding the Products.

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- 14.2 Relationship of the Parties. The relationship of the Parties is that of independent contractors. Nothing in this Agreement shall be deemed or construed to constitute or create between the Parties hereto a partnership, joint venture, agency, or other relationship other than as expressly set forth herein. This Agreement does not constitute any one Party hereto as the agent or legal representative of the other Party for any purpose whatsoever. Neither of the Parties grants to the other any right or authority to assume or create any obligation or responsibility, express or implied, on behalf of it or in its name in any manner whatsoever, unless otherwise agreed to in writing by the other Party.
- 14.3 Inurement & Assignment. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns. Except as otherwise expressly provided herein, neither Party may assign or transfer its rights or obligations under this Agreement, in whole or in part, without the prior written consent of the other Party. Notwithstanding the foregoing, both LANNETT and ELITE shall be entitled to assign its rights and performance of its obligations under this Agreement to any Affiliate or to the acquirer of all or substantially all of the business or assets to which this Agreement relates (whether by stock sale, asset sale, merger, consolidation or otherwise), provided that the assigning Party remains fully responsible for the performance of the obligations of its Affiliates under this Agreement. Any assignment or transfer by a Party other than in accordance with the terms hereof shall be void and shall entitle the other Party to terminate this Agreement.
- 14.4 No Waiver; Remedies. No Party to this Agreement shall be deemed or taken to have waived any provision of this Agreement unless such waiver is in writing, and then such waiver shall be limited to the circumstances set forth in such written waiver. No failure or delay on the part of a Party in exercising any right, power or remedy shall operate as a waiver thereof, nor shall any single or partial exercise of any such right, power or remedy preclude any other or further exercise thereof or the exercise of any other right, power or remedy. All remedies provided for hereunder shall be cumulative of and in addition to any and all other remedies, at law or in equity, which any Party may have, and the exercise of any one or more of such remedies shall not preclude the exercise of any others.
- 14.5 Force Majeure. If either Party is prevented from complying, either totally or in part, with any of the terms or provisions of this Agreement by reason of force majeure, including fire, flood, earthquake, storm, general strike, lockout, riot, war, terrorism, rebellion, accident, acts of God and/or any other cause or externally induced similar casualty beyond its reasonable control and without the fault or negligence of either Party (a “**Force Majeure Event**”), then, upon written notice by the Party liable to perform to the other Party, the requirements of this Agreement or such of its provisions as may be affected, and to the extent so affected, shall be suspended during the period of such disability, *provided* that the Party asserting force majeure shall bear the burden of establishing the existence of such Force Majeure Event by clear and convincing evidence, and *provided further* that the Party prevented from complying shall use its best efforts to remove such disability, and shall continue performance with the utmost dispatch whenever such causes are removed, and shall notify the other Party of the Force Majeure Event not more than five (5) Business Days from the time of the event and state the nature of the Force Majeure Event, its anticipated duration and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is reasonably required. When such circumstances arise, the Parties shall discuss what, if any, modification of the terms of this Agreement may be required in order to arrive at an equitable solution. Notwithstanding the foregoing, if a Force Majeure Event shall continue for a period of longer than three (3) consecutive months or one hundred and twenty (120) days in any twelve (12) month period, then the Party unaffected by such event may terminate this Agreement immediately upon giving written notice of termination to the other Party. Notwithstanding any provision contained herein, any action taken by a Regulatory Authority as a result of a Party’s negligence or willful misconduct shall not constitute a Force Majeure Event under this **Article 14.5**.

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- 14.6 Dispute Resolution. The Parties recognize that disputes as to certain matters may from time to time arise which relate to a Party's rights and/or obligations under this Agreement. It is the objective of the Parties to establish procedures to facilitate the resolution of such disputes in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this **Article 14.6** if and when such a dispute arises between the Parties. Notwithstanding the provisions of this **Article 14.6** however, nothing herein contained shall preclude a Party from seeking equitable remedies in any court of competent jurisdiction as set forth in **Article 14.7** hereof. If any controversy, dispute or claim arises between the Parties relating to the interpretation, breach, performance, enforcement, termination or validity of this Agreement and the Parties cannot resolve the dispute within thirty (30) days of a written request by one Party to any other Party, the Parties agree to hold a meeting, attended by each Parties authorized representatives , to attempt in good faith to negotiate a resolution of the dispute prior to pursuing other available remedies. If, within thirty (30) days after such written request, the Parties have not succeeded in negotiating a resolution of the dispute, the Party may seek any other remedies available to it in at law or in equity.
- 14.7 Governing Law & Venue. This Agreement shall be governed by, and construed in accordance with, the laws of the State of Delaware, without giving effect to any choice of law or conflict of law rules or provisions that would cause the application of the laws of any jurisdiction other than the State of Delaware. Each Party hereby irrevocably submits to the exclusive jurisdiction of any federal or state court in Delaware for the purposes of any suit, action or other proceeding arising out of this Agreement or any transaction contemplated hereby. Each Party further agrees that service of any process, summons, notice or document by certified or registered mail to such Party's address set forth in **Article 14.1** or such other address or to the attention of such other person as the recipient Party has specified by prior written notice to the sending Party shall be effective service of process in any action, suit or proceeding in Delaware with respect to any matters to which it has submitted to jurisdiction as set forth above in the immediately preceding sentence. Each Party irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of this Agreement or the transactions contemplated hereby in the federal or the state courts in Delaware and hereby irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such action, suit or proceeding brought in such court has been brought in an inconvenient forum.
- 14.8 Waiver of Trial by Jury. TO THE FULLEST EXTENT PERMITTED BY LAW, THE PARTIES HEREBY WAIVE THEIR RESPECTIVE RIGHTS TO A JURY TRIAL OF ANY PROCEEDING BASED UPON, ARISING OUT OF OR RELATED TO THIS AGREEMENT INCLUDING ANY DISPUTE ARISING OUT OF OR RELATING TO THE PERFORMANCE THEREOF, OR ANY OF THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT. THE SCOPE OF THIS WAIVER IS INTENDED TO BE AN ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT AND THAT RELATE TO THE SUBJECT MATTER OF THIS AGREEMENT, INCLUDING CONTRACT CLAIMS, TORT CLAIMS, BREACH OF DUTY CLAIMS AND ALL OTHER COMMON LAW AND STATUTORY CLAIMS.
- 14.9 Severability. If any provision in this Agreement is held to be invalid, void or unenforceable, then the remainder of this Agreement, or the application of such provision to the Parties or to the circumstances other than those as to which it is held invalid or unenforceable, shall not be affected thereby and shall be enforced to the fullest extent permitted by law. The Parties agree to renegotiate any such invalid, void or unenforceable provision in good faith in order to provide a reasonably acceptable alternative consistent with the basic purposes of this Agreement.

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- 14.10 Entire Agreement. This Agreement (including the Schedules attached hereto, the SDEA and the Quality Agreement) constitutes the entire agreement between the Parties with respect to the subject matter hereof, and all prior or agreements, whether written or oral, are superseded hereby. This Agreement may be amended only in writing executed by the Parties.
- 14.11 Sub-contracting. ELITE shall not sub-contract any of the work to be performed under this Agreement without the prior written consent of LANNETT. No such sub-contracting shall relieve ELITE of any of its obligations hereunder.
- 14.12 Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed shall be deemed to be an original and all of which when taken together shall constitute this Agreement.
- 14.13 Headings. The captions and headings contained herein are for convenience of the Parties and in no way define, limit or describe the scope of this Agreement.
- 14.14 Language. The language of this Agreement and all proceedings taken in relation thereto shall be English.
- 14.15 Currency. Unless otherwise specifically provided, all references to money amounts are expressed in terms of United States Dollars (USD) and all payments made pursuant to this Agreement shall be made in that currency.
- 14.16 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any Section of this Agreement are and shall otherwise be deemed to be for purposes of Section 365(n) of Title 11, of the United States Code (the "**Bankruptcy Code**") licenses of rights to "intellectual property" as defined in Section 101(35A) of the Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights and elections under the Bankruptcy Code. Upon the bankruptcy of any Party, the non-bankrupt Party shall use its best efforts to transfer its Product responsibilities to a third party, unless the bankrupt Party elects to continue, and continues, to perform all of its obligations under this Agreement.
- 14.17 Construction of Agreement. The terms and provisions of this Agreement represent the results of negotiations between the Parties and their representatives, each of which has been represented by counsel of its own choosing, and neither of which has acted under duress or compulsion, whether legal, economic or otherwise. Accordingly, the terms and provisions of this Agreement shall be interpreted and construed in accordance with their usual and customary meanings, and each of the Parties hereto hereby waives the application in connection with the interpretation and construction of this Agreement of any rule of law to the effect that ambiguous or conflicting terms or provisions contained in this Agreement shall be interpreted or construed against the Party whose attorney prepared the executed draft or any earlier draft of this Agreement.

[SIGNATURE PAGE FOLLOWS]

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IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the date first written above.

ELITE PHARMACEUTICALS, INC.

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

LANNETT COMPANY, INC.

By: /s/ John Kozlowski
Name: John Kozlowski
Title: COSSO

ELITE LABORATORIES, INC.

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

- Schedule A: Products and Prices
- Schedule B: Product Specifications
- Schedule C: Quarterly Report for Calculation of Net Profit
- Schedule D: Shipping Instructions

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SCHEDULE A

Products and Prices

Product List

Generic Name	ANDA #	Reference Listed Drug
Dantrolene Sodium	76686	Dantrium®, Par Sterile Products, LLC

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Transfer Prices (\$/bottle)

Name	Strength	Full Batch Qty.	Bottle Size	Cost per bottle
Dantrolene Sodium	25 mg	[**] bottles	100 count	\$[**]
Dantrolene Sodium	50 mg	[**] bottles	100 count	\$[**]
Dantrolene Sodium	100 mg	[**]	100 count	\$[**]

The Transfer Price for the Product is the cost of goods sold and means the fully burdened cost of manufacturing a Product, which consists of the direct and indirect costs associated with acquiring the materials, including the manufacturing, testing and analysis of the finished dosage of a Product, quality control, quality assurance, labeling, and packaging, labor (including benefits), serialization, annual generic drug user fees (GDUFA), depreciation and overhead, all determined in accordance with GAAP and is subject pricing adjustments in Section 4.1(d).

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Schedule B

PRODUCT SPECIFICATIONS

[]**

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SCHEDULE C

QUARTERLY REPORT FOR CALCULATION OF NET PROFIT

PRODUCT NAME: _____

QUANTITY SOLD BY SKU	XXXX UNITS
GROSS SALES	\$
DEDUCTIONS:	
CHARGEBACKS	
REBATES	
ADMINISTRATIVE FEES	
BILLBACKS	
RETURNS	
SHELF STOCK ADJUSTMENTS	
OTHER DEDUCTIONS	
CASH DISCOUNTS	
MEDICAID	
NET SALES	\$
TRANSFER PRICE	
DISTRIBUTION FEES	
SHIPPING COSTS	
NET PROFITS	
PROFIT SHARE PAYMENT TO ELITE AT THE APPLICABLE LICENCE FEE PERCENTAGE SET FORTH IN SECTION 3.3	

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SCHEDULE D

SHIPPING INSTRUCTIONS

All shipments inbound to LANNETT must arrive intact and in a certain and dry condition that is free from defects and damage.

All material must have 85% of its maximum shelf life remaining at the time of delivery and in no case less than 15 months.

All truckloads of the Products should be in sealed trailers, with the seal number noted on the delivery receipt.

All truckload and less than truckload shipments must be on 40"x48" 4-way heat treated pallets that are shrink-wrapped and free of broken boards.

Finished goods materials should have a maximum height of 51" from the floor to the top of the pallet.

Each shipment must be labelled with a minimum of the name of the material, the manufacturer's lot number, the gross, tare, and net weights, the LANNETT item number for the material, and the LANNETT purchase order number.

All finished products must be packaged as agreed in the product specification and case labels must be HDMA complaint.

A dock appointment must be scheduled for deliveries consisting of 5 or more pallets and for all hazardous material. Receiving hours are 7am-3pm Eastern. For Seymour, IN deliveries, please contact the representative at 812-523-5446 to schedule all freight deliveries.

Please email invoices to the following email address: AccountsPayable@Lannett.com

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LICENSE, SUPPLY
AND DISTRIBUTION AGREEMENT

ELITE PHARMACEUTICALS, INC.,

ELITE LABORATORIES, INC.,

- and -

LANNETT COMPANY, INC.

Dated as of March 6, 2019

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THIS LICENSE, SUPPLY AND DISTRIBUTION AGREEMENT made as of March 6, 2019 (the “**Effective Date**”), by and between ELITE PHARMACEUTICALS, INC. a Nevada corporation and ELITE LABORATORIES, INC., Delaware corporation located at 165 Ludlow Avenue, Norwood, New Jersey 07647 (collectively, “**ELITE**”), and LANNETT COMPANY, INC., USA, a Delaware corporation located at 9000 State Road, Philadelphia, Pennsylvania 19136 and/or its Affiliates (“**LANNETT**”).

WHEREAS:

- A. ELITE and their ANDA co-owner, SunGen Pharma LLC (303C College Road East, Princeton, NJ 08540) (“SunGen”), have ownership rights in the Products and/or ANDAs specified in Schedule A (the “Products”), and LANNETT wishes to license from ELITE the exclusive rights to market and sell the Products on the terms and conditions set forth in this Agreement.
- B. ELITE has significant experience in developing, manufacturing and marketing finished dosage forms of pharmaceutical products, including the Products;
- C. LANNETT has significant experience in marketing pharmaceutical products; and
- D. Subject to the terms and conditions of this Agreement, LANNETT desires to engage ELITE on an exclusive basis to manufacture, supply, package and label the Products and ELITE agrees to grant LANNETT the right under this Agreement to commercialize the Products in the Territory on an exclusive basis.

NOW, THEREFORE in consideration of the mutual covenants and obligations contained herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereto agree as follows:

ARTICLE 1 - DEFINITIONS

- 1.1 In addition to terms defined elsewhere in this Agreement, the terms set forth below shall be defined in this Agreement (including the recitals) as follows:
 - (a) “**Affiliate**” with respect to either Party means any Person who directly or indirectly through one or more intermediaries controls, is controlled by, or is under common control with such Party. The term “control” means the beneficial (direct or indirect) ownership of more than fifty-percent (50%) of the voting or equity interests of such Person or the power or right to direct the management and affairs of its business, whether through the ownership of voting securities, by contract, or otherwise.
 - (b) “**Agreement**” means this License, Supply and Distribution Agreement, together with all schedules hereto.
 - (c) “**Analytical Specifications**” has the meaning given in **Article 4.1(a)**.
 - (d) “**ANDA**” means an Abbreviated New Drug Application pursuant to Section 505(j) of the FDCA.
 - (e) “**Bankruptcy Code**” has the meaning given in **Article 14.16**.

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- (f) “**Business Day**” in relation to each Party means any day other than a Saturday, a Sunday, or any statutory or public holiday on which banks are generally closed for regular business in New York, New York.
- (g) “**Certificate of Analysis**” means a certificate of analysis that certifies that a given batch of Product meets the release Product Specifications.
- (h) “**Claim**” means any claim, action, cause of action, or demand.
- (i) “**Commercially Reasonable Efforts**” with respect to any activity means the efforts and resources that would be used in the performance of the relevant activity in compliance with Law by a Person (engaged in the manufacture and supply or distribution, sale and commercialization of pharmaceutical products, as applicable) of comparable size and resources as the applicable Party with regard to a product at a similar stage in its product life taking into account the following factors to the extent reasonable and relevant: issues of safety and efficacy, product profile, market potential, competitive market conditions, duration of exclusivity or other proprietary position of the product and the potential profitability and economic return of the product, all as measured by the facts and circumstances at the time such efforts are due.
- (j) “**Confidential Information**” has the meaning given in **Article 12.2**.
- (k) “**DEA**” shall mean the United States Drug Enforcement Administration or any successor entity.
- (l) “**Debarred Entity**” has the meaning given in **Article 9.2(c)**.
- (m) “**Debarred Individual**” has the meaning given in **Article 9.2(c)**.
- (n) “**Distribution Fees**” means [**] percent ([**]%) of Net Sales for all Products.
- (o) “**Effective Date**” has the meaning given in the preamble.
- (p) “**Facility**” means the ELITE FDA-approved manufacturing site located at Ludlow Avenue, Northvale, New Jersey 07647.
- (q) “**FDA**” means the United States Food and Drug Administration or any successor government agency.
- (r) “**FDCA**” means the Federal Food, Drug, and Cosmetic Act.
- (s) “**Force Majeure Event**” has the meaning given in **Article 14.5**.
- (t) “**ELITE**” has the meaning given in the preamble.
- (u) “**GMP**” means current good manufacturing practices for the manufacture of finished pharmaceutical products in effect within the Territory from time to time during the Term of this Agreement, which set minimum standards to ensure that pharmaceutical products meet established requirements for identity, strength, quality and purity, as established under the Laws of the Territory, including 21 C.F.R. Parts 210 and 211.

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- (v) “**Gross Profit**” means the Net Sales of a Product each calendar quarter less Transfer Price of Product, Distribution Fees and shipping cost from the Facility.
- (w) “**Gross Sales**” means the gross amount invoiced by LANNETT or its Affiliates or sublicensees for sales of the Product to Third Parties in the Territory.
- (x) “**Indemnitee**” has the meaning given in **Article 11.3**.
- (y) “**Indemnitor**” has the meaning given in **Article 11.3**.
- (z) “**Intellectual Property Rights**” means any patent, trademark, copyright, trade secret, right in unpatented know-how, right of confidence and any other intellectual or industrial property right of any nature whatsoever in any part of the world, whether registered or unregistered.
- (aa) “**LANNETT**” has the meaning given in the preamble.
- (bb) “**Law**” means any federal, state, provincial and local laws, statutes, regulations, rules, guidelines, orders, ordinances, and any other requirements of any government or Regulatory Authority in the Territory applicable to the development, registration, manufacturing, testing, packaging, storing, shipping, marketing, distribution and sale of pharmaceutical products or as otherwise applicable to the Parties respective obligations under this Agreement, including the FDCA.
- (cc) “**Losses**” means any damages, liabilities, obligations, costs, expenses or losses, including reasonable legal fees and expenses, court costs, penalties, fines, costs of investigation and amounts paid in settlement of claims.
- (dd) “**Major Change**” shall mean a change that has the potential to adversely impact quality, identity, purity or stability of the Products or the compliance and validity of the Products Marketing Authorizations, as these factors may relate the safety or efficacy of the Product and as defined in the FDA regulations and guidance.
- (ee) “**Marketing Authorization**” means all approvals, licenses, registrations or authorizations of any Regulatory Authority, necessary for the manufacturing, use, storage, import, transport, marketing, promotion and sale of the Product in the Territory, together with pricing or reimbursement approval in countries where governmental approval is required for pricing or for the Product to be reimbursed by national health insurance.
- (ff) “**Net Sales**” shall mean with respect to the Product, Gross Sales less the following items (whether or not separately stated on such invoice but only to the extent included in Gross Sales):
 - (i) Any and all promotional allowances, rebates, charge backs, quantity and cash discounts, and other usual and customary discounts to customers;

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- (ii) Amounts refunded, repaid or credited by reason of rejections, returns or recalls of goods;
- (iii) Any sales, excise, turnover, inventory, value-added, and similar taxes and duties assessed on applicable sales;
- (iv) Failure to Supply penalties (in the case if Article 4.4 (i) and (ii)), Non-affiliate third party administrative fees granted, Medicaid and state and/or governmental rebates, and shelf stock adjustments and retroactive price reductions.

Components of Net Sales shall be determined using the accrual method of accounting in accordance with US GAAP or an equivalent stipulated method of accounting in the Territory.

- (gg) “**Non-Conforming Product**” has the meaning given in **Article 4.8(b)**.
- (hh) “**Original Agreement**” has the meaning given in Recital A.
- (ii) “**Packaging**” means all material used to prepare fully packaged Products, including labeling, containers, closures, cartons, and shipping cases, as applicable.
- (jj) “**Parties**” means the parties to this Agreement referred to collectively, and “**Party**” means either party to this Agreement referred to individually.
- (kk) “**Person**” includes any individual, partnership, corporation, unincorporated organization or association, joint venture, limited liability company, trust or any other form of entity.
- (ll) “**Safety Data Exchange Agreement or SDEA**” means the pharmacovigilance agreement to be entered into by the Parties which shall set forth the safety data exchange procedures to be followed by the Parties for the collection, investigation, reporting and exchange of information concerning adverse events.
- (mm) “**Products**” means the finished pharmaceutical products in commercially saleable form, as manufactured by ELITE exclusively supplied to LANNETT pursuant to this Agreement as set forth on Schedule A.
- (nn) “**Purchase Order**” means a written, binding purchase order for a certain quantity of Product properly issued by LANNETT in accordance with the terms of this Agreement.
- (oo) “**Quality Agreement**” means a quality agreement to be entered into by the Parties which will set forth certain obligations of the Parties in relation to the manufacture, packaging, quality control and testing of the Products in accordance with GMP.
- (pp) “**Recall**” shall mean a recall, removal, market withdrawal, seizure, or field correction of Product.
- (qq) “**Regulatory Authorities**” means any federal, state, local or international regulatory agency, department, bureau or other governmental entity responsible for regulating the manufacture, use, storage, importation, transportation, distribution marketing, promotion and sale of pharmaceutical products in the Territory, including the FDA and DEA.

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- (rr) **“Regulatory Approval”** means all approvals or authorizations granted by the FDA for marketing the Products in the Territory.
- (ss) **“Specifications”** means the written methods, formulae, procedures, specifications, tests (and testing protocols) and standards pertaining to the Products as approved by FDA in the Product’s ANDA and attached herein as Schedule B, which may be amended from time-to-time by the written agreement of the Parties.
- (tt) **“SunGen”** has the meaning given in the preamble.
- (uu) **“Term”** has the meaning given in **Article 8.1**.
- (vv) **“Territory”** means the United States of America and its possessions, territories, protectorates, military bases and commonwealths.
- (ww) **“Third Party”** means any Person other than LANNETT or ELITE or SunGen, or any of their respective Affiliates.
- (xx) **“Trademarks”** has the meaning given in **Article 4.3(a)**.

1.2 Interpretation of “Include”. Where the words “include”, “includes” or “including” are used in this Agreement, they shall mean, respectively, “include without limitation”, “includes without limitation”, “including but not limited to”, or “including without limitation”.

ARTICLE 2 - MARKETING AUTHORIZATIONS

- 2.1 Subject to the terms of this Agreement, ELITE shall exclusively manufacture, supply, package and label the Products for LANNETT, and LANNETT shall have the right to promote, market, store, distribute and sell the Products in the Territory. ELITE hereby grants to LANNETT and its Affiliates an exclusive right to fully commercialize the Products in the Territory. LANNETT agrees to exclusively purchase Products it requires from ELITE.
- 2.2 ELITE and their ANDA co-owner SunGen shall, at their expense, maintain and update the Marketing Authorizations for the Products as may be required for the Parties to perform their obligations hereunder. ELITE and their ANDA co-owner SunGen shall be solely responsible for all communications with the Regulatory Authorities in the Territory relating to any Marketing Authorizations for the Products. ELITE shall provide LANNETT with timely notice of any communications from the Regulatory Authorities which may affect ELITE’s right or ability to supply LANNETT with the Products.

ARTICLE 3 - PAYMENT TERMS

- 3.1 Transfer Price. ELITE shall sell each Product to LANNETT at the prices set forth in Schedule A, which Transfer price shall be inclusive of all costs and expenses associated with the manufacture, supply, packaging, labeling of the Product to LANNETT.

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- 3.2 Upon delivery of the Products to LANNETT, ELITE shall submit invoices therefore to LANNETT. LANNETT shall pay each undisputed invoice full within thirty (30) days of its receipt in full of the Products reflected in the invoice and the Certificate of Analysis, which Certificate is in a form sufficient for release of the Products. A late payment fee of one percent (1%) per month may be imposed upon LANNETT for payments past due unless Products therein are subject to a quality dispute. In the event of any inconsistency between an invoice and this Agreement, the terms of this Agreement shall control.
- 3.3 License Fees. Throughout the Initial Term and Renewal Term, LANNETT shall pay to ELITE [**] percent ([**]%) of the Gross Profits received from sales of each Product within forty-five (45) days of the end of each calendar quarter ("License Fees"). Such payment shall additionally include a sales summary for each Product generally in the format as provided in Schedule C. In no case shall the License Fees for any calendar quarter be negative; provided, however in the event of a loss in any calendar quarter, subject to ELITE's written approval of any Product pricing by LANNETT that leads to quarterly losses and subject to the loss carryover clause that follows, the amount of that loss shall be carried forward to subsequent calendar quarters until the amount of such loss has been fully absorbed. In the event that Net Profits for calendar quarter are negative, LANNETT shall carry over seventy percent ([**]%) of the value by which the Net Profits are negative in such calendar quarter and deduct this amount from the calculation of Net Sales for the following calendar quarter. If Net Profits are negative in two (2) or more consecutive calendar quarters, LANNETT shall invoice ELITE for seventy percent ([**]%) of the value by which the Net Profits are negative for the previous calendar quarter and carry over seventy percent ([**]%) of the value by which Net Profits are negative for the current calendar quarter and deduct this amount from the calculation of Net Sales for the following calendar quarter. For the avoidance of doubt, if Net Profits are negative in subsequent calendar quarters, the amount will be similarly carried over or reimbursed as per the terms set forth in this Section 3.3 until Net Profits are positive. Reimbursement of negative Net Profits owed by ELITE in this Section 3.3 shall be payable to LANNETT within forty-five (45) days after receipt of an invoice from LANNETT.
- 3.4 Lannett shall pay to Elite seven hundred and fifty thousand dollars (US\$750,000) upon commercial launch of the [**] Product.

ARTICLE 4 - MANUFACTURING AND SUPPLY; COMMERCIALIZATION

4.1 Supply of Products.

- (a) During the Term of this Agreement, ELITE shall use Commercially Reasonable Efforts to manufacture, timely supply, package and label for delivery to LANNETT the Products in accordance with any Purchase Orders issued by LANNETT under the terms of this Agreement. Purchase Orders shall include the shipping instructions in accordance with Schedule D hereto. ELITE shall manufacture, supply, package and label the Products in compliance with all Laws, including the GMPs, the Marketing Authorization, the Quality Agreement, and the Specifications ("Analytical Specifications").
- (b) ELITE shall manufacture the Products in the Facility and use Commercially Reasonable Efforts to maintain access to sufficient supplies of raw materials, components and other required resources to perform its obligations under this Agreement, and meet LANNETT's supply requirements for the Products. ELITE shall not manufacture the Products at a site other than the Facility without first obtaining LANNETT's prior written consent, which consent shall not be unreasonably withheld. ELITE shall be solely responsible for all costs and expenses incurred in connection with the manufacture of the Products hereunder, including without limitation costs and expenses of personnel, quality control, testing, manufacturing, facilities, equipment, materials, FDA product fees, FDA establishment fees and government sales, use, excise property or similar taxes or excises.

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- (c) ELITE shall have procedures in place to ensure that the oldest approved inventory of the Products is distributed first. In addition, each Part shall maintain a tracking system by which the distribution of each lot of the Products may be readily determined to facilitate its Recall if necessary.

Transfer Price Adjustments. The Transfer Prices for the Products under Schedule A are valid through December 31, 2019. After December 31, 2019, the Transfer Price for Products may be adjusted for any increase in the cost of active pharmaceutical ingredients, annual Generic Drug User Fees (GDUFA fees) proportional allocation, and other material government mandated requirements. ELITE shall provide at least thirty (30) days written notice to LANNETT for any such Transfer Price adjustments with justifications for any increase. ELITE shall use commercially reasonable efforts to reduce its manufacturing expenses for the Products. At either Party's written request, the Parties will discuss in good faith the revision of the Transfer Price (and any subsequently agreed prices) to take into account adverse market conditions resulting in unsatisfactory returns for LANNETT or changes in the manufacturing costs for the Products. The revised Transfer Price shall be laid down in writing and inserted as an amended Schedule A to this Agreement. Confirmed orders are excluded from Transfer Price negotiations. If, after good faith negotiations, the Parties are unable to reach agreement on an adjustment to the Transfer Pricing for the Products, then LANNETT shall be entitled to terminate this Agreement, effective upon at least sixty (60) days' prior written notice to ELITE.

- (d) The Parties shall enter into a Safety Data Exchange Agreement and Quality Agreement. The respective roles and responsibilities for quality assurance personnel of the Parties in carrying out the transactions pursuant to this Agreement shall be defined and stipulated in the Quality Agreement. The fully executed SDEA (SDEA) and Quality Agreement are hereby incorporated and made a part of this Agreement by reference. In the event of any inconsistency between the provisions of the SDEA and the provisions of this Agreement, the wording of the SDEA shall govern any and all patient safety matters and this Agreement shall govern all other matters. The Parties hereby acknowledge and agree that in the event of any conflict between the terms of this Agreement and the terms of the Quality Agreement, this Agreement shall control with respect to all issues (other than with respect to all quality matters), and the Quality Agreement shall control with respect to all quality matters.

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4.2 Master Production Plan and Purchase Orders On or before fifteen (15) days prior to the end of each calendar quarter during the Term, LANNETT shall deliver to ELITE a master production plan which covers a twelve (12) month period, which includes three (3) months binding purchase order, and nine (9) months non-binding forecast (the “**Master Production Plan**”). The first three months (beginning with the first month following the month in which the Master Production Plan is due) of each Master Production Plan shall be deemed to be a binding purchase order (the “**Binding Forecast**”). Months four (4) through twelve (12) of the Master Production Plan shall be LANNETT’s non-binding, good faith estimate of such requirements based on forecasted trade and LANNETT shall have the ability to adjust the quantities forecast. Unless the Parties otherwise agree in writing, all firm orders for Product (the “**Purchase Order**”) placed shall specify: (i) the type of Product being ordered; (ii) the amount of such Product being requested (which shall be in whole batch size quantities); and (iii) the requested delivery date which, unless otherwise agreed by ELITE in writing, shall be no less than ninety (90) days after receipt of the Purchase Order. Each Master Production Plan and accompanying binding Purchase Order shall be deemed to be automatically accepted unless ELITE notifies LANNETT of its rejection of the same within four (4) Business Days of receipt. ELITE may only reject a Purchase Order if a Purchase Order is not consistent with the terms of this **Article 4.2** or is not timely delivered. Once a Purchase Order is accepted by ELITE, ELITE shall be obligated to timely manufacture, supply, package, label, and have ready for delivery the full quantities of Products set forth in the Purchase Order by the required delivery date at the Facility. In the event that the terms of any Purchase Order are not consistent with, or attempt to modify, the terms of this Agreement, the terms of this Agreement shall prevail. If LANNETT requests changes to any Purchase Order after receipt thereof by ELITE, ELITE shall use Commercially Reasonable Efforts to comply with such changes. ELITE shall use commercially reasonable efforts to supply up to one hundred twenty-five percent (125%) of LANNETT’S requirement forecast of Products for the applicable period.

4.3 Delivery Terms.

- (a) LANNETT shall provide ELITE packaging specifications and related materials that comply with FDA requirements and the Parties shall finalize all packaging by the time of the first Purchase Order. If requested by LANNETT, ELITE shall affix on the Product and/or on the label and/or the packages certain proprietary or registered marks, logos or insignia relating to the Product in accordance with the directions and specifications given by LANNETT, along with any other marks, logos or insignia, as LANNETT may stipulate from time to time (collectively, “**Trademark**”). Pursuant to the aforesaid, LANNETT hereby grants to ELITE, a non-exclusive, non-transferable, no assignable and non-sublicensable right to the Trademarks, solely for the purpose of affixing such Trademarks to the Product in accordance with LANNETT’s directions and specifications during the Term. LANNETT shall have sole approval authority over all Product labeling and packaging specifications of the Products supplied to LANNETT pursuant to this Agreement.
- (b) ELITE shall deliver the full quantities of the Products set forth in each Purchase Order (Incoterms 2010 EXW) to LANNETT or designee. All Products shall be packaged for shipment in accordance with the packaging specifications set forth in the Marketing Authorizations and packing instructions reasonably required by LANNETT.
- (c) Each Product shipment made by ELITE shall be accompanied by and shall include a Certificate of Analysis for each shipment of the Products manufactured and supplied hereunder. ELITE shall be responsible for all applicable release testing of the Products in accordance with the Analytical Specifications. ELITE shall perform all required in-process quality control tests and quality assurance reviews on the Products, including without limitation, stability testing at its sole cost and expense. In addition, ELITE shall furnish LANNETT, along with the first shipment of the Products, ELITE’s Material Safety Data Sheets containing the relevant safety and health information and such other similar information as LANNETT may reasonably request from time-to-time in connection therewith.

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- (d) All Products provided to LANNETT shall have no less than eighty five percent (85%) remaining shelf-life remaining as per the Product ANDA.
- (e) All orders containing at least ninety percent (90%) of the specified amount of Product in a given Purchase Order shall be deemed satisfied.
- 4.4 **Failure to Supply.** ELITE shall notify LANNETT as promptly as possible, but in no event later than five (5) Business Days, after ELITE discovers that it will not be able to supply the quantity of Products ordered by the delivery date specified in a Purchase Order. In such event: (i) ELITE shall cooperate with LANNETT in taking all actions that LANNETT deems reasonably necessary in order to remedy such inability to supply, at ELITE's expense; and (ii) If ELITE's inability to supply continues past twenty (20) days from the required delivery date set forth in the Purchase Order at LANNETT's election, any or all outstanding Purchase Orders relating to such Product may be cancelled and LANNETT shall have no obligation with respect to such Purchase Orders; provided, however, ELITE must cover any Failure to Supply (as defined below) obligations set forth in this Section. Compliance by ELITE with this **Article 4.4** shall not relieve ELITE of any other obligation or liability under this Agreement. LANNETT shall otherwise retain all of its rights under this Agreement and/or at law against ELITE for its failure to deliver all or any portion of the quantity of Products ordered by LANNETT. With regards to a Binding Forecast or if ELITE accepted a Purchase Order from LANNETT, pursuant to the procedure defined in Section 4.2 of this Agreement, then ELITE shall be responsible for the late charges and any penalties assessed against LANNETT by its Customers or any other third party or any costs, fees, charges, or penalties incurred by Lannett ("Failure to Supply"), unless the delay is attributable to: (i) action or controls imposed by the DEA that do not result from ELITE's negligence, gross negligence or willful misconduct; or (ii) demonstrable raw material shortages that are beyond ELITE's control, but ELITE will use commercially reasonable efforts to keep three (3) to six (6) months of raw materials inventory on hand at all times. Late charges and any penalties assessed against ELITE by LANNETT under this paragraph are due and payable within thirty (30) days of being invoiced by LANNETT and, if not timely paid, may be deducted against amounts owed by LANNETT to ELITE.
- 4.5 **Samples and Batch Records** ELITE shall prepare and maintain batch records and file samples, properly stored, for each lot or batch of Product manufactured and shipped hereunder in compliance with all GMPs and Laws in the Territory.
- 4.6 **Commercialization.** LANNETT shall use Commercially Reasonable Efforts to market and sell the Products in the Territory. All commercial matters regarding the marketing, promotion, sale, offer for sale, pricing or distribution of the Products in the Territory shall be under the exclusive control of LANNETT.
- 4.7 **Change of Specification** No alterations of the Specifications for the Products or other changes requiring prior approval by the FDA, or material changes to the manufacturing process or validated processes, can be made without the prior written approval of LANNETT. ELITE shall notify LANNETT in writing of any proposed alterations for the Specifications for the Products or any Major Changes to the manufacturing process or validated processes. LANNETT shall notify ELITE of LANNETT's decision within thirty (30) days of receipt of such proposal from ELITE. If ELITE does not receive LANNETT's decision in writing within thirty (30) days, the alteration of the Specifications or other Major Changes to the manufacturing process or validated process proposed by ELITE shall be deemed rejected by LANNETT. In the event that the FDA or any other governmental authority shall suggest or mandate any change or revision to the Product, such that the Specifications would no longer comply with such suggestion or mandate, the Parties shall work together in good faith to develop revised Specifications that meet all changes or revisions suggested or mandated by the FDA or other governmental authority and **Schedule B** shall be amended in writing to set forth the new agreed upon Specifications.

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4.8 Acceptance of the Product.

- (a) Following receipt of a shipment of Product at the final destination, LANNETT, or its designee, shall conduct a visual inspection of the Product and all accompanying documents provided by ELITE, including without limitation, the Certificate of Analysis, in accordance with its customary procedures. LANNETT shall advise ELITE, in writing, if it is rejecting a shipment of Product due to obvious physical damage or obvious packaging defect that are evident upon such visual inspection of the packaged Product as shipped by ELITE. LANNETT (and its designees) shall have no obligation to inspect the Product beyond the visual inspection provided for in this **Article 4.8(a)**.
- (b) In the case of defects other than those obvious defects described in **Article 4.8(a)**, including, by way of example, any failure of the Product, at the time of delivery, to meet the Analytical Specifications and the representations, warranties and covenants of **Article 9.2(f)**, LANNETT shall promptly notify ELITE if it becomes aware of such non-obvious defect(s). Any defect in physical condition of Products delivered by ELITE or Products that do not conform with the Analytical Specifications (as may be in effect from time to time) or the representations, warranties and covenants of **Article 9.2(f)** for any reason shall be deemed to be a non-conforming product ("**Non-Conforming Product**"). LANNETT, or its designee, shall have the right to reject any Non-Conforming Product and no failure on the part of LANNETT, or its designee, or passage of time shall prejudice LANNETT's right to reject or revoke acceptance of Non-Conforming Product. All Non-Conforming Product shall be returned to ELITE at its sole cost and expense.
- (c) If ELITE confirms the Non-Conforming Product or lab testing pursuant to **Article 4.8(d)** determines that the Product is Non-Conforming Product, ELITE shall, at LANNETT's election, either replace such Non-Conforming Product with conforming Product or, refund LANNETT, the price paid for such Non-Conforming Product.
- (d) If the Parties cannot agree as to whether a delivered quantity of Product is Non-Conforming Product, then the Parties agree to have the batch in dispute tested and further analyzed by a recognized independent testing laboratory selected by the Parties or a quality consultant (if not a laboratory analysis issue). The appointment of such laboratory or quality consultant shall not be unreasonably withheld or delayed by either Party. The decision of the laboratory or quality consultant shall be in writing and, save for manifest error on the face of the decision, shall be binding on both Parties. Should said laboratory's testing or quality consultant determine that the Product is Non-Conforming Product then ELITE will bear the cost of such testing or quality consultant and comply with the terms of **Article 4.8(c)**. If said Product is determined to have been conforming, then LANNETT shall bear all costs of the independent laboratory testing or quality consultant as well as accept the Product shipment and pay for same within forty-five (45) days of such acceptance.

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ARTICLE 5 - INSPECTIONS

- 5.1 Inspections. During the Term of this Agreement and thereafter in the event of a Claim against either Party regarding use of the Products is threatened or commenced, ELITE shall permit LANNETT's representatives to enter ELITE's facilities, upon reasonable prior notice (except in the event of for-cause audit) and during normal business hours, for the purpose of inspecting the facility and quality control procedures and confirming compliance with all applicable GMPs and Laws in the Territory, the requirements of the Regulatory Authorities in the Territory, the Quality Agreement and this Agreement. If during any such inspection LANNETT discovers any instances in which ELITE has not complied with the foregoing, then ELITE shall promptly provide to LANNETT a written plan for correcting such deficiencies, including a proposed timetable for implementing such corrections, and shall ensure that such deficiencies are corrected, at ELITE's sole expense, as soon as reasonably practicable. ELITE agrees to provide LANNETT with copies of all: (i) reasonably requested documentation in its possession relating to the manufacture of Product, Specifications, compliance with quality assurance standards, raw material vendors and manufacturing processes; and (ii) U.S. and international regulatory approvals, regulatory inspections of the manufacturing process, facilities and documentation, and other communications with Regulatory Authorities related to the Product; however ELITE shall not be required to provide copies to LANNETT of ELITE's proprietary information and ELITE shall only be required to allow LANNETT to inspect such proprietary information such as batch records at ELITE's site and under ELITE's supervision. Notwithstanding the provision of this **Article 5.1**, LANNETT shall have no obligation or be deemed to have an obligation to inspect ELITE's facilities.
- 5.2 Regulatory Authority Inspections. ELITE shall permit any Regulatory Authority to inspect the facility used to manufacture the Products and all associated records to the full extent permitted by applicable Law ("**Regulatory Inspection**"). ELITE shall notify LANNETT within forty-eight (48) hours of becoming aware of any planned or actual Regulatory Inspection. ELITE agrees to reasonably cooperate with the applicable Regulator Authority in connection with such audits. ELITE shall notify LANNETT prior to the commencement of any meetings with, or inspection activity by any Regulatory Authority, unless such inspection activity is an unannounced inspection. Further, ELITE shall provide a reasonable description to LANNETT of any such governmental inquiries, notifications or inspections related to Products promptly (but in no event later than five (5) calendar days) after such visit or inquiry. ELITE shall furnish to LANNETT: (i) within five (5) calendar days after receipt, any report or correspondence issued by the Regulatory Authority in connection with such visit or inquiry, including but not limited to, any FDA Form 483, establishment inspection report, or warning letter; and (ii) copies of any and all responses or explanations to any Regulatory Authority relating to items set forth above prior to the submission of such responses or explanations to any Regulatory Authority by ELITE for comment, which comments shall be taken into consideration by ELITE in good faith. ELITE shall also provide LANNETT with a copy of all final responses.

ARTICLE 6 - RECORDS

- 6.1 Records. ELITE and LANNETT shall maintain all records necessary to comply with all applicable Laws in the Territory relating to the performance of their respective obligations under this Agreement. ELITE shall also maintain, or cause to be maintained (i) all manufacturing records, standard operating procedures, validation records, equipment log books, batch records, laboratory notebooks and all raw data relating to the manufacturing of the Products, and (ii) such other records as LANNETT may reasonably require in order to ensure compliance by ELITE with the terms of this Agreement. All such records shall be maintained for such period as may be required pursuant to the applicable Laws.

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- 6.2 Inspection of ELITE Books and Records. During the Term of this Agreement, and thereafter for the greater of (i) the period stipulated by the Laws in the Territory, and (ii) two (2) years from the expiration of the last Products manufactured, ELITE agrees that LANNETT, at reasonable times upon reasonable prior notice, may inspect the research and development books and records of ELITE pertaining to ELITE's obligations under the Agreement for purposes of ensuring compliance with the terms of this Agreement.
- 6.3 Inspection of LANNETT Books and Records. LANNETT shall keep, and shall require its Affiliates to maintain, in connection with the handling, sale and distribution of the Product hereunder, books and records necessary to allow the accurate calculation, consistent with GAAP, of the amounts due to ELITE, the reporting obligations contemplated herein, and compliance with the terms of this Agreement, and LANNETT shall maintain such books and records for a period of at least two (2) years after the end of the calendar year in which they were generated, or for such longer period as may be required by Applicable Law. Upon at least thirty (30) days prior written notice, ELITE, at its expense, shall have the right to have an independent public accounting or auditing firm, reasonably acceptable to LANNETT, obtain access to such books and records as may be reasonably necessary to determine or verify the amount of payments due under this Agreement and compliance with the obligations hereof; provided, however, that this right may not be exercised more than once in any calendar year. Such accounting firm shall conduct such examination, and LANNETT shall make such books and records available, during normal business hours at the facility(ies) where such books and records are customarily maintained. Each such examination shall be limited to pertinent books and records for any year ending not more than twenty-four (24) months prior to the date of request, except that ELITE shall not be permitted to audit the same period of time more than once. The independent accounting firm will prepare and provide to each Party a written report stating whether the reports submitted and amounts paid are correct or incorrect and the amounts of any discrepancies. The conclusions of such accounting firm shall be final and binding on the Parties absent demonstrable error. If there was an underpayment by LANNETT hereunder, LANNETT shall promptly (but in no event later than thirty (30) days after its receipt of the independent auditor's report so concluding) make payment to ELITE of any shortfall by wire transfer in U.S. dollars, plus interest on the amount of such shortfall calculated at the lesser of (a) five percent (5%) per annum, or (b) the maximum rate permitted by law from the date such payment should have been made to the date the shortfall is paid. If there was an overpayment by LANNETT hereunder, ELITE shall promptly (but in no event later than thirty (30) days after ELITE's receipt of the independent auditor's report so concluding) refund to LANNETT the excess amount by wire transfer in U.S. dollars. All costs of the audit, including the expenses of the independent accounting firm, shall be borne by ELITE unless the underpayment by LANNETT results in a cumulative discrepancy during any calendar year in excess of the greater of (i) ten percent (10%) of the total amount reported to ELITE for that period or (ii) one hundred thousand dollars (\$100,000.00), in which case all reasonable and documented costs of the audit, including the expenses of the independent accounting firm, shall be borne and promptly paid by LANNETT. ELITE shall ensure that the independent public accountant or auditor maintains the confidentiality of LANNETT's Confidential Information on terms no less restrictive than those set forth in this Agreement.
- 6.4 Annual Reports. ELITE shall provide LANNETT in a timely manner copies of ELITE's annual reports to the FDA or any other Regulatory Authority with respect to the Products.

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ARTICLE 7 - RECALLS

- 7.1 Notification of Recall. If any Regulatory Authority or other governmental agency issues or requests a Recall or takes similar action in connection with a Product in the Territory, or if LANNETT reasonably determines after consultation with ELITE that an event has occurred which may result in the need for a Recall, the Party notified of or wishing to implement such Recall shall, within forty-eight (48) hours (regardless of weekday, weekend or holiday), advise the other Party thereof by telephone or facsimile, after which the Parties shall promptly discuss and work together to effect an appropriate course of action. ELITE shall be responsible for notifying the Regulatory Authorities in the Territory of any voluntary Recall and implementing any Recalls. LANNETT shall fully cooperate with ELITE to fully implement any Recall. ELITE agrees to forward to LANNETT a copy of any field communication associated with the Products that it plans to issue before such communication is issued or sent to any governmental agency. ELITE will maintain complete and accurate records of any activities conducted with respect to any Recall for such period as may be required by Law. Following any Recall, ELITE will review all of its procedures as impacted by the identified root cause in the associated investigation, and will revise such procedures, as necessary, to correct the cause of such Recall subject to the change control requirements set forth in the Quality Agreement. ELITE will provide LANNETT with such information regarding such review and revisions as LANNETT may request and ELITE shall provide LANNETT the right to approve, reject or request modifications to the proposed changes.
- 7.2 Recall Expenses. If a Recall results from the acts or omissions of one Party, then such Party shall bear the full expenses of both Parties incurred in the Recall. For clarity, if a Recall is due to a defect during the manufacture, processing, packaging or labelling of the Product prior to delivery, the cost and expense shall be borne solely by ELITE. If a Recall is partially caused by the actions or omissions of both Parties, then each Party shall be responsible for its proportionate share of the Recall expenses based on its proportionate share of causation. Recall expenses include the expenses of notification, shipping, return, replacement (if possible), customer fees and penalties, and destruction of recalled Products (including Products which cannot be shipped due to the condition causing the Recall). The Parties shall discuss in good faith and agree on the scope and costs of Recall, if practicable, prior to enforcement of the Recall.
- 7.3 Notice of Failure to Meet Specifications. If ELITE discovers that there is a potential that any batch or lot of the Products already delivered to LANNETT may fail to conform to the Specifications, then ELITE shall notify LANNETT within twenty-four (24) hours (or one (1) business day) of such determination of failure to meet the Specifications and of the nature thereof in detail, including, but not limited to, supplying LANNETT with a copy of investigatory reports, data and communications, out-of-specification reports and data and the results of all outside laboratory testing and conclusions, if any. ELITE shall investigate all such failures promptly, and at its sole expense, cooperate with LANNETT in determining the cause for the failure and take a corrective action to prevent future failures.

ARTICLE 8 - TERM & TERMINATION

- 8.1 Term. This Agreement shall commence upon the Effective Date, and, unless terminated earlier in accordance with the provisions hereof, shall continue for a period of three (3) years from the Effective Date ("**Initial Term**"). Unless earlier terminated pursuant to this Agreement, the Initial Term may be extended for successive one (1) year periods ("**Renewal Term**") upon mutual agreement of the Parties in writing. The Initial Term and all Renewal Term (if any) are collectively referred to as the "Term."

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8.2 Termination. If any one or more of the following events of default shall occur, then this Agreement may be terminated as set forth herein:

- (a) if a Party files a petition in bankruptcy or is adjudged as bankrupt, or a petition in bankruptcy is filed against it and is not dismissed within sixty (60) days, or it becomes insolvent, takes advantage of legislation for creditor relief, has a receiver or receiver-manager appointed in relation to its assets, or discontinues its business, then the other Party may terminate this Agreement upon delivering written notice of termination;
- (b) if a Party hereto violates or fails to perform any of its material undertakings, agreements, covenants or obligations under this Agreement (excluding matters otherwise specifically addressed with a termination right elsewhere in this Agreement) and the failure is not remedied within thirty (30) days after written notice from the non-defaulting Party, then the non-defaulting Party may terminate this Agreement upon delivering written notice of termination to the breaching Party; *provided* that if the breaching Party is diligently pursuing in good faith the remedy of the breach at the expiration of such thirty (30) day cure period, then such thirty (30) day cure period may be extended as reasonably required to effect the cure if agreed to by the non-defaulting Party;
- (c) if a Party hereto willfully or fraudulently misrepresents any fact, information or report disclosed pursuant to this Agreement and such misrepresentation is not cured or remedied within thirty (30) days after the receipt of written notice thereof by the non-defaulting Party, then the other Party may terminate this Agreement upon delivering written notice of termination;
- (d) if a court of competent jurisdiction makes a final determination that the marketing and sale of a Product in the Territory infringes the patent or other Intellectual Property Rights in the Territory of a third party and enjoins the marketing and sale of the Product in the Territory, and if all rights to appeal have been exhausted or expired, then LANNETT may, upon delivering written notice to ELITE, terminate this Agreement with respect to such Product;
- (e) by ELITE or LANNETT, on a Product by Product basis, if any time after the first twelve (12) months from the first commercial sale, the average License Fee paid by Lannett is less than three hundred thousand dollars (US\$300,000) for a six (6) month sales period for the Product; and
- (f) Lannett will also have the right to suspend further performance under this Agreement and/or terminate this Agreement in its entirety, without liability except for unpaid previously delivered Products, if: (i) ELITE loses any approval(s) from the FDA required to perform its obligation under this Agreement; (ii) ELITE or its principals are involved in felonious or fraudulent activities related to Elite's business; or (iii) ELITE is unable to successfully address material deficiencies identified by the FDA that prevent Elite from manufacturing Product as a result of an inspection of ELITE'S facility within sixty (60) days after ELITE'S receipt of a deficiency notice from the FDA; or (iv) more than three (3) late shipments of the Products occur during any 12-month period during the Term. In any such event, LANNETT may terminate this Agreement immediately by written notice to ELITE. For purposes of this Section, a late shipment shall mean failure by ELITE to deliver LANNETT ninety (90) percent (90%) of the Products ordered by LANNETT for delivery within twenty (20) days of the date specified for such delivery in the applicable Purchase Order.

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- 8.3 Other Termination Rights. In addition to **Article 8.2**, (i) either Party may terminate this Agreement pursuant to **Articles 14.3** (Assignment without Consent) and **14.5** (Force Majeure), and (ii) LANNETT may terminate this Agreement pursuant to **Article 4.4** (Failure to Supply) and **Article 9.2(c)** (Debarred), and (iii) ELITE may terminate this Agreement pursuant to **Article 9.3(c)** (Debarred). LANNETT may terminate this Agreement for any reason upon providing ELITE with six (6) months written notice.
- 8.4 Effect of Termination. Upon termination or expiration of this Agreement, the provisions of this Agreement shall continue to apply with respect to the Parties' respective rights and obligations in relation to any Purchase Order made prior to such termination, including without limitation ELITE's obligation to manufacture, release and deliver Products to LANNETT, and LANNETT's obligation to make payment for such Products. If this Agreement is terminated while LANNETT is still in possession of Products ("**Remaining Products**"), ELITE hereby grants LANNETT and its Affiliates a license to promote, market, distribute and sell the Remaining Products in the Territory, subject to the License Fees in Article 3.3.
- 8.5 Survival. The expiration or earlier termination of this Agreement shall not relieve either Party hereto from any obligations which accrued prior to such expiration or earlier termination, and shall not destroy or diminish the binding force and effect of any of the terms and conditions of this Agreement that expressly or by implication come into or continue in effect on or after termination or expiration, including **ARTICLE 1 - , ARTICLE 5 - , ARTICLE 6 - , ARTICLE 7 - , Section 8.4, ARTICLE 9 - , ARTICLE 11 - , ARTICLE 12 - , Sections 14.6, and 14.7**. Further, the provisions from the Original Agreement that were deemed to survive the termination or expiration of that Agreement shall further survive.

ARTICLE 9 - REPRESENTATIONS & WARRANTIES

- 9.1 Representations and Warranties. Each Party represents and warrants to the other Party as follows, which representations and warranties shall be true as at the date hereof and throughout the Term of this Agreement:
- (a) it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this Agreement; and
 - (b) this Agreement is its legal, valid and binding obligation, enforceable in accordance with the terms and conditions hereof.
- 9.2 ELITE General and Supply Warranties. ELITE represents and warrants to LANNETT as follows:
- (a) No Other Agreements. No contracts, commitments or agreements of any nature exist, and none will be entered into during the Term of this Agreement, that impair or inhibit the ability of ELITE to perform its obligations hereunder.

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- (b) No Lawsuits. As of the date hereof there have not been any Claims, lawsuits, arbitrations, legal or administrative or regulatory proceedings, charges, or complaints or investigations, by any third party or government authority threatened, commenced, pending or proceeding against ELITE, and ELITE has not received any notice thereof, which could prevent ELITE from complying with its material obligations under the Agreement.
- (c) Debarred. Neither ELITE nor any of its officers, directors, or employees or consultants performing services under this Agreement has been or is: (1) an individual who has been debarred by the FDA pursuant to 21 U.S.C. § 335a(a) or (b) (“**Debarred Individual**”) from providing services in any capacity to a person that has an approved or pending drug product application with FDA, or an employer, employee, or partner of such a Debarred Individual; or (2) a corporation, partnership or association that has been debarred by FDA pursuant to 21 U.S.C. § 335a(a) or (b) (“**Debarred Entity**”) from submitting or assisting in the submission of an ANDA, or an employee, partner, shareholder, member, subsidiary, or affiliate of a Debarred Entity; or (3) an employer, employee or partner of an individual convicted within the last five years for crimes described in subsections (a) or (b) of Section 306 of the FDCA. If and when ELITE becomes aware of any fact that makes or gives rise to make this representation and warranty untrue, ELITE shall immediately notify LANNETT in writing and any such breach may result in immediate termination of this Agreement by LANNETT.
- (d) Non-Infringement.
- (i) ELITE’s performance of its obligations hereunder to the best of ELITE’s knowledge does not and will not infringe any intellectual property rights of a third party.
- (ii) To the best of ELITE’s knowledge no patents, patent applications if issued, or any other proprietary rights of any third party would be infringed by the manufacture, use or sale of the Product and ELITE shall indemnify, defend and hold harmless LANNETT and its Affiliates against any and all such infringement claims, demands, actions, losses, damages, fines, penalties, costs and expenses (including reasonable attorneys’ fees). The indemnification obligation of ELITE shall include Third Party patents issued after the Effective Date.
- (e) Facility. The Facility is in compliance with all Laws, including without limitation GMP, and that there are no, nor have been any, citations or adverse conditions of a material nature noted in any inspection of the site which would cause the Product to be misbranded or adulterated. It has and shall maintain sufficient knowledge and experience and adequate production facility(s), equipment and processes to produce the Product and perform its obligations under this Agreement in compliance with all Laws.
- (f) Products Supply. ELITE warrants, represents and covenants to LANNETT that all Products delivered to LANNETT hereunder shall:
- (i) comply with the Specifications;
- (ii) comply with the applicable Purchase Order;

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- (iii) be manufactured, tested, packaged, labeled, stored, handled and delivered by ELITE in accordance with (i) the terms of the Agreement, including the Specifications, and the Quality Agreement, (ii) the requirements of the Marketing Authorization, (iii) all applicable GMPs and Laws in the Territory, including regulations set forth by the DEA, (iv) all of ELITE'S quality control procedures and associated test methods for the Products;
 - (iv) be manufactured at the Facility approved by the Regulatory Authorities in the Territory;
 - (v) not be adulterated or misbranded under any applicable Laws in the Territory;
 - (vi) have at least eighty-five percent (85%) of the Product's shelf-life remaining at the time of delivery; and
 - (vii) be free of all liens, security interests, and other claims of any nature and free from defects in material, manufacturing and workmanship for the shelf-life of the Products.
- (g) be manufactured, supplied, packaged, labeled and delivered in compliance with all serialization and aggregation requirements set forth in the Drug Supply Chain Security Act (DSCSA) Marketing Authorizations. The serialization requirements include, but are not limited to, the addition of Product identifiers imprinted on each sellable unit, on each homogenous case and on each pallet intended to be introduced in the Territory. Unique Product identifiers will include a national drug code, serial identifier (provided by LANNETT), lot number and expiration date. Serial numbers must be aggregated from item to case and case to pallet. ELITE warrants, represents and covenants to LANNETT that (i) all Marketing Authorizations have been obtained as necessary to permit LANNETT to manufacture, use, store, import, transport and sell the Product in the Territory pursuant to the terms of this Agreement and (ii) ELITE shall maintain all necessary Marketing Authorizations in good standing to permit LANNETT to manufacture, use, store, import, transport and sell the Product in the Territory pursuant to the terms of this Agreement.
- (h) It is and shall at all times relevant to this Agreement be in full compliance with all applicable Laws relating or impacting in the performance of ELITE's duties and obligations under this Agreement, including but not limited to, those rules, regulations, and/or guidance promulgated or issued by the FDA, the Centers for Medicare & Medicaid Services, the U.S. Department of Health and Human Services Office of Inspector General, the U.S. Drug Enforcement Agency, the U.S. Department of Justice, as well as any applicable environmental requirements and a serialization and aggregation requirements set forth in the Drug Supply Chain Security Act.
- (i) Subject to DEA quotas, it has access to sufficient supplies of raw materials, components and other required resources to perform the services required under this Agreement, and shall exercise commercially reasonable and diligent efforts to maintain access to sufficient supplies without interruption during the Term.

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9.3 LANNETT General Warranties. LANNETT represents and warrants to ELITE that:

- (a) No Other Agreements. No contracts, commitments or agreements of any nature exist, and LANNETT covenants that none will be entered into during the Term of this Agreement that impair or inhibit the ability of LANNETT to perform its obligations hereunder.
- (b) No Lawsuits. As of the date hereof there have not been any Claims, lawsuits, arbitrations, legal or administrative or regulatory proceedings, charges, or complaints or investigations by any third party or government authority threatened, commenced, pending or proceeding against LANNETT, and LANNETT has not received any notice thereof, which could prevent LANNETT from complying with its material obligations under this Agreement.
- (c) Debarred. Neither LANNETT nor any of its officers, directors, or employees or consultants performing services under this Agreement has been or is: (1) a Debarred Individual or an employer, employee, or partner of such a Debarred Individual; or (2) a Debarred Entity, or an employee, partner, shareholder, member, subsidiary, or affiliate of a Debarred Entity; or (3) an employer, employee or partner of an individual convicted within the last five years for crimes described in subsections (a) or (b) of Section 306 of the FDCA. If and when LANNETT becomes aware of any fact that makes or gives rise to make this representation and warranty untrue, LANNETT shall immediately notify ELITE in writing and any such breach may result in immediate termination of this Agreement by ELITE.
- (d) It is and shall at all times relevant to this Agreement be in full compliance with all applicable Laws relating or impacting in the performance of LANNETT's duties and obligations under this Agreement, including, to the extent applicable, but not limited to, those rules, regulations, and/or guidance promulgated or issued by the FDA, the Centers for Medicare & Medicaid Services, the U.S. Department of Health and Human Services Office of Inspector General the U.S. Drug Enforcement Agency, the U.S. Department of Justice, as well as any applicable environmental requirements and all applicable requirements set forth in the Drug Supply Chain Security Act.

9.4 Disclaimer. EXCEPT FOR THE WARRANTIES AND REPRESENTATIONS PROVIDED OR REFERENCED IN THIS AGREEMENT, THE PARTIES MAKE NO OTHER WARRANTIES OR REPRESENTATIONS TO EACH OTHER, EXPRESS OR IMPLIED, IN CONNECTION WITH THOSE WITH RESPECT TO THE PRODUCTS, WHETHER STATUTORY OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ALL OTHER WARRANTIES, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 10 - COVENANTS

- 10.1 Compliance. Each Party shall perform its obligations under this Agreement in strict compliance with all applicable GMPs and Laws in the Territory and all applicable licenses, governmental permits or applications in the Territory.
- 10.2 Permits and Licenses. Each Party shall throughout the Term of this Agreement obtain and maintain any and all licenses, permits, orders, applications and consents (including facility licenses and permits) required by the Regulatory Authorities in the Territory, and all applicable Laws, regulations and GMPs necessary or required to perform its obligations under this Agreement.

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ARTICLE 11 - INDEMNIFICATION & INSURANCE

11.1 Indemnification of ELITE LANNETT shall defend, indemnify and hold harmless ELITE, its Affiliates and their respective officers, director employees, agents and representatives from and against all Losses from any Third-Party Claim directly resulting from:

- (a) any breach of any obligations, actions, or representations made by LANNETT under this Agreement; and
- (b) any negligent, grossly negligent or intentionally wrongful act or omission of LANNETT or of any person acting on LANNETT's behalf, with authorization, when the wrongful act or omission occurred in performance of LANNETT's obligations under this Agreement;

provided, however, that the foregoing indemnification obligations shall not apply to the extent such Losses are caused by an act or omission for which ELITE is contributorily negligent and/or otherwise required to indemnify LANNETT under **Article 11.2**.

11.2 Indemnification of LANNETT ELITE shall defend, indemnify and hold harmless LANNETT, its Affiliates and their respective officers, director employees, agents and representatives from and against all Losses from any Third-Party Claim directly resulting from:

- (a) any breach of any obligations, actions, or representations made by ELITE under this Agreement;
- (b) any infringement or claim of infringement of any patent, trademark or other intellectual property rights based on the manufacture and release of the Product furnished under the provisions of this Agreement;
- (c) personal injury (including death) or property damage relating to or arising out of any use, distribution or sale of the Products by LANNETT or its Affiliates to the extent that such Loss was the result of the Product not being manufactured to meet the Analytical Specifications;
- (d) any negligent, grossly negligent or intentionally wrongful act or omission of ELITE or of any person acting on ELITE's behalf, with authorization, when the wrongful act or omission occurred in performance of ELITE's obligations under this Agreement;
- (e) the condition of any Products sold, supplied or delivered to LANNETT under this Agreement, including any defect in material, workmanship, design, manufacturing or formulation;
- (f) any warnings and instructions, or lack thereof, for any Product;
- (g) the possession, distribution, sale and/or use of, or by reason of the seizure of, any Product; and
- (h) any actual or asserted violation(s) of the FDCA or any applicable Law by virtue of which any Product sold, supplied or delivered to Lannett under this Agreement is alleged or determined to be adulterated, misbranded, mislabeled or otherwise not in full compliance with, or in contravention of, any applicable Law.

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provided, however, that the foregoing indemnification obligations shall not apply to the extent such Losses are caused by an act or omission for which LANNETT is contributorily negligent or is required to indemnify ELITE under **Article 11.1**. ELITE shall also indemnify LANNETT for any damages arising from any interruption in supply of the Products to LANNETT occasioned by ELITE's commitments, contractual or otherwise, with Third Party subject to **Article 4.4**.

- 11.3 Indemnification Procedure. Any Party entitled to indemnification hereunder (the "**Indemnitee**") shall notify the indemnifying Party (the "**Indemnitor**") promptly of any claim threatened or commenced against the Indemnitee. The Indemnitor shall assume control and direct the defense investigation and handling of the claim for and on behalf of the Indemnitee, *provided, however* that the Indemnitor shall not settle or consent to judgment without the Indemnitee's approval, which approval shall not to be unreasonably withheld. The Indemnitee shall cooperate with the Indemnitor, and may participate, at the Indemnitee's expense, in the defense of such claim. If the Indemnitor fails to assume control of the defense of any claim, or, having elected to assume control, thereafter fails to diligently defend the claim, the Indemnitee shall, without limitation to the Indemnitor's obligations hereunder, be entitled to contest, settle or pay the amount of the claim, and the Indemnitor shall be bound by the results obtained by the Indemnitee with respect to the claim.
- 11.4 Insurance. Each Party hereby represents to the other that it has, and during the Initial Term and any Renewal Term and for three (3) years after termination or expiration of this Agreement, will maintain, products liability insurance coverage of not less than US five million dollars (\$5,000,000.00) per occurrence and five million dollars (\$5,000,000) in the aggregate. ELITE shall increase its product liability insurance coverage to ten million dollars (\$10,000,000) prior to the launch of [**] Product. For the sake of clarity, should ELITE increase its product liability insurance coverage beyond this amount, the new levels shall automatically apply to this Agreement. Upon the request of the other Party hereto, the insured Party shall furnish the other Party with a certificate of insurance evidencing such coverage and each Party shall endeavor to provide notice to the other Party if there is a material change or cancellation of the policy. Each Party shall list the other Party as an additional insured on such Party's applicable insurance coverage. Each Party shall provide the certificate of insurance within ten (10) days of its receipt of a request for proof of insurance.
- 11.5 Survival. The obligations set forth in this **ARTICLE 11** shall survive the termination of this Agreement and remain in full force and effect for an indefinite period after termination in relation to any claim based on events which occur during the term hereof.

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ARTICLE 12 - CONFIDENTIALITY

- 12.1 **Confidentiality.** During the Term of this Agreement and for five (5) years thereafter, each Party shall maintain in strict confidence the Confidential Information (as defined below) of the other Party. Each Party shall not use the Confidential Information of the other Party for any purpose other than the purposes expressly permitted by this Agreement, and shall not disclose such Confidential Information to any third party (including in connection with any publications, presentations or other disclosures) except to its employees, agents or advisors (“**Representatives**”) who have a need to know such Confidential Information to perform such Party’s obligations under this Agreement. Each Party shall ensure that any Representative to whom it discloses the other Party’s Confidential Information is informed of the confidential nature of and duty not to disclose the information, and is obligated under written obligation to maintain the confidentiality thereof on terms at least as restrictive as those set forth herein. Each Party shall be responsible for any breach of this Agreement by its Representatives, which shall be considered a breach by such Party. Under no circumstances shall the receiving Party use the disclosing Party’s Confidential Information for its own commercial advantage to the detriment of the disclosing Party. Each Party may disclose such of the Confidential Information of the other Party as may be required by the order of a court of competent jurisdiction or by any governmental authority having jurisdiction, *provided* that prior to any such disclosure the Party required to disclose shall, to the extent permitted by Law, notify the other Party prior to disclosing any Confidential Information and provide such other Party with a reasonable opportunity to contest or limit the scope of the required disclosure and obtain any protective orders as may be appropriate. In the event the disclosure is nonetheless compelled, the Party making the disclosure shall only disclose the information to the extent required to comply with the Law. Upon termination or expiration of this Agreement, or upon request, a Party shall destroy or return all Confidential Information of the other Party and certify in writing that such return (or destruction) has been completed; provided, however, that each Party shall be entitled to retain one archival copy of such Confidential Information solely for purposes of monitoring such Party’s compliance with its obligations under this **ARTICLE 12 -** .
- 12.2 **Definition.** “**Confidential Information**” means all proprietary technical information, marketing, business and financial information, scientific data, information, whether or not labeled “Confidential”, and all tangible and intangible embodiments and oral disclosures thereof of any kind whatsoever, and all other materials which a disclosing Party treats confidentially that relates to a Product or the business of a Party and is disclosed or developed under or in connection with this Agreement. Confidential Information shall not include any information which the receiving Party can show by competent proof:
- (a) was known to or in the possession of the receiving Party prior to the date of its actual receipt from the disclosing Party;
 - (b) is readily available to the public other than through the fault of the receiving Party;
 - (c) was disclosed by a third party not under an obligation of confidentiality to the disclosing Party; or
 - (d) is subsequently independently developed by the receiving Party without use of the Confidential Information as demonstrated by competent written records.
- 12.3 **Injunctive Relief.** The Parties acknowledge that any breach of this **ARTICLE 12 -** may constitute irreparable harm, and that the non-breaching Party shall be entitled to seek specific performance or injunctive relief to enforce this **ARTICLE 12 -** in addition to whatever remedies such Party may otherwise be entitled to at law or in equity, without the necessity of posting bond or any other security.
- 12.4 **Separate Confidentiality Agreement.** LANNETT and ELITE have entered into a separate Mutual Confidential Disclosure Agreement dated January 7, 2019 (“**Confidentiality Agreement**”). Such Confidentiality Agreement will be and remain in full force and effect as provided therein. In the event of any conflict between the terms of this Agreement and the terms of any such Confidentiality Agreement, the terms of such Confidentiality Agreement will control.

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- 12.5 No Publicity. Except as required by law, neither Party shall originate any publicity, news release or other public announcements, written or oral, whether to the public press, to stockholders, or otherwise, relating to this Agreement, any amendment hereto, performance hereunder or the existence of an arrangement between the Parties without the prior written approval of the other Party, which approval shall not be unreasonably withheld. Nothing in the provision shall be deemed to prevent a Party from making such disclosures or announcements that are legally required of such Party *provided* that in any event the non-disclosing Party shall have the right to review any such disclosure and revise such disclosure to the extent it relates to the use of the non-disclosing Party's name or Confidential Information. No Party shall, without the prior written consent of the affected Party, use in advertising, publicity, or otherwise, the name, trademark, logo, symbol, or other image of the affected Party without the other Party's prior written consent.

ARTICLE 13 - REGULATORY MATTERS

- 13.1 Regulatory Responsibilities. ELITE will, at its own cost and expense, continue to own and maintain the applicable Regulatory Approvals necessary to market the Products in the Territory. ELITE shall be responsible for all regulatory and safety reporting requirements associated with ownership of the Regulatory Approval, including, without limitation, adverse event reports, annual reports mandated by the applicable Laws in the Territory. Additionally, ELITE shall be responsible for complying with applicable Laws to appropriately categorize and report changes to the FDA, including without limitation, amendments, supplements, and annual reports. All communications by ELITE with the FDA relating to the Products as marketed in the Territory shall be promptly provided in writing to LANNETT, and ELITE shall promptly provide to LANNETT copies of all documents sent to or received from the FDA regarding the Products.
- 13.2 Labeling. ELITE shall be responsible for the creation, content, and printing of the labeling for the Products. ELITE shall send LANNETT all labeling materials (e.g., package insert, container label, carton label, medication guide, patient labeling, etc.) in final format for the Products for LANNETT's review and final written approval. ELITE is responsible for ensuring the most current labeling content, consistent with the reference listed drug ("RLD") labeling content and all requested FDA updates, is used on Products supplied to LANNETT. ELITE is responsible for notifying LANNETT within three (3) business days of any FDA communication requesting changes to labeling materials, including Safety Change Notifications and changes requested per section 505(o)(4) of the FDCA. ELITE will provide LANNETT with a copy of all FDA communications related to labeling. All changes to labeling materials for the Products require LANNETT'S review and final written approval. Labeling materials that have not been subject to LANNETT'S review and written approval are prohibited to be used on Products supplied to LANNETT. ELITE is responsible for submitting the content of labeling in Structured Product Labeling ("SPL") format to the FDA for LANNETT'S NDC numbers within fourteen (14) days of ANI approval to ensure proper drug listing. ELITE is also responsible for submitting updated SPL files within fourteen (14) days when labeling changes are made and approved and as required by applicable Laws.

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ARTICLE 14 - MISCELLANEOUS

14.1 Notices. Any notice or other document required or permitted to be given pursuant to this Agreement shall be in writing and shall be delivered by personally by hand; by courier; by prepaid certified mail, return receipt requested; or by email, in each case addressed to the Party to whom it is to be given at the address set forth below or at such other address as the Party to whom such notice is to be given shall have last notified the other Party in accordance with the provisions of this section:

In the case of LANNETT at:	Lannett Company, Inc., USA 9000 State Road Philadelphia, PA 19136 Attention: Legal Department Email: [**]
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And in the case of ELITE at:	Elite Pharmaceuticals, Inc. 165 Ludlow Avenue Northvale, NJ 07647 Attention: CEO Email: [**]
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Any such notice or other document shall:

- (i) if delivered by hand, courier, or email be deemed to have been given and received at the place of receipt on the date of delivery, *provided* that if delivery is other than during business hours (9:00 a.m. to 5:00 p.m., local time) on a Business Day in the place of receipt, such notice shall be deemed to have been given and received at the place of receipt on the first Business Day thereafter; and
- (ii) if mailed, be deemed to have been given and received at the place of receipt on the earlier of the date of actual receipt and three (3) Business Days after the date of mailing. In the event of postal disruption, such notices or documents must be delivered by means other than by mail.

14.2 Relationship of the Parties. The relationship of the Parties is that of independent contractors. Nothing in this Agreement shall be deemed or construed to constitute or create between the Parties hereto a partnership, joint venture, agency, or other relationship other than as expressly set forth herein. This Agreement does not constitute any one Party hereto as the agent or legal representative of the other Party for any purpose whatsoever. Neither of the Parties grants to the other any right or authority to assume or create any obligation or responsibility, express or implied, on behalf of it or in its name in any manner whatsoever, unless otherwise agreed to in writing by the other Party.

14.3 Inurement & Assignment. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns. Except as otherwise expressly provided herein, neither Party may assign or transfer its rights or obligations under this Agreement, in whole or in part, without the prior written consent of the other Party. Notwithstanding the foregoing, both LANNETT and ELITE shall be entitled to assign its rights and performance of its obligations under this Agreement to any Affiliate or to the acquirer of all or substantially all of the business or assets to which this Agreement relates (whether by stock sale, asset sale, merger, consolidation or otherwise), provided that the assigning Party remains fully responsible for the performance of the obligations of its Affiliates under this Agreement. Any assignment or transfer by a Party other than in accordance with the terms hereof shall be void and shall entitle the other Party to terminate this Agreement.

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- 14.4 No Waiver; Remedies. No Party to this Agreement shall be deemed or taken to have waived any provision of this Agreement unless such waiver is in writing, and then such waiver shall be limited to the circumstances set forth in such written waiver. No failure or delay on the part of a Party in exercising any right, power or remedy shall operate as a waiver thereof, nor shall any single or partial exercise of any such right, power or remedy preclude any other or further exercise thereof or the exercise of any other right, power or remedy. All remedies provided for hereunder shall be cumulative of and in addition to any and all other remedies, at law or in equity, which any Party may have, and the exercise of any one or more of such remedies shall not preclude the exercise of any others.
- 14.5 Force Majeure. If either Party is prevented from complying, either totally or in part, with any of the terms or provisions of this Agreement by reason of force majeure, including fire, flood, earthquake, storm, general strike, lockout, riot, war, terrorism, rebellion, accident, acts of God and/or any other cause or externally induced similar casualty beyond its reasonable control and without the fault or negligence of either Party (a “**Force Majeure Event**”), then, upon written notice by the Party liable to perform to the other Party, the requirements of this Agreement or such of its provisions as may be affected, and to the extent so affected, shall be suspended during the period of such disability, *provided* that the Party asserting force majeure shall bear the burden of establishing the existence of such Force Majeure Event by clear and convincing evidence, and *provided further* that the Party prevented from complying shall use its best efforts to remove such disability, and shall continue performance with the utmost dispatch whenever such causes are removed, and shall notify the other Party of the Force Majeure Event not more than five (5) Business Days from the time of the event and state the nature of the Force Majeure Event, its anticipated duration and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is reasonably required. When such circumstances arise, the Parties shall discuss what, if any, modification of the terms of this Agreement may be required in order to arrive at an equitable solution. Notwithstanding the foregoing, if a Force Majeure Event shall continue for a period of longer than three (3) consecutive months or one hundred and twenty (120) days in any twelve (12) month period, then the Party unaffected by such event may terminate this Agreement immediately upon giving written notice of termination to the other Party. Notwithstanding any provision contained herein, any action taken by a Regulatory Authority as a result of a Party’s negligence or willful misconduct shall not constitute a Force Majeure Event under this **Article 14.5**.
- 14.6 Dispute Resolution The Parties recognize that disputes as to certain matters may from time to time arise which relate to a Party's rights and/or obligations under this Agreement. It is the objective of the Parties to establish procedures to facilitate the resolution of such disputes in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this **Article 14.6** if and when such a dispute arises between the Parties arises. Notwithstanding the provisions of this **Article 14.6** however, nothing herein contained shall preclude a Party from seeking equitable remedies in any court of competent jurisdiction as set forth in **Article 14.7** hereof. If any controversy, dispute or claim arises between the Parties relating to the interpretation, breach, performance, enforcement, termination or validity of this Agreement and the Parties cannot resolve the dispute within thirty (30) days of a written request by one Party to any other Party, the Parties agree to hold a meeting, attended by each Parties authorized representatives , to attempt in good faith to negotiate a resolution of the dispute prior to pursuing other available remedies. If, within thirty (30) days after such written request, the Parties have not succeeded in negotiating a resolution of the dispute, the Party may seek any other remedies available to it in at law or in equity.

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- 14.7 Governing Law & Venue. This Agreement shall be governed by, and construed in accordance with, the laws of the State of Delaware, without giving effect to any choice of law or conflict of law rules or provisions that would cause the application of the laws of any jurisdiction other than the State of Delaware. Each Party hereby irrevocably submits to the exclusive jurisdiction of any federal or state court in Delaware for the purposes of any suit action or other proceeding arising out of this Agreement or any transaction contemplated hereby. Each Party further agrees that service of any process, summons, notice or document by certified or registered mail to such Party's address set forth in **Article 14.1** or such other address or to the attention of such other person as the recipient Party has specified by prior written notice to the sending Party shall be effective service of process in any action, suit or proceeding in Delaware with respect to any matters to which it has submitted to jurisdiction as set forth above in the immediately preceding sentence. Each Party irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of this Agreement or the transactions contemplated hereby in the federal or the state courts in Delaware and hereby irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such action, suit or proceeding brought in such court has been brought in an inconvenient forum.
- 14.8 Waiver of Trial by Jury. TO THE FULLEST EXTENT PERMITTED BY LAW, THE PARTIES HEREBY WAIVE THEIR RESPECTIVE RIGHTS TO A JURY TRIAL OF ANY PROCEEDING BASED UPON, ARISING OUT OF, OR RELATED TO THIS AGREEMENT, INCLUDING ANY DISPUTE ARISING OUT OF OR RELATING TO THE PERFORMANCE THEREOF, OR ANY OTHER TRANSACTION CONTEMPLATED BY THIS AGREEMENT. THE SCOPE OF THIS WAIVER IS INTENDED TO ENCOMPASS ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT AND THAT RELATE TO THE SUBJECT MATTER OF THIS AGREEMENT, INCLUDING CONTRACT CLAIMS, TORT CLAIMS, BREACH OF DUTY CLAIMS AND ALL COMMON LAW AND STATUTORY CLAIMS.
- 14.9 Severability. If any provision in this Agreement is held to be invalid, void or unenforceable, then the remainder of this Agreement, or the application of such provision to the Parties or to the circumstances other than those as to which it is held invalid or unenforceable, shall not be affected thereby and shall be enforced to the fullest extent permitted by law. The Parties agree to renegotiate any such invalid, void or unenforceable provision in good faith in order to provide a reasonably acceptable alternative consistent with the basic purposes of this Agreement.
- 14.10 Entire Agreement. This Agreement (including the Schedules attached hereto, the SDEA and the Quality Agreement) constitutes the entire agreement between the Parties with respect to the subject matter hereof, and all prior or contemporaneous agreements, whether written or oral, are superseded hereby. This Agreement may be amended only in writing executed by the Parties.
- 14.11 Sub-contracting. ELITE shall not sub-contract any of the work to be performed under this Agreement without the prior written consent of LANNETT. No such sub-contracting shall relieve ELITE of any of its obligations hereunder.
- 14.12 Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed shall be deemed to be an original and all of which when taken together shall constitute this Agreement.

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- 14.13 Headings. The captions and headings contained herein are for convenience of the Parties and in no way define, limit or describe the scope of this Agreement.
- 14.14 Language. The language of this Agreement and all proceedings taken in relation thereto shall be English.
- 14.15 Currency. Unless otherwise specifically provided, all references to money amounts are expressed in terms of United States Dollars (USD) and a payments made pursuant to this Agreement shall be made in that currency.
- 14.16 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any Section of this Agreement are and shall otherwise be deemed to be for purposes of Section 365(n) of Title 11, of the United States Code (the "**Bankruptcy Code**") licenses of rights to "intellectual property" as defined in Section 101(35A) of the Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights and elections under the Bankruptcy Code. Upon the bankruptcy of any Party, the non-bankrupt Party shall use its best efforts to transfer its Production responsibilities to a third party, unless the bankrupt Party elects to continue, and continues, to perform all of its obligations under this Agreement.
- 14.17 Construction of Agreement. The terms and provisions of this Agreement represent the results of negotiations between the Parties and their representatives, each of which has been represented by counsel of its own choosing, and neither of which has acted under duress or compulsion, whether legal, economic or otherwise. Accordingly, the terms and provisions of this Agreement shall be interpreted and construed in accordance with their usual and customary meanings, and each of the Parties hereto hereby waives the application in connection with the interpretation and construction of this Agreement of any rule of law to the effect that ambiguous or conflicting terms or provisions contained in this Agreement shall be interpreted or construed against the Party whose attorney prepared the executed draft or any earlier draft of this Agreement.

[SIGNATURE PAGE FOLLOWS]

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IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the date first written above.

ELITE PHARMACEUTICALS, INC.

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

LANNETT COMPANY, INC.

By: /s/ Tim Crew
Name: Tim Crew
Title: CEO

ELITE LABORATORIES, INC.

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

Schedule A: Products

Schedule B: Product Specifications

Schedule C: Quarterly Report for Calculation of Gross Profit

Schedule D: Shipping Instructions

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SCHEDULE A

Products and Prices

Product List

Generic Name	ANDA #	Reference Listed Drug
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Tablets (Mixed Salts of a Single Entity Amphetamine Product)	211352	Adderall®
[**]	[**]	[**]

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Transfer Prices (\$/bottle)

Name	Strength	Full Batch Qty.	Bottle Size	Cost per bottle
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Tablets (Mixed Salts of a Single Entity Amphetamine Product)	5 mg	[**] bottles	100 count	[\$]**
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Tablets (Mixed Salts of a Single Entity Amphetamine Product)	7.5 mg	[**] bottles	100 count	[\$]**
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Tablets (Mixed Salts of a Single Entity Amphetamine Product)	10 mg	[**] bottles	100 count	[\$]**
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Tablets (Mixed Salts of a Single Entity Amphetamine Product)	12.5 mg	[**] bottles	100 count	[\$]**
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Tablets (Mixed Salts of a Single Entity Amphetamine Product)	15 m g	[**] bottles	100 count	[\$]**
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Tablets (Mixed Salts of a Single Entity Amphetamine Product)	20 mg	[**] bottles	100 count	[\$]**
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Tablets (Mixed Salts of a Single Entity Amphetamine Product)	30 mg	[**] bottles	100 count	[\$]**
[**]	[**] mg	[**] bottles	100 count	[\$]**
[**]	[**] mg	[**] bottles	100 count	[\$]**
[**]	[**] mg	[**] bottles	100 count	[\$]**
[**]	[**] mg	[**] bottles	100 count	[\$]**
[**]	[**] mg	[**] bottles	100 count	[\$]**
[**]	[**] mg	[**] bottles	100 count	[\$]**

Pricing includes all Product manufacturing and packaging costs, quality assurance, batch quality control testing and stability testing, and is subject pricing adjustments in Section 4.1(d).

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SCHEDULE B

PRODUCT SPECIFICATIONS

[]**

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SCHEDULE C

QUARTERLY REPORT FOR CALCULATION OF GROSS PROFIT

PRODUCT NAME: _____

QUANTITY SOLD BY SKU	XXXX UNITS
GROSS SALES	\$
<i>DEDUCTIONS:</i>	
CHARGEBACKS	
REBATES	
ADMINISTRATIVE FEES	
BILLBACKS	
RETURNS	
SHELF STOCK ADJUSTMENTS	
OTHER DEDUCTIONS	
CASH DISCOUNTS	
MEDICAID	
NET SALES	\$
TRANSFER PRICE	
DISTRIBUTION FEES	
SHIPPING COSTS	
GROSS PROFIT	
NET PROFIT	
PROFIT SHARE PAYMENT TO ELITE AT [**]%	

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SCHEDULE D

SHIPPING INSTRUCTIONS

All shipments inbound to LANNETT must arrive intact and in a certain and dry condition that is free from defects and damage.

All material must have 85% of its maximum shelf life remaining at the time of delivery and in no case less than 15 months.

All truckloads of the Products should be in sealed trailers, with the seal number noted on the delivery receipt.

All truckload and less than truckload shipments must be on 40"x48" 4-way heat treated pallets that are shrink-wrapped and free of broken boards.

Finished goods materials should have a maximum height of 51" from the floor to the top of the pallet.

Each shipment must be labelled with a minimum of the name of the material, the manufacturer's lot number, the gross, tare, and net weights, the LANNETT item number for the material, and the LANNETT purchase order number.

All finished products must be packaged as agreed in the product specification and case labels must be HDMA complaint.

A dock appointment must be scheduled for deliveries consisting of 5 or more pallets and for all hazardous material. Receiving hours are 7am-3pm Eastern. For Seymour, IN deliveries, please contact the representative at 812-523-5446 to schedule all freight deliveries.

Please email invoices to the following email address: AccountsPayable@Lannett.com

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THAT HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND
(II) WOULD BE COMPETITIVELY HARMFUL IN PUBLICLY DISCLOSED.**

DEVELOPMENT AGREEMENT FOR PRODUCTS BETWEEN ELITE PHARMACEUTICALS, INC. AND MIKAH PHARMA

This DEVELOPMENT AGREEMENT (the “Agreement”), dated December 3, 2018 (the “Effective Date”) between Mikah Pharma LLC, 20 Kilmer E Hillsborough, NJ 08844 (“Mikah”) and Elite Laboratories, Inc. (a subsidiary of Elite Pharmaceuticals, Inc.), organized under the laws of the State of Delaware with offices at 165 Ludlow Avenue, Northvale, New Jersey, USA (“Elite”); Mikah and Elite may sometimes hereinafter be referred to as a “Party” collectively as the “Parties”.

WHEREAS Mikah is engaged in the research, development, and licensing of generic pharmaceutical products; and

WHEREAS Elite is engaged in the research, development, manufacturing, sales and marketing of generic products;

WHEREAS Mikah and Elite wish to collaborate to develop and commercialize generic products including formulation development and analytic method development and bioequivalence studies and manufacture of development batches of generic products:

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

ARTICLE 1

DEFINITIONS

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

- 1.1 “Affiliate” 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.
 - 1.2 “Agreement” shall have the meaning set forth in the Preamble and shall include any exhibits and attachments hereto.
 - 1.3 “ANDA” shall mean Abbreviated New Drug Application pursuant to the applicable part of FD&C Act, and any supplements and amendments theret which may be filed by the Parties.
 - 1.4 “API” shall mean the active pharmaceutical ingredient.
 - 1.5 “Data” shall refer to all data, materials, plans, reports, test results and other information developed in connection with the Products.
-

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- 1.6 “FDA” shall mean the United States Food and Drug Administration.
- 1.7 “FD&C Act” shall mean the United States Federal Food, Drug and Cosmetics Act, (21 U.S.C. 301, et seq.), as amended from time to time, and all regulation promulgated thereunder, including, without limitation, all current Good Manufacturing Practices and current good laboratory practices as defined therein, in each case, as amended from time to time.
- 1.8 “Force Majeure” shall mean the occurrence of an event which materially interferes with the ability of a Party to perform its obligations or duties hereunder which is not within the reasonable control of the Party affected, not due to malfeasance, and which could not with the exercise of due diligence have been avoided, including, but not limited to, fire, accident, work stoppage, sabotage, strike, riot, civil commotion, terrorism, act of God or change in law.
- 1.9 “Know-How” means proprietary know-how, trademarks, inventions, data, technology and information relating to Product, which either Party hereto has the lawful right to disclose to the other Party. “Know-How” shall include, without limitation, processes and analytical methodology used in development, testing, analysis and manufacture and medical, clinical, toxicological testing as well as other scientific data relating to Product.
- 1.10 “Product” means products as listed in Exhibit A.
- 1.11 “Regulatory Filings” means filings with the FDA such as the ANDA.
- 1.12 “Regulatory Approvals” shall mean the approvals required under the FD&C Act to sell and market the Product in the Territory.
- 1.13 “Territory” means the United States of America, its territories, possessions, commonwealths.

ARTICLE 2

DEVELOPMENT

- 2.1 Product Development. Mikah will provide, at its sole cost and expense, an approvable, generic bioequivalent formulation of the Product, including all formulation know-how, analytical methods and API sourcing
- 2.2 The Parties will collaborate to transfer the formulation and methods to Elite’s facility and to file the product.
- 2.3 Elite will, on a contract basis, transfer in the formulation, manufacture submission batches and file the Product as directed by Mikah. Elite will provide its facility including, but not limited to, equipment, analytical, quality assurance, regulatory support and legal. Elite will manufacture, as directed by Mikah, required pilot, pivotal clinical trials, and registration batches. Elite will, as directed by Mikah, transfer in all methods and perform method validation for assay, dissolution, impurity, and cleaning. Elite will perform release testing and stability studies for development. These functions performed by Elite are collectively the “Services”.

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2.4 Mikah will be responsible for API costs.

2.5 Mikah will be responsible for the cost of the BE studies.

2.6 The parties will negotiate in good faith a Manufacturing and Supply Agreement to produce the Products in which Elite will have the right to contract manufacture Product at cost plus [**]% (cost of materials, labor, and allocable overhead costs per GAAP including GDUFA facility fee).

ARTICLE 3

REGULATORY

3.1 Elite shall be responsible for the filing and prosecution of the ANDA with the FDA and Mikah shall own any ANDA filed and/or approved. Following Regulatory Approval, Mikah shall have sole discretion with respect to the maintenance of the ANDA, correspondence with and reporting to the FDA and other regulatory authorities,

ARTICLE 4

PAYMENTS

4.1 Mikah shall pay Elite for services rendered at cost plus [**]%. Services hours shall be tracked by Elite with appropriate signed offs. Out-of-pocket expenses will be charged at the invoiced cost.

ARTICLE 5

REPRESENTATIONS, WARRANTIES AND COVENANTS

5.1 Representations and warranties:

- (a) Each Party represents and warrants to the other that it is authorized to enter into and to perform its obligations under this Agreement.
- (b) Each Party represents and warrants to the other that its obligations created under this Agreement do not conflict in any manner with any of its pre-existing obligations.

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- (c) Each Party represents and warrants to the other that it is the owner of any Know-How to be used or relied upon by such Party in performing its obligations under this Agreement.
 - (d) Both Mikah and Elite represent and warrant that:
 - (i) it has not received any notice or claim that the use of its Know-How infringes any patent or intellectual property rights of any third party in the Territory; and
 - (ii) to its actual knowledge, without any independent investigation, the use of its Know-How will not infringe any patent or intellectual property rights of any third party in the Territory.
 - (e) Each Party hereby represents and warrants that it is not in violation of any law or regulation, nor is it aware of any violation of any law or regulation by any other Person, which violation could reasonably be expected to adversely affect its performance of its obligations hereunder, and except as otherwise contemplated hereby, such Party holds each of the licenses, permits, approvals or authorizations necessary with respect to its current business and operations (and its rights and obligations contemplated hereby) in compliance with all laws and regulations and maintains compliance with cGMP.
- 5.2 Cooperation Upon Bankruptcy. If there is a voluntary or involuntary filing of a petition for bankruptcy, insolvency or placing in receivership of either Party, the Party shall use, and cause its representatives and affiliates to use, best efforts to make all necessary arrangements and take all required actions to permit the other Party to retain all rights hereunder with respect to the Products.

ARTICLE 6

INTELLECTUAL PROPERTY RIGHTS

- 6.1 Elite shall be responsible for the patent reviews.
- 6.2 With respect to any Product developed hereunder, Mikah shall own the Know-how and Intellectual Property. Mikah shall be responsible for filing and prosecuting the patents, defending the patents against infringement and defending patent infringement claims brought by others.

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6.3 LIMITATION OF DAMAGES. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR LOST PROFITS (OTHER THAN AS ARE ORDINARILY ENCOMPASSED BY CONTRACT DAMAGES), LOSS OF GOODWILL, OR ANY SPECIAL, INDIRECT, CONSEQUENTIAL OR INCIDENTAL DAMAGES, HOWEVER CAUSED, ARISING UNDER ANY THEORY OF LIABILITY. THIS LIMITATION SHALL APPLY EVEN IF A PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY.

ARTICLE 7

TERM AND TERMINATION AND DEFAULT

7.1 Termination. Either Party shall have the option to terminate this Agreement upon the 30 day written notice to the other Party.

7.2 WARRANTY LIMITATION. EXCEPT AS EXPRESSLY SET FORTH IN SECTION 5, THE PARTIES MAKE NO WARRANTY, EXPRESSED OR IMPLIED, CONCERNING TECHNOLOGY, GOODS, SERVICES, RIGHTS OR THE MANUFACTURE AND PRODUCTS, AND HEREBY DISCLAIM ANY OTHER WARRANTIES, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR PURPOSE OR NON-INFRINGEMENT WITH RESPECT TO ALL OF THE FOREGOING.

ARTICLE 8

MISCELLANEOUS

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

8.2 Survival. Except as expressly provided in this Agreement, expiration or termination of this Agreement will not relieve the Parties of any obligation that accrued prior to such expiration or termination. Upon expiration or early termination of this Agreement, all rights and obligations of the Parties shall cease, except as follows:

- (a) The obligations of confidentiality set forth in Section 8.5 of Article 8 shall survive;
- (b) The Parties obligations under Article 5 shall survive; and
- (c) Any cause of action or claim of Mikah or Elite accrued or to accrue because of any breach or default by the other Party hereunder shall survive.

8.3 Entire Agreement; Amendment. This Agreement, with all of the Exhibits, contains the entire understanding of the Parties with respect to the subject matter hereof and supersedes all previous verbal and written agreements, representations and warranties. This Agreement may be released, waived or modified only by written agreement signed by the Party against whom enforcement of any release, waiver, modification, or other change is sought.

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- 8.4 Standard Forms. In ordering and delivering the services or Product, Mikah and Elite may employ their standard forms, but nothing in those forms shall be construed to modify, amend or supplement the terms of this Agreement and, in the case of any conflict herewith, the terms of this Agreement shall govern and control.
- 8.5 Confidentiality. Elite and Mikah shall not use, except in connection with this Agreement, nor disclose any information concerning the other Party's business or any proprietary information of the other Party, including but not limited to, technical or scientific data, unpublished findings, biological material, know-how, specifications, processes, techniques, patent, patent litigation strategies or tactics, trade secrets, algorithms, programs, designs, drawings, or formulae; and any engineering, manufacturing, marketing, financial, litigation, intellectual property or business plan, confidential knowledge, data or other similar information, whether received pursuant to this Agreement or otherwise ("Confidential Information") without the prior written consent of such other Party. The obligation of non-disclosure referred to above shall not apply to:
- (i) Information which is known to the receiving Party or one of its Affiliates or independently developed by the receiving Party or one of its Affiliates prior to the time of disclosure, in each case, to the extent evidenced by written records;
 - (ii) Information disclosed to the receiving Party by a third party, which has a right to make such disclosure;
 - (iii) Information which is or becomes patented, published or otherwise part of the public domain as a result of acts by the disclosing Party or a third person obtaining such information as a matter of right; or
 - (iv) Information which is required to be disclosed by order of the FDA or similar authority in other countries or a court of competent jurisdiction provided that the Parties shall use their best efforts to obtain confidential treatment of such information by the court or agency.
- 8.6 Force Majeure. Failure of any Party to perform its obligations under this Agreement as a result of Force Majeure shall not subject such Party to an liability or place it in breach of any term or condition of this Agreement to the other Party if such failure is caused by any cause beyond the reasonable control of such non-performing Party. The Party prevented from performing its obligations or duties because of Force Majeure shall promptly notify the other Party hereto of the occurrence and particulars of such Force Majeure and shall provide the other Party, from time to time, with its best estimate of the duration of such Force Majeure and with notice of the termination thereof. The Party so affected shall use its best efforts to avoid or remove such causes of nonperformance. Upon termination of Force Majeure, the performance of any suspended obligation or duty shall promptly recommence. Neither Party shall be liable to the other Party for any direct, indirect, consequential, incidental, special, punitive or exemplary damages arising out of or relating to the suspension or termination of any of its obligations or duties under this Agreement by reason of the occurrence of Force Majeure. In the event that Force Majeure has occurred and is continuing for a period of at least three (3) months, the other Party shall have the right to terminate this Agreement upon thirty (30) day notice.

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- 8.7 Waiver. The failure of a Party to enforce any breach or provision of this Agreement shall not constitute a continuing waiver of such breach or provision and such Party may at any time thereafter act upon or enforce such breach or provisions of this Agreement. Any waiver of breach executed by either Party shall affect only the specific breach and shall not operate as a waiver of any subsequent or preceding breach.
- 8.9 Severability. If a court of competent jurisdiction declares any clause or provision of this Agreement invalid or unenforceable, such provision shall be severed and the remaining provisions of the Agreement shall continue in full force and effect. The Parties shall use their best efforts to agree upon a valid and enforceable provision as a substitute for the severed provision, taking into account the intent of this Agreement.
- 8.10 Notices. Except as otherwise specifically provided, any notice or other documents to be given under this Agreement shall be in writing and shall be deemed to have been duly given if sent by registered mail, nationally recognized overnight delivery service or facsimile transmission to a party or delivered in person to a party at the address or facsimile number set out below for such party or such other address as the party may from time to time designate by written notice to the other:

If to Elite, to:

Elite Pharmaceuticals, Inc.
Attn: CFO
165 Ludlow Avenue Northvale
New Jersey 07647

If to Mikah to:

Mikah Pharma LLC
Attn: CEO
20 Kilmer Drive
Hillsborough, NJ 08844

Any such notice provided pursuant to this Section 8.10 shall be deemed to have been received by the addressee ten business days following the date of dispatch of the notice or other document by registered mail or, where the notice or other document is sent by overnight delivery service, by hand or is given by facsimile, simultaneously with the transmission or delivery. Notwithstanding the foregoing, any notice or other document sent by overnight delivery service, by hand or by facsimile and received by the recipient after 5:30 p.m. local time (of the recipient) shall be deemed to be delivered the next Business Day. To prove the giving of a notice or other document it shall be sufficient to show that it was dispatched. Either party may change its address at which notice is to be received by written notice provided pursuant to this Section 8.10.

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- 8.11 Governing Law; Dispute Resolution; Venue. Agreement shall be construed, and the rights of the Parties determined, in accordance with the laws of the State of New Jersey without regard to conflict of law or choice of law rules. Any controversy or claim pursuant to this Agreement or the breach thereof shall be settled in accordance with Article 9 of this Agreement. Judgment upon the award rendered by the Arbitrator(s) may be entered in any court having jurisdiction thereof, including any non-U.S. Court and both Parties agree that such non-U.S. Court shall apply judicial comity to any such judgment and enforcement thereof. For purposes of dispute resolution, including litigation, each Party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in Essex County, State of New Jersey, 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 or inconvenient venue for such proceeding. 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.
- 8.12 Independent Parties. The relationship of the Parties under this Agreement is that of independent contractors. Neither Party shall be deemed to be the agent of the other, nor shall the Parties be deemed to be partners or joint venturers, and neither is authorized to take any action binding upon the other. Elite expressly acknowledges for itself, its employees, agents and subcontractors, that none of them are employees of Mikah and that none of them are entitled to participate in any benefit plans of Mikah. Elite further acknowledges that none of its employees, agents or subcontractors are eligible to participate in any benefit plans of Mikah, even if it is later determined that the status of any of them was that of an employee during the period of this engagement of Elite by Mikah.
- 8.13 Headings. The headings contained in this Agreement are included herein for reference and convenience and shall not affect the meaning of the provisions of this Agreement.
- 8.14 Publicity. Neither Party shall 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 Party 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, government agencies, the U.S. Securities and Exchange Commission, or the rules of any stock exchange on which such Party's or its Affiliates' securities trade; provided, however, the Party making such disclosure shall 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 shall coordinate with one another regarding the timing, form and content of such disclosure.

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- 8.15 No Third Party Beneficiaries. Except as specifically stated to the contrary herein, no person or entity not a Party to this Agreement, including an employee of any Party to this Agreement, shall have or acquire any rights by reason of this Agreement, nor shall either Party have any obligations or liabilities to such other person or entity by reason of this Agreement.
- 8.16 Remedies Cumulative. Except as otherwise provided herein, any and all remedies herein expressly conferred upon a Party shall be deemed cumulative with and not exclusive of any other remedy conferred hereby, or by law or equity upon such Party, and the exercise by a Party of any one remedy shall not preclude the exercise of any other remedy.
- 8.17 Further Assurances. Each Party shall execute and deliver such additional instruments and other documents and use commercially reasonable efforts to take or cause to be taken, all actions and to do, or cause to be done, all things necessary under applicable law to consummate the transactions contemplated hereby.
- 8.18 Counterparts; Facsimile, Electronic Signatures. This Agreement may be executed in counterparts, each of which shall be deemed an original, and all of which together shall constitute a single agreement. This Agreement may be executed by facsimile signatures or by a pdf (or other similar format) copy of the signature delivered by e-mail, which signatures shall have the same force and effect as original signatures.
- 18.19 Drafting. The Parties have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the Parties and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any of the provisions of this Agreement.
- 8.20 Currency. Wherever a monetary currency is indicated throughout this Agreement, that currency shall be United States Dollars, unless otherwise clearly indicated.
- 8.21 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. Wherever reference is made to "Business Days" such reference shall exclude weekend days and dates which are official government holidays in New Jersey.

(Signature Page follows)

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IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

Mikah Pharma, LLC

Elite Pharmaceuticals, Inc.

By: /s/ Nasrat Hakim
Name: Nasrat Hakim
Title: CEO
Date: 12/5/18

By: /s/ Carter Ward
Name: Carter Ward
Title: CFO
Date: 12/5/18

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Exhibit A

PRODUCTS

The following table lists Products as defined in Section 1.10.

Products	RLD
TDB	TBD

Subsidiary of the Company

Elite Laboratories, Inc., a Delaware corporation.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following documents of our reports dated June 14, 2019, relating to the consolidated financial statements of Elite Pharmaceuticals, Inc. and Subsidiary, and the effectiveness of internal control over financial reporting of Elite Pharmaceuticals, Inc. and Subsidiary included in the Annual Report on Form 10-K of the Company for the year ended March 31, 2019.

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 21, 2019

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, 2019 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 21, 2019

/s/ Nasrat Hakim

Nasrat Hakim, Chief Executive Officer

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, 2019 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 21, 2019

/s/ Carter J. Ward

Carter J. Ward, Chief Financial Officer

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE
SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Elite Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended March 31, 2018 filed with 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 21, 2019

/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.

**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, 2019 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 21, 2019

/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.