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, 2021

OR

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

FOR THE TRANSITION PERIOD FROM _____ TO _____

COMMISSION FILE NUMBER: 001-15697

ELITE PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

NEVADA	**22-3542636**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
165 LUDLOW AVENUE NORTHVALE, NEW JERSEY	**07647**
(Address of principal executive offices)	(Zip Code)

(201) 750-2646

(Registrant's telephone number, including area code)

Securities Registered pursuant to Section 12(g) 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	X	Smaller reporting company	X
		Emerging growth company	☐

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C.7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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, 2020, the last business day of the registrant's most recently completed second fiscal quarter was $56,138,409.

The number of shares of the registrant's Common Stock outstanding as of June 7, 2021 was 1,009,176,752.

FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K and the documents incorporated herein contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). 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 are forward-looking statements, and include, without limitation, estimated future results of operations, estimates of future revenues, future expenses, future net income and future net income per share, as well as statements regarding future financing activities, the impact of the novel strain of coronavirus referred to as COVID-19 on the health and welfare of our employees and on our business, including any response to COVID-19 such as anticipated return to historical purchasing decisions by customers, the economic impact of COVID-19, changes in consumer spending, decisions to engage in certain medical procedures, future governmental orders that could impact our operations and the ability of our manufacturing facilities and suppliers to fulfill their obligations to us, and any other statements that refer to our expected, estimated or anticipated future results. Without limiting the foregoing, the words "plan", "intend", "may," "will," "expect," "believe", "could," "would", "continue", "pursue", "anticipate," "estimate," "forecast", "contemplate", "envisage", "project", or "continue" or the negative other variations thereof, 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 and subsequent to the commercialization of products under development and those currently related to commercial operations, 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.

In addition, because these statements reflect our current views concerning future events, these forward-looking statements involve risks and uncertainties including, without limitation, the risks related to the impact of COVID-19 (such as, without limitation, the scope and duration of the pandemic and the resulting economic crisis and levels of unemployment, governmental actions and restrictive measures implemented in response, material delays and cancellations of certain medical procedures, potential manufacturing and supply chain disruptions and other potential impacts to the business as a result of COVID-19) and the other risks and uncertainties more fully described under the caption "Risk Factors" in Part I, Item 1A of this document. These risks and uncertainties, many of which are outside of our control, and any other risks and uncertainties that we are not currently able to predict or identify, individually or in the aggregate, could have a material adverse effect on our business, financial condition, results of operations and cash flows and could cause our actual results to differ materially and adversely from those expressed in forward-looking statements contained or incorporated by reference in this document. Additionally, the prolonged impact of COVID-19 could heighten the impact of one or more of such risk factors.

We do not undertake any obligation to update our forward-looking statements after the date of this document for any reason, even if new information becomes available or other events occur in the future, except as may be required under applicable securities law. You are advised to consult any further disclosures we make on related subjects in our reports filed with the Securities and Exchange Commission (the "SEC"). Also, please note that in Part 1, Item 1A, we provide a cautionary discussion of the risks, uncertainties and possibly inaccurate assumptions relevant to our business. These are factors that, individually or in the aggregate, we think could cause our actual results to differ materially from expected and historical results. We note these factors for investors as permitted by Section 27A of the Securities Act and Section 27E of the Exchange Act. You are notified and should understand that it is not possible to predict or identify all such factors and consequently should not consider this to be a complete, all-inclusive discussion of all potential risks or uncertainties.

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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 generic products, using proprietary know-how and technology. 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 exploiting 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) manufacturing of a line of generic pharmaceutical products with approved Abbreviated New Drug Applications ("ANDAs"); (ii) development of additional generic pharmaceutical products; (iii) development of the other products in our pipeline including the products with our partners; (iv) commercial exploitation of our products either by license and the collection of royalties, or through the manufacture of our formulations; and (v) 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 generic drug products which require ANDAs as well as 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").

We believe that our business strategy enables us to reduce its risk by having a diverse product portfolio that includes 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, contract manufacture or receive royalties from 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
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
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
Dantrolene Sodium Capsules 25mg, 50mg and 100mg ("Dantrolene 25mg", "Dantrolene 50mg", Dantrolene 100mg")	Dantrium®	Muscle Relaxant	June 2019
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, Amphetamine Sulfate Extended Release 5mg, 10mg, 15mg, 20mg, 25mg, and 30mg capsules ("Amphetamine ER 5mg", "Amphetamine ER 10mg", "Amphetamine ER 15mg", "Amphetamine ER 20mg", "Amphetamine ER 25mg", and "Amphetamine ER 30mg")	Adderall XR®	Central Nervous System ("CNS") Stimulant	March 2020
Loxapine Succinate 5mg, 10mg, 25mg and 50gm capsules ("Loxapine 5mg", "Loxapine 10mg", "Loxapine 25mg", and Loxapine 50mg")	Loxapine®	Antipsychotic	May 2021

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". 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". 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". Dantrolene 25mg, Dantrolene 50mg and Dantrolene 100mg are collectively and individually referred to as "Dantrolene Capsules". Amphetamine ER 5mg, Amphetamine ER 10mg, Amphetamine ER 15mg. Amphetamine ER 20mg, Amphetamine ER 25mg

and Amphetamine ER 30mg are collectively and individually referred to as "Amphetamine ER Capsules". Loxapine 5gm, Loxapine 10mg, Loxapine 25mg and Loxapine 50mg are collectively and individually referred to as "Loxapine Capsules".

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.

Phentermine 37.5mg is currently being manufactured by Elite and distributed by TAGI under the Precision Dose License Agreement.

Phendimetrazine Tartrate 35mg

The ANDA for Phendimetrazine was acquired by Elite in 2013.

Phendimetrazine 35mg is currently a commercial product being manufactured at the Northvale Facility and distributed by Elite.

Phentermine 15mg and Phentermine 30mg

Phentermine 15mg capsules and Phentermine 30mg capsules were developed by the Company, with Elite receiving approval from the United States Food and Drug Administration ("FDA") 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.

Phentermine 15mg and Phentermine 30mg are currently being manufactured by Elite and distributed by TAGI under the Precision Dose License Agreement.

Naltrexone 50mg

The ANDA for Naltrexone 50mg was acquired by Elite in 2010.

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. 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 in 2013

Isradipine 2.5mg and Isradipine 5mg are currently a commercial product being manufactured by Elite at the Northvale Facility and distributed by Epic Pharma LLC ("Epic"), on an exclusive basis.

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

This product was an Identified IR Product in the Epic Strategic Alliance Agreement Dated March 18, 2009 (the "*Epic Strategic Alliance*"). Methods used by Epic in the manufacture of Oxy IR were developed at the Northvale Facility pursuant to the Epic Strategic Alliance, in which we are entitled to a Product Fee of 15% of Profits through March 2026, as defined in the Epic Strategic Alliance. The first commercial sale of Oxy IR occurred in March 2016. Epic has reported no profit or profit split for this product since September 2019.

Trimipramine 25mg, Trimipramine 50mg and Trimipramine 100mg

The approved ANDA for Trimipramine was acquired by Elite in 2017.

Trimipramine 25mg, Trimipramine 50mg and Trimipramine 100mg are currently a commercial product being manufactured by Elite at the Northvale Facility and distributed by Epic, 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.

Amphetamine IR Tablets are currently a commercial product being manufactured by Elite and distributed by Lannett Company Inc. ("Lannett"), on an exclusive basis.

Dantrolene Capsules

The approved ANDAs for Dantrolene 25mg, Dantrolene 50mg and Dantrolene 100mg were acquired by Elite in 2013. Dantrolene Capsules are currently a commercial product being manufactured by Elite at the Northvale Facility and distributed by Lannett, on an exclusive basis.

Amphetamine ER Capsules

On December 12, 2019, the Company received approval from the FDA for Amphetamine ER Capsules, a generic version of Adderall XR®, an extended-release mixed salt of a single entity Amphetamine product (Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, Amphetamine Sulfate) with strengths of 5mg, 10mg, 15mg, 20mg, 25mg, and 30 mg tablets. The product is a central nervous system stimulant and is indicated for the treatment of ADHD and Narcolepsy.

Amphetamine ER Capsules are currently a commercial product being manufactured by Elite and distributed by Lannett, on an exclusive basis.

Loxapine Capsules

The approved ANDA for Loxapine was acquired by Elite in 2013. Loxapine Succinate 5, 10, 25 and 50 mg are currently commercial products being manufactured by Elite at the Northvale Facility, launched commercially in May 2021 and distributed by Burel Pharmaceuticals, Inc, an affiliate of Prasco, LLC ("Burel"), on an exclusive basis.

Filed products under FDA review

SequestOx™ - Immediate Release Oxycodone with sequestered Naltrexone

SequestOx™ is our 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 or 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 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. 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 an antibiotic product

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 $85 million for the twelve months ending September 30, 2019. The product is jointly owned by Elite and SunGen Pharma LLC. 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, 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

Acetaminophen and Codeine Phosphate

The Company received approval from the FDA of an ANDA 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). The Company is not pursuing licensing deals for any opioids at this time until the market changes. The Company will wait for the market to stabilize before pursuing these opportunities.

There can be no assurances in relation to any of the above approved products not yet commercialized, that there will be future revenues of profits, or that any such future revenues or profits would be in amounts that provide adequate return on the significant investments made to secure these marketing authorizations.

Discontinued and Transferred Products

As part of standard operating practices, the Company, from time to time, as relevant, conducts evaluations of all ANDAs owned, consisting, without limitation, of ANDAs acquired or approved prior to the fiscal year ended March 31, 2021 ("Fiscal 2021") and ANDAs acquired or approved during the Fiscal 2021. Such evaluations include, without limitation, costs and benefits relating to each ANDA owned, with such costs including those fees required under the FDA's Generic Drug User Fee Amendment ("GDUFA") which is significantly influenced by the number of ANDAs owned, and other costs and benefits taking into consideration various specific market factors for each ANDA. Those ANDAs with a cost/benefit profile not consistent with management criteria for continuation are identified for disposition and effort is made to determine the optimal course of action to achieve disposition of the ANDA.

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. The 2015 SequestOx™ License Agreement expired on June 4, 2020. During the term of this agreement, the Company received $7.5 million in non-refundable payments, with such amount consisting of $5 million due and owing on the execution date of the *2015 SequestOx™ License Agreement* and $2.5 million being earned upon the Company's filing of an NDA with the FDA for the relevant product in January 2016. The remaining $7.5 million in non-refundable payments required FDA approval of the relevant product, a milestone that was not achieved prior to the expiration of the agreement.

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 instalments. The first instalment was paid upon execution of the Precision Dose License Agreement. The remaining instalments 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 three successive terms, each of five 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 and 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. The Company has received approval from the FDA for Amphetamine IR Tablets, Amphetamine ER Capsules and has filed an ANDA 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 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. The product is jointly owned by Elite and SunGen. Elite manufactures and packages this product, at the Northvale Facility, on a cost-plus basis, and it is currently sold pursuant to the Lannett Alliance, with the 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.

On December 12, 2019, the Company received approval from the FDA for Amphetamine ER Capsules, a generic version of Adderall XR®, an extended-release mixed salt of a single entity Amphetamine product (Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, Amphetamine Sulfate) with strengths of 5mg, 10mg, 15mg, 20mg, 25mg and 30mg capsules. The product is a central nervous system stimulant and is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). The product is jointly owned by Elite and SunGen. Elite manufactures and packages this product, at the Northvale Facility, on a cost plus basis and it is currently sold pursuant to the Lannett Alliance, with the first commercial shipment of this product occurring in March 2020. Please see the section below titled "Strategic Marketing Alliance with Lannett Company Inc." for further details on the Lannett Alliance.

On April 3, 2020, Elite and SunGen mutually agreed to discontinue any further joint product development activities under the SunGen Agreement except for the antibiotic tablet product which has been filed with the FDA and the antibiotic capsule product not yet filed. These two products remain jointly owned assets of the parties.

In May 2020, SunGen, under an asset purchase agreement, assigned its rights and obligations under the SunGen Agreement for Amphetamine IR and Amphetamine ER to Mikah Pharmaceuticals. The ANDAs for Amphetamine IR and Amphetamine ER are now registered under Elite's name. Mikah will now be Elite's partner with respect to Amphetamine IR and ER and will assume all the rights and obligations for these products from SunGen.

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 22, 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*"). The license for Methadone Tablets was terminated by mutual agreement in December 2019. The license for Phendimetrazine Capsules was terminated by mutual agreement in February 2020. The licenses for Trimipramine Capsules and Isradipine Capsules expired in May 2021.

During the term of the Glenmark Alliance, Glenmark had exclusive marketing rights to the following products: Methadone Tablets, Trimipramine Capsules and Isradipine Capsules. Glenmark also had semi-exclusive marketing rights to Phendimetrazine Tablets. All products included in the Glenmark Alliance were manufactured by Elite. In addition to the purchase prices for the products, Elite also received license fees in excess of 50% of gross profits, with such being defined as net sales less the price paid to Elite for the products, distribution fees of less than 10% and shipping costs.

Marketing License with Epic Pharma LLC

On November 21, 2020 we entered into a license, manufacturing and supply agreement with Epic Pharma LLC ("*Epic*") to market the two Elite generic products described below in the United States (the "*Epic Pharma License*").

Beginning on May 23, 2021 and continuing until the agreement terminates, Epic has exclusive marketing rights to Trimipramine Capsules and Isradipine Capsules. The products are manufactured by Elite for Epic on a cost plus basis. In addition to the purchase prices for the products, Elite also receives license fees of 50% of gross profits or greater, with such being defined as net sales less the price paid to Elite for the products, distribution fees of less than 10% and shipping costs. The initial term of the agreement is three (3) years from the execution of the agreement. Epic has the option to extend the agreement for an additional two (2) years if certain license fee targets are met.

Marketing License with Prasco, LLC and Burel Pharmaceuticals, Inc.

On February 14, 2020, and as amended on July 30, 2020, the Company entered into a license, manufacturing and supply agreement with Prasco, LLC and its affiliate Burel Pharmaceuticals, Inc. ("*Burel*") to market generic Loxapine Succinate capsules in the United States (the "*Burel License*"). Burel sales for the product began May 2021.

Under the agreement, Burel has exclusive marketing rights to Loxapine. The product is manufactured by Elite, and the Company receives manufacturing fees and license fees of 50% of gross profits or greater, with such being defined as net sales less the price paid to Elite for the products, distribution fees of less than 10% and shipping costs. The term of the agreement is three (3) years from the execution date of the agreement and will automatically renew for one (1) year periods unless one of the parties gives prior written notice.

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 9, 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, Lannett will be the exclusive U.S. distributor for Amphetamine IR Tablets and Amphetamine ER Capsules. Elite manufactures these products, which are purchased, marketed and distributed by Lannett under the Lannett label. In addition to the purchase prices for the products, Elite will receive license fees well in excess of 50% of net profits, which will be shared equally with SunGen, pursuant to the SunGen Agreement. Net profits are defined as net sales less the price paid to Elite for the products, distribution fees (less than 10%) and shipping costs. 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 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 Lannett for such product is less than $100,000 for a six month sales period. In addition to manufacturing fees and license fees, Lannett also paid a $750,000 milestone, upon the March 2020 commercial launch of Amphetamine ER Capsules. This milestone payment was earned during March 2020 and was 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.

The first commercial shipment of Amphetamine ER Capsules, a generic version of Adderall XR®, with strengths of 5mg, 10mg, 15mg, 20mg, 25mg and 30mg, pursuant to the Lannett-SunGen Product Alliance occurred in March 2020.

Pursuant to the Lannett-Elite Product Alliance, Lannett will be the exclusive U.S. distributor for Dantrolene Capsules. The first commercial shipment of Dantrolene Capsules, with strengths of 25mg, 50mg and 100mg occurred in June 2019.

Pursuant to the Lannett-Elite Product Alliance, Elite manufactures for Lannett's purchase, marketing, and distribution of Dantrolene Capsules under the Lannett label. In addition to the purchase prices for the products, Elite will receive license fees well in excess of 50% of gross profits. Gross profits are defined as net sales less the price paid to Elite for the products, distribution fees (less than 10%) and shipping costs. Lannett will have exclusive marketing rights to Dantrolene Capsules. 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 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 Lannett for such product is less than $100,000 for a six month sales period. In addition to manufacturing fees and license fees.

Please also note that in May 2020, SunGen, under an asset purchase agreement, assigned its rights and obligations under the SunGen Agreement for Amphetamine IR and Amphetamine ER to Mikah Pharmaceuticals. The ANDAs for Amphetamine IR and Amphetamine ER are now registered under Elite's name. Mikah will now be Elite's partner with respect to Amphetamine IR and ER and will assume all the rights and obligations for these products from SunGen.

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.

The Company is currently not selling opioids nor are we pursuing licensing deals for opioids until the market conditions improve. Further, we have divested some opioid products. The Company will wait for the market to stabilize before pursuing these opportunities.

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*".

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.

The Company is currently not selling opioids nor are we pursuing licensing deals for opioids until the market conditions improve. Further, we have divested some opioid products. The Company will wait for the market to stabilize before pursuing these opportunities.

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 8,182,836	March 2024
U.S. patent 8,425,933	March 2025
U.S. patent 8,703,186	March 2025
Canadian patent 2,521,655	April 2023
Canadian patent 2,541,371	April 2024
U.S. patent 9,056,054	June 2030
U.S. patent 10213388	June 2030

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.

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.

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 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 labelling 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, wastewater 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 labelling 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 customers, suppliers and other third parties for core business aspects"

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 Lannett, Epic Pharma, Burel Pharmaceuticals and Precision Dose for the licensing, 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. Please see the Risk Factor in Part I, Item 1A entitled We are dependent on a small number of customers, suppliers and other third parties for core business aspects"

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 branded pharmaceuticals. For the years ended March 31, 2021 and 2020 revenue from our ANDA segment were $25.2 million and $17.0 million, respectively. For the years ended March 31, 2020 and 2019 revenue from our NDA segment were $0.2 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 7, 2021, we had 43 full time employees. Full-time employees are engaged in operations, administration, research, and development. None of our employees is represented by a labor union and we have never experienced a work stoppage. We believe our relationship with our employees to be good. However, our ability to achieve our financial and operational objectives depends in large part upon our continuing ability to attract, integrate, retain, and motivate highly qualified personnel, and upon the continued service of our senior management and key personnel.

ITEM 1A. RISK FACTORS

An investment in the Company's securities 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.

Risk Factor Summary

The following is a summary of the risk factors contained in this Annual Report on Form 10-K that could adversely affect our business, ability to operate, financial condition, results of operation, equity and cash flows. This summary does not address all of the risks that we face and is qualified in its entirety by reference to the more detailed descriptions included below. In addition to this summary, we strongly encourage you to carefully review the full risk factors in their entirety.

Business Related Risks

- The pharmaceutical industry is highly competitive.
- Global pandemic and natural disasters.
- Interruptions in operations at our sole facility could have a material adverse effect on our business.
- We are dependent on a small number of customers, suppliers and other third parties for core business aspects.
- We may sell, withdraw or discontinue manufacture of certain products.
- We may fail to successfully identify, develop, complete clinical trials, secure regulatory approvals and commercialize new products.
- Our operations could be disrupted by failure of our information systems or cyber-attacks.

- Delays in product development may result in failure to achieve adequate return on investment.
- Our business is dependent on market perceptions, social and political pressures.
- Unstable economic conditions may adversely affect our business.
- We depend on qualified scientific and technical personnel and our ability to attract and retained such.
- Unsuccessful collaboration or licensing arrangements could limit revenues and product development.

Financial and Liquidity Related Risks

- We have a relatively limited operating history and our operating results could fluctuate significantly.
- Our ability to fund operations is uncertain and we may require additional financing to meet objectives.
- We have substantial indebtedness which may adversely affect our financial condition.
- There is a risk impairment of significant intangible assets on our balance sheet.
- GAAP requires estimates, judgements and assumptions which inherently contain uncertainties.

Legal and Regulatory Risks

- The pharmaceutical industry is heavily regulated which creates uncertainty and substantial compliance costs.
- Decreases in the degree to which individuals are covered by healthcare insurance and levels of third party reimbursement could result in decreased use of our products and lower prices.
- Our business may be adversely affected by legislation or healthcare regulatory reform and initiatives.
- Use of generics may be limited through legislative, regulatory or efforts of pharma companies.
- New tariffs and evolving trade policy between the US and other countries may adversely affect our business.
- The DEA could limit the availability of active ingredients used in many of our products.
- Changes in FDA approval requirements may prevent or delay approval of new products.
- We received a CRL from the FDA indicating that the SequestOx™ NDA is not ready for approval.
- Regulatory factors may cause us to be unable to manufacture products or face interruptions in our manufacturing process.
- Agreements between branded pharmaceutical companies and generic pharmaceutical companies are facing increased government scrutiny in the United States and Internationally.

Litigation and Liability Related Risks

- We may not be able to obtain or maintain adequate insurance coverages.
- Litigation, product liability claims, product recalls, government investigations and other significant legal proceedings are common in the pharmaceutical industry.
- Our products contain narcotic ingredients which may subject us to increased litigation risk and regulation.
- Public concern over abuse of opioids has negatively affected our business.
- Illegal distribution and third party sale of counterfeit versions of our products could have a detrimental effect on our reputation and business.

Structural and Organizational Risks

- We have identified material weaknesses in internal controls in prior years.
- Provisions of our Articles of Incorporation could deter a change of management and discourage offers to acquire us.

Intellectual Property Related Risks

- Our ability to protect intellectual property rights and successfully defend third party allegations of intellectual property infringement is vital to our business and uncertain.

Risks Related to our Common Shares

- Dilution from issuance of shares to Lincoln Park, Directors, Employees, Consultants or upon exercise of warrants and options or the perception that dilution may occur could cause the price per share of common stock to fall.

- Our common stock is a penny stock, quoted on the OTC bulletin board, with rules in place that could limit trading and liquidity of our shares, increased transaction costs that could adversely affect our price per share.
- Shareholder activism could negatively affect us.
- Our stock price has been volatile.
- Capital raises through sales of securities may cause substantial dilution to existing shareholders.
- Issuance of shares of common or preferred stock could make achieving a change of control more difficult.
- We have no plans to pay regular dividends or conduct ordinary share purchases.

Business Related Risks

The pharmaceutical industry is highly competitive.

The pharmaceutical industry is highly competitive and subject to rapid and significant technological change, and we may be unable to compete effectively, which could impair our ability to implement our business model. Competitive factors faced include, without limitation, product development, safety, efficacy, commercialization, marketing, promotion, product quality, cost-effectiveness, reputation, service, patient convenience, access to scientific and technical information, and ability to manage operations in an economic environment that is severely impacted by a global pandemic such as COVID-19. 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, they, and future competitors, may have greater financial, research and development, marketing, and other resources than we do. Furthermore, recent trends in this industry include market consolidation, which may further concentrate financial, technical, market and other strengths and resources with the result being a further increase competitive pressures existent in this industry. 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.

In addition, 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 and 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.

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

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

The existence and occurrence of any of the above could have a material adverse effect on our business, financial condition, results of operations, cash flow, ability to operate and stock price.

Global pandemic and natural disasters.

Widespread health problems, including the recent global COVID-19 pandemic, natural disasters or other unexpected events could materially and adversely affect our business.

Public health outbreaks, epidemics or pandemics, such as the coronavirus, could materially and adversely impact our business. For example, the COVID-19 pandemic has resulted in global business and economic disruption and extreme volatility in the financial markets as many jurisdictions have placed restrictions on travel and non-essential business operations and implemented social distancing, shelter-in-place, quarantine and other similar measures for their residents with the stated objective being to contain the spread of the virus. In response to these public health directives and orders, we have implemented alternative working practices and work-from-home capabilities for appropriate employees, installed improved air flow and filtration at the Northvale Facility, as well as social distancing, modified schedules, shift rotation, daily temperature checks, multiple hand sanitation stations and other similar policies at our manufacturing facilities. We have also suspended international and domestic travel on behalf of the Company. Despite these actions, the Company continues to be exposed to the risk of a significant disruption or ceasing of all manufacturing or other operations resulting from laws, executive orders or other directives from various governmental authorities which could require such disruption or ceasing of operations due to our products and or operations being determined to be non-essential or any other reason for which it has been determined that such actions taken against the Company will further the protection of the general population from harm that may be caused or related to COVID-19 or any similar threat to public health.

The effects of COVID-19, including these public health directives and orders and our policies, have had an impact on our business and may in the future materially disrupt our business, including our manufacturing and supply chain operations by significantly reducing our output, negatively impact our productivity and delay our product development programs. The global pandemic may have significant impacts on third-party arrangements, including those with our manufacturing, supply chain and distribution partners, information technology and other vendors and other service providers and business partners. For example, there may be significant disruptions in the ability of any or all of these third-party providers to meet their obligations to us on a timely basis, or at all, which may be caused by their own financial or operational difficulties, including any closures of their facilities pursuant to a governmental order or otherwise. As a result of these disruptions and other factors, including changes in our workforce availability and increased demand for any of our products during this pandemic, our ability to meet our obligations to third-party marketing and distribution partners may be negatively impacted. As a result, the Company, or our third-party providers may deliver notices of the occurrent of *force majeure* or similar event under certain contracts which could result in prolonged commercial disputes and ultimately legal proceedings to enforce contractual performance and/or recover losses. Any such occurrences could result in significant management distraction and use of resources and, in the event of an adverse judgment, could result in significant cash payments. Further, the publicity of any such dispute could harm our reputation and make the negotiation of any replacement contracts more difficult and costly, thereby prolonging the effects of any resulting disruption in our operations. Such disruptions could be acute with respect to certain of our raw material suppliers where we may not have readily accessible alternatives or alternatives may take longer to source than usual. While we attempt, when possible, to mitigate our raw material supply risks through stock management and alternative sourcing strategies, some raw materials are only available from one source. Any of these disruptions could harm our ability to meet consumer demand, including any increase in demand for any of our products used during a pandemic.

While to date we have not experienced a significant detrimental change in customer demand, the heightened possibility of changes in customer demand as the COVID-19 pandemic evolves remains. The current economic crisis and higher levels of unemployment rates resulting from COVID-19 have the potential to significantly reduce individual disposable income and depress consumer confidence, which could limit the ability of some consumers to purchase certain pharmaceutical products and reduce consumer spend on certain medical procedures in the short-, medium- and long term. Additionally, as part of the measures to address COVID-19, certain healthcare providers are not currently performing various medical procedures and an increased portion of the general public are reducing their consumption of medical services which may result in decreased demand for certain of our products.

Furthermore, we are unable to predict the impact that COVID-19 may have going forward on the business, results of operations or financial position of any of our major customers, which could impact each customer to varying degrees and at different times and could ultimately impact our own financial performance. Certain or many of our competitors may also be better equipped to weather the impact of COVID-19 domestically and may be better equipped to address changes in customer demand. Additionally, our product development programs may be adversely affected by the global pandemic and the prioritization of production during this pandemic. The public health directives in response to COVID-19 requiring social distancing and restricting non-essential business operations have in certain cases caused and may continue to cause delays, increased costs and additional challenges in our product development programs, including obtaining adequate patient enrolment and successfully bringing product candidates to market. In addition, we may face additional challenges receiving regulatory approvals as previously scheduled dates or anticipated deadlines for action by the FDA on our applications and products in development, including dates scheduled for 2021, if any, could be subject to delays beyond our control as regulators such as the FDA focus on COVID-19.

To the extent our operating cash flows, together with our cash, cash equivalents, restricted cash and restricted cash equivalents, become insufficient to cover our liquidity and capital requirements, including funds for any future acquisitions and other corporate transactions, we may be required to seek third-party financing, and/or engage in one or more capital markets transactions. The COVID-19 pandemic has resulted in significant disruptions to and volatility in the local, national and global financial markets and, there can be no assurance that we would be able to obtain any required financing on a timely basis or at all. Further, lenders and other financial institutions could require us to agree to more restrictive covenants, grant liens on our assets as collateral (resulting in an increase in our total outstanding secured indebtedness) and/or accept other terms that are not commercially beneficial to us in order to obtain financing, as a result of the actual or perceived impact that financial institutions believe the pandemic will have on our business. Such terms could further restrict our operations and exacerbate any impact on our results of operations and liquidity that may result from COVID-19.

In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our ordinary shares.

Additionally, COVID-19 could increase the magnitude of many of the other risks described herein and have other adverse effects on our operations that we are not currently able to predict. For example, the global economic disruptions and volatility in the financial markets could further depress our ability to obtain or renew insurance on satisfactory terms or at all. Additionally, we may also be required to delay or limit our internal strategies in the short- and medium-term by, for example, redirecting significant resources and management attention away from implementing our strategic priorities or executing opportunistic corporate development transactions. The magnitude of the effect of COVID-19 on our business will depend, in part, on the length and severity of the restrictions (including the effects of recently announced “re-opening” plans following a recent slowdown of the virus infection rate in certain countries and localities) and other limitations on our ability to conduct our business in the ordinary course. The longer the pandemic continues or resurges, the more severe the impacts described above will be on both our domestic business and international supply chains. The full extent to which COVID-19 may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with accuracy or confidence, such as the duration of the outbreak, the severity of COVID-19, the possibility of re-occurrences of outbreaks of COVID-19, future legal requirements, executive orders or other actions requiring compliance by the Company and general population, or the effectiveness of actions to contain and treat COVID-19, particularly in the geographies where we or our third party suppliers or other strategic partners operate or our customers and end-users of our products reside. Taking the speed and frequency of continuously evolving developments with respect to this pandemic, or in the event of a pandemic relating to something other than COVID-19, we cannot reasonably estimate the magnitude of any impact on our operations, and the full extent to which COVID-19 or another pandemic may impact, in a material and adverse fashion, our business, financial condition, results of operations and cash flow, and could cause significant volatility in the trading prices of our securities.

Furthermore, 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.

Interruptions in operations at our sole facility could have a material adverse effect 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.

Furthermore, all of our manufacturing operations are conducted at the Northvale Facility and any delays or unanticipated expenses in connection with the operation at the Northvale Facility, resulting in 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.

We are dependent on a small number of customers, suppliers and other third parties for core business aspects.

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.

We also 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 Lannett, Epic Pharma, Burel 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.

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.

Furthermore, we are dependent on third parties to supply raw materials used in our products and to provide services for certain core aspects of our business. Any interruption or failure by these suppliers, distributors and collaboration partners to meet their obligations pursuant to various agreements with us could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We rely on third parties to supply raw material used in our products. In addition, we rely on third party suppliers, distributors and other third party service providers to provide services for certain core aspects of our business, including, without limitation, manufacturing, warehousing, freight and distribution, medical affairs services, regulatory compliance activities, sales and marketing, clinical studies, lab services and other technical and financial services. Many such third-party suppliers and contractors are subject to requirements proscribed by FDA, DEA or both. Our business and financial viability are dependent on the continued supply of goods, materials and services, by these third parties, their regulatory compliance and on the strength, validity and terms of our various contracts and arrangements with these third parties. Any interruption or failure by our third party suppliers, distributors and other third party service providers to meet their obligations pursuant to the various agreements with us on schedule or in accordance terms and/or expectations, or any termination by these third parties of their arrangements with us, which in each case, could be the result of one or more factors outside of our control, could

delay or prevent the development, approval, commercialization or manufacture of our products, result in non-compliance with applicable laws and/or regulations, cause us to incur failure to supply penalties, disrupt our operations, increase the cost of our operations or cause harm to our reputation in the industry, any or all of which could have a material adverse effect on our business, financial condition, results of operations, cash flows and stock price. We may also be unsuccessful in resolving any underlying issues with such suppliers, distributors or other third-party service providers or in replacing them within a reasonable time frame on commercially reasonable terms.

Furthermore, 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.

We may sell, withdraw or discontinue manufacture of certain products.

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.

In addition, 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, 2020, 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, 2020 through September 30, 2021, the annual fee for large sized ANDA holders was approximately $0.9 million greater than the fee for medium sized ANDA holders. After conducting a study of ANDAs held, with the GDUFA program fee levels being one of several relevant factors considered, we identified and sold ANDAs relating to Methadone Tablets, Second Phendimetrazine Product, Hydromorphone Tablets, Oxycodone and Acetaminophen Tablets and Hydrocodone and Acetaminophen Tablets.

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.

All of the foregoing could have a material adverse effect on our business, results of operations, financial condition, cash flows and ability to operate.

We may fail to successfully identify, develop and commercialize new products.

Elite's product pipeline, including the paused development of 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. 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.

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.

Our ability to sustain current operations, engender business growth, achieve current and future revenues and profitability, significantly depends on our ability to successfully identify, develop, obtain regulatory approval, commercialize and market new pharmaceutical products, including, without limitation, our own products as well as those that may be developed in partnership with other entities, such as those that were previously developed with SunGen pursuant to a now terminated product development agreement. 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. There are 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 consistent with initial indications. 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 received marketing approval from the FDA, for which continued development has been paused and 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.

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.

Our operations could be disrupted by failure of our information systems or cyber-attacks.

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.

Any breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information or other confidential information, whether as a result of theft, hacking, fraud, trickery or other forms of deception, or for any other cause, could enable others to produce competing products, use our proprietary technology or information and/or adversely affect our business position. Further, any such interruption, security breach, loss or disclosure of confidential information could result in financial, legal, business and reputational harm to our company and could have a material adverse effect on our business, financial condition, results of operations, cash flows and stock price.

Delays in product development may result in failure to achieve adequate return on investment.

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.

There are also risks and uncertainties inherent in conducting clinical trials could delay or prevent the development and commercialization of our own branded products. 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 enrolment, 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 enrolment 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.

Our business is dependent on market perceptions, social and political pressures.

Market acceptance of our products among physicians, patients, health care payors and the medical community, is a key component of commercial success and if such is not achieved, 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 also experience downward 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 which could have a material adverse effect on our business, growth prospects, financial condition, results of operations, cash flow and stock price.

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, which could have a material adverse effect on our business, growth prospects, financial condition, results of operations, cash flow and stock price.

Furthermore, public concern over the abuse of opioid medications, including increased legal and regulatory action, could also negatively affect our business. While Elite has de-emphasized its programs with respect to opioids and will continue to focus on products other than 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 three opioid products approved during fiscal years prior to the twelve months ended March 31, 2021 and a cessation of orders for another two other opioid products that had been marketed by our marketing partners. During the year ended March 31, 2020, we disposed of four approved ANDA's for opioid products. As of March 31, 2021, we continue to hold one approved ANDA for an opioid product that, while approved by the FDA, has not been launched commercially. Further, defense against any such opioid related lawsuits could be cost-prohibitive 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.

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

Any or all of the above could result in a material adverse effect on our business, financial condition, results of operations, cash flow, ability to operate and stock price.

Unstable economic conditions may adversely affect our business.

The global economy has undergone a period of significant volatility, especially during a global pandemic, such as the COVID-19 pandemic, 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 fulfil 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, cash flows and stock price.

We depend on qualified scientific and technical personnel and our ability to attract and retain such personnel.

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, should we reinstate development and achieve commercialization of this product. 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, financial condition, cash flows and stock price.

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.

Unsuccessful collaboration or licensing arrangements could limit revenues and product development.

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.

Any or all of the above could result in a material adverse effect on our business, financial condition, results of operations, cash flow, ability to operate and stock price.

Financial and Liquidity Risks

We have a relatively limited operating history and our 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:

- Effects of a global pandemic or similar situation, including, without limitation the COVID-19 pandemic that emerged in 2020, with such effects to include actions taken by the Company, its suppliers, partners, competitors, other entities involved in the industry, other entities, and any laws, regulations, executive orders or other governmental/regulatory actions taken in relation to such a pandemic or similar circumstance;
- 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 non-competitive;
- The ability to maintain selling prices and gross margin on our products;
- Mix of product manufactured and sold due to each product having different gross margins;
- 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 and magnitude of the variation(s).

In addition, although we have been in operation since 1990, we have a relatively short operating history, have only achieved profitability for the first time during the fiscal year ended March 31, 2021 and have limited financial data upon which you may evaluate our business and prospects. There can be no assurances of our ability to sustain current

profitability and in certain years prior to the year ended March 31, 2021, the auditor's opinion on our financials were qualified with respect to there being substantial doubt as to the Company's ability to continue as a going concern due to continued losses not being sufficiently offset by operating revenues. A failure to generate sufficient revenues to offset related costs of operations will have a material adverse effect on our business, results of operations, financial condition, cash flow and ability to operate.

Furthermore, 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 and there can be no assurances of continued profitability subsequent to the current fiscal year. 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; and,
- Sustain operations during a global pandemic or similar situation, such as the COVID-19 global pandemic first identified in 2020.

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.

Our ability to fund operations is uncertain and we may require additional financing to meet objectives.

Our ability to fund our operations, maintain liquidity and meet our financing obligations is reliant on our operations, which are subject to significant risks and uncertainties. We rely on cash generated by operations as well as access to financial markets, such as the equity line with Lincoln Park and equipment financings, to fund our commercial, product development and other operations, maintain liquidity and meet our financial obligations. Amounts available under the equity line with Lincoln Park have a strong and direct correlation to the Company's publicly traded price per share and volumes. There can be no assurances of our traded price per share and volumes being at sufficient levels to provide adequate funding from the equity line with Lincoln Park. In addition, there can be no assurances of our ability to secure equipment financing, resulting in an increased risk of our inability to achieve critical or necessary facility upgrades.

Our operations are also subject to many significant risks and uncertainties, as described, without limitation, in this "Risk Factors" section, including, without limitation, those risks related to the effects of a global pandemic such as or similar to the COVID-19 pandemic, competition in the markets in which we operate, litigation risks, government investigations, including those related to our sale, marketing and/or distribution of prescription opioid medications in prior periods, and others. Any negative development or outcome in connection with any or all of these risks and uncertainties could result in significant consequences, including, without limitation, one or more of the following:

- The dedication of a substantial portion of our cash flows from operations to the payment of legal or related expenses, resulting in these same funds being unavailable for other purposes, including, without limitation, debt service, operations, capital expenditures, product development and future business opportunities;
- A limitation in our ability to adjust to changing market conditions, causing us to be more vulnerable to periods of negative or impaired growth in the general economy or in our business, resulting the company being put at a competitive disadvantage as a result of a decreased or unavailable ability to engage in capital spending and take all other actions that would otherwise be required to ensure growth and competitiveness;
- A limitation in our ability to attract and retain key personnel;
- A decrement in our debt service and compliance obligations related to certain of our outstanding debt obligations, exposing us to events of default and reduced credit ratings, which in turn lead to increased capital costs and potential unavailability of capital; and,
- An overall inability to fund our operations and liquidity needs.

The occurrence or possibility of one or more of these or similar events may cause us to pursue one or more significant corporate transactions as well as other remedial measures, including refinancing all or part of our then-existing indebtedness, selling assets, reducing, delaying or eliminating capital expenditures, seeking to raise additional capital or pursuing internal reorganizations, restructuring activities, strategic alliances, or cost-saving initiatives. Any refinancing of our substantial indebtedness could be at significantly higher interest rates, which will depend on both the conditions of the market as well as the Company's finances at such time, and may also require our compliance with covenants that could be more onerous than current, which in turn could result in the further restriction of our business operations. Any refinancing may also increase the amount of our secured indebtedness. In addition, the terms of existing or future debt agreements may restrict us from adopting any of the alternatives. Internal reorganizations, restructuring activities, asset sales and cost saving initiatives may also be complex and could entail significant costs and charges or could otherwise negatively impact shareholder value. There can also be no assurance that we will be able to accomplish any of these alternatives on terms acceptable to us, or at all, or that even if accomplished, that the intended results and benefits would be realized.

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

We also will likely 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, 2021, we had cash on hand of approximately $3.2 million and a working capital surplus of $6.8 million, and, for the fiscal year ended March 31, 2021, we had profits from operations totaling $2.5 million, net other income totaling $3.0 million and net income of $5.5 million.

On July 8, 2020, we entered into another purchase agreement (the "*2020 LPC Purchase Agreement*"), together with a registration rights agreement (the "*2020 LPC Registration Rights Agreement*"), with Lincoln Park. Under the terms and subject to the conditions of the 2020 LPC Purchase Agreement, we have the right to sell to and Lincoln Park is obligated to purchase up to $25 million in shares of our common stock, subject to certain limitations, from time to time, over the 36-month period commencing on July 27, 2020 and expiring on August 1, 2023.

While growth in our current generic product line, consisting of Phentermine Tablets, Phentermine Capsules, Phendimetrazine Tablets, Naltrexone Tablets, Isradipine Capsules, Trimipramine Capsules, Amphetamine IR Tablets, Amphetamine ER Capsules, Dantrolene Capsules, and Loxapine Capsules combined with manufacturing, profit split and royalty revenues earned pursuant to the Lannett Alliance, the Precision Dose License Agreement, the Burel License Agreement and the Epic License Agreement, and successful commercialization of other products in our product development pipeline, may lead to sustained profitability, there can be no assurances of such. 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 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.

Please also see the risk factor titled "***Global pandemic and natural disasters***".

We have substantial indebtedness which may adversely affect our financial condition.

We currently have substantial indebtedness. Total liabilities as of March 31, 2021, were $10.1 million, with such amount including, without limitation, $2.4 million in various loans, leases and bonds payable, $2.3 million in derivative liabilities, and $5.3 million in current payables and accruals. The consequences of this substantial indebtedness could include:

- An increase in our vulnerability to general economic and industry conditions, including recessions, depressions, effects of global pandemics such as the COVID-19 pandemic, significant inflation and other financial market volatility;
- Exposure to the risk of increased interest rates;
- The Company being required to dedicate a substantial portion of cash flow from operations for debt service and the attendant result of a diminished ability to fund working capital, capital expenditures and other expenses;
- A limitation in our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate;
- Our being at a competitive disadvantage as compared to competitors with less indebtedness; and
- A limitation in our ability to borrow additional funds that may be needed to operate and expand our business.

In addition, 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.

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*".

There is a risk impairment of significant intangible assets on our balance sheet.

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, 2021, intangible assets were approximately $6.6 million, or approximately 25% of our assets.

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

GAAP requires estimates, judgements and assumptions which inherently contain uncertainties.

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.

Legal and Regulatory Risks

The pharmaceutical industry is heavily regulated which creates uncertainty and substantial compliance costs.

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

Before obtaining regulatory approvals for the sale of any of our new product candidates, we must demonstrate through preclinical studies and clinical trials that the product is safe and effective for each intended use. Preclinical and clinical studies may fail to demonstrate the safety and effectiveness of a product. Likewise, we may not be able to demonstrate through clinical trials that a product candidate's therapeutic benefits outweigh its risks. Even promising results from preclinical and early clinical studies do not always accurately predict results in later, large scale trials. A failure to demonstrate safety and efficacy could or would result in our failure to obtain regulatory approvals. Clinical trials can be delayed for reasons outside of our control, which can lead to increased development costs and delays in regulatory approval. For example, due to competition to enroll

patients in clinical trials, there have been instances of delays in clinical development of our products in the past, as a result of patients not enrolling in clinical trials at the rate expected, or patients dropping out of trials after enrolling, at rates that were higher than expected. In addition, we rely on collaboration partners and third-party subject matter experts that may recommend changes in trial protocol and design enhancements that are put into effect, or encounter clinical trial compliance-related issues, which may also delay clinical trials. Product supplies may be delayed or be insufficient to treat the patients participating in the clinical trials, or manufacturers or suppliers may not meet the requirements of the FDA or foreign regulatory authorities, such as those relating to Current Good Manufacturing Practices. We also may experience delays in obtaining, or we may not obtain, required initial and continuing approval of our clinical trials from institutional review boards. We cannot confirm to you that we will not experience delays or undesired results in these or any other of our clinical trials.

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

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

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

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

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

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

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

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 labelling 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.

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 labelling 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 labelling changes to address those risks. The FDA also can require companies to formulate approved Risk Evaluation and Mitigation Strategies (REMS) to confirm a drug's benefits outweigh its risks.

The FDA's exercise of its authority under the FFDCA could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with additional post-approval regulatory requirements and potential restrictions on sales of approved products. Foreign regulatory agencies often have similar authority and may impose comparable requirements and costs. Post-marketing studies and other emerging data about marketed products, such as adverse event reports, may also adversely affect sales of our products. Furthermore, the discovery of significant safety or efficacy concerns or problems with a product in the same therapeutic class as one of our products that implicate or appear to implicate the entire class of products could have an adverse effect on sales of our product or, in some cases, result in product withdrawals. The FDA has continuing authority over the approval of an NDA or ANDA and may withdraw approval if, among other reasons, post-marketing clinical or other experience, tests, or data show that a drug is unsafe for use under the conditions upon which it was approved, or if FDA determines that there is a lack of substantial evidence of the drug's efficacy under the conditions described in its labelling. 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 FFDCA. At the end of such an inspection, FDA could issue a Form 483 Notice of Inspectional Observations, which could cause us to modify certain activities identified during the inspection. Following such inspections, the FDA may issue an untitled letter as an initial correspondence that cites violations that do not meet the threshold of regulatory significance of a Warning Letter. FDA guidelines also provide for the issuance of Warning Letters for violations of "regulatory significance" for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action. FDA also may issue Warning Letters and untitled letters in connection with events or circumstances unrelated to an FDA inspection.

Similar to other pharmaceutical companies, during Fiscal 2021, 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.

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

Regulatory agencies such as the FDA regularly inspect our manufacturing facilities and the facilities of our third-party suppliers. The failure of the Northvale Facility, or a facility of one of our third-party suppliers, to comply with applicable laws and regulations may lead to breach of representations made to our customers or to regulatory or

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

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

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

Decreases in the degree to which individuals are covered by healthcare insurance and levels of third party reimbursement could result in decreased use of our products and lower prices.

Employers may seek to reduce costs by reducing or eliminating employer group healthcare plans or by transferring a greater portion of their healthcare costs to their employees. Job losses, or other economic hardships, especially, but not limited to those hardships resulting from the effects of the COVID-19 global pandemic, may also result in reduced levels of coverage for some individuals, potentially resulting in lower healthcare coverage for themselves or their families. Furthermore, increased instability in the insurance marketplace or an increase in uninsured Americans or others living and working in the USA may result from the Tax Cuts and Jobs Act of 2017 elimination of the Patient Protection and Affordable Care Act (PPACA)'s requirement that individuals maintain health insurance or incur a financial penalty and other steps taken by various governmental and other organizations to limit or end subsidies to such individuals at comparatively lower income levels. These economic conditions may affect an individual's ability to afford healthcare as a result of increased premiums, co-pay or deductible obligations, greater cost sensitivity to existing co-pay or deductible obligations, lost healthcare coverage or for other reasons. It is possible that such conditions could lead to changes in patient behavior and spending patterns that could negatively affect prescription and usage of certain or all of our products, including, without limitation, delaying of treatment, rationing of prescription medications, non-filling of prescriptions, reduction in the frequency of visits to healthcare facilities, utilizing alternative therapies or foregoing healthcare insurance coverage altogether. Such changes may result in the reduced demand for any or all of our products, which could have a material adverse effect on our business, results of operations, financial condition, cash flows and ability to operate as a going concern.

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 (known as the individual mandate) are no longer permissible under the U.S. Congress' taxing power, the entire PPACA is no longer constitutional. The decision was appealed to the U.S. Court of Appeals for the Fifth Circuit. In December 2019, the Fifth Circuit issued an opinion holding that, while the individual mandate was no longer constitutional, the case must be remanded to the district court to further evaluate whether the mandate can be severed from the PPACA or the entire PPACA must be stricken down. In January 2020, petitions for certiorari were filed requesting that the U.S. Supreme Court review the Fifth Circuit's decision and ultimately decide the constitutionality of the PPACA. In March 2020, the U.S. Supreme Court granted certiorari in the consolidated cases of *Texas v. California* and *California v. Texas*, both of which address the Fifth Circuit's decision to strike down the individual mandate, while sending back to the district court the question of the overall law's constitutionality. The cases were argued before the U.S. Supreme Court in November 2020 and a decision is expected during the current Supreme Court term in 2021. Changes in law resulting from this ongoing lawsuit or other court challenges to the PPACA could have a material adverse effect on our business, results of operations, financial condition, cash flows and ability to operate as a going concern.

Furthermore, 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. For example, government agencies or third-party payers could attempt to reduce reimbursement for physician administered products through their interpretation of complex government price reporting obligations and payment and reimbursement coding rules, and could attempt to reduce reimbursement for separate physician administered products that share an active ingredient by requiring the blending of sales and pricing information in the same payment and reimbursement code.

There have been several recent U.S. Congressional inquiries, hearings and proposed and enacted federal and state legislation and rules, as well as executive orders, designed to, among other things: (i) reduce or limit the prices of drugs and make them more affordable for patients, such as by tying the prices that Medicare reimburses for physician administered drugs to the prices of drugs in other countries; (ii) reform the structure and financing of Medicare Part D pharmaceutical benefits, including through increasing manufacturer contributions to offset Medicare beneficiary costs; (iii) bring more transparency to how manufacturers price their medicines; (iv) enable the government to directly negotiate prices for drugs covered under Medicare; (v) revise rules associated with the calculation of Medicaid Average Manufacturer Price and Best Price, including with regard to the manner in which pharmaceutical manufacturers may provide copayment assistance to patients and the identification of "line extension" drugs, which affect the amount of rebates that manufacturers must pay on prescription drugs under Medicaid; (vi) eliminate anti-kickback statute discount safe harbor protection for manufacturer rebate arrangements with Medicare Part D Plan Sponsors and pharmacy benefit managers on behalf of Part D Plan Sponsors; (vii) create new anti-kickback statute safe harbors applicable to certain point-of-sale discounts to patients and fixed-fee administrative fee payment arrangements with pharmacy benefit managers; and (viii) and facilitate the importation of certain lower-cost drugs from other countries. In addition, state legislatures have enacted legislation and regulations designed to control pharmaceutical and biological product pricing, including restrictions on pricing or reimbursement at the state government level, marketing cost disclosure and transparency measures, and, in some cases, policies to encourage importation of drugs from other countries (subject to federal approval) and bulk purchasing, including the National Medicaid Pooling Initiative. While we cannot predict the final form of pending legislative, regulatory and/or administrative measures, some of the pending and enacted legislative proposals or executive rulemaking, such as those incorporating International Pricing Index or Most-Favored-Nation models, could significantly reduce the coverage and levels of reimbursement for products.

The unavailability of, or reduction in, the reimbursement of our products could have a material adverse effect on our business, ability to operate as a going concern, financial condition, results of operations and cash flow.

Our business may be adversely affected by legislation or healthcare regulatory reform and initiatives.

Our business and financial condition may be adversely affected by legislation or regulatory reform of the healthcare system in the United States. We cannot predict with any certainty how existing laws may be applied or how laws or legal standards may change in the future. Current or future legislation, whether state or federal, or in any of the non-U.S. jurisdictions with authority over our suppliers, customers or operations, may have a material effect on our business, ability to operate, financial condition, results of operations and cash flows.

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). The Stewardship Act is a component in the degradation of commercial prospects of SequestOx™, which are significant factor in the decision to pause development of this product. 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 us for payments made related to products manufactured by us 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.

Providing further impediment to the commercial viability of SequestOx™, New York State, in April 2019 enacted an excise tax on the first sale of every opioid unit in New York.

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 not reasonably unlikely 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 detrimental 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.

Extensive industry regulation has had and will continue to have, a significant impact on business in the areas of cost of goods, product development and our manufacturing and distribution capabilities. We, like all other pharmaceutical companies located or engaged in business in the U.S. are subject to extensive, complex, costly and evolving regulation by the federal government, including the FDA and, in the case of controlled drugs, the DEA, as well as applicable state government agencies. The Federal Food, Drug and Cosmetic Act, the Controlled Substance Act and multiple other federal statutes, regulations and guidance govern or influence the development, testing, manufacture, packing, labelling, storing, record keeping, safety, approval, advertising, promotion, sale, shipment and distribution of our products.

The process for obtaining governmental approval to manufacture and market pharmaceutical products is rigorous, time-consuming and costly and we cannot predict the extent to which we may be affected by legislative and regulatory developments. We are dependent on receiving FDA and other governmental or third-party approvals prior to manufacturing, marketing and shipping our products. The FDA approval process for a particular product candidate can take several years and requires us to dedicate substantial resources to complete all activities necessary to secure approvals and we may not be able to obtain regulatory approval for our product candidates in a timely manner, or at all. In order to obtain approval for our generic product candidates, we must demonstrate that our drug product is therapeutically equivalent and bioequivalent to a drug previously approved by the FDA through the drug approval process, known as the reference listed drug ("RLD") or reference standard drug ("RS"). Bioequivalence may be demonstrated in vivo or in vitro by comparing the generic product candidate to the innovator drug product. During the FDA review process, the FDA may request additional information and studies to support approval of an application, which could delay approval of the product and impair our ability to compete with other versions of the generic drug product.

Inherent to this process is the possibility that we will not obtain FDA or other necessary approvals, or that the rate, timing and cost of such approvals will adversely affect our product introduction plans or results of operations. We may carry inventories of certain products in anticipation of launch and if such products are not subsequently launched, we may be required to write-off the related inventory, if such inventories have no foreseeable commercial value to us.

In addition, facilities used to manufacture and/or test materials and drug products we market are subject to periodic inspection of facilities by the FDA, the DEA, and other authorities to confirm that firms are in compliance with all applicable regulations. The FDA conducts pre-approval and/or post-approval inspections to determine whether systems and processes are in compliance with cGMP and other FDA regulations. A Form 483 notice is generally issued at the conclusion of an FDA inspection and lists conditions the FDA inspectors believe may violate cGMP or other FDA regulations. If more serious violations are identified, the FDA may take additional action, such as issuing warning letters, import alerts, etc. The DEA and comparable state-level agencies also heavily regulate the manufacturing, holding, processing, security, record-keeping and distribution of drugs that are controlled substances. We manufacture and/or distribute certain controlled substances and are accordingly subject to oversight, regulation and inspection by the DEA. The DEA periodically inspects facilities for compliance with its regulations. If our manufacturing facilities or those of our suppliers fail to comply with applicable regulatory requirements, it could result in regulatory action and additional costs.

Our inability or the inability of our suppliers to comply with applicable FDA and other regulatory requirements can result in, among other things, delays in or denials of new product approvals, warning letters, import alerts, fines, consent decrees restricting or suspending manufacturing operations, injunctions, civil penalties, recall or seizure of products, total or partial suspension of sales and/or criminal prosecution. Any of these or other regulatory actions could have an adverse material effect on our business, financial condition, results of operations, cash flows and stock price.

While we have instituted internal compliance programs, if these programs do not meet regulatory agency standards or if compliance is deemed deficient in any significant way, it could have an adverse material effect on our business, financial condition, results of operations, cash flows and stock price.

Furthermore, health care initiatives and other third-party payor cost-containment pressures have caused and could continue to cause us to sell our products at lower prices, resulting in decreased revenues. Some of our products that are marketed under license granted to marketing partners such as Lannett, Burel, Epic Pharma and TAGI, in turn, purchased or reimbursed by state and federal government authorities, private health insurers and other organizations, such as health maintenance organizations, or HMOs and managed care organizations, or MCOs. Third-party payors increasingly challenge pharmaceutical product pricing. There also continues to be a trend toward managed health care in the United States. Pricing pressures by third-party payors and the growth of organizations such as HMOs and MCOs could result in lower prices and a reduction in demand for our products.

One such governmental program, known as the 340B Program, requires pharmaceutical manufacturers to enter into an agreement, called a pharmaceutical pricing agreement (PPA), with the Secretary of Health and Human Services. Under the PPA, the manufacturer agrees to provide front-end discounts on covered outpatient drugs purchased by specified providers, called "covered entities," that serve the nation's most vulnerable patient populations. Outpatient prescription drugs, over the counter drugs (accompanied by a prescription), and clinic-administered drugs within eligible facilities are covered.

In addition, legislative and regulatory proposals and enactments to reform health care and government insurance programs could significantly influence the manner in which pharmaceutical products and medical devices are prescribed and purchased. We expect there will continue to be federal and state laws and/or regulations, proposed and implemented, that could limit the amounts that federal and state governments will pay for health care products and services. The extent to which future legislation or regulations, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted or what effect such legislation or regulation would have on our business remains uncertain. For example, H.R.987, the "Strengthening Health Care and Lowering Prescription Drug Costs Act," which incorporated a bipartisan effort to address prescription drug pricing combined with broader provisions protecting the Affordable Care Act, was passed by the House of Representatives on May 16, 2019, but it is not expected to pass in the Senate. The bill does represent bipartisan consensus on the need to reform the drug pricing system. Such measures or other health care system reforms that are adopted could have a material adverse effect on our industry generally and our ability to successfully commercialize our products or could limit or eliminate our spending on development projects and affect our ultimate profitability, which could have a material adverse effect on our business, financial condition, results of operations, cash flow and stock price.

Recently enacted state laws could also affect the pricing of our products and could reduce our profitability. Since 2016, several state legislatures have enacted laws regulating the pricing of various types of pharmaceutical products, including generic pharmaceutical products. These laws vary in applicability and scope, and generally require manufacturers to notify various state agencies of price increases over a given threshold for a given period of time and to include a justification for any price increases. At least one state law (subsequently struck by the court) authorized the state attorney general to seek civil penalties and disgorgement in the event a price increase is deemed unconscionable. To the extent these laws apply to our products, they could limit the prices which the company may charge for its products and reduce the company's profitability and could have a material adverse effect on our business, growth prospects, financial condition, results of operations, cash flow and stock price.

Use of generics may be limited through legislative, regulatory or efforts of pharma companies.

Many pharmaceutical companies increasingly have used state and federal legislative and regulatory means to delay generic competition, which, if successful, could limit the use of generic pharmaceuticals. 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.
- Seeking changes to U.S. Pharmacopeia, an organization that publishes industry recognized compendia of drug standards;
- Attaching patent extension amendments to non-related federal legislation;
- Persuading regulatory bodies to withdraw the approval of brand-name drugs for which the patents are about to expire and converting the market to another product of the brand company on which longer patent protection exists;
- Entering into agreements whereby other generic companies will begin to market an authorized generic at the same time or after generic competition initially enters the market;
- Filing suits for patent infringement and other claims that may delay or prevent regulatory approval, manufacture and/or scale of generic products; and,
- Introducing "next generation" products prior to the expiration of market exclusivity for the reference product, which often materially reduces demand for the generic or the reference product for which we seek regulatory approval for a generic equivalent.

Some pharmaceutical companies have lobbied the United States Congress for amendments to the Hatch-Waxman Act that would give them additional advantages over generic competitors. For example, although the term of a company's drug patent can be extended to reflect a portion of the time an NDA is under regulatory review, some companies have proposed extending the patent term by a full year for each year spent in clinical trials rather than the one-half year that is currently permitted.

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.

New tariffs and evolving trade policy between the US and other countries may adversely affect our business.

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 uncertainty about the future

relationship between the U.S. and various other countries, including China, with respect to trade policies, treaties, government regulations and tariffs under the Biden Administration.

It is unclear to what extent the Biden Administration will continue to pursue the trade policies of the Trump Administration. The Biden Administration may seek to impose certain additional restrictions on international trade, such as increased tariffs on goods imported into the U.S. Such tariffs could potentially disrupt our existing supply chains and impose additional costs on our business, including 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, it could cause us to raise prices for our products, which may result in the loss of customers. If we are unable to pass along increased costs to our customers, our margins could be adversely affected. Additionally, it is possible that further tariffs may be imposed that could affect imports of APIs and other materials used in our products, or our business may be adversely impacted by retaliatory trade measures taken by other countries, including restricted access to APIs or other materials used in our products, causing us to raise prices or make changes to our products. Further, 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. For example, the Trump Administration placed tariffs on certain goods imported from China. In January 2020, the U.S. and China agreed to roll back certain tariffs, expand trade purchases and impose binding commitments on intellectual property, technology transfer and currency practices. Nevertheless, given the volatility and uncertainty regarding the scope and duration of these tariffs and other aspects of U.S. international trade policy, the impact on our operations and results is uncertain and could be significant. Further governmental action related to tariffs, additional taxes, regulatory changes or other retaliatory trade measures could occur in the future. Any of these factors could have a material adverse effect on our business, financial condition, results of operations and cash flows.

The DEA could limit the availability of active ingredients used in many of our products.

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.

Changes in FDA approval requirements may prevent or delay approval of new products.

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

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

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

We received a CRL from the FDA indicating that the SequestOx™ NDA is not ready for approval.

We received a Complete Response Letter from the FDA that indicated that our SequestOx™ NDA is not ready for approval in its present form. We have paused further development of this product and we cannot assure that development will restart. If we are unable to obtain approval for SequestOx™ or if we incur significant costs or delays in obtaining such approval, our ability to commercialize SequestOx™ may be materially adversely affected.

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

Regulatory factors may cause us to be unable to manufacture products or face interruptions in our manufacturing process.

Our manufacturing operations as well as our suppliers' manufacturing operations are subject to establishment registration by the FDA and periodic inspections by the FDA to assure compliance regarding the manufacturing of our products. If we or our suppliers do not maintain the current registrations or if we or our partners receive notices of manufacturing and quality-related observations following inspections by the FDA, our operating results would be materially negatively impacted.

Our facilities, as well as those of applicable suppliers, rely on maintaining current FDA, and DEA if applicable, registration and other license to produce and develop generic drugs and raw materials used in such operations. If we, or one of our suppliers does not successfully renew and maintain current FDA, DEA and other required licenses, our operations and financial results would be negatively impacted. We and our suppliers are subject to periodic inspection by the FDA, DEA and other regulatory agencies, as applicable, to assure regulatory compliance regarding the manufacture and distribution of pharmaceutical products and raw materials. These regulatory bodies impose stringent

mandatory requirements on the manufacture and distribution of pharmaceutical products to ensure their safety and efficacy. If we or any of our third party suppliers receive notices of manufacturing and quality-related observations and are unable to satisfactorily resolve the issues and observations identified in a timely fashion, there could be a material adverse effect on our business, financial condition, results of operations, cash flow and stock 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.

Litigation and Liability Related Risks

We may not be able to obtain or maintain adequate insurance coverages.

The cost of insurance, including directors and officer insurance, workers compensation, product liability, truck and general liability insurance have increase significantly in recent years and may continue to increase in the future. We have increased deductibles and/or decreased coverages to mitigate some of these costs. These insurance premium increases, as well as our increased risk due to reduced coverage and increased deductibles could have an adverse material effect on our business, financial condition, results of operations, cash flows and stock price.

We may not have and may be unable to obtain or maintain in the future insurance, on acceptable terms, that provide adequate coverage against potential liabilities or other losses, such as the cost of a recall or defense against claims, if any claim is brought against us, for any reason, regardless of the merits, success or failure of such claim. In the past year, as a result of product liability and securities litigation in the general marketplace, and a threatened claim of action against us in relation to the shareholder vote conducted in December 2019, our insurance premiums have increased significantly, while also providing no greater, and in most cases, lower levels of coverage. The significant premium increases experienced were prior to, and accordingly did not consider, the impact of the COVID-19 global pandemic on the legal and litigation environment in which we and all other companies operate.

The amount of our insurance coverage is accordingly limited by our financial resources and greatly impacted by the significant premium increases of the past year and reasonably expected further increases in the near to mid-term due to the global pandemic. Furthermore, even where claims are submitted to insurance carriers for defenses and indemnity that are within coverage limits, there can be no assurance that such claims will be fully covered by insurance or that the indemnitors or insurers will remain financially viable to provide reimbursement consistent with coverage maintained.

Any failure by us, to obtain sufficient insurance coverage, with reimbursement of claims being provided and generate sufficient cash flow, if needed, above insurance coverage, to pay amounts due in relation to potential claims, will have a material adverse effect on our business, financial condition, results of operations, cash flow and ability to operate as a going concern.

Litigation, product liability claims, product recalls, government investigations and other significant legal proceedings are common in the pharmaceutical industry.

Litigation, product liability claims, other significant legal proceedings, government investigations and product recalls are 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.

As a business that operates in the pharmaceutical industry, we are inherently exposed to significant potential risks from lawsuits, product liability claims, patent and proprietary rights claims, other significant proceedings, government investigations or product recalls, including, without limitation, such matters associated with the testing, manufacturing, marketing and sale of our products. While no such judgements have been made against us to date, some plaintiffs have received substantial damage awards or settlements against other healthcare companies based upon various legal theories, including, without limitation, claims for injuries allegedly caused by use of their products. Our business continues to be inherently exposed to the risk of being subject to product liability cases, as well as other significant legal proceedings and government investigations.

For example, we have been a manufacturer of prescription opioid medications in the past, and while we have not been subject to lawsuits, other manufacturers of such products, as well as distributors and other sellers of such medications, have been subjects of subject of lawsuits and have received subpoenas and other requests for information from various federal, state and local government agencies regarding the sale, marketing and/or distribution of prescription opioid medications. Numerous claims against opioid manufacturers, have been and may continue to be filed by or on behalf of states, counties, cities, Native American tribes, other government-related persons or entities, hospitals, health systems, unions, health and welfare funds, other third-party payers and/or individuals. In these cases, plaintiffs seek various remedies, including without limitation declaratory and/or injunctive relief; compensatory, punitive and/or treble damages; restitution, disgorgement, civil penalties, abatement, attorneys' fees, costs and/or other relief. Settlement demands may seek significant monetary and other remedies, or otherwise be on terms that would result in material adverse effects on our business and ability to operate as a going concern. The precedent of awards against and settlements by our competitors could also incentivize parties to bring additional claims against us. In addition to the risks of direct expenditures for defense costs, settlements and/or judgments in connection with these claims, proceedings and investigations, there is a possibility of loss of revenues, injunctions and disruption of business. Furthermore, we and other manufacturers of prescription opioid medications have been, and will likely continue to be, subject to negative publicity and press, which could harm our brand and the demand for our products. In addition, current or future regulatory and legislative proposals could impact us and other manufacturers of prescription opioid medications. See the risk factor "Our business and financial condition may be adversely affected by legislation" for more information.

In addition, our current and former products may cause or appear to cause serious adverse side effects or potentially dangerous drug interactions if misused or improperly

prescribed or as a result of faulty surgical technique. Any failure to effectively identify, analyze, report and protect adverse event data and/or to fully comply with relevant laws, rules and regulations around adverse event reporting could expose the Company to legal proceedings, penalties, fines and/or reputational damage.

Also, through the use of social media, plaintiff's attorneys have a wide variety of tools to advertise their services and solicit new clients for litigation, including using judgments and settlements obtained in litigation against us or other pharmaceutical companies as an advertising tool. For these or other reasons, any significant product liability or mass tort litigation in which we are a defendant could have a larger number of plaintiffs than such actions have seen historically and we could also see an increase in the number of cases filed against us because of the increasing use of widespread and media-varied advertising. Furthermore, a ruling against other pharmaceutical companies in product liability or mass tort litigation in which we are not a defendant could have a negative impact on pending litigation where we are a defendant.

In addition, in certain circumstances, such as in the case of products that do not meet approved specifications or for which subsequent data demonstrate such products may be unsafe, ineffective or misused, it may be necessary for us to initiate voluntary or mandatory recalls or withdraw such products from the market. Any such recall or withdrawal could result in adverse publicity, costs connected to the recall and loss of revenue. Adverse publicity could also result in an increased number of additional product liability claims, whether or not these claims have a basis in scientific fact. See the risk factor "Public concern around the abuse of opioids or other products, including without limitation law enforcement concerns over diversion or marketing practices, regulatory efforts to combat abuse, and litigation could result in costs to our business" for more information.

We are also inherently exposed to litigation concerning patents and proprietary rights which 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.

If we are found liable in any lawsuits, including patent infringement, violation of proprietary rights, product liability claims or actions related to our manufacture, sales, marketing or pricing practices or the sale, marketing and/or distribution of prescription opioid medications, or if we are subject to government investigations or product recalls, it could result in the imposition of damages, including punitive damages, fines, reputational harm, civil lawsuits, criminal penalties, interruptions of business, modification of business practices, equitable remedies and other sanctions against us or our personnel as well as significant legal and other costs. We may also voluntarily settle cases even if we believe that we have meritorious defenses because of the significant legal and other costs that may be required to defend such actions. Any judgments, claims, settlements and related costs could be well in excess of any applicable insurance. As a result, we may experience significant negative impacts on our operations. To satisfy judgments or settlements, we also may need to seek financing, which may not be available on terms acceptable to us, or at all, when required. Judgments also could cause defaults under our debt agreements and/or restrictions on our product use and we could incur losses as a result. Any of the risks above could have a material adverse effect on our business, financial condition, results of operations and cash flows and ability to operate as a going concern.

The occurrence or possibility of any such result may cause us to pursue one or more significant corporate transactions as well as other remedial measures, including internal reorganizations, restructuring activities, strategic corporate alignments, cost saving initiatives or asset sales. See the risk factor "Our ability to fund our operations, maintain liquidity and meet our financing obligations is reliant on our operations, which are subject to significant risks and uncertainties" for more information. Likewise, any internal reorganizations, restructuring activities, strategic corporate alignments, cost-saving initiatives or asset sales may be complex, could entail significant costs and charges or could otherwise negatively impact shareholder value and there can be no assurance that we will be able to accomplish any of these alternatives on terms acceptable to us, or at all, or that they will result in their intended benefits.

We also 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 labelling 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 are also subject to state and federal laws that govern the submission of claims for reimbursement. The FFCA imposes civil liability on individuals or entities that knowingly submit, or cause to be submitted, false or fraudulent claims for payment to the government. Violations of the FFCA and other similar laws may result in criminal fines, imprisonment and substantial civil penalties for each false claim submitted (including civil penalties presently in excess of $22 thousand per claim, plus treble damages, plus liability for attorney's fees) and exclusion from federally funded health care programs, including Medicare and Medicaid. The FFCA also allows private individuals to bring a suit on behalf of the government against an individual or entity for violations of the FFCA. These suits, also known as Qui Tam or whistle-blower actions, may be brought by, with only a few exceptions, any private citizen who has material information of a false claim that has not yet been previously disclosed. These suits have increased significantly in recent years because the FFCA allows an individual to share in the amounts paid to the federal government in fines or settlement as a result of a successful Qui Tam action, in addition to the recovery of legal fees in bringing such an action. If our past or present operations are found to be in violation of any of such laws or any other governmental regulations that may apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from federal health care programs and/or the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment, or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Action against us for violation of these laws, even if we successfully defend against them, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Recently, the Department of Justice has begun to use the 1961 federal Travel Act as a tool to pursue criminal charges in the case of health care kickback and commercial bribery allegations. This law was enacted as part of the Kennedy administration's war on organized crime. It formed the basis for a federal enforcement action against a Texas

physician-owned specialty hospital and a number of surgeons and administrators, who were convicted of conspiring to pay or receive bribes in exchange for referrals of patients in violation of a state commercial bribery law. Importantly, this case was not limited to claims covered under federal programs, and the failure of the state to bring charges under its own statute did not prevent the federal case from proceeding. The Travel Act may be used by the Justice Department as a way to expand its reach to penalize kickbacks and similar arrangements even when the Anti-Kickback Statute and FFCA would not apply. These efforts could increase our vulnerability to litigation and penalties if our past or present operations are found to be in violation of applicable law which could have a material adverse effect on our business, financial condition, results of operations, cash flow and stock price.

Furthermore, the design, development, manufacture, distribution and sale of our products involve an inherent risk of product liability claims and associated adverse publicity. Insurance coverage is expensive, increasing in price to prohibitive levels, may be difficult to obtain or may be not available in the future on acceptable terms, or at all. Although we currently maintain product liability insurance for our products in amounts we believe to be commercially reasonable, if the coverage limits of these insurance policies are not adequate, a claim brought against us, whether covered by insurance or not, could have a material adverse effect on our business, financial condition, results of operations, cash flow and stock price.

Our products contain narcotic ingredients which may subject us to increased litigation risk and regulation.

Some of our current products and products under development contain narcotics. Misuse or abuse of such drugs can lead to physical or other hard. The FDA and/or the DEA may impose new regulations concerning the manufacture, storage, transportation, distribution, and sale of prescription narcotics. Such regulations may include new labelling 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 labelling 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 be provided to prescribers of these products and that information is provided to prescribers that they can use in counselling patients on the risks and benefits of opioid drug use. Elite does not currently own a product that requires a REMS plan, but some of the products in our pipeline may require a REMS plan. The federal government has also released a comprehensive action plan to reduce prescription drug abuse, which may include proposed legislation to amended existing controlled substances laws to require healthcare practitioners who request DEA registration to prescribe controlled substances to receive training on opioid prescribing practices as a condition of registration. In addition, state health departments and boards of pharmacy have authority to regulate distribution and may modify their regulations with respect to prescription narcotics in an attempt to curb abuse.

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

Public concern over abuse of opioids has negatively affected our business.

While Elite has de-emphasized its programs with respect to opioids and will continue to focus on products other than 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 three opioid products approved during fiscal years prior to the twelve months ended March 31, 2020 and a cessation of orders for another two other opioid products that had been marketed by our marketing partners. During the year ended March 31, 2020, we disposed of four approved ANDA's for opioid products. As of March 31, 2020, we continue to hold one approved ANDA for an opioid product that, while approved by the FDA, has not been launched commercially. 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.

Illegal distribution and third party sale of counterfeit versions of our products could have a detrimental effect on our reputation and business.

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.

Structural and Organizational Risks

We have identified material weaknesses in internal controls in prior years.

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.

During the prior fiscal year ended March 31, 2019, the Company identified certain material weaknesses in internal controls over financial reporting which were remediated during the fiscal year ended March 31, 2020, with such remediation also being effective during this current fiscal year. 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 remediation actions taken required the retention of additional personnel and consultants, the continued retention of which is subject to the Company's financial condition.

Despite the successful remediation of material weaknesses identified in the prior fiscal year, there can be no assurances of the continued operation of controls, due to the financial burden such controls place on the Company, as well as the effects of other operating challenges, such as the COVID-19 global pandemic or similar situation, which may result in our inability to maintain an environment of internal controls over financial reporting that does not have material weaknesses.

Furthermore, additional material weaknesses in our internal controls may be discovered or occur in the future that may materially adversely affect our ability to report our financial condition and results of operations in a timely and fairly stated manner and there will be an increased risk of future misstatements.

Although we regularly review and evaluate 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 are unable to timely remediate our previously identified 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, if such is required, 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 fairly stated 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.

Provisions of our Articles of Incorporation could deter a change of management and discourage offers to acquire us.

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

Intellectual Property Related Risks

Our ability to protect intellectual property rights and successfully defend third party allegations of intellectual property infringement is vital to our business and uncertain.

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 six patents. 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, such as government or regulatory authorities, or become known, obtained, or independently developed by our competitors or by other entities through means beyond our control. 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.

Furthermore, companies that produce branded pharmaceutical products routinely bring litigation against ANDA or similar applicants that seek regulatory approval to manufacture and market generic forms of branded products, alleging patent infringement or other violations of intellectual property rights. Patent holders may also bring patent infringement suits against companies that are currently marketing and selling approved generic products. Litigation often involves significant expense. Additionally, if the patents of others are held valid, enforceable and infringed by our current products or future product candidates, we would, unless we could obtain a license from the patent holder, need to delay selling our corresponding generic product and, if we are already selling our product, cease selling and potentially destroy existing product stock. Additionally, we could be required to pay monetary damages or royalties to license proprietary rights from third parties and we may not be able to obtain such licenses on commercially reasonable terms or at all.

There may be situations in which we may make business and legal judgments to market and sell products that are subject to claims of alleged patent infringement prior to final resolution of those claims by the courts based upon our belief that such patents are invalid, unenforceable or are not infringed by our marketing and sale of such products. This is commonly referred to in the pharmaceutical industry as an "at-risk" launch. The risk involved in an at-risk launch can be substantial because, if a patent holder ultimately prevails against us, the remedies available to such holder may include, among other things, damages calculated based on the profits lost by the patent holder, which can be significantly higher than the profits we make from selling the generic version of the product. Moreover, if a court determines that such infringement is willful, the damages could be

subject to trebling. We could face substantial damages from adverse court decisions in such matters. We could also be at risk for the value of such inventory that we are unable to market or sell.

The occurrence of any of the above could have a material adverse effect on our business, financial condition, results of operations, cash flow and stock price.

Risks Related to our Common Shares

Dilution from issuance of shares to Lincoln Park, Directors, Employees, Consultants or upon exercise of warrants and options or the perception that dilution may occur could cause the price per share of common stock to fall.

On July 8, 2020, we entered into the Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park has committed to purchase up to $25,000,000 of our common stock. Concurrently with the execution of the Purchase Agreement, we issued 5,975,857 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 5,975,857 shares will be issued based upon the relative proportion of the aggregate amount of $25,000,000 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 July 27, 2020 and expiring on August 1, 2023. 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, 2021, there were outstanding warrants to purchase an aggregate of approximately 79 million shares of Common Stock at a cash exercise price of $0.1521 per share, vested options to purchase an aggregate of approximately 5.2 million shares at a weighted average cash exercise price of $0.13. Additional shares of Common Stock may be issuable as a result of anti-dilution provisions in the outstanding warrants, with such provisions excluding any shares issued to Lincoln Park from consideration .

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 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.

Furthermore, 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 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.

Our common stock is a penny stock, quoted on the OTC bulletin board, with rules in place that could limit trading and liquidity of our shares, increased transaction costs that could adversely affect our price per share.

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.

In addition, our Common stock is quoted on the Over-the-Counter Bulletin Board (the "OTCBB") which 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 cancelled or edited like orders for other securities. All requests to change or cancel an order must be submitted to, received, and processed by the OTCBB. Due to the manual order processing involved in handling OTCBB trades, order processing and reporting may be delayed, and an individual may not be able to cancel or edit his order. Consequently, one may not be able to sell shares of Common Stock at the optimum trading prices.

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

Shareholder activism could negatively affect us.

In recent years, shareholder activism involving corporate governance, fiduciary duties of Directors and Officers, strategic direction and operations has become

increasingly prevalent. If we become the subject of such shareholder activism, their demands may disrupt our business and divert the attention of our management, Board and employees. Also, we may incur substantial costs, including legal fees and other expenses, related to such activist shareholder matters. Perceived uncertainties resulting from such activist shareholder matters may result in loss of potential business opportunities with our current and potential customers and business partners, be exploited by our competitors and make attracting and retaining qualified personnel more difficult. In addition, such shareholder activism may cause significant fluctuations in our share price based on temporary or speculative market perceptions, uncertainties or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

The effects of shareholder activism pursued against the Company could have an adverse material effect on our business, financial condition, results of operations, cash flows and stock price.

Our stock price has been volatile.

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, 2021, the closing sale price on the OTC Bulletin Board ("*OTCBB*") of our Common Stock fluctuated from a high of $0.10 per share to a low of $0.05 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.

Capital raises through sales of securities may cause substantial dilution to existing shareholders.

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.

Issuance of shares of common or preferred stock could make achieving a change of control more difficult.

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.

We have no plans to pay regular dividends or conduct share purchases.

We do not intend to pay any cash dividends either currently or in the foreseeable future on our common shares. Additionally, we do not intend to conduct 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. A significant increase in the number of claims or an increase in amounts owing under successful claims could materially adversely affect our business, financial condition, results of operations and cash flows.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

PART II

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

Market Information

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

Quarter Ended	High	Low
Fiscal Year Ending March 31, 2021		
March 31, 2021	$ 0.09	$ 0.05
December 31, 2020	$ 0.09	$ 0.05
September 30, 2020	$ 0.09	$ 0.07
June 30, 2020	$ 0.10	$ 0.07
Fiscal Year Ending March 31, 2020		
March 31, 2020	$ 0.11	$ 0.05
December 31, 2019	$ 0.11	$ 0.08
September 30, 2019	$ 0.14	$ 0.04
June 30, 2019	$ 0.10	$ 0.03

As of June 7, 2021, the last reported sale price of our Common Stock, as reported by the OTCBB, was $0.60.

Holders

As of June 7, 2021, there were, respectively, approximately 116 holders of record of our Common Stock.

Dividends

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

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, 2021:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price per share of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders [1]	—	—	2,150,000

(1) Represents securities reserved and available for grant under the 2014 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 fulfilment 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.

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.

Results of Operations:

Years Ended March 31, 2021 and 2020

Revenue, Cost of revenue and Gross profit:

	For the Years Ended March 31,		Change	
	2021	2020	Dollars	Percentage
Manufacturing fees	$ 20,997,310	$ 14,526,048	$ 6,471,262	45%
Licensing fees	4,383,439	3,468,591	914,848	26%
Total revenue	25,380,749	17,994,639	7,386,110	41%
Cost of manufacturing	13,513,611	10,015,855	3,497,756	35%
Gross profit	$ 11,867,138	$ 7,978,784	$ 3,888,354	49%
Gross profit - percentage	47%	44%		

Total revenues for the year ended March 31, 2021 increased by $7.4 million or 41%, to $25.4 million, as compared to $18.0 million for the prior year, primarily due to revenues earned from Amphetamine ER Capsules, which were launched during the current fiscal year, increased revenues from Amphetamine IR Tablets, as compared to the prior year, offset by decreases in license fee revenues resulting from the full amortization of SequestOx™ milestone revenues occurring in June 2020 and accordingly providing partial year contribution to revenues during the year ended March 31, 2021, while contributing a full year of revenues to the prior year.

Manufacturing fees increased by $6.5 million, or 45%, primarily due to manufacturing revenues earned from Amphetamine ER Capsules, which were launched during the current fiscal year, and increased sales of Amphetamine IR Tablets, as compared to the prior year.

Licensing fees increased by $0.9 million, or 26%.This increase is primarily due to licensing fees earned from the sale of Amphetamine ER Capsules, which were launched during the current fiscal year, and increased licensing revenues earned from the sale of Amphetamine IR Tablets and Isradipine Capsules, as compared to the prior year.

Costs of revenue consists of manufacturing and assembly costs. Our costs of revenue increased by $3.5 million or 35%, to $13.5 million as compared to $10.0 million for the prior fiscal year. This increase was due in large part to increased manufacturing activities and related manufacturing revenues during the year ended March 31, 2021, as compared to the prior year, and also due to there being a strong positive correlation of costs of revenue to manufacturing revenues.

Our gross profit margin was 47% during the year ended March 31, 2021 as compared to 44% during the comparable prior fiscal year.

Operating expenses:

	For the Years Ended March 31,		Change	
	2021	2020	Dollars	Percentage
Operating expenses:				
Research and development	$ 5,112,542	$ 5,532,462	$ (419,920)	(8)%
General and administrative	3,323,045	3,349,837	(26,792)	(1)%
Non-cash compensation	13,181	62,098	(48,917)	(79)%
Depreciation and amortization	1,313,847	1,319,795	(5,948)	0%
Total operating expenses	$ 9,762,615	$ 10,264,192	$ (501,577)	(5)%

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 31,2021 decreased by $0.5 million or 5% to $9.8 million, as compared to $10.3 million for the prior year.

Research and development costs for the year ended March 31,2021 were $5.1 million, a decrease of $0.4 million, or 8%, from $5.5 million of such costs for the prior year. The decrease was a result of the timing and nature of product development activities during the year ended March 31,2021 as compared to the prior year.

General and administrative expenses for the year ended March 31,2021 were $3.32 million, a decrease of less than $0.1 million or 1%, from $3.35 million of such costs for the prior year. The decrease was due in large part to savings achieved from ongoing cost reduction and control initiatives.

Non-cash compensation expense for the years ended March 31, 2021 and 2020 was less than $0.1 million.

Depreciation and amortization expenses for the year ended March 31, 2021 were $1.3 million, and remained consistent related to such costs for the prior year.

As a result of the foregoing, our income from operations for the year ended March 31, 2021 was $2.1 million, compared to an operating loss of $2.3 million for the prior year.

Other income (expense):

	For the Years Ended March 31,		Change	
	2021	2020	Dollars	Percentage
Other income (expense):				
Change in fair value of derivative instruments	$ 1,237,132	$ (1,111,548)	$ 2,348,680	-211%
Interest expense and amortization of debt issuance costs	(259,598)	(355,874)	96,276	-27%
Gain on sale of fixed assets	48,463	—	48,463	n/a
Gain on transfer/discontinuance of intangible assets	—	1,502,500	(1,502,500)	-100%
Interest income	514	11,979	(11,465)	-96%
PPP Loan Forgiveness	1,013,480	—	1,013,480	n/a
Other income, net	$ 2,039,991	$ 47,057	$ 1,992,934	4,235%

Other income, net for the year ended March 31, 2021 was $2.0 million, an increase in other income, net of $1.9 million from other income of $0.1 million for the prior year. The increase in other income (expense), net was due to an increase in income relating to changes in the fair value of our outstanding derivative warrants, as compared to the prior fiscal year, PPP loan forgiveness which occurred during the current fiscal year and not during the prior fiscal year, offset by gains on transfer/discontinuance of intangible assets which were recognized during the prior fiscal year and not during the current fiscal year. Please note that the change in the fair value of derivative instruments is determined in large part by the change in the closing price of the Company's Common Stock as of the end of the period, as compared to the closing price at the beginning of the period, with a strong inverse relationship between the fair value of our derivatives instruments and decreases in the closing price of the Company's Common Stock.

As a result of the foregoing, our income before income taxes for the year ended March 31,2021 was $4.3 million, compared to a loss before income taxes of $2.2 million for the prior year.

Liquidity and Capital Resources

Capital Resources

	March 31, 2021	March 31, 2020	Change
Current assets	$ 12,194,667	$ 10,251,279	$ 1,943,388
Current liabilities	$ 5,812,531	$ 8,639,548	$ (2,827,017)
Working capital	$ 6,382,136	$ 1,611,731	$ 4,770,405

The Company considers cash and working capital balances as several of the factors the Company uses in evaluating its performance. As of March 31, 2021, the Company had cash on hand of $3.2 million and accounts receivable to be collected within expected operating cycles of $3.5 million. The Company believes that such resources, combined with the working capital surplus of $6.4 million and the continuation of ongoing operations are sufficient to fund operations through the current operating cycle. For the year ended March 31, 2021, the Company had income from operations totaling $2.1 million, net other income totaling $2.0 million and a net income of $5.1 million. The Company's other income and net income (loss) available to common shareholders are significantly influenced by the fluctuations in the fair value of warrant derivatives with such fair value bearing a strong inverse correlation to the market share price of the Company's Common Stock.

Our working capital (total current assets less total current liabilities) increased by $4.8 million from $1.6 million as of March 31, 2020 to $6.4 million as of March 31, 2021, with such increase being primarily related to the net income of $5.1 million and a net positive cash flow of $2.1 million achieved during the year ended March 31, 2021

Summary of Cash Flows:

	For the Years Ended March 31,	
	2021	2020
Net cash provided by (used in) operating activities	$ 3,193,861	$ (1,793,821)
Net cash used in investing activities	$ (262,781)	$ (34,953)
Net cash (used in) provided by financing activities	$ (869,829)	$ 689,536

Net cash provided by operating activities for the year ended March 31, 2021 was $3.2 million, which included net income of $5.1 million and increases in non-cash expenses totaling $0.2 million, offset by net increases in assets and decreases in liabilities totaling $2.1 million.

Net cash used in investing activities for the year ended March 31, 2021 was comprised of purchases of purchases of property and equipment of $0.3 million offset by proceeds from the sale of property and equipment of less than $0.1 million.

Net cash used in financing activities was $0.9 million for the year ended March 31, 2021 which consisted primarily of proceeds from the payroll protection program loan offset by loan payments.

Lincoln Park Capital

July 8, 2020 Purchase Agreement

On July 8, 2020, Elite Pharmaceuticals, Inc., a Nevada corporation (the "Company"), entered into a purchase agreement (the "2020 LPC Purchase Agreement"), and a registration rights agreement (the "Registration Rights Agreement"), with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which Lincoln Park has committed to purchase up to $25.0 million of the Company's common stock, $0.001 par value per share (the "Common Stock"), from time to time over the term of the Purchase Agreement, at the Company's direction.

During the year ended March 31, 2021 the Company issued an aggregate of 5,975,857 shares of Common Stock in the amount of $469,105 to Lincoln Park as initial commitment shares. The Company sold 640,543 shares of its Common Stock pursuant to the 2020 LPC Purchase Agreement during the year ended March 31, 2021 for net proceeds totaling $42,223. In addition, 10,094 shares were issued to Lincoln Park as additional commitment shares, pursuant to the 2020 LPC Agreement.

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 semi-annually 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 $354,454 were paid from the bond proceeds and are being amortized over the life of the bonds. Amortization of bond issuance costs amounted to $14,178 for the fiscal year ended March 31, 2021.

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

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

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.

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 15 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 Contacts with Customers ("ASC 606"), the Company recognizes revenue when the customer obtains control of promised goods or services, in an amount that reflects the consideration which is expected to be received in exchange for those goods or services. The Company 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 ASC 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 March 31, 2020.

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.

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, if any. 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.

Contingencies

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

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences

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

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

The Company operates in multiple tax jurisdictions within the United States of America. The Company remains subject to examination in all tax jurisdiction until the applicable statutes of limitation expire. As of March 31, 2021, a summary of the tax years that remain subject to examination in our major tax jurisdictions are: United States – Federal, 2015 and forward, and State, 2011 and forward. The Company did not have any unrecognized tax positions for the years ended March 31, 2021 and 2020.

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 for each trading day of the quarter then ended.

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 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 adopted the guidance as of April 1, 2020. The Company is not materially impacted by the implementation of this pronouncement.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808)*, Clarifying the Interaction between Topic 808 and Topic 606. The ASU clarifies when transactions between collaborative participants are in the scope of ASC 606. The ASU also provides some guidance on presentation of transactions not in the scope of ASC 606. ASU 2018-18 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2019. Early adoption is permitted for fiscal years, and interim periods within those years. The Company adopted the guidance as of April 1, 2020. The Company is not materially impacted by the implementation of this pronouncement.

In March 2020, the FASB issued ASU 2020-03, *Codification Improvements to Financial Instruments*. The ASU clarifies disclosure guidance for fair value options, adds clarifications to the subsequent measurement of fair value, clarifies disclosure for depository and lending institutions, clarifies the line-of-credit or revolving-debt arrangements guidance, and the interaction of Financial Instruments - Credit Losses (Topic 326) with Leases (Topic 842) and Transfers and Servicing-Sales of Financial Assets (Subtopic 860-20). In accordance with ASU 2020-03, the Company adopted the guidance as of April 1, 2020. The Company is not materially impacted by the implementation of this pronouncement.

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. This update requires immediate recognition of management's estimates of current expected credit losses ("CECL"). Under the prior model, losses were recognized only as they were incurred. The new model is applicable to all financial instruments that are not accounted for at fair value through net income. The standard is effective for fiscal years beginning after December 15, 2022 for public entities qualifying as smaller reporting companies. Early adoption is permitted. The Company is currently assessing the impact of this update on the consolidated financial statements and does not expect a material impact on the consolidated financial statements.

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

ITEM 7A QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not Applicable.

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

Evaluation of Disclosure Controls and Procedures

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act, refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. As required by Rules 13a-15(b) and 15d-15(b) of the Exchange Act, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective as of March 31, 2021 at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, 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, and 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 our assets; (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 our receipts and expenditures are being made only in accordance with authorizations of our management and directors; 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.

Internal control over financial reporting may not prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are achieved. Further, the design of a control system must be balanced against resource constraints, and therefore the benefits of controls must be considered relative to their costs. Given the inherent limitations in all systems of controls, no evaluation of controls can provide absolute assurance all control issues and instances of fraud, if any, within a company have been detected. These inherent limitations include the realities that judgments in decision making can be faulty and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions or the degree of compliance with policies or procedures may deteriorate. Accordingly, given the inherent limitations in a cost-effective system of internal control, financial statement misstatements due to error or fraud may occur and may not be detected. Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance of achieving their objectives. We conduct periodic evaluations of our systems of controls to enhance, where necessary, our control policies and procedures.

Management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting. Management has used the framework set forth in the report entitled "Internal Control—Integrated Framework (2013)" published by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of our internal control over financial reporting. Based on its evaluation, management has concluded that our internal control over financial reporting was effective as of March 31, 2021 at the reasonable assurance

level.

Changes in internal control over financial reporting

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the fiscal quarter ended March 31, 2021 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

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

Name	Age	Position	Director/Officer Since	Director Tier
Nasrat Hakim	60	President, Chief Executive Officer and Director	August 2013	III
Barry Dash, Ph. D.	90	Director	April 2005	II
Jeffrey Whitnell	65	Director	October 2009	III
Davis Caskey	73	Director	April 2016	I
Marc Bregman	50	Chief Financial Officer, Secretary and Treasurer	May 2021	
Douglas Plassche	58	Executive Vice President of Operations	August 2013	

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

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

Nasrat Hakim

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

Barry Dash, Ph.D.

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

Jeffrey Whitnell

Jeffrey Whitnell has served as a Director since October 23, 2009, Chairman of the Audit Committee, member of the Compensation Committee since October 2009 and designated by the Board as an "*audit committee financial expert*" as defined under applicable rules under the Exchange Act. Since April 2015, Mr. Whitnell has provided financial advisory services, primarily to the healthcare industry, including LifeWatch Services, where he served as the Vice President, Finance & Controller. From June2010 to March 2015,

Mr. Whitnell was the Chief Financial Officer for ReliefBand Medical Technologies, a medical device company. From June 2009 to June 2010, Mr. Whitnell provided financial advisory services to various healthcare companies, including ReliefBand Medical Technologies. From June 2004 to June 2009, Mr. Whitnell was Chief Financial Officer and Senior Vice President of Finance at Akorn, Inc. From June 2002 to June 2004, Mr. Whitnell was Vice President of Finance and Treasurer for Ovation Pharmaceuticals. From 1997 to 2001, Mr. Whitnell was Vice President of Finance and Treasurer for MediChem Research. Prior to 1997, Mr. Whitnell held various finance positions at Akzo Nobel and Motorola. Mr. Whitnell began his career as an auditor with Arthur Andersen & Co. He is a certified public accountant and holds an M.B.A. in Finance from the University of Chicago Booth School of Business and a B.S. in Accounting from the University of Illinois. Mr. Whitnell's qualifications as an accounting and audit expert provide specific experience to serve as a director for the Company.

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.

Marc Bregman

Marc Bregman has served as Chief Financial Officer, Secretary and Treasurer of the Company since May 17, 2021. Prior to joining the Company, from February 2015 to May 2021, Mr. Bregman served as Controller of Langan Engineering. From 2013 to 2015, Mr. Bregman served as financial controller at Chemtrade Logistics. From 2009 to 2013, Mr. Bregman held corporate finance positions at Chemetall. From 1999 to 2009, Mr. Bregman held multiple corporate finance positions at National Starch and Chemical Company. Mr. Bregman began his career as a certified public accountant in the audit department of Ernst & Young, LLP. Mr. Bregman is a Certified Public Accountant ("CPA"), and holds a Master in Business degree from the New Jersey Institute of Technology, Newark, NJ and Bachelor of Science in Accounting from William Paterson College, Wayne, NJ. Mr. Bregman's experience and expertise in the areas of finance, financial planning & analysis, Sarbanes Oxley compliance, financial auditing and manufacturing accounting, 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.

Committees of the Board

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

Audit Committee

During Fiscal 2021, 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 2021, 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 2021, 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.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our directors and executive officers and persons who beneficially own more than ten percent of our common stock to report their ownership of, and transactions in, our stock in filings with the SEC. Copies of these reports are also required to be supplied to VPG. VPG believes, based solely on a review of the copies of such reports received, that our directors and executive officers and persons who beneficially own more than ten percent of our common stock complied with all applicable Section 16(a) reporting requirements during the year ended March 31, 2021, except that Mr. Plassche filed one late Form 4 reporting the award of salary shares.

ITEM 11 EXECUTIVE COMPENSATION

Role of the Compensation Committee

The Company formed the Compensation Committee in June 2007. Since the formation of the Compensation Committee all elements of the executives' compensation are determined by the Compensation Committee, which currently is comprised of three 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. The members of the Compensation Committee are Dr. Barry Dash (Chairman of the Compensation Committee), Jeffrey Whitnell, Davis Caskey and Nasrat Hakim. The Committee operates pursuant to a charter. Under the Compensation Committee charter, the Compensation Committee has authority to retain compensation consultants, outside counsel, and other advisors that the committee deems appropriate, in its sole discretion, to assist it in discharging its duties, and to approve the terms of retention and fees to be paid to such consultants. During the fiscal year ended March 31, 2021, the Compensation Committee did not engage any advisors.

Named Executive Officers

The named executive officers for the fiscal year ended March 31, 2021 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*".

Our executive compensation program

Overview

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. Our plan to obtain and retain highly skilled employees is to provide significant incentive compensation opportunities and market competitive salaries. We strive 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 ownership serves to align the interests of our executives with those of our stockholders. As such, equity is a key component of our compensation program.

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 stock awards. 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.

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.

In the section below entitled "*Agreements with Named Executive Officers*", we describe the breakdown between compensation paid in cash and in equity for each Named Executive Officer during the fiscal year ended March 31, 2021.

Bonuses

Named Executive Officers may earn discretionary bonuses, which are awarded by the Compensation Committee in its discretion after the end of a fiscal year based on its assessment of factors including Company and individual performance. Pursuant to his employment agreement, Mr. Hakim was eligible to earn a discretionary bonus for the fiscal year ended March 31, 2021 up to 100% of his base salary ($500,000 for fiscal 2021), which he earned in full. In addition, as described in the section below entitled "Agreements with Named Executive Officers," Mr. Plassche was guaranteed a $75,000 annual bonus for the fiscal year ended March 31, 2021. Mr. Ward was awarded a $25,000 discretionary bonus for his service during fiscal 2021.

Equity

As noted above, certain components of our Named Executive Officers' fiscal year 2021 base salary and bonuses were payable in shares of Common Stock. In addition, Messrs. Ward and Plassche are each entitled to an annual grant of restricted shares of Common Stock, as described in the section entitled "*Agreements with Named Executive Officers*" below. During the fiscal year ended 2021, this amount was $25,000 worth of fully vested restricted shares for Mr. Ward and $30,000 worth of fully vested restricted shares for Mr. Plassche.

From time to time, we also grant stock options to our Named Executive Officers which generally vest over time, obtainment of a corporate goal or a combination of the two. We did not grant any stock options to our named executive officers in fiscal year 2021.

Retirement Benefits

We maintain a tax-qualified retirement plan under Section 401(k) of the Code. The plan allows employees to defer compensation on a pre-tax basis subject to certain limits; however, Elite does not provide a matching contribution to its participants.

Perquisites

Mr. Hakim receives a monthly car allowance of up to $1,500 pursuant to the terms of his employment agreement. Mr. Plassche receives a monthly car allowance of up to $500. Mr. Hakim is also entitled to a monthly housing allowance up to $5,000. 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. The Company generally covers life insurance premiums for its employee population, including its Named Executive Officers. For more information on perquisites provided to the Named Executive Officers, please see the "*All Other Compensation*" column of the Summary Compensation Table.

Agreements with Named Executive Officers

Nasrat Hakim

Pursuant to his August 2013 employment agreement, 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 performance bonus equal to up to 100% of his annual salary, payable in shares of Common Stock as well. 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 of up to $1,500 per month. The Hakim Employment Agreement contains restrictive covenants including a confidentiality provision and a one year post-termination non-solicit provision.

Mr. Hakim's employment is terminable by the Company for cause (as defined below). The Hakim Employment Agreement also may be terminated by the Company upon at least 30 days written notice due to disability (as defined below) 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 to a pro rata annual bonus through the date of termination (payable in Stock), payable in a lump sum. In addition, in the event of the termination of Mr. Hakim's employment due to his disability, he will be entitled to a lump sum payment within 60 days of the termination date equal to one year of his base salary (payable in Stock), subject to his execution of a release. 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 in a lump sum within 60 days of the termination date), and 12 months of continued health insurance continuation under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), at active employee rates, subject to his execution of a release and his continued compliance with applicable restrictive covenants.

Upon a termination of employment in connection with a Change of Control (as defined below), in addition to Basic Termination Benefits, Mr. Hakim is entitled to a pro rata annual bonus and payment in an amount equal to two year's base annual salary in effect upon the Date of Termination, less applicable deductions, and withholdings, payable in Stock in a lump sum within 60 days, and two years of health care continuation benefits. In addition, all outstanding unvested equity held by Mr. Hakim will then vest.

Under the Hakim Employment Agreement:

"Cause" means (1) Mr. Hakim's failure or refusal to perform the services required under the agreement, (2) the material breach by Mr. Hakim of any of the terms of the agreement, or (3) Mr. Hakim's conviction of a crime that results in imprisonment or involves embezzlement, dishonest or activities injurious to the Company or its reputation.

"Change of Control" means generally (1) an acquisition or merger resulting in the holders of the Company's voting stock immediately prior to the transaction holding less than fifty (50%) percent of the combined voting power after the transaction; (2) the sale of all or substantially all of the assets or capital stock of the Company; or (3) the securities of the Company representing greater than fifty (50%) percent of the combined voting power of the Company's then outstanding voting securities are acquired in a single transaction or series of related transactions.

"Disability" means that Mr. Hakim is prevented by illness, accident or other disability (mental or physical) from performing the essential functions of his position for one or more periods cumulatively totaling 3 months during any consecutive 12 month period.

Carter J. Ward

On November 12, 2009, the Company entered into an employment agreement with Mr. Carter J. Ward (the "*Ward Employment Agreement*") which superseded his prior agreement with the Company. 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. Under the Ward Employment Agreement, Mr. Ward was entitled to an initial base salary of $125,000 in accordance with the Company's payroll practices and an additional $25,000 per annum 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 $6,250 divided by the average daily closing price of the Company's Common Stock for the quarter just ended.

On April 1, 2020, Mr. Ward's compensation was adjusted to include a total compensation of $200,529, consisting of $170,529 being paid in cash in accordance with the Company's payroll practices and $30,000 being paid by the issuance of restricted shares of Common Stock.

On March 1, 2021, Mr. Ward's compensation was adjusted to include a total compensation of $208,543, consisting of $178,543 being paid in accordance with the Company's payroll practices and $30,000 being paid by the issuance of restricted shares of Common Stock.

Mr. Ward subsequently resigned as CFO of the Company, effective May 14, 2021.

Douglas Plassche

On July 20, 2013, the Company entered into an employment agreement with Mr. Douglas Plassche (the "*Plassche Employment Agreeme*nt"). 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 an initial base salary of $205,000 being paid in accordance with the Company's payroll practices and an additional $25,000 being paid by the issuance of restricted shares of Common Stock. The Common Stock component of Mr. Plassche's compensation is to be computed on an annual basis, with the number of shares issued being equal to the quotient of the annual amount due, divided by the average daily closing price of the Company's Common Stock for the calendar year just ended.

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 initially 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 vested 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.

Throughout his tenure, Mr. Plassche's compensation was increased from time to time by the Board.

On June 21, 2019, Mr. Plassche entered into a retention agreement with the Company (the "Plassche Retention Agreement"), as an in incentive for his continued employment and cooperating during a transitional period for the Company. Pursuant to the Plassche Retention Agreement, Mr. Plassche is entitled to a lump sum retention payment of $253,552 as of June 30, 2021, provided Mr. Plassche remains continuously employed by the Company through such date. In addition, Mr. Plassche was paid a one-time $30,000 relocation payment during fiscal year 2020. Under the Plassche Retention Agreement, the Company also guaranteed Mr. Plassche a salary of $253,552 and an annual bonus of $75,000 during the two year period following the agreement date.

On April 1, 2020, Mr. Plassche's compensation was adjusted to include a total base compensation package of $272,530, consisting of $247,530 being paid in accordance with the Company's payroll practices and $25,000 being paid by the issuance of restricted shares of Common Stock.

On March 1, 2021, Mr. Plassche's compensation was adjusted to include a total base compensation package of $278,606, consisting of $253,606 being paid in accordance with the Company's payroll practices and $25,000 being paid by the issuance of restricted shares of Common Stock.

Potential Payments Upon Termination or Change of Control

Messrs. Hakim and Plassche are entitled to certain benefits upon a termination event (and in the case of Mr. Hakim, in connection with a change of control), as described in the section entitled "*Agreements with Named Executive Officers*" above. 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 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 not to exceed 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.

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.

Summary Compensation Table

Name and Principal Position	Fiscal Year	Salary ($)	Bonus ($)	Stock Awards ($)	All Other Compensation ($)	Total ($)
Nasrat Hakim, President, Chief Executive Officer and Chairman of the Board of Directors						
	2021	500,000(1)	500,000(2)	—	78,000(3)	1,078,000
	2020	500,000	500,000	—	78,000	1,078,000
Carter J. Ward, Chief Financial Officer						
	2021	201,197(4)	25,000(5)	—	—	226,197
	2020	192,816	30,000	—	—	222,816
Douglas Plassche, Executive Vice President						
	2021	267,536(6)	75,000(7)	—	6,000(8)	348,536
	2020	253,552	75,000	—	36,000	364,552

(1) Represents salary earned by Mr. Hakim pursuant to the Hakim Employment Agreement for Fiscal 2021, 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 2021. A total of 7,388,707 shares of Common Stock are due and owing to Mr. Hakim in payment of salaries earned during Fiscal 2021. A total of 6,305,856 shares of Common Stock are due and owing to Mr. Hakim in payment of salaries earned during Fiscal 2020. In aggregate, a total of $2,125,000 is accrued, due and owing to Mr. Hakim for salaries earned during Fiscal 2021, Fiscal 2020, and the thirty-six months ended March 31, 2019, but not paid. This amount is to be paid via the issuance of 24,342,733 shares of Common Stock, with the date of such issuance of shares of Common Stock being undetermined.

(2) The bonus earned by Mr. Hakim for fiscal 2021.
Bonuses earned by Mr. Hakim during Fiscal 2021 were paid in accordance with the Company's payroll practices during Fiscal 2021.
Mr. Hakim was also paid $437,500 during Fiscal 2021 for bonuses earned and accrued during the twelve months ended March 31, 2018, and not paid previously. Mr. Hakim was also paid $312,500 during Fiscal 2021 for bonuses earned and accrued during the twelve months ended March 31, 2019, and not previously paid. Mr. Hakim accordingly was paid a total of $1,250,000 during Fiscal 2021, with such amount representing bonuses earned during Fiscal 2021 and the twenty-four month period ending March 31, 2019, and not previously paid.
A total of $125,000 of bonus earned by Mr. Hakim during Fiscal 2020 was paid in accordance with the Company's payroll practices. A total of $375,000 of bonus earned by Mr. Hakim during Fiscal 2020 was accrued and is owing to Mr. Hakim.
As of March 31, 2021, Mr. Hakim is owed $562,500 in bonuses earned during the twenty-four-month period ending March 31, 2020. Pursuant to the Hakim Employment Agreement, these bonuses are to be paid in accordance with the Company's payroll practices.

(3) Represents $18,000 amounts paid for auto allowance and $60,000 for housing allowances.

(4) Represents salaries earned by Mr. Ward pursuant to the Ward Employment Agreement.
Fiscal 2021 salaries consist of $171,197 being paid in accordance with the Company's payroll practices and $30,000 being accrued, due, owing and to be paid via the issuance of 443,355 shares of Common Stock.

In aggregate, salaries totaling $97,500 are accrued, due and owing to Mr. Ward for salaries earned and not paid during Fiscal 2021, Fiscal 2020 and the twenty-four month period ended March 31, 2019, with such accrued amount being paid via the issuance of 1,218,536 shares of Common Stock during May 2021.

(5) Represents the bonus earned by Mr. Ward for fiscal 2021.

(6) Represents salaries earned by Mr. Plassche pursuant to the Plassche Employment Agreement.
Fiscal 2021 salaries consist of $242,536 being paid in accordance with the Company's payroll practices and $25,000 being accrued, due, owing and to be paid via the issuance of 369,462 shares of Common Stock.

In aggregate, salaries totaling $25,000 are accrued, due and owing to Mr. Plassche for salaries earned and not paid during Fiscal 2021, with such accrued amount to be paid via the issuance of 369,462 shares of Common Stock, with the date of such issuance of shares of Common Stock being undetermined.

(7) Represents the bonus earned by Mr. Plassche for fiscal 2021 pursuant to the Plassche Employment Agreement.

(8) Represents amounts paid for auto allowances.

Outstanding Equity Awards at March 31, 2021

	Option Awards				
Name	Number of securities underlying unexercised options Exercisable (#)	Number of securities underlying unexercised options Unexercisable (#)	Equity Incentive Plan Awards: Number of securities underlying unexercised unearned options (#)	Options Exercise Price ($)	Option Expiration Date
Nasrat Hakim					
Carter Ward	150,000	-	-	0.12	6/19/2022
Douglas Plassche	3,000,000	-	-	0.07	7/23/2023

Director Compensation

The following table sets forth information concerning director compensation for the year ended March 31, 2021:

Name	Fees Earned or Paid In Cash (1) ($)	Stock Awards (1) ($)	Option Awards ($)			All Other Compensation ($)	Total ($)
Barry Dash	10,000(2)	20,000(3)	-	-	-	-	30,000
Jeffrey Whitnell	10,000(2)	20,000(3)	-	-	-	-	30,000
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. No directors held unexercised or unvested stock awards as of March 31, 2021.

(2) Amounts represent Director fees earned during the fiscal year ended March 31, 2021 which are to be paid in cash. These fees were accrued and unpaid as of March 31, 2021, with a payment date being undetermined. In aggregate, Directors fees totaling $30,000 ($10,000 for each of the Company's three non-employee Directors) is accrued, due and owing for Director fees earned during Fiscal 2021. This amount is to be paid in cash, with the date of such payment being undetermined.

(3) Director equity compensation for the fiscal year ended March 31, 2021 consists of an entitlement to 295,570 shares of Common Stock for each of Dr. Dash, Mr. Whitnell and Mr. Caskey each receiving 295,570 shares of Common Stock. Payment of this amount due via share issuance will be made at an as yet undetermined date.

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, and the remaining $10,000 being paid in cash; (iv) Directors and the Chairman do not receive any additional compensation for attendance at or chairing of any meetings.

Director Equity Compensation

As described above, members of the Board of Directors and the Chairman are paid a portion of their annual retainer fees via the issuance of restricted shares of Common Stock of the Company. 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 year ended March 31, 2021 did not receive any options or equity compensation for serving as directors other than shares of Common Stock earned in lieu of cash in relation to Director fees due.

Other

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

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

The following table sets forth certain information, as of June 7, 2021 (except as otherwise indicated), regarding beneficial ownership of our Common 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, 2021, we had 1,009,176,752 shares of Common Stock outstanding (exclusive of 0.1 million treasury shares). On any matter presented to the holders of our Common Stock for their action or consideration at any meeting of our Shareholders, each share of Common Stock entitles the holder to one vote.

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, 2021. 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	Common Stock	Percent (%) of Voting Securities Beneficially Owned
Nasrat Hakim, President, Chief Executive Officer and Chairman of the Board of Directors*	273,166,287(1)	24.4%
Barry Dash, Director*	2,228,362(2)	**%
Jeffrey Whitnell, Director*	2,179,827(3)	**%
Davis Caskey, Director*	1,042,243(4)	**%
Carter J. Ward, Former Chief Financial Officer	5,185,023(5)	**%
Douglas Plassche, Executive Vice President *	4,503,394(6)	**%
All Directors and Officers as a group	283,120,113(7)	25.3%

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

** Less than 1%

(1) Includes 169,814,882 shares of Common Stock held and 24,342,744 shares of Common Stock due and owing to Mr. Hakim as of March 31, 2021 (the latest practicable date) for compensation earned pursuant to Mr. Hakim's employment agreement with the Company and 79,008,661 shares of Common Stock issuable upon cash exercise of the Series J Warrants with an exercise price of $0.1521 per share.

(2) Includes 1,932,792 shares of Common Stock held and 295,570 shares of Common Stock due and owing to Dr. Dash as of March 31, 2021 (the latest practicable date) for Directors fees accrued as of such date.

(3) Includes 1,884,257 shares of Common Stock held and 295,570 shares of Common Stock due and owing to Mr. Whitnell as of March 31, 2021 (the latest practicable date) for Directors fees accrued as of such date.

(4) Includes 746,673 shares of Common Stock held and 295,570 shares of Common Stock due and owing to Mr. Caskey as of March 31, 2021 (the latest practicable date) Date for Directors fees accrued as of such date.

(5) Mr. Ward resigned on May 14, 2021. Address is c/o Enveric Biosciences Inc., 4851 Tamiami Trail N, Naples FL 34103.
Includes 3,771,919 shares of Common Stock held and 1,263,104 shares of Common Stock due and owing to Mr. Ward as of May 14, 2021. for salaries earned pursuant to Mr. Ward's employment agreement with the Company, with such shares being issued to Mr. Ward during May 2021, and vested options to purchase 150,000 shares of Common Stock.

(6) Includes 1,133,932 shares of Common Stock held 369,462 shares of Common Stock due and owing to Mr. Plassche as of March 31, 2021 (the latest practicable date) for salaries earned pursuant to Mr. Plassche's employment agreement with the Company, and shares of Common Stock issuable upon cash exercise of vested options to purchase 3,000,000 shares of Common Stock.

(7) Relates only to current directors and officers. Includes 175,512,536 shares of Common Stock held, 25,598,916 shares of Common Stock due and owing as of March 31, 2021 (the latest practicable date) for director's fees and salaries accrued as of such date, 3,000,000 shares of Common Stock issuable upon cash exercise of vested options and 79,008,661 shares of Common Stock issuable upon cash exercise of warrants at an exercise price of $0.1521 per share of Common Stock.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Certain Related Person Transactions

In May 2020, SunGen, under an asset purchase agreement, assigned its rights and obligations under the SunGen Agreement for Amphetamine IR and Amphetamine ER to Mikah Pharmaceuticals. The ANDAs for Amphetamine IR and Amphetamine ER are now registered under Elite's name. Mikah will now be Elite's partner with respect to Amphetamine IR and ER and will assume all the rights and obligations for these products from SunGen. Mikah Pharmaceuticals was founded in 2009 by Nasrat Hakim.

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 for the fiscal year ending March 31, 2022 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 2021	Fiscal 2020
Audit Fees	$ 120,000	$ 120,000
Audit-Related Fees	—	—
Tax Fees	8,000	8,000

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 2021.

Pre-Approval Procedures

The Audit Committee pre-approves all audit 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)	Articles of Incorporation of Elite-Nevada, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the SEC on January 9, 2012.
3.1(b)	Certificate of Designations of the Series G Convertible Preferred Stock as filed with the Secretary of State of the State of Nevada on April 18, 2013, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated April 18, 2013 and filed with the SEC on April 22, 2013.
3.1(c)	Certificate of Designation of the Series H Junior Participating Preferred Stock, incorporated by reference to Exhibit 2 (contained in Exhibit 1) to the Registration Statement on Form 8-A filed with the SEC on November 15, 2013.
3.1(d)	Certificate of Designations of the Series I Convertible Preferred Stock as filed with the Secretary of State of the State of Nevada on February 6, 2014, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K, dated February 6, 2014 and filed with the SEC on February 7, 2014.
3.1(e)	Certificate of Designations of the Series J Convertible Preferred Stock as filed with the Secretary of State of the State of Nevada on May 3, 2017, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K, dated April 28, 2017 and filed with the SEC on April 28, 2017.
3.1(f)	Certificate of Amendment to Articles of Incorporation, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K, dated June 24, 2020 and filed with the SEC on June 24, 2020.
3.2(a)	Amended and Restated By-Laws of the Company, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K dated April 23, 2020 and filed with the SEC on April 23, 2020.
4.1	Form of specimen certificate for Series G Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated April 18, 2013 and filed with the SEC on April 22, 2013.

4.2	Form of specimen certificate for Series I Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated February 6, 2014 and filed with the SEC on February 7, 2014.
4.3	Rights Agreement, dated as of November 15, 2013, between the Company and American Stock Transfer & Trust Company, LLC., incorporated by reference to Exhibit 1 to the Registration Statement on Form 8-A filed with the SEC on November 15, 2013.
4.4	Form of Series H Preferred Stock Certificate, incorporated by reference to Exhibit 1 to the Registration Statement on Form 8-A filed with the SEC on November 15, 2013.
4.5	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.

4.6	Description of Common Stock, incorporated by reference to Exhibit 4.6 to the Report 10-K filed in June 2020.
10.1	Elite Pharmaceuticals, Inc. 2014 Equity Incentive Plan, incorporated by reference to Appendix B to the Company's Definitive Proxy Statement for its Annual Meeting of Shareholders, filed with the SEC on April 3, 2014.
10.2	Form of Confidentiality Agreement (corporate), incorporated by reference to Exhibit 10.7 to the Form SB-2.
10.3	Form of Confidentiality Agreement (employee), incorporated by reference to Exhibit 10.8 to the Form SB-2.
10.4	Loan Agreement, dated as of August 15, 2005, between New Jersey Economic Development Authority ("NJEDA") and the Company, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
10.5	Series A Note in the aggregate principal amount of $3,660,000.00 payable to the order of the NJEDA, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
10.6	Series B Note in the aggregate principal amount of $495,000.00 payable to the order of the NJEDA, incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
10.7	Mortgage from the Company to the NJEDA, incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
10.8	Indenture between NJEDA and the Bank of New York as Trustee, dated as of August 15, 2005, incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
10.13	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.+
10.15	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	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.+
10.18	August 1, 2013 Mikah LLC Asset Purchase Agreement, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K/A, dated August 1, 2013 and filed with the SEC on August 30, 2018. (Confidential Treatment granted with respect to portions of the Agreement).
10.19	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.
10.20	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.
10.21	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.
10.22	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.
10.23	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.

10.24	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.+

10.25	January 28, 2015 First Amendment to the Loan Agreement between Nasrat Hakim and Elite Pharmaceuticals dated October 15, 2013, incorporated by reference to Exhibit 10.83 to the Quarterly Report on Form 10-Q for the period ended December 31, 2014 and filed with the SEC on February 17, 2015.
10.26	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.
10.28	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.
10.29	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).
10.30	Purchase Agreement between the Company and Lincoln Park Capital LLC dated July 8, 2020, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated July 9, 2020 and filed with the SEC on July 9, 2020.
10.31	Registration Rights Agreement between the Company and Lincoln Park Capital LLC dated July 8, 2020, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated July 9, 2020 and filed with the SEC on July 9, 2020.
10.33	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.
10.34	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.
10.35	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.
10.36	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.
10.37	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.
10.38	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).
10.39	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).
10.40	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).
10.41	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).
10.42	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).

10.45	License, Supply And Distribution Agreement effective March 6, 2019 by and between Elite Pharmaceuticals, Inc., and Elite Laboratories, Inc. and Lannett Company, Inc., USA, incorporated by reference to Exhibit 10.45 to the Quarterly Report on Form 10-Q, for the period ended December 31, 2019 and filed with the SEC on February 10, 2020. (Portions of this Agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)).
10.46	License, Supply and Distribution Agreement effective April 9, 2019 by and between Elite Pharmaceuticals, Inc., and Elite Laboratories, Inc. and Lannett Company, Inc., USA, incorporated by reference to Exhibit 10.49 to the Annual Report on Form 10-K for the period ended March 31, 2019 and filed with the SEC on June 21, 2019 (portions of this Agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)).
10.47	License, Supply and Distribution Agreement effective March 6, 2019 by and between Elite Pharmaceuticals, Inc., and Elite Laboratories, Inc. and Lannett Company, Inc., USA, incorporated by reference to Exhibit 10.50 to the Annual Report on Form 10-K for the period ended March 31, 2019 and filed with the SEC on June 21, 2019 (portions of this Agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)).
10.48	Development Agreement effective December 3, 2018 by and between Mikah Pharma LLC and Elite Laboratories, Inc., incorporated by reference to Exhibit 10.51 to the Annual Report on Form 10-K for the period ended March 31, 2019 and filed with the SEC on June 21, 2019 (portions of this Agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)).
10.49	Asset Purchase Agreement dated November 13, 2019 by and between the Company and Nostrum Laboratories Inc. , incorporated by reference to Exhibit 10.49 to the Quarterly Report on Form 10-Q, for the period ended December 31, 2019 and filed with the SEC on February 10, 2020.
10.50	January 2, 2020 Amendment to the Glenmark Pharmaceuticals Inc. USA License, Supply and Distribution Agreement, incorporated by reference to Exhibit 10.50 to the Quarterly Report on Form 10-Q, for the period ended December 31, 2019 and filed with the SEC on February 10, 2020. (Portions of this Agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)).

10.51	Asset Purchase Agreement executed January 16, 2020 by and between the Company and Nostrum Laboratories Inc., incorporated by reference to Exhibit 10.49 to the Quarterly Report on Form 10-Q, for the period ended December 31, 2019 and filed with the SEC on February 10, 2020.
10.52	Employment Agreement with Douglas Plassche *+
10.53	June 21, 2019 Retention Agreement with Douglas Plassche.*+
10.54	July 29, 2019 Amendment To The License, Supply And Distribution Agreement Between Elite Pharmaceuticals, Inc./Elite Laboratories, Inc. And Lannett Company, Inc. (Portions of this Agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)).*
21	Subsidiaries of the Company, incorporated by reference to Exhibit 21 to the Annual Report on Form 10-K, for the period ended March 31, 2019 and filed with the SEC on June 21, 2019.

23.1	Consent of Buchbinder Tunick & Company LLP, Independent Registered Public Accounting Firm*
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a) and Rule 15d-14(a)*
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a) and Rule 15d-14(a)*
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy 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
104	Cover Page Interactive Data File

* Filed herewith.

** Furnished herewith.

\+ Indicates management contract or compensatory plan or arrangement.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ELITE PHARMACEUTICALS, INC.

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

Dated: June 14, 2021

By: /s/ Marc Bregman
Marc Bregman
Chief Financial Officer

Dated: June 14, 2021

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

Signature	Title	Date
/s/ Nasrat Hakim	Chief Executive Officer, President and Chairman of the Board of Directors (Principal Executive Officer)	June 14, 2021
/s/ Marc Bregman	Chief Financial Officer, Treasurer, Secretary (Principal Financial Officer and Principal Accounting Officer)	June 14, 2021
/s/ Barry Dash	Director	June 14, 2021
/s/ Jeffrey Whitnell	Director	June 14, 2021
/s/ Davis Caskey	Director	June 14, 2021

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEARS ENDED MARCH 31, 2021 AND 2020

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders 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, 2021 and 2020, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the two-year period ended March 31, 2021, 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, 2021 and 2020 and the results of its operations and its cash flows for each of the years in the two-year period ended March 31, 2021 in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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 consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which they relate.

Indefinite-Lived Intangible Assets Impairment Assessments of ANDAs and Patents — Refer to Notes 1, 4 and 15 to the financial statements

Critical Audit Matter Description

As of March 31, 2021, the Company has capitalized costs of $6,168,351 for ANDAs and $465,684 for patents. The Company evaluates its intangible assets for impairment annually during the fourth quarter in accordance with ASC Topic 350, Intangibles Goodwill and Other, and between annual evaluations if events occur or circumstances change that would more likely than not reduce the fair value of the assets carrying amount.

Management evaluates qualitative factors to determine whether it is more likely than not that the fair value of the intangible assets is less than its carrying amount. The qualitative factors management considers include, but are not limited to, the current project status, expected future cash flows, decline in the Company's stock price, legal and regulatory factors and industry and market considerations.

We identified the impairment evaluation of the intangibles as a critical audit matter because of the significant judgements made by management to estimate the fair value of the intangible assets.

Our audit procedures related to impairment of indefinite lived intangible assets included review of management's analysis and testing the significant assumptions used by management.

/s/ Buchbinder Tunick & Company LLP

Buchbinder Tunick & Company LLP

We have served as the Company's auditor since 2010.

Little Falls, New Jersey 07424

June 14, 2021,

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

	March 31, 2021	March 31, 2020
ASSETS		
Current assets:		
Cash	$ 3,192,768	$ 1,131,728
Accounts receivable, net of allowance for doubtful accounts of $-0-, respectively	3,496,376	4,106,846
Inventory	5,012,902	4,142,472
Prepaid expenses and other current assets	492,621	870,233
Total current assets	12,194,667	10,251,279
Property and equipment, net of accumulated depreciation of $12,153,626 and $10,957,334, respectively	6,649,365	7,227,648
Intangible assets, net of accumulated amortization of $-0-, respectively	6,634,035	6,634,035
Operating lease - right-of-use asset	214,674	363,282
Other assets:		
Restricted cash - debt service for NJEDA bonds	405,013	404,802
Security deposits	91,738	75,534
Total other assets	496,751	480,336
Total assets	**$ 26,189,492**	**$ 24,956,580**
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 929,690	$ 1,577,860
Accrued expenses	4,270,600	4,821,132
Deferred revenue, current portion	13,333	180,000
Bonds payable, current portion, net of bond issuance costs	95,822	90,822
Loans payable, current portion	314,996	561,550
Lease obligation - operating lease, current portion	188,090	208,184
Senior secured promissory note - related party, current portion	—	1,200,000
Total current liabilities	5,812,531	8,639,548
Long-term liabilities:		
Deferred revenue, net of current portion	45,558	58,891
Bonds payable, net of current portion and bond issuance costs	1,240,668	1,336,489
Loans payable, net of current portion	500,066	463,902
Lease obligation - operating lease, net of current portion	38,866	167,109
Derivative financial instruments - warrants	2,362,246	3,599,378
Other long-term liabilities	37,628	35,442
Total long-term liabilities	4,225,032	5,661,211
Total liabilities	**10,037,563**	**14,300,759**

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

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

	March 31, 2021	March 31, 2020
Shareholders' equity:		
Series J convertible preferred stock; par value of $0.01; 50 shares authorized; 0 issued and outstanding as of March 31, 2021 and 24.0344 issued and outstanding as of March 31, 2020	—	13,903,960
Common Stock; par value $0.001; 1,445,000,000 shares authorized; 1,009,276,752 shares issued and 1,009,176,752 shares outstanding as of March 31, 2021; 840,504,367 shares issued and 840,404,367 shares outstanding as of March 31, 2020	1,009,279	840,507
Additional paid-in capital	164,407,480	150,264,605
Treasury stock; 100,000 shares as of March 31, 2021 and March 31, 2020; at cost	(306,841)	(306,841)
Accumulated deficit	(148,957,989)	(154,046,410)
Total shareholders' equity	**16,151,929**	**10,655,821**
Total liabilities and shareholders' equity	**$ 26,189,492**	**$ 24,956,580**

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

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

	For the Years Ended March 31,	
	2021	2020
Revenue:		
Manufacturing fees	$ 20,997,310	$ 14,526,048
Licensing fees	4,383,439	3,468,591
Total revenue	25,380,749	17,994,639
Cost of manufacturing	13,513,611	10,015,855
Gross profit	11,867,138	7,978,784
Operating expenses:		
Research and development	5,112,542	5,532,462
General and administrative	3,323,045	3,349,837
Non-cash compensation through issuance of stock options	13,181	62,098
Depreciation and amortization	1,313,847	1,319,795
Total operating expenses	9,762,615	10,264,192
Income (loss) from operations	2,104,523	(2,285,408)
Other income (expense):		
Change in fair value of derivative instruments	1,237,132	(1,111,548)
Interest expense and amortization of debt issuance costs	(259,598)	(355,874)
Gain on sale of fixed assets	48,463	—
Gain on transfer/discontinuance of intangible assets	—	1,502,500
Interest income	514	11,979
PPP loan forgiveness	1,013,480	—
Other income, net	2,039,991	47,057
Income (loss) from operations before income taxes	4,144,514	(2,238,351)
Income tax benefit (expense)	943,907	(2,000)
Net income (loss) attributable to common shareholders	$ 5,088,421	$ (2,240,351)
Basic net income (loss) per share attributable to common shareholders	$ 0.01	$ (0.00)
Diluted net income (loss) per share attributable to common shareholders	$ 0.01	$ (0.00)
Basic weighted average Common Stock outstanding	942,997,875	832,326,965
Diluted weighted average Common Stock outstanding	942,997,875	993,260,953

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

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

	Series J Preferred Stock		Common Stock		Additional Paid-In	Treasury Stock		Accumulated	Total Shareholders' Equity
	Shares	Amount	Shares	Amount	Capital	Shares	Amount	Deficit	(Deficit)
Balance as of March 31, 2019	—	$ —	824,946,559	$ 824,949	$ 148,780,087	100,000	$ (306,841)	$ (151,806,059)	$ (2,507,864)
Net loss	—	—	—	—	—	—	—	(2,240,351)	(2,240,351)
Common Stock sold pursuant to the Lincoln Park purchase agreement	—	—	15,358,627	15,359	1,422,620	—	—	—	1,437,979
Common Stock issued as additional commitment shares pursuant to the LPC purchase agreement	—	—	199,181	199	20,111	—	—	—	20,310
Costs associated with raising capital	—	—	—	—	(20,311)	—	—	—	(20,311)
Non-cash compensation through the issuance of employee stock options	—	—	—	—	62,098	—	—	—	62,098
Reclassification of mezzanine equity to permanent equity	24	13,903,960	—	—	—	—	—	—	13,903,960
Balance at March 31, 2020	24	$ 13,903,960	840,504,367	$ 840,507	$ 150,264,605	100,000	$ (306,841)	$ (154,046,410)	$ 10,655,821
Net income	—	—	—	—	—	—	—	5,088,421	5,088,421
Conversion of Preferred Stock to Common Stock	(24)	(13,903,960)	158,017,321	158,017	13,745,943	—	—	—	—
Initial commitment shares issued pursuant to the 2020 Lincoln Park purchase agreement	—	—	5,975,857	5,976	463,129	—	—	—	469,105
Common Stock sold pursuant to the Lincoln Park purchase agreement	—	—	640,543	641	41,582	—	—	—	42,223
Common Stock issued as additional commitment shares pursuant to the LPC purchase agreement	—	—	10,094	10	722	—	—	—	732
Costs associated with raising capital	—	—	—	—	(469,837)	—	—	—	(469,837)
Non-cash compensation through the issuance of employee stock options	—	—	—	—	13,181	—	—	—	13,181
Shares issued in payment of Director fees	—	—	1,550,343	1,551	133,449	—	—	—	135,000
Shares issued in payment of salaries	—	—	646,336	645	55,605	—	—	—	56,250
Shares issued in payment of consulting fees	—	—	1,931,891	1,932	159,101	—	—	—	161,033
Balance at March 31, 2021	—	$ —	1,009,276,752	$ 1,009,279	$ 164,407,480	100,000	$ (306,841)	$ (148,957,989)	$ 16,151,929

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(AUDITED)

	For the Years Ended March 31,	
	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$ 5,088,421	$ (2,240,351)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	1,313,847	1,319,795

Amortization of operating leases - right-of-use assets	210,744	190,806
Gain on the disposal of property and equipment	(48,463)	—
Change in fair value of derivative financial instruments - warrants	(1,237,132)	1,111,548
PPP loan forgiveness	(1,013,480)	—
Non-cash compensation accrued	922,443	966,655
Non-cash compensation from issuances of options	13,181	62,098
Non-cash rent expense and lease accretion	2,186	2,081
Change in operating assets and liabilities:		
Accounts receivable	610,470	(2,785,041)
Inventory	(870,430)	373,251
Prepaid expenses and other current assets	361,408	216,091
Accounts payable, accrued expenses and other current liabilities	(1,768,862)	344,395
Deferred revenue and customer deposits	(180,000)	(1,163,332)
Lease obligations - operating leases	(210,472)	(191,817)
Net cash provided by (used in) operating activities	3,193,861	(1,793,821)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(329,981)	(34,953)
Proceeds from disposal of property and equipment	67,200	—
Net cash used in investing activities	(262,781)	(34,953)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of Common Stock	42,223	1,437,978
Proceeds from PPP loan	1,013,480	—
Payment of related party note payable	(1,200,000)	—
Payment of bond principal	(105,000)	(95,000)
Other loan payments	(620,532)	(653,442)
Net cash (used in) provided by financing activities	(869,829)	689,536
Net change in cash and restricted cash	2,061,251	(1,139,238)
Cash and restricted cash, beginning of year	1,536,530	2,675,768
Cash and restricted cash, end of year	$ 3,597,781	$ 1,536,530
Supplemental disclosure of cash and non-cash transactions:		
Cash paid for interest	$ 176,179	$ 240,785
Financing of equipment purchases and insurance renewal	$ 410,141	$ 54,462
Stock issued in payment of Directors fees, salaries and consulting expenses	$ 352,283	$ —
Commitment shares issued to Lincoln Park Capital	$ 722	$ 20,311
Conversion of preferred stock to Common Stock	$ 13,903,960	$ —
Supplemental non-cash amounts of lease liabilities arising from obtaining right of use assets	$ —	$ 554,088

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") was incorporated on August 23, 1990 under the laws of the State of Delaware. On January 5, 2012, Elite Pharmaceuticals was reincorporated under the laws of the State of Nevada. Elite Labs engages primarily in researching, developing, licensing and 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 allergy, bariatric, attention deficit and infection. Research and development activities are performed 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 ("GAAP"). The audited consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Elite Laboratories, Inc. All significant intercompany accounts and transactions have been eliminated in consolidation. The audited consolidated financial statements reflect all adjustments, consisting of normal recurring items, which are, in the opinion of management, necessary for a fair presentation of such statements.

Segment Information

Financial Accounting Standards Board ("FASB") Accounting Standards Codification 280 ("ASC 280"), *Segment Reporting*, establishes standards for reporting information about operating segments. Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance.

The Company's chief operating decision maker is the Chief Executive Officer, who reviews the financial performance and the results of operations of the segments prepared in accordance with GAAP when making decisions about allocating resources and assessing performance of the Company.

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

There are currently no intersegment revenues. Asset information by operating segment is not presented below since the chief operating decision maker does not review this information by segment. The reporting segments follow the same accounting policies used in the preparation of the Company's audited consolidated financial statements. Please see Note 15 for further details.

Revenue Recognition

The Company generates revenue primarily from manufacturing and licensing fees. Manufacturing fees include the development of pain management products, manufacturing of a line of generic pharmaceutical products with approved ANDA, through the manufacture of formulations and the development of new products. Licensing fees include the commercialization of products either by license and the collection of royalties, or the expansion of licensing agreements with other pharmaceutical companies, including co-development projects, joint ventures and other collaborations.

Under ASC 606, *Revenue from Contacts with Customers* ("ASC 606"), the Company recognizes revenue when the customer obtains control of promised goods or services, in an amount that reflects the consideration which is expected to be received in exchange for those goods or services. The Company 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. The Company also develops and markets (either on its own or by license to other companies) generic and proprietary controlled-release 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. 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 recognize revenue from the milestone when 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 ASC 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 March 31, 2021.

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

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. The 2015 Epic License Agreement expired on June 4, 2020 without renewal.

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. On April 3, 2020, Elite and SunGen mutually agreed to discontinue any further joint product development activities.

Disaggregation of revenue

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

	For the Years Ended March 31,	
	2021	2020
NDA:		
Licensing fees	$ 166,167	$ 1,000,000
Total NDA revenue	166,167	1,000,000
ANDA:		
Manufacturing fees	$ 20,997,310	$ 14,526,048
Licensing fees	4,217,272	2,468,591
Total ANDA revenue	25,214,582	16,994,639
Total revenue	$ 25,380,749	$ 17,994,639

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, 2021 and March 31, 2020, the Company had restricted cash of $405,013 and $404,802, respectively, related to debt service reserve in regard to the New Jersey Economic Development Authority ("NJEDA") bonds (see Note 5).

Accounts Receivable

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

Inventory

Inventory is recorded at the lower of cost or market on 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, 2021, the Company did not identify any indicators of impairment.

Please also see Note 4 for further details on intangible assets.

Research and Development

Research and development expenditures are charged to expense as incurred.

Contingencies

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

Income Taxes

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

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

The Company operates in multiple tax jurisdictions within the United States of America. The Company remains subject to examination in all tax jurisdiction until the applicable statutes of limitation expire. As of March 31, 2021, a summary of the tax years that remain subject to examination in our major tax jurisdictions are: United States – Federal, 2016 and forward, and State, 2012 and forward. The Company did not record unrecognized tax positions for the years ended March 31, 2021 and 2020.

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 is assessed with determinations made regarding the proper classification in the Company's financial statements.

Stock-Based Compensation

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

In accordance with the Company's Director compensation policy and certain employment contracts, director's fees and a portion of employee's salaries are to be paid via the issuance of shares of the Company's Common Stock ("Common Stock"), in lieu of cash, with the valuation of such shares being calculated on a quarterly basis and equal to the simple average closing price of the Company's Common Stock for each trading day of the quarter just ended.

Earnings (Loss) Per Share Attributable 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. The computation of diluted net income (loss) per share does not include the conversion of securities that would have an antidilutive effect.

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

	For the Years Ended March 31,	
	2021	**2020**
Numerator		
Net income (loss) - basic	$ 5,088,421	$ (2,240,351)
Effect of dilutive instrument on net income	—	1,111,548
Net income (loss) - diluted	$ 5,088,421	$ (1,128,803)
Denominator		
Weighted average shares of Common Stock outstanding - basic	942,997,875	832,326,965
Dilutive effect of stock options and convertible securities	—	160,933,988
Weighted average shares of Common Stock outstanding - diluted	942,997,875	993,260,953
Net income (loss) per share		
Basic	$ 0.01	$ (0.00)
Diluted	$ 0.01	$ (0.00)

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Fair Value of Financial Instruments

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

ASC 820 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. ASC 820 establishes a fair value hierarchy that distinguishes between (1) market participant assumptions developed based on market data obtained from independent sources (observable inputs) and (2) an entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances (unobservable inputs).

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

- Level 1 – Unadjusted quoted prices in active markets for identical assets or liabilities that are accessible at the measurement date.
- Level 2 – Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs include quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar assets or liabilities in markets that are not active; inputs other than quoted prices that are observable for the asset or liability; and inputs that are derived principally from or corroborated by observable market data by correlation or other means.
- Level 3 – Inputs that are unobservable for the asset or liability.

Measured on a Recurring Basis

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

	Amount at Fair Value	Fair Value Measurement Using		
		Level 1	Level 2	Level 3
March 31, 2021				
Liabilities				
Derivative financial instruments - warrants	$ 2,362,246	$ —	$ —	$ 2,362,246
March 31, 2020				
Liabilities				
Derivative financial instruments - warrants	$ 3,599,378	$ —	$ —	$ 3,599,378

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

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Treasury Stock

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

Recently Adopted Accounting Standards

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 adopted the guidance as of April 1, 2020. The Company is not materially impacted by the implementation of this pronouncement.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808)*, Clarifying the Interaction between Topic 808 and Topic 606. The ASU clarifies when transactions between collaborative participants are in the scope of ASC 606. The ASU also provides some guidance on presentation of transactions not in the scope of ASC 606. ASU 2018-18 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2019. Early adoption is permitted for fiscal years, and interim periods within those years. The Company adopted the guidance as of April 1, 2020. The Company is not materially impacted by the implementation of this pronouncement.

In March 2020, the FASB issued ASU 2020-03, *Codification Improvements to Financial Instruments*. The ASU clarifies disclosure guidance for fair value options, adds clarifications to the subsequent measurement of fair value, clarifies disclosure for depository and lending institutions, clarifies the line-of-credit or revolving-debt arrangements guidance, and the interaction of Financial Instruments - Credit Losses (Topic 326) with Leases (Topic 842) and Transfers and Servicing-Sales of Financial Assets (Subtopic 860-20). In accordance with ASU 2020-03, the Company adopted the guidance as of April 1, 2020. The Company is not materially impacted by the implementation of this pronouncement.

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. This update requires immediate recognition of management's estimates of current expected credit losses ("CECL"). Under the prior model, losses were recognized only as they were incurred. The new model is applicable to all financial instruments that are not accounted for at fair value through net income. The standard is effective for fiscal years beginning after December 15, 2022 for public entities qualifying as smaller reporting companies. Early adoption is permitted. The Company is currently assessing the impact of this update on the consolidated financial statements and does not expect a material impact on the consolidated financial statements.

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

NOTE 2. INVENTORY

Inventory consisted of the following:

	March 31, 2021	March 31, 2020
Finished goods	$ 274,603	$ 138,981
Work-in-progress	781,350	677,824
Raw materials	3,956,949	3,325,667
	$ 5,012,902	$ 4,142,472

NOTE 3. PROPERTY AND EQUIPMENT, NET

Property and equipment consisted of the following:

	March 31, 2021	March 31, 2020
Land, building and improvements	$ 5,456,523	$ 5,260,524
Laboratory, manufacturing, warehouse and transportation equipment	12,580,457	12,167,754
Office equipment and software	373,601	373,601
Furniture and fixtures	392,410	383,103
	18,802,991	18,184,982
Less: Accumulated depreciation	(12,153,626)	(10,957,334)
	$ 6,649,365	$ 7,227,648

Depreciation expense was $1,299,668 and $1,305,616 for the years ended March 31, 2021 and 2020, respectively.

NOTE 4. INTANGIBLE ASSETS

The following table summarizes the Company's intangible assets:

	March 31, 2021					
	Estimated Useful Life	Gross Carrying Amount	Additions	Reductions	Accumulated Amortization	Net Book Value
Patent application costs	*	$ 465,684	$ —	$ —	$ —	$ 465,684
ANDA acquisition costs	Indefinite	6,168,351	—	—	—	6,168,351
		$ 6,634,035	$ —	$ —	$ —	$ 6,634,035

	March 31, 2020					
	Estimated Useful Life	Gross Carrying Amount	Additions	Reductions	Accumulated Amortization	Net Book Value
Patent application costs	*	$ 465,684	$ —	$ —	$ —	$ 465,684
ANDA acquisition costs	Indefinite	6,168,351	—	—	—	6,168,351
		$ 6,634,035	$ —	$ —	$ —	$ 6,634,035

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

NOTE 5. NJEDA BONDS

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

In relation to the Series A Notes, the Company is required to maintain a debt service reserve. The debt service reserve is classified as restricted cash on the accompanying 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, 2021	March 31, 2020
Gross bonds payable		
NJEDA Bonds - Series A Notes	$ 1,470,000	$ 1,575,000
Less: Current portion of bonds payable (prior to deduction of bond offering costs)	(110,000)	(105,000)
Long-term portion of bonds payable (prior to deduction of bond offering costs)	$ 1,360,000	$ 1,470,000
Bond offering costs	$ 354,454	$ 354,454
Less: Accumulated amortization	(220,944)	(206,765)
Bond offering costs, net	$ 133,510	$ 147,689
Current portion of bonds payable - net of bond offering costs		
Current portions of bonds payable	$ 110,000	$ 105,000
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	$ 95,822	$ 90,822
Long term portion of bonds payable - net of bond offering costs		
Long term portion of bonds payable	1,360,000	$ 1,470,000
Less: Bond offering costs to be amortized subsequent to the next 12 months	(119,332)	(133,511)
Long term portion of bonds payable, net of bond offering costs	$ 1,240,668	$ 1,336,489

Amortization expense was $14,179 and $14,174 for the year ended March 31, 2021 and 2020, respectively. As of March 31, 2021 and 2020, interest payable was $7,963 and $8,531, respectively.

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

Years ending March 31,	Amount
2022	110,000
2023	115,000
2024	125,000
2025	130,000
Thereafter	990,000
	$ 1,470,000

NOTE 6. LOANS PAYABLE

Loans payable consisted of the following:

	March 31, 2021	March 31, 2020
Equipment and insurance financing loans payable, between 3.5% and 12.73% interest and maturing between January 2021 and October 2026	$ 815,062	$ 1,025,452
Less: Current portion of loans payable	(314,996)	(561,550)
Long-term portion of loans payable	$ 500,066	$ 463,902

The interest expense associated with the loans payable was $77,218 and $79,870 for the years ended March 31, 2021 and 2020, respectively.

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

Years ending March 31,	Amount
2022	$ 314,996
2023	245,405
2024	129,275
2025	96,117
Thereafter	29,269
	$ 815,062

2020 Paycheck Protection Program Term Note

In April 2020, the Company entered into a Paycheck Protection Program Term Note (the "PPP Note") with TD Bank, NA in the amount of $1,013,480. The PPP Note was issued to the Company pursuant to the Coronavirus, Aid, Relief, and Economic Security Act's (the "CARES Act") (P.L. 116-136) Paycheck Protection Program (the "Program"). Under the Program, all or a portion of the PPP Note may be forgiven in accordance with the Program requirements.

On January 12, 2021, the Company received notification that the United States Small Business Administration ("SBA"), had approved, in full, the Company's application for forgiveness of amounts received pursuant to the CARES Act and the Program.

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

For consideration of the assets acquired on May 15, 2017, the Company issued a Secured Promissory Note (the "Mikah Note") to Mikah Pharma, LLC ("Mikah") for the principal sum of $1,200,000. Mikah was founded in 2009 by Nasrat Hakim ("Hakim"), a related party and, the Company's President, Chief Executive Officer and Chairman of the Board. The Mikah Note matured on December 31, 2020 and was retired at par in March 2021. The principal amount of $1,200,000 was repaid by the Company at maturity.

Interest expense associated with the Note was $90,000 and $120,000 for the years ended March 31, 2021 and 2020, respectively. A total of $435,000 in accrued interest expense, representing interest expense accrued during the life of the Mikah Note was due and owing as of the maturity date of the Note. Of the $435,000 accrued interest due at maturity, $238,451 of accrued interest was satisfied by offset against amounts due from Mikah pursuant to the development agreement between the Company and Mikah, dated December 3, 2018 (see Note 16). The balance of $196,549 of accrued interest expense owing in relation to the Mikah Note is recorded as a non-interest bearing, general liability of the Company.

NOTE 8. DEFERRED REVENUE

Deferred revenues in the aggregate amount of $58,891 as of March 31, 2021, were comprised of a current component of $13,333 and a long-term component of $45,558. Deferred revenues in the aggregate amount of $238,891 as of March 31, 2020, were comprised of a current component of $180,000 and a long-term component of $58,891. These line items represent the unamortized amounts of a $200,000 advance payment received for a TAGI Pharma ("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 sheet date and the long-term component is equal to the amount of revenue to be earned thereafter.

NOTE 9. COMMITMENTS AND CONTINGENCIES

Occasionally, the Company may be involved in claims and legal proceedings arising from the ordinary course of its business. The Company records a provision for a liability when it believes that is both probable that a liability has been incurred, and the amount can be reasonably estimated. If these estimates and assumptions change or prove to be incorrect, it could have a material impact on the Company's 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

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

The 135 Ludlow Ave. modified lease 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.

The Company plans to exercise the second option pursuant to the 135 Ludlow Ave. Modified Lease in June 2021. This option includes a term that begins on January 1, 2022 and expires on December 31, 2026. Minimum lease payments required during the five year term of this option total $1,212,480.

In October 2020, the Company entered into an operating lease for office space in Pompano Beach, Florida (the "Pompano Office Lease"). The Pompano Office Lease is for approximately 1,275 square feet of office space, with Elite taking occupancy on November 1, 2020. The Pompano Office includes a 3 month abatement from November 2020 through February 2021 and has a term of three years, ending on October 31, 2023.

The Company assesses whether an arrangement is a lease or contains a lease at inception. For arrangements considered leases or that contain a lease that is accounted for separately, the Company determines the classification and initial measurement of the right-of-use asset and lease liability at the lease commencement date, which is the date that the underlying asset becomes available for use. The Company has elected to account for non-lease components associated with its leases and lease components as a single lease component.

The Company recognizes a right-of-use asset, which represents the Company's right to use the underlying asset for the lease term, and a lease liability, which represents the present value of the Company's obligation to make payments arising over the lease term. The present value of the lease payments is calculated using either the implicit interest rate in the lease or an incremental borrowing rate.

Lease assets and liabilities are classified as follows on the consolidated balance sheet:

Lease	Classification	As of March 31, 2021

Assets		
Operating	Operating lease – right-of-use asset	$ 214,674
Total leased assets		$ 214,674
Liabilities		
Current		
Operating	Lease obligation – operating lease	$ 188,090
Long-term		
Operating	Lease obligation – operating lease, net of current portion	38,866
Total lease liabilities		$ 226,956

Rent expense is recorded on the straight-line basis. Rent expense under the 135 Ludlow Ave. Modified lease for the years ended March 31, 2021 and 2020, is $219,638 and $220,650, respectively. Rent expense under the Pompano Office Lease for the years ended March 31, 2021 and 2020, is $9,544 and $0, respectively. Rent expense is recorded in general and administrative expense in the audited consolidated statements of operations.

The table below show the future minimum rental payments, exclusive of taxes, insurance and other costs, in aggregate, under the 135 Ludlow Ave. modified lease and the Pompano Office Lease:

Years ending March 31,	**Amount**
2022	$ 195,331
2023	25,638
2024	15,214
2025	---
2026	---
Subsequent to March 31, 2026	---
Total future minimum lease payments	236,183
Less: interest	(9,227)
Present value of lease payments	$ 226,956

The weighted-average remaining lease term and the weighted-average discount rate of our lease was as follows:

Lease Term and Discount Rate	**March 31, 2021**
Remaining lease term (years)	
Operating leases	2.6
Discount rate	
Operating leases	6%

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, 2021, and March 31, 2020, the Company had a liability of $37,628 and $35,442, respectively, recorded as a component of other long-term liabilities.

NOTE 10. 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, zero shares are outstanding, with a stated value of $1,000,000 per share and a par value of $0.01 as of March 31, 2021.

On April 27, 2017, a total of 24.0344 shares of Series J Preferred were issued pursuant to an exchange agreement (the "Exchange Agreement") with Nasrat Hakim ("Mr. Hakim"), a related party and the Company's President, Chief Executive Officer and Chairman of the Board of Directors. The Exchange Agreement provided for Hakim to exchange 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, 2021 (See Note 11).

An amendment to the Company's Articles of Incorporation to increase the number of shares of Common Stock the Company is authorized to issue from 995,000,000 shares to 1,445,000,000 shares was approved at the Company's Annual Meeting of Shareholders held on December 4, 2019. Prior to the approval of the increase in the number of authorized shares, there were insufficient authorized shares if the Series J Preferred Stock were converted. As a result, the shares were classified in mezzanine equity. After the approval of the increase in the number of authorized shares, there are now sufficient authorized shares in the event of a full conversion of Series J Preferred Stock. With the approval of the increase in the number of authorized shares, there is no longer the presumption that a cash settlement will be required. Therefore, the Series J Preferred was reclassified from mezzanine equity to permanent equity at its carrying amount of $13,903,960 on the consolidated balance sheet as of March 31, 2020.

On June 23, 2020, the Company held a Special Meeting of Shareholders, with such including a proposal for shareholders to again vote on the above referenced amendment to the Company's Articles of Incorporation. This proposal was also passed by shareholder vote.

On August 24, 2020, Hakim converted the 24.0344 shares of Series J Preferred into 158,017,321 shares of Common Stock at a conversion price of $0.1521 per share.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY
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NOTE 11. DERIVATIVE FINANCIAL INSTRUMENTS – WARRANTS

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

The Company issued warrants, with a term of ten years, to affiliates in connection with an exchange agreement dated April 28, 2017, as further described in this note below.

A summary of warrant activity is as follows:

	March 31, 2021		March 31, 2020	
	Warrant Shares	Weighted Average Exercise Price	Warrant Shares	Weighted Average Exercise Price
Balance at beginning of period	79,008,661	$ 0.1521	79,008,661	$ 0.1521
Warrants granted pursuant to the issuance of Series J convertible preferred shares	—		—	$ —
Warrants exercised, forfeited and/or expired, net	—		—	$ —
Balance at end of period	79,008,661	$ 0.1521	79,008,661	$ 0.1521

On April 28, 2017, the Company entered into an Exchange Agreement with Mr. Hakim, the Chairman of the Board, President, and Chief Executive Officer of the Company, pursuant to which the Company issued to Hakim 24.0344 shares of its 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 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, other than shares issued pursuant to the 2020LPC Purchase Agreement (as defined below), 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 fair value of the Series J Warrants was calculated using a Black-Scholes model. The following assumptions were used in the Black-Scholes model to calculate the fair value of the Series J Warrants:

	March 31, 2021	March 31, 2020
Fair value of the Company's Common Stock	$ 0.0610	$ 0.0720
Volatility	75.18%	83.81%
Initial exercise price	$ 0.1521	$ 0.1521
Warrant term (in years)	6.1	7.1
Risk free rate	1.40%	0.55%

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY
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The changes in warrants (Level 3 financial instruments) measured at fair value on a recurring basis for the years ended March 31, 2021 were as follows:

Balance at March 31, 2019	$ 2,487,830
Change in fair value of derivative financial instruments - warrants	1,111,548
Balance at March 31, 2020	3,599,378
Change in fair value of derivative financial instruments - warrants	(1,237,132)
Balance at March 31, 2021	$ 2,362,246

NOTE 12. SHAREHOLDERS' EQUITY

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 had the right to sell to and Lincoln Park was 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 that commenced on June 5, 2017. The 2017 LPC Purchase Agreement expired on July 1, 2020.

During the year ended March 31, 2021, there were no shares sold to Lincoln Park pursuant to the 2017 LPC Purchase Agreement. In addition, there were no shares issued to Lincoln Park as additional commitment shares, pursuant to the 2017 LPC Purchase Agreement. During the year ended March 31, 2020, a total of 15,358,627 shares were sold to Lincoln Park pursuant to the 2017 LPC Purchase Agreement for net proceeds totaling $15,359. In addition, 199,181 shares were issued to Lincoln Park as additional commitment shares, pursuant to the 2017 LPC Purchase Agreement.

Lincoln Park Capital Transaction - July 8, 2020 Purchase Agreement

On July 8, 2020, Elite Pharmaceuticals, Inc., a Nevada corporation (the "Company"), entered into a purchase agreement (the "Purchase Agreement"), and a registration rights agreement (the "Registration Rights Agreement"), with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which Lincoln Park has committed to purchase up to $25.0 million of the Company's common stock, $0.001 par value per share (the "Common Stock"), from time to time over the term of the Purchase Agreement, at the Company's direction.

During the year ended March 31, 2021 the Company issued an aggregate of 5,975,857 shares of Common Stock in the amount of $469,105 to Lincoln Park as initial commitment shares. The Company sold 640,543 shares of its Common Stock pursuant to the 2020 LPC Purchase Agreement during the year ended March 31, 2021 for net proceeds totaling $42,223. In addition, 10,094 shares were issued to Lincoln Park as additional commitment shares, pursuant to the 2020 LPC Agreement.

Summary of Common Stock Activity

During the years ended March 31, 2021 and 2020, the Company issued 168,772,385 and 15,557,808 shares of Common Stock, respectively, with such issuances of Common Stock being summarized as follows:

	March 31,	
	2021	**2020**
Common Stock issued as of March 31, 2021 and 2020, respectively	840,504,367	824,946,559
Common stock converted from Preferred Stock	158,017,321	—
Common Stock sold pursuant to the Lincoln Park Capital Purchase Agreements, with net proceeds of such shares totaling $42,223 and $1,437,978 for the years ended March 31, 2021 and 2020, respectively.	640,543	15,358,627
Common Stock issued as initial and additional commitment shares pursuant to the Lincoln Park Capital Purchase Agreements	5,985,951	199,181
Common Stock issued in payment of Directors fees, salaries and consulting fees	4,128,570	—
Common Stock issued during the fiscal year	168,772,385	15,557,808
Common Stock issued as of March 31, 2021 and 2020, respectively	1,009,276,752	840,504,367

NOTE 13. STOCK-BASED COMPENSATION

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

Stock-based Director Compensation

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

During the year ended March 31, 2021, the Company issued 1,550,343 shares of Common Stock to its Directors in payment of director's fees totaling an aggregate of $135,000 and with such aggregate director's fees being earned and accrued over the twenty-seven month period beginning on January 1, 2018 and ending on March 31, 2020. In addition, the Company made cash payments totaling an aggregate of $67,500 in payment of director's fees earned over the same twenty-seven month period.

During the year ended March 31, 2021, the Company accrued director's fees totaling $60,000, which will be paid via cash payments totaling $30,000 and the issuance of 886,710 shares of Common Stock.

As of March 31, 2021, the Company owed its Directors a total of $30,000 in cash payments and 886,710 shares of Common Stock in payment of director fees totaling $60,000 due and owing. The Company anticipates that these shares of Common Stock will be issued prior to the end of the subsequent fiscal year.

Stock-based Employee/Consultant Compensation

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

During the year ended March 31, 2021, the Company issued 646,336 shares of Common Stock in payment of salaries totaling $56,250 pursuant to the employment contract of the Company's Executive Vice President of Operations and with such salaries being earned and accrued over the thirty-month period beginning on January 1, 2018 and ending on June 30, 2020.

During the year ended March 31, 2021, the Company accrued salaries totaling $748,750 owed to the Company's President and Chief Executive Officer, Chief Financial Officer and certain other employees which will be paid via the issuance of 11,250,185 shares of Common Stock.

As of March 31, 2021, the Company owed its President and Chief Executive Officer, Chief Financial Officer and certain other employees' salaries totaling $3,060,000 which

will be paid via the issuance of 36,085,114 shares of Common Stock.

During the year ended March 31, 2021, the Company issued 1,931,891 shares of Common Stock in payment of consulting fees totaling $161,033, pursuant to engagement contracts with a certain consultant, and with such consulting expenses being earned and accrued over the twenty seven month period beginning on January 1, 2018 and ending March 31, 2020.

Options

Under its 2014 Stock Option Plan and prior options plans, the Company may grant stock options to officers, selected employees, as well as members of the Board of Directors and advisory board members. All options have generally been granted at a price equal to or greater than the fair market value of the Company's Common Stock at the date of the grant. Generally, options are granted with a vesting period of up to three years and expire ten years from the date of grant. A summary of the activity of Company's 2014 Stock Option Plan for the years ended March 31, 2021and 2020 is as follows:

	Shares Underlying Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at March 31, 2019	6,158,000	$ 0.15	5.0	$ 87,330
Granted	115,000	0.10	9.5	
Forfeited and expired	(898,000)			
Outstanding at March 31, 2020	5,375,000	0.14	4.1	6,000
Granted	600,000	0.06	9.7	
Forfeited and expired	(75,000)			
Outstanding at March 31, 2021	5,900,000	$ 0.13	3.7	$ 6,000
Exercisable at March 31, 2021	5,246,667	$ 0.13	3.7	$ 6,000

The aggregate intrinsic value for outstanding options is calculated as the difference between the exercise price of the underlying awards and the quoted price of the Company's Common Stock as of March 31, 2021 and March 31, 2020 of $0.06 and $0.07, respectively.

NOTE 14. CONCENTRATIONS AND CREDIT RISK

Revenues

Two customers accounted for approximately 92% of the Company's revenues for the year ended March 31, 2021. These two customers accounted for approximately 77% and 15% of revenues each, respectively.

Three customers accounted for approximately 92% of the Company's revenues for the year ended March 31, 2020. These three customers accounted for approximately 55%, 24%, and 13% of revenues each, respectively.

Accounts Receivable

Three customers accounted for approximately 99% of the Company's accounts receivable as of March 31, 2021. These three customers accounted for approximately 73%, 15% and 11% of accounts receivable each, respectively.

Four customers accounted for substantially all the Company's accounts receivable as of March 31, 2020. These four customers accounted for approximately 73%, 13%, 8%, and 5% of accounts receivable each, respectively.

Purchasing

Four suppliers accounted for approximately 78% of the Company's purchases of raw materials for the year ended March 31, 2021. These four suppliers accounted for approximately 54%, 13%, 6% and 5% of purchases each, respectively.

Three suppliers accounted for more than 71% of the Company's purchases of raw materials for the year ended March 31, 2020. These three suppliers accounted for approximately 41%, 23%, and 7% of purchases each, respectively.

NOTE 15. 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 ANDAs for generic products and NDAs 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 consolidated financial statements. Disaggregated revenue by reportable segments is disclosed in Note 1.

The following represents selected information for the Company's reportable segments:

	For the Years Ended March 31,

	2021	2020
Operating Income by Segment		
ANDA	$ 6,512,632	$ 3,579,047
NDA	142,812	580,414
	$ 6,655,444	$ 4,159,461

The table below reconciles the Company's operating income by segment to income (loss) from operations before provision for income taxes as reported in the Company's consolidated statements of operations.

	For the Years Ended March 31,	
	2021	2020
Operating income by segment	$ 6,655,444	$ 4,159,461
Corporate unallocated costs	(2,252,983)	(2,721,103)
Interest income	514	11,980
Interest expense and amortization of debt issuance costs	(259,598)	(355,874)
Depreciation and amortization expense	(1,313,847)	(1,319,795)
Significant non-cash items	(935,628)	(901,472)
PPP loan forgiveness	1,013,480	---
Change in fair value of derivative instruments	1,237,132	(1,111,548)
Income (loss) from operations before income taxes	$ 4,144,514	$ (2,238,351)

NOTE 16. RELATED PARTY AGREEMENTS WITH MIKAH PHARMA, LLC

On December 3, 2018, the Company executed a development agreement with Mikah pursuant to which Mikah and the Company will collaborate to develop and commercialize generic products including formulation development, analytical method development, bioequivalence studies and manufacture of development batches of generic products. As of the date of this report, the Company has incurred costs which are $238,451 in excess of advanced payments received to date from Mikah. This balance due from Mikah was offset, in full, against accrued interest due and owing to Mikah pursuant to the Mikah Note (see Note 7).

In May 2020, SunGen Pharma LLC ("SunGen"), under an asset purchase agreement, assigned its rights and obligations under the SunGen Agreement for Amphetamine IR and Amphetamine ER to Mikah Pharmaceuticals. The ANDAs for Amphetamine IR and Amphetamine ER are now registered under Elite's name. Mikah will now be Elite's partner with respect to Amphetamine IR and ER and will assume all the rights and obligations for these products from SunGen. Mikah Pharmaceuticals was founded in 2009 by Nasrat Hakim.

NOTE 17. INCOME TAXES

The components of the income taxes benefit (expense) are as follows:

	Year Ended March 31,	
	2021	2020
Federal		
Current	—	—
Deferred	—	—
State		
Current	—	—
Deferred	—	—
Benefit from sale of state net operating loss credits	904,528	—
Net benefit from sale of state net operating loss credits	$ 904,528	$ —

The major components of deferred tax assets and liabilities as of March 31, 2021 and 2020 are as follows (amounts in thousands of dollars):

	Year Ended March 31,	
	2021	2020
Federal		
Net operating loss carry forward	20,890	21,360
Valuation allowance	(20,890)	(21,360)
	$ —	$ —
State		
Net operating loss carry forward	841	2,258
Valuation Allowance	(841)	(2,258)
	$ —	$ —

At March 31, 2021 and 2020 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 carry forwards. Absent the above mentioned allowance, at March 31, 2021, the Company's federal and state income taxes due were $0.4 million and $0.2 million, respectively. Absent the above mentioned allowance, at March 31, 2020, the Company's federal and state income taxes due were $0.2 million and $0.1 million, respectively.

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, 2021, Elite has a federal net operating loss carry forward of $99.5 million, which do not expire and net operating loss carry forward in state tax jurisdictions

of $9.3 million some of which will began to expire in 2021.

Sale of New Jersey Net Operating Loss

In April 2020, Elite Laboratories Inc., a wholly owned subsidiary of Elite Pharmaceuticals Inc., received final approval from the New Jersey Economic Development Authority for the sale of net tax benefits of $607,635 relating to New Jersey net operating losses and net tax benefits of $338,772, relating to R&D tax credits. The Company sold the net tax benefits approved for sale for total proceeds of $946,407.

NOTE 18. COVID-19 UPDATE

In December 2019, the Novel Corona Virus, COVID-19 was reported to have emerged in Wuhan, China. In March 2020, the World Health Organization ("WHO") declared the COVID-19 outbreak a global pandemic. Governments at the national, state and local level in the United States, and globally, have implemented aggressive actions to reduce the spread of the virus, with such actions including, without limitation, lockdown and shelter in place orders, limitations on non-essential gatherings of people, suspension of all non-essential travel, and ordering certain businesses and governmental agencies to cease non-essential operations at physical locations. Under current and applicable laws and regulations, the Company's business is deemed essential and it has continued to operate in all aspects of its pharmaceutical manufacturing, distribution, product development, regulatory compliance and other activities. The Company's management has developed and implemented a range of measures to address the risks, uncertainties, and operational challenges associated with operating in a COVID-19 environment. The Company is closely monitoring the rapidly evolving and changing situation and are implementing plans intended to limit the impact of COVID-19 on our business so that the Company can continue to manufacture those medicines used by end user patients. Actions the Company has taken to date are, without limitation, further described below.

Workforce

The Company has taken and will continue to take, proactive measures to provide for the well-being of its workforce while continuing to safely produce pharmaceutical products. The Company has implemented alternative working practices, which include, without limitation, modified schedules, shift rotation and work at home abilities for appropriate employees to best ensure adequate social distancing. In addition, the Company increased its already thorough cleaning protocols throughout its facilities and has prohibited visits from non-essential visitors. Certain of these measures have resulted in increased costs.

Manufacturing and Supply Chain

During the year ended March 31, 2021, the Company has not experienced material, detrimental issues related to COVID-19 in its manufacturing, supply chain, quality assurance and regulatory compliance activities, and has been able to operate without interruption. The Company has taken, and plans to continue to take, commercially practical measures to keep its facilities open. The Company's supply chains remain intact and operational, and the Company is in regular communications with its suppliers and third-party partners. A prolonging of the current situation relating to COVID-19 may result in an increased risk of interruption in the Company supply chain in the future, with no assurances given as the materiality of such future interruption on the Company's business, financial condition, results of operations and cash flows.

NOTE 19. SUBSEQUENT EVENTS

Sale of New Jersey Net Operating Loss and Research and Development Tax Credit

In April 2021, Elite Laboratories Inc., a wholly owned subsidiary of Elite Pharmaceuticals Inc. received final approval from the New Jersey Economic Development Authority for the sale of net tax benefits of $798,889 relating to New Jersey net operating losses and net tax benefits of $58,490, relating to research and development tax credits. The Company sold the net tax benefits approved for sale at a transfer price equal to ninety three and one half cents for every benefit dollar and incurred transaction fees of $12,861, resulting in net proceeds to the Company of $788,789.

July 20, 2013

Personal and Confidential

Douglas Plassche
18 Sunrise Circle
Clinton, NJ 08809

Dear Doug,

This letter agreement (the "Agreement") shall confirm our understanding as to the terms of your employment with Elite Laboratories, Inc., a Delaware corporation (the "Company").

1. Commencing on April 12, 2013, you shall become an employee of the Company as a Vice President of Operations and your job responsibilities will include: scheduling and overseeing the manufacture and packaging of pharmaceutical products according to Food and Drug Administration (FDA) guidelines and Good Manufacturing Practices (cGMP) for generic and branded products; managing raw material and component purchasing for production; overseeing facility maintenance and shipping and receiving; preparing department budget including capital requirements; identifying personnel needs and motivating subordinates; training and developing junior staff members in a growing company; interfacing and consulting with R&D, Analytical and Quality Assurance Groups and writing Standard Operating Procedures and validation protocols. You will report directly to the CEO.

2. You shall receive an annual base salary equal to $205,000.00 which shall be payable in accordance with the Company's payroll practices.

3. In addition to your base salary, you shall receive annual stock compensation at the rate of $25,000 (the "Stock Compensation"). The Stock Compensation is earned in equal increments, on an annual basis, with amounts accruing only while you are employed by the Company. The Stock Compensation shall be paid to you annually on or before March 31st after the end of each year via the issuance of shares of $0.001 par value common stock (the "ELTP Shares") of Elite Pharmaceuticals Inc. ("Elite"). The number of ELTP Shares to be issued in payment of the Stock Compensation is calculated as the quotient of the annual amount of Stock Compensation accrued to you as of the December 31st immediately preceding such issuance of ELTP Shares divided by the simple average of the daily closing price (as posted on Google, Yahoo, Wall Street Journal or any similar data source) of each trading day during which you were employed by the Company during the prior year. The ELTP Shares will be registered on Form S-8, if deemed appropriate by Elite's Board of Directors.

4. In addition, you are eligible for an annual bonus in cash and/or equity-based awards for up to an equivalent of 30% of your base salary. Such awards would be granted based upon agreed upon milestones in the discretion of the Company and its Chief Executive Officer (the "CEO").

5. You shall receive a monthly automobile allowance in the amount of Five Hundred Dollars ($500).

6. Upon the approval by the Board of Directors of Elite, you will be granted stock options to purchase 3,000,000 ELTP Shares at the stock price on the closing day of the signing of this letter. The options will vest over a three-year period, commencing one year from the date of issuance.

7. You shall receive 15 days paid vacation time during each calendar year, pro rated for periods of less than a full calendar year; provided, that the timing and duration of any particular vacation shall not interfere with the business of the Company or the effective performance of your duties hereunder, as reasonably determined in good faith by the CEO.

8. Starting with the first day of your employment at the Company, you shall be entitled to participate in all health insurance plans maintained by the Company for its employees, subject to applicable eligibility requirements. Nothing in the foregoing shall limit or restrict the Company's discretion to amend, revise or terminate any benefit or plan without your notice or consent.

9. While you are employed by the Company, you agree to devote your best efforts to the interests of the Company and to not knowingly undertake or engage in any employment, occupation or business enterprise that is directly or indirectly adverse to the interest of the Company. You agree to observe in all material respects any and all rules and policies that the Company may now or hereafter establish from time to time, governing the conduct of its employees or business.

10. You understand and agree that your employment with the Company is terminable at will by either the Company or you. You may terminate your employment at any time with or without notice and the Company has a similar right to terminate your employment for any reason or no reason. You acknowledge that there have been no representations or promises made to you that your employment will continue for a set period of time or that your employment will be terminated only under particular circumstances. You acknowledge that no representations, express or implied, may be made that are inconsistent with this policy and no one at the Company is authorized to make representations, express or implied, inconsistent with this policy. If the Company terminates this Agreement without Cause it will give Executive notice at least thirty (30) days prior to the effective termination date; further Company shall pay you an amount equal to six months of base annual salary in effect upon the date of termination

11. You represent that your employment with the Company will not conflict with or be constrained by any prior employment obligations, covenants not to compete, confidentiality obligations or similar restrictions.

12. As a condition to entering into this Agreement and being employed by the Company you agree to execute and deliver the Proprietary Rights Agreement in the form attached hereto as Exhibit A.

13. This Agreement contains the entire understanding between the Company and you with respect to its subject matter. It may not be extended, varied, modified, supplemented, or otherwise changed except by written agreement signed by both you and an authorized officer of the Company. A waiver by the Company of any right or provision under this Agreement shall not operate or be construed as a waiver of such right or provision at any other time. If a court finds a portion of this Agreement unenforceable, such finding shall not affect enforcement of the other portions of this Agreement. Any portion found to be unenforceable shall be construed to be reformed to extend as far as is enforceable. This Agreement shall inure to the benefit of, and may be enforced by the successor and assigns of, the Company. This Agreement is entered into under the laws of the State of New Jersey and shall be governed by the laws of the State of New Jersey. Any lawsuit or legal action or proceeding relating to this Agreement shall be brought in one of the state of federal courts sitting in the City and State of New York, and both you and the Company submit to the jurisdiction of such courts for that purpose.

14. If any term or provision hereof is determined to be invalid or unenforceable, the remaining terms and provisions hereof shall be unimpaired and the invalid or unenforceable term or provision shall, for purposes of such jurisdiction, be deemed replaced by a term or provision that is valid and enforceable and that comes closest to expressing the intention of the invalid or unenforceable term or provision.

15. You represent and warrant that you have had a full opportunity to seek legal advice and representation by an independent counsel of your own choosing in connection with this Agreement.

16. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original and all of which taken together shall constitute one and the same agreement (and all signatures need not appear on any one counterpart), and this Agreement shall become effective when one or more counterparts has been signed by each of the parties hereto and delivered to each of the other parties hereto. This Agreement, once executed by a party, may be delivered to the other party hereto by facsimile or electronic transmission of a copy of this Agreement bearing the signature of the party so delivering this Agreement. A faxed or electronically delivered signature shall have the same legally binding effect as an original signature.

If you find the foregoing arrangement acceptable and believe that the foregoing accurately summarizes our understanding, please kindly so indicate by executing and dating the attached copy of this Agreement in the space provided and returning a copy to me.

Very truly yours,

Elite Laboratories, Inc.

By: s/Jerry Treppel
Name: Jerry Treppel
Title: Chairman & Ceo
7/24/13

ACCEPTED & AGREED AS OF

By: s/Doug Plassche 7/23/13
Name: Doug Plassche

June 21, 2019

Personal and Confidential

Douglas Plassche

Dear Doug,

This letter agreement (the "Agreement") shall confirm our understanding as to the terms of your continuing employment with Elite Laboratories, Inc., a Delaware corporation (the "Company").

In recognition of the value Elite places on your past and continued service to the Company, we are pleased to offer you an incentive to continue to remain employed with the Company and to provide for the continuity of management and the success of the Company's operations during a period of substantial change by ensuring your commitment to continue to serve diligently in your present position for an additional two year period starting June 30, 2019. In consideration of the foregoing Elite will pay you $30,000 for relocation expenses within two weeks of executing this letter agreement. In addition, at any time after June 30, 2021 and provided that you remain continuously employed with the Company through June 30, 2021, you will be entitled to a lump sum retention payment of $253,552, less applicable withholding taxes, regardless of whether you remain with the Company or leave the Company any time after June 30, 2021. Further in the two-year period up to June 30, 2021 your salary of $253,552 per year and bonus of $75,000 is guaranteed. These benefits will replace what is stated in your offer letter.

(Signature Page follows)

If you find the foregoing arrangement acceptable and believe that the foregoing accurately summarizes our understanding, please kindly so indicate by executing and dating the attached copy of this Agreement in the space provided and returning a copy to me.

Very truly yours,

Elite Laboratories, Inc

By: /s/ Nasrat Hakim
Nasrat Hakim
President and CEO

ACCEPTED & AGREED

By: /s/Douglas Plassche
Douglas Plassche

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.

FIRST AMENDMENT TO

THE LICENSE, SUPPLY AND DISTRIBUTION AGREEMENT BETWEEN ELITE PHARMACEUTICALS, INC./ELITE LABORATORIES, INC. AND LANNETT COMPANY, INC.

This Amendment, dated as of July 29, 2019 (the "Amendment"), by and between Elite Pharmaceuticals, Inc., a Nevada corporation and Elite Laboratories, Inc., a Delaware corporation with offices at 165 Ludlow Avenue, Northvale, New Jersey 07647 (collectively "Elite") and Lannett Company, Inc., a Delaware corporation located at 9000 State Road, Philadelphia, PA 19136 and/or its Affiliates ("Lannett") (and together the "Parties") relating to that License, Supply and Distribution Agreement between the Parties dated March 6, 2019 (the "Agreement");

WHEREAS Lannett and Elite desire to amend the Agreement on the terms and subject to the conditions contained herein, and

WHEREAS, capitalized terms used herein and not otherwise defined shall have the meaning assigned to such terms in the Agreement.

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

1. Section 1.1 (v) shall be replaced in its entirety with the new Section 1.1 (v) below:

v. "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:

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.

2. Section 3.3 shall be replaced in its entirety with new Section 3.3 below:

   a. License Fees. Throughout the Initial Term and Renewal Term, LANNETT shall pay to ELITE *** percent (***%) of the Net 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 *** 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 *** percent (***%) of the value by which the Net Profits are negative for the previous calendar quarter and carry over *** 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 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.

3. The Title Page for the Schedules that follows the signatures and precedes the schedules shall be replaced in its entirety with the new titles listed below:

   Schedule A: Products

   Schedule B: Product Specifications

   Schedule C: Quarterly Report for Calculation of Net Profit

   Schedule D: Shipping Instructions

4. Schedule C of the Agreement shall be replaced in its entirety with new Schedule C below:

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.

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 PROFIT	
PROFIT SHARE PAYMENT TO ELITE AT THE APPLICABLE LICENSE FEE PERCENTAGE SET FORTH IN SECTION 3.3	

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.

Except as expressly provided in this Amendment, the Agreement and all provisions therein are and shall continue to be in full force and effect in accordance with its terms.

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

Elite Pharmaceuticals, Inc.

By: s/ Nasrat Hakim
Name: Nasrat Hakim
Title: President and CEO
Date: 7-29-2019

Elite Laboratories, Inc.

By: s/ Nasrat Hakim
Name: Nasrat Hakim
Title: President and CEO
Date: 7-29-2019

Lannett Company, Inc.

By: s/ John Kozlowski
Name: John Kozlowski
Title: COSSO
Date: 7-31-2019

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following documents of our report dated June 14, 2021, relating to the consolidated financial statements of Elite Pharmaceuticals, Inc. and Subsidiary, included in the Annual Report on Form 10-K of the Company for the year ended March 31, 2021.

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
Registration Statement No. 333-239847 on Form S-3

/s/ Buchbinder Tunick & Company LLP

Little Falls, New Jersey

June 14, 2021

Exhibit 31.1

CERTIFICATION BY PRINCIPAL EXECUTIVE OFFICER

I, Nasrat Hakim, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended March 31, 2021 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 most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting.

5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: June 14, 2021

/s/ Nasrat Hakim

Nasrat Hakim
Chief Executive Officer, President and Chairman of the Board of Directors
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION BY PRINCIPAL FINANCIAL OFFICER

I, Marc Bregman certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended March 31, 2021 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 periods 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 most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting.

5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: June 14, 2021

/s/ Marc Bregman

Marc Bregman
Chief Financial Officer, Treasurer and Secretary
(Principal Accounting and Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Elite Pharmaceuticals, Inc. (the "Registrant") on Form 10-K for the year ended March 31, 2021 filed with the Securities and Exchange Commission (the "Report"), I, Nasrat Hakim, Chief Executive Officer of the Registrant, certify, pursuant to 18 U.S. C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

Information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: June 14, 2021

/s/ Nasrat Hakim
Nasrat Hakim
Chief Executive Officer, President and Chairman of the Board of Directors
(Principal Executive Officer)

This certification has been furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

A signed original of this written statement required by Section 906 has been provided to Elite Pharmaceuticals, Inc. and will be retained by Elite Pharmaceuticals Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Elite Pharmaceuticals, Inc. (the "Registrant") on Form 10-K for the year ended March 31, 2021 filed with the Securities and Exchange Commission (the "Report"), I, Marc Bregman, Chief Financial Officer and Treasurer of the Registrant, certify, pursuant to 18 U.S. C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

Information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: June 14, 2021

/s/ Marc Bregman
Marc Bregman
Chief Financial Officer, Treasurer and Secretary
(Principal Accounting and 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.