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, 2022

OR

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

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 such files). Yes X No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	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, 2021, the last business day of the registrant's most recently completed second fiscal quarter was $40,455,280.

The number of shares of the registrant's Common Stock outstanding as of June 23, 2022 was 1,011,281,988.

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.

Table of Contents

ITEM 1. BUSINESS

General

Elite Pharmaceuticals, Inc., a Nevada corporation (the "Company", "Elite", "Elite Pharmaceuticals", the "registrant", "we", "us" or "our") was incorporated on October 1, 1997 under the laws of the State of Delaware, and its wholly-owned subsidiary, Elite Laboratories, Inc. ("Elite Labs"), was incorporated on August 23, 1990 under the laws of the State of Delaware. On January

5, 2012, Elite Pharmaceuticals was reincorporated under the laws of the State of Nevada.

We are a specialty pharmaceutical company principally engaged in the development and manufacture of oral, controlled-release products and the manufacture of generic pharmaceuticals. Our strategy includes developing generic versions of controlled-release drug products with high barriers to entry.

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. Our website address is www.elitepharma.com.

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 products co-developed with partners; (iv) commercial exploitation of our products either by sales under our own label, license and the collection of royalties, or through the manufacture of our formulations; and (v) development of new products for sale under our own label, and the expansion of our licensing agreements with other pharmaceutical companies, including co-development projects, joint ventures and other collaborations.

We continue to evaluate opportunities for the development of various types of drug products, including branded drug products which require New Drug Applications ("NDAs") under Section 505(b)(1) or 505(b)(2) of the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Drug Price Competition Act") as well as generic drug products which require ANDAs.

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

Commercial Products

We own, license, 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.

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.

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 Company has provided the pilot data to the FDA, requesting clarification as to the requirements for resubmission of the NDA. The FDA has provided guidance for repeated bio-equivalence studies in order to bridge the new formulation to the original SequestOx™ studies and also extended our filing fee waiver until July 2023. Due to the prohibitive cost of such repeated bio-equivalence studies and the uncertain commercial viability given the regulatory and competitive landscape, 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 has been reinitiated with a target filing in Q1 2023 .

There can be no assurances that any of these products will receive marketing authorization and achieve commercialization. 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 on September 10, 2019 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.

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 Praxgen Pharmaceuticals LLC, formerly SunGen Pharma LLC, ("Praxgen"). The product was approved in April 2022.

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, 2022 ("Fiscal 2022") and ANDAs acquired or approved during the Fiscal 2022. 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

Precision Dose License Agreement

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

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

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 in 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 Praxgen (the "Lannett- Praxgen 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- Praxgen Product Alliance with Lannett, 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 Praxgen, pursuant to the Praxgen 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- Praxgen 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 Praxgen, pursuant to the Praxgen 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-Praxgen 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-Praxgen 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, Praxgen, under an asset purchase agreement, assigned its rights and obligations under the Praxgen Agreement for Amphetamine IR and Amphetamine ER to Mikah. 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 Praxgen.

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 and is evaluating the market place when deciding to proceed with the above listed filed applications.

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 requests and subsequent submissions can significantly extend the time for the FDA review process. Until a product 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 approved 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 and to commercialize a product, if approved. 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. 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 and is evaluating the market place when deciding to proceed with the above listed filed applications.

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 10,213,388	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, manufacturing, and marketing of pharmaceutical compounds, on which our success depends, are intensely regulated by governmental regulatory agencies, in particular the FDA and DEA. 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 through an NDA or an ANDA, each of which is discussed below.

NDAs and NDAs under Section 505(b)(2) 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. The IND contains results of animal and in vitro studies assessing the toxicology, pharmacokinetic, pharmacological, and pharmacodynamics characteristics of the product candidate; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the product candidate. 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. Clinical trials are typically conducted in three sequential phases that may overlap or be combined:

Phase One: The product candidate is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism, and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing;

Phase Two: The product candidate is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages, and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning;

Phase Three: The product candidate is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality, and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development nonclinical and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances.

The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality, and purity. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes 12 months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after the application is submitted. The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. If the FDA determines that the application, manufacturing process, or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical data, such as an additional pivotal Phase 3 clinical trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies, or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA with a REMS to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential

serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use. It could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. The FDA also may offer conditional approval subject to, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may also require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could impact the timeline for regulatory approval or otherwise impact ongoing development programs.

The FDA closely regulates the marketing, labeling, advertising, and promotion of drug products. A company can make only those claims relating to safety and efficacy that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising, and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labeling.

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.

NDAs under Section 505(b)(2)

Section 505(b)(2) NDAs may provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from clinical trials not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. The FDA may then approve the new product candidate for all, or some, of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on the FDA's findings of safety and effectiveness for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. Thus approval of a Section 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired; until any non-patent exclusivity, such as exclusivity for obtaining approval of a NCE, listed in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as the "Orange Book," for the referenced product has expired; and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant. In the interim period, the FDA may grant tentative approval. Tentative approval indicates that the FDA has determined that the applicant meets the standards for approval as of the date that the tentative approval is granted. Final regulatory approval can only be granted if the FDA is assured that there is no new information that would affect final regulatory/ approval.

ANDAs

To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application, or ANDA, to the agency. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, bioequivalence, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. ANDAs are "abbreviated" because they cannot include preclinical and clinical data to demonstrate safety and effectiveness. Instead, in support of such applications, a generic manufacturer must rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference listed drug, or RLD.

In order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, the strength of the drug and the conditions of use of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug." Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in the Orange Book. Physicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

When an ANDA applicant submits its application to the FDA, it is required to certify to the FDA concerning any patents listed for the reference product in the FDA's Orange Book. Specifically, the ANDA applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product.

If the follow-on applicant does not challenge the innovator's listed patents, FDA will not approve the ANDA application until all the listed patents claiming the referenced product have expired. A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the follow-on applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

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

The federal Controlled Substances Act of 1970, or CSA, and its implementing regulations establish a "closed system" of regulations for controlled substances. The CSA imposes registration, security, recordkeeping and reporting, storage, manufacturing, distribution, importation, exportation, disposal and other requirements under the oversight of the Drug Enforcement Agency, or DEA. The DEA is the federal agency responsible for regulating controlled substances, and requires those individuals or entities that manufacture, import, export, distribute, research, or dispense controlled substances to comply with the regulatory requirements in order to prevent the diversion of controlled substances to illicit channels of commerce.

The DEA categorizes controlled substances into one of five schedules — Schedule I, II, III, IV or V — with varying qualifications for listing in each schedule. Schedule I substances by definition have a high potential for abuse, have no currently accepted medical use in treatment in the United States and lack accepted safety for use under medical supervision. Pharmaceutical products having a currently accepted medical use that are otherwise approved for marketing may be listed as Schedule II, III, IV or V substances, with Schedule II substances presenting the highest potential for abuse and physical or psychological dependence, and Schedule V substances presenting the lowest relative potential for abuse and dependence. The regulatory requirements are more restrictive for Schedule II substances than Schedule III-V substances.

Facilities that manufacture, distribute, import or export any controlled substance must register annually with the DEA. The DEA registration is specific to the particular location,

activity(ies) and controlled substance schedule(s). For example, separate registrations are required for importation and manufacturing activities, and each registration authorizes which schedules of controlled substances the registrant may handle. Certain coincident activities are permitted without obtaining a separate DEA registration, however, such as distribution of controlled substances by the manufacturer that produces them.

The DEA inspects all manufacturing facilities to review security, recordkeeping, reporting and handling prior to issuing a controlled substance registration. The specific security requirements vary by the type of business activity and the schedule and quantity of controlled substances handled. The most stringent requirements apply to manufacturers of Schedule I and Schedule II substances. Required security measures commonly include background checks on employees and physical control of controlled substances through storage in approved vaults, safes and cages, and through use of alarm systems and surveillance cameras. Once registered, manufacturing facilities must maintain records documenting the manufacture, receipt and distribution of all controlled substances. Manufacturers must submit periodic reports to the DEA of the distribution of Schedule I and II controlled substances, Schedule III narcotic substances, and other designated substances. Registrants must also report any controlled substance thefts or significant losses, and must obtain authorization to destroy or dispose of controlled substances.

For drugs manufactured in the United States, the DEA establishes annually an aggregate quota for the amount of substances within Schedules I and II that may be manufactured or produced in the United States based on the DEA's estimate of the quantity needed to meet legitimate medical, scientific, research and industrial needs. The quotas apply equally to the manufacturing of the active pharmaceutical ingredient and production of dosage forms. The DEA may adjust aggregate production quotas, and individual manufacturing or procurement quotas from time to time, although the DEA has substantial discretion in whether or not to make such adjustments for individual companies. The DEA quota system was amended in 2018 to require sponsors to strengthen controls over diversion of controlled substances, controls and limits the availability and production of controlled substances in Schedule I or II. In November 2017, the DEA reduced the amount of almost every Schedule II opiate and opioid medication that may be manufactured in the U.S. in calendar year 2018 by 20%. For 2019, the DEA proposed decreased manufacturing quotas for the six most frequently misused opioids, including oxycodone, by an average of 10% as compared to the 2018 quotas. The DEA proposed further decreasing manufacturing quotas in 2020 for five of the six opioids (fentanyl, hydrocodone, hydromorphone, oxycodone, oxymorphone), by an average of 28%. In October 2019, the DEA proposed additional regulations to amend the manner in which the agency grants quotas to manufacturers. The proposed regulations will establish use-specific quotas, including commercial sales, product development, transfer, replacement and packaging. To decrease the risk of diversion and increase accountability, inventory allowances will be reduced, and procurement quota certifications will be required. In April 2020 in response to the COVID-19 pandemic, the DEA adjusted the established 2020 aggregate production quotas and assessment of annual needs for select Schedule II substances. The DEA took this action to ensure that the country has an adequate and uninterrupted supply of these substances during the public health emergency.

Federal laws have been enacted to address the national epidemics of prescription opioid abuse and illicit opioid use. In 2016, the Comprehensive Addiction and Recovery Act ("CARA"), was enacted to address the national epidemics of prescription opioid abuse and heroin use. CARA expands the availability of naloxone for law enforcement and other first responders, forms an interagency task force to develop best practices for pain management with opioid medications and provides resources to improve state monitoring of opioids. The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act ("SUPPORT Act"), which was signed into law in November 2018, includes a number of measures directed towards regulation and improvement of treatment for substance use-disorder and increased coverage by CMS of medically-assisted treatment options. In addition, the SUPPORT Act requires HHS to report to Congress on existing barriers to access to abuse-deterrent opioid formulations by Medicare Part C and D beneficiaries

The states also maintain separate controlled substance laws and regulations, including licensing, recordkeeping, security, distribution, and dispensing requirements. State authorities, including Boards of Pharmacy, regulate use of controlled substances in each state. Failure to maintain compliance with applicable requirements, particularly as manifested in the loss or diversion of controlled substances, can result in enforcement action that could have a material adverse effect on business, operations and financial conditions. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal prosecution.

Other Healthcare Laws and Compliance Requirements

Our activities are subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil False Claims Act, and laws and regulations pertaining to limitations on and reporting of healthcare provider payments (physician sunshine laws). These laws and regulations are interpreted and enforced by various federal, state and local authorities including CMS, the Office of Inspector General for the U.S. Department of Health and Human Services, the U.S. Department of Justice, individual U.S. Attorney offices within the Department of Justice, and state and local governments. These laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order, or arranging for or recommending the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the U.S. civil False Claims Act (which can be enforced through "qui tam," or whistleblower actions, by private citizens on behalf of the federal government), prohibits any person from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the U.S. federal government;

- U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal liability and amends provisions on the reporting, investigation, enforcement, and penalizing of civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for healthcare benefits, items or services by a healthcare benefit program, which includes both government and privately funded benefits programs; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- state laws and regulations, including state anti-kickback and false claims laws, that may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payer, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and

- the Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to CMS information related to certain payments made in the preceding calendar year and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; beginning in 2022, applicable manufacturers are required to report such information regarding payments and transfers of value provided, as well as ownership and investment interests held, during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives.

Violations of any of these laws or any other governmental regulations that may apply to us, may subject us to significant civil, criminal and administrative sanctions including penalties, damages, fines, imprisonment, and exclusion from government funded healthcare programs, such as Medicare and Medicaid, and/or adverse publicity.

Moreover, government entities and private litigants have asserted claims under state consumer protection statutes against pharmaceutical companies for alleged false or misleading statements in connection with the marketing, promotion and/or sale of pharmaceutical products, including state investigations and litigation by certain government entities regarding the marketing of opioid products.

Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or the FCPA, generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our industry is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently, the SEC and Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. Violations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Enforcement actions may be brought by the Department of Justice or the Securities and Exchanges Commission ("SEC"), and recent enacted legislation has expanded the SEC's power to seek disgorgement in all FCPA cases filed in federal court and extended the statute of limitations in SEC enforcement actions in intent-based claims such as those under the FCPA from five years to ten years.

Coverage and Reimbursement

Sales of any pharmaceutical product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance, and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Significant uncertainty exists as to the coverage and reimbursement status of any newly approved product. Decisions regarding the extent of coverage and amount of reimbursement to be provided for any product are made on a plan-by-plan basis. One third-party payor's decision to cover a particular product does not ensure that other payors will also provide coverage for the product. As a result, the coverage determination process can require manufacturers to provide scientific details, information on cost-effectiveness, and clinical support for the use of a product to each payor separately. This can be a time-consuming process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

In addition, third-party payors are increasingly reducing reimbursements for pharmaceutical products and related services. The U.S. government and state legislatures have continued implementing cost-containment programs, including price controls and restrictions on coverage and reimbursement. Third-party payors are increasingly challenging the prices charged, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical products, in addition to questioning their safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product.

We expect that additional federal, state and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that third-party payors, including government payors, will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

Compliance with Environmental Laws

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

Competition

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

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

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

We also face competition in the generic pharmaceutical market. The principal competitive factors in the generic pharmaceutical market include: (i) introduction of other generic drug manufacturers' products in direct competition with our products under development, (ii) introduction of authorized generic products in direct competition with any of our products under development, particularly if such products are approved and sold during exclusivity periods, (iii) consolidation among distribution outlets through mergers and acquisitions and the formation of buying groups, (iv) ability of generic competitors to quickly enter the market after the expiration of patents or exclusivity periods, diminishing the amount and duration of significant profits, (v) the willingness of generic drug customers, including wholesale and retail customers, to switch among pharmaceutical manufacturers, (vi) pricing pressures and product deletions by competitors, (vii) a company's reputation as a manufacturer and distributor of quality products, (viii) a company's level of service (including maintaining sufficient inventory levels for timely deliveries), (ix) product appearance and 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 Company, Prasco, LLC, Epic Pharma, LLC, and TAGI Pharma, LLC 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, 2022 and 2021 revenue from our ANDA segment were $32.3 million and $25.2 million, respectively. For the years ended March 31, 2022 and 2021 revenue from our NDA segment were $0.0 million and $0.2 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 15, 2022, 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 supply chain disruption.
- 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, 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, including public concern over the abuse of opioids.
- 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.
- Growing inflation impacts
- 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 of impairment of 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.
- Our business may be adversely affected by legislation or healthcare regulatory reform and initiatives.
- 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.
- We are subject to various fraud and abuse laws which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits and future earnings.

- Our products contain controlled substances which may subject us to increased litigation risk and regulation.
- Mandatory REMS programs could increase the cost, burden, and liability associated with the commercialization of certain products.

Structural and Organizational Risks

- 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 the ongoing COVID-19 pandemic. 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, including the ongoing COVID-19 pandemic.

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

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.

The effects of COVID-19, including the resultant supply chain issues and inflation, 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. 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.

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, 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.

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 Company, Prasco, LLC, Epic Pharma, LLC, and TAGI Pharma, LLC 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.

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.

When conducting clinical trials, we rely on third parties to conduct the 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 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 when conducting 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 not 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 Praxgen 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 may develop may not receive the marketing authorizations 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™, which are currently paused, 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, the development of which is currently paused, 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, preclinical or clinical trials will delay the filing of our drug applications with the FDA and, ultimately, our ability to commercialize 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 generic 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 generic products, including, without limitation, drug formulation, testing, and FDA review and approval, often takes three or more years. We must also successfully address any challenges brought by the owner of the listed patent. 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.

Our business is dependent on market perceptions, social and political pressures, including public concern over the abuse of opioids.

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 products 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 products, then such products will not be commercially successful, and our business will be adversely affected.

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

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

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 the ongoing 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™, if approved, will require much greater use of a direct sales force compared to marketing of our generic products, should we reinstate development and successfully commercialize 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 products, if approved, 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 limited financial data upon which you may evaluate our business and prospects. There can be no assurances of our ability to sustain current profitability. Additionally, in certain years prior to the year ended March 31, 2021, the auditor's opinion on our financials was 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. 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.
- 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 most likely will need additional funding to accomplish our plans to conduct the clinical development and commercialization of a range of multiple abuse deterrent opioids or initiate, continue or complete the development of additional generic products already identified for development or currently in development.

As of March 31, 2022, we had cash on hand of approximately $8.5 million and a working capital surplus of $12.2 million, and, for the fiscal year ended March 31, 2022, we generated income from operations totaling $5.1 million, net other income totaling $1.2 million and net income of $8.9 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, Oxy IR, Amphetamine IR Tablets, Amphetamine ER Capsules and Dantrolene Capsules, combined with manufacturing, profit split and royalty revenues earned pursuant to the Lannett Alliance, the Epic Alliance, the Prasco Alliance, the TAGI License Agreement, and successful commercialization of other products in our product development pipeline, may lead to eventual profitability, there can be no assurances of Elite becoming profitable. Furthermore, there can be no assurances of the continuation revenues being earned from the current generic product line, no assurances of Elite's successful commercialization of other products in our development pipeline, and no assurances of Elite's ability to continue as a going concern. In addition, there can be no assurances of Elite being able to raise additional funds in a timely manner, on acceptable terms, if needed to support commercial operations 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, 2022, were $9.9 million, with such amount including, without limitation, $2.9 million in various loans, leases and bonds payable, $0.9 million in derivative liabilities, and $6.1 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 of 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, 2022, intangible assets were approximately $6.6 million, or approximately 20% 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, labeling, marketing, advertising, promotion, distribution and sale of therapeutic pharmaceutical products through lengthy and detailed laboratory and clinical testing and other costly and time-consuming procedures. In addition, before obtaining regulatory approvals for certain generic products, we must conduct limited bioequivalence studies and other research to show comparability to the branded products. A failure to obtain satisfactory results in required pre-marketing trials may prevent us from obtaining required regulatory approvals. The FDA may also require companies to conduct post-approval studies and companies are subject to post-approval surveillance regarding their drug products and to report adverse events. The FDA also can require companies to formulate approved Risk Evaluation and Mitigation Strategies (REMS) to help ensure that a drug's benefits outweigh its risks.

We may seek FDA approval for certain product candidates 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.

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 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.

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.

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.

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 third-party payors, including government healthcare programs, such as Medicaid and Medicare, private health insurers and other payors. 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 certain 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.

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.

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

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.

Changes 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. 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 any clinical trials we may conduct. 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.

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 return on investment in SequestOx™ will 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™, we will be unable to commercialize the product. 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 or DOJ for information about a settlement agreement and there is a risk of the FTC or DOJ alleging a violation of antitrust laws and commencing an action against us.

Any such action could have an adverse effect on the Company's business operations and financial condition.

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 over abuse of opioids could negatively affect 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 FFDCA 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 subject to various fraud and abuse laws which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits.

Our activities are subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil False Claims Act, and laws and regulations pertaining to limitations on and reporting of healthcare provider payments (physician sunshine laws). These laws and regulations are interpreted and enforced by various federal, state and local authorities including CMS, the Office of Inspector General for the U.S. Department of Health and Human Services, the U.S. Department of Justice, individual U.S. Attorney offices within the Department of Justice, and state and local governments. These laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order, or arranging for or recommending the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the U.S. civil False Claims Act (which can be enforced through "qui tam," or whistleblower actions, by private citizens on behalf of the federal government), prohibits any person from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the U.S. federal government;

- U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal liability and amends provisions on the reporting, investigation, enforcement, and penalizing of civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for healthcare benefits, items or services by a healthcare benefit program, which includes both government and privately funded benefits programs; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- state laws and regulations, including state anti-kickback and false claims laws, that may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payer, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities;

- the Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to CMS information related to certain payments made in the preceding calendar year and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; beginning in 2022, applicable manufacturers are required to report such information regarding payments and transfers of value provided, as well as ownership and investment interests held, during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives; and

- the Foreign Corrupt Practices Act, or the FCPA, which generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our industry is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently, the SEC and Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies.

Violations of any of these laws or any other governmental regulations that may apply to us, may subject us to significant civil, criminal and administrative sanctions including penalties, damages, fines, imprisonment, and exclusion from government funded healthcare programs, such as Medicare and Medicaid, and/or adverse publicity. Moreover, government entities and private litigants have asserted claims under state consumer protection statutes against pharmaceutical companies for alleged false or misleading statements in connection with the marketing, promotion and/or sale of pharmaceutical products, including state investigations and litigation by certain government entities regarding the marketing of opioid products.

Our products contain controlled substances which may subject us to increased litigation risk and regulation.

Some of our current products and products under development contain controlled substances. 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.

Mandatory REMS programs could increase the cost, burden and liability associated with the commercialization of certain products.

The FDA has imposed a class-wide REMS on all IR, ER and long acting ("LA") opioid drug products (known as the Opioid Analgesic REMS). The FDA continually evaluates whether the REMS program is meeting its goal of ensuring that the benefit of these drugs continue to outweigh their risks, and whether the goals or elements of the program should be modified. If the FDA determines that additional measures are necessary, the modification of the Opioid Analgesic REMS to impose additional or more burdensome requirements could increase the costs associated with marketing opioid products and/or reduce the willingness of healthcare providers to prescribe those products, both which would have a material adverse effect on the ability to successfully commercializing, or to generate sufficient revenue from, such products.

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

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, 2022, 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, 2022, the closing sale price on the OTC Bulletin Board ("OTCBB") of our Common Stock fluctuated from a high of $0.06 per share to a low of $0.03 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 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 began on January 1, 2017 and expired on December 31, 2021. On June 30, 2021, the Company exercised the second of the renewal options, with such option including a term that began on January 1, 2022 and expires on December 31, 2026.

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.

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 three-month rent abatement from November 2020 through February 2021 and has a term of three years, ending on October 31, 2023.

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

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.

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, 2022		
March 31, 2022	$ 0.05	$ 0.03
December 31, 2021	$ 0.05	$ 0.03
September 30, 2021	$ 0.05	$ 0.04
June 30, 2021	$ 0.06	$ 0.05
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

As of June 23, 2022, the last reported sale price of our Common Stock, as reported by the OTCBB, was $0.05.

Holders

As of June 23, 2022, there were, respectively, approximately 115 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, 2022:

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 fulfillment of such vesting schedule and employment requirements as the Administrator shall determine. Prior to the lifting of the restrictions, the participant will nevertheless be entitled to receive distributions in liquidation and dividends on, and to vote the shares of, the restricted stock. The 2014 Plan provides for forfeiture of restricted stock for breach of conditions of grant.

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

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

Issuer Purchases of Equity Securities

None.

ITEM 6. [RESERVED]

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

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, 2022 compared to March 31, 2021

Revenue, Cost of revenue and Gross profit:

	For the Years Ended March 31,		Change	
	2022	2021	Dollars	Percentage
Manufacturing fees	$ 26,951,863	$ 20,997,310	$ 5,954,553	28%
Licensing fees	5,310,254	4,383,439	926,815	21%
Total revenue	32,262,117	25,380,749	6,881,368	27%
Cost of manufacturing	17,466,763	13,513,611	3,953,152	29%
Gross profit	$ 14,795,354	$ 11,867,138	$ 2,928,216	25%
Gross profit - percentage	46%	47%		

Total revenues for the year ended March 31, 2022 increased by $6.9 million or 27%, to $32.3 million, as compared to $25.4 million for the prior year, primarily due to increased revenues from Amphetamine ER Capsules, which were launched during the prior fiscal year, and increased revenue from the sales of Amphetamine Tablets, Naltrexone Tablets, and Loxapine Capsules as compared to prior year. The Amphetamine ER was launched during the prior fiscal year ended March 31, 2021.

Manufacturing fees increased by $6.0 million, or 28%, primarily due to manufacturing revenues increased from Amphetamine ER Capsules, as compared to the fiscal year ended March 31, 2021.

Licensing fees increased by $0.9 million, or 21%. This increase was primarily due to licensing fees increased from the sale of Amphetamine IR Tablets and Naltrexone Tablets as compared to the fiscal year ended March 31, 2021.

Costs of revenue consists of manufacturing and assembly costs. Our costs of revenue increased by $4.0 million or 29%, to $17.5 million as compared to $13.5 million for the prior fiscal year. This increase was due in large part to the increased manufacturing activities and related manufacturing revenues during the year ended March 31, 2022, 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 46% during the year ended March 31, 2022 as compared to 47% during the comparable prior fiscal year.

Operating expenses:

	For the Years Ended March 31,		Change	
	2022	2021	Dollars	Percentage
Operating expenses:				
Research and development	$ 4,051,349	$ 5,112,542	$ (1,061,193)	(21)%
General and administrative	4,464,003	3,323,045	1,140,958	34%

Non-cash compensation	14,353	13,181	1,172	9%
Depreciation and amortization	1,194,939	1,313,847	(118,908)	(9)%
Total operating expenses	$ 9,724,644	$ 9,762,615	$ (37,971)	—%

Operating expenses consist of research and development costs, general and administrative, non-cash compensation and depreciation and amortization expenses. Operating expenses totaled for $9.7 million the year ended March 31, 2022, which remained relatively unchanged as compared to the prior year.

Research and development costs for the year ended March 31, 2022 were $4.1 million, a decrease of $1.1 million, or 21%, from $5.1 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, 2022 as compared to the prior year.

General and administrative expenses for the year ended March 31, 2022 were $4.5 million, an increase of $1.1 million or 34%, from $3.3 million of such costs for the prior year. The increase was due in large part to the increase in payroll-related expense and professional expense.

Non-cash compensation expense for the years ended March 31, 2022 and 2021 was less than $0.1 million.

Depreciation and amortization expenses for the year ended March 31, 2022 were $1.2 million, and remained relatively unchanged from $1.3 million of such costs for the prior year.

As a result of the foregoing, our income from operations for the year ended March 31, 2022 was $5.1 million, compared to income from operations of $2.1 million for the prior year.

Other income (expense):

	For the Years Ended March 31,		Change	
	2022	2021	Dollars	Percentage
Other income, net:				
Change in fair value of derivative instruments	$ 1,425,409	$ 1,237,132	$ 188,277	15%
Interest expense and amortization of debt issuance costs	(191,816)	(259,598)	67,782	(26)%
Gain on sale of fixed assets	—	48,463	(48,463)	(100)%
Interest income	126	514	(388)	(75)%
PPP loan forgiveness	—	1,013,480	(1,013,480)	(100)%
Other income, net	$ 1,233,719	$ 2,039,991	$ (806,272)	(40)%

Other income, net for the year ended the year ended March 31, 2022 was $1.2 million, a reduction of $0.8 million from the prior year. The decrease in other income, net was due to PPP loan forgiveness which occurred during the prior fiscal year, offset by increased gains on the fair value of derivative instruments.

As a result of the foregoing, our income before income taxes for the year ended March 31, 2022 was $6.3 million, compared to $4.1 million for the prior year.

Liquidity and Capital Resources

Capital Resources

	March 31, 2022	March 31, 2021	Change
Current assets	$ 18,861,389	$ 12,194,667	$ 6,666,722
Current liabilities	$ 6,694,241	$ 5,812,531	$ 881,710
Working capital	$ 12,167,148	$ 6,382,136	$ 5,785,012

The Company considers cash and working capital balances as several of the factors the Company uses in evaluating its performance. As of March 31, 2022, the Company had cash on hand of $8.5 million and accounts receivable to be collected within expected operating cycles of $3.1 million. The Company believes that such resources, combined with the working capital surplus of $12.2 million and the continuation of ongoing operations are sufficient to fund operations through the current operating cycle. For the year ended March 31, 2022, the Company had income from operations totaling $5.1 million, net other income totaling $1.2 million and a net income of $8.9 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 $5.8 million from $6.4 million as of March 31, 2021 to $12.2 million as of March 31, 2022, with such increase being primarily related to the net income of $8.9 million and a net positive operating cash flows of $6.5 million achieved during the year ended March 31, 2022.

Summary of Cash Flows:

	For the Years Ended March 31,	
	2022	2021
Net cash provided by operating activities	$ 6,508,314	$ 3,193,861
Net cash used in investing activities	$ (498,566)	$ (262,781)
Net cash used in financing activities	$ (667,133)	$ (869,829)

Net cash provided by operating activities for the year ended March 31, 2022 was $6.5 million, which included net income of $8.9 million, offset by non-cash (income) expenses totaling $1.4 million and net increases in assets and decreases in liabilities totaling $1.0 million.

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, 2022 was comprised of purchases of property and equipment of $0.5 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 $0.7 million for the year ended March 31, 2022 which was offset primarily by loan payments.

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, the Company entered into a purchase agreement (the "2020 LPC Purchase Agreement"), and a registration rights agreement (the "2020 LPC 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, from time to time over the term of the 2020 LPC Purchase Agreement, at the Company's direction.

During the year ended March 31, 2022, the Company did not issue any shares of Common Stock to Lincoln Park.

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 $14,180 for the fiscal year ended March 31, 2022.

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 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, 2022.

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

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.

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, 2022, a summary of the tax years that remain subject to examination in our major tax jurisdictions are: United States – Federal, 2014 and forward, and State, 2010 and forward. The Company did not have any unrecognized tax positions for the years ended March 31, 2022 and 2021.

Warrants and Preferred Shares

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

Stock-Based Compensation

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

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

Earnings (Loss) Per Share Applicable to Common Shareholders'

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

Fair Value of Financial Instruments

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

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

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

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

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

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

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

Treasury Stock

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

Recently 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, 2022 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, 2022 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, 2022 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

None.

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 Class
Nasrat Hakim	61	President, Chief Executive Officer and Director	August 2013	III
Barry Dash, Ph. D.	91	Director	April 2005	II
Jeffrey Whitnell	66	Director	October 2009	III
Davis Caskey	74	Director	April 2016	I
Robert Chen	63	Chief Financial Officer, Secretary and Treasurer	May 2022	
Douglas Plassche	58	Executive Vice President of Operations	August 2013	

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

Pursuant to our recently amended and restated bylaws, our Board of Directors is now classified into three separate classes of directors. Each director currently holds office until the expiration of the term of his class (each for three years) and until his successor is duly elected and qualified, or until such director's death, resignation, or removal.

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 2017, Mr. Whitnell has provided financial advisory services, primarily to the healthcare industry, including Southside Master, where he served as Chief Financial Officer from September 2018 to present. In 2016, Mr. Whitnell served as Vice President, Finance and Controller for LifeWatch Services and other Private Equity-backed portfolio companies. From June 2010 to March 2015, Mr. Whitnell was the Chief Financial Officer for ReliefBand Medical Technologies, a medical device company. From June 2009 to June 2010, Mr. Whitnell provided financial advisory services to various healthcare companies, including ReliefBand Medical Technologies. From June 2004 to June 2009, Mr. Whitnell was Chief Financial Officer and Senior Vice President of Finance at Akorn, Inc. From June 2002 to June 2004, Mr. Whitnell was Vice President of Finance and Treasurer for Ovation Pharmaceuticals. From 1997 to 2001, Mr. Whitnell was Vice President of Finance and Treasurer for MediChem Research. Prior to 1997, Mr. Whitnell held various finance positions at Akzo Nobel and Motorola. Mr. Whitnell began his career as an auditor with Arthur Andersen & Co. He is a certified public accountant and holds an M.B.A. in Finance from the University of Chicago Booth School of Business and a B.S. in Accounting from the University of Illinois. Mr. Whitnell's qualifications as an accounting and audit expert led to the conclusion that he is qualified to serve as a director.

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, and this experience led to the conclusion that he is qualified to serve as a director. Mr. Caskey attended the University of Texas (Austin) and Lamar University, and holds bachelor's and master's degrees.

Robert Chen

Robert Chen has served as Chief Financial Officer, Secretary, and Treasurer of the Company since May 5, 2022. Mr. Chen joins Elite with broad experience in financial and operational leadership for life science companies, both private and public, ranging from preclinical development to commercial operations. Before joining Elite, Mr. Chen served as Vice President for KBP Biosciences from December 2020 to February 2022. From July 2019 to October 2020, Mr. Chen was the Chief Financial Officer at Victory Commercial Management. During 2019, Mr. Chen served as Sr. Director of Finance for WuXi Advanced Therapies. From 2014 to 2019, Mr. Chen was the Sr. Director of Finance at Taiho Oncology. Mr. Chen held various other financial positions in the life sciences sector with increasing responsibilities. Mr. Chen is a certified public accountant and began his career with Price Waterhouse and served as an Industrial Financial Analyst. Mr. Chen brings with him extensive and diversified financial leadership background in the areas of financial reporting, including manufacturing, financial and cost accounting, SEC, GAAP and IFRS, as well as financial planning and analysis, and this experience led to the conclusion that he is qualified to serve as a director. Mr. Chen has a Bachelor of Science in Business Administration, Accounting, and a Master of Professional Accountancy degree from the University of Southern Mississippi. He is a Certified Public Accountant (CPA).

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 the year ended March 31, 2022, the members of the Audit Committee were Jeffrey Whitnell (Chairman of the Audit Committee), Dr. Barry Dash, Davis Caskey and Nasrat Hakim. The Board of Directors has determined that 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 the year ended March 31, 2022, 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 the year ended March 31, 2022, the members of the Compensation Committee were Dr. Barry Dash (Chairman of the Compensation Committee), Jeffrey Whitnell, Davis Caskey and Nasrat Hakim.

Delinquent Section 16 Reports

Section 16(a) of the Exchange Act requires the Company's officers and directors, and persons who own more than ten percent of a registered class of the Company's stock, to file reports of ownership and changes in ownership with the SEC. Officers, directors and greater than ten percent stockholders are required by SEC regulation to furnish the Company with copies of all Section 16(a) reports they file.

Based solely on its review of copies of such reports and upon written representations from each of the Company's officers and directors, the Company believes that, for the year ended March 31, 2022, all Section 16(a) filing requirements applicable to the Company's officers, directors and greater than ten percent stockholders were complied with on a timely basis, except for one Form 4 filed on July 7, 2021 to report an award of options to Marc Bregman on May 17, 2021 that was late due to an administrative error.

Code of Conduct and Ethics

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

ITEM 11. EXECUTIVE COMPENSATION

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 Executive 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, 2022, the Compensation Committee did not engage any advisors.

Named Executive Officers

The named executive officers for the fiscal year ended March 31, 2022 were:

- Nasrat Hakim, Chief Executive Officer, and President for the full year;
- Marc Bregman, Chief Financial Officer, Secretary, and Treasurer from May 17, 2021 through April 29, 2022;
- 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, 2022.

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 an annual bonus for the fiscal year ended March 31, 2022 up to 100% of his base salary ($500,000 for fiscal 2022), which he earned in full. In addition, as described in the section below entitled "*Agreements with Named Executive Officers*," Mr. Plassche was entitled to earn an annual bonus for the fiscal year ended March 31, 2022 up to 30% of his base salary $78,493 for fiscal 2022. Mr. Plassche was awarded an $83,600 bonus for the fiscal year ended March 31, 2022. Mr. Bregman was entitled to earn an annual bonus for the fiscal year ended March 31, 2022 up to 20% of his base salary $37,400 for fiscal 2022, which he earned in full.

Equity

As noted above, certain components of our Named Executive Officers' fiscal year 2022 base salary and bonuses were payable in shares of Common Stock. In addition, Mr. Plassche is entitled to an annual grant of shares of Common Stock, as described in the section entitled "*Agreements with Named Executive Officers*" below. During the fiscal year ended March 31, 2022, this amount was $18,750 worth of fully vested shares for Mr. Plassche, which he elected to take as a cash bonus payment. Mr. Plassche's annual grant of shares of Common Stock in lieu of salary was terminated on December 31, 2021.

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. Mr. Bregman was granted stock options to purchase 300,000 shares of Common Stock with the strike price being closing price of the Company's stock as traded on the OTC Bulletin Board (symbol ELTP) on the first day of employment. The options were to vest over a three-year period commencing one year from the date of issuance. Mr. Bregman resigned prior to any of the options vesting. We did not grant any other stock options to our named executive officers during the fiscal year ended March 31, 2022.

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. The value of the perquisites we provide are taxable to the Named Executive Officers and the incremental cost to us of providing these perquisites are 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 bonus equal to up to 100% of his annual salary, payable in accordance with the Company's payroll practices. The Board may also award discretionary bonuses in its sole discretion. Mr. Hakim is entitled to employee benefits (e.g., health, vacation, employee benefit plans and programs) consistent with other Company employees of his seniority and a car allowance of up to $1,500 per month. The Hakim Employment Agreement contains confidentiality, non-competition and other standard restrictive covenants.

Mr. Hakim's employment is terminable by the Company for cause (as defined in the Hakim Employment Agreement). The Hakim Employment Agreement also may be terminated by the Company upon at least 30 days written notice due to disability (as defined in the Hakim Employment Agreement) or without cause. Mr. Hakim can terminate the Hakim Employment Agreement by resigning, provided he gives notice at least 60 days prior to the effective resignation date.

If Mr. Hakim is terminated for cause or he resigns, he only is entitled to accrued and unpaid annual salary, accrued vacation time and any reasonable and necessary business expenses, all through the date of termination and payable in stock ("Basic Termination Benefits"). If Mr. Hakim is terminated because of disability or death, in addition to Basic Termination Benefits, he is entitled 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.

Marc Bregman

On April 26, 2021, the Company entered into an employment agreement with Mr. Marc Bregman (the "Bregman Employment Agreement"). Pursuant to the terms of the Bregman Employment Agreement, Mr. Bregman served as an at-will employee of the Company as its Chief Financial Officer. Mr. Bregman received a base salary of $187,000, payable in accordance with the Company's payroll practices. He was also eligible for an annual bonus, equal to up to 20% of his base salary.

Mr. Bregman was granted stock options to purchase 300,000 shares of Common Stock. The options were to vest over a three-year period, commencing one year from the date of issuance.

Mr. Bregman was entitled generally to the same employee benefits offered to other employees of the Company, subject to applicable eligibility requirements.

Mr. Bregman subsequently resigned as CFO of the Company, effective April 29, 2022.

Douglas Plassche

On July 20, 2013, the Company entered into an employment agreement with Mr. Douglas Plassche (the "Plassche Employment Agreement"). Pursuant to the Plassche Employment Agreement, Mr. Plassche serves as an at-will employee, in the position of Vice President of Operations, commencing on August 12, 2013. The Plassche Employment Agreement includes 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 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 awarded 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, Mr. Plassche 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 is entitled to a monthly automobile allowance of $500.

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

Mr. Plassche is party to two retention agreements with the Company. On June 21, 2019, he entered into an agreement as an incentive for his continued employment and cooperation during a transitional period for the Company, which provided a retention bonus of $253,552, subject to his continued employment through June 30, 2021. This amount was earned during fiscal 2022 and is reflected in the Summary Compensation Table below.

On February 18, 2022, Mr. Plassche entered into a subsequent retention agreement with the Company (the "Plassche Retention Agreement"), also as an incentive for his continued employment and cooperation during a transitional period for the Company. Pursuant to the Plassche Retention Agreement, Mr. Plassche is entitled to a $150,000 retention payment on each of October 31, 2022 and June 30, 2023, subject in each case to his continued employment through such date.

On March 1, 2022, Mr. Plassche's compensation was adjusted to include a total base compensation package of $300,000 payable in accordance with the Company's payroll practices.

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 ($)	Bonus ($)	Option Awards ($)	All Other Compensation ($)	Total ($)
Nasrat Hakim, President, Chief Executive Officer and Chairman of the Board of Directors						
	2022	500,000[1]	500,000[2]	—	78,000[3]	1,078,000
	2021	500,000	500,000	—	78,000	1,078,000
Marc Bregman, Chief Financial Officer						
	2022	187,000[4]	37,400[5]	—	—	224,400

	2021	—	—	—	—	—
Douglas Plassche, Executive Vice President						
	2022	261,6446	393,9027	—	6,0008	661,546
	2021	267,536	75,000	—	6,000	348,536

[1] Represents salary earned by Mr. Hakim pursuant to the Hakim Employment Agreement for Fiscal 2022, 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 2022. A total of 11,570,858 shares of Common Stock are due and owing to Mr. Hakim in payment of salaries earned during Fiscal 2022. 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. In aggregate, a total of $2,625,000 is accrued, due and owing to Mr. Hakim for salaries earned during Fiscal 2022, Fiscal 2021, and the forty-eight months ended March 31, 2020, but not paid. This amount is to be paid via the issuance of 35,913,602 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 2022. Bonuses earned by Mr. Hakim during Fiscal 2022 were paid in accordance with the Company's payroll practices during Fiscal 2022. Mr. Hakim was also paid $187,500 during Fiscal 2022 for bonuses earned and accrued during the twelve months ended March 31, 2019, and not paid previously. Mr. Hakim was also paid $375,000 during Fiscal 2022 for bonuses earned and accrued during the twelve months ended March 31, 2020, and not previously paid. Mr. Hakim accordingly was paid a total of $1,062,000 during Fiscal 2022, with such amount representing bonuses earned during Fiscal 2022 and the twenty-four month period ending March 31, 2020, and not previously paid. A total of $500,000 of bonus earned by Mr. Hakim during Fiscal 2021 was paid in accordance with the Company's payroll practices. Mr. Hakim was also paid a total of $750,000 of bonuses earned and accrued during the twenty-four month period ending March 31, 2019 and not previously paid.

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

[4] Represents salaries earned by Mr. Bregman pursuant to the Bregman Employment Agreement.

[5] Represents bonus earned by Mr. Bregman during fiscal 2022.

[6] Represents salaries earned by Mr. Plassche pursuant to the Plassche Employment Agreement. Fiscal 2022 salaries consist of $261,644 being paid in accordance with the Company's payroll practices.

[7] Represents the bonus of $83,600 earned by Mr. Plassche for fiscal 2022 pursuant to the Plassche Employment Agreement, $18,750 of salaries earned during Fiscal 2022 which Mr. Plassche has elected to receive in cash instead of the issuance of common stock, and $291,552 as retention bonus under the June 2019 retention agreement.

[8] Represents amounts paid for auto allowances.

Outstanding Equity Awards at March 31, 2022

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
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, 2022:

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, 2022.

(2) Amounts represent Director fees earned during the fiscal year ended March 31, 2022 which are to be paid in cash. These fees were accrued and unpaid as of March 31, 2022, 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 2022.

(3) Director equity compensation for the fiscal year ended March 31, 2022 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.

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 Common Stock, and the remaining $10,000 being paid in cash; (iv) Directors 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 are paid a portion of their annual retainer fees via the issuance of shares of Common Stock of the Company. The number of shares to be issued to each Director is equal to the quotient of the quarterly amount due to each Director, 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, 2022 did not receive any additional equity compensation for serving as directors.

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 23, 2022 (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 23, 2022, we had 1,011,281,988 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 23, 2022. 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*	284,737,145(1)	28.2%
Barry Dash, Director*	2,723,718(2)	**%
Jeffrey Whitnell, Director*	2,675,363(3)	**%
Davis Caskey, Director*	1,537,779(4)	**%
Douglas Plassche, Executive Vice President *	4,491,484(5)	**%
All Directors and Officers as a group	296,165,489(6)	29.3%

* 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 35,913,602 shares of Common Stock due and owing to Mr. Hakim as of March 31, 2022 (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 2,228,182 shares of Common Stock held and 495,536 shares of Common Stock due and owing to Dr. Dash as of March 31, 2022 (the latest practicable date) for Directors fees accrued as of such date.
(3) Includes 2,179,827 shares of Common Stock held and 495,536 shares of Common Stock due and owing to Mr. Whitnell as of March 31, 2022 (the latest practicable date) for Directors fees accrued as of such date.
(4) Includes 1,042,243 shares of Common Stock held and 495,536 shares of Common Stock due and owing to Mr. Caskey as of March 31, 2022 (the latest practicable date) Date for Directors fees accrued as of such date.
(5) Includes 1,133,932 shares of Common Stock held 357,552 shares of Common Stock due and owing to Mr. Plassche as of March 31, 2022 (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.
(6) Relates only to current directors and officers. Includes 176,399,066 shares of Common Stock held, 37,757,762 shares of Common Stock due and owing as of March 31, 2022 (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, Praxgen, under an asset purchase agreement, assigned its rights and obligations under the Praxgen Agreement for Amphetamine IR and Amphetamine ER to Mikah. The ANDAs for Amphetamine IR and Amphetamine ER are now registered under Elite's name. Mikah is now Elite's partner with respect to Amphetamine IR and ER and Mikah will assume all the rights and obligations for these products from Praxgen. Mikah 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, 2023 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 2022	Fiscal 2021
Audit Fees	$ 122,000	$ 120,000
Audit-Related Fees	$ —	$ —
Tax Fees	$ 8,500	$ 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 2022.

Pre-Approval Procedures

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

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 4.1 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 29, 2020 and filed with the SEC on June 29, 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 Annual Report on Form 10-K, filed with the SEC on June 29, 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.
10.19	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.
10.27	June 4, 2015 License Agreement with Epic Pharma LLC, incorporated by reference to Exhibit 10.85 to Amendment No. 1 to the Annual Report on Form 10-K for the fiscal year ended March 31, 2015 and filed with the SEC on June 15, 2015. (Confidential Treatment granted with respect to portions of the Agreement).
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 May 1, 2017, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated May 2, 2017 and filed with the SEC on May 2, 2017.
10.31	Registration Rights Agreement between the Company and Lincoln Park Capital LLC dated May 1, 2017, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated May 2, 2017 and filed with the SEC on May 2, 2017.
10.32	April 28, 2017 Exchange Agreement between the Company and Nasrat Hakim, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated April 28, 2017 and filed with the SEC on April 28, 2017.

10.33	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).
10.43	May 22, 2018 License, Manufacturing and Supply Agreement with Glenmark Pharmaceuticals Inc. USA, incorporated by reference to Exhibit 10.60 to the Annual Report on Form 10-K for the fiscal year ended March 31, 2018 and filed with the SEC on June 14, 2018. (Confidential treatment granted with respect to portions of the Agreement).
10.44	August 1, 2018 Amendment to the Glenmark Pharmaceuticals Inc. USA License, Supply and Distribution Agreement, incorporated by reference to Exhibit 10.44 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)).of this Agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)).
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, incorporated by reference to Exhibit 10.52 to the Annual Report on Form 10-K, filed with the SEC on June 14, 2021.
10.53	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)), incorporated by reference to Exhibit 10.54 to the Annual Report on Form 10-K, filed with the SEC on June 14, 2021.

10.54	Master Development and License Agreement for Products Between Elite Pharmaceuticals, Inc. and Mikah Pharma LLC, effective as of June 10, 2021.(Portions of this Agreement have been redacted in compliance with Regulation S-K Item 601(b)(10), incorporated by reference to the 10-Q for the period ended June 30, 2021 and filed with the SEC on August 16, 2021.
10.55	License, Supply, and Distribution Agreement by and between Elite Pharmaceuticals, Inc. and Lannett Company, Inc, dated October 18, 2021.*
10.56	License, Supply, and Distribution Agreement by and between Elite Pharmaceuticals, Inc. and Lannett Company, Inc, dated October 18, 2021.*
10.57	License and Distribution Agreement by and between Elite Pharmaceuticals, Inc. and Dexcel Ltd. (Or Akiva, Israel), dated December 6, 2021.*
10.58	February 18, 2022 Retention Agreement with Douglas Plassche.*
10.59	License, Supply, and Distribution Agreement by and between Elite Pharmaceuticals and Lannett, Inc., dated July 20, 2021*
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*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

** Furnished herewith.

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 29, 2022

By: */s/ Robert Chen*
Robert Chen
Chief Financial Officer

Dated: June 29, 2022

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 29, 2022
/s/ Robert Chen	Chief Financial Officer, Secretary, and Treasurer	June 29, 2022
/s/ Barry Dash	Director	June 29, 2022
/s/ Jeffrey Whitnell	Director	June 29, 2022
/s/ Davis Caskey	Director	June 29, 2022

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEARS ENDED MARCH 31, 2022 AND 2021

TABLE OF CONTENTS

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, 2022 and 2021, 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, 2022, 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, 2022 and 2021 and the results of its operations and its cash flows for each of the years in the two year period ended March 31, 2022 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.

Intangible Assets — Refer to Notes 1 and 4 to the consolidated financial statements

Critical Audit Matter Description

As described in Note 1 and 4 to the consolidated financial statements, 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 whenever events or circumstances change that indicate impairment may have occurred.

Management performs a qualitative assessment of each intangible assets prior to performing a quantitative impairment test. Qualitative factors management considers include, the current project status, cost factors of raw material and labor, current cash flows, legal and regulatory factors and industry and market considerations. If the qualitative assessment indicates the fair value is more likely than not less than the carrying value a quantitative test is performed. The management performed a quantitative test on certain intangible assets using a discounted cash flow methodology and market approach. The methods used to estimate the fair value of intangible assets involve significant assumptions. The significant assumptions applied by management in estimating the fair value of intangible assets included income projections and discount rates. Due to the significant estimates and assumptions management is required to make, we identified the fair value of intangible assets as a critical audit matter. Performing audit procedures to evaluate the reasonableness of these estimates and assumptions required a high degree of auditor judgment and an increased extent of effort.

How We Addressed the Matter in Our Audit

The primary procedures we performed to address this critical audit matter included:

We obtained an understanding and evaluated the design and implementation of controls over the intangible valuation process. This included management's review over the assessment of the methodology, significant inputs and assumptions included in the fair value estimate, as well as management's review around the completeness, accuracy and reasonableness of the data used in this estimate.

Our audit procedures assessed whether the valuation methodology used was appropriate and tested the mathematical accuracy of the valuation model.

We evaluated whether the assumptions used were reasonable by considering the past performance, and discount rates, and whether such assumptions were consistent with evidence obtained in other areas of the audit.

/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 29, 2022

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

	March 31, 2022	March 31, 2021
ASSETS		
Current assets:		
Cash	$ 8,535,357	$ 3,192,768
Accounts receivable, net of allowance for doubtful accounts of $-0-, respectively	3,057,913	3,496,376
Inventory	6,741,170	5,012,902
Prepaid expenses and other current assets	526,949	492,621
Total current assets	18,861,389	12,194,667
Property and equipment, net of accumulated depreciation of $13,348,565 and $12,153,626, respectively	5,952,992	6,649,365
Intangible assets	6,634,035	6,634,035
Operating lease - right-of-use asset	1,031,884	214,674
Deferred income tax asset	2,171,821	—
Other assets:		
Restricted cash - debt service for NJEDA bonds	405,039	405,013
Security deposits	91,738	91,738

Total other assets	496,777	496,751
Total assets	**$ 35,148,898**	**$ 26,189,492**
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,430,985	$ 929,690
Accrued expenses	4,693,142	4,270,600
Deferred revenue, current portion	13,333	13,333
Bonds payable, current portion, net of bond issuance costs	100,822	95,822
Loans payable, current portion	253,006	314,996
Lease obligation - operating lease, current portion	202,953	188,090
Total current liabilities	6,694,241	5,812,531
Long-term liabilities:		
Deferred revenue, net of current portion	32,226	45,558
Bonds payable, net of current portion and bond issuance costs	1,139,848	1,240,668
Loans payable, net of current portion	249,046	500,066
Lease obligation - operating lease, net of current portion	835,893	38,866
Derivative financial instruments - warrants	936,837	2,362,246
Other long-term liabilities	38,780	37,628
Total long-term liabilities	3,232,630	4,225,032
Total liabilities	**9,926,871**	**10,037,563**

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

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

(continued)

	March 31, 2022	March 31, 2021
Shareholders' equity:		
Common stock; par value $0.001; 1,445,000,000 shares authorized; 1,011,381,988 shares issued and 1,011,281,988 shares outstanding as of March 31, 2022; 1,009,276,752 shares issued and 1,009,176,752 shares outstanding as of March 31, 2021	1,011,385	1,009,279
Additional paid-in capital	164,577,227	164,407,480
Treasury stock; 100,000 shares as of March 31, 2022 and March 31, 2021; at cost	(306,841)	(306,841)
Accumulated deficit	(140,059,744)	(148,957,989)
Total shareholders' equity	**25,222,027**	**16,151,929**
Total liabilities and shareholders' equity	**$ 35,148,898**	**$ 26,189,492**

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

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

	For the Years Ended March 31,	
	2022	2021
Revenue:		
Manufacturing fees	$ 26,951,863	$ 20,997,310
Licensing fees	5,310,254	4,383,439
Total revenue	32,262,117	25,380,749
Cost of manufacturing	17,466,763	13,513,611
Gross profit	14,795,354	11,867,138
Operating expenses:		
Research and development	4,051,349	5,112,542
General and administrative	4,464,003	3,323,045
Non-cash compensation through issuance of stock options	14,353	13,181
Depreciation and amortization	1,194,939	1,313,847
Total operating expenses	9,724,644	9,762,615
Income from operations	5,070,710	2,104,523
Other income, net:		
Change in fair value of derivative instruments	1,425,409	1,237,132
Interest expense and amortization of debt issuance costs	(191,816)	(259,598)
Gain on sale of fixed assets	—	48,463
Interest income	126	514
PPP loan forgiveness	—	1,013,480
Other income, net	1,233,719	2,039,991
Income from operations before income taxes	6,304,429	4,144,514
Income tax benefit	1,736,437	
Net benefit for sale of state net operating losses and credits	857,379	943,907
Net income attributable to common shareholders	$ 8,898,245	$ 5,088,421

Basic net income per share attributable to common shareholders	$ 0.01	$ 0.01
Diluted net income per share attributable to common shareholders	$ 0.01	$ 0.00
Basic weighted average Common Stock outstanding	1,010,607,713	942,997,875
Diluted weighted average Common Stock outstanding	1,010,607,713	942,997,875

The accompanying notes are an integral part of these 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'
	Shares	Amount	Shares	Amount	Capital	Shares	Amount	Deficit	Equity
Balance as of 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 2020 Lincoln Park purchase agreement	—	—	640,543	641	41,582	—	—	—	42,223
Common Stock issued as additional commitment shares pursuant to the 2020 Lincoln Park 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 expenses	—	—	1,931,891	1,932	159,101	—	—	—	161,033
Balance as of March 31, 2021	—	$ —	1,009,276,752	$ 1,009,279	$ 164,407,480	100,000	$ (306,841)	$ (148,957,989)	$ 16,151,929
Net income	—	—	—	—	—	—	—	8,898,245	8,898,245
Non-cash compensation through the issuance of employee stock options	—	—	—	—	14,353	—	—	—	14,353
Shares issued in payment of salaries	—	—	2,105,236	2,106	155,394	—	—	—	157,500
Balance at March 31, 2022	—	$ —	1,011,381,988	$ 1,011,385	$ 164,577,227	100,000	$ (306,841)	$ (140,059,744)	$ 25,222,027

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

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

	For the Years Ended March 31,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	$ 8,898,245	$ 5,088,421
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	1,209,119	1,313,847
Amortization of operating leases - right-of-use assets	225,590	210,744
Gain on sale of fixed assets	—	(48,463)
Change in fair value of derivative financial instruments - warrants	(1,425,409)	(1,237,132)
PPP loan forgiveness	—	(1,013,480)
Deferred income tax asset	(2,171,821)	—
Non-cash compensation accrued	767,122	922,443
Non-cash compensation through the issuance of employee stock options	14,353	13,181
Non-cash rent expense and lease accretion	1,152	2,186
Change in operating assets and liabilities:		
Accounts receivable	438,463	610,470
Inventory	(1,728,268)	(870,430)
Prepaid expenses and other current assets	209,796	361,408
Accounts payable, accrued expenses and other current liabilities	314,214	(1,768,862)
Deferred revenue and customer deposits	(13,332)	(180,000)
Lease obligations - operating leases	(230,910)	(210,472)
Net cash provided by operating activities	6,508,314	3,193,861

CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(498,566)	(329,981)
Proceeds from disposal of property and equipment	—	67,200
Net cash used in investing activities	(498,566)	(262,781)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from PPP loan	—	1,013,480
Proceeds from the issuance of Common Stock	—	42,223
Payment of related party note payable	—	(1,200,000)
Payment of bond principal	(110,000)	(105,000)
Other loan payments	(557,133)	(620,532)
Net cash used in financing activities	(667,133)	(869,829)
Net change in cash and restricted cash	5,342,615	2,061,251
Cash and restricted cash, beginning of period	3,597,781	1,536,530
Cash and restricted cash, end of period	$ 8,940,396	$ 3,597,781
Supplemental disclosure of cash and non-cash transactions:		
Cash paid for interest	$ 177,636	$ 176,179
Financing of equipment purchases and insurance renewal	$ 244,124	$ 410,141
Stock issued in payment of Directors fees, salaries and consulting expenses	$ 157,500	$ 352,283
Supplemental non-cash amounts of lease liabilities arising from obtaining right of use assets	$ 1,042,800	$ —
Commitment shares issued to Lincoln Park Capital	$ —	$ 722
Conversion of preferred stock to Common Stock	$ —	$ 13,903,960
Reconciliation of cash and restricted cash		
Cash	$ 8,535,357	$ 3,192,768
Restricted cash - debt service for NJEDA bonds	405,039	405,013
Total cash and restricted cash shown in statement of cash flows	$ 8,940,396	$ 3,597,781

The accompanying notes are an integral part of these 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 Labs. All significant intercompany accounts and transactions have been eliminated in consolidation.

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, 2022.

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 Praxgen, formerly known as 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 Praxgen 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,	
	2022	**2021**
NDA:		
Licensing fees	$ —	$ 166,167
Total NDA revenue	—	166,167
ANDA:		
Manufacturing fees	$ 26,951,863	$ 20,997,310
Licensing fees	5,310,254	4,217,272
Total ANDA revenue	32,262,117	25,214,582
Total revenue	$ 32,262,117	$ 25,380,749

Selected information on reportable segments and reconciliation of operating income by segment to income (loss) from operations before income taxes are disclosed within Note 15.

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, 2022, and March 31, 2021, the Company had $405,039 and $405,013, of restricted cash, 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, 2022, 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 condensed consolidated financial statements. Contingencies are inherently unpredictable, and the assessments of the value can involve a series of complex judgments about future events and can rely heavily on estimates and assumptions.

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, 2022, 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, 2013 and forward. The Company did not record unrecognized tax positions for the years ended March 31, 2022 and 2021.

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 share being calculated on a quarterly basis and equal to the average closing price of the Company's Common Stock.

Earnings Per Share Attributable to Common Shareholders'

The Company follows ASC 260, Earnings Per Share, which requires presentation of basic and diluted earnings 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 per share is computed by dividing net income by the weighted average number of shares of Common Stock outstanding during the period. The computation of diluted net income per share does not include the conversion of securities that would have an antidilutive effect.

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

	For the Years Ended March 31,	
	2022	**2021**
Numerator		
Net income - basic	$ 8,898,245	$ 5,088,421
Effect of dilutive instrument on net income	(1,425,409)	(1,237,132)
Net income - diluted	$ 7,472,836	$ 3,851,289
Denominator		
Weighted average shares of Common Stock outstanding - basic	1,010,607,713	942,997,875
Dilutive effect of stock options and convertible securities	—	—
Weighted average shares of Common Stock outstanding - diluted	1,010,607,713	942,997,875
Net income per share		
Basic	$ 0.01	$ 0.01
Diluted	$ 0.01	$ 0.00

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, 2022				
Liabilities				
Derivative financial instruments - warrants	$ 936,837	$ —	$ —	$ 936,837
March 31, 2021				
Liabilities				
Derivative financial instruments - warrants	$ 2,362,246	$ —	$ —	$ 2,362,246

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.

Treasury Stock

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

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, 2022	March 31, 2021
Finished goods	$ 159,808	$ 274,603
Work-in-progress	1,203,204	781,350
Raw materials	5,378,158	3,956,949
	$ 6,741,170	$ 5,012,902

NOTE 3. PROPERTY AND EQUIPMENT, NET

Property and equipment consisted of the following:

	March 31, 2022	March 31, 2021
Land, building and improvements	$ 5,456,524	$ 5,456,523
Laboratory, manufacturing, warehouse and transportation equipment	13,017,731	12,580,457
Office equipment and software	373,601	373,601
Furniture and fixtures	453,701	392,410
	19,301,557	18,802,991
Less: Accumulated depreciation	(13,348,565)	(12,153,626)
	$ 5,952,992	$ 6,649,365

Depreciation expense was $1,194,939 and $1,299,668 for the years ended March 31, 2022 and 2021, respectively.

NOTE 4. INTANGIBLE ASSETS

The following table summarizes the Company's intangible assets:

	March 31, 2022					
	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, 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

* 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 audited consolidated balance sheets. The NJEDA Bonds require the Company to make an annual principal payment on September 1st based on the amount specified in the loan documents and semi-annual interest payments on March 1st and September 1st, equal to interest due on the outstanding principal. The annual interest rate on the Series A Note is 6.5%. The NJEDA Bonds are collateralized by a first lien on the Company's facility and equipment acquired with the proceeds of the original and refinanced bonds.

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

	March 31, 2022	March 31, 2021
Gross bonds payable		
NJEDA Bonds - Series A Notes	$ 1,360,000	$ 1,470,000
Less: Current portion of bonds payable (prior to deduction of bond offering costs)	(115,000)	(110,000)
Long-term portion of bonds payable (prior to deduction of bond offering costs)	$ 1,245,000	$ 1,360,000
Bond offering costs	$ 354,454	$ 354,454
Less: Accumulated amortization	(235,124)	(220,944)
Bond offering costs, net	$ 119,330	$ 133,510
Current portion of bonds payable - net of bond offering costs		
Current portions of bonds payable	$ 115,000	$ 110,000
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	$ 100,822	$ 95,822
Long term portion of bonds payable - net of bond offering costs		
Long term portion of bonds payable	1,245,000	$ 1,360,000
Less: Bond offering costs to be amortized subsequent to the next 12 months	(105,152)	(119,332)
Long term portion of bonds payable, net of bond offering costs	$ 1,139,848	$ 1,240,668

Amortization expense was $14,180 and $14,179 for the years ended March 31, 2022 and 2021, respectively. As of March 31, 2022 and March 31, 2021, interest payable was $7,367 and $7,963, respectively.

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

Years ending March 31,	Amount
2023	115,000
2024	125,000
2025	130,000
2026	140,000
Thereafter	850,000
	$ 1,360,000

NOTE 6. LOANS PAYABLE

Loans payable consisted of the following:

	March 31, 2022	March 31, 2021
Equipment and insurance financing loans payable, between 3.30% and 12.02% interest and maturing between October 2022 and October 2025	$ 502,052	$ 815,062
Less: Current portion of loans payable	(253,006)	(314,996)
Long-term portion of loans payable	$ 249,046	$ 500,066

The interest expense associated with the loans payable was $62,845 and $77,218 for the years ended March 31, 2022 and 2021, respectively.

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

Years ending March 31,	Amount
2023	253,006
2024	129,275
2025	96,117
2026	23,654
	$ 502,052

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 for the year ended March 31, 2021. 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 Mikah Note. Of the $435,000 accrued interest due at maturity, $435,000 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).

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

NOTE 8. DEFERRED REVENUE

Deferred revenues in the aggregate amount of $45,559 as of March 31, 2022, were comprised of a current component of $13,333 and a long-term component of $32,226. 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. 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. 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 it is both probable that a liability has been incurred, and the amount can be reasonably estimated. If these estimates and assumptions change or prove to be incorrect, it could have a material impact on the Company's condensed consolidated financial statements. Contingencies are inherently unpredictable, and the assessments of the value can involve a series of complex judgments about future events and can rely heavily on estimates and assumptions.

Operating Leases – 135 Ludlow Ave.

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

The 135 Ludlow Ave. modified lease includes an initial term, which 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. On June 30, 2021, the Company exercised the second of the renewal options, with such option including a term that begins on January 1, 2022 and expires on December 31, 2026.

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.

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.

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

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

Lease	Classification	As of March 31, 2022
Assets		
Operating	Operating lease – right-of-use asset	$ 1,031,884
Total leased assets		$ 1,031,884
Liabilities		
Current		
Operating	Lease obligation – operating lease	$ 202,953
Long-term		
Operating	Lease obligation – operating lease, net of current portion	835,893
Total lease liabilities		$ 1,038,846

Rent expense is recorded on the straight-line basis. Rent expense under the 135 Ludlow Ave. modified lease for the years ended March 31, 2022 and 2021 was $229,563 and $219,636, respectively. Rent expense under the Pompano Office Lease for the year ended March 31, 2022 was $23,430. There was no rent expense under the Pompano Office lease for the year ended March 31, 2021 as there was a rent abatement period from November 2020 through February 2021. Rent expense is recorded in general and administrative expense in the audited consolidated statements of operations.

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

Years ending March 31,	Amount
2023	259,794
2024	254,050
2025	243,612
2026	248,484
Thereafter	189,144
Total future minimum lease payments	1,195,084
Less: interest	(156,238)
Present value of lease payments	$ 1,038,846

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, 2022

Remaining lease term (years)	
Operating leases	7
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, 2022, and March 31, 2021, the Company had a liability of $38,780 and $37,628, 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 issued and outstanding, with a stated value of $1,000,000 per share and a par value of $0.01 as of March 31, 2022.

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 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 audited consolidated balance sheet as of March 31, 2022 (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 sheets as of March 31, 2022 and 2021.

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.

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, 2022		March 31, 2021	
	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 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 Hakim, the "Securities") in exchange for 158,017,321 shares of Common Stock owned by 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 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 instead of a Monte Carlo Simulation because the probability with the shareholder approval provisions was no longer a factor. The following assumptions were used in the Black-Scholes model to calculate the fair value of the Series J Warrants:

	March 31, 2022	March 31, 2021
Fair value of the Company's Common Stock	$ 0.0350	$ 0.0610
Volatility	76.55%	75.18%
Initial exercise price	$ 0.1521	$ 0.1521
Warrant term (in years)	5.1	6.1
Risk free rate	2.40%	1.40%

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

The changes in warrants (Level 3 financial instruments) measured at fair value on a recurring basis for the year ended March 31, 2022 were as follows:

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
Change in fair value of derivative financial instruments - warrants		(1,425,409)
Balance at March 31, 2022	$	936,837

NOTE 12. SHAREHOLDERS' EQUITY

Lincoln Park Capital Transaction - July 8, 2020 Purchase Agreement

On July 8, 2020, the Company entered into a purchase agreement (the "2020 LPC Purchase Agreement"), and a registration rights agreement (the "2020 LPC 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, from time to time over the term of the 2020 LPC Purchase Agreement, at the Company's direction.

The Company did not issue any shares of its Common Stock pursuant to the 2020 LPC Purchase Agreement during the year ended March 31, 2022. In addition, there were no shares issued to Lincoln Park as additional commitment shares, pursuant to the 2020 LPC Agreement.

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.

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

Summary of Common Stock Activity

During the years ended March 31, 2022 and 2021, the Company issued 2,105,236 and 168,772,385 shares of Common Stock, respectively, with such issuances of Common Stock being summarized as follows:

	March 31,	
	2022	**2021**
Common Stock issued as of March 31, 2021 and 2020, respectively	1,009,276,752	840,504,367
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 $- and $42,223 for the years ended March 31, 2022 and 2021, respectively.	—	6,616,400
Common Stock issued as initial and additional commitment shares pursuant to the Lincoln Park Capital Purchase Agreements	—	10,094
Common Stock issued in payment of Directors fees, salaries and consulting fees	2,105,236	4,128,570
Common Stock issued during the fiscal year	2,105,236	168,772,385
Common Stock issued as of March 31, 2022 and 2021, respectively	1,011,381,988	1,009,276,752

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, 2022, the Company accrued director's fees totaling $90,000, which will be paid via cash payments totaling $30,000 and the issuance of 1,378,608 shares of Common Stock.

As of March 31, 2022, the Company owed its Directors a total of $30,000 in cash payments and 1,378,608 shares of Common Stock in payment of director fees totaling $90,000 due and owing. The Company anticipates that these shares of Common Stock will be issued prior to the end of the current fiscal year.

Stock-based Employee/Consultant Compensation

Employment contracts with the Company's President and Chief Executive Officer 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, 2022, the Company issued 1,218,526 shares of Common Stock in payment of salaries totaling $97,500 pursuant to the employment contract of the Company's former Chief Financial Officer, with such salaries being earned and accrued over the forty one month period beginning on October 1, 2018 and ending on March 31, 2021.

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

During the year ended March 31, 2022, the Company accrued salaries totaling $84,000 owed to a certain other employees which will be paid via the issuance of 14,105,665 shares of

Common Stock.

As of March 31, 2022, the Company owed its President and Chief Executive Officer and certain other employees' salaries totaling $3,625,000 which will be paid via the issuance of 50,190,779 shares of Common Stock.

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, 2022 and 2021 is as follows:

	Shares Underlying Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
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
Granted	500,000	$ 0.05		
Forfeited and expired	(750,000)			
Outstanding at March 31, 2022	5,650,000	$ 0.14	2.8	$ —
Exercisable at March 31, 2022	4,530,001	$ 0.16	2.3	$ —

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, 2022 and March 31, 2021 of $0.10 and $0.06, respectively. As of March 31, 2022, there was $25,328 in unrecognized stock-based compensation expense that will be recognized over a 3 year period.

NOTE 14. CONCENTRATIONS AND CREDIT RISK

Revenues

Two customers accounted for approximately 95% of the Company's revenues for the year ended March 31, 2022. These two customers accounted for approximately 84% and 11% of revenues each, respectively.

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.

Accounts Receivable

Two customers accounted for approximately 91% of the Company's accounts receivable as of March 31, 2022. These two customers accounted for approximately 78% and 13% of accounts receivable each, respectively.

Three customers accounted for substantially all the Company's accounts receivable as of March 31, 2021. These three customers accounted for approximately 73%, 15% and 10% of accounts receivable each, respectively.

Purchasing

Four suppliers accounted for approximately 69% of the Company's purchases of raw materials for the year ended March 31, 2022. These four suppliers accounted for approximately 51%, 7%, 6% and 5% of purchases each, respectively.

Four suppliers accounted for more than 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.

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 audited consolidated financial statements.

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

	For the Years Ended March 31,	
	2022	2021
Operating Income by Segment		
ANDA	10,744,005	6,512,632
NDA	—	142,812
	$ 10,744,005	$ 6,655,444

The table below reconciles the Company's operating income by segment to income from operations before provision for income taxes as reported in the Company's audited consolidated statement of operations:

	For the Years Ended March 31,	
	2022	2021

Operating income by segment	$ 10,744,005	$ 6,655,444
Corporate unallocated costs	(3,696,881)	(2,252,983)
Interest income	126	514
Interest expense and amortization of debt issuance costs	(191,816)	(259,598)
Depreciation and amortization expense	(1,194,939)	(1,313,847)
Significant non-cash items	(781,475)	(935,628)
PPP loan forgiveness	—	1,013,480
Change in fair value of derivative instruments	1,425,409	1,237,132
Income from operations before income taxes	$ 6,304,429	$ 4,144,514

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 March 31, 2021, 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, Praxgen, pursuant to an asset purchase agreement, assigned its rights and obligations under the Praxgen 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 Praxgen. Mikah Pharmaceuticals was founded in 2009 by Nasrat Hakim, a related party and the Company's President, Chief Executive Officer and Chairman of the Board.

In June 2021, the Company entered into a development and license agreement with Mikah Pharma LLC, pursuant to which Mikah Pharma LLC will engage in the research, development, sales and licensing of generic pharmaceutical products. In addition, Mikah Pharma LLC will collaborate to develop and commercialize generic products including formulation development, analytical method development, manufacturing, sales and marketing of generic products. Initially two generic products were identified for the parties to develop.

NOTE 17. INCOME TAXES

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

	Year Ended March 31,	
	2022	2021
Federal		
Current	$ —	$ —
Deferred	2,171,821	—
State		
Current	(435,384)	—
Deferred	—	—
Income tax benefit	$ 1,736,437	$ —
Benefit from sale of state net operating loss credits	$ 857,379	$ 943,907
Net benefit from sale of state net operating loss credits	$ 857,379	$ 943,907

The major components of deferred tax assets and liabilities as of March 31, 2022 and 2021 are as follows (amounts in thousands of dollars):

	Year Ended March 31,	
	2022	2021
Federal		
Net operating loss carry forward	$ 21,180	$ 20,890
Tax credits	4,764	—
Valuation allowance	(23,772)	(20,890)
	$ 2,172	$ —
State		
Net operating loss carry forward	$ 747	$ 841
Valuation Allowance	(747)	(841)
	$ —	$ —

At March 31, 2022 and 2021 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.

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, 2022, Elite has a federal net operating loss carry forward of $100.8 million, which do not expire and net operating loss carry forward in state tax jurisdictions of $8.4 million some of which will begin to expire in 2022. During 2022, the Company was able to release a portion of its valuation allowance as it determined future profits will offset a portion of its valuation allowance. During 2022, the Company recorded a tax benefit of $2.2 million as a result of this change in judgment. Absent the above mentioned allowance, at March 31, 2022, the Company's federal and state income taxes due were $0.0 million and $0.4 million, respectively.

Sale of New Jersey Net Operating Loss

In April 2020, Elite Labs 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 during the year ended March 31, 2021.

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

In April 2021, Elite Labs received final approval from the New Jersey Economic Development Authority for the sale of net tax benefits of $796,860 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 $857,379, during the year ended March 31, 2022.

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, 2022, and as of the date of this Annual Report on Form 10-K, 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

On April 2, 2022, the Company entered into a loan and security agreement with East West Bank, pursuant to which the Company was granted by the Bank a term loan of $12,000,000 for a duration of five years and an asset-based Revolving Line of Credit up to $2,000,000. The Company has received the proceeds of $11,959,880 out of the term loan net of applicable professional changes, and it will be used for general working capital purpose. In return for the term loan, the Company is required to meet certain financial terms and conditions.

On April 8, 2022, the Company entered into an Asset Purchase Agreement to purchase the building located at 135-137 Ludlow Avenue in Northvale NJ and is currently in escrow. The Company has leased the entire 35,000 square feet of floor space since 2014. This property is occupied by the Company's Quality Assurance department, commercial manufacturing, packaging, and warehouse. The closing date is expected to take place in July 2022.

On June 27, 2022, the Company received notification from the US Food and Drug Administration (FDA) for the approval of the Company's Abbreviated New Drug Application (ANDA) for a generic version of Sabril® (Vigabatrin USP) 500 mg powder for solution packet. Lannett Company, Inc. has an exclusive license to market and distribute the product in the U.S. and territories. Elite will exclusively manufacture and package the product for sale for an agreed-upon transfer price. The companies will share in product net profits.

Exhibit 10.55

September 20, 2021

Lannett Company, Inc.
9000 State Road
Philadelphia, PA 19136

Re: Letter of Agreement between Elite Pharmaceuticals, Inc. and Lannett Company, Inc. ("Amphetamine Renewal Letter")

Mr. Block,

Lannett Company, Inc., a Delaware corporation located at 9000 State Road, Philadelphia, PA 19136 and/or its Affiliates ("Lannett"), and Elite Pharmaceuticals, Inc. a Nevada corporation and Elite Laboratories, Inc. a Delaware corporation (a subsidiary of Elite Pharmaceuticals, Inc.), located at 165 Ludlow Avenue, Northvale, NJ 07647 (together "Elite") are parties to a License, Supply and Distribution Agreement for Mixed Salts for Single Entity Amphetamine Tablets and Mixed Salts for Single Entity Amphetamine Extended Release Capsules effective as of March 6, 2019 ("Amphetamines Agreement"). Under the Agreement, Elite granted the right to Lannett to sell and distribute the Mixed Salts for Single Entity Amphetamine Tablets and Mixed Salts for Single Entity Amphetamine Extended Release Capsules ("Amphetamines"). All capitalized terms used without definition in this Amphetamine Renewal Letter shall have the meanings provided in the Amphetamines Agreement.

Effective as of the date of execution of this Amphetamine Renewal Letter, the parties agree to the following:

Per Section 8.1 of the Amphetamine Agreement, Elite and Lannett agree to extend the Term of the Amphetamine Agreement for two (2) years. The Initial Term is for three (3) years, from the Effective Date of March 6, 2019 until March 5, 2022. The First Renewal Term mutually agreed upon with this letter shall be from March 6, 2022 until March 5, 2024. All terms and conditions of the Amphetamine Agreement shall remain in full force and effect.

If the foregoing correctly sets forth our agreement and understanding, please execute the enclosed counterpart of this letter agreement and return the executed counterpart to the undersigned at your convenience.

- SIGNATURE PAGE FOLLOWS -

ELITE PHARMACEUTICALS, INC.

By *[/s/ Nasrat Hakim]*
Name: Nasrat Hakim
Title: CEO

Accepted and agreed as of this September 20, 2021

LANNETT COMPANY, INC.

By *[/s/ Michael Block]*
Name: Michael Block
Title: Vice President, Business Development

Exhibit 10.56

September 20, 2021

Lannett Company, Inc.
9000 State Road
Philadelphia, PA 19136

Re: Letter of Agreement between Elite Pharmaceuticals, Inc. and Lannett Company, Inc. for Dantrolene ("Dantrolene Renewal Letter")

Mr. Block,

Lannett Company, Inc., a Delaware corporation located at 9000 State Road, Philadelphia, PA 19136 and/or its Affiliates ("Lannett"), and Elite Pharmaceuticals, Inc. a Nevada corporation and Elite Laboratories, Inc. a Delaware corporation (a subsidiary of Elite Pharmaceuticals, Inc.), located at 165 Ludlow Avenue, Northvale, NJ 07647 (together "Elite") are parties to a License, Supply and Distribution Agreement for Dantrolene Capsules effective as of April 9, 2019 ("Dantrolene Agreement"). Under the Agreement, Elite granted a right to Lannett to sell and distribute the product Dantrolene Sodium ("Dantrolene"). All capitalized terms used without definition in this Dantrolene Renewal Letter shall have the meanings provided in the Dantrolene Agreement.

Effective as of the date of execution of this Letter Agreement, the parties agree to the following:

Per Section 8.1 of the Dantrolene Agreement, Elite and Lannett agree to extend the Term of the Dantrolene Agreement for two (2) years. The Initial Term is for three (3) years, from the Effective Date of April 9, 2019 until April 8, 2022. The First Renewal Term mutually agreed upon with this letter shall be from April 9, 2022 until April 8, 2024. All terms and conditions of the Dantrolene Agreement shall remain in full force and effect.

If the foregoing correctly sets forth our agreement and understanding, please execute the enclosed counterpart of this letter agreement and return the executed counterpart to the undersigned at your convenience.

- SIGNATURE PAGE FOLLOWS -

ELITE PHARMACEUTICALS, INC.

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

Accepted and agreed as of this September 20, 2021

LANNETT COMPANY, INC.

By /s/ *Michael Block*
Name: Michael Block
Title: Vice President of Business Development

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 IF PUBLICLY DISCLOSED

SUPPLY & DISTRIBUTION AGREEMENT

This Supply & Distribution Agreement ("**Agreement**") is effective as of the Effective Date by and between:

ELITE PHARMACEUTICALS, INC., with its offices located at 165 Ludlow Avenue, Northvale, New Jersey 07647, United States ("**Elite**"); and **DEXCEL LTD**., with its offices located at 1 Dexcel Street, Or Akiva 3060000, Israel ("**Dexcel**"). Elite and Dexcel are each a "**Party**" and together are the "**Parties**".

WHEREAS: Elite is a pharmaceutical company engaged in various activities including, but not limited to, the research, development, manufacture, and marketing of various drugs and pharmaceutical specialties; and

WHEREAS: Dexcel is a pharmaceutical company engaged in various activities including, but not limited to, the marketing, distribution and sale of pharmaceutical products in the Territory; and

WHEREAS: Elite is the owner of the approved ANDA for the Product in the United States and, subject to the terms and conditions set forth herein, Elite (a) agrees to grant to Dexcel the exclusive rights to use Elite's Registration Dossier and to refer to Elite's ANDA for the Product, so as to enable Dexcel to obtain one Marketing Authorization per each strength of the Product in the Territory, and to import, market, sell and distribute the Product in the Territory, and (b) supply the Product exclusively to Dexcel for sale and distribution by Dexcel in the Territory; and

WHEREAS: Subject to the terms and conditions set forth herein, Dexcel is willing (a) to receive from Elite the rights to use the Registration Dossier to obtain one Marketing Authorization per each strength to the Product, and to import, market, sell and distribute the Product in the Territory, and (b) to purchase, during the Term of this Agreement, all of its requirements for the Product exclusively from Elite in order to import, market, distribute and sell the Product in the Territory;

NOW THEREFORE, in consideration of the mutual promises and covenants set forth herein and for good and valuable consideration, the adequacy and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

1 **Definitions**

1.1 "**Act**" means the United States Federal Food, Drug and Cosmetic Act, as amended, 21 U.S.C. §301 et seq., and any related or successor federal and/or state law or regulation in the Territory pertaining to the safety, effectiveness, adulteration, misbranding, mishandling, packaging, labeling or storage of pharmaceutical ingredients and/or finished pharmaceutical products that may be applicable to the Product during the Term.

1.2 "**Affiliate**" shall mean, with regards to a Party, any entity that directly or indirectly (a) is under Control of such Party, (b) has Control over such Party, or (c) is under common Control with such Party.

1.3 "**ANDA**" shall mean Abbreviated New Drug Application A211352, approved by the FDA.

1.4 "**Anti-Corruption and Anti-Bribery Laws**" shall mean the Bribery Act 2010 (2010 Chapter 23) of the Parliament of the United Kingdom, the United States Foreign Corrupt Practices Act of 1977 ("**FCPA**"), as amended any rules or regulations thereunder, and any other applicable anti-corruption or anti-bribery statutes, laws or regulations in the applicable country specifically applicable to a Party.

1.5 "**API**" shall mean the active pharmaceutical ingredients used in the manufacturing of the Product: *Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine Saccharate*, and *Dextroamphetamine Sulfate*.

CONFIDENTIAL

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 IF PUBLICLY DISCLOSED

1.6 "**Calendar Quarter**" shall mean a three (3) month period ending on March 31, June 30, September 30 or December 31 in any calendar year.

1.7 "**Change of Control**" shall mean (i) any change, sale, merger, reorganization, or any other event or action that results in a third party acquiring: (x) all or substantially all of the business or assets of a Party relating to this Agreement, (y) Control, directly or indirectly, of such Party (and/or any corporate entity that Controls, directly or indirectly, such Party), or (ii) any assignment or delegation of, sale or transfer of a Party's rights and obligations under this Agreement (or any part hereof) to a third party. Notwithstanding anything in the immediately preceding sentence to the contrary, where the Party in question is Dexcel, any of the foregoing events or actions shall not be considered a Change of Control where any one or more of the relevant third party or parties referred to in clause (i) above is (A) Mr. Dan Oren's wife, the lineal descendants (including by adoption and stepchildren) of Mr. Oren's ancestors, and the spouses or spousal equivalents of any such lineal descendants ("**Family Member**"), or (B) any entity Controlled by Mr. Dan Oren and/or a Family Member.

1.8 "**Commercialization Date**" with respect to the Product, shall mean the date on which the Product is first sold by Dexcel to an unaffiliated Third Party in the Territory ("**Launch**").

1.9 **"Commercially Reasonable Efforts"** means carrying out obligations or tasks consistent with the efforts and reasonable good practices typically and reasonably exerted in the pharmaceutical industry for the development, manufacturing, registration, or commercialization (as applicable) of pharmaceutical products having similar market potential, profit potential or strategic value as the applicable Product in the Territory, based on conditions then prevailing.

1.10 "**Confidentiality Agreement**" shall mean the Confidentiality Agreement entered into between the Parties on the4th day of August, 2021.

1.11 "**Control**," as used with respect to any entity, shall mean (a) the possession, directly or indirectly, of more than fifty (50%) of the outstanding voting security of such entity or other voting power of such entity, (b) the right to appoint a majority of such entity's board of directors, directly or indirectly, or (c) the right to and control the management, affairs or policies of such entity, directly or indirectly.

1.12 "**Delivery**" for all Products shall occur, and title and risk of loss and damage to the Product shall pass to Dexcel, based on the Incoterms® set forth in Section 5.3.7.

1.13 "**Effective Date**" shall mean the date of the last Party to sign this Agreement.

1.14 "**Elite's IP**" shall mean all Intellectual Property Rights invented, developed, derived or acquired by Elite itself or from a Third Party relating to the manufacture, testing, and/or use of the Product (including, inter alia, the Registration File). Such information shall include, but is not limited to, any toxicological, pharmacological, analytical and clinical data, forms and formulations, control assays and specifications, methods of preparation, stability data, and any patents, which for all purposes of this Agreement shall be deemed to include certificates of invention, applications for certificates of invention, and utility models, and corresponding patents, if any, throughout the world, covering the Product, including any substitutions, extensions, reissues, re-examinations, renewals, divisions, continuations, or continuations-in-part, which Elite owns or control.

1.15 "**FDA**" shall mean the United States Food and Drug Administration, or any successor entity.

1.16 "**Floor Price**" shall mean the floor prices set forth in Appendix 1.

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 IF PUBLICLY DISCLOSED

1.17 "**Force Majeure**" shall mean an event beyond a Party's reasonable control and without such Party's fault, which prevents such Party from performing its obligations hereunder; such events may include, but not be limited to, fire, flood, earthquake, storm, hurricane or other natural disaster, war, invasion, act of foreign enemies, hostilities (regardless of whether war is declared), civil war, rebellion, revolution, insurrection, military or usurped power or confiscation, terrorist activities, pandemic or epidemic which materially disrupts normal business activities, nationalization, governmental activities relating to emergency situations, blockage, embargo, strikes or lockouts (except of the personnel of such Party). The Parties confirm that the current consequences of the SARS-CoV-2 / COVID-19 pandemic do not constitute Force Majeure events hereunder.

1.18 "**Good Manufacturing Practice**" or "**cGMP**" shall mean the applicable regulatory standards and requirements for current good manufacturing practice promulgated by the FDA under and in accordance with the Act, Parts 210 and 211 of the U.S. Code of Federal Regulations, and the guidelines and standards published by the FDA relating thereto, as may be amended from time-to-time, or any successors thereto.

1.19 "**Gross Sales**" shall mean the contractually-agreed prices for the Product between Dexcel and the four Israeli health insurance companies (Kupat Holim Clalit, Kupat Holim Maccabi, Kupat Holim Meuhedet, and Kupat Holim Leumit), the Palestinian sub-distributors, if any, and any other unaffiliated Third Parties in the Territory, multiplied by the number of Packs sold during the relevant period.

1.20 "**Health Authorities**" shall mean the relevant governmental or regulatory entity in the Territory which is authorized to approve/reject Marketing Authorization applications.

1.21 "**Intellectual Property Rights**" means all intellectual property rights, including rights in respect of the following: (i) all inventions, materials, compounds, compositions, substances and other results of whatsoever nature, whether or not patentable, and whether or not applied for registration as a patent; (ii) Know-How; (iii) patents, including all reissues, extensions, renewals, patents of addition, substitution, re-registrations, re-examinations, including all provisional applications, continuations, continuations-in-part and divisions, but excluding patents that have been invalidated or cancelled, and patent applications, (iv) copyrights, proprietary intellectual or industrial rights directly or indirectly deriving therefrom, whether registered or not; (v) trademarks, trade names, service marks and similar marks, whether registered or not; (vi) designs, whether registered or not; and (vii) any work of authorship, regardless of copyrightability and patentability, all compilations and all copyrights.

1.22 "**Know-How**" means any all technical, scientific and other know-how, information, inventions, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other intangible materials, manufacturing procedures, test procedures and purification and isolation techniques (whether or not confidential, proprietary, patented or patentable) and all tangible embodiments of any of the foregoing in written, electronic or any other form or other tangible materials that are used as research or development tools, such as assays and reference substances.

1.23 "**Lead Time**" shall mean not less than one hundred and twenty (120) days prior to the requested delivery date.

1.24 "**Livery**" shall mean the graphics and text appearing on each Pack of the Product as approved by the Health Authorities in the Territory.

1.25 "**Manufacturer**" shall mean Elite, its Affiliates, or any Third Party included as an approved manufacturer of the Product in the approved Marketing Authorization.

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 IF PUBLICLY DISCLOSED

1.26 "**Marketing Authorization**" shall mean the authorization of the Health Authorities required for the sale and marketing of the Product in each country of the Territory.

1.27 "**Minimum Order Quantity**" shall mean one (1) full batch of the relevant Product. The batch sizes are:

10mg Product – *** tablets
20mg Product – *** tablets
30mg Product – *** tablets

1.28 "**Net Sales**" means the Gross Sales of the Product during the relevant computation period (for purposes of determining whether a given sale occurs during a computation period, such Product will be considered sold as of the date of shipment to an unaffiliated Third Party customer of Dexcel in the Territory), less the following items and amounts:

a. Customs duties, value added, and similar sales related taxes, if any, imposed on the Product, to the extent applicable to such sale;

b. Amounts allowed or credited by reason of rejections, return of goods (including as a result of recalls), any retroactive price reductions or allowances or rebates, relating to the Product (including those resulting from inventory management or similar agreements with wholesalers) or quantity and/or cash discounts actually allowed or taken, whether simultaneously with the sale of the Product or at any time thereafter;

c. Amounts incurred resulting from government-mandated rebate programs, including programs mandated by any agency thereof;

d. Patient discount programs, administrative fees and chargebacks or similar price concessions related to the sale of the Product;

e. Any bad debts due;

f. Any withholding tax amounts that were actually deducted from the gross sales of the Product by the Third Party customer provided that a tax return or credit regarding the same was not credited;

g. Freight, postage, shipping and applicable insurance charges, to the extent same are separately itemized on invoices and actually paid; and

h. To the extent agreed by the Parties in writing, such agreement not to be unreasonably withheld, any other specifically identifiable appropriate allowances or deductions as may be similar to those deductions listed above.

1.29 "**Net Selling Price**" shall mean, for each relevant computation period during the Term, the total Net Sales *divided by* the number of Packs sold during such Calendar Quarter; provided that the Net Selling Price per Pack shall never be lower than the Floor Price per Pack.

1.30 "**Non-Obvious Defect**" shall mean any instance where a batch of a Product fails to conform to the Specifications or is otherwise defective or fails to conform to the Required Standards, and such failure would not be discoverable upon reasonable physical inspection or standard testing.

1.31 "**Obvious Defect**" shall mean any instance where a batch of the Product fails to conform to the Specifications or is otherwise defective or fails to conform to the Required Standards, and such failure is discoverable upon reasonable physical inspection or standard testing of such Product upon receipt by Dexcel in accordance with its standard operating procedures.

1.32 "**Pack**" shall mean a bottle containing thirty (30) tablets of the Product in the Livery. Each Pack will include the batch number, the expiry date, and a patient information leaflet ("**PIL**").

1.33 "**Packaging**" shall mean all primary containers (including bottles), cartons, and the PIL, and all shipping cases or any other like matter used in packaging and/or accompanying the Product (including, without limitation, electronic files).

1.34 "**Person**" shall mean an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority or any other form of entity not specifically listed herein.

1.35 "**Product**" shall mean Dextroamphetamine and Amphetamine combinations containing Amphetamine Aspartate, Amphetamine Sulfate, Dextroamphetamine Saccharate, and Dextroamphetamine Sulfate, in the strengths and dosage form approved by the FDA in the ANDA, and as described in Appendix 1.

1.36 "**Quality Agreement**" shall mean the agreement concerning the manufacturing, packaging and quality control relating to the Product, to be signed by Elite and Dexcel within ninety (90) days following the Effective Date in a form substantially similar to the form set forth in Appendix 2 hereof.

1.37 "**Recall**" shall mean a voluntary or governmental action to quarantine, stop-sale or withdraw the Product from the market in the Territory.

1.38 "**Recall Costs**" shall have the meaning set forth in Section 6.5.3 herein.

1.39 "**Registration File**" shall mean all written pertinent and necessary information regarding the Product (full approved consolidated dossier modules 2-5), which has been approved by the FDA (ANDA 211352), and that shall include, *inter alia*:

- Elite's cGMP certificate;
- Elite's manufacturing license;
- Elite's QA audits of the API manufacturers;
- Any bio-studies and/or clinical studies available to Elite on the Effective Date hereof (each, a "**BE Study**");
- A current, valid US Free Sale Certificate or US Certificate of Pharmaceutical Product ("**CPP**") for the marketed Product;
- Certificate of compliance with good laboratory practice principles for the laboratories conducting the analytical tests for the BE Study. The certificate should be from a suitable authority in a recognized country (US, Canada etc.);
- Dissolution data of the reference product registered in Israel (Dexcel shall purchase and provide the samples of the reference product registered in Israel to Elite, at Dexcel's cost; Elite shall perform the required studies, at Dexcel's cost), (see **Appendix 4).**

1.40 "**Representative**" shall mean a Party's Affiliates, and its and their agents, professional advisors, attorneys, directors, officers, and employees.

1.41 "**Required Standards**" shall have the meaning set forth in Section 6.1 herein.

1.42 "**Safety Data Exchange Agreement**" or "**SDEA**" shall mean the agreement to be entered into between the Parties within ninety (90) days following the Effective Date in a form substantially similar to the form set forth in Appendix 3 hereof, which generally governs the Parties' responsibilities related to the safety data and regulatory reporting requirements for the Products.

1.43 "**Specifications**" shall mean the pharmaco-chemical, manufacturing, stability and other specifications of the Product, as defined in the Marketing Authorization and subject to change from time to time as reasonably required to meet any requirements of the Health Authorities in the Territory.

1.44 "**Term**" shall mean the Initial and any Renewal Term, as defined in Section 11.1 herein.

1.45 "**Territory**" shall mean the State of Israel (including all portions of the West Bank under full Israeli control) and the Palestinian Authority (which shall include the portions of the West Bank under Palestinian control and Gaza).

1.46 "**Third Party**" means any Person other than the Parties hereto or their respective Affiliates.

1.47 "**US DEA**" shall mean the United States Drug Enforcement Agency or any successor entity.

1.48 "**Working Day**" shall mean a day, excluding a Friday, Saturday or Sunday, on which banks are open for business, and, for the avoidance of doubt, excluding statutory holidays in the United States and the Territory.

2 Grant of Exclusive Rights

2.1 Subject to Dexcel fulfilling its obligations in accordance with the terms and conditions of this Agreement, Elite hereby grants to Dexcel the exclusive right, for and during the Term, to (a) use Elite's approved Registration File and (b) to allow Dexcel to refer to Elite's ANDA for the Product to enable Dexcel to obtain one Marketing Authorization for each strength of the Product in the Territory and to import into, market, sell and distribute the Product in the Territory.

2.2 During the Term of the Agreement and subject to the terms and conditions of this Agreement, Dexcel may designate the following sub-distributors; provided further that Dexcel may designate other sub-distributors in the Territory with the prior written consent of Elite (not to be unreasonably withheld):

a. Within Israel and Israeli-controlled areas: **Chemipal Ltd.**, 44 Giborei Israel Street, Poleg Industrial Zone, Netanya 4250432, Israel;

b. In the areas under Palestinian Authority control: **The Al-Ram Drugstore**, Qalonia St., Jerusalem

3 Regulatory Affairs

3.1 Elite shall transmit a complete copy of the Registration File, and such other information included in the ANDA as Dexcel may reasonable request, to Dexcel using Commercially

Reasonable Efforts to provide within fourteen (14) Working Days after the Effective Date hereof.

3.2 Upon the receipt of the complete Registration File, Dexcel shall audit and review such Registration File to determine its suitability for submission to the Health Authorities in order to receive a Marketing Authorization for the Product in the Territory. In the event that, in Dexcel's sole discretion, additional information is required in order to submit the Registration File, Dexcel shall request such information from Elite in writing. Elite shall provide Dexcel with such information reasonably in its possession using Commercially Reasonable Efforts within fourteen (14) Working Days from receiving Dexcel's written request. In the event that, in Dexcel's sole and absolute discretion, such additional information provided to Dexcel is still insufficient to submit the Registration File, such additional information is not reasonably in Elite's possession, or in the event that Dexcel's audit has determined that the Registration File is not and cannot be made suitable for submission, Dexcel may terminate this Agreement by providing Elite with a written notification of such decision with an immediate effect.

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 IF PUBLICLY DISCLOSED

3.3 Following Dexcel's determination that the Registration File is suitable for submission as provided in Section 3.2, Dexcel shall use Commercially Reasonable Efforts to submit the Registration File to the Health Authorities for the purpose of obtaining a Marketing Authorization in the Territory within six (6) months after the receipt of the complete Registration File.

3.4 Following Dexcel's submission of the application for the Marketing Authorization to the Health Authorities in the Territory, Elite will use Commercially Reasonable Efforts to assist Dexcel in addressing any issues raised by the Health Authorities and replying to the assessment or deficiency letter issued by the Health Authority in relation to the application for the Marketing Authorization in the Territory. Elite shall use Commercially Reasonable Efforts to provide Dexcel with responses to any such letter, questions or issues requested or raised by the Health Authorities within the timeframe as required by the Health Authorities, but Elite shall not be obliged to conduct any new or additional study for any such purpose.

3.5 Variations

3.5.1 Elite will notify Dexcel in writing of any changes which will affect the Registration File and/or Marketing Authorization for the Product in the Territory, and Dexcel will notify Elite in writing of any changes requested by Dexcel or required by the Health Authorities which will affect the Registration File and the Marketing Authorization for the Product in the Territory (each such change being hereinafter a "**Variation**"). Elite shall provide all technical or other documentation reasonably necessary for Dexcel to submit the Variation for approval to the Health Authorities in the Territory. Elite agrees to use Commercially Reasonable Efforts to support and assist Dexcel as may be necessary for the Variation to be approved.

3.5.2 The costs of any Variation shall be borne as follows:

a. For any Variation requested or required by Elite, Elite shall be responsible for all costs and fees in the Territory;

b. For any Variation (i) required by the Health Authorities in the Territory or (ii) requested by Dexcel and accepted by Elite, Dexcel shall bear all costs and fees in the Territory.

3.5.3 Dexcel shall not have any obligation to accept any Variation to the Registration File if (a) the Launch or the continuous supply of the Product in the Territory may be affected thereby or (b) if there will be a material negative impact on the commercialization of the Product in the Territory (unless Elite can reasonably show that failing to implement the change makes the continuity of Product supply impracticable).

3.5.4 Variations shall only be implemented after successful completion of the variation procedures in the Territory. Elite shall continue to supply the Product in conformance with the approved Required Standards until any Variation is approved by the relevant health authorities.

3.6 During the Term, Elite undertakes to timely inform Dexcel in writing of any material information concerning the Registration File and to provide Dexcel with any related documents, provided that such related document is reasonably in Elite's possession, free of charge, including (a) additional three-year ICH stability studies and validation reports on industrial batches in order to satisfy regulatory requirements, and (b) changes to the Product labeling and/or the PIL imposed by the FDA or any other regulatory authority.

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 IF PUBLICLY DISCLOSED

4 **Marketing Obligations**

4.1 Dexcel shall be solely responsible, at its own expense, for all activities directly or indirectly related to the promotion, marketing, sale and distribution of the Product throughout the Territory, including, *inter alia*, the importation into, the warehousing, storage, collection, shipping, order fulfillment, and invoicing of the Product.

4.2 Dexcel shall at all times maintain inventories of the Product, pending sale, in facilities that are properly equipped (including any required temperature and humidity controls) and in accordance with the Health Authorities' regulations for the storage of pharmaceutical products and the conditions appearing in the Marketing Authorization. Elite shall provide Dexcel with all relevant information in its possession relating to said storage regulations and conditions.

4.3 Dexcel shall not, without the prior written permission of Elite:

4.3.1 during the Term of this Agreement, order the Product from any Third Party;

4.3.2 use the Registration File or the Marketing Authorization for any purpose unrelated to this Agreement;

4.3.3 use the Registration File and any information provided pursuant to the provisions hereof for the purpose of applying for any Marketing Authorization for the Product in countries outside the Territory and/or additional Marketing Authorizations and/or duplicate Marketing Authorizations in the Territory;

4.3.4 promote, market, sell or distribute the Product to customers having their place of business, or establish Product distribution channels, outside the Territory; or

4.3.5 maintain any distribution depot for the Product outside the Territory.

5 **Purchase/Supply of Product**

5.1 Subject to the terms and conditions of this Agreement, throughout the Term, Elite shall manufacture and supply all Product ordered by Dexcel for sale and distribution in the Territory.

5.2 Packaging; Artwork

5.2.1 Elite shall acquire all Labeling and Packaging materials for the Products supplied to Dexcel under this Agreement, such Labeling and Packaging materials to be in accordance with the requirements of the Marketing Authorization.

5.2.2 Dexcel shall be responsible for providing Elite with the initial artwork for the Livery, which shall include Dexcel's trademarks and logos, address, and Label format, not less than one hundred and twenty (120) days before the requested delivery date for the Launch of the Product. Elite shall provide Dexcel with printer's proofs for its review of such initial artwork and text. Dexcel shall promptly provide Elite with any necessary corrections thereto and/or notify Elite in writing of its approval of such proofs, such written approval to be maintained by Elite.

5.2.3 Should Dexcel desire or be required by the Health Authorities to make any change to such Label or Labeling, Dexcel shall promptly supply approved new artwork and related materials to Elite not less than one hundred and twenty (120) days before the next requested delivery date for such Product. Elite shall be responsible for the updating of all artwork and text associated with such change and for providing Dexcel with printer's proofs for its review. Dexcel shall promptly provide Elite with any necessary corrections thereto and/or notify Elite in writing of its approval of such proofs, such written approval to be maintained by Elite. Dexcel shall bear the costs for the disposal by Elite of any Packaging materials bearing the previous Artwork but not exceeding the costs for Packaging materials purchased by Elite for the next following six (6) months of the current forecast; provided that, if Elite requests changes to the Artwork, Elite shall assume all costs of such change (which will not be implemented until any required Variation is approved).

5.2.4 Dexcel shall be responsible for ensuring the accuracy of all information contained on the Packaging, Labels and Labeling for the Product and for compliance with the Marketing Authorization.

5.3 Forecasts, Orders and Supply

5.3.1 Dexcel shall provide Elite, two (2) times each calendar year, with a rolling, non-binding and good faith forecast of its Product requirements (by SKU), for each of the following six (6) months.

5.3.2 Dexcel shall provide Elite with written purchase orders in a form reasonably acceptable to Elite and which shall specify at least the following: a description of the Product ordered, the quantity ordered, the relevant Floor Price, the place of delivery and the required delivery date thereof; provided that (a) all purchase orders shall meet the Minimum Order Quantity and (b) the required delivery date shall not be less than the Lead Time. Notwithstanding the aforesaid, in the event of any delay of the obtainment by Elite of an export permit from the US DEA, the Lead Time will be extended by an additional thirty (30) days; provided, however, that such delay is not derived from any negligent act or omission of Elite.

5.3.3 No purchase order shall be binding on Elite unless accepted in writing by Elite. Elite shall have a maximum of ten (10) Working Days from receipt of the purchase order whether to accept or reject the purchase order. Once the order is confirmed by Elite (which shall not unreasonably reject or delay such acceptance), it shall be treated as "**Confirmed Order**," the requested delivery date shall be the "**Confirmed Delivery Date,**" and the Confirmed Order shall be binding on both Parties.

5.3.4 Elite shall use its best commercial efforts to deliver the Confirmed Orders to Dexcel in full on the Confirmed Delivery Date. Each shipment shall be accompanied by certificates of analysis, certificates of compliance and such information required to be included pursuant to the Quality Agreement, as well as any other documentation required by the relevant authorities for the export of the Product from the United States and the import of the Product into the Territory.

5.3.5 Before each delivery, Elite will provide Dexcel with a packing list and the invoice for the Product, by email to *Fany.Harry@dexcel.com* and to *Tammy.Hod@dexcel.com.*

a. Elite shall obtain and maintain all permits, authorizations, consents, and approvals (including any special exemptions or approvals), including any release from any quotas or other limitations, if needed, required to enable it to export the Product from the United States. Elite will send a scanned copy of its export permit to Dexcel prior to shipment of the Product. Dexcel shall receive the original export permit by courier.

b. Dexcel obtain the required import license from the relevant regulatory authority in the Territory, using such invoice and packing list. As soon as such license is granted to Dexcel, Dexcel will send an original copy of the license to Elite.

5.3.6 Elite will provide Dexcel's forwarder with all documentation regarding the Product reasonably requested by Dexcel, as well as that required by the Quality Agreement.

5.3.7 All Product shall be Delivered to Dexcel Incoterms® 2020 FCA Elite's warehouse, 135 Ludlow Avenue, Northvale, New Jersey USA and/or such other location reasonably designated by Elite and approved in advance by Dexcel. Elite shall be responsible for obtaining the export permit for the export of the Product from the United States.

5.3.8 Elite will be responsible for Packaging the Product for appropriate export Product packing, marking and labelling for shipment (by air or sea, as requested by Dexcel), and including data loggers, thermal blankets or other special packaging, if requested and provided by Dexcel and as provided in the Quality Agreement (the cost of which will be paid by Dexcel in accordance with Appendix 1).

5.3.9 Nothing in a purchase order, written order confirmation or acceptance, delivery acceptance or any other document created or sent by either Party which adds additional or conflicting terms and conditions to those contained in this Agreement shall be binding on the Parties. The terms of supply of the Product shall be governed solely by the terms of this Agreement.

5.4 Product Price

5.4.1 Elite shall provide Dexcel with an invoice at the relevant Product Floor Price at Delivery. Dexcel shall pay Elite the total invoiced amount set out in such invoice to Elite in U.S. dollars by direct bank transfer to the following bank account designated by Elite not more than thirty (30) days following the date of the invoice, with each Party responsible for its own bank's charges:

Bank: ***
Routing Number: ***
Account Number: ***
Swift: ***

5.4.2 Not more than thirty (30) days following the end of each Calendar Quarter during the Term, commencing with the end of the Calendar Quarter during which the Commercialization Date occurred, Dexcel shall pay Elite an amount equal to *** *percent (***%) of the Net Selling Price derived from all sales of the Product in the Territory by Dexcel during such Calendar Quarter, less the total Floor Price paid for such Product, and multiplied by the number of Product Packs sold*, and shall further include a report in an agreed format setting forth the calculation of the Net Selling Price during such Calendar Quarter.

5.4.3 Upon Elite's request and not more frequently than annually, Dexcel will provide Elite with a written confirmation by Dexcel's external auditors (currently, BDO) with respect to Dexcel's Net Selling Price calculations and the amounts payable under this Agreement.

5.4.4 Dexcel shall only use the payment route and payment information set forth in this Section 5.4 for payments to Elite. Dexcel shall only accept changes to such instructions by written Notice from Elite.

5.5 Supply Failure

5.5.1 Elite will promptly notify Dexcel in writing in the event that Elite is unable, or anticipates that it will be unable, to supply the Product on the Confirmed Delivery Date (each, a "**Supply Failure**"), together with an estimate of the revised collection date of the Product. In such event, the Parties shall determine a reasonable course of action (including, without limitation, agreeing to the revised collection date ("**Revised Delivery Date**")) to rectify the matter as soon as possible; provided, however, that in the event that Elite fails to remedy such Supply Failure by the Revised Delivery Date and the actual delivery date is more than thirty (30) Working Days from the Confirmed Delivery Date, then, unless such Supply Failure is caused by a Force Majeure event or due to failure by Dexcel to secure an export permit for the shipment, Dexcel shall be entitled, at its reasonable discretion, to: (i) suspend payment of any invoices then due, and which may subsequently become due, to Elite until the delay has been remedied; and/or (ii) to postpone, cancel or modify the relevant Confirmed Order with respect to the quantities that Elite could not deliver. In addition, any penalty actually paid by Dexcel to a Third Party customer as a result of the Supply Failure shall be reimbursed by Elite unless the delay is attributable to (i) action or controls imposed by the DEA or other governmental agency that that do not result from Elite's negligence, gross negligence or willful misconduct or (ii) demonstrable raw material shortages that are beyond Elite's control. A Supply Failure shall not apply to the first lot of each strength ordered and delivered under this Agreement.

5.5.2 Except for Dexcel's right of termination provided in Section 11.2.4 and its rights to indemnification under Section 10.1 for Third Party Claims, the remedies under Section 5.5.1 shall be the sole and exclusive remedy available to Dexcel under the Agreement with respect to such Supply Failure.

6 **Quality; Recalls**

6.1 Elite warrants and represents that (a) the Product manufactured hereunder shall conform with the Specifications; (b) the Product shall be manufactured in accordance with all applicable laws and regulations in the country of manufacture, cGMP, the Quality Agreement, and the Registration File; (c) to Elite's knowledge the manufacture of the Product does not infringe the Intellectual Property Rights of any Person in the country where the Product is manufactured; (d) all the Product supplied under this Agreement will, upon Delivery, have a shelf life which is at least 90% of the longest registered shelf life for the Product in the Territory (as of the Effective Date, the shelf life of the Product is 24 months); (e) for the Term of this Agreement, it will maintain any license or clearance in respect of cGMP granted to it under any scheme in the country of manufacture of the Product, and will provide Dexcel with evidence of any such licenses or clearances when requested by Dexcel to do so; and (f) the Product will be free of all liens and encumbrances at the time of Delivery (collectively, the "**Required Standards**").

6.2 Within twenty (20) days of receipt the Product at Dexcel's warehouse in Israel, Dexcel shall perform appropriate samplings and inspections for the purpose of determining whether the Product meets the Specifications and contains no Obvious Defects. Dexcel shall be deemed to have accepted any Product which has not been refused within such twenty (20) day period; provided that such implicit acceptance shall not be applicable to Non-Obvious Defects of the Product pursuant to Section 6.3 hereof, below. In the event that Dexcel wishes to refuse acceptance, Dexcel shall, within such thirty (30) day period, inform Elite in writing of its rejection and its reasons for such rejection.

6.2.1 If Elite agrees with Dexcel's rejection of the defective Product, Elite shall replace the defective Product as soon as reasonably practicable.

6.2.2 If Elite and Dexcel do not agree upon the rejection of Product, then the matter shall be referred to a specialized independent laboratory reasonably acceptable to both Parties for the purpose of final analysis. Any determination by any such laboratory shall be binding upon both Parties. The cost of any such testing and evaluation by an independent Third Party shall be borne by Dexcel if it is determined that the Product conforms to the requirements of this Agreement and by Elite if determined that it does not. If such laboratory determines that the Product does not conform to the requirements of this Agreement, Elite shall replace the defective Product as soon as practicable and shall bear and reimburse Dexcel for its actual costs incurred.

6.3 As soon as either Party becomes aware of a Non-Obvious Defect, it shall promptly give notice of such to the other Party. In the event that the Product is found to contain a Non-Obvious Defect, the Product shall be deemed rejected pursuant to Section 6.2, above, as of the date of such notice. The rights and obligations of the Parties with respect to the rejected Product shall thereafter be governed by the testing and replacement provisions of Section 6.2, subject to the Non-Obvious Defect not being a result of negligence after Delivery, following which the Product is under Dexcel' responsibility.

6.4 Inspections

6.4.1 Dexcel and/or any representatives authorized by Dexcel, upon approval by Elite (which shall not be unreasonably withheld or delayed) and under reasonable confidentiality requirements, shall have the right, at Dexcel's sole expense, to audit Elite's facilities involved in the manufacturing, packaging, testing, and release of the Product for compliance with cGMP, on reasonable notice, during normal business hours, and not more than once in each calendar year. Such audit shall include the right to inspect documents and records relevant to the manufacture of the Product. Elite shall as promptly as practical respond to issues raised by Dexcel to Elite in writing as a result of the audit. Elite shall take such actions as promptly as practical, at its expense, as may be reasonably necessary to address and correct any such issues.

6.4.2 Elite shall permit the FDA and the Health Authorities to inspect Elite's facilities involved in the manufacturing, packaging, testing and release of the Product when so required by the FDA or such Health Authorities, and shall provide reasonable assistance for such purpose. Elite shall, as soon as reasonably possible, notify Dexcel of any notice it receives from the FDA or the Health Authorities requesting an inspection of Elite's facilities in relation to the Product.

6.5 Recalls

6.5.1 Each Party shall promptly provide the other Party with copies of correspondence to or from the FDA and/or the Health Authorities relating to any corrective action or Recall in the Territory concerning the Product.

6.5.2 If there is a Recall of the Product in the Territory, then Dexcel agrees to stop shipping Recalled lots immediately after Dexcel receives written notification of such Recall from Elite. The Parties shall cooperate fully in any such Recall, including any notice, restriction, change, corrective act or market action or any Product change requested or ordered by the Health Authorities or any other governmental agency having jurisdiction in the Territory.

6.5.3 In the event of a Recall, it is agreed and understood that any Recall Costs (defined below) shall be borne as follows:

a. if the Recall arises from Dexcel's acts or omissions in the marketing, distribution, storage or handling of the Product following Delivery, the costs and expenses related to the Recall, including, but not limited to (a) reasonable fees of any experts and/or attorneys that may be utilized by either Party, (b) government fines or penalties related to such Recall, quarantine or stop-sale, (c) costs and expenses for notification, (d) transportation, shipping and distribution expenses attributable to the Product subject to Recall, (e) cost of all replacement Product and its distribution, (f) the Transfer Price for all Product in Dexcel's inventory subject to Recall, and (g) and third party recall expenses (collectively, "**Recall Costs**") shall be borne solely by Dexcel; and

b. if the Recall arises from the development, manufacturing, testing, handling, storage, or Packaging of any Product (including but not limited to any latent Product

defects) prior to delivery to Dexcel, the Recall Costs shall be borne solely by Elite.

6.5.4 If there is any dispute concerning whether Dexcel or Elite is responsible for the Recall Costs, such dispute will be referred for decision to an independent expert appointed by agreement of the Parties with the costs borne equally between them. The decision of such independent expert must be in writing and, except for manifest error on the face of the decision, will be binding on both Parties.

6.5.5 All payments for undisputed Recall Costs assessed pursuant to this Section 6.5 are due and payable within thirty (30) days of being invoiced by Elite or Dexcel, as applicable.

7 **Warranties**

7.1 Each Party hereby represents and warrants to the other Party:

7.1.1 Such Party is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is incorporated.

7.1.2 Such Party (a) has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder, and (b) has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms.

7.1.3 All necessary consents, approvals and authorizations of all governmental authorities and other persons required to be obtained by such Party in connection with its performance of this Agreement have been obtained.

7.1.4 Such Party, on its own behalf and on behalf of its Affiliates (including any of their officers, directors, or employees) has in place adequate procedures to prohibit, directly or indirectly, the use any corporate funds for unlawful contributions, gifts, entertainment or other unlawful expenses relating to political activity, nor has such Party, its Affiliates and their officers, directors or employees made any unlawful payment to foreign or domestic government officials or employees or made any bribe, rebate, payoff, influence payment, kickback or other similar unlawful payment, or taken any action which would cause it to be in violation of or taken any action which would cause it to be in violation of any Anti-Corruption and Anti-Bribery Laws.

7.1.5 There is no pending or, to such Party's knowledge, threatened claims, charges, investigations, violations, settlements, civil or criminal enforcement actions, lawsuits, or other court actions against such Party or any of its Affiliates with respect to any Anti-Corruption and Anti-Bribery Laws.

7.1.6 To such Party's knowledge, there are no actions, conditions or circumstances pertaining to such Party's activities that may give rise to any future claims, charges, investigations, violations, settlements, civil or criminal actions, lawsuits, or other court actions under any Anti-Corruption and Anti-Bribery Laws.

8 **Confidentiality**

8.1 The terms of the Confidentiality Agreement are incorporated herein by reference and will apply to any and all discussions and Confidential Information exchanged by the Parties and/or made available by a Party or its Affiliates to the other Party or its Affiliates in connection with or under this Agreement, in any form, whether oral, written, electronic or otherwise (whether or not marked "confidential").

8.2 For the purposes of this Agreement, "**Confidential Information**" shall have the same meaning as that set forth in the Confidentiality Agreement and shall be deemed to include the terms of this Agreement; and the "**Agreed Purpose**" set forth in the Confidentiality Agreement shall be deemed to include the Parties' respective activities hereunder and the implementation of this Agreement.

8.3 This Article 8 shall survive the Term for a period of five (5) years.

9 **Intellectual Property Rights; Suspension; Third Party Actions**

9.1 Elite warrants that, as of the Effective Date: (a) to its knowledge Elite is not aware that the manufacture of the Product as conducted for Elite as of the Effective Date infringes, misappropriates, or violates any intellectual property rights of any Third Party in the country where the Product are manufactured, (b) to its knowledge Elite is not aware that the API used in the manufacture of the Product infringes, misappropriates, or violates any intellectual property rights of any Third Party in the country where the API and/or the Product are manufactured, (c) to its knowledge the development of the Product was undertaken by Elite for its own account, and Elite owns or has the right to provide all relevant rights granted to Dexcel hereunder, (d) to its knowledge it has not received any communications, in writing and/or oral, alleging any infringement, misappropriation, or violation by the manufacture or sale of Product (including any claim that Elite must license or refrain from using any intellectual property rights of any third party) in the Territory or the place of manufacturing of the API or Product, and (e) to its knowledge it has not received any notice that any proceedings have been instituted or are pending which challenge any rights of Elite with respect to the Product or Elite's Product intellectual property in the Territory or the place of manufacturing of the API or Product.

9.2 Elite shall provide Dexcel with all reasonable assistance and co-operation which is reasonably requested by Dexcel in order for Dexcel to undertake any due diligence review in respect of Intellectual Property Rights subsisting in the Product; provided that Elite has and shall not to its knowledge willfully fail or refuse to disclose to Dexcel any relevant information relating to the Product and any Intellectual Property Rights relating to the Product (unless such disclosure is prevented or restricted by applicable laws, regulations or any duty of confidentiality).

9.3 Subject to Elite's full compliance with the terms of Section 9.2, Dexcel hereby undertakes the responsibility of the final verification of the patents and the status of Intellectual Property Rights for the Product in the Territory and is fully responsible and liable for possible infringements of any Third Party's Intellectual Property Rights which result from the application for Marketing Authorization for the Product in the Territory, the importation of the Product into the Territory, and the promotion, marketing, distribution and sale of the Product and all other activities as envisaged under this Agreement in the Territory.

9.4 Suspension.

9.4.1 If, because of any administrative, arbitral or court decision, or because in a Party's reasonable opinion in reference to potential risks related to intellectual property issues, such Party must refrain from launching, continuing to sell and market the Product in the Territory, or from manufacturing and supplying the Product for sale in the

Territory (as applicable), such Party shall have the right to suspend the launching, sale, manufacturing or the supplying of the Product under this Agreement to the extent that and only for so long as this suspension is reasonably deemed necessary or advisable by that Party to prevent or limit actual or possible damages, liabilities or injuries.

9.4.2 Such suspension shall be deemed temporary and shall not give a right to either Party to terminate this Agreement nor shall it be considered to have caused a termination of this Agreement, unless the Parties agree in writing that termination of this Agreement is reasonably necessary to prevent or limit such actual or possible damages, liabilities or injuries, and provided further that if any such suspension lasts for 180 days or more, Elite may terminate the Agreement on written notice.

9.5 Third Party Actions. Each Party threatened with suit or sued by a Third Party for intellectual property infringement because of activities in connection with the Product shall promptly notify the other Party in writing of such event. In case of an actual suit based on the commercialization of the Product in the Territory, Dexcel shall have the right (but not the obligation) to defend such suit in the Territory to the extent that it relates to commercialization of the Product, and shall have the right to settle with such Third Party (provided that Elite shall in any event have the right to defend itself against any claims or allegations at its own cost). Each Party agrees that it shall reasonably cooperate with the other Party in defending the suit, even if not a party to the suit.

10 **Indemnification; Insurance**

10.1 Subject to the provisions of this Article 10, Elite agrees to defend, indemnify and hold Dexcel, its Affiliates and its and their officers, directors, shareholders, employees, agents, and other representatives ("**Dexcel Indemnitees**") harmless from and against any and all claims, actions, causes of action, assessments, losses, damages, injuries, liabilities, costs and expenses (including, without limitation, reasonable attorneys' fees and expenses) of the Dexcel Indemnitees, filed, raised, initiated or made by any government authority and/or third party (collectively, "**Claims**") arising from (i) any material breach by Elite of its representations, warranties, covenants, agreements or obligations under this Agreement, the Quality Agreement or the SDEA; (ii) negligence or willful misconduct on the part of Elite, its Affiliates or any of their agents, employees, distributors or subcontractors; (iii) any product liability claims, whether arising out of warranty, negligence, strict liability (including manufacturing, storage in Elite's warehouse or that of any Affiliate or Manufacturer, or any other product or quality based claims in relation to the Product), and (iv) any claim for infringement of any Third Party Intellectual Property Rights in the country where the Product is manufactured, in each case except to the extent that any such damages give rise to an indemnification claim by Elite under Section 10.2 hereinafter.

10.2 Subject to the provisions of this Article 10, Dexcel agrees to defend, indemnify and hold harmless Elite and its Affiliates, and their respective shareholders, officers, directors, employees and agents ("**Elite Indemnitees**"), from and against any Claims by Third Parties and/or government organizations arising from: (i) the handling, possession, storing, labeling, use, marketing, distribution, promotion or sale of any Product by Dexcel, its Affiliates, or any of their distributors, employees, or sub-distributors following Delivery of the Product to Dexcel; (ii) any material breach by Dexcel of its representations, warranties, covenants, agreements or obligations under this Agreement, the Quality Agreement or the SDEA; and (iii) negligence or willful misconduct on the part of Dexcel, its Affiliates or any of their agents, employees, distributors or subcontractors; or (iv) any claim for infringement of any third party intellectual property in the Territory (provided that the information concerning the Product that was provided by Elite is in full and accurate and subject to Elite's compliance with the terms of Section 9.1.2 hereinabove), except to the extent that any such damages give rise to an indemnification claim by Dexcel under Section 10.1 hereinabove.

10.3 Unless and to the extent otherwise specifically provided herein, in the event that the Dexcel Indemnitees or the Elite Indemnitees intend to claim indemnification under this Article 10 with respect to any Claim (such one of the Dexcel Indemnitees or the Elite Indemnitees being herein referred to as the "**Indemnitee**") shall promptly notify the other Party ("**Indemnitor**") of a Claim in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall assume the defense thereof with counsel of its own choosing; additionally, an Indemnitee shall have the right to retain its own counsel with reasonable and documented fees and expenses to be paid by the Indemnitor.

a. An Indemnitee shall not be entitled to indemnification under this Section 10.3 if any settlement or compromise of such Claim is concluded by the Indemnitee without the consent of the Indemnitor, which consent shall not be unreasonably withheld or delayed.

b. An Indemnitor shall not enter into any settlement or compromise of any Claim or consent to the entry of any judgment or other order with respect to any Claim which does not contain, as a part thereof, an unconditional release of the Indemnitee for liability for all loss, cost or damage that may arise from such Claim or which contains any injunctive or other non-monetary relief that might in any way interfere with the future conduct of business by the Indemnitee.

c. Any Indemnitee, and its employees, agents and representatives, shall cooperate fully with the Indemnitor and its legal representatives, at the Indemnitor's expense for out-of-pocket costs, in the investigation of any Claim covered by these indemnification provisions

10.4 Any breach of warranty, representation or covenant by a Party shall constitute a breach of contract.

10.5 Each Party shall, during the Term and for three (3) years after termination or expiration of this Agreement, obtain and maintain, at its own cost and expense from a qualified insurance company, product liability insurance in accordance with the following provisions:

10.5.1 Elite's Insurance: Elite's insurance shall provide protection against any and all claims, demands, and causes of action arising out of any defects, alleged or otherwise, of the Product(s), or their use, design, manufacture, Packaging, testing, release, or any material (including API) incorporated in the Product(s). The amount of coverage shall be a minimum of Ten Million US Dollars (US$10,000,000) per occurrence and in the aggregate and shall be provided from an insurance company qualified to write global product liability coverage. Elite shall name Dexcel as an additional insured on its insurance policies maintained pursuant to this Section 10.5.

10.5.2 Dexcel's Insurance: Dexcel's insurance policy shall provide protection against any and all claims, demands, and causes of action arising out of any defects, alleged or otherwise, of the Product(s) following Delivery to Dexcel. The amount of coverage shall be a minimum of Ten Million US Dollars (US$10,000,000) per occurrence and in the aggregate and shall be provided from an insurance company qualified to write product liability coverage in the Territory.

10.5.3 Certificate. Each Party agrees to furnish the other Party with a certificate of insurance evidencing such insurance coverage (at the execution of this Agreement and at each anniversary hereof) and shall provide the other Party with a thirty (30) day written notice of cancellation or non-renewal of such coverage.

11 **Term and Termination**

11.1 Unless terminated earlier in accordance with the provisions of this Article 11, this Agreement shall have an initial term of three (3) years from the Commercialization Date ("Initial Term"); provided, however, that if, during the third (3rd) year of the Initial Term, Dexcel sells at least 65,000 bottles of the Product (in any combination of strengths), coupled with a positive Net Selling Price which shall never be lower than the Floor Price derived from all sales of the Product in the Territory by Dexcel in such year, then the Initial Term shall automatically be extended for an additional (4th) year. In the event that, in the fourth (4th) year of the Initial Term, Dexcel sells at least 65,000 bottles of the Product (in any combination of strengths), coupled with a positive Net Selling Price which shall never be lower than the Floor Price derived from all sales of the Product in the Territory by Dexcel in such year, then the Initial Term shall automatically be extended for an additional (5th) year. At any time during the Initial Term (including as extended for a 4th or 5th year, as provided above), the Parties may extend the Initial Term or renew the Agreement following the end of the Initial Term (each, a "Renewal Term"), by written agreement (the Initial Term and all Renewal Terms being herein referred to as the "Term").

11.2 This Agreement may be terminated prior to the end of the Term:

11.2.1 by either Party, effective immediately with written notice, if (i) a receiver, trustee, or liquidator of the other Party is appointed for any of properties or assets of the other Party; (ii) the other Party makes a general assignment for the benefit of its creditors; (iii) the other Party files a petition under the relevant statute for the bankruptcy, reorganization of the other Party or any arrangement with its creditors or readjustment of its debt, or its dissolution or liquidation, or such a petition is filed against the other Party and is not dismissed within sixty (60) days thereafter; or (iv) the other Party ceases doing business or commences dissolution or liquidation proceedings;

11.2.2 in the event that a Party is in material breach of a term of this Agreement, the SDEA, or the Quality Agreement and fails to remedy such breach (in case of a breach which is possible to be remedied) within thirty (30) calendar days from receipt of written notification (mentioning the causes and consequences in details) of same, the non-breaching Party shall have the right to terminate this Agreement upon provision of thirty (30) calendar days' written notice to the breaching Party;

11.2.3 by Dexcel, with immediate notice, upon (a) any Manufacturer losing its license, authorization or approval required by law in order to manufacture and supply the Product to Dexcel, and such license, authorization or approval was not reinstated within one hundred and eighty (180) days; (b) Elite notifies Dexcel of any change to, or non-renewal, expiration or withdrawal by the FDA or any other relevant regulatory authority, of the cGMP status of any Manufacturer that would prevent Dexcel from importing, marketing or selling the Product in the Territory, and such cGMP status was not reinstated within one hundred and eighty (180) days; or (c) an audit or inspection performed by the FDA or the Health Authorities of the facilities involved in the manufacture of the Product has shown a Critical Finding and the Manufacturer cannot make or has not made the necessary remedies within the time period requested by such Regulatory Authority. For the purpose of this provision, "Critical Finding" shall mean that there is a clear cGMP failure which could materially affect the quality of the relevant Product and which could, or would, be harmful to the patient;

11.2.4 in the event of two (2) or more Supply Failures within any twelve (12) month period, Dexcel shall be entitled (but not obligated) to terminate this Agreement upon immediate notice to Elite; and

11.2.5 by either Party pursuant to Section 14.2 hereof.

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 IF PUBLICLY DISCLOSED

11.3 It is specifically understood by Elite and by Dexcel that, upon termination of this Agreement for any reason, the only rights of the other Party shall be those specified in Article 12 hereof.

12 **Rights and Obligations upon Termination**

12.1 Upon termination or expiration of this Agreement, Dexcel shall cease distributing the Product and shall immediately return to Elite, via courier, at Dexcel' sole cost and expense, all of Elite's pharmaceutical and technical Know-how relating to the Product and/or any Confidential Information (including any and all copies of the Registration File), and shall provide Elite with written confirmation of the same. Dexcel shall refrain from making any further use of Elite's pharmaceutical and technical Know-how relating to the Product and/or Confidential Information, except as provided in Section 12.2 hereof. If Dexcel terminates the Agreement for any reason other than pursuant to Section 11.2.2 or 11.2.3, Dexcel shall be excluded from selling the Product (except as allowed for in Section 12.2) for a period of three (3) years after the date the Agreement terminates. The obligation to return, as aforementioned, shall not include documentation required to be kept by Dexcel in accordance with Health Authorities' instructions or regulations.

12.2 Outstanding Orders; Inventory

12.2.1 Except in the event that Elite terminates this Agreement pursuant to Section 11.2.2 due to a material breach by Dexcel, any Confirmed Orders made on or before the expiration or termination of this Agreement but not yet delivered by Elite shall be delivered to Dexcel and Dexcel shall be liable to pay for the same in accordance with the provisions of the Agreement.

12.2.2 Dexcel may, at its discretion, sell any remaining Product stock then in its possession according to the terms of this Agreement for a period not exceeding the shelf life of such remaining Product and shall be liable to pay Net Selling Price adjustments according to Section 5.4.2. In the event Dexcel determines not to sell the remaining Product stock, it shall return it to Elite or destroy at its own cost such remaining Product stock as directed by Elite.

12.3 Except as provided herein, neither Party shall be relieved of its duty to discharge in full all obligations accrued or due prior to the date of termination or expiration (including, but not limited to, the obligation to pay all amounts due under any Confirmed Orders which remain open as of the date of such termination or expiration; provided, however, that Dexcel shall have no obligation to pay for any Product in the event this Agreement was terminated pursuant to Section 11.2.3); all sums owed by either Party to the other shall become immediately due and payable on such date.

12.4 Each Party shall remove all reference to the other, if any, from its letterhead, business forms, advertising literature and place of business, and shall not thereafter use any name or trademark suggesting that it has any relationship with the other Party.

12.5 Each Party shall immediately deliver to the other (and cause its Affiliates and its and their Representatives to so deliver), at such Party's expense, all Confidential Information of the other Party, including without limitation any and all copies, duplications, summaries and/or notes thereof or derived there from, regardless of format.

12.6 Except as specifically set forth herein, all rights granted by each Party to the other Party hereunder shall be immediately terminated.

12.7 The rights and obligations of the Parties to this Agreement set forth in Sections 5.4, 6.1, 6.3, 6.5, 7, 8, 9, 10, 12, 17, 18, 21 shall survive any termination or expiration of this Agreement.

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 IF PUBLICLY DISCLOSED

13 **No Assignment**

13.1 The provisions of this Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and assigns; provided however, that neither Party may assign, delegate or otherwise transfer any of its rights or obligations under this Agreement, whether voluntary or by operation of law, , without first receiving the prior written consent of the other Party. Any assignment by a Party not in accordance with this Section 13 shall be null and void. Notwithstanding the foregoing to the contrary, Elite and Dexcel may assign and delegate their respective rights and duties hereunder, without obtaining the consent of the other Party, to any Affiliate; provided that the assignee agrees in writing to bound by the terms and conditions of this Agreement, and the assigning Party likewise agrees to remain responsible as an obligor hereunder or to the acquirer of all or substantially all of the business or assets to which this Agreement relates (whether by stock sale, asset sale, merger, consolidation or otherwise).

14 **Force Majeure**

14.1 If a Party asserts the occurrence of an event of Force Majeure as an excuse for failure to perform such Party's obligations, then the obligations of the Parties hereunder shall be suspended for so long as the Force Majeure event renders performance of the Agreement impossible; provided, however, that (a) the nonperforming Party shall timely notify the other Party in writing of the likelihood or actual occurrence of an event of Force Majeure by the nonperforming Party; (b) the nonperforming Party must reasonably prove that it took all commercially reasonable steps to minimize delay or damages caused by such event; and (c) the nonperforming Party substantially fulfilled all non-excused obligations,

unless the other Party has notified the nonperforming Party to the contrary.

14.2 In the event that such Force Majeure continues for a period in excess of ninety (90) days and the Party which is unable to fulfil its obligations hereunder owing to Force Majeure beyond such period of ninety (90) days, the other Party shall be entitled to provide written notice of immediate termination to the Party unable to fulfil its obligations hereunder. The Parties agree to undertake discussions with a view to reaching some other mutually acceptable and reasonable arrangement for alleviating the effects of such force majeure.

15 **Severability**

15.1 If any provision of this Agreement is found by any court or administrative body of competent jurisdiction to be invalid or unenforceable, the invalidity or unenforceability of such provision shall not affect the other provisions of this Agreement, and all provisions not affected by such invalidity or unenforceability shall remain in full force and effect. The Parties agree to attempt to substitute for any invalid or unenforceable provision a valid or enforceable provision which achieves, to the greatest extent possible, the economic objectives of the invalid or unenforceable provision.

16 **Relationship of the Parties**

16.1 The relationship of the Parties to this Agreement is one of independent contractors.

17 **Governing Law and Jurisdiction**

17.1 This Agreement shall be construed under and exclusively governed by the laws of the State of New York, United States of America, regardless of any choice of law principles. In the event of a dispute, the parties will first attempt to resolve the situation amicably. In the event that the parties are not able to come to an amicable agreement within sixty (60) days, then each of the Parties irrevocably submits to the sole and exclusive jurisdiction of the Supreme Court of the State of New York located in the County of New York and the jurisdiction of the United States Federal District Court located in New York City, for the purpose of any suit, action or other proceeding arising from this Agreement and agrees that no such suit, action or proceeding shall be brought by it or its Affiliates except in such courts. Furthermore, each Party irrevocably waives, to the fullest extent permitted by law, any objection which it may now or hereafter have to the laying of the venue of such suit, action or proceeding brought in any such court or any claim that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum and agrees not to plead or claim the same.

17.2 The United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement and is hereby excluded.

18 **Waiver**

18.1 The waiver by either Party of a breach of any of the provisions of this Agreement, the Quality Agreement or the SDEA by the other Party shall not be construed as a waiver of any succeeding breach of the same or other provisions; nor shall any delay or omission by either Party in exercising any right that it may have under this Agreement, the Quality Agreement or the SDEA operate as a waiver of any breach or default by the other Party.

18.2 No waiver of any right under this Agreement shall be deemed effective unless contained in writing and signed by the Party charged with such waiver, and no waiver of any right shall be deemed to be a waiver of any future right or any other right arising under this Agreement. Failure by a Party to exercise any of its rights under this Agreement, including the right to terminate this Agreement, shall not constitute a waiver of any of its rights thereafter.

19 **Remedies**

19.1 All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall serve to limit any other remedy, right, undertaking, obligation or agreement which may otherwise arise.

20 **Construction**

20.1 The headings in this Agreement and their associated numbers are included for ease of reference purposes only and shall have no legal, constructive or interpretive effect. This Agreement shall be construed as if drafted jointly by the Parties and no presumption or burden of proof shall arise favoring or disfavoring either Party by virtue of the authorship of any of the provisions of this Agreement.

21 **Notices**

21.1 Unless otherwise stated in this Agreement, any and all communications required as provided for in this Agreement shall be in writing to the addresses noted below and shall be sent by (i) certified or registered mail, postage prepaid, return receipt requested, (ii) confirmed email followed by a letter of confirmation sent by any of the methods stated in (i) and/or (iii) of this clause, or (iii) by an express overnight courier service (for example, Federal Express or Airborne), postage prepaid, return receipt requested and addressed as set forth below:

Dexcel Ltd.
1 Dexcel Street.
Or Akiva 3060000
Israel

Attn: Vice President & General Manager
Tel: ***
Email: ***

Elite Pharmaceuticals, Inc.
165 Ludlow Avenue
Northvale, New Jersey 07647
United States

Attn: CEO & President
Tel: ***
Email: ***

CONFIDENTIAL

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 IF PUBLICLY DISCLOSED

20 **Construction**

20.1 The headings in this Agreement and their associated numbers are included for ease of reference purposes only and shall have no legal, constructive or interpretive effect. This Agreement shall be construed as if drafted jointly by the Parties and no presumption or burden of proof shall arise favoring or disfavoring either Party by virtue of the authorship of any of the provisions of this Agreement.

21 **Notices**

21.1 Unless otherwise stated in this Agreement, any and all communications required as provided for in this Agreement shall be in writing to the addresses noted below and shall be sent by (i) certified or registered mail, postage prepaid, return receipt requested, (ii) confirmed email followed by a letter of confirmation sent by any of the methods stated in (i) and/or (iii) of this clause, or (iii) by an express overnight courier service (for example, Federal Express or Airborne), postage prepaid, return receipt requested and addressed as set forth below:

Dexcel Ltd.
1 Dexcel Street.
Or Akiva 3060000
Israel

Elite Pharmaceuticals, Inc.
165 Ludlow Avenue
Northvale, New Jersey 07647
United States

Attn: Vice President & General Manager	Attn: CEO & President
Tel: ***	Tel: ***
Email: ***	Email: ***

21.2 Notices shall be deemed given three (3) days following mailing by certified or registered mail, and one (1) day following overnight courier, and if sent by email, upon receipt by the sender of an acknowledgment of receipt, including, without limitation, an automatically-generated emailed read receipt (provided that a Party shall still comply with the additional requirements set forth in Section 21.1(ii), above).

22 **Entire Agreement; Amendments; Preamble and Appendices**

22.1 This Agreement, together with all the Appendices, the Confidentiality Agreement, the Quality Agreement and the SDEA, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof, and supersedes any and all prior agreements, understandings, promises and representations between the Parties, whether written or oral, with respect to the subject matter hereof.

22.2 This Agreement may not be amended, modified, released, or discharged in any manner except by a written instrument, referring to this Agreement and signed by both Parties.

22.3 Any preamble and appendix to the Agreement is incorporated herein and forms an integral part hereof.

IN WITNESS WHEREOF the Parties have caused this Agreement to be executed by their respective duly authorized representatives as of the Effective Date.

ELITE PHARMACEUTICALS, INC.		**DEXCEL LTD.**	
By:	*/s/ Nasrat Hakim*	By:	*/s/ Ilan Oren*
Name:	Nasrat Hakim	Name:	Ilan Oren
Title:	CEO	Title:	Co-Chief Executive Officer
Date:	12/06/2021	Date:	12/05/2021

CONFIDENTIAL

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 IF PUBLICLY DISCLOSED

Appendix 1 – Products, Floor Prices, Batch Sizes, PQR

Products:

Dextroamphetamine and Amphetamine combinations of the API in the following dosages and Pack sizes:

10mg (2.5mg x 4API) – Packs of 30 tablets
20mg (5mg x 4API) – Packs of 30 tablets
30mg (7.5mg x 4API) – Packs of 30 tablets

The 5mg (1.25 x 4 API), 7.5mg (1.875mg x 4 API), 12.5mg (3.125mg x 4 API), 15mg (3.75mg x 4API) approved in the US, will not initially be marketed in the Territory

Floor Prices:

10mg / Pack of 30 tablets - $***
20mg / Pack of 30 tablets - $***
30mg / Pack of 30 tablets - $***

Pricing for Incoterms® set forth in Section 5.3.7

Elite shall prepare a periodic Product Quality Review for the Product ("**PQR"**) in accordance with the provisions of the Quality Agreement and shall provide Dexcel with a copy of the PQR, upon request.

Costs for items in Section 5.3.8 are included in the Floor Price.

CONFIDENTIAL

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 IF PUBLICLY DISCLOSED

Appendix 2 – Form of Quality Agreement

TEMPLATE – DO NOT SIGN

TECHNICAL AGREEMENT

This **TECHNICAL AGREEMENT** ("**Agreement**") is entered into as of the date of the last Party to sign this Agreement ("**Effective Date**") by and between **DEXCEL ENTITY**, with its registered address at [DEXCEL ENTITY ADDRESS] ("**Dexcel**"), and **OTHER PARTY**, with its registered address at _____ ("**Company**"). Dexcel and Company hereinafter sometimes referred to as the "**Parties**" or individually as a "**Party**."

PREAMBLE

A. Dexcel and Company have entered into a [Name of Commercial Agreement], dated [Date] ("**Main Agreement**"), pursuant to which Company shall manufacture for and supply certain medicinal products to Dexcel for sale and distribution in the Territory;

B. The manufacturer of pharmaceutical products is responsible for manufacturing and controlling the products it provides in accordance with cGMP, in accordance with the Marketing Authorization in the Territory, and to comply with the requirements of "The Rules Governing Medicinal Products in the European Community," Chapter 7;

C. Company has a manufacturing authorization in accordance with the laws of [*country where facility is located*] and is subject to the ongoing monitoring by the relevant health authorities in such country, and further has provided Dexcel with copy of its certificate of cGMP issued by the relevant health authorities in [*country where facility is located*], indicating that Company's Facility complies with local cGMP requirements; and

D. The Marketing Authorization holder for the Product in the Territory is Dexcel.

NOW, THEREFORE, THE PARTIES AGREE AS FOLLOWS:

23 **DEFINITIONS**

23.1 "**Active Pharmaceutical Ingredient**" or "**API**" shall mean that part of the Product ingredients intended to furnish pharmacological activity or to otherwise have a direct and intended effect on the patient; for the purpose of this Agreement, the API is [Name of API].

23.2 "**ALCOA Standard**" means, with respect to data integrity, that all data is Attributable, Legible, Contemporaneous, Original, and Accurate, as well as complete, durable, corroborated, version- based, accessible, and consistent.

Attributable – data must be able to be attributed to an individual, and the identity of the person performing the activity must be clearly documented.

Legible – data must be clearly legible whether it is handwritten, images or electronic formatting viewed as a printed page or in the electronic system, with no ambiguity regarding the clarity of the data.

Contemporaneous – data must be recorded as the event happens (in real time).

Original – raw or source data must be retained appropriately, and subject to review and approval.

Original data is not a copy.

Accurate – fully correct and representative of the event recorded.

23.3 "**Certificate of Analysis**" shall mean the document for the relevant batch of the Product signed by Company's Qualified Person or produced by a computer system which provides a degree of control equivalent to that given by a signature, which states that such batch is suitable for release and includes a description of the Specifications for, and results of testing applied by Company to the Product and the other details set forth in **Exhibit E** hereof. A sample of a Certificate of Analysis is attached hereto as **Exhibit E1**.

23.4 "**Certificate of Conformity**" shall mean the document for the relevant batch of the Product signed by Company's Qualified Person or produced by a computer system which provides a degree of control equivalent to that given by a signature, which certifies that such batch of the Product was manufactured and tested in compliance with the Specifications therefor, the Marketing Authorization and cGMP and includes the details set forth in **Exhibit F** hereof. A sample of a Certificate of Conformity is attached hereto as **Exhibit F1** .

23.5 "**Change Control Form**" shall mean the document prepared by Company to document any change from the defined production processes of the Product.

23.6 "**Complaints**" shall mean defects observed and communicated to Company or Dexcel related to the use of the Product.

23.7 "**Deviation**" shall mean (i) an incident that occurs during bulk manufacture, packaging, storage, transportation, sampling, or testing of a batch of Product, which is OOS with regard to components, materials, in-process controls, Product, and/or stability; and/or (ii) a variation or departure from processes, procedures, predefined critical parameters, specifications, or cGMP and/or Health Authority requirements, during bulk manufacture, packaging, transportation, storage, sampling, or testing of a batch of Product.

23.8 "**Deviation Report**" shall mean the report compiled by Company to document any Deviations.

23.9 "**Facility**" shall mean the approved facilities of Company where the production, packaging, in- process controls, storage, testing, and release of the Products takes place, as set forth in **Exhibit A** hereof.

23.10 "**Good Distribution Practice**" or "**GDP**" shall mean the applicable guidelines for the proper distribution of medicinal products for human use.

23.11 "**Good Manufacturing Practices**" or "**cGMPs**" shall mean the current good manufacturing practices for pharmaceutical substances or products as adopted in the relevant country/ies in the Territory and in the country in which the Products are manufactured, as may be amended or supplemented from time to time, including (i) as specified in [21 Code of Federal Regulations ("**CFR**") Parts 210 and 211 [cGMP for Finished Pharmaceuticals] and 21 CFR Parts 1301, 1304, 1307, 1312 ("**FDA cGMP**")][the EC Guide to Good Manufacturing Practices for Medicinal Products v.4, and in the European Community Directive 2017/1752/EC GMP Guidelines, as amended from time to time ("**[EU cGMP Guidelines]|[FDA cGMP]**")], and, if applicable, the International Conference of Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ("**ICH**") Guidance for Industry Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients; and (ii) as required by applicable laws and regulations and/or the Health Authorities in the relevant country/ies in the Territory and in the country in which the Products are manufactured.

23.12 "**Health Authorities**" shall mean any applicable federal, state or local government authority, quasi-governmental authority, regulatory or administrative agency, authority, body, court, commission or tribunal in the relevant country/ies in the Territory or in the country of manufacture of the Product with jurisdiction or authority in such country over the development, manufacture, supply, storage, import, export, marketing, sale or commercialization (including approval of Marketing Authorizations) and/or reimbursement of pharmaceutical products, including [the FDA] [the UK Medicines and Healthcare Products Regulatory Agency][the Bundesinstitut für Arzneimittel und Medizinprodukte] [the European Medicines Agency].

23.13 "**Marketing Authorization**" shall mean the marketing authorization granted by the Health Authorities in order to permit the importation, promotion, distribution and sale of the Product in the Territory.

23.14 "**Marketing Authorization Dossier**" shall mean the package of technical and clinical information, processes, techniques and data relating to the Product (and the relevant manufacturing site) as may be required for the purposes of obtaining and/or varying a Marketing Authorization in the Territory.

23.15 "**OOS**" shall mean a test result that shows that the Product, after an initial investigation, was determined not to have a clear obvious error due to external circumstances, does not comply with the predetermined acceptance criteria, or has fallen outside of acceptance criteria which have been established in official compendia and/or by documentation included in the Product's approved Marketing Authorization Dossier.

23.16 "**Packaging Materials**" shall mean the components used in both the primary and secondary packaging of the Product.

23.17 "**Product(s)**" shall mean the finished form pharmaceutical product(s) described in **Exhibit A**.

23.18 "**PQR**" shall mean the annual Product review and report, in English, prepared by Company for Dexcel and meeting the requirements of the [EU cGMP Guidelines][FDA cGMP].

23.19 "**Qualified Person**" or "**Responsible Pharmacist**" or "**QP**" shall mean a person named on the Manufacturing Authorization and recognized by the relevant Health Authorities

applicable to the Product as having the necessary scientific and technical background and experience to allow such person to be responsible for the release of batches of Product for sale and distribution and/or supply.

23.20 "**Quality Defects**" refers to Critical and Major Quality Defects:

23.20.1 **Critical** – These are quality defects which are potentially life-threatening or could cause serious risk to patient health, including, but not limited to: wrong Product (label and contents are different products); correct Product but wrong strength, with serious medical consequences; microbial, physical or chemical contamination, with serious medical consequences; mix up of products ('rogues') within a pack (for example, two different blister strips within one carton or two different tablets within one blister strip); wrong active pharmaceutical ingredient in a multi-component Product with serious medical consequences; or non-compliance with Specifications (for example, assay, stability, fill/weight).

23.20.2 **Major** – These are quality defects which could cause illness or mistreatment but not to a life-threatening extent, including, but not limited to: mislabeling – wrong or missing text or figures; missing or incorrect information – leaflets or inserts; microbial, physical or chemical contamination, with medical consequences; or insecure closure with serious medical consequences (for example, lack of child-resistant containers, potent product, sterile product).

23.21 "**Recall**" shall mean (i) a voluntary or governmental action to quarantine, stop-sale or withdraw the Product from the market in the Territory; and (ii) all field actions with respect to the Product in the Territory, product recalls, market withdrawals, stock recoveries, corrections (repair, modification, adjustment, relabeling, destruction, or inspection, including patient monitoring), safety alerts, and press releases. This definition does not apply to the retrieval or return of samples of the Product from the distribution network to facilitate an investigation into a possible Quality Defect.

23.22 "**Reference Samples**" shall mean the samples of all starting materials and the Product which are collected and retained in order to investigate any Deviations, OOS results, Quality Defects, or Complaints concerning the Products.

23.23 "**Responsible Contact Persons**" shall mean the key personnel of Company and Dexcel listed in **Exhibit D** hereof.

23.24 "**Sharing of Pharmaceutical Responsibilities**" shall mean the allocation of the relevant pharmaceutical responsibilities for the Products between Company and Dexcel as described in **Exhibit C** hereof.

23.25 "**Specifications**" shall mean all written product, regulatory, manufacturing, quality control and quality assurance procedures, processes, practices, standards, instructions and specifications, including, manufacturing process, analytical procedures and acceptance criteria, as set forth in the registered Marketing Authorization Dossier and the Marketing Authorization the Product, from time to time.

23.26 "**Standard Operating Procedures**" or "**SOP's**" shall mean the written set of instructions compiled by a Party for any process or system that is followed during the operation of any activities, system or equipment, including, *inter alia*, quality assurance, quality control, maintenance, utilities, human resources, etc.

23.27 "**Subcontractor**" shall mean a third Party or an affiliate of Company which has a contract or other relationship with Company to provide some portion of the work or services related to the manufacture, packaging, storage, sampling, or testing of a Product which Company is obliged to perform under this Agreement. A list of all approved Subcontractors as of the Effective Date of this Agreement is set forth in **Exhibit B.**

23.28 "**Territory**" shall have the meaning set forth in the Main Agreement.

24 GENERALLY

24.1 Company agrees to manufacture the Products for Dexcel according to the Specifications, cGMP, and the Marketing Authorization of the Product.

24.2 Company shall have and maintain adequate facilities and equipment, knowledge and experience, and competent personnel, to satisfactorily supply the Products to Dexcel in accordance with the provisions of this Agreement and the Main Agreement.

24.3 Company and Dexcel agree to the Sharing of Pharmaceutical Responsibilities as described in **Exhibit C**.

24.4 Company shall timely notify Dexcel of any change or restriction to Company's cGMP manufacturing authorization certificate, where such change is specifically relevant to any one or more of the Products.

25 RESPONSIBLE CONTACT PERSONS; PERSONNEL; TRAINING

25.1 Company and Dexcel have appointed the key personnel listed in **Exhibit D** as Responsible Contact Persons.

25.2 Any change of the Responsible Contact Persons must be notified by one Party to the other, in writing, sent to the address first set out above, or to such other address as the other Party has provided in writing.

25.3 Company's (and all of Company's Subcontractors') personnel shall receive initial and continuing training relevant to their tasks, including data integrity, based on written standard operating procedures (SOPs) and in accordance with a written training program.

25.4 A record of all training should be kept by Company, and the practical effectiveness of training shall be periodically assessed and documented. Such record and assessments shall be available for review by Dexcel during any audit of Company's Facility as provided in Section **35.1**.

26 STARTING MATERIALS

26.1 Suppliers of API and Excipients

26.1.1 Company shall be responsible for the procurement and testing of the API and for auditing the API supplier, which audit shall be performed at least once every three (3) years. On request, an executive summary of the most recent audit of the API supplier shall be provided to Dexcel by Company. Company shall provide Dexcel with a QP declaration of cGMP compliance of the API supplier relating to the use of the API in the manufacturing of the Product.

26.1.2 Company shall sign a technical agreement with all of its API suppliers relevant to any Product, and shall, on request, provide Dexcel with a declaration that a technical agreement has been concluded with each such API supplier.

26.1.3 Company shall be responsible for the procurement and testing of the raw materials (excipients). Company shall be responsible for the cGMP compliance of the raw material suppliers. Documentation showing cGMP compliance of the raw materials shall be provided to Dexcel by Company upon request.

26.2 Packaging Materials

26.2.1 The information for the artwork necessary for the preparation of the Packaging Materials for the Product shall be provided by Dexcel to Company. Dexcel is responsible for ensuring that the text in the artwork is accurate, correct and in compliance with the approved Marketing Authorization.

26.2.2 Company is responsible for the procurement and quality of all Packaging Materials in accordance with the approved artwork.

26.2.3 Company is responsible for evaluation of suppliers of Packaging Materials for cGMP compliance and to make available the relevant documentation to Dexcel upon request. An executive summary of the most recent audit of the Packaging Materials' suppliers shall be provided to Dexcel by Company.

26.2.4 Company shall be responsible for compliance with Transmissible Spongiform Encephalopathy ("**TSE**") and Bovine spongiform encephalopathy ("**BSE**") risk regulations based on the API supplier's TSE/BSE Declarations and the Packaging Material supplier's TSE/BSE Declarations. Updated TSE/BSE declarations must be issued after any change to the manufacturing process which involves new raw materials that have been sourced from a different supplier. All relevant TSE/BSE declarations shall be provided by Company to Dexcel.

26.3 Company shall be responsible for performing a risk assessment for ascertaining the appropriate good manufacturing practice for excipients of medicinal products for human use according to [guideline EU-2015/C 95/02].

26.4 Company shall be responsible for performing a risk assessment for nitrosamine in all relevant active ingredients, excipients and other raw materials in accordance with EMA/189634/2019.

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

27 PRODUCTION AND QUALITY CONTROL; FACILITY

27.1 Company shall arrange the production, the packaging, the in-process controls, and the storage of the Products at its Facility according to cGMP and in compliance with the requirements of the Marketing Authorization Dossier. Company is responsible for ensuring that all Product batches are manufactured under cGMP conditions and as required by the Marketing Authorization Dossier.

27.2 Company will not use an alternate facility for, or transfer at a later date, any of the manufacturing, bulk packaging, packaging, processing, testing, storage or release operations for any of the Products without the prior written approval of Dexcel. Such approval by Dexcel of any new facility shall not be unreasonably withheld or delayed, but will also be contingent upon approval of the new facility by the Territory's Health Authorities.

27.3 Company warrants that it does not handle specified risk materials, hazardous or potentially hazardous materials such as penicillins, cephalosporins, betalactams, hormones (including androgens, estrogens, progestins), steroids and cytotoxic products in the same building or buildings where the manufacturing of the Products takes place.

27.4 Company warrants that there are segregated areas in the Facility designated for the storage of products awaiting further decision, including, without limitation, any products suspected of falsification, returned products, rejected products, products awaiting disposal, and recalled products. Company further warrants that these items are kept separate from saleable stock.

27.5 The respective responsibilities of the parties are set forth in Appendix C.

28 DEVIATIONS

28.1 Company's Qualified Person is responsible for reviewing the Deviation Reports relating to all Deviations involving the sampling and testing of the API, excipients and primary Packaging Materials and to the production of the bulk Product, before approval of the Product.

28.2 Company shall inform Dexcel in the Certificate of Compliance about any Deviation and provide a Deviation Report summary in English for each batch that is included with each shipment of the Product to Dexcel. In the event that the Product has already been received by Dexcel when such Deviation is noted by Company, Company shall immediately notify Dexcel by electronic mail.

29 DOCUMENTATION

29.1 Company undertakes to deliver to Dexcel together with every batch of Products the following documents:

a. Certificate of Analysis of the Product (**Exhibit E**).
b. Certificate of Compliance (**Exhibit F**).
c. Certificate of Analysis of the API from the API supplier.
d. A Deviation Report summary, in English, of any Deviation that may adversely affect the Product's quality, safety, efficacy, stability and/or purity.
e. Packing list for delivery from Company's site to the relevant Dexcel Party.

30 RELEASE

30.1 Company will deliver only Products manufactured in compliance with the Specifications and cGMP.

30.2 Dexcel is responsible for release of the Products to the market based on the documents provided by Company in Section **29.1**.

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 IF PUBLICLY DISCLOSED

31 STORAGE CONDITIONS & SHIPPING

31.1 All starting materials (API, excipients and Packaging Materials) held by Company shall be stored within prescribed storage conditions at all times from the receipt thereof. In addition, the Products covered by the Agreement must be stored and transported in accordance with the storage and transport conditions set forth in **Exhibit A** and the *Incoterms*® agreed to in the Main Agreement.

31.2 Temperature data loggers shall be used to record temperature conditions during transit.

31.2.1 Company is responsible for (i) providing the data loggers, (ii) including at least two (2) dataloggers with each shipment of Product to Dexcel, and (iii) providing the

temperature specifications for the Product during shipment. [*One (1) data logger shall be used per pallet of each shipment.*] [*Shipment documentation will indicate the placement location of all data loggers.*]

31.2.2 Dexcel is responsible for (i) reviewing the temperature data from the data loggers upon receipt of each shipment of Product, (ii) immediately notifying Company in the event of any OOS results, and (iii) promptly returning the data loggers to Company, unless single-use data loggers are used.

32 **REFERENCE SAMPLES**

32.1 Company is responsible for ensuring that Reference Samples of (a) all relevant starting materials and (b) Product (each batch) are kept for at least the Product shelf life plus one (1) year.

32.2 The number of Reference Samples of the Product must be sufficient to perform at least two (2) full quality control analyses (including microbiological testing).

33 **STABILITY REPORTS & PQR**

33.1 Company shall provide ongoing stability summaries at the request of Dexcel in accordance with ICH guidelines. In the event of a confirmed stability OOS, Dexcel must be notified immediately.

33.2 In case stability concerns are raised during the review of a PQR or for any other reason (e.g. a Complaint), the Qualified Persons of the Parties shall agree upon the steps to be taken to address the concern.

33.3 Company undertakes to prepare an annual PQR (in English) for the Product supplied to Dexcel. The PQR will be for a twelve (12) month period and contain, at the minimum, the contents required by the [EU cGMP Guidelines][FDA cGMP]. On request, a copy of the completed and approved PQR will be provided by Company to Dexcel within three (3) months of its completion.

34 **COMPLAINTS AND RECALL**

34.1 Complaints

34.1.1 Any non-medical / technical Complaint regarding the quality of the Product received by Dexcel in the Territory shall be communicated by Dexcel to Company in accordance with the notice provisions set forth in the Main Agreement ("**Notice**").

34.1.2 Company shall be responsible for performing an investigation concerning the Complaint and for sending a report containing the results of the investigation and any corrective actions taken or to be taken to solve the problem that originated the Complaint to Dexcel within thirty (30) calendar days following Company's receipt of the Notice.

34.1.3 All complaints of a medical nature and all adverse drug event reporting shall be done in accordance with the safety data exchange agreement signed by Company and Dexcel.

34.2 Recall

34.2.1 The Parties agree to contact each other immediately as soon as they become aware of the potential for a Recall caused by a Quality Defect concerning the Products, including a Recall by the Company or its distributors of the same product in another country. Twenty-four (24) hour contact details are set out in **Exhibit E**.

34.2.2 Dexcel is responsible for the management of any Recall of the Products in the Territory. Company must cooperate fully in ensuring a fast and effective recall.

34.2.3 Nothing stated herein shall prevent, constrain or delay any unilateral action which either Party, in its sole discretion, reasonably deems to be necessary to protect the public, comply with the law or to protect its business interests or reputation, provided that no such action will be taken without reasonable prior written notice by mail or electronic mail to the applicable contact for the other Party as set forth in **Exhibit E**.

34.3 Suspected Counterfeit Goods

34.3.1 If either Party becomes aware of any suspicion that Products could be counterfeit, actual counterfeit incidents, or incidents relating to illegal handling with respect to the Product, such Party will inform the other Party immediately (within twenty-four (24) hours).

34.3.2 Dexcel will inform the Health Authorities in the Territory of the suspicion or incident in accordance with local law or regulation.

35 **INSPECTIONS**

35.1 During normal working hours and upon reasonable notice, Company agrees that Dexcel will be entitled to audit the Facilities where the Product is manufactured, packed, tested, stored, and released.

35.2 Company will inform Dexcel within five (5) days following notice of any regulatory inspection that relates to the manufacturing, bulk packaging, packaging, processing, testing, storage and/or release of the Product.

35.3 A copy of any reports, summaries or notices issued by a regulatory authority that relate to a Product shall be provided to Dexcel within three (3) days of receipt by Company. Company shall be responsible for responding to the inspection and shall provide Dexcel with a copy of its submitted responses. Company must consult with Dexcel regarding any proposed *corrective and preventative actions* ("**CAPA**") that may affect the Products and reach a mutual agreement regarding regulatory responses prior to Company's submission of the responses to the relevant regulatory authority. Dexcel shall not unreasonably withhold its prior written approval of the proposed CAPA response.

36 **DATA INTEGRITY**

36.1 Company agrees to have procedures in place to ensure quality-relevant data meets the ALCOA Standard. The data should be able to be traced to its source and be readily available during regulatory inspections.

36.2 Company further agrees to notify Dexcel of any breach to the integrity of the data affecting the quality or the safety of any Product batches already shipped to Dexcel, as soon as possible, but not to exceed two (2) days after becoming aware of the event.

37 **CHANGE CONTROL**

37.1 Both Parties shall inform each other in advance of any relevant quality-related regulatory changes ("**Change**") affecting the Product's manufacturing, testing or release procedures, equipment, or materials or any other items affecting Product quality or the Marketing Authorization Dossier of the Products.

37.1.1 All major Changes, as defined by Company's change control SOPs as a change that will require a formal variation to the Marketing Authorization Dossier, shall be sent, before implementation, for approval by Dexcel. It is the responsibility of Dexcel to perform the proper variation procedures at the Health Authorities in the Territory according to the requirements of such country's variation guidelines.

37.1.2 The implementation of any Changes can only be carried out after Company receives the written approval of Dexcel and, if required, the Health Authorities in the Territory.

37.1.3 It is the responsibility of Company to transfer these changes to its internal documentation.

37.1.4 All minor changes, as defined by Company change control procedures as a change that will not require a formal variation to the Marketing Authorization Dossier, shall be approved by Company's Quality department before implementation.

38 **SUBCONTRACTORS**

38.1 Company is allowed to subcontract any work related to the manufacture, quality control and/or release of the Product only with the prior written approval of Dexcel. It is the responsibility of Company to perform quality audits of such Subcontractors in order to assure the quality system and cGMP compliance of such Subcontractors. Company shall enter into a technical agreement with each such Subcontractor, a copy of which shall be provided to Dexcel upon request.

38.2 Subcontractors must meet the same quality requirements as Company. No subcontracting shall release Company from its responsibilities or its obligations under this Agreement. Company is responsible for auditing its Subcontractors. Company's audit reports will be made available to Dexcel upon request.

39 **FINAL PROVISIONS**

39.1 This Agreement shall become effective upon its signature by the authorized representatives of both Parties and shall be reviewed by Company and Dexcel every three (3) years to assure its efficiency and accuracy.

39.2 In the event of a conflict between this Agreement and the Main Agreement with respect to quality-related activities, including compliance with cGMPs and all other regulatory obligations regarding the Product, the provisions of this Agreement shall govern and with respect to all other matters, the provisions of the Main Agreement shall govern.

39.3 Any alteration or amendment of this Agreement and its Exhibits requires the written consent of the Parties. New versions of Appendices become valid only after signature by the authorized representatives of both Parties and may be added to this Agreement without the need for updating the entire Agreement.

39.4 Upon request, this Agreement (or part thereof) may be forwarded or disclosed to the relevant Health Authorities in order to comply with applicable regulations.

39.5 The term of this Agreement and its termination is subordinated to the term and termination of the Main Agreement; provided, however, that this Agreement shall remain in effect until the last expiry date of all Products supplied to Dexcel by Company. In addition, regulatory obligations or other obligations which expressly or by implication are intended to survive the termination or expiration hereof, shall survive the termination of this Agreement.

39.6 The validity, construction, interpretation and effect of this Agreement and the respective rights and obligations of the Parties hereunder shall be governed and determined by and in accordance with the choice of law and jurisdiction clauses in the Main Agreement.

39.7 This Agreement may be executed in any number of counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

39.8 Signatures to this Agreement transmitted by electronic mail in "portable document format" ("pdf"), or by any other electronic means which preserves the original graphic and pictorial appearance of the Agreement, shall have the same effect as physical delivery of the paper document bearing the original signature.

IN WITNESS WHEREOF, this Agreement has been executed by the duly authorized representatives of the Parties hereto, effective as provided above.

DEXCEL ENTITY	**Company**
TEMPLATE	
By: _____	By: _____
Name:	Name:
Title:	Title:
Date:	Date:

LIST OF EXHIBITS

	DESCRIPTION
A	Products, Storage/Transportation, Facilities
B	Approved Subcontractors
C	Sharing of Pharmaceutical Responsibility
D	Responsible Contact Persons
E	Certificate of Analysis Requirements
F	Certificate of Conformity Requirements
G	Change History

COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED

EXHIBIT A

Product, Storage/Transportation Conditions & Facilities

PRODUCT	STORAGE/TRANSPORTATION CONDITIONS	FACILITY ADDRESS

CONFIDENTIAL

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 IF PUBLICLY DISCLOSED

EXHIBIT B

Approved Subcontractors

CONFIDENTIAL

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 IF PUBLICLY DISCLOSED

EXHIBIT C

Sharing of Pharmaceutical Responsibilities between Company and Dexcel

RESPONSIBILITY OF	Company	Dexcel
Compliance of manufacturing and control SOPs with EU GMP Guidelines and with Marketing Authorization and Specifications	X	
ACTIVE INGREDIENTS		
Procurement	X	
Control and compliance with Specifications	X	
Reserve Samples	X	
Technical Agreement with API Supplier	X	
EXCIPIENTS AND MATERIALS		
Definition of Specifications	X	
Procurement	X	
Control and compliance with Specifications	X	
Reserve Samples	X	
ELEMENTAL IMPURITIES AND NITROSAMINES RISK ASSESSMENT		
Perform a risk assessment to identify and mitigate the risk of nitrosamines presence in API and finished product manufacturing process in accordance with EMA/189634/2019.	X	
Re-evaluate the risk assessment if there are any changes to API manufacturer or the finished product manufacturing process that may impact the risk assessment.	X	
Provide a copy of the risk assessment upon request.	X	
Perform a risk assessment to consider the elemental impurities of the finished products according to ICH Q3D.	X	
Re-evaluate the risk assessment if there are any changes to equipment, starting materials, manufacturing process, packaging materials or any other changes that may impact the risk assessment.	X	
Provide a copy of the risk assessment upon request.	X	
PACKAGING MATERIALS		
PRIMARY PACKAGING MATERIALS		
Definition of Specifications	X	
Preparation of artwork	X	
Artwork Text		X
Release of artwork	X	
Approval of artwork		X
Procurement	X	
Control and compliance with Specifications	X	
Reserve Samples	X	
SECONDARY PACKAGING MATERIALS		
Definition of Specification	X	
Preparation of artwork	X	
Artwork Text		X

CONFIDENTIAL

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 IF PUBLICLY DISCLOSED

RESPONSIBILITY OF	Company	Dexcel
Release of artwork	X	
Approval of artwork		X
Procurement	X	
Control and compliance with Specifications	X	
Reserve samples	X	
INTERMEDIATE AND BULK PRODUCTS		
Definition of Specifications	X	
Manufacturing instructions	X	
In-process controls	X	
Production/manufacturing records	X	
Testing instructions	X	
Quality controls/test records	X	
Batch Record	X	
FINISHED PRODUCTS		

Definition of Specifications	X	
Primary packaging instructions	X	
Primary packaging/packaging records	X	
Testing instructions for packaged Cartridges	X	
Quality controls/test records	X	
Secondary packaging instructions	X	
Secondary packaging records	X	
Certificate of Analysis	X	
Certificate of Compliance including Deviations	X	
Issue of batch numbers	X	
Definition of shelf-life	X	
Issue of expiry date	X	
Reserve samples	X	
Release for dispatch	X	
Transport of the Product from Company's Facility to Dexcel's premises		X
Inclusion of data loggers during shipping	X	
Reading of data loggers; communicating temperature excursions or other transport condition non-compliances to Company		X
Communicating OOS results to Company		X
Release for marketing in the Territory		X
On-going stability studies	X	
Communication of complaints to Company		X
Investigation and resolution of Product complaints	X	
Management of any recall of the Products in the Territory		X
Product recall – Product quality	X	
Informing the other Party about Product recall situation (within or outside the Territory)	X	X
Process Deviations Reports	X	
Change Control Forms	X	
Product Quality Reports	X	

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 IF PUBLICLY DISCLOSED

EXHIBIT D

Responsible Contact Persons

Dexcel:

Title	Name	Contact Information
Vice President, Quality	***	***@dexcel.com ***
Responsible Pharmacist	***	***@dexcel.com ***
QP Pharmacist	***	***@dexcel.com ***
QP Pharmacist	***	***@dexcel.com ***
Vendors QA Manager	***	***@dexcel.com ***
Pharmacovigilance Unit Manager	***	**@dexcel.com ***

Company:

Title	Name	Contact Information

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 IF PUBLICLY DISCLOSED

EXHIBIT E

Certificate of Analysis Requirements

The Certificate of Analysis must contain at least the following information:

Product Name
Product Code
Batch No
Batch Size
AR No
Mfg Date
Expiry Date
Specification No
Revision No

Name and test methods of the Test
Specification of the Test
Result
Remarks
Comments
Prepared by
Checked by
QP Sign/Date

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 IF PUBLICLY DISCLOSED

EXHIBIT E1

Sample Certificate of Analysis

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 IF PUBLICLY DISCLOSED

EXHIBIT F

Certificate of Conformity Requirements

The Certificate of Conformity must contain at least the following information:

Product Name and Strength
Company
Batch Number
Manufacturing Date
No of Packs Released
MA/PL Number
Pack Size
Expiry Date
Total Number of packs sent for Analysis/Retained Samples
Check List for Review of the documents
Deviations / Comments
QP Sign/Date

Statement required on CoC:

It is hereby certified that the above information is authentic and accurate. This batch has been manufactured, packaged and quality controlled, at MANUFACTURER'S site, in accordance with the original and current version of the Batch Record and in full compliance with cGMPs requirements and with the specifications of the above license.

☐ *No deviation occurred during batch processing, packaging and analysis which could adversely affect product quality.*

☐ *Deviation number:*

☐ *Deviation Classification:* ☐ *Minor* ☐ *Major* ☐ *Critical*

The batch processing, packaging, in-process controls and final analysis records were reviewed by me and found to be in compliance with cGMPs.

I hereby approve the batch for shipment.

[Signed by releasing QP]

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 IF PUBLICLY DISCLOSED

EXHIBIT F1

Sample Certificate of Conformity

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 IF PUBLICLY DISCLOSED

EXHIBIT G

Change History

Rev. No.	Reason	Date
1.0	Initial Issue	

Appendix 3 – Form of SDEA

TEMPLATE – NOT FOR SIGNATURE

SAFETY DATA EXCHANGE AGREEMENT

This Safety Data Exchange Agreement ("**SDEA**") is entered into as of the date on which this document has been signed by both parties ("**Effective Date**"), by and between **DEXCEL LTD**., with its registered address at 1 Dexcel Street, Or Akiva 3060000, Israel ("**Dexcel**") and **OTHER PARTY NAME**, with its registered address at [Company Address] ("**Company**").

1 **Scope**

1.1 As the holder of approved marketing authorizations (each, a "**Marketing Authorization**") in [the State of Israel (including the areas of the West Bank under Israeli control) and the Palestinian Authority (including the areas of the West Bank under Palestinian Authority control and Gaza)] ("**Territory**") for the pharmaceutical products listed in Appendix –PV1 ("**Products**"), Dexcel, as the holder of the Marketing Authorization in the Territory ("**MAH**") has local responsibilities for pharmacovigilance reporting and monitoring in the Territory. Company has responsibility for the global database for the Products; therefore, Company is responsible for oversight of pharmacovigilance for the all the markets for which it has outsourced distribution and marketing rights for the Products, including the Territory.

1.2 This SDEA is a supplement to the [_____] Agreement between Dexcel and Company, dated _____ ("**Commercial Agreement**"), and describes the pharmacovigilance and exchange of safety information responsibilities of the parties for the Products, overrides any conflicting provisions regarding pharmacovigilance, safety issues and/or exchanges of safety information in any other agreement between the parties with respect to the Products (including, without limitation, the Commercial Agreement), and it supersedes any previous procedure that existed between the parties with respect to the exchange of pharmacovigilance information for the Products.

1.3 This Agreement, with the exception of Article **6** (Confidentiality), will be automatically terminated on the date that the final batch of any Product supplied by Company to Dexcel has reached its expiry. For the avoidance of doubt, the latest possible date based on product expiry for all Products supplied by Company to Dexcel shall be used as the automatic termination date of this SDEA.

1.4 All exchanges of information pursuant to this SDEA between Company and Dexcel and with the relevant health authorities in the Territory ("**Health Authorities**") shall use the current rules, terms and definitions as stated in the Good Pharmacovigilance Practices [*as published by the European Medicines Agency (EMA), and the equivalent*] rules, regulations and guidelines applicable in the Territory ("**Israeli Rules**"), as all such may be amended from time to time.

1.5 The guidelines stated herein shall apply only as a minimum, it being understood by the parties that the Israeli Rules relating to pharmacovigilance applicable in the Territory shall be abided by and prevail to the extent the Israeli Rules are more restrictive than the provisions of this SDEA.

2 **Pharmacovigilance Terms and Definitions**

2.1 '**Adverse Drug Reaction**' ('**ADR**') concerns noxious and unintended or undesirable responses to a medicinal product. This means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility. Adverse reactions may arise from use of a medicinal product within or outside the terms of the medicinal product's marketing authorization or from occupational exposure, including, *inter alia*, off-label use, overdose, misuse, abuse and medication errors.

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 IF PUBLICLY DISCLOSED

2.2 '**Adverse Event**' ('**AE**') is any untoward medical occurrence in a patient administered a medicinal product and which does not necessarily have to have a causal relationship with this treatment. An adverse event can therefore be any unfavourable and unintended sign (e.g. an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

2.3 '**Serious Adverse Drug Reaction**' ('**SADR**') shall mean any untoward medical occurrence that, at any dose:

a. results in death,
b. is life-threatening,
c. requires in-patient hospitalisation or prolongation of existing hospitalisation,
d. results in persistent or significant disability/incapacity,
e. is a congenital anomaly/birth defect, and/or
f. is a medically (or clinically) important event or reaction.

2.4 '**Unexpected Adverse Drug Reaction**' shall mean an adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g. Investigator's Brochure for an unapproved investigational medicinal product).

2.5 '**ICSR**' is an individual case safety report in the form required by the Health Authorities in the Territory.

2.6 '**Product Complaint**' is a report of product deficiency which can stem from any source in the product distribution chain once the product has been placed in commercial distribution (including samples), excluding reports classified as or containing adverse reactions/adverse events.

2.7 '**Date of First Receipt**' ('**DFR**') shall mean the calendar date when the first person at either party is notified of a suspected adverse drug reaction.

2.8 '**Healthcare Professional**' for the purposes of reporting suspected adverse reactions, healthcare professionals are defined as medically qualified persons, such as physicians, dentists, pharmacists, nurses and coroners or as otherwise specified by local regulations.

3 **Correspondence**

3.1 Dexcel, as the MAH for the Products in the Territory, shall be responsible for all correspondence relating to the Product with the Health Authorities in the Territory, as required.

3.2 All correspondence, communications and reports between Dexcel and Company pursuant to this SDEA will be in English. English translations of reports, data, or other documents within the scope of this SDEA shall be the responsibility of the party that is sending the report, data or other documents.

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 IF PUBLICLY DISCLOSED

3.3 Dexcel, as the MAH for the Products in the Territory, is also responsible for responding to any safety-related inquiries received from Healthcare Professionals, consumers or the

Health Authorities regarding the Products in the Territory.

4 **Safety Information Exchange**

4.1 Dexcel shall be responsible for the following with respect to all suspected Adverse Drug Reactions associated with the Products (including all spontaneous serious and non-serious reports, both expected and unexpected), occurring in the Territory:

4.1.1 Investigation and follow-up of ADRs reported in the Territory shall be the responsibility of Dexcel. Company shall provide Dexcel, upon request, with reasonable assistance to ensure that appropriate investigations or testing is carried out on any Products thought to be associated with an ADR.

4.1.2 Dexcel shall be responsible for reporting suspected ADRs relating to the Products to the relevant Health Authority in the Territory in line with current legislation.

4.1.3 ADR reports should contain at least the following minimum information. However, the reports with any of the below information missing should also be forwarded to Company:

a. An identifiable reporter / source (e.g. Healthcare Professional or consumer) with contact details for the reporter / source;
b. An identifiable patient (e.g. gender / age or age group);
c. The suspected ADR; and
d. The suspect medicinal product (with an active ingredient the same as that used in the Product).

4.1.4 Dexcel will forward all reports (initial and follow-up, serious and non-serious, unlisted and listed) occurring in the Territory to Company within five (5) calendar days of DFR (including, but not limited to, Spontaneous, Competent Authority, and Solicited reports). In addition, the following shall be forwarded to the Company:

a. Knowledge of any Adverse Event or Adverse Drug Reaction;
b. Details of any publication reporting any Adverse Event or Adverse Drug Reaction identified from its review of scientific literature;
c. Details of any reported lack of Efficacy, change in reported efficacy of the product, abuse, misuse, medication error or overdose.
d. Details of any pregnancy / report or exposure (including paternal exposure)
e. Details of any occupational exposure
f. Details of the product use during lactation
g. Adverse reaction related to product use outside the terms of the marketing authorization (off-label use);
h. Adverse reactions related to counterfeit product;
i. Adverse reaction related to transmission via a medicinal product of an infectious agent;
j. Adverse reaction data from class action lawsuits;

Company, as owner of the global safety database for the Product, will capture all suspected ADRs forwarded by Dexcel and include such reports in periodic safety update reports ("**PSURs**") that are generated in association with the Product. For reports forwarded by Dexcel, Company shall be ultimately responsible for assessing the seriousness, causality of each report that is added to the global safety database.

4.1.5 All Communications between the Parties themselves shall be in English and, where possible, in writing. Any required translation into English of a Communication will be the responsibility of the Informing Party.

4.1.6 As an absolute minimum, Dexcel will provide information outlined in Section 4.1.4 in English to enable case processing for Adverse Events or Adverse Drug Reaction or Other Pharmacovigilance information. A full English translation of the source document and translation date will be provided as a follow-up report.

4.1.7 Company will provide Dexcel with Company's evaluation of reports occurring in the Territory following assessment as specified in Section 4.1.4:

a. For serious ADR reports, Company will provide its evaluation within twelve (12) calendar days of DFR,

b. For non-serious ADR reports, Company will provide its evaluation within thirty (30) calendar days of DFR.

4.1.8 ADR reports occurring in the Territory which were received during the first twelve (12) months of the marketing of any new formulation of the Product will be expedited to the local Health Authority within a fifteen (15) day period, as per local legislation. In order to be in line with reporting timeframes, the case exchange will be according to time frames of serious case reports as specified in Section 4.1.4 and Section 4.1.7 0.

4.1.9 If Company receives a spontaneous ICSR associated with the Products in the Territory, Company will immediately (within two (2) business day, as defined in the Territory) forward the ICSR to Dexcel for processing as defined above.

4.1.10 ICSRs shall be sent electronically (e.g. as a PDF attachment, via email) between the contacts defined in Appendix PV-II to this SDEA. Facsimile transmission or telephone may be used in circumstances where the usual email mode of transmission is not available.

4.1.11 Format: All ICSRs received from spontaneous notification shall be transmitted in a format agreed by both parties. This can be any of the following forms: CIOMS I or E2B files consistent with the ICH E2B/M2 Guideline on the Data Elements for Electronic Transmission of ICSR or other agreed form in English.

4.2 Literature Searches.

4.2.1 Dexcel is responsible for local literature search in the Territory for articles that include reports of suspected adverse drug reactions possibly associated with a Product. Dexcel is subsequently responsible for processing (including requests for additional information from the authors where appropriate) and reporting to the relevant Health Authorities any ICSRs identified where required to do so by current legislation. Such reports identified by Dexcel from local literature search should be forwarded to Company according to the timelines defined in section 5.1.5.

4.2.2 Company is responsible for global literature search.

4.3 Signal Detection.

4.3.1 Company shall be responsible for identifying new risks of the product and for informing Dexcel immediately any safety concern or any change in risk- benefit balance of the product. Company will inform Dexcel about a validated signal within 10 days of validation. Dexcel will inform Company of any safety concerns identified by Dexcel within 10 calendar days. Dexcel will inform the national Health Authority with this information, if applicable.

4.3.2 Each party shall notify the other party within five (5) business days regarding any Health Authorities actions or enquiries regarding the Product, including, without limitation:

a. Restrictions on distribution or recall actions due to safety issues;
b. Clinical trial suspension or protocol amendment for safety and/or efficacy reasons;
c. Dosage modification for safety reasons;
d. Changes in target population or indications for safety reasons;
e. Formulation changes for safety reasons; or
f. Modification of the investigator brochure and/or core safety data sheet and/or labelling for safety reasons.

4.4 Periodic Safety Update Reports (PSURs).

Company, as owner of the global safety database for the Product, will prepare PSURs based on the European Union reference date (EURD) list. These reports will be made available to Dexcel to support their submissions relating to maintenance of the marketing authorisation in the Territory.

4.5 Risk management Plans

4.5.1 If a Risk Management Plan (RMP) for the Product is required by Regulatory Authorities in the Territory as a post-authorization commitment, Dexcel will inform Company within (2) two business days in order to allow an adequate timeframe for preparation of such a document. RMPs will be prepared and updated by Company and provided to Dexcel in a timely manner.

4.5.2 Dexcel is responsible for implementing any risk minimization activities for the Product in the Territory.

4.6 Training of employees

The parties are both responsible for instituting systems, procedures and training (including training records) within their company (including affiliate companies where necessary) to appropriately collect, document, submit all pharmacovigilance data consistent with the procedures set forth in this Article 4.

4.7 Reconciliation

4.7.1 Where information has been exchanged between the parties, an e-mail or fax acknowledging receipt of the information must be sent to the other party within three (3) calendar days. If information has been forwarded but an acknowledgement is not received, the discrepancy must be investigated and resolved by both parties.

4.7.2 Quarterly reconciliation listing will be set up so that the case transmissions to each party are verified. Dexcel will send a line listing of all cases received at Dexcel for the Product. Company shall review the line listing and notify Dexcel of any cases not received at Company. Dexcel shall provide further information that Company reasonably requests in order to complete the quarterly reconciliation. Reconciliation of the prior quarter shall be completed by the beginning of the following month e.g. Reconciliation for the quarter January to March, must be completed by end of April.

4.8 Medical Information

4.8.1 Each party shall be responsible for providing medical information scientific services to consumers and healthcare professionals in their Territories for the Product. Dexcel may use only the Product labelling to answer directly enquiries it receives from either health care professionals or consumers, but in instances where this data does not provide a suitable response, the enquiry may be forwarded to Company for its help with responding to the enquirer. The contact information for Company Medical information is provided in Appendix PV-2.

4.8.2 If a medical information inquiry involves an ICSR, such ICSR should be reported by Dexcel to Company in accordance with the instructions and timeframes specified in this Article 4.

5 **Product Quality Complaints**

5.1 Quality complaints concerning the Product will be handled in the manner described in the Technical Agreement signed by and between the parties.

5.2 For Product quality complaints that also have an associated suspected ADR, the ICSR must be reported between the parties as defined in section 5.1 of this SDEA.

6 **Confidentiality**

Both parties agree that the information exchanged under this SDEA is Confidential Information as defined in the Commercial Agreement and shall not be disclosed to any third party other than for the purposes described in this SDEA (i.e. for compliance with international and local pharmacovigilance legislation).

7 **Audit**

Upon reasonable written notice, either party may initiate an audit of the other Party's relevant activities to monitor compliance with this SDEA and applicable laws and regulations. An audit may be performed by internal personnel with reasonable qualifications and experience or both Parties may agree upon a third party auditor who will be performing the audit. The audit will relate only to the scope of and compliance with this SDEA and applicable laws and regulations, and will be performed during normal business hours on dates to be agreed between the parties. All audit-related out-of- pocket expense shall be borne by the Party seeking the audit. Neither Party may require an audit more than once in one calendar year.

8 **Miscellaneous**

8.1 Neither party may assign this SDEA or any rights or obligations hereunder in any manner without the prior written consent of the other party.

8.2 The parties agree to update this SDEA according to any changes made in regulatory requirements. Dexcel will inform Company in the event of any updates or changes in the national regulatory requirements in the Territory concerning pharmacovigilance.

8.3 Failure or breach by either party to comply with any of the obligations and conditions hereof, unless such failure is caused by applicable laws or regulations, shall entitle the other party to give to the party in default notice requiring it to remedy such failure or breach. If such failure or breach is not remedied within thirty (30) days after receipt of such notice (or in the case of a failure or breach not capable of being remedied within such thirty (30) days period, the party in default has failed within such period to commence and diligently

continue actions to cure such failure or breach), the notifying party shall be entitled to terminate this SDEA and/or the Commercial Agreement between the parties relating to the Product, by giving notice to take effect immediately.

8.4 The provisions of this SDEA shall be deemed separate. Therefore, if any part of this SDEA is rendered void, invalid or unenforceable, such rendering shall not affect the validity and enforceability of the remainder of this SDEA unless the part or parts which are void, invalid or unenforceable shall substantially impair the value of the whole SDEA to either party.

8.5 The headings used in this SDEA are for the convenience of the parties only, and shall not be considered in interpreting or applying the provisions of this SDEA.

8.6 This SDEA may be executed in any number of counterparts, each of which shall be deemed an original and all of which taken together shall be one and the same agreement. Counterparts may be delivered via electronic mail (including pdf or electronic signatures) and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

IN WITNESS WHEREOF, the Parties have executed this SDEA as of the Effective Date.

DEXCEL LTD.		**OTHER PARTY NAME**	
Signature:		Signature:	
Name:	***	Name:	
Position:	Vice President, Quality	Position:	
Date:	_____, 202__	Date:	_____, 202__

CONFIDENTIAL

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 IF PUBLICLY DISCLOSED

Appendix PV-1

Products

Trade name	**Active ingredient (INN)**	**MA NUMBER**

CONFIDENTIAL

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 IF PUBLICLY DISCLOSED

Appendix PV-2

Contact List

Dexcel:

Name	**Title**	**Contact Details**
***	***	T: *** M: *** T ***@dexcel.com
***	***	T: *** M: *** ***@dexcel.com

Company:

Name	**Title**	**Contact Details**

CONFIDENTIAL

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 IF PUBLICLY DISCLOSED

Appendix 4 – Comparative dissolution requirements

Qualification of use of EU/US reference product

To justify the use of the biostudy conducted with US reference product a comparison should be made to Israeli reference product. The comparison, including the dissolution study, physical characterization and qualitative composition, as described below should include all strengths from the bio study.

Comparative dissolution study:

Comparative dissolution study reports should include a 12 unit dissolution profile of the Israeli reference product, in the following media: 0.1N HCl, pH 4.5 and pH 6.8 with no addition of surfactant (unless justified), and QC medium.

All dissolution profile studies should be done using the QC dissolution method parameters (volume, stirring rate and temperature).

In case USP monograph for the drug product is available, 12 units of dissolution profile of the Israeli reference product at dissolution conditions described in the monograph should be provided.

Comparative dissolution data on the US Bio reference product vs. test product should be provided. In case comparative dissolution of original reference vs. test product were not performed at 0.1N HCl, pH 4.5, pH 6.8, QC medium and/or USP dissolution conditions, then these tests should be completed using 12 units of each product. Use of new batches different than the bio-batches

is allowed.

Results of all dissolution studies shall be presented in tabulated format including individual results, average and RSD, and on charts.

F_2 calculations between the US reference vs. the Israeli reference and between the Israeli references vs. test product shall be provided. Please also include the list of values that used for the F_2 calculations.

Physical characterization

Physical characterization of the IL RLD, US RLD such as description (i.e., shape, color, debossing, presence of film coating), dimensions and weight should be provided by the partner as part of the study using 12 units of each product.

Qualitative composition

A tabulated comparison of the qualitative composition of Israeli reference product and of the US reference product used in the bio study should be provided.

Exhibit 10.58

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 IF PUBLICLY DISCLOSED

February 18, 2022

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 through June 30, 2023. In consideration of the foregoing, provided that you remain continuously employed with the Company through June 30, 2023, you will be entitled to a retention bonus of $300,000 less applicable withholding taxes, regardless of whether you remain with the Company or leave the Company any time after June 30, 2023. The retention bonus shall be paid in two installments. The first installment shall be paid on October 31, 2022, and the second on June 30, 2023. Further, in the period up to June 30, 2023 your salary will be adjusted to $300,000 per year effective March 1st, 2021. 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 IF PUBLICLY DISCLOSED

LICENSE, SUPPLY AND DISTRIBUTION AGREEMENT

FOR VIGABATRIN

ELITE PHARMACEUTICALS, INC.,

ELITE LABORATORIES, INC.,

- and -

LANNETT COMPANY, INC.

Dated as of July 20, 2021

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 IF PUBLICLY DISCLOSED

THIS LICENSE, SUPPLY AND DISTRIBUTION AGREEMENT is made as of July 20, 2021 (the "Effective Date"), by and between ELITE PHARMACEUTICALS, INC. a Nevada corporation and ELITE LABORATORIES, INC., a Delaware corporation located at 165 Ludlow Avenue, Northvale, New Jersey 07647 (collectively, "**ELITE**"), and LANNETT COMPANY, INC., USA, a Delaware corporation located at 9000 State Road, Philadelphia, PA 19136 and/or its Affiliates ("**LANNETT**").

WHEREAS:

A. ELITE has ownership rights to Products and/or ANDAs specified in Schedule A (the "Products"), and LANNETT wishes to license from ELITE the exclusive rights to market and sell the Products on the terms and conditions set forth in this Agreement.

B. ELITE has significant experience in developing, manufacturing and marketing finished dosage forms of pharmaceutical products, including the Products;

C. LANNETT has significant experience in marketing pharmaceutical products; and

D. Subject to the terms and conditions of this Agreement, LANNETT desires to engage ELITE on an exclusive basis to manufacture, supply, package and label the Products and ELITE agrees to grant LANNETT the right under this Agreement to commercialize the Products in the Territory on an exclusive basis.

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

ARTICLE 1 - DEFINITIONS

1.1 In addition to terms defined elsewhere in this Agreement, the terms set forth below shall be defined in this Agreement (including the recitals) as follows:

(a) "**Affiliate**" with respect to either Party means any Person who directly or indirectly through one or more intermediaries controls, is controlled by, or is under common control with such Party. The term "control" means the beneficial (direct or indirect) ownership of more than fifty percent (50%) of the voting or equity interests of such Person or the power or right to direct the management and affairs of its business, whether through the ownership of voting securities, by contract, or otherwise.

(b) "**Agreement**" means this License, Supply and Distribution Agreement, together with all schedules hereto.

(c) **Analytical Specifications**" has the meaning given in **Article 4.1(a)**.

(d) "**ANDA**" means an Abbreviated New Drug Application pursuant to Section 505(j) of the FDCA.

(e) "**Bankruptcy Code**" has the meaning given in **Article 14.16**.

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 IF PUBLICLY DISCLOSED

(f) "**Business Day**" in relation to each Party means any day other than a Saturday, a Sunday, or any statutory or public holiday on which banks are generally closed for regular business in New York, New York.

(g) "**Certificate of Analysis**" means a certificate of analysis that certifies that a given batch of Product meets the release Product Specifications.

(h) "**Claim**" means any claim, action, cause of action, or demand.

(i) "**Commercially Reasonable Efforts**" with respect to any activity means the efforts and resources that would be used in the performance of the relevant activity in compliance with Law by a Person (engaged in the manufacture and supply or distribution, sale and commercialization of pharmaceutical products, as applicable) of comparable size and resources as the applicable Party with regard to a product at a similar stage in its product life taking into account the following factors to the extent reasonable and relevant: issues of safety and efficacy, product profile, market potential, competitive market conditions, duration of exclusivity or other proprietary position of the product and the potential profitability and economic return of the product, all as measured by the facts and circumstances at the time such efforts are due.

(j) "**Confidential Information**" has the meaning given in **Article 12.2**.

(k) "**DEA**" shall mean the United States Drug Enforcement Administration or any successor entity.

(l) "**Debarred Entity**" has the meaning given in **Article 9.2(c).**

(m) "**Debarred Individual**" has the meaning given in **Article 9.2(c).**

(n) **"Distribution Fees"** means three percent (3%) of Net Sales for all Products.

(o) "**Effective Date**" has the meaning given in the preamble.

(p) "**Facility**" means the ELITE FDA-approved manufacturing site located at 135/165 Ludlow Avenue, Northvale, NJ, USA 07647.

(q) "**FDA**" means the United States Food and Drug Administration or any successor government agency.

(r) "**FDCA**" means the Federal Food, Drug, and Cosmetic Act.

(s) "**Force Majeure Event**" has the meaning given in **Article 14.5**.

(t) "**ELITE**" has the meaning given in the preamble.

(u) "**GMP**" means current good manufacturing practices for the manufacture of finished pharmaceutical products in effect within the Territory from time to time during the Term of this Agreement, which set minimum standards to ensure that pharmaceutical products meet established requirements for identity, strength, quality and purity, as established under the Laws of the Territory, including 21 C.F.R. Parts 210 and 211.

(v) **"Gross Sales"** means the gross amount invoiced by LANNETT or its Affiliates or sublicensees for sales of the Product to Third Parties in the Territory.

(w) "**Indemnitee**" has the meaning given in **Article 11.3**.

(x) "**Indemnitor**" has the meaning given in **Article 11.3**.

(y) "**Intellectual Property Rights**" means any patent, trademark, copyright, trade secret, right in unpatented know-how, right of confidence and any other intellectual or industrial property right of any nature whatsoever in any part of the world, whether registered or unregistered.

(z) "**LANNETT**" has the meaning given in the preamble.

(aa) "**Law**" means any federal, state, provincial and local laws, statutes, regulations, rules, guidelines, orders, ordinances, and any other requirements of any government or Regulatory Authority in the Territory applicable to the development, registration, manufacturing, testing, packaging, storing, shipping, marketing, distribution and sale of pharmaceutical products or as otherwise applicable to the Parties respective obligations under this Agreement, including the FDCA.

(bb) "**Losses**" means any damages, liabilities, obligations, costs, expenses or losses, including reasonable legal fees and expenses, court costs, penalties, fines, costs of investigation and amounts paid in settlement of claims.

(cc) "**Major Change**" shall mean a change that has the potential to adversely impact quality, identity, purity or stability of the Products or the compliance and validity of the Products Marketing Authorizations, as these factors may relate the safety or efficacy of the Product and as defined in the FDA regulations and guidance.

(dd) "**Marketing Authorization**" means all approvals, licenses, registrations or authorizations of any Regulatory Authority, necessary for the manufacturing, use, storage, import, transport, marketing, promotion and sale of the Product in the Territory, together with pricing or reimbursement approval in countries where governmental approval is required for pricing or for the Product to be reimbursed by national health insurance.

(ee) **"Net Sales"** shall mean with respect to the Product, Gross Sales less the following items (whether or not separately stated on such invoice but only to the extent included in Gross Sales):

(i) Any and all promotional allowances, rebates, charge backs, quantity and cash discounts, and other usual and customary discounts to customers;

(ii) Amounts refunded, repaid or credited by reason of rejections, returns or recalls of goods;

(iii) Any sales, excise, turnover, inventory, value-added, and similar taxes and duties assessed on applicable sales;

(iv) Failure to Supply penalties (in the case if Article 4.4 (i) and (ii)), Non-affiliate third party administrative fees granted, Medicaid and state and/or governmental rebates, and shelf stock adjustments and retroactive price reductions.

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

(ff) "**Net Profits**" is calculated as listed in Schedule C and means the Net Sales of a Product, minus the sum of (i) the Distribution Fee, (ii) Transfer Price of Product and (iii) shipping costs from the Facility.

(gg) "**Non-Conforming Product**" has the meaning given in **Article 4.8(b)**.

(hh) "**Original Agreement**" has the meaning given in Recital A.

(ii) "**Packaging**" means all material used to prepare fully packaged Products, including labeling, containers, closures, cartons, and shipping cases, as applicable.

(jj) "**Parties**" means the parties to this Agreement referred to collectively, and "**Party**" means either party to this Agreement referred to individually.

(kk) "**Person**" includes any individual, partnership, corporation, unincorporated organization or association, joint venture, limited liability company, trust or any other form of entity.

(ll) "**Safety Data Exchange Agreement or SDEA**" means the pharmacovigilance agreement to be entered into by the Parties which shall set forth the safety data exchange procedures to be followed by the Parties for the collection, investigation, reporting and exchange of information concerning adverse events.

(mm) "**Products**" means the finished pharmaceutical products in commercially saleable form, as manufactured by ELITE exclusively supplied to LANNETT pursuant to this Agreement as set forth on Schedule A.

(nn) "**Purchase Order**" means a written, binding purchase order for a certain quantity of Product properly issued by LANNETT in accordance with the terms of this Agreement.

(oo) "**Quality Agreement**" means a quality agreement to be entered into by the Parties which will set forth certain obligations of the Parties in relation to the manufacture, packaging, quality control and testing of the Products in accordance with GMP.

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 IF PUBLICLY DISCLOSED

(pp) "**Recall**" shall mean a recall, removal, market withdrawal, seizure, or field correction of Product.

(qq) "**Regulatory Authorities**" means any federal, state, local or international regulatory agency, department, bureau or other governmental entity responsible for regulating the manufacture, use, storage, importation, transportation, distribution marketing, promotion and sale of pharmaceutical products in the Territory, including the FDA and DEA.

(rr) **"Regulatory Approval"** means all approvals or authorizations granted by the FDA for marketing the Products in the Territory.

(ss) **"Specifications"** means the written methods, formulae, procedures, specifications, tests (and testing protocols) and standards pertaining to the Products as approved by FDA in the Product's ANDA and attached herein as Schedule B, which may be amended from time-to-time by the written agreement of the Parties.

(tt) "**Term**" has the meaning given in **Article 8.1**.

(uu) "**Territory**" means the United States of America and its possessions, territories, protectorates, military bases and commonwealths.

(vv) "**Third Party**" means any Person other than LANNETT or ELITE, or any of their respective Affiliates.

(ww) "**Trademarks**" has the meaning given in **Article 4.3(a)**.

(xx) **"Transfer Price"** is listed and defined in Schedule A.

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

ARTICLE 2 - MARKETING AUTHORIZATIONS

2.1 Subject to the terms of this Agreement, ELITE shall exclusively manufacture, supply, package and label the Products for LANNETT, and LANNETT shall have the right to promote, market, store, distribute and sell the Products in the Territory. ELITE hereby grants to LANNETT and its Affiliates an exclusive right to fully commercialize the Products in the Territory. LANNETT agrees to exclusively purchase Products it requires from ELITE.

2.2 ELITE shall, at their expense, maintain and update the Marketing Authorizations for the Products as may be required for the Parties to perform their obligations hereunder. ELITE shall be solely responsible for all communications with the Regulatory Authorities in the Territory relating to any Marketing Authorizations for the Products. ELITE shall provide LANNETT with timely notice of any communications from the Regulatory Authorities which may affect ELITE's right or ability to supply LANNETT with the Products.

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 IF PUBLICLY DISCLOSED

ARTICLE 3 - PAYMENT TERMS

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

3.2 Upon delivery of the Products to LANNETT, ELITE shall submit invoices therefore to LANNETT. LANNETT shall pay each undisputed invoice in full within thirty (30) days of its receipt in full of the Products reflected in the invoice and the Certificate of Analysis, which Certificate is in a form sufficient for release of the Products. A late payment fee of one percent (1%) per month may be imposed upon LANNETT for payments past due, unless Products therein are subject to a quality dispute. In the event of any inconsistency between an invoice and this Agreement, the terms of this Agreement shall control.

3.3 License Fees. Within forty-five (45) days of the end of each calendar quarter, LANNETT shall pay to ELITE a License Fee of *** percent (**%) of the Net Profits received from sales of each Product. Such payment shall additionally include a sales summary for each Product generally in the format as provided in Schedule C. In no case shall the License Fee for any calendar quarter be negative; provided, however in the event of a loss in any calendar quarter, subject to ELITE's written approval of any Product pricing by LANNETT that leads to quarterly losses and subject to the loss carryover clause that follows, the amount of that loss shall be carried forward to subsequent calendar quarters until the amount of such loss has been fully absorbed. If Net Profits for calendar quarter are negative, LANNETT shall carry over the applicable License Fee percentage set forth above multiplied by the value by which the Net Profits are negative in such calendar quarter and deduct this amount from the calculation of Net Sales for the following calendar quarter. If Net Profits are negative in two (2) or more consecutive calendar quarters, LANNETT shall invoice ELITE the applicable License Fee percentage set forth above multiplied by the value by which the Net Profits are negative for the previous calendar quarter and carry over the applicable License Fee percentage set forth above multiplied by the value by which Net Profits are negative for the current calendar quarter and deduct this amount from the calculation of Net Sales for the following calendar quarter. For the avoidance of doubt, if Net Profits are negative in subsequent calendar quarters, the amounts will be similarly carried over or reimbursed as per the terms set forth in this Section 3.3 until Net Profits are positive. Reimbursement of negative Net Profits owed by ELITE in this Section 3.3 shall be payable to LANNETT within forty-five (45) days after receipt of an invoice from LANNETT.

ARTICLE 4 - MANUFACTURING AND SUPPLY; COMMERCIALIZATION

4.1 Supply of Products.

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

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 IF PUBLICLY DISCLOSED

(b) ELITE shall manufacture the Products in the Facility and use Commercially Reasonable Efforts to maintain access to sufficient supplies of raw materials, components and other required resources to perform its obligations under this Agreement, and meet LANNETT's supply requirements for the Products. ELITE shall not manufacture the Products at a site other than the Facility without first obtaining LANNETT's prior written consent, which consent shall not be unreasonably withheld. ELITE shall be solely responsible for all costs and expenses incurred in connection with the manufacture of the Products hereunder, including without limitation costs and expenses of personnel, quality control, testing, manufacturing, facilities, equipment, materials, FDA product fees, FDA establishment fees and government sales, use, excise, property or similar taxes or excises.

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

(d) Transfer Price Adjustments. The Transfer Prices for the Products under Schedule A are valid through December 31, 2022. After December 31, 2022, the Transfer Price for Products may be adjusted for any increase in the cost of active pharmaceutical ingredients, annual Generic Drug User Fees (GDUFA fees) proportional allocation, and other material government mandated requirements. ELITE shall provide at least thirty (30) days written notice to LANNETT for any such Transfer Price adjustments with justifications for any increase. ELITE shall use commercially reasonable efforts to reduce its manufacturing expenses for the Products. At either Party's written request, the Parties will discuss in good faith the revision of the Transfer Price (and any subsequently agreed prices) to take into account adverse market conditions resulting in unsatisfactory returns for LANNETT or changes in the manufacturing costs for the Products. The revised Transfer Price shall be laid down in writing and inserted as an amended Schedule A to this Agreement. Confirmed orders are excluded from Transfer Price negotiations. If, after good faith negotiations, the Parties are unable to reach agreement on an adjustment to the Transfer Pricing for the Products, then LANNETT shall be entitled to terminate this Agreement, effective upon at least sixty (60) days' prior written notice to ELITE.

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

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 IF PUBLICLY DISCLOSED

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

4.3 Delivery Terms.

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

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 IF PUBLICLY DISCLOSED

(b) ELITE shall deliver the full quantities of the Products set forth in each Purchase Order (Incoterms 2010 EXW) to LANNETT or its designee. All Products shall be packaged for shipment in accordance with the packaging specifications set forth in the Marketing Authorizations and packing instructions reasonably required by LANNETT.

(c) Each Products shipment made by ELITE shall be accompanied by and shall include a Certificate of Analysis for each shipment of the Products manufactured and supplied hereunder. ELITE shall be responsible for all applicable release testing of the Products in accordance with the Analytical Specifications. ELITE shall perform all required in-process quality control tests and quality assurance reviews on the Products, including without limitation, stability testing at its sole cost and expense. In addition, ELITE shall furnish LANNETT, along with the first shipment of the Products, ELITE's Material Safety Data Sheets containing the relevant safety and health information and such other similar information as LANNETT may reasonably from time-to-time request in connection therewith.

(d) All Products provided to LANNETT shall have no less than eighty five percent (85%) remaining shelf-life remaining as per the Product's ANDA.

(e) All orders containing at least ninety percent (90%) of the specified amount of Product in a Purchase Order shall be deemed satisfied.

4.4 Failure to Supply. ELITE shall notify LANNETT as promptly as possible, but in no event later than five (5) Business Days, after ELITE discovers that it will not be able to supply the quantity of Products ordered by the delivery date specified in a Purchase Order. In such event: (i) ELITE shall cooperate with LANNETT in taking all actions that LANNETT deems reasonably necessary in order to remedy such inability to supply, at ELITE's expense; and (ii) If ELITE's inability to supply continues past twenty (20) days from the required delivery

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

4.5 Samples and Batch Records. ELITE shall prepare and maintain batch records and file samples, properly stored, for each lot or batch of Products manufactured and shipped hereunder in compliance with all GMPs and Laws in the Territory.

4.6 Commercialization. LANNETT shall use Commercially Reasonable Efforts to market and sell the Products in the Territory. All commercial matters regarding the marketing, promotion, sale, offer for sale, pricing or distribution of the Products in the Territory shall be under the exclusive control of LANNETT.

4.7 Change of Specification. No alterations of the Specifications for the Products or other changes requiring prior approval by the FDA, or material changes to the manufacturing process or validated processes, can be made without the prior written approval of LANNETT. ELITE shall notify LANNETT in writing of any proposed alterations for the Specifications for the Products or any Major Changes to the manufacturing process or validated processes. LANNETT shall notify ELITE of LANNETT's decision within thirty (30) days of receipt of such proposal from ELITE. If ELITE does not receive LANNETT's decision in writing within thirty (30) days, the alteration of the Specifications or other Major Changes to the manufacturing process or validated process proposed by ELITE shall be deemed rejected by LANNETT. In the event that the FDA or any other governmental authority shall suggest or mandate any change or revision to the Product, such that the Specifications would no longer comply with such suggestion or mandate, the Parties shall work together in good faith to develop revised Specifications that meet all changes or revisions suggested or mandated by the FDA or other governmental authority and Schedule B shall be amended in writing to set forth the new agreed upon Specifications.

4.8 Acceptance of the Product.

(a) Following receipt of a shipment of Product at the final destination, LANNETT, or its designee, shall conduct a visual inspection of the Product and all accompanying documents provided by ELITE, including without limitation, the Certificate of Analysis, in accordance with its customary procedures. LANNETT shall advise ELITE, in writing, if it is rejecting a shipment of Product due to obvious physical damage or obvious packaging defect that are evident upon such visual inspection of the packaged Product as shipped by ELITE. LANNETT (and its designees) shall have no obligation to inspect the Product beyond the visual inspection provided for in this **Article 4.8(a)**.

(b) In the case of defects other than those obvious defects described in **Article 4.8(a)**, including, by way of example, any failure of the Product, at the time of delivery, to meet the Analytical Specifications and the representations, warranties and covenants of **Article 9.2(f)**, LANNETT shall promptly notify ELITE if it becomes aware of such non-obvious defect(s). Any defect in physical condition of Products delivered by ELITE or Products that do not conform with the Analytical Specifications (as may be in effect from time to time) or the representations, warranties and covenants of **Article 9.2(f)** for any reason shall be deemed to be a non-conforming product ("**Non-Conforming Product**"). LANNETT, or its designee, shall have the right to reject any Non-Conforming Product and no failure on the part of LANNETT, or its designee, or passage of time shall prejudice LANNETT's right to reject or revoke acceptance of Non-Conforming Product. All Non-Conforming Product shall be returned to ELITE at its sole cost and expense.

(c) If ELITE confirms the Non-Conforming Product or lab testing pursuant to **Article 4.8(d)** determines that the Product is Non-Conforming Product, ELITE shall, at LANNETT's election, either replace such Non-Conforming Product with conforming Product or, refund to LANNETT, the price paid for such Non-Conforming Product.

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

ARTICLE 5 - INSPECTIONS

5.1 Inspections. During the Term of this Agreement and thereafter in the event of a Claim against either Party regarding use of the Products is threatened or commenced, ELITE shall permit LANNETT's representatives to enter ELITE's facilities, upon reasonable prior notice (except in the event of a for-cause audit) and during normal business hours, for the purpose of inspecting the facility and quality control procedures and confirming compliance with all applicable GMPs and Laws in the Territory, the requirements of the Regulatory Authorities in the Territory, the Quality Agreement and this Agreement. If during any such inspection LANNETT discovers any instances in which ELITE has not complied with the foregoing, then ELITE shall promptly provide to LANNETT a written plan for correcting such deficiencies, including a proposed timetable for implementing such corrections, and shall ensure that such deficiencies are corrected, at ELITE's sole expense, as soon as reasonably practicable. ELITE agrees to provide LANNETT with copies of all: (i) reasonably requested documentation in its possession relating to the manufacture of Product, Specifications, compliance with quality assurance standards, raw material vendors and manufacturing processes; and (ii) U.S. and international regulatory approvals, regulatory inspections of the manufacturing process, facilities and documentation, and other communications with Regulatory Authorities related to the Product; however ELITE shall not be required to provide copies to LANNETT of ELITE's proprietary information and ELITE shall only be required to allow LANNETT to inspect such proprietary information such as batch records at ELITE's site and under ELITE's supervision. Notwithstanding the provision of this **Article 5.1**, LANNETT shall have no obligation or be deemed to have an obligation to inspect ELITE's facilities.

5.2 Regulatory Authority Inspections. ELITE shall permit any Regulatory Authority to inspect the facility used to manufacture the Products and all associated records to the full extent permitted by applicable Law ("**Regulatory Inspection**"). ELITE shall notify LANNETT within forty-eight (48) hours of becoming aware of any planned or actual Regulatory Inspection. ELITE agrees to reasonably cooperate with the applicable Regulatory Authority in connection with such audits. ELITE shall notify LANNETT prior to the commencement of any meetings with, or inspection activity by, any Regulatory Authority, unless such inspection activity is an unannounced inspection. Further, ELITE shall provide a reasonable description to LANNETT of any such governmental inquiries, notifications or inspections related to Products promptly (but in no event later than five (5) calendar days) after such visit or inquiry. ELITE shall furnish to LANNETT: (i) within five (5) calendar days after receipt, any report or correspondence issued by the Regulatory Authority in connection with such visit or inquiry, including but not limited to, any FDA Form 483, establishment inspection report, or warning letter; and (ii) copies of any and all responses or explanations to any Regulatory Authority relating to items set forth above prior to the submission of such responses or explanations to any Regulatory Authority by ELITE for comment, which comments

shall be taken into consideration by ELITE in good faith. ELITE shall also provide LANNETT with a copy of all final responses.

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 IF PUBLICLY DISCLOSED

ARTICLE 6 - RECORDS

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

6.2 Inspection of ELITE Books and Records. During the Term of this Agreement, and thereafter for the greater of (i) the period stipulated by the Laws in the Territory, and (ii) two (2) years from the expiration of the last Products manufactured, ELITE agrees that LANNETT, at reasonable times upon reasonable prior notice, may inspect the research and development books and records of ELITE pertaining to ELITE's obligations under this Agreement for purposes of ensuring compliance with the terms of this Agreement.

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

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 IF PUBLICLY DISCLOSED

6.4 Annual Reports. ELITE shall provide LANNETT in a timely manner copies of ELITE's annual reports to the FDA or any other Regulatory Authority with respect to the Products.

ARTICLE 7 - RECALLS

7.1 Notification of Recall. If any Regulatory Authority or other governmental agency issues or requests a Recall or takes similar action in connection with a Product in the Territory, or if LANNETT reasonably determines after consultation with ELITE that an event has occurred which may result in the need for a Recall, the Party notified of or wishing to implement such Recall shall, within forty-eight (48) hours (regardless of weekday, weekend or holiday), advise the other Party thereof by telephone or facsimile, after which the Parties shall promptly discuss and work together to effect an appropriate course of action. ELITE shall be responsible for notifying the Regulatory Authorities in the Territory of any voluntary Recall and implementing any Recalls. LANNETT shall fully cooperate with ELITE to fully implement any Recall. ELITE agrees to forward to LANNETT a copy of any field communication associated with the Products that it plans to issue before such communication is issued or sent to any governmental agency. ELITE will maintain complete and accurate records of any activities conducted with respect to any Recall for such period as may be required by Law. Following any Recall, ELITE will review all of its procedures as impacted by the identified root cause in the associated investigation, and will revise such procedures, as necessary, to correct the cause of such Recall subject to the change control requirements set forth in the Quality Agreement. ELITE will provide LANNETT with such information regarding such review and revisions as LANNETT may request and ELITE shall provide LANNETT the right to approve, reject or request modifications to the proposed changes.

7.2 Recall Expenses. If a Recall results from the acts or omissions of one Party, then such Party shall bear the full expenses of both Parties incurred in the Recall. For clarity, if a Recall is due to a defect during the manufacture, processing, packaging or labelling of the Product prior to delivery, the cost and expense shall be borne solely by ELITE. If a Recall is partially caused by the actions or omissions of both Parties, then each Party shall be responsible for its proportionate share of the Recall expenses based on its proportionate share of causation. Recall expenses include the expenses of notification, shipping, return, replacement (if possible), customer fees and penalties, and destruction of recalled Products (including Products which cannot be shipped due to the condition causing the Recall). The Parties shall discuss in good faith and agree on the scope and costs of Recall, if practicable, prior to enforcement of the Recall.

7.3 Notice of Failure to Meet Specifications. If ELITE discovers that there is a potential that any batch or lot of the Products already delivered to LANNETT may fail to conform to the Specifications, then ELITE shall notify LANNETT within twenty-four (24) hours (or one (1) business day), of such determination of failure to meet the Specifications and of the nature thereof in detail, including, but not limited to, supplying LANNETT with all investigatory reports, data and communications, out-of-specification reports and data and the results of all outside laboratory testing and conclusions, if any. ELITE shall investigate all such failures promptly, and at its sole expense, cooperate with LANNETT in determining the cause for the failure and a corrective action to prevent future failures.

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 IF PUBLICLY DISCLOSED

ARTICLE 8 - TERM & TERMINATION

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

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

(a) if a Party files a petition in bankruptcy or is adjudged as bankrupt, or a petition in bankruptcy is filed against it and is not dismissed within sixty (60) days, or it

becomes insolvent, takes advantage of legislation for creditor relief, has a receiver or receiver-manager appointed in relation to its assets, or discontinues its business, then the other Party may terminate this Agreement upon delivering written notice of termination;

(b) if a Party hereto violates or fails to perform any of its material undertakings, agreements, covenants or obligations under this Agreement (excluding matters otherwise specifically addressed with a termination right elsewhere in this Agreement) and the failure is not remedied within thirty (30) days after written notice from the non-defaulting Party, then the non-defaulting Party may terminate this Agreement upon delivering written notice of termination to the breaching Party; *provided* that if the breaching Party is diligently pursuing in good faith the remedy of the breach at the expiration of such thirty (30) day cure period, then such thirty (30) day cure period may be extended as reasonably required to effect the cure if agreed to by the non-defaulting Party;

(c) if a Party hereto willfully or fraudulently misrepresents any fact, information or report disclosed pursuant to this Agreement and such misrepresentation is not cured or remedied within thirty (30) days after the receipt of written notice thereof by the non-defaulting Party, then the other Party may terminate this Agreement upon delivering written notice of termination;

(d) if a court of competent jurisdiction makes a final determination that the marketing and sale of a Product in the Territory infringes the patent or other Intellectual Property Rights in the Territory of a third party and enjoins the marketing and sale of the Product in the Territory, and if all rights to appeal have been exhausted or expired, then LANNETT may, upon delivering written notice to ELITE, terminate this Agreement with respect to such Product;

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 IF PUBLICLY DISCLOSED

(e) by ELITE or LANNETT, on a Product by Product basis, if any time after the first twelve (12) months from the first commercial sale, the average License Fee paid by Lannett is less than three hundred thousand dollars (US$300,000) for a six (6) month sales period for that Product; and

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

(g) If at initial commercial launch the Product must be launched at a negative Net Profit (due to market average sales price falling), then the parties shall meet and discuss the best path forward to minimize losses. If the best path is not to launch, then the Parties agree to share inventory costs for the first batch of finished product that Lannett has purchased at launch according to the agreed upon Net Profit split.

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

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

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

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 IF PUBLICLY DISCLOSED

ARTICLE 9 - REPRESENTATIONS & WARRANTIES

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

(a) it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this Agreement; and

(b) this Agreement is its legal, valid and binding obligation, enforceable in accordance with the terms and conditions hereof.

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

(a) No Other Agreements. No contracts, commitments or agreements of any nature exist, and none will be entered into during the Term of this Agreement, that impair or inhibit the ability of ELITE to perform its obligations hereunder.

(b) No Lawsuits. As of the date hereof there have not been any Claims, lawsuits, arbitrations, legal or administrative or regulatory proceedings, charges, or complaints or investigations, by any third party or government authority threatened, commenced, pending or proceeding against ELITE, and ELITE has not received any notice thereof, which could prevent ELITE from complying with its material obligations under this Agreement.

(c) Debarred. Neither ELITE nor any of its officers, directors, or employees or consultants performing services under this Agreement has been or is: (1) an individual who has been debarred by the FDA pursuant to 21 U.S.C. § 335a(a) or (b) ("**Debarred Individual**") from providing services in any capacity to a person that has an approved or pending drug product application with FDA, or an employer, employee, or partner of such a Debarred Individual; or (2) a corporation, partnership or association that has been debarred by FDA pursuant to 21 U.S.C. § 335a(a) or (b) ("**Debarred Entity**") from submitting or assisting in the submission of an ANDA, or an employee, partner, shareholder, member, subsidiary, or affiliate of a Debarred Entity; or (3) an employer, employee or partner of an individual convicted within the last five years for crimes described in subsections (a) or (b) of Section 306 of the FDCA. If and when ELITE becomes aware of any fact that makes or gives rise to make this representation and warranty untrue, ELITE shall immediately notify LANNETT in writing and any such breach may result in immediate termination of this Agreement by LANNETT.

(d) Non-Infringement.

(i) ELITE's performance of its obligations hereunder to the best of ELITE's knowledge does not and will not infringe any intellectual property rights of a third party.

(ii) To the best of ELITE's knowledge no patents, patent applications if issued, or any other proprietary rights of any third party would be infringed by the manufacture, use or sale of the Product and ELITE shall indemnify, defend and hold harmless LANNETT and its Affiliates against any and all such infringement claims, demands, actions, losses, damages, fines, penalties, costs and expenses (including reasonable attorneys' fees). The indemnification obligation of ELITE shall include Third Party patents issued after the Effective Date.

(e) Facility. The Facility is in compliance with all Laws, including without limitation GMP, and that there are no, nor have been any, citations or adverse conditions of a material nature noted in any inspection of the site which would cause the Product to be misbranded or adulterated. It has and shall maintain sufficient knowledge and experience and adequate production facility(s), equipment and processes to produce the Product and perform its obligations under this Agreement in compliance with all Laws.

(f) Products Supply. ELITE warrants, represents and covenants to LANNETT that all Products delivered to LANNETT hereunder shall:

(i) comply with the Specifications;

(ii) comply with the applicable Purchase Order;

(iii) be manufactured, tested, packaged, labeled, stored, handled and delivered by ELITE in accordance with (i) the terms of this Agreement, including the Specifications, and the Quality Agreement, (ii) the requirements of the Marketing Authorization, (iii) all applicable GMPs and Laws in the Territory, including regulations set forth by the DEA, (iv) all of ELITE'S quality control procedures and associated test methods for the Products;

(iv) be manufactured at the Facility approved by the Regulatory Authorities in the Territory;

(v) not be adulterated or misbranded under any applicable Laws in the Territory;

(vi) have at least eighty-five percent (85%) of the Product's shelf-life remaining at the time of delivery; and

(vii) be free of all liens, security interests, and other claims of any nature and free from defects in material, manufacturing and workmanship for the shelf-life of the Products.

(g) be manufactured, supplied, packaged, labeled and delivered in compliance with all serialization and aggregation requirements set forth in the Drug Supply Chain Security Act (DSCSA) Marketing Authorizations. The serialization requirements include, but are not limited to, the addition of Product identifiers imprinted on each sellable unit, on each homogenous case and on each pallet intended to be introduced in the Territory. Unique Product identifiers will include a national drug code, serial identifier (proved by LANNETT), lot number and expiration date. Serial numbers must be aggregated from item to case and case to pallet. ELITE warrants, represents and covenants to LANNETT that (i) all Marketing Authorizations have been obtained as necessary to permit LANNETT to manufacture, use, store, import, transport and sell the Product in the Territory pursuant to the terms of this Agreement and (ii) ELITE shall maintain all necessary Marketing Authorizations in good standing to permit LANNETT to manufacture, use, store, import, transport and sell the Product in the Territory pursuant to the terms of this Agreement.

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

(i) Subject to DEA quotas, it has access to sufficient supplies of raw materials, components and other required resources to perform the services required under this Agreement, and shall exercise commercially reasonable and diligent efforts to maintain access to sufficient supplies without interruption during the Term.

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

(a) No Other Agreements. No contracts, commitments or agreements of any nature exist, and LANNETT covenants that none will be entered into during the Term of this Agreement that impair or inhibit the ability of LANNETT to perform its obligations hereunder.

(b) No Lawsuits. As of the date hereof there have not been any Claims, lawsuits, arbitrations, legal or administrative or regulatory proceedings, charges, or complaints or investigations by any third party or government authority threatened, commenced, pending or proceeding against LANNETT, and LANNETT has not received any notice thereof, which could prevent LANNETT from complying with its material obligations under this Agreement.

(c) Debarred. Neither LANNETT nor any of its officers, directors, or employees or consultants performing services under this Agreement has been or is: (1) a Debarred Individual or an employer, employee, or partner of such a Debarred Individual; or (2) a Debarred Entity, or an employee, partner, shareholder, member, subsidiary, or affiliate of a Debarred Entity; or (3) an employer, employee or partner of an individual convicted within the last five years for crimes described in subsections (a) or (b) of Section 306 of the FDCA. If and when LANNETT becomes aware of any fact that makes or gives rise to make this representation and warranty untrue, LANNETT shall immediately notify ELITE in writing and any such breach may result in immediate termination of this Agreement by ELITE.

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

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

ARTICLE 10 - COVENANTS

10.1 Compliance. Each Party shall perform its obligations under this Agreement in strict compliance with all applicable GMPs and Laws in the Territory, and all applicable licenses, governmental permits or applications in the Territory.

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

ARTICLE 11 - INDEMNIFICATION & INSURANCE

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

(a) any breach of any obligations, actions, or representations made by LANNETT under this Agreement; and

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

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

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 IF PUBLICLY DISCLOSED

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

(a) any breach of any obligations, actions, or representations made by ELITE under this Agreement;

(b) any infringement or claim of infringement of any patent, trademark or other intellectual property rights based on the manufacture and release of the Product furnished under the provisions of this Agreement;

(c) personal injury (including death) or property damage relating to or arising out of any use, distribution or sale of the Products by LANNETT or its Affiliates to the extent that such Loss was the result of the Product not being manufactured to meet the Analytical Specifications;

(d) any negligent, grossly negligent or intentionally wrongful act or omission of ELITE or of any person acting on ELITE's behalf, with authorization, when the wrongful act or omission occurred in performance of ELITE' obligations under this Agreement;

(e) the condition of any Products sold, supplied or delivered to LANNETT under this Agreement, including any defect in material, workmanship, design, manufacturing or formulary;

(f) any warnings and instructions, or lack thereof, for any Product;

(g) the possession, distribution, sale and/or use of, or by reason of the seizure of, any Product; and

(h) any actual or asserted violation(s) of the FDCA or any applicable Law by virtue of which any Product sold, supplied or delivered to Lannett under this Agreement is alleged or determined to be adulterated, misbranded, mislabeled or otherwise not in full compliance with, or in contravention of, any applicable Law.

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

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

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 IF PUBLICLY DISCLOSED

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

11.5 Survival. The obligations set forth in this **ARTICLE 11 -** shall survive the termination of this Agreement and remain in full force and effect for an indefinite period after termination in relation to any claim based on events which occur during the term hereof.

ARTICLE 12 - CONFIDENTIALITY

12.1 Confidentiality. During the Term of this Agreement and for five (5) years thereafter, each Party shall maintain in strict confidence the Confidential Information (as defined below) of the other Party. Each Party shall not use the Confidential Information of the other Party for any purpose other than the purposes expressly permitted by this Agreement and shall not disclose such Confidential Information to any third party (including in connection with any publications, presentations or other disclosures) except to its employees, agents or advisors ("**Representatives**") who have a need to know such Confidential Information to perform such Party's obligations under this Agreement. Each Party shall ensure that any Representative to whom it discloses the other Party's Confidential Information is informed of the confidential nature of and duty not to disclose the information and is obligated under written obligation to maintain the confidentiality thereof on terms at least as restrictive as those set forth herein. Each Party shall be responsible for any breach of this Agreement by its Representatives, which shall be considered a breach by such Party. Under no circumstances shall the receiving Party use the disclosing Party's Confidential Information for its own commercial advantage to the detriment of the disclosing Party. Each Party may disclose such of the Confidential Information of the other Party as may be required by the order of a

court of competent jurisdiction or by any governmental authority having jurisdiction, *provided* that prior to any such disclosure the Party required to disclose shall, to the extent permitted by Law, notify the other Party prior to disclosing any Confidential Information and provide such other Party with a reasonable opportunity to contest or limit the scope of the required disclosure and obtain any protective orders as may be appropriate. In the event the disclosure is nonetheless compelled, the Party making the disclosure shall only disclose the information to the extent required to comply with the Law. Upon termination or expiration of this Agreement, or upon request, a Party shall destroy or return all Confidential Information of the other Party and certify in writing that such return (or destruction) has been completed; provided, however, that each Party shall be entitled to retain one archival copy of such Confidential Information solely for purposes of monitoring such Party's compliance with its obligations under this **ARTICLE 12 -** .

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 IF PUBLICLY DISCLOSED

12.2 Definition. "**Confidential Information**" means all proprietary technical information, marketing, business and financial information, scientific data, information, whether or not labeled "Confidential", and all tangible and intangible embodiments and oral disclosures thereof of any kind whatsoever, and all other materials which a disclosing Party treats confidentially that relates to a Product or the business of a Party and is disclosed or developed under or in connection with this Agreement. Confidential Information shall not include any information which the receiving Party can show by competent proof:

(a) was known to or in the possession of the receiving Party prior to the date of its actual receipt from the disclosing Party;

(b) is readily available to the public other than through the fault of the receiving Party;

(c) was disclosed by a third party not under an obligation of confidentiality to the disclosing Party; or

(d) is subsequently independently developed by the receiving Party without use of the Confidential Information as demonstrated by competent written records.

12.3 Injunctive Relief. The Parties acknowledge that any breach of this **ARTICLE 12 -** may constitute irreparable harm, and that the non-breaching Party shall be entitled to seek specific performance or injunctive relief to enforce this **ARTICLE 12 -** in addition to whatever remedies such Party may otherwise be entitled to at law or in equity, without the necessity of posting bond or any other security.

12.4 Separate Confidentiality Agreement. LANNETT and ELITE have entered into a separate Mutual Confidential Disclosure Agreement dated January 7, 2019 ("**Confidentiality Agreement**"). Such Confidentiality Agreement will be and remain in full force and effect as provided therein. In the event of any conflict between the terms of this Agreement and the terms of any such Confidentiality Agreement, the terms of such Confidentiality Agreement will control.

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

ARTICLE 13 - REGULATORY MATTERS

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

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 IF PUBLICLY DISCLOSED

13.2 Labeling. ELITE shall be responsible for the creation, content, and printing of the labeling for the Products. ELITE shall send LANNETT all labeling materials (e.g., package insert, container label, carton label, medication guide, patient labeling, etc.) in final format for the Products for LANNETT'S review and final written approval. ELITE is responsible for ensuring the most current labeling content, consistent with the reference listed drug ("RLD") labeling content and all requested FDA updates, is used on Products supplied to LANNETT. ELITE is responsible for notifying LANNETT within three (3) business days of any FDA communication requesting changes to labeling materials, including Safety Change Notifications and changes requested per section 505(o)(4) of the FDCA. ELITE will provide LANNETT with a copy of all FDA communications related to labeling. All changes to labeling materials for the Products require LANNETT'S review and final written approval. Labeling materials that have not been subject to LANNETT'S review and written approval are prohibited to be used on Products supplied to LANNETT. ELITE is responsible for submitting the content of labeling in Structured Product Labeling ("SPL") format to the FDA for LANNETT'S NDC numbers within fourteen (14) days of ANDA approval to ensure proper drug listing. ELITE is also responsible for submitting updated SPL files within fourteen (14) days when labeling changes are made and approved and as required by applicable Laws.

ARTICLE 14 - MISCELLANEOUS

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

In the case of LANNETT at:
Lannett Company, Inc., USA
1150 Northbrook Drive
Suite 155
Trevose, PA 19053
Attention: Legal Department
Email: ***@lannett.com

And in the case of ELITE at:
Elite Pharmaceuticals, Inc.
165 Ludlow Avenue
Northvale, NJ 07647
Attention: CEO
Email: ***@elitepharma.com

Any such notice or other document shall:

(i) if delivered by hand, courier, or email be deemed to have been given and received at the place of receipt on the date of delivery, *provided* that if delivery is other than during business hours (9:00 a.m. to 5:00 p.m., local time) on a Business Day in the place of receipt, such notice shall be deemed to have been given and received at the place of receipt on the first Business Day thereafter; and

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 IF PUBLICLY DISCLOSED

(ii) if mailed, be deemed to have been given and received at the place of receipt on the earlier of the date of actual receipt and three (3) Business Days after the date of mailing. In the event of postal disruption, such notices or documents must be delivered by means other than by mail.

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

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

14.4 No Waiver; Remedies. No Party to this Agreement shall be deemed or taken to have waived any provision of this Agreement unless such waiver is in writing, and then such waiver shall be limited to the circumstances set forth in such written waiver. No failure or delay on the part of a Party in exercising any right, power or remedy shall operate as a waiver thereof, nor shall any single or partial exercise of any such right, power or remedy preclude any other or further exercise thereof or the exercise of any other right, power or remedy. All remedies provided for hereunder shall be cumulative of and in addition to any and all other remedies, at law or in equity, which any Party may have, and the exercise of any one or more of such remedies shall not preclude the exercise of any others.

14.5 Force Majeure. If either Party is prevented from complying, either totally or in part, with any of the terms or provisions of this Agreement by reason of force majeure, including fire, flood, earthquake, storm, general strike, lockout, riot, war, terrorism, rebellion, accident, acts of God and/or any other cause or externally induced similar casualty beyond its reasonable control and without the fault or negligence of either Party(a "**Force Majeure Event**"), then, upon written notice by the Party liable to perform to the other Party, the requirements of this Agreement or such of its provisions as may be affected, and to the extent so affected, shall be suspended during the period of such disability, *provided* that the Party asserting force majeure shall bear the burden of establishing the existence of such Force Majeure Event by clear and convincing evidence, and *provided further* that the Party prevented from complying shall use its best efforts to remove such disability, and shall continue performance with the utmost dispatch whenever such causes are removed, and shall notify the other Party of the Force Majeure Event not more than five (5) Business Days from the time of the event and state the nature of the Force Majeure Event, its anticipated duration and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is reasonably required. When such circumstances arise, the Parties shall discuss what, if any, modification of the terms of this Agreement may be required in order to arrive at an equitable solution. Notwithstanding the foregoing, if a Force Majeure Event shall continue for a period of longer than three (3) consecutive months or one hundred and twenty (120) days in any twelve (12) month period, then the Party unaffected by such event may terminate this Agreement immediately upon giving written notice of termination to the other Party. Notwithstanding any provision contained herein, any action taken by a Regulatory Authority as a result of a Party's negligence or willful misconduct shall not constitute a Force Majeure Event under this **Article 14.5**.

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 IF PUBLICLY DISCLOSED

14.6 Dispute Resolution. The Parties recognize that disputes as to certain matters may from time to time arise which relate to a Party's rights and/or obligations under this Agreement. It is the objective of the Parties to establish procedures to facilitate the resolution of such disputes in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this **Article 14.6** if and when such a dispute arises between the Parties arises. Notwithstanding the provisions of this **Article 14.6** however, nothing herein contained shall preclude a Party from seeking equitable remedies in any court of competent jurisdiction as set forth in **Article 14.7** hereof. If any controversy, dispute or claim arises between the Parties relating to the interpretation, breach, performance, enforcement, termination or validity of this Agreement and the Parties cannot resolve the dispute within thirty (30) days of a written request by one Party to any other Party, the Parties agree to hold a meeting, attended by each Parties authorized representatives , to attempt in good faith to negotiate a resolution of the dispute prior to pursuing other available remedies. If, within thirty (30) days after such written request, the Parties have not succeeded in negotiating a resolution of the dispute, the Party may seek any other remedies available to it in at law or in equity.

14.7 Governing Law & Venue. This Agreement shall be governed by, and construed in accordance with, the laws of the State of Delaware, without giving effect to any choice of law or conflict of law rules or provisions that would cause the application of the laws of any jurisdiction other than the State of Delaware. Each Party hereby irrevocably submits to the exclusive jurisdiction of any federal or state court in Delaware for the purposes of any suit, action or other proceeding arising out of this Agreement or any transaction contemplated hereby. Each Party further agrees that service of any process, summons, notice or document by certified or registered mail to such Party's address set forth in **Article 14.1** or such other address or to the attention of such other person as the recipient Party has specified by prior written notice to the sending Party shall be effective service of process in any action, suit or proceeding in Delaware with respect to any matters to which it has submitted to jurisdiction as set forth above in the immediately preceding sentence. Each Party irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of this Agreement or the transactions contemplated hereby in the federal or the state courts in Delaware and hereby irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such action, suit or proceeding brought in such court has been brought in an inconvenient forum.

14.8 Waiver of Trial by Jury. TO THE FULLEST EXTENT PERMITTED BY LAW, THE PARTIES HEREBY WAIVE THEIR RESPECTIVE RIGHTS TO A JURY TRIAL OF ANY PROCEEDING BASED UPON, ARISING OUT OF, OR RELATED TO THIS AGREEMENT, INCLUDING ANY DISPUTE ARISING OUT OF OR RELATING TO THE PERFORMANCE THEREOF, OR ANY OF THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL-ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT AND THAT RELATE TO THE SUBJECT MATTER OF THIS AGREEMENT, INCLUDING CONTRACT CLAIMS, TORT CLAIMS, BREACH OF DUTY CLAIMS AND ALL OTHER COMMON LAW AND STATUTORY CLAIMS.

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 IF PUBLICLY DISCLOSED

14.9 Severability. If any provision in this Agreement is held to be invalid, void or unenforceable, then the remainder of this Agreement, or the application of such provision to the Parties or to the circumstances other than those as to which it is held invalid or unenforceable, shall not be affected thereby and shall be enforced to the fullest extent permitted by law. The Parties agree to renegotiate any such invalid, void or unenforceable provision in good faith in order to provide a reasonably acceptable alternative consistent with the basic purposes of this Agreement.

14.10 Entire Agreement. This Agreement (including the Schedules attached hereto, the SDEA and the Quality Agreement) constitutes the entire agreement between the Parties with respect to the subject matter hereof, and all prior or agreements, whether written or oral, are superseded hereby. This Agreement may be amended only in writing executed by the Parties.

14.11 Sub-contracting. ELITE shall not sub-contract any of the work to be performed under this Agreement without the prior written consent of LANNETT. No such sub-contracting shall relieve ELITE of any of its obligations hereunder.

14.12 Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed shall be deemed to be an original and all of which when taken together shall constitute this Agreement.

14.13 Headings. The captions and headings contained herein are for convenience of the Parties and in no way define, limit or describe the scope of this Agreement.

14.14 Language. The language of this Agreement and all proceedings taken in relation thereto shall be English.

14.15 Currency. Unless otherwise specifically provided, all references to money amounts are expressed in terms of United States Dollars (USD) and all payments made pursuant to this Agreement shall be made in that currency.

14.16 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any Section of this Agreement are and shall otherwise be deemed to be for purposes of Section 365(n) of Title 11, of the United States Code (the "**Bankruptcy Code**") licenses of rights to "intellectual property" as defined in Section 101(35A) of the Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights and elections under the Bankruptcy Code. Upon the bankruptcy of any Party, the non-bankrupt Party shall use its best efforts to transfer its Product responsibilities to a third party, unless the bankrupt Party elects to continue, and continues, to perform all of its obligations under this Agreement.

14.17 Construction of Agreement. The terms and provisions of this Agreement represent the results of negotiations between the Parties and their representatives, each of which has been represented by counsel of its own choosing, and neither of which has acted under duress or compulsion, whether legal, economic or otherwise. Accordingly, the terms and provisions of this Agreement shall be interpreted and construed in accordance with their usual and customary meanings, and each of the Parties hereto hereby waives the application in connection with the interpretation and construction of this Agreement of any rule of law to the effect that ambiguous or conflicting terms or provisions contained in this Agreement shall be interpreted or construed against the Party whose attorney prepared the executed draft or any earlier draft of this Agreement.

[SIGNATURE PAGE FOLLOWS]

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 IF PUBLICLY DISCLOSED

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

ELITE PHARMACEUTICALS, INC.

By: _____
Name: _____
Title: _____

LANNETT COMPANY, INC.

By: _____
Name: _____
Title: _____

ELITE LABORATORIES, INC.

By: _____
Name: _____
Title: _____

Schedule A: Products and Prices

Schedule B: Product Specifications

Schedule C: Quarterly Report for Calculation of Net Profit

Schedule D: Shipping Instructions

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 IF PUBLICLY DISCLOSED

SCHEDULE A

Products and Prices

Product List

Generic Name	ANDA #	Reference Listed Drug
Vigabatrin	214961	Sabril®, Lundbeck Pharmaceuticals

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 IF PUBLICLY DISCLOSED

Transfer Prices ($/carton)

Name	Strength	Full Batch Qty. (cartons)	Carton Size	Cost per carton
Vigabatrin	500 mg	2,500 cartons	50 packets	$ **.00

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

EXPLANATORY NOTE: [***] INDICATES THE PORTION OF THIS EXHIBIT THAT HAS BEEN OMITTED BECAUSE IT IS BOTH

SCHEDULE B

PRODUCT SPECIFICATIONS

Elite Laboratories Inc.
FINISHED PRODUCT ANALYSIS **Page 1 of 2**

Vigabatrin for Oral Solution			Number: **SP0940**
Manufacturer: Elite Laboratories, Inc	DEPARTMENT: ANALYTICS AND QC	Version: 6	Item Code: 0940
QC#:	Batch #:		

Drug Product Powder			
Test / Method	**Specification**	**Results**	**Reference**
Appearance Powder – Visual	White to off white granular powder in foil laminate package with no tears or observed leakage.		
Identification – A Spectroscopic Identification USP <197>	The spectrum of the Sample corresponds to that of the spectrum of USP Vigabatrin RS prepared in a similar manner		
Identification – B HPLC ATM-0940-ASCU	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay		
Assay ATM-0940-ASCU	95.0% -105.0%		
Uniformity of Dosage (Weight Variation) ATM-0940-WV	Meets USP <905> Acceptance Value ≤15.0		
Organic Impurities ATM-0940-IMP ATM-0940-IMP2	a. Related Compound A: NMT 0.15% b. Any individual unspecified degradation product: NMT 0.10% c. Total Impurities: NMT 0.5%[1]		
Microbial Enumeration Tests USP <61> Tests for Specified Microorganisms USP <62>	Total aerobic microbial count: NMT 2000 cfu/g Total combined molds and yeast: NMT 200 cfu/g It meets the requirements of the test for absence of *Escherichia coli*		
Water Content USP <921> method 1a	NMT 1.0% using 2000mg of powder		
Residual Solvents	USP <467> option 1	Complies	
Elemental Impurities	Meets USP <232> and ICH Q3D option 2	Complies	

[1] Sum of total impurities = unknown degradants and known degradants

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 IF PUBLICLY DISCLOSED

Vigabatrin for Oral Solution			Number: **SP0940**
Manufacturer: Elite Laboratories, Inc	DEPARTMENT: ANALYTICS AND QC	Version: 6	Item Code: 0940
QC#:	Batch #:		

Drug Product Solution			
Test / Method	**Specification**	**Results**	**Reference**
Appearance Visual[1]	A clear colorless solution of the labeled volume (10 mL)		
Reconstitution Time / Visual[1]	A clear solution should be obtained within 1 minute of the labeled volume (10 mL)		
pH / USP <791>[1]	Between 6.0 and 7.0 of the labeled volume (10 mL)		
Deliverable Volume / USP <698>	Average volume of 10 containers should be NLT 100% of labeled volume (10 mL)		

[1] Use first sample preparation from Deliverable Volume test

Reviewed by: _____ Date: _____ Approved by: _____ Date: _____

2

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 IF 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 PROFITS	
PROFIT SHARE PAYMENT TO ELITE AT THE APPLICABLE LICENCE 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 IF PUBLICLY DISCLOSED

SCHEDULE D

SHIPPING INSTRUCTIONS

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

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

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

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

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

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

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

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

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

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 29, 2022, 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, 2022.

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 29, 2022

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 quarter ended March 31, 2022 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 29, 2022

/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, Robert Chen, certify that:

1. I have reviewed this Annual Report on Form 10-K for the quarter ended March 31, 2022 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 29, 2022

/s/ Robert Chen

Robert Chen
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, 2022 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, as amended; 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 29, 2022

/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, 2022 filed with the Securities and Exchange Commission (the "Report"), I, Robert Chen, 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, as amended; 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 29, 2022

/s/ Robert Chen
Robert Chen
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.