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

FORM 10-K

(Mark One)

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

For the fiscal year ended March 31, 2026

OR

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

FOR THE TRANSITION PERIOD FROM TO

Commission File Number 001-15697

Elite Pharmaceuticals, Inc.
(Exact name of Registrant as specified in its Charter)

Nevada **(State or other jurisdiction of incorporation or organization)**	**22-3542636** **(I.R.S. Employer Identification No.)**
165 Ludlow Avenue **Northvale, New Jersey** **(Address of principal executive offices)**	**07647** **(Zip Code)**

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**ELTP**	**OTCQB**

Securities registered pursuant to Section 12(g) of the Act: **None**

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 15(d) of the Act. 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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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 the voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price of the shares of common stock on the last business day of the registrant's most recently completed second fiscal quarter, was approximately $534 million, based on the last sales price reported for such date on the OTCQB Venture Market.

The number of shares outstanding of each of the registrant's classes of common stock, as of June 27, 2026:

Common Stock - 1,077,196,442 shares

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, 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 United States Food and Drug Administration ("FDA") 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.

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

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PART I

ITEM 1. BUSINESS

General

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

We are a specialty pharmaceutical company principally engaged in the development and manufacture of oral, controlled-release 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 135, 144, and 165 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 product candidates 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 our risk by having a diverse product portfolio.

Commercial Products

We own, license, manufacture, sell, distribute 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
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
Methotrexate Sodium 2.5mg tablets ("Methotrexate 2.5mg")	Otrexup PF®	Antimetabolite	August 2024
Acetaminophen and Codeine Phosphate 300mg/15mg, 300mg/30mg, 300mg/60mg tablets ("APAP Codeine 300mg/15mg", "APAP Codeine 300mg/30mg", and "APAP Codeine 300mg/60mg")	Tylenol® with Codeine	Pain	October 2024

Acetaminophen and Hydrocodone Bitartrate 325mg/2.5mg, 325mg/5mg, 325mg/7.5mg and 325mg/10mg tablets ("APAP Hydrocodone 325mg/2.5mg", "APAP Hydrocodone 325mg/5mg", APAP Hydrocodone 325mg/7.5mg and APAP Hydrocodone 325mg/10mg")	Norco®	Pain	December 2024
Lisdexamfetamine Dimesylate 10mg, 20mg, 30mg, 40mg, 50mg, 60mg and 70mg capsules ("Lisdex 10mg", "Lisdex 20mg", "Lisdex 30mg", "Lisdex 40mg", "Lisdex 50mg", "Lisdex 60mg" and "Lisdex 70mg")	Vyvanse®	ADHD	December 2024
Oxycodone Hydrochloride and Acetaminophen 5mg/325mg, 7.5mg/325mg and 10mg/325mg tablets ("Oxy APAP 5/325", "Oxy APAP 7.5/325" and "Oxy APAP 10/325")	Percocet®	Pain	April 2025
Methadone Hydrochloride 5mg and 10mg tablets ("Methadone 5mg" and "Methadone 10mg")	Dolophine®	Pain	April 2026

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". 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, and Loxapine 25mg, Loxapine 50mg are collectively and individually referred to as "Loxapine Capsules", Vigabatrin 500mg is collectively and individually referred to as "Vigabatrin Powder", Methotrexate 2.5mg" is collectively and individually referred to as "Methotrexate Tablets", APAP Codeine 300mg/15mg, APAP Codeine 300mg/30mg, and APAP Codeine 300mg/60mg are collectively and individually referred to as "APAP Codeine Tablets, APAP Hydrocodone 325mg/2.5mg, APAP Hydrocodone 325mg/5mg, APAP Hydrocodone 325mg/7.5mg and APAP Hydrocodone 325mg/10mg are collectively and individually referred to as "APAP Hydrocodone Tablets", Lisdex 10mg, Lisdex 20mg, Lisdex 30mg, Lisdex 40mg, Lisdex 50mg, Lisdex 60mg and Lisdex 70mg are collectively and individually referred to as "Lisdex Capsules" and Oxy APAP 5/325, Oxy APAP 7.5/325 and Oxy APAP 10/325 are collectively and individually referred to as "Oxy APAP Tablets". Methadone 5mg and Methadone 10mg are collectively and individually referred to as "Methadone Tablets".

Phentermine 37.5mg

The Company acquired two ANDAs for Phentermine 37.5mg, in 2010 and 2013, respectively.

Sales and marketing rights for Phentermine 37.5mg relating to the approved ANDA acquired in 2010 were licensed under an agreement between the Company and Precision Dose Inc. ("Precision Dose") dated September 10, 2010 (the "Precision Dose License Agreement") and the Precision Dose License Agreement expired in accordance with its terms on September 10, 2025. The Company retains all sales and marketing rights for this product.

The Phentermine 37.5mg product relating to the approved ANDA acquired in 2013 is currently a commercial product being manufactured at the Northvale Facility and distributed by Elite Labs.

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 Labs.

Phentermine 15mg and Phentermine 30mg

Phentermine 15mg capsules and Phentermine 30mg capsules were developed by the Company, with Elite receiving approval from the 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. The Precision Dose License Agreement expired in accordance with its terms on September 10, 2025. The Company retains all sales and marketing rights for this product.

Phentermine 15mg and Phentermine 30mg are currently commercial products being manufactured at the Northvale Facility and distributed by Elite Labs.

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. The Precision Dose License Agreement expired in accordance with its terms on September 10, 2025.

Naltrexone 50mg is currently a commercial product being manufactured at the Northvale Facility and distributed by Elite Labs.

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 commercial products being manufactured by Elite at the Northvale Facility and distributed by Elite Labs.

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 a commercial product being manufactured by Elite at the Northvale Facility and distributed by Elite Labs.

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 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 Elite Labs.

On December 6, 2021, the Company executed a license and distribution agreement with Dexcel Ltd (or Akiva, Israel) ("Dexcel"), pursuant to which the Company manufactures and supplies Amphetamine IR Tablets to Dexcel and Dexcel is granted exclusive distribution rights for the Israeli market for this product, under the Dexcel label (the "Dexcel Agreement"). The first shipment of Amphetamine IR Tablets pursuant to the Dexcel Agreement occurred in July 2025.

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 at the Northvale Facility and distributed by Elite Labs as well as being manufactured by Elite at the Northvale Facility and distributed by Prasco, LLC ("Prasco") pursuant to the non-exclusive license agreement between the Company and Prasco dated April 5, 2023 (the "Prasco Non-Exclusive License Agreement").

Dantrolene Capsules

The approved ANDAs for Dantrolene 25mg, Dantrolene 50mg and Dantrolene 100mg (collectively, "Dantrolene Capsules") were acquired by Elite in 2013. Dantrolene Capsules are a commercial product being manufactured by Elite at the Northvale Facility and distributed by Elite Labs.

Loxapine Capsules

The approved ANDA for Loxapine was acquired by Elite in 2013.

Loxapine Succinate 5, 10, 25 and 50 mg are commercial products being manufactured by Elite at the Northvale Facility and distributed by Elite Labs.

During the year ended March 31, 2026, the Company recognized an impairment of the Loxapine Capsules, as a result of reassessments of the expected future cash flows for this product.

Methotrexate Tablets

On May 20, 2024, the Company received approval from the FDA for Methotrexate Tablets, a product that belongs to the antimetabolite class of drugs. Methotrexate Tablets were commercially launched in August 2024 and are manufactured at the Northvale Facility and distributed by Elite Labs.

APAP Codeine Tablets

On June 17, 2024, the Company entered into an asset purchase agreement with Nostrum Laboratories Inc. (the "Nostrum Asset Purchase Agreement"), pursuant to which the Company acquired all rights in and to the approved ANDA for APAP Codeine Tablets and a royalty-free, non-exclusive perpetual license to use the manufacturing technology, proprietary information, processes, techniques, protocols, methods, know-how and improvements necessary or used to manufacture this product.

APAP Codeine Tablets were commercially launched in October 2024 and are manufactured at the Northvale Facility and distributed by Elite Labs.

APAP Hydrocodone Tablets

On June 17, 2024, pursuant to the Nostrum Asset Purchase Agreement, the Company acquired all rights in and to the approved ANDA to APAP Hydrocodone Tablets and a royalty-free, non-exclusive perpetual license to use the manufacturing technology, proprietary information, processes, techniques, protocols, methods, know-how and improvements necessary or used to manufacture this product.

APAP Hydrocodone Tablets were commercially launched in December 2024 and are manufactured at the Northvale Facility and distributed by Elite Labs.

Lisdex Capsules

On November 18, 2024, the Company received approval from the FDA for Lisdex Capsules, a product indicated for the treatment of Attention Deficit Hyperactivity Disorder. Lisdex Capsules were commercially launched in December 2024 and are manufactured at the Northvale Facility and distributed by Elite Labs.

Oxy APAP Tablets

On June 17, 2024, pursuant to the Nostrum Asset Purchase Agreement, the Company acquired all rights in and to the approved ANDA for Oxy APAP Tablets and a royalty-free, non-exclusive perpetual license to use the manufacturing technology, proprietary information, processes, techniques, protocols, methods, know-how and improvements necessary or used to manufacture this product.

Oxy APAP Tablets were commercially launched in April 2025 and are manufactured at the Northvale Facility and distributed by Elite Labs.

Methadone Tablets

On June 17, 2024, pursuant to the Nostrum Asset Purchase Agreement, the Company acquired all rights in and to the approved ANDA for Methadone Tablets and a royalty-free, non-exclusive perpetual license to use the manufacturing technology, proprietary information, processes, techniques, protocols, methods, know-how and improvements necessary or used to manufacture this product.

Methadone tablets were commercially launched in April 2026 and are manufactured at the Northvale Facility and distributed by Elite Labs.

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, ("CRL"), regarding the NDA. The CRL stated that the review cycle for the SequestOx™ NDA was complete and the application is not ready for approval in its present form.

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

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.

Generic Products Filed

Currently the Company has filed the following ANDAs which have been accepted for review by the FDA:

- A generic opiate analgesic for pain management accepted for review in September 2023
- A generic anticoagulant which was filed with the FDA in May 2026 and for which the Company is awaiting the FDA's acceptance for review.

Approved Products Not Yet Commercialized

Doxycycline Hyclate Tablets

The Company received approval in April 2022 from the FDA of an ANDA for a generic version of an antibiotic product, Doxycycline Hyclate Tablets. The product is jointly owned by Elite and Praxgen Pharmaceuticals LLC, formerly SunGen Pharma LLC, ("Praxgen").

Ropinirole ER

The Company received approval in November 2025 for a generic version of Requip XL® (Ropinirole Extended-Release Tablets USP) ("Ropinirol Tablets"). Ropinirole belongs to a class of drugs known as a non-ergoline dopamine used to treat symptoms of Parkinson's disease.

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

Discontinued and Transferred Products

As part of standard operating practices, the Company, from time to time, as relevant, conducts evaluations of all ANDAs owned, consisting, without limitation, of ANDAs acquired or approved prior to the fiscal year ended March 31, 2026 ("Fiscal 2026") and ANDAs acquired or approved during the Fiscal 2026. 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 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.

During the year ended March 31, 2026, the Company moved ANDAs for Phentermine 15mg and Phentermine 30mg onto the discontinued list as it does not intend to engage in commercial operations with these products at this time. Elite continues to sell Phentermine 15mg and Phentermine 30mg, however, with a different ANDA that remains active.

Licensing, Manufacturing and Development Agreements

Precision Dose License Agreement

On September 10, 2010, the Company executed 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 had the exclusive right to market these products in the United States and Puerto Rico and a non-exclusive right to market the products in Canada.

Pursuant to the Precision Dose License Agreement, Elite received a license fee and milestone payments. The license fee was 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 was payable monthly for the term of the Precision Dose License Agreement. The milestone payments consisted of payments due upon execution of the Precision Dose License Agreement and upon FDA approval and initial shipments of products to Precision Dose.

The Precision Dose License Agreement had an initial term of 15 years and expired in accordance with its terms, on September 10, 2025.

Prasco Non-Exclusive License Agreement

On April 5, 2023, the Company entered into a non-exclusive license agreement to manufacture, supply and distribute with Prasco, LLC and its affiliate Burel to distribute generic mixed amphetamine extended-release capsules in the United States. The agreement commenced on January 1, 2024 and was terminated with notice on March 31, 2025.

Pyros Manufacturing and Supply Agreement

In conjunction with the sale of its Product to Pyros, the Company executed a Manufacturing and Supply Agreement (the "Pyros Agreement") with Pyros on November 21, 2002. Under the terms of the Pyros Agreement, the Company received an agreed-upon price per drug for the manufacturing and packaging of Sabril. Revenue per the Pyros Agreement was recognized as control of the manufactured and supplied drugs is transferred to Pyros (at the time of delivery). The Pyros Agreement was terminated by mutual agreement on January 10, 2025.

Dexcel Agreement for Israel

On December 6, 2021, the Company entered into the Dexcel Agreement for Amphetamine IR 10mg, Amphetamine IR 20mg and Amphetamine IR 30mg. Pursuant to the Dexcel Agreement, Elite manufactures and packages the product under Dexcel's label. Dexcel provides sales, marketing and distribution. Dexcel pays an agreed upon transfer price for the product and shares any profits when the net selling price exceeds a floor price, as defined in the Dexcel Agreement. The first shipment of product under this agreement was made in July 2025.

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 the same receptors in the brain as the opioid agonist and thereby reducing the incentive for abuse or misuse by recreational drug abusers.

The Company 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 evaluating the marketplace when deciding to proceed with the above listed filed application.

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 abuse-deterrent and sustained release opioids and is evaluating the market place when deciding to proceed with the above listed filed applications.

Patents

The Company owns the following patents (as of March 31, 2026):

PATENT	EXPIRATION DATE
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.

During the year ended March 31, 2026, a patent related to the Company's abuse deterrent opioid technology expired before marketing authorization was obtained from the FDA, and therefore all capitalized costs related to the application of this patent were impaired in full during the year ended March 31, 2026. Refer to Note 4 of our consolidated financial statements for additional information.

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.

Elite sells its own products under an "Elite Labs" label.

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 ("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 good clinical practices ("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 CRL. 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 Risk Evaluation and Mitigation Strategy ("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 new chemical entity ("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 ANDA, to the FDA. 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 ("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, route of administration, dosage form, strength of the drug and 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, it is required to certify to the FDA concerning any patents listed for the reference product in the 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 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 ("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 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 annually establishes 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.

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 Centers for Medicare and Medicaid Services ("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 and impose civil and criminal penalties), 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;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates and their subcontractors that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;

- 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 ("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 DOJ 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 DOJ or the SEC, and 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.

The Inflation Reduction Act of 2022 ("IRA") contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the HHS that would require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. Substantial penalties can be assessed for noncompliance with the drug pricing provisions.

Drugs with an available generic or biosimilar, certain drugs that represent a limited portion of Medicare program spending, drugs with an orphan designation as their only FDA approved indication, and all plasma-derived products are exempt from direct negotiation. The number of negotiated products will be phased in between 2026 and 2029, and the law sets a maximum fair price the manufacturer can charge based on the number of years the product has been on the market. The law allows HHS to levy an excise and civil monetary penalties against non-compliant manufacturers or those who refuse to negotiate.

The IRA also imposes rebate requirements on manufacturers of single-source generics and other drugs covered under Medicare Part B and Part D where the price of the drug increases faster than inflation. Multisource generics and all products with an average manufacturer's price less than $100 per year, per individual, are exempt from rebate requirements. Beginning on October 1, 2022 for Part D products and on January 1, 2023 for Part B products, CMS will monitor for products with price increases higher than the rate of inflation on a quarterly basis. Rebates will be calculated as the total number of units sold by the amount the product exceeds the inflation-adjusted price, with 2021 as the base year to measure cumulative changes relative to inflation. Noncompliant manufacturers will be subject to a civil monetary penalty of at least 125% of the calculated rebate amount.

The effect of the IRA on our business, generic manufacturers, and the pharmaceutical industry in general is not yet known.

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 or additional pricing pressures. On May 12, 2025, President Trump issued an executive order implementing the concept of most-favored nation ("MFN") pricing. Under this order, the Department of Health and Human Services would direct federal health insurers to pay no more than the lowest price paid by other high-income countries for medications covered by such insurers, including Medicare and Medicaid. Under the order, MFN pricing will apply only to brand products without generic or biosimilar competition. The effect of this order on our business and the pharmaceutical industry in general is not yet known.

As an alternative to the Affordable Care Act, President Trump announced the Great Healthcare Plan in January 2026. As presented, the plan is intended to lower drug prices by increasing competition and benchmarking U.S. drug prices to other countries, reduce insurance premiums by redirecting subsidies from insurers to individuals, increase accountability and transparency from insurers, and promote consumer choice by giving individuals more direct control over how healthcare dollars are spent. Legislative and regulatory action will be required to fully implement the plan. It is unclear how these proposed changes will impact our business and the pharmaceutical industry in general.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and in some cases, designed to encourage importation from other countries and bulk purchasing. Additional reform measures may be adopted in the future

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

The Company has competition with respect to our principal areas of operation. We develop, manufacture and distribute generic products. Elite's product lines consist of solid oral dose products, both immediate-release and controlled-release, which are marketed under the Elite Labs label, as well as pursuant to licenses granted to third-party pharmaceutical marketing and distribution organizations. 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.

Our Reporting Segments

We had previously determined that we operated in two segments, which were (i) products whose marketing approvals were secured via an ANDA and (ii) 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. During the year ended March 31, 2026, we determined that NDA was no longer a segment as the Company has paused further development of NDAs and has not engaged in business activities for several years and does not intend to engage in business activities related to the development of NDAs for the foreseeable future. Therefore, as of March 31, 2026, the Company has determined that it operates in a single operating and reportable segment, which is ANDA. For the years ended March 31, 2026 and 2025, revenue from our ANDA segment was $148.9 million and $84.0 million, respectively.

Segment information is consistent with the financial information regularly reviewed by our chief operating decision maker, who we have determined to be the Chief Executive Officer, for the purpose 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 CODM does not review this information by segment.

Employees

As of June 25, 2026, we had 65 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.
- Natural disasters and associated supply chain effects.
- Interruptions in operations at our sole facility could have a material adverse effect on our business.
- We may sell, withdraw or discontinue manufacture of certain products.
- We may fail to successfully identify, develop, and commercialize new products.
- Introduction of generic equivalents of our products by competitors.
- Our operations could be disrupted by failure of our information systems or cyber-attacks.
- Artificial intelligence ("AI") based platforms may present new risks and challenges to our business.
- Delays in product development may result in failure to achieve adequate return on investment.

- Our business is dependent on market acceptance of our products and social and political pressures, including public concern over the abuse of certain products, including opioids may adversely affect our business.
- 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.
- Substantial portion of revenues is derived from a limited number of products.
- We depend to a large extent on third-party suppliers and distributors for the raw materials for our products.
- Risks related to incorrect or inadequate provision for price adjustments and sales allowances

Financial and Liquidity Related Risks

- We have identified material weaknesses in our internal controls over financial reporting
- While we currently qualify as a smaller reporting company under SEC regulations, we cannot be certain, if we take advantage of the reduced disclosure requirements applicable to these companies, that we will not make our stock less attractive to investors. Once we lose smaller reporting company status, the costs and demands placed upon our management are expected to increase.
- Our operating results could fluctuate significantly.
- Our ability to fund operations is uncertain and we may require additional financing to meet objectives.
- There is a risk of impairment of significant intangible assets on our balance sheet.
- GAAP requires estimates, judgments and assumptions which inherently contain uncertainties.

Legal and Regulatory Risks

- The pharmaceutical industry is heavily regulated, which creates uncertainty and substantial compliance costs.
- Disruptions at the FDA, the DEA, the SEC, and other government agencies could negatively impact our business.
- Our business may be adversely affected by legislation or healthcare regulatory reform and initiatives.
- Use of generics may be limited through legislative, regulatory or efforts of pharmaceutical companies.
- Our revenues and profits from generic products may decline as a result of changes in regulatory policy.
- New tariffs and evolving trade policy between the US and other countries may adversely affect our business.
- The DEA could limit the availability of active ingredients used in many of our products.

- 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.
- Complex reporting and payment obligations under the Medicaid rebate and other governmental programs.
- Investigations and litigation concerning the calculation of average wholesale prices may adversely affect our business

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.

- Illegal distribution and third-party sale of counterfeit versions of our products could have a detrimental effect on our reputation and business.
- Competitors or other third parties may allege that we are infringing upon their intellectual property.

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 pursuant to the 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:

- Introduction of other generic drug manufacturers' products in direct competition with our generic drug products;
- Introduction of authorized generic drug products in direct competition with our products, particularly during any period of exclusivity;
- The ability of generic drug product competitors to quickly enter the market after the expiration of patents or exclusivity periods, diminishing the amount and duration of significant profits;
- Consolidation among distribution outlets through mergers and acquisitions and the formation of buying groups;
- The willingness of generic drug customer, including, without limitation, wholesale and retail customers, to switch among products of different generic pharmaceutical manufacturers;
- Pricing pressures by competitors and customers, even if similar price savings are not passed on to consumers;
- A company's reputation as a manufacturer and distributor of quality generic pharmaceutical products;
- A company's level of service, including, without limitation, maintaining sufficient inventory levels for deliveries consistent with customer expectations;
- A company's ability to use and integrate technology, including the use and integration of AI;
- Product appearance and labeling;

- A company's breadth of product offerings;
- Rapid and significant technological change;
- Development and commercialization of advanced or novel drug delivery systems;
- Availability of greater financial resources to fund research and development, marketing, human resources and other operational and overhead resources and capabilities;
- Development of new formulations and products, or improvement of existing ones, at higher levels of efficiency; and
- We depend on third-party suppliers and distributors for the raw materials for our products.
- Our success, if any, will depend in part on our ability to successfully keep pace with these factors.

As we expand our presence in the generic pharmaceuticals market our products 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.

Natural disasters could cause closures of our facilities and disrupt our operations.

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 and natural disasters. 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.

In addition, outbreaks of contagious diseases and other adverse public health developments affecting us and/or the third parties on which we rely could have a material and adverse effect on our business, financial condition and results of operations. For example, the COVID-19 pandemic, which impacted the operation of healthcare systems, global travel, supply and labor markets and other business and economic activity worldwide, had a disruptive and adverse impact on our financial condition and results of operations and on those of many of the third parties on which we rely.

Although the acute COVID-19 public health emergency has lapsed, we will continue to monitor its long-term impacts, including impacts on market practices and on the labor market, and adjust our policies and practices as needed to mitigate any adverse impacts to our business operations and financial condition. We will also work with our internal teams and the third-parties on which we rely to assess, and seek to mitigate, the potential impacts on our business operations and financial condition of any future outbreaks of contagious diseases or other adverse public health developments that may emerge from time to time.

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 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, pandemics, 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 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.

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, bioequivalence 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 or bioequivalence to the reference listed drug. To meet these requirements, we must conduct extensive preclinical testing and "adequate and well-controlled" clinical trials and/or bioequivalence studies. Conducting clinical trials and bioequivalence studies is a lengthy, time-consuming, and expensive process. Completion of necessary clinical trials may take several years or more. Delays associated with product candidates 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 or bioequivalence studies;
- 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, including as a result of staffing reductions at FDA, DEA or other governmental agencies; and,

- Clinical trial or bioequivalence costs that are greater than we currently anticipate.

Even if we achieve positive interim results in clinical trials and bioequivalence studies, these results do not necessarily predict final results, and positive results in early trials and studies may not be indicative of success in later trials and studies. 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 or bioequivalence studies will demonstrate safety and efficacy, or bioequivalence to the reference listed drug, 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 or bioequivalence studies 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, product candidates which initially show promise in preliminary pharmacological or marketing studies, but fail to yield the positive results consistent with initial indications. Product candidates 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.

As our competitors introduce their own generic equivalents of our generic drug products, our revenues and gross margin from such products generally decline, often rapidly.

Revenues and gross margin derived from generic pharmaceutical products often follow a pattern based on regulatory and competitive factors that we believe are unique to

the generic pharmaceutical industry. As the patent(s) for a brand name product or any statutory period of marketing exclusivity expires, the first generic manufacturer to receive regulatory approval for a generic equivalent of the product is often able to capture a substantial share of the market. However, as other generic manufacturers receive regulatory approvals for their own generic versions, that market share, and the price of that product, will typically decline depending on several factors, including, without limitation, the number of competitors, the price of the branded product and the pricing strategy of the new competitors. Significant competition in the generic pharmaceutical marketplace is not uncommon with one result of such being significant decline in revenue and gross margins. There can be no assurances of our ability to continue to develop new products or that the number of competitors for any given product will not increase to such an extent that we may stop marketing a generic drug product for which we previously obtained approval, resulting in a material adverse effect on our business, financial condition, results of operations, cash flow, ability to operate and stock price.

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

Significant disruptions to our IT systems or breaches of information security could adversely affect our business. In the ordinary course of business, we collect, store and transmit what we consider to be large amounts of confidential information, and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such information. Additionally, our IT systems are critical to our ability to store electronic and financial information and to manage a variety of business processes and activities, including, without limitation, manufacturing, financial, logistics, sales, marketing and administrative functions. We depend on our IT infrastructure to communicate internally and externally with employees, customers, suppliers and others. We also use IT networks and systems to comply with regulatory, legal and tax requirements. We have outsourced significant elements of our IT infrastructure. As a result, we manage independent vendor relationships with third-parties who are responsible for maintaining significant elements of our IT systems and infrastructure and who may or could have access to our confidential information. The size and complexity of our IT systems, and those of our third-party vendors, make such systems potentially vulnerable to service interruptions and security breaches from inadvertent or intentional actions by our employees, partners or vendors. These systems are also vulnerable to attacks by malicious third-parties, such as phishing or ransomware attacks, and may be susceptible to intentional or accidental physical damage to the infrastructure maintained by us or by third parties, including, without limitation, as a result of extreme weather events, such as fires, floods, hurricanes or tornadoes or as the result of the use of AI or other new technologies.

Maintaining the secrecy of confidential, proprietary, and/or trade secret information is important to our competitive business position. We continually assess these threats and make investments to increase internal protection, detection, and response capabilities, as well as ensure our third-party providers have required capabilities and controls, to address these risks. Like other public companies, our computer systems and those of our third-party vendors and service providers are regularly subject to, and will continue to be the target of, computer viruses, malware or other malicious code (including ransomware), unauthorized access, cyber-attacks or other computer-related penetrations, which have caused, and may continue to cause, disruptions to our operations. Over time, the sophistication of these threats continues to increase. Our reliance on unsupported and vulnerable operating systems and other software in certain cases may increase both the likelihood and potential severity of cyber incidents. The preventative actions we take to reduce the risk of cyber incidents and protect our information may be insufficient. Our efforts may not prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful use or disclosure of confidential information that could adversely affect our business operations or result in the loss, dissemination, or misuse of critical or sensitive information. A 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 us and could have a material adverse effect on our business, financial condition, results of operations, cash flow, ability to operate and stock price.

Artificial intelligence based platforms may present new risks and challenges to our business.

AI technologies may exacerbate existing risks, including risks associated with data privacy, cybersecurity, IP, healthcare fraud and abuse, drug development and manufacturing, and risks to patients or human subjects in clinical trials. AI also introduces new risks, due to the autonomous nature of the technology, which, in some cases, may be deployed to perform tasks, inform decisions, automate decisions, and make predictions. AI may amplify biased and discriminatory decision making, perform unreliably and malfunction, generate insights which are difficult to interpret and explain, and cause direct harm to individuals or groups.

Regulators are proposing, adopting, and implementing new AI laws and regulations. We may be required to change our business practices and policies as a result of such laws and regulations and may incur substantial compliance-related costs.

Regulators are also using existing laws and regulations to take enforcement actions related to the deployment of AI in ways that result in non-compliance with current laws and regulations. If we fail to comply with AI laws and regulations, we may be subject to sanctions, fines, and reputational damage, orders to stop certain processing of personal data, orders to delete certain data or destroy AI algorithms derived from data collects, legal action on behalf of impacted individuals or other enforcement or other actions. If we fail to take steps to protect our confidential data, trade secrets, IP and personal data, we may be subject to legal, regulatory, financial, and reputational risks. AI technologies present significant opportunities and risks to our business. Harnessing AI's transformative potential may enable us to speed up the discovery and development of new drugs, optimize our manufacturing processes, and drive efficiencies. Our failure to use AI technologies in a way that maintains trust, quality and control in our business activities and to capitalize on opportunities presented by AI may also place us at a competitive disadvantage. Failure to address AI risks will reduce our ability to deliver strategic objectives. Also, investments in AI may not realize the benefits that were anticipated.

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 acceptance of our products and social and political pressures, including public concern over the abuse of opioids may adversely affect our business.

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. 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 year ended March 31, 2021 and a cessation of orders for another two other opioid products that had been marketed by our marketing partners. During the year ended March 31, 2020, we disposed of four approved ANDAs for opioid products. We currently hold four approved ANDAs for opioid products. 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, 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 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.

A substantial portion of our total revenues is expected to be derived from sales of a limited number of products to a limited number of customers.

We expect that we will continue to derive a substantial portion of our revenue from sales of a limited number of products. For the year ended March 31, 2026, our significant product families (defined as the top four products based on active pharmaceutical ingredient) accounted for in excess of 75% of allocated revenues (defined as gross revenues less chargebacks and government rebates processed). The sale of our products may be significantly influenced by market conditions, as well as regulatory actions. We may experience decreases in the sale of our products in the future as a result of actions taken by our competitors, such as price reductions, or as a result of regulatory actions, such as changes in quota, related to our products or to competing products, which could result in a material adverse on our business, financial condition, results of operations, cash flow, ability to operate and stock price.

We also expect that we will continue to derive a substantial portion of our revenue from sales to a limited number of customers. For the year ended March 31, 2026, our six largest customers accounted for in excess of 75% of revenues. The loss of any one or more of these customers, without replacement by a customer of similar significance, or the substantial reduction in orders from any one or more of these customers, without replacement of orders of a similar magnitude from other customers, could result in a material adverse effect on our business, financial condition, results of operations, cash flow, ability to operate and stock price.

We depend to a large extent on third-party suppliers and distributors for the raw materials for our products, particularly the chemical compounds comprising the active pharmaceutical ingredients ("API's") that we use to manufacture our products, as well as for certain finished goods.

We purchase the bulk of the raw materials essential to our manufacturing business from third parties. If we experience supply interruptions or delays, or if a supplier discontinues the sale of certain products, we may have to obtain substitute materials or products, which in turn would require us to obtain amended or additional regulatory approvals, subjecting us to additional expenditures of significant time and resources. In addition, changes in our raw material suppliers could result in significant delays in production, higher raw material costs and loss of sales and customers, because regulatory authorities must generally approve raw material sources for pharmaceutical products, which may be time consuming. For example, it may take as long as 18 months to find and qualify a new sole-source supplier. If we receive less than one year's termination notice from a sole-source supplier that intends to cease supplying raw materials, it could result in disruption of our ability to produce the drug involved. Any significant interruption could result in a material adverse on our business, financial condition, results of operations, cash flow, ability to operate and stock price.

We issue price adjustments and other sales allowances to our customers. Although we may establish reserves based on our estimates of these amounts, if estimates are incorrect and the reserves are inadequate, it may result in adjustments to these liabilities that may have a material adverse effect on our financial position and results of operations.

Based on estimates, we establish liabilities for sales allowances, including, without limitation, sales discounts, returns, chargebacks, sales volume rebates, shelf stocks, cash discounts and Medicaid rebate obligations at each reporting period. Although we believe our liabilities are adequate as of the date of this report, there can be no assurances given by us that our reserves will ultimately prove to be adequate. Increases in such sales allowances may exceed our estimates for a variety of reasons, including, without limitation, unanticipated competition, an unexpected change in one or more contractual relationships or changes in ratios in contractual sales volumes as compared to historical ratios. We will continue to evaluate the relevant factors upon which our estimates and reserves are calculated and record appropriate adjustments if and when deemed necessary. Any failure to establish adequate liabilities with respect to these sales allowances could result in a material adverse effect on our business, financial position, results of operations, cash flows, ability to operate and cash flows.

Financial and Liquidity Risks

We have identified material weaknesses in our internal control over financial reporting which could, if not remediated, adversely affect our ability to report our financial condition, cash flows and results of operations in a timely and fairly stated manner and/or increase the risk of future misstatements, which could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our common shares and/or debt securities to decline.

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

The Company has identified certain remediation actions and is in the process of implementing them, but such efforts are not complete, most likely require the retention of additional personnel or consultants, both of which are further subject to the Company's financial condition and financial ability to retain such resources. Although no material misstatement of historical financial statements was identified, if we are unable to complete our remediation in a timely manner or if our remedial measures are insufficient to address the material weaknesses, or if additional material weaknesses in our internal controls are discovered or occur in the future, it may adversely affect our ability to report our financial condition and results of operations in a timely and accurate manner and there will continue to be an increased risk of future misstatements. In our periodic review and evaluation of internal control systems to allow management to assess the effectiveness of our internal controls over financial reporting, we may discover additional weaknesses in our internal controls over financial reporting or disclosure controls and procedures. The next time we evaluate our internal controls over financial reporting and disclosure controls and procedures, if we identify one or more new material weaknesses or have been unable to timely remediate our existing material weaknesses, we would be unable to conclude that our internal controls over financial reporting or disclosure controls and procedures are effective. If we are unable to conclude that our internal controls over financial reporting or our disclosure controls and procedures are effective or, if required to issue such an opinion, our independent registered public accounting firm expresses an opinion that our internal controls over financial reporting is ineffective, we may not be able to report our financial condition and results of operations in a timely and accurate manner, which could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our common shares to decline. In addition, any potential future restatements could subject us to additional adverse consequences, including sanctions by the SEC, shareholder litigation and other adverse actions.

Moreover, we may be the subject of further negative publicity focusing on such financial statement adjustments and resulting restatement and negative reactions from our shareholders, creditors or others with whom we do business. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our common shares to decline. Please see Item 9A "*Controls and Procedures*" in Part II.

While we currently qualify as a smaller reporting company under SEC regulations, we cannot be certain, if we take advantage of the reduced disclosure requirements applicable to these companies, that we will not make our stock less attractive to investors. Once we lose smaller reporting company status, the costs and demands placed upon our management are expected to increase.

The SEC's rules exempt smaller reporting companies, like us, from various reporting requirements applicable to public companies that are not smaller reporting companies. As long as we qualify as a smaller reporting company based on our public float and report less than $100 million in annual revenues in a fiscal year, we are permitted, and we intend, to omit the auditor's attestation on internal control over financial reporting that would otherwise be required by the Sarbanes-Oxley Act. This Annual Report on Form 10-K reports annual revenues for the fiscal year ended March 31, 2026 in excess of $100 million. We therefore expect to no longer qualify for smaller reporting company status in the near future.

Until such time that we lose smaller reporting company status, it is unclear if investors will find our stock less attractive because we may rely on certain disclosure exemptions. If some investors find our stock less attractive as a result, there may be a less active trading market for the stock, and our stock price may be more volatile and could cause our stock price to decline. Even if we remain a smaller reporting company, if our public float exceeds $75 million and we report $100 million or more in annual revenues in a fiscal year, we will become subject to the provisions of Section 404(b) of the Sarbanes-Oxley Act, requiring our independent registered public accounting firm to provide an attestation report on the effectiveness of our internal control over financial reporting, making the public reporting process more costly.

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:

- 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, IP 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.

In addition, we have been in operation since 1990, and were not profitable until the fiscal year ended March 31, 2021. In certain years prior to the fiscal year ended March 31, 2021, the auditor's opinion on our financial statements 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. There can be no assurances of our ability to sustain current profitability and 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 and
- Attract, retain, and motivate qualified personnel; and respond to competitive developments.

If we do not effectively address the risks we face, our business model may become unworkable and we may not achieve or sustain profitability or successfully develop any products, resulting in a material adverse effect on Elite's business, results of operations, financial condition, and cash flow and ability to operate in the future.

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

Our ability to fund current operations, maintain liquidity and execute growth plans is reliant on resources generated from our operations, which are subject to significant risks and uncertainties. We rely mainly on cash generated by operations and have also in the past accessed financial markets and equipment financings, to fund our commercial, product development and other operations, maintain liquidity and meet our financial obligations.

As of March 31, 2026, we had cash on hand of approximately $30 million and a working capital of approximately $95 million, and for the year ended March 31, 2026, we generated income from operations totaling approximately $49 million, net other income totaling approximately $8 million and a net tax expense of approximately $12 million, resulting in a net income of approximatley $45 million. There can be no assurances of the continuation of revenues being earned from the current generic product line, nor Elite's successful commercialization of other products in our development pipeline. 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, implement necessary facility upgrades or finance the execution of strategic growth initiatives, resulting in a material detrimental effect on Elite's operations and profits as well as having a material adverse effect on our business, results of operations, financial condition, and cash flow.

Our operations are also subject to many significant risks and uncertainties, as described, without limitation, in this "*Risk Factors*" section, including, without limitation, 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 in 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 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.

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 material asset on our balance sheet. As of March 31, 2026, intangible assets were approximately $4.8 million.

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. During the year ended March 31, 2026, we recorded impairment of approximately $1 million related to our ANDA and patent intangible assets.

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

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

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

Legal and Regulatory Risks

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

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

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

Disruptions at the FDA, the DEA, the SEC and other government agencies could negatively impact our business.

Disruptions at, without limitation, the FDA, the DEA, and other regulatory agencies, including due to changes in government or significant changes in leadership or personnel, could increase the time required for new products to be reviewed and approved, or otherwise cause delays to the regulatory approval or post-approval processes for our products, which could adversely affect our business. The ability of the FDA, the DEA or other regulatory agencies to review and approve new products or manage post-approval requirements for marketed products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, political and policy changes. Average review times for product submissions have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely is subject to the impacts of political events, which are inherently fluid and unpredictable.

For example, over the last several years, the U.S. government has shut down several times, including the fall of 2025, and certain regulatory agencies, such as the FDA, the DEA and the SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, or if other global, political or economic conditions impact the regulatory agencies with which we interact, it could significantly impact the ability of the FDA, the DEA, the SEC and other agencies to timely review and process our submissions, 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.

There have been, and there will continue to be, legislative, regulatory and third-party payor proposals to change the healthcare system in ways that could impact our ability to commercialize our products profitably. We anticipate that the federal and state legislatures and the private sector will continue to consider and may adopt and implement healthcare policies, such as the IRA and the Patient Protection and Affordable Care Act enacted in 2010 ("ACA"), intended to curb rising healthcare costs. These cost-containment measures may include, among other measures: requirements for pharmaceutical companies to negotiate prescription drug prices with government healthcare programs; controls on government-funded reimbursement for drugs; new or increased requirements to pay prescription drug rebates to government healthcare programs, including if drug prices increase at a higher rate than inflation; controls on healthcare providers; challenges to or limits on the pricing of drugs, including pricing controls or limits or prohibitions on reimbursement for specific products through other means; requirements to try less expensive products or generics before a more expensive branded product; and public funding for cost effectiveness research, which may be used by government and private third-party payors to make coverage and payment decisions.

For example, the ACA includes numerous provisions that affect pharmaceutical companies, including provisions intended to expand healthcare coverage to the uninsured through private health insurance reforms and an expansion of Medicaid. The ACA also imposes substantial costs on pharmaceutical manufacturers, such as an increase in liability

for rebates paid to Medicaid, new drug discounts that must be offered to certain enrollees in the Medicare prescription drug benefit and an annual fee imposed on all manufacturers of brand prescription drugs in the U.S. The ACA also requires increased disclosure obligations and an expansion of an existing program requiring pharmaceutical discounts to certain types of hospitals and federally subsidized clinics and contains cost-containment measures that could reduce reimbursement levels for pharmaceutical products. The ACA also includes provisions known as the Physician Payments Sunshine Act, which require manufacturers of drugs, biologics, devices and medical supplies covered under Medicare and Medicaid to record any transfers of value to certain U.S. healthcare providers (including, but not limited to, physicians, physician assistants, nurse practitioners, dentists, optometrists, podiatrists, chiropractors and other healthcare providers) and teaching hospitals and to report this data to the CMS annually for subsequent public disclosure. Similar reporting requirements have also been enacted on the state level domestically, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with healthcare professionals. Failure to report appropriate data may result in civil or criminal fines and/or penalties.

In addition, the IRA contains provisions intended to lower beneficiary drug spending. The IRA enables Medicare to negotiate prescription drug prices with manufacturers of certain high-cost drugs for the first time. A separate provision requires drug manufacturers to pay rebates to Medicare if their drug prices increase at a higher rate than the rate of inflation (the so-called inflation rebate provision). Additionally, beginning in 2024, the IRA eliminated the 5% coinsurance for catastrophic coverage under Medicare Part D; and in 2025, the IRA capped the beneficiary annual out-of-pocket expenditure and required new mandatory manufacturer discounts. Since its enactment, CMS has taken steps to implement various provisions of the IRA, including negotiating and publishing maximum fair prices for drugs selected under the IRA's negotiation framework. The ultimate impact of the IRA's drug pricing provisions on the pharmaceutical industry, including on pricing, reimbursement, and market dynamics, remains uncertain.

Legislative and regulatory efforts to implement drug pricing reforms, including MFN models, can adversely affect our business, if implemented. These reforms create uncertainty for our business, and they remain subject to change through potential legal challenges or subsequent rulemaking or sub-regulatory guidance. While we are unable to predict whether any pending or future reforms may be adopted, if such reforms are adopted they could lower our pricing, which would have a material negative impact on our competitive position in the market, our sales levels and our profitability.

In addition, while we are not currently engaged in clinical trials at this time, if that changes and we are unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted. For example, in December 2022, with the passage of Food and Drug Omnibus Reform Act ("FDORA"), Congress required sponsors to develop and submit a Diversity Action Plan ("DAP") for each Phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. In June 2024, as mandated by FDORA, the FDA issued draft guidance outlining the general requirements for DAPs. Unlike most guidance documents issued by the FDA, the DAP guidance when finalized will have the force of law because FDORA specifically dictates that the form and manner for submission of DAPs are specified in FDA guidance. In January 2025, in response to an Executive Order issued by the President of the United States on Diversity, Equity and Inclusion programs, the FDA removed this draft guidance from its website. This action raises questions about the applicability of statutory obligations to submit DAPs and the agency's current thinking on best practices for clinical development.

Any new laws or regulations that have the effect of imposing additional costs or regulatory burden on pharmaceutical manufacturers, or otherwise negatively affect the industry, could adversely affect our ability to successfully commercialize our products and any future product candidates, if approved. The implementation of any price controls, caps on prescription drugs or price transparency requirements, whether at the federal level or state level, 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. Sections 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.

Our revenues and profits from generic products may decline as a result of changes in regulatory policy.

The IRA contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the HHS that would require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. Substantial penalties can be assessed for noncompliance with the drug pricing provisions.

Drugs with an available generic or biosimilar, certain drugs that represent a limited portion of Medicare program spending, drugs with an orphan designation as their only FDA approved indication, and all plasma-derived products are exempt from direct negotiation. The number of negotiated products will be phased in between 2026 and 2029, and the law sets a maximum fair price the manufacturer can charge based on the number of years the product has been on the market. The law allows HHS to levy an excise and civil monetary penalties against non-compliant manufacturers or those who refuse to negotiate.

The IRA also imposes rebate requirements on manufacturers of single-source generics and other drugs covered under Medicare Part B and Part D where the price of the drug increases faster than inflation. Multisource generics and all products with an average manufacturer's price of less than $100 per year, per individual, are exempt from rebate requirements. Beginning on October 1, 2022 for Part D products and on January 1, 2023 for Part B products, CMS will monitor for products with price increases higher than the rate of inflation on a quarterly basis. Rebates will be calculated as the total number of units sold by the amount the product exceeds the inflation-adjusted price, with 2021 as the base year to measure cumulative changes relative to inflation. Noncompliant manufacturers will be subject to a civil monetary penalty of at least 125% of the calculated rebate amount.

The effect of the IRA on our business, generic manufacturers, and the pharmaceutical industry in general is not yet known.

On May 12, 2025, President Trump issued an executive order implementing the concept of MFN pricing. Under this order, the Department of Health and Human Services would direct federal health insurers to pay no more than the lowest price paid by other high-income countries for medications covered by such insurers, including Medicare and Medicaid. Under the order, MFN pricing will apply only to brand products without generic or biosimilar competition. The effect of this order on our business and the generic pharmaceutical industry in general is not yet known.

New tariffs, evolving trade policy, and geopolitical factors and military conflicts 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, retaliatory actions 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.

Further, recent global events may adversely affect workforces, organizations, economies, and financial markets globally, leading to economic downturns, inflation, and increased market volatility. Military conflicts and wars (such as the ongoing conflicts between the US and Iran, Russia and Ukraine, and Israel and Hamas), terrorist attacks, other geopolitical events, high inflation, increasing interest rates, bank failures and associated financial instability and crises, and supply chain and logistics issues can cause exacerbated volatility and disruptions to various aspects of the global economy. The uncertain nature, magnitude, and duration of hostilities stemming from such conflicts, including the potential effects of sanctions and counter-sanctions, or retaliatory cyber-attacks on the world economy and markets, have contributed to increased market volatility and uncertainty, which could have an adverse impact on macroeconomic factors that affect our business and operations.

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 CRL 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 DOJ being required by law. The FTC has stated publicly its view that some of these settlement agreements violate antitrust laws and has commenced actions against the branded and generic companies that are parties to these agreements. Accordingly, in the event of the Company being party to a settlement agreement, either as the branded, innovator product owner, or as the generic applicant, we may receive formal or informal requests from the FTC for information about a settlement agreement and there is a risk of the FTC 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.

Our reporting and payment obligations under the Medicaid rebate program and other governmental purchasing and rebate programs are complex and may involve subjective decisions. Any determination that we have failed to comply with those obligations could subject us to penalties and sanctions which could have a material adverse effect on our business.

We participate in, without limitation, the Medicaid Drug Rebate Program, the 340B program, the U.S. Department of Veterans Affairs' FSS pricing program and other governmental purchasing and rebate programs and have obligations to report the average sales price for certain of our drugs.

Pricing and rebate calculations vary across products and programs, are complex and are often subject to interpretations by us, governmental or regulatory agencies and the courts, which can change and evolve over time. In the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are generally obligated to resubmit the corrected data for up to three years after those data were originally due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate Program and could result in an adjustment to our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B program and give rise to an obligation to refund entities participating in the 340B program for overcharges during past quarters by a price recalculation.

Civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we are found to have made a misrepresentation in the reporting of our average sales price, if we fail to submit the required price data on a timely basis, or if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. CMS could also decide to terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect.

Our failure to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program and other governmental programs could negatively impact our financial results. CMS issued a final regulation, which became effective in April 2016, to implement the changes to the Medicaid Drug Rebate Program under the Affordable Care Act. Since that time, CMS has issued multiple proposed and final rules that change the Medicaid Drug Rebate Program. Regulatory and legislative changes, and judicial rulings relating to the Medicaid Drug Rebate Program and related policies have increased and will continue to increase our costs and the complexity of compliance, have been and will continue to be time-consuming to implement, and could have a material adverse effect on our results of operations, particularly if CMS or another agency challenges the approach we take in our implementation.

Health Resources and Service Administration ("HRSA") issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective in January 2019.

Implementation of this regulation could affect our obligations and potential liability under the 340B program in ways we cannot anticipate. We are also required to report the 340B ceiling prices for our covered outpatient drugs to HRSA, which then publishes them to 340B covered entities. Any charge by HRSA that we have violated this regulation or other requirements of the program could negatively impact our financial results. Moreover, HRSA has established an administrative dispute resolution ("ADR") process, which is governed by a final regulation effective June 2024, for claims by covered entities that a manufacturer engaged in overcharging, including claims that a manufacturer limited the ability of a covered entity to purchase the manufacturer's drugs at the 340B ceiling price, and by manufacturers that a covered entity violated the prohibitions against diversion or duplicate discounts. Such claims are to be resolved through an ADR panel of government officials rendering a decision that could be appealed only in federal court. An ADR proceeding could potentially subject us to discovery by covered entities and other onerous procedural requirements and could result in additional liability. HRSA could also decide to terminate a manufacturer's agreement to participate in the 340B program for a violation of that agreement or other good cause shown, in which case the manufacturer's covered outpatient drugs may no longer be eligible for federal payment under the Medicaid or Medicare Part B program.

Further, legislation may be introduced that, if passed, would, among other things, further expand the 340B program to include additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting, and any additional future changes to the definition of average manufacturer price or the Medicaid rebate amount could affect our 340B ceiling price calculations and negatively impact our results of operations. Additionally, we have implemented a policy governing the eligibility of covered entities to purchase our products at the 340B price for shipment to a contract pharmacy. We implemented this policy out of concern that contract pharmacy arrangements are diverting the benefits of the 340B program from patients to contract pharmacies and contributing to the pervasive lack of transparency within the 340B program, rendering it difficult to identify inappropriate duplicate discounts and product diversion. Certain pharmaceutical manufacturers and the industry group, Pharmaceutical Research and Manufacturers of America ("PhRMA") are involved in ongoing litigation with the HRSA regarding manufacturer initiatives that restrict covered entities' ability to purchase products at the 340B program price for shipment through an unlimited number of contract pharmacies. Additionally, several states have enacted, and many other states are considering, laws that prohibit manufacturer restrictions on contract pharmacies. Certain pharmaceutical manufacturers and PhRMA have initiated litigation challenging these state laws. The outcome of pending judicial proceedings and the potential impact on the way in which manufacturers extend discounts to covered entities through contract pharmacies remain uncertain and negative legal rulings, or the passage of legislation in respect of this topic, may materially adversely impact our results of operations.

We have obligations to report the average sales price for certain of our drugs to the Medicare program. In addition, we are required to report the best price for our drugs, as defined under the Medicaid Drug Rebate Program, to CMS. Statutory or regulatory changes or changes in CMS guidance could affect the average sales price or best price calculations for our products and the resulting Medicare payment rate or rebates we owe to state Medicaid programs. Such changes could negatively impact our results of operations.

Pursuant to applicable law, knowing provision of false information in connection with price reporting under the U.S. Department of Veterans Affairs, FSS or Tricare programs can subject a manufacturer to civil monetary penalties. These program obligations also contain extensive disclosure and certification requirements. If we overcharge the government in connection with our arrangements with FSS or Tricare, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Investigations and litigation concerning the calculation of average wholesale prices may adversely affect our business

Many government and third-party payers, including Medicare, Medicaid, HMOs and others, reimburse doctors and others for the purchase of certain prescription drugs based on a drug's average wholesale price ("AWP"). In the past several years, state and federal government agencies have conducted ongoing investigations of manufacturers' reporting practices with respect to AWP, as a result of which certain agencies have suggested that reporting of inflated AWPs by manufacturers has led to excessive payments for prescription drugs. Numerous pharmaceutical companies have been named as defendants in actions brought by various State Attorneys General and have faced state law *qui tam* actions brought on behalf of various states, alleging generally that the defendants defrauded state Medicaid systems by purportedly reporting or causing the reporting of AWP and/or "Wholesale Acquisition Costs" that exceeded the actual selling price of the defendants' prescription drugs. These cases generally seek some combination of actual damages, and/or double damages, treble damages, compensatory damages, statutory damages, civil penalties, disgorgement of excessive profits, restitution, disbursements, counsel fees and costs, litigation expenses, investigative costs, injunctive relief, punitive damages, imposition of a constructive trust, accounting of profits or gains derived through the alleged conduct, expert fees, interest and other relief that the court may have deemed proper.

We can give no assurance that we will be able to settle current or future actions on terms that we deem reasonable, or that such settlements or adverse judgments, if entered, will not exceed the amount of any liability we have recorded. Accordingly, such actions could adversely affect us and may have a material adverse effect on our business, results of operations, financial condition, cash flows ability to operate and stock price.

Litigation and Liability Related Risks

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

The cost of insurance, including directors and officers insurance, workers compensation, product liability for products containing opioids and products not containing opioids, truck and general liability insurance have increased 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 past years, 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 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 "*Our business is dependent on market perceptions, social and political pressures, including public concern over the abuse of opioids*" 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 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 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 and future earnings.

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 HHS, DOJ, 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 and impose civil and criminal penalties), 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;

- 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;

- HIPAA, as amended by HITECH, and its implementing regulations, which also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates and their subcontractors that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;

- 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 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 DOJ 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 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.

Our competitors or other third parties may allege that we are infringing upon their IP, forcing us to expend substantial resources in litigation, the outcome of which is uncertain. Any unfavorable outcome of such litigation, including, without limitation, losses related to "at-risk" product launches, could have a material effect our business, financial position and results of operations.

Companies that produce branded pharmaceutical products routinely bring litigation against ANDA filers or similar applicants that seek regulatory approval to manufacture and market generic forms of their branded products alleging patent infringement or other violations of IP 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 and can delay or prevent introduction or sale of our generic and/or biosimilar products. If valid and enforceable patents are infringed by our products, we would need to delay selling the infringing generic product unless

we could obtain a license from the patent holder, and, if we were already selling the infringing product, cease selling and potentially destroy existing product stock.

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 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 measured by the profits lost by the patent holder or treble damages, which can be significantly higher than the profits we make from selling the generic version of the product. We may also be harmed by the loss of any value of such inventory that we are unable to market or sell. Any or all of the above could have a material adverse effect on our business, financial condition, results of operations, cash flow, ability to operate as a going concern and stock price.

Intellectual Property Related Risks

Our ability to protect intellectual property rights and successfully defend against third-party allegations of IP 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 IP rights. If we fail to protect our intellectual property adequately, competitors may manufacture and market products similar to ours.

We currently hold two patents and we may intend to file further patent applications in the future. We cannot be certain that any further 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 upon exercise of warrants and options or the perception that dilution may occur could cause the price per share of common stock to fall.

As of March 31, 2026, there were outstanding warrants to purchase an aggregate of approximately 79.0 million shares of Common Stock at a cash exercise price of $0.1521 per share and vested options to purchase an aggregate of approximately 5 million shares at a weighted average cash exercise price of $0.06. Additional shares of Common Stock may be issuable as a result of anti-dilution provisions in the outstanding warrants. We may also issue shares from time to time to our directors, officers, employees, and consultants.

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, 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. Additionally, 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.

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 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 Venture Market (the "OTCQB"), 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 OTCQB 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 OTCQB, 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 OTCQB at the time of the order entry. Orders for OTCQB 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 OTCQB. Due to the manual order processing involved in handling OTCQB 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 OTCQB 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 OTCQB may not have a bid price for securities bought and sold through the OTCQB. Due to the foregoing, demand for securities that are traded through the OTCQB 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 year ended March 31, 2026, the closing sale price on the OTCQB of our Common Stock fluctuated from a high of $0.77 per share to a low of $0.32 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 1C. CYBERSECURITY

Risk Management & Strategy

Elite maintains a cyber risk management program designed to identify, assess, manage, mitigate and respond to cybersecurity threats. This program addresses cybersecurity risks to corporate information technology, or IT, environment including systems, hardware, software, data, people and processes.

The underlying processes and controls of Elite's cyber risk management program incorporate recognized best practices and standards for cybersecurity and information technology, including principles of the National Institute of Standards and Technology ("NIST") Cybersecurity Framework 2.0 ("CSF"), and processes and controls supporting data protection requirements under applicable law. NIST CSF offers a thorough set of guidelines and best practices to help establish a strong cybersecurity posture. Aligning our cybersecurity processes and controls to NIST CSF enables us to systemically identify, assess, and manage cybersecurity risks most relevant and impactful to our business operations. It is important to note that using the NIST CSF as a guide does not imply our cybersecurity program meets any specific technical standards or requirements.

Elite engages a third-party specialist to perform an annual assessment of its cybersecurity risk management program against the NIST CSF. The annual risk assessment identifies, quantifies, and categorizes material cyber risks. Elite, in conjunction with its third-party cyber risk management specialists, develops a risk mitigation plan to address such risks, and where necessary, remediate potential vulnerabilities identified through the annual assessment process. In evaluating the risks identified through the annual cybersecurity risk assessment process, our cybersecurity specialists and partners, including but not limited to Managed Service Providers, assist Elite to assess and prioritize the likelihood, severity, and impact of relevant risks, including the impact on employees, stakeholders, and vendors.

In addition, Elite maintains governance processes and controls designed to protect Elite's IT assets, data, and services from threats and vulnerabilities. Elite employs key practices within the cybersecurity risk management program including maintaining restricted access to privileged accounts, intrusion prevention systems/detection systems including maintenance of protection systems such as firewalls, network and data traffic monitoring, and critical data backups to mitigate cybersecurity risk.

Elite's cybersecurity partners, including consultants and other third-party service providers, are a key part of Elite's cybersecurity risk management strategy and infrastructure. Elite partners with industry-recognized cybersecurity providers leveraging third-party technology and expertise and engages with these partners to monitor and maintain the performance and effectiveness of IT assets, data, and services that are deployed in company data and technology environment. The cybersecurity partners provide services necessary to maintain Elite's IT infrastructure and execute the current cybersecurity strategy, including continuous improvement and remediation efforts.

Elite monitors service level agreements and third-party contracts as part of our efforts to monitor third-party risks associated with reliance on vendors, critical service providers, and other third-parties that may lead to service disruption or an adverse cybersecurity incident.

Our cybersecurity risk management program includes an incident response plan that includes relevant and critical members of management and third-party service providers alike. This team is responsible for assessing and managing cybersecurity incident response processes, response times, and communication plans in the event corrective actions and mitigation procedures are required to isolate and eradicate an incident.

Governance & Oversight

Elite's management team, with assistance from cybersecurity service providers, is responsible for oversight and administration of Elite's cyber risk management program, and for informing senior management and other relevant stakeholders regarding the prevention, detection, mitigation, and remediation of cybersecurity incidents. Elite's management team has prior experience selecting, deploying, and overseeing cybersecurity technologies, initiatives, and processes directly or via the use of strategic third-party partners. Elite's management team also relies on threat intelligence as well as other information obtained from governmental, public or private sources, including external consultants engaged by Elite for strategic cyber risk management, advisory and decision making.

The Audit Committee of the Board of Directors oversees Elite's cybersecurity risk exposures and the steps taken by management to monitor and mitigate cybersecurity risks. The cybersecurity stakeholders, including members of management assigned with cybersecurity oversight responsibility and/or third-party consultants providing cyber risk services, brief the Audit Committee on cyber vulnerabilities identified through the risk management process, the effectiveness of Elite's cyber risk management program, and the emerging threat landscape and new cyber risks on at least an annual basis. This includes updates on processes to prevent, detect, and mitigate cybersecurity incidents.

Elite faces risks from cybersecurity threats that could have a material adverse effect on its business, financial condition, results of operations, cash flows or reputation. Elite acknowledges that the risk of cyber incidents is prevalent in the current threat landscape and that a future cyber incident may occur in the normal course of its business. However, as of the date of this Annual Report on Form 10-K, Elite is not aware of any risks from cybersecurity threats that have materially affected or are reasonably likely to materially affect Elite's business strategy, financial condition, results of operations, or cash flows. Elite proactively seeks to detect and investigate unauthorized attempts and attacks against IT assets, data, and services, and to prevent their occurrence and recurrence where practicable through changes or updates to internal processes and tools and changes or updates to Elite's service delivery; however, potential vulnerabilities to known or unknown threats will still remain. Further, there are continuous regulatory considerations regarding responses to cybersecurity incidents, including reporting to regulators, investors, and additional stakeholders, which could subject Elite to additional liability and reputational harm. In response to such risks, Elite has implemented initiatives such as implementation of the cybersecurity risk assessment process and development of an incident response plan. See Item 1A. "*Risk Factors*" for more information on cybersecurity risks.

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 own a facility located at 135-137 Ludlow Avenue, Northvale, New Jersey ("135 Ludlow") which contains approximately 35,000 square feet of floor space. This real property and the improvements thereon are encumbered by a mortgage in favor of East West Bank.

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 abatement from November 2020 through February 2021 and had an original term of three years, ending on October 31, 2023. The Pompano Office Lease was extended for one additional year to October 31, 2024. The Pompano Office Lease expired on October 31, 2024.

In October 2024, the Company entered into an operating lease for office space in Pompano Beach, Florida, at a different location than the property related to the Pompano Office Lease (the "Pompano Office 2 Lease"). The Pompano Office 2 Lease is for approximately 1,270 square feet of office space, with the Company taking occupancy on October 1, 2024. The Pompano Office 2 Lease has a term of three years, ending on September 30, 2027.

The Company has entered into a lease agreement for approximately 35,000 square feet of floor space in a building located at 144 Ludlow Avenue, Northvale, New Jersey (the "144 Ludlow Ave. Lease"). The 144 Ludlow Ave. Lease began on January 22, 2024, and has a term of five years. The 144 Ludlow Ave. Lease will expire on December 31, 2028. The lease terms also include a Company option to extend the term by two years.

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

On August 17, 2023, Elite filed a Paragraph IV certification with its ANDA to generic Oxycontin and after Elite got acceptance of the ANDA by the FDA on September 19, 2023, Elite sent the patentee and NDA holder a Notice Letter as required under the Hatch-Waxman Act. On November 14, 2023, a patent infringement suit was filed in the District Court of New Jersey by Purdue Pharma. The parties agreed to a stipulated dismissal of the case and the judge signed the order dismissing the case on June 12, 2026.

Elite's launch of a generic Oxycontin will depend on approval by the FDA and the outcome of various litigation involving Purdue or the expiry of the patents listed on the Orange Book.

In the ordinary course of business, we may be subject to litigation from time to time. There is no current, pending or, to our knowledge, threatened litigation or administrative action to which we are a party or of which our property is the subject (including litigation or actions involving our officers, directors, affiliates, or other key personnel, or holders of record or beneficially of more than 5% of any class of our voting securities, or any associate of any such party) which in our opinion has, or is expected to have, a material adverse effect upon our business, prospects financial condition or operations. A significant increase in the number of claims or an increase in amounts owing under successful claims could materially adversely affect our business, financial condition, results of operations and cash flows.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

PART II

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

Market Information

Our Common Stock is quoted on the OTCQB under the ticker symbol "ELTP".

Holders

As of June 25, 2026, there were approximately 105 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, 2026:

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)	6,906,666	$ 0.07	—
Equity compensation plans not approved by security holders (2)	—	—	80,000,000
Total	6,906,666	—	80,000,000

(1) Represents securities reserved and granted under the 2014 Equity Incentive Plan

(2) Represents securities reserved and available for grant under the 2024 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 linking 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 15,730,000 shares of Common Stock were initially 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.

The 2014 Plan expired on March 17, 2024.

2024 Equity Incentive Plan

Our 2024 Equity Incentive Plan (the "2024 Plan") was adopted by the Board on March 27, 2024, to enhance the Company's and its Affiliates' ability to attract and retain highly qualified employees, officers, Non-Employee Directors, and Consultants, and to motivate such employees, officers, Non-Employee Directors, and Consultants to serve the Company and its Affiliates and to expend maximum effort to improve the business results and earnings of the Company, by providing to such persons an opportunity to acquire or increase a direct proprietary interest in the operations and future success of the Company. To this end, the 2024 Plan provides for the grant of Options, Stock Appreciation Rights ("SAR"), Restricted Stock, Restricted Stock Units, and Other Stock-based Awards. Any of these Awards may, but need not, be made as performance incentives to reward attainment of performance goals in accordance with the terms hereof. Options may only be granted as NSOs and will not qualify as ISOs. Upon becoming effective, the Plan replaced, and no further awards shall be made under, the 2014 Plan.

Each option granted under the 2024 Plan shall be an NSO, with such being defined as an option to purchase shares of Common Stock that does not meet the criteria of an incentive stock option within the meaning of Section 422 of Code. The exercise price for share of Common Stock subject to an option shall be fixed by the Board and shall be at least the fair market value of a share of Common Stock on the grant date, provided that in no case shale the option price be less than the par value of a share of Common Stock.

A SAR shall confer on the participant a right to receive, upon exercise thereof, the excess of the fair market value of one share of Common Stock on the date of exercise over the SAR exercise price, as determined by the Board. The award agreement for a SAR shall specify the SAR exercise price, which shall be fixed on the grant date as not less than the fair market value of a share of Common Stock on that date, provided, however that the SAR's grant price may not be less than the fair market value of a share of Common Stock on the grant date of the SAR to the extent required by Section 409A of the Code.

Under the restricted stock and restricted stock units component of the 2024 Plan, the Board may award grants of share of Common Stock or bookkeeping entries representing the equivalent shares of Common Stock with restrictions determined by the Board, which include, without limitation, a restricted period of time and the satisfaction of corporate or individual performance objectives.

Payment of the option price for shares purchased pursuant to the exercise of an option, or the purchase price for restricted stock shall be made in cash or in cash equivalents acceptable to the Company, except that with respect to an option only, to the extent permitted by law and to the extent the option award agreement so provides, payment of the option price may be made all or in part by delivery (on a form acceptable to the Company) of an irrevocable direction to a licensed securities broker acceptable to the Company to sell shares of Common Stock and to deliver all or part of the sales proceeds to the Company in payment of the option price and any withholding taxes required under applicable laws.

The 2024 Plan provides for the Board's granting of other stock based awards in addition to or in conjunction with other awards under the 2024 Plan. Such other stock based awards may be used in the settlement of amounts payable in shares of Common Stock under any other compensation plan or arrangement of the Company.

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:

For the Years Ended March 31, 2026 and 2025

Revenue, Cost of manufacturing and Gross profit:

	For the Years Ended March 31,		Change	
	2026	2025	Dollars	Percentage
Manufacturing fees	$ 147,810,122	$ 81,986,079	$ 65,824,043	80%
Licensing fees	1,059,997	2,057,850	(997,853)	(48)%
Total revenue	148,870,119	84,043,929	64,826,190	77%
Cost of manufacturing	73,845,784	43,957,274	29,888,510	68%
Gross profit	$ 75,024,335	$ 40,086,655	$ 34,937,680	87%
Gross profit - percentage	50%	48%		

Total revenues for the year ended March 31, 2026 increased by $64.8 million or 77%, to $148.9 million, as compared to $84.0 million, for the comparable period of the prior year. This increase is primarily due to revenue from sales of Oxy APAP tablets launched during the current fiscal year, Naltrexone Tablets and Phentermine Tablets which the Company began selling exclusively under the Elite Labs label during the last half of the current fiscal year and with full year contributions of the four products launched during the prior fiscal year, most notable Lisdex capsules, which was launched during the last quarter of the prior fiscal year and increased sales from the existing Elite Label product line, as compared to the comparable period of the prior year.

Manufacturing fees revenue increased by $65.8 million, or 80%, as compared to the comparable period of the prior year. This increase is primarily due to revenue contributions from three products launched during the current fiscal year, combined with the full year contributions from four products launched during the during the middle and end of the prior fiscal year and increased sales from the existing Elite Label product line, as compared to the comparable period of the prior year.

Licensing fees revenue decreased by $1.0 million, or 48% as compared to the comparable period of the prior year. This decrease is primarily due to the Company's transitioning away from licensing product to third parties to marketing of the Elite label, which does not result in revenues earned from licensing fees.

Cost of manufacturing consists of manufacturing and assembly costs. Our cost of manufacturing increased by $29.9 million or 68%, to $73.8 million as compared to $44.0 million for the comparable period of the prior year. This increase was due to the cost of manufacturing having a strong positive correlation with manufacturing fees, combined with an increased volume of products sold during the year ended March 31, 2026, as compared to the prior fiscal year, as noted above.

Our gross profit margin was 50% during the year ended March 31, 2026 as compared to 48% during the prior fiscal year. The increase is due to product mix in the current fiscal year including greater proportion of higher margin products.

Operating expenses:

	For the Years Ended March 31,		Change	
	2026	2025	Dollars	Percentage
Operating expenses:				
Research and development	$ 5,742,955	$ 7,964,837	$ (2,221,882)	(28)%
General and administrative	17,596,803	9,001,930	8,594,873	95%
Non-cash compensation	176,507	227,565	(51,058)	(22)%
Impairment of intangible assets	847,012	1,603,426	(756,414)	(47)%
Depreciation and amortization	1,547,874	1,688,429	(140,555)	(8)%
Total operating expenses	$ 25,911,151	$ 20,486,187	$ 5,424,964	26%

Operating expenses for the year ended March 31, 2026 increased by $5.4 million, or 26%, to $25.9 million as compared to $20.5 million for the prior fiscal year, largely due to increases in general and administrative expenses of $8.6 million, offset by decreases in research and development of $2.2 million, non-cash compensation of $0.1 million, depreciation and amortization of $0.1 million and impairment of intangible asset expense of $0.8 million.

Research and development costs during the year ended March 31, 2026 were $5.7 million, a decrease of $2.2 million, or 28%, from approximately $8.0 million of such costs for the prior year. The decrease was a result of greater proportion of laboratory and regulatory resources being allocated to supporting increasing commercial operations as well as the timing and nature of product development activities, which consist primarily of material consumption, internal and external lab costs, human resource costs and analytical studies, during the year ended March 31, 2026 as compared to the prior fiscal year.

General and administrative expenses during the year ended March 31, 2026 were $17.6 million as compared to $9.0 million for the prior fiscal year, an increase of $8.6 million or approximately 95%, largely due to increased employee compensation rates and bonuses as compared to the prior fiscal year as well higher operational support and infrastructure costs related to product launches and expansion of product line distribution activities and increases in technology, legal, audit and consulting costs during the current year as compared to the comparable period of the prior year.

Non-cash compensation expenses during the year ended March 31, 2026 was $0.18 million as compared to $0.23 million for the prior fiscal year, a decrease of $0.05 million or approximately 22%, with such decrease being attributed to the current year including full year amortization of non-cash compensation from employee stock options issued during the prior year, as compared to the comparable period of the prior which included partial year periods amortization of non-cash compensation encompassing only that part of the year subsequent to the grant date of each employee option.

Depreciation and amortization expenses during the year ended March 31, 2026 were $1.55 million as compared to $1.69 million for the prior fiscal year, a decrease of $0.14 million or approximately 8%. This decrease is due to depreciation charges relating to current fiscal year fixed asset additions being less than depreciation charges for investments made in prior periods which achieved full depreciation during the current fiscal year.

Impairment of intangible assets for the year ended March 31, 2026 was $0.8 million as compared to $1.6 million for the prior fiscal year, a decrease of $0.8 million or approximately 47%. This decrease is related to impairments of ANDAs for Loxapine Capsules and patent development costs during the current year being less than the impairments recorded during the comparable period of the prior year. Impairments of intangible assets are recorded when, after assessments and evaluation, an entity concludes that the fair value of an indefinite lived intangible asset is more likely than not impaired.

As a result of the foregoing, our income from operations during the year ended March 31, 2026 was $49.1 million, compared to income from operations of $19.6 million for the comparable period of the prior year.

Other income (expense):

	For the Years Ended March 31,		Change	
	2026	2025	Dollars	Percentage
Other income (expense):				
Change in fair value of derivative financial instruments - warrants	$ 7,855,607	$ (18,901,185)	$ 26,756,792	(142)%
Interest expense and amortization of debt issuance costs	(396,664)	(772,367)	375,703	(49)%
Interest income	207,857	20,944	186,913	892%
Other income	34,500	—	34,500	—%
Other income (expense), net	$ 7,701,300	$ (19,652,608)	$ 27,353,908	(139)%

Other income (expense) for the year ended March 31, 2026 was an other income of $7.7 million, an increase in net other income (expense) of $27.4 million from other (expense) of $19.7 million for the comparable period of the prior year. The increase was primarily due to increases in other income of $26.8 million relating to the change in warrant derivative instruments. The change in the fair value of derivative instruments and stock-based liabilities is determined in large part by the change in the closing price of the Company's Common Stock as of the end of the period, as compared to the closing price at the beginning of the period. There is a strong correlation between changes in the closing price of the Company's Common Stock and other income or (expense) recorded, with increases in the closing price of Common Stock resulting in other expenses and decreases in the closing price of Common Stock resulting in other income. The closing price of the Company's Common Stock at the end of the fiscal year ended March 31, 2026 of $0.36 per share was lower than the comparable price at the end of the fiscal year ended March 31, 2025 of $0.44 per share, resulting in the Company recording net other income of $7.9 million for the fiscal year ended March 31, 2026. This compares with the closing price of the Company's Common stock at the end of the fiscal year ended March 31, 2025 of $0.44 per share being greater than the comparable price at the end of the fiscal ended March 31, 2024 of $0.15 per share, resulting in the Company recording a net other (expense) of $18.9 million for the fiscal year ended March 31, 2025. Interest expense decreased by $0.4 million or 49% from $0.8 million in the prior fiscal year to $0.4 million in the current fiscal year. This decrease in interest expense is due to the decreased loan principal balances existing during the current fiscal as compared to the comparable period of the prior fiscal year, which resulted from the Company's payment of outstanding loan principal amounts in accordance with the terms of the underlying loans.

As a result of the foregoing, our net income before income taxes for the year ended March 31, 2026 was $56.8 million, compared to net loss before income taxes of $0.1 million for the comparable period of the prior year.

Income Taxes:

The Company recorded tax expense of approximately (21)% and 8,175% of income (loss) before income tax expense, for the years ended March 31, 2026 and 2025, respectively. The decrease of the effective tax rate for the current period as compared to the prior period is primarily due to the release of the valuation allowance on the Company's deferred tax assets as of March 31, 2025 and the nondeductible fair market value change in the Company's warrant derivative liabilities.

	For the Years Ended March 31,	
	2026	2025
Income tax expense	$ (11,941,798)	$ (4,262,519)

Income tax expense for the year ended March 31, 2026 was $11.9 million as compared to $4.3 million for the year ended March 31, 2025, an increase of $7.6 million or 180%. The increase was due to the Company's net income before income taxes being approximately $56.9 million greater this year than the comparable period of the prior year, combined with there being a strong positive correlation between net income before taxes and income tax expense. Please also note that income tax expense includes certain non-deductible expenses and non-taxable income items, including, without limitation income and expenses relating to the change in fair value of derivative liabilities.

Liquidity and Capital Resources

Capital Resources

	March 31, 2026	March 31, 2025	Change
Current assets	$ 112,106,551	$ 57,739,147	$ 54,367,404
Current liabilities	$ 17,391,464	$ 11,840,435	$ 5,551,029
Working capital	$ 94,715,087	$ 45,898,712	$ 48,816,375

The Company considers cash and working capital balances as several of the factors the Company uses in evaluating its performance. As of March 31, 2026, the Company had cash on hand of $29.8 million and accounts receivable to be collected within expected operating cycles of $59.7 million. The Company believes that the working capital surplus of $94.7 million, which includes these cash and accounts receivable resources, and the continuation of ongoing operations, are sufficient to fund operations through the next twelve months. For the year ended March 31, 2026, the Company had income from operations totaling $49.1 million, net other income totaling $7.7 million and a net income attributable to common shareholders of $44.9 million. The Company's other income and net income attributable to common shareholders are significantly influenced by the fluctuations in the fair value of warrant derivatives, as noted above, with there being a strong correlation between changes in the market share price of Common Stock and other income or expenses recorded in relation to the change in fair value of the warrant derivatives.

Our working capital (total current assets less total current liabilities) increased by $48.8 million from $45.9 million as of March 31, 2025 to $94.7 million as of March 31, 2026, with such increase being primarily related to the increases in cash of $18.5 million, inventory of $5.0 million, and accounts receivable of $30.5 million, offset by increases in current liabilities of $5.6 million, as compared to the comparable balances as of March 31, 2025. The increase in cash, inventory, and accounts receivable are primarily due to increased customer orders and revenues achieved during the year ended March 31, 2026 as compared to the comparable period of the prior year. The increase in current liabilities is primarily due to increased trade accounts payables as of March 31, 2026 as compared to March 31, 2025 resulting from increased commercial operations and increased accrued expenses, as of March 31, 2026 compared to March 31, 2025 resulting from increases in accruals for employee bonuses, taxes, audit, legal and professional fees, salaries and other similar expenses.

Summary of Cash Flows:

	For the Years Ended March 31,	
	2026	2025
Net cash provided by operating activities	$ 23,748,094	$ 7,455,639
Net cash used in investing activities	$ (925,626)	$ (2,399,832)
Net cash used in financing activities	$ (4,322,309)	$ (825,740)

Net cash provided by operating activities for the year ended March 31, 2026 was $23.7 million, which included a net income of $44.9 million, offset by depreciation and other non-cash expenses totaling $6.8 million and reduced by the change in operating assets and liabilities totaling $27.9 million,

Net cash provided by operating activities for the year ended March 31, 2025 was $7.5 million, which included a net loss of $4.3 million, offset by depreciation and other non-cash expenses totaling $26.9 million and reduced by the change in operating assets and liabilities totaling $15.2 million.

Net cash used in investing activities for the year ended March 31, 2026 was comprised of purchases of property and equipment of approximately $0.9 million.

Net cash used in investing activities for the year ended March 31, 2025 was comprised of purchases of property and equipment of approximately $1.6 million and purchases of intangible assets consisting of ANDA products of approximately $0.9 million.

Net cash used in financing activities was $4.3 million for the year ended March 31, 2026 which consisted primarily of payments of bond and related party loan principal totaling $4.3 million and payments on principal on finance lease obligations of $0.4 million, offset by proceeds received from the exercise of stock options of $0.3 million.

Net cash used in financing activities was $0.8 million for the year ended March 31, 2025 which consisted primarily of payments of bond and loan principal totaling $0.5 million and payments on principal of finance lease obligations of $0.3 million.

East West Bank

On July 1, 2022, EWB provided a mortgage loan ("EWB Mortgage Loan") in the amount of $2.55 million for the purchase of the property at 135-137 Ludlow Avenue, which was formerly a lease held by the Company. The EWB Mortgage Loan matures in 10 years and bears interest at a rate of 4.75% fixed for 5 years then adjustable at WSJP plus 0.5% with floor rate of 4.5%. The total transaction costs associated with the EWB Mortgage Loan incurred as of March 31, 2026, were $13,251, which are being amortized on a monthly basis over ten years, beginning in July 2022. The EWB Mortgage Loan contains customary representations, warranties and covenants. These covenants include maintaining a minimum debt coverage ratio of 1.50 to 1.00 tested annually and a minimum trailing 12-month debt coverage ratio of 1.50 to 1.00. As of March 31, 2026, and through the date of filing of this Annual Report on Form 10-K, the Company was not aware of the existence of any violations of financial covenants included in the EWB Mortgage Loan.

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. 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, 2026, 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 proceeds of the Bonds and are being amortized over the life of the Bonds. Amortization of Bond issuance costs amounted to $14,178 for the fiscal year ended March 31, 2026.

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.

In addition, the Company had previously received Notices of Default from the Trustee of the NJEDA Bonds as a result of the utilization of the debt service reserve being used to pay interest payments as well as the company's failure to make scheduled principal payments. All monetary defaults were cured during Fiscal 2015 and the Company is current on all NJEDA Bond interest and principal payments.

As of the date of filing of this Annual Report on Form 10-K, there are no interest or principal amounts in arrears.

Recent Developments

On April 2, 2026, we announced the commercial launch of our generic methadone hydrochloride 5 mg and 10 mg tablets. The product is marketed and sold under the Elite Labs label and represents an expansion of the Company's generic product portfolio.

On June 1, 2026, we filed an Abbreviated New Drug Application with the US Food and Drug Administration for a generic version of an undisclosed drug product in the class of medications called anticoagulants.

On June 12, 2026, pursuant to a stipulated dismissal agreed to by both parties, the District Court of New Jersey signed an order dismissing the patent infringement suit filed by Purdue Pharma against the Company in November 2023.

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 Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of our consolidated financial statements and related disclosures requires us to make estimates, assumptions and judgments that affect the reported amount of assets, liabilities, costs and expenses and related disclosures. Our critical accounting estimates are those estimates that involve a significant level of uncertainty at the time the estimate was made, and changes in them have had or are reasonably likely to have a material effect on our financial condition or results of operations. Accordingly, actual results could differ materially from our estimates. The following discussion addresses our most critical accounting estimates, which are those that are both important to the portrayal of our financial condition and results of operations and that require significant judgment or use of complex estimates.

Revenue Recognition - Manufacturing Fees

The Company's revenues are offset by variable consideration, which may include, without limitation, chargebacks, distribution fees, rebates, group purchasing organization fees, prompt payment cash discounts, consideration payable to the customer, billbacks, Medicaid and other government pricing programs, price protection and shelf stock adjustments, sales returns and profit shares. The Company's estimates for variable consideration are adjusted as required at each reporting period for specific known developments that may result in a change in the amount of total consideration it expects to receive as well as updating estimate assumptions to reflect current and/or historical trends.

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.

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.

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 based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission on Internal Control ("COSO"), 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 not effective as of March 31, 2026 to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms and such information is accumulated and communicated to management as appropriate to allow timely decisions regarding required disclosures.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. As of March 31, 2026, we identified the following control deficiencies that we believe constituted individually, and in the aggregate, material weaknesses in the design and operation components of our internal controls within the COSO framework:

- We were unable to formalize and implement revised controls, policies and procedure documentation to evidence a system of internal controls, including testing of such revised controls, that was consistent with available personnel and resources;
- We failed to maintain effective control activities over our control environment, risk assessment and response, information technology and communication, objective setting, event identification, control activities and monitoring components and;
- We had insufficient segregation of duties, oversight of work performed and lack of compensating controls in our finance and accounting functions due to limited personnel and resources.

Management's Annual 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: (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets; (ii) 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 (iii) 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 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, utilizing those criteria, management has determined that, as of March 31, 2026, because of the material weaknesses described below, our internal control over financial reporting was not effective.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. As of March 31, 2026, we identified the following control deficiencies that we believe constituted individually, and in the aggregate, material weaknesses in the design and operation components of our internal controls within the COSO framework:

The deficiencies in our internal controls over financial reporting and disclosure controls and procedures are described above and our efforts to remediate these deficiencies are described below. Please also see Item 1A-Risk Factors: "*We have identified material weaknesses in our internal control over financial reporting which could, if not remediated, adversely affect our ability to report our financial condition, cash flows and results of operations in a timely and fairly stated manner and/or increase the risk of future misstatements, which could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our common shares and/or debt securities to decline.*"

Changes in Internal Controls Over Financial Reporting

During the fiscal year ended March 31, 2025, as a result of reviews and assessments of internal controls over financial reporting conducted by the Company's CFO, the Company identified material weaknesses in internal controls over financial reporting as further detailed above and began remediation efforts which are detailed below, with such activities expected to result in further changes in internal control over financial reporting as necessary to remediate the identified material weaknesses.

*Remediation efforts to address material weaknesses in internal controls over financial report*ing

We are in the process of revising and expanding control environment documentation and increasing personnel resources needed to support the Company's growth. We have begun designing and implementing controls, policies and procedure documentation that are consistent with current and planned personnel, resources and capabilities, with significant focus on controls relating to financial oversight, management, analysis and reporting of operations emanating from the Company's manufacturing, marketing and distribution of its Elite Label product line as well as enhanced segregation of duties and testing of control procedures. Please note that these material weaknesses cannot be considered remediated until the applicable remedial controls operate for a sufficient period of time, allowing management, through testing, to reach a conclusion on such controls design and operational effectiveness.

Item 9B. OTHER INFORMATION.

During the fiscal year ended March 31, 2026, none of the Company's directors or officers (as defined in Rule 16a-1(f) of the Securities Exchange Act of 1934, as amended) adopted or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K of the Securities Act of 1933, as amended).

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

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

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

Name	Age	Position	Director/Officer Since	Director Class
Nasrat Hakim	65	Chairman of the Board of Directors	August 2013	III
Barry Dash, Ph. D.	95	Director	April 2005	II
Jeffrey Whitnell	70	Director	October 2009	III
Davis Caskey	78	Director	April 2016	I
Kirko Kirkov	58	Chief Commercial Officer	September 2022	
Douglas Plassche	62	Executive Vice President of Operations	August 2013	
Carter Ward	62	Chief Financial Officer	September 2023	

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 amended and restated bylaws, our Board of Directors is 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 2015, Mr. Whitnell has provided financial advisory services, primarily to the healthcare industry. He worked for Southside Master, a specialty pharmacy company from September 2018 to June 2022, where he served as Chief Financial Officer. From April 2015 to August 2018, Mr. Whitnell provided financial advisory services to various Private Equity portfolio companies, including Lifewatch Services (acquired by BioTelemetry), where he served as Vice President, Finance & Controller. Mr. Whitnell was the Chief Financial Officer for ReliefBand Medical Technologies, a medical device company, from June 2010 to March 2015. From July 2009 to May 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., a specialty pharmaceuticals company. From 2002 to 2004, Mr. Whitnell was Vice President of Finance and Treasurer for Ovation Pharmaceuticals (acquired by Lundbeck). From 1997 to 2001, Mr. Whitnell was Vice President of Finance and Treasurer for MediChem Research (acquired by deCODE genetics). Prior to 1997, Mr. Whitnell held various finance positions with 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 ("ECR"), 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.

Kirko Kirkov

Mr. Kirkov joined Elite in September 2022, as an accomplished and multi-faceted leader with more than twenty years of in-depth business development skills across international pharmaceutical organizations. Before joining Elite, Mr. Kirkov served as General Manager of Vertice Pharma, a specialty generics pharmaceutical company, from February 2020 to August 2022. From April 2008 to February 2020, Mr. Kirkov was employed by Sandoz and served in positions of increasing responsibilities beginning with Country Head & Managing Director of Bulgaria from 2008 to 2011. From 2011 to 2013, Mr. Kirkov served as Sandoz's Business Unit Head, Branded Prescription Generics in Russia, and most recently, from January 2013 to February 2020, served as Sandoz's Executive Director, Commercial Operations. Mr. Kirkov brings with him a broad range of experience in the areas of business development, operationalization of commercial strategy, and implementation of retail and wholesale channel sales operations, having overseen sales portfolios consisting of 400+ product families, and 1,500+ SKUs covering both generic and branded products.

Mr. Kirkov has a Bachelor of Science in Mechanical Engineering/Engineering Management from the University of Ottawa, two Masters of Science degrees in Naval Architecture and Ocean Systems Management, respectively, from the Massachusetts Institute of Technology, a Master of Science in Applied Positive Psychology and Coaching from the University of East London, and an MBA from the University of Durham.

Douglas Plassche

Douglas Plassche has served as the Company's 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.

Carter Ward

Carter Ward has served as Chief Financial Officer, Secretary and Treasurer of the Company since September 5, 2023. This is Mr. Ward's second tenure with the Company, previously serving in the same positions from July 2009 through May 2021. In between Mr. Ward's roles with the Company, he served as Chief Financial Officer of Mirror Biologics, a privately held biotech organization from September 2022 to July 2023 and as CFO of Enveric Biosciences, a NASDAQ listed biotech company, from May 2021 to September 2022. Prior to initially joining the Company, from July 2005 to April 2009, Mr. Ward filled multiple finance and supply chain leadership roles with the Actavis Group and its U.S. subsidiary, Amide Pharmaceuticals. From September 2004 to June 2005, Mr. Ward was a consultant, mainly engaged in improving internal controls and supporting Sarbanes Oxley compliance of Centennial Communications, Inc, a NASDAQ listed wireless communications provider. Mr. Ward began his career as a certified public accountant in the audit department of KPMG. Mr. Ward holds a B.S. in Accounting from Long Island University from where he graduated summa cum laude.

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

The members of the Audit Committee are Mr. Jeffrey Whitnell (Chairman of the Audit Committee), Dr. Barry Dash, Mr. Davis Caskey and Mr. Nasrat Hakim. The Board of Directors has determined that Messrs. Whitnell, Caskey and Dr. Dash are independent and Mr. Whitnell is qualified as an audit committee financial expert. The Board of Directors has determined that Messrs. Whitnell, Caskey and Dr. Dash 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

The members of the Nominating Committee are Mr. Nasrat Hakim (Chairman of the Nominating Committee), Dr. Barry Dash, and Mr. 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

The members of the Compensation Committee are 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, 2026, 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.

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.

Insider trading policy

The Company has adopted insider trading policies and procedures governing the purchase, sale and/or other dispositions of its securities by directors, officers and employees of the Company, that are reasonably designed to promote compliance with insider trading laws, rules and regulations and any listing standards applicable to the Company. Such policies are described in our Code of Business Conduct and Ethics filed as Exhibit 14.1 to this Annual Report on Form 10-K.

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 and equity awards are subject to ratification by the full Board of Directors. The members of the Compensation Committee are Dr. Barry Dash (Chairman of the Compensation Committee), and Messrs Jeffrey Whitnell, Davis Caskey and Nasrat Hakim. The Compensation 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, 2026, the Compensation Committee did not engage any advisors.

Named Executive Officers

The named executive officers for the fiscal year ended March 31, 2026 were:

- Nasrat Hakim, Chief Executive Officer and President for the full year;

- Douglas Plassche, Executive Vice President for the full year and;
- Carter Ward, Chief Financial Officer 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 is driven 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. 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 each of the Named Executive Officers. 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 titled "*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, 2026.

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. For the fiscal year ended March 31, 2026, Mr. Plassche received a discretionary cash bonus of $178,482 and Mr. Ward received a discretionary cash bonus of $141,625. Mr. Hakim was awarded a discretionary cash bonus of $5,000,000 that was accrued and owing as of March 31, 2026 and paid subsequent to March 31, 2026.

In the section below titled "Agreements with Named Executive Officers," we describe Mr. Ward's guaranteed annual bonus.

Equity

In addition to cash compensation, our Named Executive Officers from time to time are granted stock options. All Options granted typically include vesting periods consisting of one-third of total options granted vesting on each of the first, second and third anniversaries of the grant date, with current employment being a requisite for all vesting. Options granted expire the earlier of ten years from the grant date or 90 days subsequent to the employee's last date of employment. There were no stock options granted to our Named Executive Officers during the fiscal year ended March 31, 2026.

Although we do not have a formal policy regarding the timing of awards of stock options, stock appreciation rights ("SARs") and/or similar option-like instruments grants to our Named Executive Officers, we do not make these awards or any other form of equity compensation in anticipation of the release of material, non-public information. Similarly, we do not time the release of material, non-public information based on stock option, SARs or other equity award grant dates for the purpose of affecting the value of any Named Executive Officer award.

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. 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 aggregate incremental cost to us for 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 1, 2013 employment agreement, as amended on January 12, 2016 and September 13, 2023 (the "Hakim Employment Agreement"), as of April 1, 2023, Mr. Hakim receives an annual salary of $1,000,000 per year 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, a car allowance of $1,500 per month and housing allowance of $5,000 per month, respectively. 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. The Hakim Employment Agreement shall also automatically terminate upon Mr. Hakim's death. 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 reimbursement of any reasonable and necessary business expenses, all through the date of termination, payable in stock ("Basic Termination Benefits"). 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, 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 an amount equal to two years' annual base salary, payable in stock as a lump sum within 60 days of the termination date, and 12 months of partial health benefits continuation under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA") equal to amounts the Company paid immediately prior to his separation of employment, subject to his timely election of COBRA coverage, execution of a release and 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 discretionary bonus and payment in an amount equal to two year's annual base salary in effect upon the date of termination, less applicable deductions, and withholdings, 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.

Douglas Plassche

On July 20, 2013, the Company entered into an employment agreement with Mr. Douglas Plassche (as modified by the retention agreement dated February 18, 2022, 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.

Throughout his tenure, Mr. Plassche's compensation has been increased from time to time by the Board and the annual stock award has been removed. On March 1, 2026, Mr. Plassche's compensation was adjusted to include an annual salary of $374,812, payable in accordance with the Company's payroll practices. In addition, Mr. Plassche is entitled to a monthly automobile allowance of $500 and an annual bonus based upon the achievement of agreed milestones and at the discretion of the Company and its Chief Executive Officer.

The Plassche Employment Agreement also provides for the granting of 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 expired, unexercised, ten years from the date of issuance, in accordance with the terms and conditions of the option agreement.

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 his then current base annual salary.

Carter Ward

On September 5, 2023, the Company entered into an employment agreement with Mr. Carter Ward, effective as of September 5, 2023 to serve as the Company's Chief Financial Officer (the "Ward Employment Letter"). Pursuant to the Ward Employment Letter, Mr. Ward receives an annual base salary of $275,000, guaranteed annual bonus equal to 20% of annual base salary and is eligible to receive additional performance bonuses of up to 30% of annual base salary as determined from time to time by the Company's Board of Directors. In addition and also pursuant to the Ward Employment Letter, the Company's Board of Directors approved the grant of options to purchase 3,000,000 shares of Common Stock at a price equal to the closing price of the Company's Common Stock on the first date of Mr. Ward's employment pursuant to the Ward Employment Letter.

The Ward Employment Agreement will remain in effect until terminated by either party with at least 60 days advance written notice. In addition, the Ward Employment Agreement is subject to early termination by Mr. Ward or the Company in accordance with the terms of the Ward Employment Agreement.

Pursuant to the Ward Agreement, if Mr. Ward's employment is terminated by the Company without cause, then the Company must pay Mr. Ward, in addition to any then-accrued and unpaid obligations owed to him, severance payments equal to two months of his then-current base salary for each year of service, up to a maximum of 12 months, and 12 months of continued health insurance continuation under COBRA equal to amounts the Company paid immediately prior to his separation of employment, at active employee rates, in each case, subject to his execution of a release and his compliance with applicable restrictive covenants.

The Ward Employment Agreement also contains covenants restricting Mr. Ward from soliciting the Company's employees or customers during his employment and for a period of 12 months after the termination of Mr. Ward's employment with the Company and prohibiting him from disclosing confidential information regarding the Company at any time.

Throughout his tenure, Mr. Ward's compensation has been increased from time to time by the Board. On March 1, 2026, Mr. Ward's compensation was adjusted to include an annual salary of $297,413, payable in accordance with the Company's payroll practices.

Potential Payments Upon Termination or Change of Control

Messrs. Hakim, Plassche and Ward 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 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 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.

Summary Compensation Table

Name and Principal Position	Fiscal Year	Salary ($)	Bonus ($)	All Other Compensation ($)	Total ($)
Nasrat Hakim, President, Chief Executive Officer and Chairman of the Board of Directors					
	2026	1,000,000 [1]	5,000,000 [3]	78,000 [2]	6,078,000
	2025	1,000,000 [1]	—	78,000 [2]	1,078,000
Douglas Plassche, Executive Vice President					
	2026	355,348 [4]	178,482 [4]	6,000 [6]	539,830
	2025	347,434 [4]	173,284 [4]	6,000 [6]	526,718
Carter Ward, Chief Financial Officer					
	2026	281,968 [7]	141,625 [8]	—	423,593
	2025	275,687 [7]	137,500 [8]	—	413,187

1 Represents salary earned by Mr. Hakim pursuant to the Hakim Employment Agreement for the fiscal years ended March 31, 2026 and 2025 and paid in accordance with the Company's payroll practices.

2 Represents annual auto and housing allowances of $18,000 and $60,000, respectively.

3 Represents discretionary cash bonus awarded to Mr. Hakim by the Board for fiscal year 2026.

4 Represents salary earned by Mr. Plassche pursuant to the Plassche Employment Agreement and paid in accordance with the Company's payroll practices.

5 Represents discretionary cash bonus earned pursuant to the Plassche Employment Agreement and paid in accordance with the Company's payroll practices.

6 Represents annual auto allowance.

7 Represents salary earned by Mr. Ward pursuant to the Ward Employment Agreement and paid in accordance with the Company's payroll practices.

8 Represents cash bonuses earned pursuant to the Ward Employment Agreement and paid in accordance with the Company's payroll practices.

Outstanding Equity Awards as of March 31, 2026

	Option Awards			
Name	**Number of securities underlying unexercised options Exercisable (#)**	**Number of securities underlying unexercised options Unexercisable (#)**	**Options Exercise Price ($)**	**Option Expiration Date**
Douglas Plassche	—	—		
Carter Ward	2,000,000	1,000,000 [1]	$ 0.0898	9/5/2033
Nasrat Hakim	—	—		

1 The remaining portion of this option grant is scheduled to vest on September 5, 2026, subject to Mr. Ward's continued employment through the vest date.

Director Fee Compensation

The Company's policy regarding director fees is as follows: (i) Directors who are employees or consultants of the Company (and/or any of its subsidiaries), including Mr. Hakim, 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, payable in cash (iv) Directors do not receive any additional compensation for attendance at or chairing of any meetings.

Director Compensation

The following table sets forth information concerning director compensation for the year ended March 31, 2026:

Name	**Fees Earned or Paid In Cash [1] ($)**	**Total ($)**
Barry Dash	30,000 [2]	30,000
Jeffrey Whitnell	30,000 [2]	30,000
Davis Caskey	30,000 [2]	30,000

1 Please refer to the section above titled "Director Fee Compensation" for details on the Company's director fee compensation policy. No directors held unexercised or unvested stock or option awards as of March 31, 2026.

2 Amounts represent Director fees earned during the fiscal year ended March 31, 2026 payable in cash.

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

The following table sets forth certain information, as of June 29, 2026 (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 29, 2026 we had 1,077,096,442 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 29, 2026. 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*	300,581,058(1)	26.0%
Barry Dash, Director*	3,235,555(2)	**%
Jeffrey Whitnell, Director*	3,187,020(3)	**%
Davis Caskey, Director*	2,049,436(4)	**%
Douglas Plassche, Executive Vice President *	6,000,000(5)	**%
Carter Ward, Chief Financial Officer	6,990,445(6)	**%
All Directors and Officers as a group	322,043,514(7)	27.9%

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

** Less than 1%

(1) Includes 219,349,250 shares of Common Stock held by Mr. Hakim and 2,223,147 shares of Common Stock held by Mr. Hakim's spouse 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 3,235,555 shares of Common Stock held by Dr. Dash

(3) Includes 3,187,020 shares of Common Stock held by Mr. Whitnell

(4) Includes 2,049,436 shares of Common Stock held by Mr. Caskey.

(5) Includes 6,000,000 shares of Common Stock held by Mr. Plassche.

(6) Includes 4,990,445 shares of Common Stock held by Mr. Ward and shares of Common Stock issuable upon cash exercise of vested options to purchase 2,000,000 shares of Common Stock and excludes 1,000,000 shares issuable upon exercise of options not vested or not exercisable within the next 60 days.

(7) Relates only to current directors and officers. Includes 241,034,853 shares of Common Stock held, 2,000,000 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, and excludes 1,000,000 shares issuable upon exercise of options not vested or not exercisable within the next 60 days.

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 has assumed all the rights and obligations for these products from Praxgen. Mikah was founded in 2009 by Nasrat Hakim, the Company's President, Chief Executive Officer and Chairman of the Board of Directors.

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 years ending March 31, 2026 and 2025 is Forvis Mazars LLP ("*Forvis Mazars*").

The following table presents fees, including reimbursements for expenses, for professional audit services rendered by Forvis Mazars, for the fiscal years ended March 31, 2026 and 2025 for the audits of our financial statements and interim reviews of our quarterly financial statements.

	Fiscal 2026	Fiscal 2025
Audit Fees - Forvis Mazars, LLP	$ 792,000	$ 369,500

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.

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.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENTS AND SCHEDULES

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

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

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

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

(c) None

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

Exhibit No.	Description
3.1(a)	Articles of Incorporation of Elite-Nevada, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the SEC on January 9, 2012.
3.1(b)	Certificate of Designations of the Series G Convertible Preferred Stock as filed with the Secretary of State of the State of Nevada on April 18, 2013, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated April 18, 2013 and filed with the SEC on April 22, 2013.
3.1(c)	Certificate of Designation of the Series H Junior Participating Preferred Stock, incorporated by reference to Exhibit 2 (contained in Exhibit 1) to the Registration Statement on Form 8-A filed with the SEC on November 15, 2013.
3.1(d)	Certificate of Designations of the Series I Convertible Preferred Stock as filed with the Secretary of State of the State of Nevada on February 6, 2014, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K, dated February 6, 2014 and filed with the SEC on February 7, 2014.
3.1(e)	Certificate of Designations of the Series J Convertible Preferred Stock as filed with the Secretary of State of the State of Nevada on May 3, 2017, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K, dated April 28, 2017 and filed with the SEC on April 28, 2017.
3.1(f)	Certificate of Amendment to Articles of Incorporation, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K, dated June 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. Restated 2014 Equity Incentive Plan , incorporated by reference to Exhibit 10.1 to the Annual Report on Form 10-K, filed with the SEC on July 1, 2024.
10.2	Form of Confidentiality Agreement (corporate), incorporated by reference to Exhibit 10.7 to the Form SB-2.
10.3	Form of Confidentiality Agreement (employee), incorporated by reference to Exhibit 10.8 to the Form SB-2.
10.4	Loan Agreement, dated as of August 15, 2005, between New Jersey Economic Development Authority ("NJEDA") and the Company, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
10.5	Series A Note in the aggregate principal amount of $3,660,000.00 payable to the order of the NJEDA, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
10.6	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.
10.7	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).
10.8	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.
10.9	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 thereof).

10.10	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 thereof).
10.11	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 thereof).
10.12	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)).
10.13	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.
10.14	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.
10.15	License and Distribution Agreement by and between Elite Pharmaceuticals, Inc. and Dexcel Ltd. (Or Akiva, Israel), dated December 6, 2021, incorporated by reference to Exhibit 10.57 to the Annual Report on Form 10-K for the period ended March 31, 2022, filed with the SEC on June 29, 2022.
10.16	February 18, 2022 Retention Agreement with Douglas Plassche, incorporated by reference to Exhibit 10.58 to the Annual Report on Form 10-K for the period ended March 31, 2022, filed with the SEC on June 29, 2022.
10.17	Agreement for Sale and Purchase of Real Estate, dated April 8, 2022, by and between Clyde Wesp and Margaret Wesp as trustees of the Wesp Family Joint Living Trust UTD November 19, 2015 and the Company, incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q, for the period ended June 30, 2022 and filed with the SEC on August 15, 2022.
10.18	Loan and Security Agreement, dated April 1, 2022, by and among East West Bank, Elite Pharmaceuticals, Inc. and Elite Laboratories, Inc., incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q, for the period ended June 30, 2022 and filed with the SEC on August 15, 2022.
10.19	Employment Agreement, dated September 5, 2022, between Elite Pharmaceuticals, Inc. and Kirko Kirkov, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on September 7, 2022.
10.20	Employment Agreement, dated April 27, 2023, between Elite Pharmaceuticals, Inc. and Mark Pellegrino, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on May 3, 2023
10.21	Employment Agreement, dated September 5, 2023, between Elite Pharmaceuticals, Inc. and Carter Ward, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on September 7, 2023.
10.22	Elite Pharmaceuticals, Inc. 2024 Equity Incentive Plan, incorporated by reference to Exhibit 99.1 to the Form S-8 filed with the SEC on March 28, 2024.
10.23	Asset Purchase Agreement, dated June 17, 2024, by and between the Company and Nostrum Laboratories Inc. incorporated by reference to Exhibit 10.59 to the Annual Report on Form 10-K, filed with the SEC on July 1, 2024
10.24	Amendment to Hakim Employment Agreement, dated September 13, 2023 incorporated by reference to Exhibit 10.24 to the Annual Report of Form 10-K, filed with the SEC on June 30, 2025.
10.25	License Agreement, dated as of September 10, 2010, by and among Precision Dose Inc. and the Company, incorporated by reference to Exhibit 10.8 to the Quarterly Report on Form 10-Q filed with the SEC on November 15, 2010 (Confidential Treatment granted with respect to portions thereof).
14.1*	Code of Business Conduct and Ethics of Elite Pharmaceuticals, Inc.
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 Forvis Mazars LLP, Independent Registered Public Accounting Firm*
31.1*	Certification of Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a) and Rule 15d-14(a)*
31.2*	Certification of Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a) and Rule 15d-14(a)*
32.1**	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
32.2**	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

** Furnished herewith.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements 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.

6/29/2026 By: */s/ Nasrat Hakim*
Nasrat Hakim
Chief Executive Officer, President and Chairman of the Board of Directors
(Principal Executive Officer)

6/29/2026 By: */s/ Carter Ward*
Carter Ward
Chief Financial Officer
(Principal Accounting Officer and Principal Financial Officer)

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 Nasrat Hakim	Chief Executive Officer, President and Chairman of the Board of Directors (Principal Executive Officer)	June 29, 2026
/s/ Carter Ward Carter Ward	Chief Financial Officer (Principal Accounting Officer and Principal Financial Officer)	June 29, 2026
/s/ Barry Dash Barry Dash	Director	June 29, 2026
/s/ Jeffrey Whitnell Jeffrey Whitnell	Director	June 29, 2026
/s/ Davis Caskey Davis Caskey	Director	June 29, 2026

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEARS ENDED MARCH 31, 2026 AND 2025

TABLE OF CONTENTS

Report of Independent Registered Public Accounting Firm

To the Shareholders, Board of Directors, and Audit Committee

Elite Pharmaceuticals, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Elite Pharmaceuticals, Inc. (the "Company") as of March 31, 2026 and 2025, the related consolidated statements of operations, shareholders' equity, and cash flows for each of the years in the two-year period ended March 31, 2026, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of March 31, 2026 and 2025, and the results of its operations and its cash flows for each of the years in the two-year period ended March 31, 2026, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits.

We are a public accounting firm registered with the 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 include examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provides 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 a 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 a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Chargeback Reserve

As described in Note 1 to the financial statements, the Company recognizes revenue from the sale of generic pharmaceutical products under the Elite label at their net realizable value, which includes reductions for variable consideration such as chargebacks. A chargeback represents the difference between the price the wholesaler pays and the price that the wholesaler's end-customer pays for a product. The Company provides for chargebacks to wholesalers for sales to various end-customers, including hospitals, group purchasing organizations, institutions, and pharmacies. The Company's estimate for chargebacks is developed based on management's assumptions regarding anticipated product returns, other rebates, and historical information.

We identified the chargeback reserve as a critical audit matter due to the subjectivity involved in management's assumptions used to estimate the reserve, including the reliance on historical chargeback data and the variability in the wholesaler's end-customer pricing arrangements. These factors required a high degree of auditor judgment in evaluating the reasonableness of the estimate.

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

- Obtaining an understanding of management's process for developing the chargeback reserve, including the methods and assumptions used;
- Testing the completeness and accuracy of the underlying data used in the estimate, including historical chargeback activity and customer arrangements;
- Developing an independent expectation of the chargeback reserve using relevant historical chargeback data to assess the reasonableness of management's estimate;
- Assessed the relevance and reliability of the data from external sources utilized in determination of the independent expectation of the chargeback reserve.

/s/ Forvis Mazars, LLP

We have served as the Company's auditor since 2024.

Iselin, New Jersey
June 29, 2026

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS

	March 31, 2026	March 31, 2025
ASSETS		
Current assets:		
Cash	$ 29,797,800	$ 11,315,385
Accounts receivable, net of allowance for expected credit losses of $1,441,523 and $387,533 respectively	59,715,676	29,207,028
Inventory	21,259,898	16,240,376
Prepaid expenses and other current assets	1,333,177	976,358
Total current assets	112,106,551	57,739,147
Property and equipment, net of accumulated depreciation of $18,100,243 and $17,028,700 respectively	10,181,328	10,327,245
Intangible assets	4,790,790	5,637,802
Finance lease - right-of-use asset, net of accumulated amortization of $984,801 and $508,470, respectively	1,295,163	1,771,494
Operating lease - right-of-use asset	1,529,468	2,000,284
Deferred income tax asset	7,823,039	18,365,748
Other assets:		
Restricted cash - debt service for NJEDA bonds	471,520	453,776
Security deposits	91,981	91,981
Total other assets	563,501	545,757
Total assets	**$ 138,289,840**	**$ 96,387,477**
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 6,053,444	$ 2,957,584
Accrued expenses	10,194,222	3,795,227
Deferred revenue	—	5,556
Bonds payable, current portion, net of bond issuance costs	135,822	125,822
Loans payable, current portion	92,774	120,744
Related party loans payable (Note 8)	—	4,000,000
Lease obligation - finance lease, current portion	378,775	363,112
Lease obligation - operating lease, current portion	536,427	472,390
Total current liabilities	17,391,464	11,840,435
Long-term liabilities:		
Bonds payable, net of current portion and bond issuance costs	651,559	787,381
Loans payable, net of current portion and loan costs	2,152,969	2,245,743
Lease obligation - finance lease, net of current portion	851,640	1,247,621
Lease obligation - operating lease, net of current portion	1,015,647	1,552,075
Derivative financial instruments - warrants	17,343,586	25,199,193
Total long-term liabilities	22,015,401	31,032,013
Total liabilities	**39,406,865**	**42,872,448**
Commitments and Contingencies (Note 9)		
Shareholders' equity:		

Common Stock; par value $0.001; 1,445,000,000 shares authorized; 1,077,196,442 and 1,068,463,108 shares issued as of March 31, 2026 and March 31, 2025, respectively; 1,077,096,442 and 1,068,363,108 shares outstanding as of March 31, 2026 and March 31, 2025, respectively	1,077,200	1,068,467
Additional paid-in capital	173,943,856	173,457,329
Treasury stock; 100,000 shares as of both March 31, 2026 and March 31, 2025, at cost	(306,841)	(306,841)
Accumulated deficit	(75,831,240)	(120,703,926)
Total shareholders' equity	**98,882,975**	**53,515,029**
Total liabilities and shareholders' equity	**$ 138,289,840**	**$ 96,387,477**

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Years Ended March 31,	
	2026	**2025**
Revenue:		
Manufacturing fees	$ 147,810,122	$ 81,986,079
Licensing fees	1,059,997	2,057,850
Total revenue	148,870,119	84,043,929
Cost of manufacturing	73,845,784	43,957,274
Gross profit	75,024,335	40,086,655
Operating expenses:		
Research and development	5,742,955	7,964,837
General and administrative	17,596,803	9,001,930
Non-cash compensation through issuance of stock options	176,507	227,565
Impairment of intangible assets	847,012	1,603,426
Depreciation and amortization	1,547,874	1,688,429
Total operating expenses	25,911,151	20,486,187
Income from operations	49,113,184	19,600,468
Other income (expense):		
Change in fair value of derivative financial instruments - warrants	7,855,607	(18,901,185)
Interest expense and amortization of debt issuance costs	(396,664)	(772,367)
Interest income	207,857	20,944
Other income	34,500	—
Other income (expense), net	7,701,300	(19,652,608)
Income (loss) before income taxes	56,814,484	(52,140)
Income tax expense	(11,941,798)	(4,262,519)
Net income (loss)	$ 44,872,686	$ (4,314,659)
Basic net income (loss) per share	$ 0.04	$ (0.00)
Diluted net income (loss) per share	$ 0.03	$ (0.00)
Basic weighted average common stock outstanding	1,072,837,856	1,068,290,368
Diluted weighted average common stock outstanding	1,138,368,235	1,068,290,368

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

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

	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, 2024	—	$ —	1,068,373,108	$ 1,068,377	$ 173,210,549	100,000	$ (306,841)	$ (116,389,267)	$ 57,582,818
Net loss	—	—	—	—	—	—	—	(4,314,659)	(4,314,659)
Non-cash compensation through the issuance of employee stock options	—	—	—	—	227,565	—	—	—	227,565
Shares issued in payment of consultants	—	—	90,000	90	19,215	—	—	—	19,305
Balance as of March 31, 2025	—	$ —	1,068,463,108	$ 1,068,467	$ 173,457,329	100,000	$ (306,841)	$ (120,703,926)	$ 53,515,029
Net income	—	—	—	—	—	—	—	44,872,686	44,872,686
Non-cash compensation through the issuance of employee stock options	—	—	—	—	176,507	—	—	—	176,507
Shares issued pursuant to exercise of employee stock options	—	—	8,733,334	8,733	310,020	—	—	—	318,753
Balance as of March 31, 2026	—	$ —	1,077,196,442	$ 1,077,200	$ 173,943,856	100,000	$ (306,841)	$ (75,831,240)	$ 98,882,975

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

	For the Years Ended March 31,	
	2026	2025
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$ 44,872,686	$ (4,314,659)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	1,071,543	1,226,399
Provision for losses on accounts receivable	1,053,990	151,258
Impairment of intangible assets	847,012	1,603,426
Amortization of operating leases - right-of-use assets	470,816	433,914
Amortization of finance leases - right-of-use assets	476,331	462,030
Amortization of debt discount - bonds offering costs	14,178	14,178
Loss on asset disposal	—	121,481
Change in fair value of derivative financial instruments - warrants	(7,855,607)	18,901,185
Deferred tax expense	10,542,709	3,795,147
Non-cash compensation through the issuance of employee stock options	176,507	227,565
Change in operating assets and liabilities:		
Accounts receivable	(31,562,638)	(9,904,985)
Inventory	(5,019,522)	(3,309,912)
Prepaid expenses and other current assets	(356,819)	(253,739)
Security deposits	—	2,259
Accounts payable	3,095,860	243,278
Accrued expenses	6,398,995	(1,506,520)
Deferred revenue	(5,556)	(13,333)
Lease obligations - operating leases	(472,391)	(423,333)
Net cash provided by operating activities	23,748,094	7,455,639
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(925,626)	(1,625,082)
Purchase of intangible assets	—	(900,000)
Proceeds from disposition of property and equipment	—	125,250
Net cash used in investing activities	(925,626)	(2,399,832)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payment of bond principal	(140,000)	(130,000)
Payments of related party loans payable	(4,000,000)	—
Payments on principal on finance lease obligations	(380,318)	(336,189)
Proceeds from exercise of stock options	318,753	19,305
Loan payments	(120,744)	(378,856)
Net cash used in financing activities	(4,322,309)	(825,740)
Net change in cash and restricted cash	18,500,159	4,230,067
Cash and restricted cash, beginning of period	11,769,161	7,539,094
Cash and restricted cash, end of period	$ 30,269,320	$ 11,769,161
Supplemental disclosure of cash and non-cash transactions:		
Cash paid for interest	$ 246,118	$ 672,409
Cash paid for income taxes	$ 1,150,785	$ 612,085
Finance directors and officers insurance premium	$ —	$ 198,457
Recognition of finance lease right of use asset and lease liabilities entered into	$ —	$ 153,870
Recognition of operating lease right of use asset and lease liabilities entered into	$ —	$ 78,997
Reconciliation of cash and restricted cash		
Cash	$ 29,797,800	$ 11,315,385
Restricted cash - debt service for NJEDA bonds	471,520	453,776
Total cash and restricted cash shown in statement of cash flows	$ 30,269,320	$ 11,769,161

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

NOTE 1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Overview

Elite Pharmaceuticals, Inc. (the "Company" or "Elite") was incorporated on October 1, 1997 under the laws of the State of Delaware, and its wholly-owned subsidiary Elite Laboratories, Inc. ("Elite Labs") was incorporated on August 23, 1990 under the laws of the State of Delaware. On January 5, 2012, Elite Pharmaceuticals was reincorporated under the laws of the State of Nevada. Elite Labs engages primarily in researching, developing, licensing, manufacturing, and sales 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 product candidates 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 product

candidates that will secure marketing approvals from the United States Food and Drug Administration ("FDA"), and thereafter, commercially exploiting such products.

Basis of Presentation

The accompanying audited consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP") and pursuant to the rules and regulations of the SEC. 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. The preparation of financial statements in accordance with GAAP requires management to make certain estimates and assumptions affecting amounts reported in the Company's consolidated financial statements.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make certain estimates and assumptions. These estimates and assumptions affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as reported amounts of revenues and expenses during the reporting period. Such management estimates and assumptions include, but are not limited to, chargeback liabilities related to revenue recognition, valuation of intangible assets, the useful life of property and equipment and identifiable intangible assets, stock-based compensation expense, and income taxes. The Company continuously evaluates its estimates, which are based on the information that is currently available to the Company and on various other assumptions that it believes to be reasonable under the circumstances. Actual results could differ from those estimates.

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 ("CODM"), or decision-making group, in deciding how to allocate resources and in assessing performance.

The Company's CODM 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 previously determined that its reportable segments were products whose marketing approvals were secured via an Abbreviated New Drug Application ("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. The Company identifies 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. The Company has paused further development of NDAs and has not engaged in business activities for several years, and does not intend to engage in business activities related to the development of NDAs for the foreseeable future. Therefore, as of March 31, 2026, the Company has determined that it operates in a single operating and reportable segment.

Asset information by operating segment is not presented below since the chief operating decision maker does not review this information by segment. The ANDA segment follows the same accounting policies used in the preparation of the Company's consolidated financial statements. Please see Note 14 for further details.

Revenue Recognition

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

Nature of goods and services

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

a) Manufacturing Fees

The Company is equipped to manufacture controlled-release products on a contract basis for third parties, if, and when, the products are approved. These products include products using controlled-release drug technology. 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 manufacturing fees related to revenue generated from wholesale customers and from direct sale customers. Wholesalers represent customers that purchase the Company's products and sell them to end customers such as hospitals, group purchasing organizations, institutions, and pharmacies. Direct sales customers purchase products directly from the Company.

The Company provides for chargebacks to wholesalers for sales to various end-customers to include, but not limited to, hospitals, group purchasing organizations, and pharmacies. Chargebacks represent the difference between the price the wholesaler pays and the price that the end-customer pays for a product. The Company's estimate for chargebacks is developed based upon management's assumption of anticipated claims as well as historical information. Chargebacks represent variable consideration within the Company's contracts and therefore as such, revenue recognized is limited to the amount for which a significant reversal of revenue related to this variable consideration is not probable.

The Company recognizes revenue when the customer obtains control of the Company's product based on the contractual shipping terms of the contract, at which time the performance obligation is deemed to be completed. The Company is primarily responsible for ensuring that the product is produced in accordance with the related supply

agreement, and fulfilling the promise to deliver the product and bearing the risk of loss while the inventory is in-transit to the purchaser or commercial partner. Revenue is measured as the amount of consideration the Company expects to receive from the sale of its products, including Elite-labeled pharmaceutical products, and is recorded at net realizable value which consists of gross amounts invoiced reduced by contractual reductions, including, without limitation, chargebacks, discounts and program rebates, as applicable.

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.

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, 2026.

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

Disaggregation of revenue

In the following table, revenue is disaggregated by type of revenue generated by the Company. The Company recognizes revenue at a point in time for all performance obligations. During the fiscal years ended March 31, 2026 and 2025, the Company has paused further development of NDAs and has not engaged in business activities in that segment. Accordingly during the fiscal years ended March 31, 2026 and 2025, the Company has only engaged in business activities in a single operating segment.

Selected information on reportable segments and the reconciliation of operating income by segment to income from operation and to income (loss) before income taxes are disclosed within Note 14.

The Company disaggregates manufacturing fees revenue by sales channel, consisting of revenues from direct and indirect wholesalers, which have different cash flows and contract economics as margins generated differ between direct and indirect revenues. Additionally, although the underlying arrangements are substantially similar, pricing to direct wholesalers yields higher margins than pricing to indirect wholesalers, while the timing and uncertainty of cash flows do not differ materially. The following table summarizes manufacturing fees by sales channel for the fiscal years ended March 31, 2026 and 2025:

	For the Years Ended March 31,	
	2026	2025
Direct sales to Wholesalers	$ 65,273,763	$ 48,008,986
Indirect sales to Wholesalers	82,536,359	33,977,093
Total Manufacturing Fees	$ 147,810,122	$ 81,986,079

The Company's revenue-generating products consist of two categories: (i) products containing an active ingredient listed by the United States Drug Enforcement Agency as a scheduled substance under the Controlled Substances Act of 1970 ("Scheduled Products") and (ii) products not containing such a scheduled active ingredient ("Unscheduled Products"). The following table summarizes the breakdown of revenues by product category for the fiscal years ended March 31, 2026 and 2025:

	For the Years Ended March 31,	
	2026	2025
Scheduled Products – Manufacturing Fees	$ 141,465,975	$ 74,756,506
Scheduled Products – Licensing Fees	465,511	248,789
Unscheduled Products – Manufacturing Fees	6,344,147	7,229,573
Unscheduled Products – Licensing Fees	594,486	1,809,061
Total Revenue	$ 148,870,119	$ 84,043,929

Cash

Cash consists of cash on deposit with banks and money market instruments. The Company places its cash 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, 2026 and 2025, the Company had $471,520 and $453,776, of restricted cash, respectively, related to debt service reserve in regard to the New Jersey Economic Development Authority ("NJEDA") bonds (see Note 6).

Accounts Receivable and Allowance for Expected Credit Losses

Accounts receivable are comprised of balances due from customers, net of estimated allowances for expected credit losses, and other contractual deductions, including, without limitation, chargebacks, discounts and program rebates. In determining collectability, historical trends are evaluated, and specific customer issues are reviewed on a periodic basis to arrive at appropriate allowances.

The allowance for expected credit losses is based on the probability of future collection under the current expected credited loss ("CECL") impairment model under Accounting Standards Update ("ASU") 2016-13, *Financial Instruments - Credit Losses (Topic 326), Measurement of Credit Losses on Financial Assets*. Under the CECL impairment model, the Company determines its allowance by applying a loss-rate method based on an aging schedule using the Company's historical loss rate. The Company also considers reasonable and supportable current information in determining its estimated loss rates, such as external forecasts, macroeconomic trends or other factors including customers' credit risk and historical loss experience. The adequacy of the allowance is evaluated on a regular basis. Account balances are written off after all means of collection are exhausted and the balance is deemed uncollectible. Subsequent recoveries are credited to the allowance. Changes in the allowance are recorded as adjustments to credit losses in the period incurred.

The Company's quantitative allowance for credit loss estimates under CECL was determined using the loss rate method, which is impacted by certain forecasted economic factors. In addition to the Company's quantitative allowance for credit losses, the Company also incorporates qualitative adjustments that may relate to unique risks, changes in current economic conditions that may not be reflected in quantitatively derived results, or other relevant factors to further inform the Company's estimate of the allowance for credit losses.

Additionally, due to the expansion of the time horizon over which the Company is required to estimate future credit losses, the Company may experience increased volatility in its future provisions for credit losses. Factors that could contribute to such volatility include, but are not limited to, changes in the composition and credit quality of customer base, economic conditions and forecasts, the allowance for credit loss models that are used, the data that is included in the models, the associated qualitative allowance framework, and the Company's estimation techniques.

During the fiscal years ended March 31, 2026 and 2025, the Company incurred bad debt expenses of $1,053,990 and $151,258, respectively. As of March 31, 2026 and 2025, the Company's allowance for credit losses was $1,441,523 and $387,533, respectively.

Inventory

Inventory is recorded at the lower of cost or net realizable value 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. 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 expenses as incurred.

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, 2026, a summary of the tax years that remain subject to examination in the Company's major tax jurisdictions are: United States – Federal, 2022 and forward, and State, 2021 and forward. The Company did not have any unrecognized tax positions for the years ended March 31, 2026 and 2025.

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. The Company accounts for forfeitures as they occur.

Earnings (Loss) Per Share

The Company follows ASC 260, *Earnings Per Share*, which requires presentation of basic and diluted income (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 income (loss) per share is computed by dividing net income (loss) by the weighted average number of shares of Common Stock outstanding during the period. The computation of diluted net income (loss) per share includes the assumed exercise of options and warrants if the effect is dilutive. The assumed exercise of the Series J Warrants was dilutive for the year ended March 31, 2026, and is therefore included in the diluted EPS calculation for that period.

As the Company was in a net loss position for the year ended March 31, 2025, the potential dilution from the Series J Warrants converting into 79,008,661 shares of Common Stock and the stock options being exercised for 15,640,000 shares of Common Stock for these periods have been excluded from the number of shares used in calculating diluted net income (loss) per share as their inclusion would have been antidilutive.

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

	For the Years Ended March 31,	
	2026	**2025**
Numerator		
Net income (loss) - basic	$ 44,872,686	$ (4,314,659)
Effect of dilutive instrument on net income - warrants	(7,855,607)	—
Net income (loss) - diluted	$ 37,017,079	$ (4,314,659)
Denominator		
Weighted average shares of Common Stock outstanding - basic	1,072,837,856	1,068,290,368
Dilutive effect of stock options and convertible securities	65,530,379	—
Weighted average shares of Common Stock outstanding - diluted	1,138,368,235	1,068,290,368
Net income (loss) per share		
Basic	$ 0.04	$ (0.00)
Diluted	$ 0.03	$ (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.

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, and related party loans payable 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.

See Note 4 for additional information for the impairment loss recorded in relation to the Company's intangible assets.

Treasury Stock

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

Right-of-Use Asset and Lease Liability

The Company accounts for leases in accordance with ASC 842, *Leases (Topic 842)* ("ASC 842").

A lessee should recognize the lease liability to make lease payments and the right-of-use asset representing its right to use the underlying asset for the lease term. For operating leases and finance leases, a right-of-use asset and a lease liability are initially measured at the present value of the lease payments by discount rates. The Company's lease discount rates are generally based on its incremental borrowing rate, as the discount rates implicit in the Company's leases is readily determinable. Operating leases are included in operating lease right-of-use assets and lease liabilities in the consolidated balance sheets. Finance leases are included in property and equipment and lease liability in the Company's consolidated balance sheets. Lease expense for operating expense payments is recognized on a straight-line basis over the lease term. Interest and amortization expenses are recognized for finance leases on a straight-line basis over the lease term.

For the leases with a term of twelve months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. If a lessee makes this election, it should recognize lease expense for such leases generally on a straight-line basis over the lease term.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* , which requires public entities, on an annual basis, to provide disclosure of specific categories in the rate reconciliation, as well as disclosure of income taxes paid disaggregated by jurisdiction. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company adopted ASU 2023-09 for the year ended March 31, 2026, and applied the new disclosure requirements prospectively to the current annual period. Prior period disclosures have not been adjusted to reflect the new disclosure requirements. See Note 16 Income Taxes in the accompanying notes to the consolidated financial statements for further detail.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses.* In January 2025, the FASB issued ASU No. 2025-01, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40), Clarifying the Effective Date* ("ASU-2024-03"). ASU 2024-03 requires public companies to disclose, in interim and reporting periods, additional information about certain expenses in the financial statements. ASU 2024-03, as clarified by ASU 2025-01, is effective for public entities for annual periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted and is effective on either a prospective basis or retrospective basis. The Company is currently evaluating the impact that the updated standard will have on the Company's disclosures within the consolidated financial statements.

In May 2025, the FASB issued ASU 2025-04, *Compensation-Stock Compensation (Topic 718) and Revenue from Contracts with Customers (Topic 606): Clarifications to Share-Based Consideration Payable to a Customer* to reduce diversity in practice and improve the decision usefulness and operability of the guidance for share-based consideration payable to a customer in conjunction with selling goods or services. The ASU is effective for fiscal years beginning after December 15, 2026 with updates to be applied on a retrospective or modified retrospective basis. Early adoption is permitted. The Company is evaluating the impact that this standard will have on the Company's consolidated financial statements.

In July 2025, the FASB issued ASU 2025-05, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets*. The ASU introduces a practical expedient and an accounting policy election to simplify the estimation of expected credit losses for current accounts receivable and current contract assets arising from transactions accounted for under ASC 606. The practical expedient allows entities to assume that conditions at the balance sheet date remain unchanged for the asset's remaining life when preparing forecasts as part of estimating expected credit losses. The ASU is effective for fiscal years beginning after December 15, 2025, and is to be adopted on a prospective basis. Early adoption is permitted. The Company is currently evaluating the impact of this standard on its consolidated financial statements.

In December 2025, the FASB issued ASU 2025-11, *Interim Reporting (Topic 270)—Narrow-Scope Improvements*. The ASU clarifies the scope of interim reporting guidance, reorganizes disclosure requirements for ease of navigation, and introduces a principle requiring disclosure of material events occurring after the last annual reporting period but before interim financial statements are issued. The ASU does not create new disclosure requirements but improves clarity and consistency in presentation. The ASU is effective for interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact this standard will have on the Company's consolidated financial statements.

Management has evaluated recently issued accounting pronouncements outside of those mentioned above and does not believe that any of these pronouncements will have a significant impact on the Company's consolidated financial statements and related disclosures.

NOTE 2. INVENTORY

Inventory consisted of the following:

	March 31, 2026	March 31, 2025
Finished goods	$ 5,389,291	$ 4,816,458
Work-in-progress	3,267,705	1,422,005
Raw materials	12,602,902	10,001,913

Inventory	$ 21,259,898	$ 16,240,376

NOTE 3. PROPERTY AND EQUIPMENT, NET

Property and equipment consisted of the following:

	March 31, 2026	March 31, 2025
Land, building and improvements	$ 11,649,918	$ 11,649,918
Laboratory, manufacturing, warehouse and transportation equipment	15,701,634	14,776,008
Office equipment and software	373,601	373,601
Furniture and fixtures	556,418	556,418
Property and equipment, gross	28,281,571	27,355,945
Less: Accumulated depreciation	(18,100,243)	(17,028,700)
Property and equipment, net	$ 10,181,328	$ 10,327,245

Depreciation expense was $1,071,543 and $1,226,399 for the years ended March 31, 2026 and 2025, respectively.

NOTE 4. INTANGIBLE ASSETS

The following table summarizes the Company's intangible assets as of and for the periods ended March 31, 2026 and 2025:

		March 31, 2026				
	Estimated Useful Life	Gross Carrying Amount	Additions	Impairment losses	Accumulated Amortization	Net Book Value
Patent application costs	*	$ 289,039	$ —	$ (289,039)	$ —	$ —
ANDA acquisition costs	Indefinite	5,348,763		(557,973)	—	4,790,790
		$ 5,637,802	$ —	$ (847,012)	$ —	$ 4,790,790

		March 31, 2025				
	Estimated Useful Life	Gross Carrying Amount	Additions	Impairment losses	Accumulated Amortization	Net Book Value
Patent application costs	*	$ 289,039	$ —	$ —	$ —	$ 289,039
ANDA acquisition costs	Indefinite	6,052,189	900,000	(1,603,426)	—	5,348,763
		$ 6,341,228	$ 900,000	$ (1,603,426)	$ —	$ 5,637,802

On June 17, 2024, the Company and Nostrum Laboratories Inc. ("Nostrum") entered into an Asset Purchase Agreement (the "Asset Purchase Agreement"), pursuant to which Nostrum was obligated to (i) sell to the Company all of its rights in and to the approved abbreviated new drug applications (ANDAs) for generic Norco® (Hydrocodone Bitartrate and Acetaminophen tablets, USP CII), generic Percocet® (Oxycodone Hydrochloride and Acetaminophen, USP CII), and generic Dolophine® (Methadone Hydrochloride tablets), each a "Product", and (ii) grant to the Company a royalty-free, non-exclusive perpetual license to use the manufacturing technology, proprietary information, processes, techniques, protocols, methods, know-how, and improvements necessary or used to manufacture each Product in accordance with the applicable ANDA, in exchange for $900,000 in cash (the "Transaction"). The Asset Purchase Agreement includes customary representations and warranties and various customary covenants. The closing of the Transaction occurred on June 21, 2024.

During the year ended March 31, 2026, the Company determined indicators of impairment occurred related to the Loxapine intangible asset, an ANDA product, and recorded impairment expense of $557,973. Additionally, the patent related to the Company's abuse deterrent opioid technology expired during the year ended March 31, 2026, before marketing authorization was obtained from the FDA, and as such the Company impaired this intangible asset in full in the amount of $289,039.

During the year ended March 31, 2025, the Company determined indicators of impairment occurred related to the Dantrolene and Phentermine intangible assets, both ANDA products, and recorded impairment expense of $1,603,426.

* Patent application costs were incurred in relation to the Company's abuse deterrent opioid technology. Amortization of the patent costs would have begun upon the issuance of marketing authorization by the FDA. During the year ended March 31, 2026, these costs were impaired in full as discussed above.

NOTE 5. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	March 31, 2026	March 31, 2025
Co-development profit split	$ 2,616,950	$ 2,617,210
Income tax	594,181	340,614
Employee bonuses	5,285,256	121,885
Audit fees	500,000	75,000
Legal and professional expense	282,672	55,000
Director dues	22,500	22,500
Salaries and fees payable	273,059	172,655
Accrued interest - related parties	—	100,000
Other accrued expenses	619,604	290,363
Total accrued expenses	$ 10,194,222	$ 3,795,227

NOTE 6. NJEDA BONDS

During August 2005, the Company refinanced a prior 1999 bond issue occurring in 1999 through the issuance of Series A and B Notes new tax-exempt bonds (the "NJEDA 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. During July 2014, the Company retired all the 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 fund. The debt service reserve is classified as restricted cash on the accompanying consolidated balance sheets. The NJEDA Bonds require the Company to make an annual principal payment on September 1st based on the amount specified in the loan documents and semi-annual interest payments on March 1st and September 1st, equal to interest due on the outstanding principal. The annual interest rate on the Series A Note is 6.5%. The NJEDA Bonds are collateralized by a first lien on the Company's facility and equipment acquired with the proceeds of the original and refinanced bonds. The bonds mature on September 1, 2030.

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

	March 31, 2026	March 31, 2025
Gross bonds payable		
NJEDA Bonds - Series A Notes	$ 850,000	$ 990,000
Less: Current portion of bonds payable (prior to deduction of bond offering costs)	(150,000)	(140,000)
Long-term portion of bonds payable (prior to deduction of bond offering costs)	$ 700,000	$ 850,000
Bond offering costs	$ 354,454	$ 354,454
Less: Accumulated amortization	(291,835)	(277,657)
Bond offering costs, net	$ 62,619	$ 76,797
Current portion of bonds payable - net of bond offering costs		
Current portions of bonds payable	$ 150,000	$ 140,000
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	$ 135,822	$ 125,822
Long term portion of bonds payable - net of bond offering costs		
Long term portion of bonds payable	$ 700,000	$ 850,000
Less: Bond offering costs to be amortized subsequent to the next 12 months	(48,441)	(62,619)
Long term portion of bonds payable, net of bond offering costs	$ 651,559	$ 787,381

Amortization expense was $14,178 and $14,178 for the years ended March 31, 2026 and 2025, respectively. Interest payable was $4,604 and $5,363 as of March 31, 2026 and 2025, respectively. Interest expense was $59,042 and $67,871 for the years ended March 31, 2026 and 2025, respectively.

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

Years ending March 31,	Amount
2027	$ 150,000
2028	160,000
2029	170,000
2030	180,000
2031	190,000
	$ 850,000

NOTE 7. LOANS PAYABLE

On July 1, 2022, the East West Bank ("EWB") provided a mortgage loan ("EWB Mortgage Loan") in the amount of $2.55 million for the purchase of the property at 135-137 Ludlow Avenue, which was formerly a lease held by the Company. The EWB Mortgage Loan matures in 10 years and bears interest at a rate of 4.75% fixed for 5 years then adjustable at the Wall Street Journal Prime Rate ("WSJP") plus 0.5% with floor rate of 4.5%. The EWB Mortgage Loan contains customary representations, warranties and covenants. These covenants include maintaining a minimum debt coverage ratio of 1.50 to 1.00 tested annually and a minimum trailing 12-month debt coverage ratio of 1.50 to 1.00. As of the date of this filing, the Company was in compliance with each financial covenant.

The Company has entered into a collateralized promissory note with individual lenders (a "Promissory Note"). As of June 2, 2023, a Promissory Note was placed with Nasrat Hakim, CEO and Chairman of the Board of Directors, for $3,000,000. Refer to Note 8 for information regarding the Promissory Note.

Loans payable consisted of the following:

	March 31, 2026	March 31, 2025
Mortgage loan payable 4.75% interest and maturing June 2032	$ 2,245,743	$ 2,334,163
Equipment and insurance financing loans payable, between 5.99% and 12.02% interest and maturing between April 2025 and October 2025	—	32,324
Less: Current portion of loans payable	(92,774)	(120,744)
Long-term portion of loans payable	$ 2,152,969	$ 2,245,743

The interest expense associated with the loans payable was $111,361 and $128,234 for the years ended March 31, 2026 and 2025, respectively.

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

Future principal balances Years ending March 31,	Amount

2027	$	92,774
2028		94,433
2029		98,447
2030		103,817
2031		109,482
Thereafter		1,746,790
Total remaining principal balance	$	2,245,743

NOTE 8. RELATED PARTY LOANS PAYABLE

The Company has entered into a collateralized promissory note with individual lenders with rates comparable to the mortgage loan, dated July 1, 2022, provided by East West Bank to the Company but with fewer covenants. These covenants include filing timely tax returns and financial statements, and an agreement not to sell, lease, or transfer a substantial portion of the Company's assets during the term of the Hakim Promissory Note. On June 2, 2023, the Company entered into a Promissory Note with Nasrat Hakim, President, Chief Executive Officer and Chairman of the Board of Directors of the Company (the "Board"), pursuant to which the Company borrowed funds in the aggregate principal amount of $3,000,000 (the "Hakim Promissory Note"). The Hakim Promissory Note had an interest rate of 9% for the first year and 10% for an optional second year and the proceeds were used for working capital and other business purposes. The original maturity date of the Hakim Promissory Note was June 2, 2024, with an optional second year extension. The second year extension was exercised pursuant to the terms of the Hakim Promissory Note. For the years ended March 31, 2026 and 2025, interest expense on the Hakim Promissory Note totaled $50,000 and $292,500, respectively, recorded on the Consolidated Statements of Operations in interest expense and amortization of debt issuance costs. On June 2, 2025, the Hakim Promissory Note was paid in full and no balance was outstanding as of this date.

On June 30, 2023, the Company entered into a collateralized promissory note with Davis Caskey (the "Caskey Promissory Note"). The Caskey Promissory Note has a principal balance of $1,000,000 and an interest rate of 9% for the first year and 10% for an optional second year. The Caskey Promissory Note is subject to the same covenants as are contained in the Hakim Promissory Note. The proceeds will be used for working capital and other business purposes. The original maturity date of the Caskey Promissory Note was June 30, 2024, with an optional second year extension. The second year extension was exercised pursuant to the terms of the Caskey Promissory Note. For the years ended March 31, 2026 and 2025, interest expense on the Caskey Promissory Note totaled $25,000 and $100,000, respectively, recorded on the Consolidated Statements of Operations in interest expense and amortization of debt issuance costs. On June 26, 2025, the Caskey Promissory Note was paid in full and no balance was outstanding as of this date.

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 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.

On August 17, 2023, Elite filed a paragraph IV certification with its ANDA to generic OxyContin® and after Elite got acceptance of the ANDA by the FDA on September 19, 2023, Elite sent the patentee and NDA holder a Notice Letter as required under the Hatch-Waxman Act. On November 14, 2023, a patent infringement suit was filed in the District Court of New Jersey by Purdue Pharma. The Parties agreed to a stipulated dismissal of the case and the judge signed the order dismissing the case on June 12, 2026.

Elite's launch of a generic OxyContin® will depend on the approval by the FDA and the outcome of various litigation involving Purdue or the expiry of the patents listed on the Orange Book.

Operating Leases

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 was for approximately 1,275 square feet of office space, with the Company taking occupancy on November 1, 2020. The Pompano Office Lease had a term of three years, ending on October 31, 2023. The Pompano Office Lease was extended for one additional year to October 31, 2024. Accordingly, the Pompano Office Lease expired at the end of the renewal term on October 31, 2024.

The Company entered into an operating lease for office space in North Bay Village, Pompano FL (the "NBV Pompano Office Lease"). The Company took occupancy on October 1, 2024. The NBV Pompano Office Lease has a term of three years, ending on September 30, 2027.

The Company entered into a lease agreement for a portion of a one-story warehouse, located at 144 Ludlow Avenue, Northvale, New Jersey (the "144 Ludlow Ave. Lease"). The lease agreement began on January 22, 2024, and has a term of five years. The 144 Ludlow Ave. Lease will expire on December 31, 2028.

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. Operating leases are included in operating lease right-of-use assets and lease liabilities in the consolidated balance sheets. Lease expense for operating expense payment is recognized on a straight-line basis over the lease term.

Finance Leases

In November 2023, the Company entered into a finance lease for equipment (the "Waters Equipment Lease"). The Waters Equipment Lease is related to lab equipment with an acquisition cost of $499,775, with the Company taking ownership of the asset on December 1, 2023. The Waters Equipment Lease has a term of five years, ending on November 29, 2028. The Company also has the option to purchase the asset at the end of the lease term for the amount of $1, which is probable to be exercised.

In February 2024, the Company entered into a finance lease for warehouse equipment (the "Warehouse Equipment Lease"). The Warehouse Equipment Lease is related to warehouse equipment with an acquisition cost of $37,500, with the Company taking ownership of the asset during February 2024. The Warehouse Equipment Lease had a term of two years, which ended in February 2026. The Company had the option to purchase the asset at the end of the lease term for the amount of $1, which the Company exercised.

In February 2024, the Company entered into a finance lease for equipment (the "February 2024 Equipment Lease"). The February 2024 Equipment Lease is related to manufacturing equipment with an acquisition cost of $455,000, with the Company taking ownership of the asset during February 2024. The February 2024 Equipment Lease has a

term of five years, ending in February 2029. The Company will retain ownership of the equipment at lease termination.

In March 2024, the Company entered into three separate finance leases for manufacturing assets (the "March 2024 Equipment Leases"). The March 2024 Equipment Leases are related to manufacturing equipment and vault installed at the Company's facility located at 144 Ludlow Avenue, Northvale NJ with an aggregate acquisition cost of $1,085,177. Each of the separate leases included in the March 2024 Equipment Leases have a term of five years, ending in March 2029. The Company will retain ownership of all related assets at lease termination.

In July 2024, the Company entered into two separate finance leases for manufacturing assets (the "July 2024 Equipment Leases"). The July 2024 Equipment Leases are related to warehouse and laboratory equipment with an aggregate acquisition cost of $153,745. One of the July 2024 Equipment Leases has a term of five years, ending in July 2029, and the other lease has a term of two years, ending in July 2026. The Company will retain ownership of all related assets at lease terminations.

A lease is classified as a finance lease if any of the following criteria are met: (i) ownership of the underlying asset transfers to the Company by the end of the lease term; (ii) the lease contains an option to purchase the underlying asset that the Company is reasonably expected to exercise; (iii) the lease term is for a major part of the remaining economic life of the underlying asset; (iv) the present value of the sum of lease payments and any residual value guaranteed by the Company equals or exceeds substantially all of the fair value of the underlying asset; or (v) the underlying asset is of a specialized nature that it is expected to have no alternative use to the lessor at the end of the lease term. A lease that does not meet any of the criteria to be classified as a finance lease is classified as an operating lease. As the Company expects to exercise the option to purchase the asset at the end of the lease term, the Waters equipment lease was determined to be a finance lease. The finance lease is included on the consolidated balance sheets as Finance lease - right-of-use asset and Lease obligation - finance lease. The finance lease costs are split between Depreciation and amortization expense related to the asset and interest expense on the lease liability, using the effective rate charged by the lessor. The Company has elected to account for lease and non-lease components separately.

Rent expense is recorded on the straight-line basis and is recorded in cost of manufacturing and general and administrative expense in the consolidated statements of operations. Rent expense is as follows:

	For the Years Ended March 31,	
Lease	**2026**	**2025**
Ludlow-144	$ 633,269	$ 610,409
Pompano-2311	—	18,870
NBV-610	18,249	14,605

The table below shows the future minimum rental payments, exclusive of taxes, insurance and other costs:

Years ending March 31,	**Operating Lease Amount**	**Financing Lease Amount**	**Total**
2027	667,307	484,151	1,151,458
2028	666,207	479,337	1,145,544
2029	440,159	438,045	878,204
2030	—	13,740	13,740
Less: interest	(221,599)	(184,858)	(406,457)
Present value of lease payments	$ 1,552,074	$ 1,230,415	$ 2,782,489

The weighted-average remaining lease term and the weighted-average discount rate of the Company's leases were as follows:

	For the Years Ended March 31,	
Lease Term and Discount Rate	**2026**	**2025**
Remaining lease term (years)		
Operating leases	2.6	3.6
Finance leases	2.9	3.8
Discount rate		
Operating leases	10.0%	10.0%
Finance leases	9.5%	9.5%

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. 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.

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.

The Company has 79,008,661 total warrants to purchase shares of Common Stock outstanding with a weighted average exercise price of $0.1521 as of March 31, 2026 and 2025.

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, including a provision within that provides the holder a choice of net cash settlement or settlement in shares upon a cashless exercise. The net cash settlement amount is the cash value obtained by subtracting the then exercise price from the closing price of the Company's Common Stock (provided such closing price is higher than the exercise price) and multiplying the difference by the number of shares exercised. As this event is at the holder's option, it is considered outside of the Company's control. As a result of the net cash settlement at the option of the holder, such warrants are classified as liabilities and measured initially and subsequently at fair value.

The exercise price is subject to adjustment for any issuances or deemed issuances of Common Stock or Common Stock equivalents at an effective price below the then exercise price. The Series J Warrants also provide for other standard adjustments upon the happening of certain customary events.

The fair value of the Series J Warrants was calculated using a Black-Scholes model. The following assumptions were used in the Black-Scholes model to calculate the fair value of the Series J Warrants:

	March 31, 2026	March 31, 2025
Fair value of the Company's Common Stock	$ 0.3601	$ 0.4350
Volatility	63.96%	82.80%
Initial exercise price	$ 0.1521	$ 0.1521
Warrant term (in years)	1.1	2.1
Risk free rate	3.47%	3.89%

The changes in warrants (Level 3 financial instruments) measured at fair value on a recurring basis were as follows:

Balance at March 31, 2024	$ 6,298,008
Change in fair value of derivative financial instruments - warrants	18,901,185
Balance at March 31, 2025	$ 25,199,193
Change in fair value of derivative financial instruments - warrants	(7,855,607)
Balance at March 31, 2026	$ 17,343,586

Measured on a Recurring Basis

The following table presents information about the Company's 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	Level 1	Level 2	Level 3
Balance as of March 31, 2025	$ 25,199,193	$ —	$ —	$ 25,199,193
Change in fair value of derivative financial instruments - warrants	(7,855,607)	—	—	(7,855,607)
Balance as of March 31, 2026	$ 17,343,586	$ —	$ —	$ 17,343,586

	Amount at Fair Value	Level 1	Level 2	Level 3
Balance as of March 31, 2024	$ 6,298,008	$ —	$ —	$ 6,298,008
Change in fair value of derivative financial instruments - warrants	18,901,185	—	—	18,901,185
Balance as of March 31, 2025	$ 25,199,193	$ —	$ —	$ 25,199,193

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

NOTE 12. STOCK-BASED COMPENSATION

Under its 2014 Equity Incentive Plan and its 2024 Equity Incentive Plan, the Company did grant and may grant stock options to officers, selected employees, as well as members of the Board of Directors and advisory board members. On July 1, 2024 the Company restated the 2014 Equity Incentive Plan to increase the shares reserved under the option plan by 12,730,000. Under the 2024 Equity Incentive Plan, 80,000,000 options are available for grant. 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.

The fair value of option awards is estimated on the date of grant using the Black-Scholes option-pricing model. The exercise price of each award is generally not less than the per share fair value in effect as of that award date. The determination of fair value using the Black-Scholes model is affected by the Company's share fair value as well as assumptions regarding a number of complex and subjective variables, including expected price volatility, risk-free interest rate and projected employee share option exercise behaviors. The Company estimates its expected volatility by using a combination of historical share price volatilities of similar companies within the Company's industry. The expected term of the Company's stock options for employees has been determined utilizing the "simplified" method for awards, since the Company does not have sufficient exercise history to estimate term of its historical option awards. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve. Expected dividend yield is zero based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

A summary of the activity of Company's 2024 Equity Incentive plan and prior equity incentive plans for the year ended March 31, 2026 is as follows:

	Shares Underlying Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at March 31, 2025	15,640,000	$ 0.05	7.8	$ 6,000,552
Granted	—	—	—	$ —
Exercised	(8,733,334)	0.04	—	$ —
Expired and Forfeited	—	—	—	$ —
Outstanding at March 31, 2026	6,906,666	$ 0.07	6.8	$ 2,002,996
Exercisable at March 31, 2026	5,440,000	$ 0.06	6.6	$ 1,610,856

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, 2026 of $0.36 for those awards with strike prices lower than the quoted price of the Company's Common Stock as of March 31, 2026. As of March 31, 2026, there was $51,659 in unrecognized stock based compensation expense that will be recognized over a weighted average 0.49 year period.

The total intrinsic value of options exercised during the year ended March 31, 2026 was $2,826,120.

NOTE 13. CONCENTRATIONS AND CREDIT RISK

Revenues

Two customers accounted for approximately 74% of the Company's revenues for the year ended March 31, 2026. These two customers accounted for approximately 64% and 10% of revenues each, respectively.

Two customers accounted for approximately 58% of the Company's revenues for the year ended March 31, 2025. These two customers accounted for approximately 39% and 19% of revenue each, respectively.

Accounts Receivable

One customer accounted for approximately 69% of the Company's accounts receivable as of March 31, 2026.

Three customers accounted for approximately 75% of the Company's accounts receivable as of March 31, 2025. These three customers accounted for approximately 46%, 19%, and 10% of accounts receivable each, respectively.

Purchasing

Three suppliers accounted for approximately 73% of the Company's purchases of raw materials for the year ended March 31, 2026. These three customers accounted for approximately 36%, 24%, and 13% of purchasing each, respectively.

Three suppliers accounted for approximately 69% of the Company's purchases of raw materials for the year ended March 31, 2025. These three customers accounted for approximately 43%, 13%, and 13%, of purchasing each, respectively.

NOTE 14. 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.

Consolidated income from operations, which is reported in the accompanying consolidated statements of operations, is the measure of segment profit or loss that is regularly reviewed by the CODM. This enables the CODM to assess the overall level of available resources and determine how best to deploy these resources across research and development projects in line with the long-term company-wide strategic goals. There are no significant segment expenses or other segment items that are separately provided to the CODM beyond research and development and general and administrative expenses. The CODM does not receive segment level information related to depreciation, amortization, capital expenditures, or other non-cash items, and therefore such items are excluded. The ANDA segment follows the same accounting policies used in the preparation of the Company's consolidated financial statements.

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

	For the Years Ended March 31,	
	2026	**2025**
Operating Income by Segment		
ANDA	$ 69,281,380	$ 32,121,818
Operating income by Segment	$ 69,281,380	$ 32,121,818

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

	For the Years Ended March 31,	
	2026	**2025**
Operating income by segment	$ 69,281,380	$ 32,121,818
Corporate unallocated costs	(17,596,803)	(9,001,930)
Impairment of intangible assets	(847,012)	(1,603,426)
Depreciation and amortization expense	(1,547,874)	(1,688,429)
Significant non-cash items	(176,507)	(227,565)
Income from operations	**49,113,184**	**19,600,468**
Change in fair value of derivative instruments	7,855,607	(18,901,185)
Interest expense and amortization of debt issuance costs	(396,664)	(772,367)
Interest income	207,857	20,944
Other income	34,500	—
Income (loss) before income taxes	**$ 56,814,484**	**$ (52,140)**

NOTE 15. RELATED PARTY AGREEMENTS

Mikah Pharma, LLC Agreements

In May 2020, Praxgen (formerly known as SunGen Pharma LLC), pursuant to an asset purchase agreement, assigned its rights and obligations under the Praxgen Agreement for Amphetamine IR and Amphetamine ER to Mikah Pharma LLC ("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. Mikah 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, pursuant to which Mikah will engage in the research, development, sales and licensing of generic pharmaceutical products. In addition, Mikah 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.

As of March 31, 2026 and 2025, the Company owed an aggregate of $2,616,950 and $2,617,210, respectively, to Mikah in accordance with the agreements, with such amounts being recorded as an accrued expense on the consolidated balance sheets.

NOTE 16. INCOME TAXES

The earnings (loss) before income taxes for the years ended March 31, 2026 and 2025 were $56.8 million and $(0.1) million, respectively.

Components of the provision for income taxes were (amounts in thousands):

For the Year Ended March 31 (in thousands)	2026	2025
Current provision (benefit):		
Federal	$ —	$ —
State and local	1,399	468
Total current provision	1,399	468
Deferred provision (benefit):		
Federal	10,335	3,871
State and local	208	(76)
Total deferred provision	10,543	3,795
Provision for income taxes	$ 11,942	$ 4,263

A reconciliation between the Company's effective tax rate and the federal statutory rate for the year ended March 31, 2026 is as follows (amounts in thousands of dollars):

	2026	
	Amount	Percent
U.S. Federal Statutory Tax Rate	$ 11,682	21.00%
State and Local Income Taxes, Net of Federal Income Tax Effect (a)	1,313	2.36%
Foreign Tax Effects	—	—%
Effect of Changes in Tax Law or Rates Enacted in the Current Period	—	—%
Effect of Cross-Border Tax Laws	—	—%
Tax Credits	—	—%
Federal R&D Credits	(360)	(0.65)%
Changes in Valuation Allowance	—	—%
Nontaxable or Nondeductible Items	—	—%
Non-deductible change in fair value of derivative financial instruments	(1,650)	(2.96)%
Officer's compensation	1,143	2.05%
Other	(186)	(0.33)%
Changes in Unrecognized Tax Benefits	—	—%
Other Adjustments	—	—%
Other	—	—%
Effective Tax Rate	$ 11,942	21.47%

(a) State taxes in New Jersey and Florida made up the majority (greater than 50 percent) of the tax effect in this category.

A reconciliation between the Company's effective tax rate and the federal statutory rate for the year ended March 31, 2025 is as follows:

For the Year Ended March 31 (in thousands)	2025
Federal income tax rate	$ (11)
State and local taxes, net of federal benefit	293
Non-deductible change in fair value of derivative financial instruments	3,969
Non-deductible change in fair value of stock-based liabilities	—
Other permanent items	17
Prior year deferred true-up	110
Tax credits	(115)
Change in valuation allowance	—
Effective tax rate	$ 4,263

The major components of deferred tax assets and liabilities as of March 31, 2026 and 2025 are as follows (amounts in thousands of dollars):

As of March 31 (in thousands)	2026	2025
Deferred tax assets:		
Lease Liability	$ 659	$ 865
Sec. 174 R&E Capitalization	123	3,104
Allowance for Expected Credit Losses	352	92
Net Operating Loss	2,489	10,664
R&D Credit	5,708	5,348
Deferred tax assets	9,331	20,073
Deferred tax liabilities:		
Fixed Assets	(218)	(98)
Right of Use Asset	(669)	(898)
Intangible Assets	(621)	(711)
Deferred tax liabilities	(1,508)	(1,707)
Net deferred tax asset	$ 7,823	$ 18,366

The Company's income tax expense was $11.9 million and $4.3 million for the years ended March 31, 2026 and 2025, respectively.

As of March 31, 2026, the Company has a federal net operating loss carry forward of $11.9 million of which $10 million can be carried forward indefinitely with limitation of 80% of taxable income and the remaining $1.9 million will expire in 2037 and has no limitation. As of March 31, 2026, the Company's has a federal research credits carryforward of $5.7 million which will begin to expire in 2032. As of March 31, 2026, the Company's federal and state income taxes due were $0 and $1.4 million, respectively.

The Company's policy for recording interest and penalties associated with unrecognized tax benefits is to record such interest and penalties as a component of income tax expense. There were no amounts accrued for interest or penalties for the year ended March 31, 2026. Management does not expect any material changes in its unrecognized tax benefits in the next year.

There are currently no federal or state income tax examinations underway. The Company's federal tax returns are open to examination from 2022 and its state tax returns are open to examination from 2021.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was enacted in the United States. The OBBBA permanently extends certain provisions of the Tax Cuts and Jobs Act, modifies aspects of the international tax framework, and restores favorable tax treatment for certain business provisions, including the immediate expensing of domestic research and development expenditures. resulting in a decrease in our deferred tax assets of approximately $3.1 million, primarily due to the immediate expensing of domestic research and development expenditures.

The amounts of cash income taxes paid by the Company were as follows:

(in thousands)	March 31, 2026
Federal	$ —
State and Local:	
Florida	435
New Jersey	575
New York	108
All Other States	33
Income taxes, net of amounts refunded	$ 1,151

NOTE 17. SUBSEQUENT EVENTS

On April 2, 2026, the Company announced the commercial launch of our generic methadone hydrochloride 5 mg and 10 mg tablets. The product is marketed and sold under the Elite Labs label.

On June 1, 2026, the Company reported that it had filed an Abbreviated New Drug Application with the US Food and Drug Administration for a generic version of an undisclosed drug product in the class of medications called anticoagulants.

On June 12, 2026, pursuant to a stipulated dismissal agreed to by both parties, the District Court of New Jersey signed an order dismissing the patent infringement suit filed by Purdue Pharma against the Company in November 2023.

CODE OF BUSINESS CONDUCT AND ETHICS OF ELITE PHARMACEUTICALS, INC.

EFFECTIVE DATE: July 2009

INTRODUCTION

Elite Pharmaceuticals, Inc., a Nevada Corporation expects that directors, officers and employees will conduct themselves ethically and properly as a matter or course and comply with the guidelines set forth below.

This Code of Business Conduct and Ethics (this "Code") is prepared, in large part, due to the requirements of the Sarbanes-Oxley Act of 2002 and rules of the American Stock Exchange, NASD Stock Market and/or any exchange upon which the Company's stock may be traded and is applicable to Elite Pharmaceuticals, Inc. and all direct and indirect U.S. subsidiaries (hereinafter referred to collectively as the "Company"). Directors, officers and employees of foreign subsidiaries are also expected to act properly and consistent with country-specific guidelines developed for such subsidiaries.

This Code exists to provide the Company's directors, officers, employees, shareholders, suppliers and members of the general public with an official statement as to how the Company conducts itself internally and in the marketplace and certain standards that the Company shall require of its directors, officers and employees.

The Company's Compliance Officer on the Effective Date of this Code is Carter J. Ward and the term "Compliance Officer", as used in this Code, refers to the Company's current Compliance Officer and any subsequent person appointed to that office.

PURPOSE

This Code is intended to provide a codification of standards that is reasonably designed to deter wrongdoing and to promote the following:

- Honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;
- Full, fair, accurate, timely and understandable disclosure in reports and documents that the Company files with, or submits to, the Securities and Exchange Commission (the "SEC") and in other public communications made by the Company;
- Compliance with applicable governmental laws, rules and regulations;
- The prompt internal reporting to an appropriate person or persons identified in this Code for violations of this Code; and
- Accountability for adherence to this Code.

SCOPE

This Code applies to the Company's Chairman of the Board, Chief Executive Officer, Chief Financial Officer and persons performing similar functions as well as to all directors, officers and employees of the Company. As used herein, the term "Employees" shall be deemed to include

each of the foregoing persons unless specifically stated otherwise or unless the context clearly indicates otherwise.

POLICY PROVISIONS

Under this Code, all Employees including directors and officers (including the Company's Chairman of the Board, Chief Executive Officer, Chief Financial Officer and persons performing similar functions) are expected to conduct business for the Company in the full spirit of honest and lawful behavior and shall not cause another Employee or non-Employee to act otherwise, either through inducement or coercion.

I. Conflicts of Interest and Other Matters

Conflicts of interest may arise when an Employee's position or responsibilities with the Company present an opportunity for personal gain apart from the normal compensation provided through employment. The following guidelines are provided:

A. *Protection and Proper Use of Company Funds and Assets*

The assets of the Company are much more than its properties, facilities, equipment, corporate funds and computer systems; they include technologies and concepts, business strategies and plans, as well as information about its business. These assets may not be improperly used and/or used to provide personal benefits for an Employee. In addition, an Employee may not provide outside persons with assets of the Company for the Employee's personal gain or in such a manner as to be detrimental to the Company. An Employee should protect the Company's assets and ensure their efficient and proper use. Theft, carelessness and waste have a direct impact on the Company's profitability. All Company assets should be used for legitimate business purposes.

B. *Confidential Information*

As part of an Employee's job, he/she may have access to confidential information about the Company, its Employees, agents, contractors, customers, suppliers and competitors. Unless released to the public by management, this information should not be disclosed to fellow Employees who did not have a business need to know or to non-Employees for any reason, except in accordance with established corporate procedures. Confidential information of this sort includes, but is not limited to, information or data on operations, business strategies and growth, business relationships, processes, systems, procedures and financial information.

C. *Outside Financial Interests Influencing an Employee's Decisions or Actions*

An Employee should avoid any outside financial interest that might influence his or her decision or action on matters involving the Company or its businesses or property. Such interests include, among other things: (i) a significant personal or immediate family interest in an enterprise that has significant business relations with the Company; or (ii) an enterprise or contract with a

supplier, service-provider or any other company or entity where the Employee or a member of the immediate family of the Employee is a principal or financial beneficiary other than as an Employee. All such interests should be disclosed by the Employee to the Company's Compliance Officer or if the Employee is the Compliance Officer, to the Chairman of the Board of Directors of the Company.

D. ***Outside Activities Having Negative Impact on Job Performance***

An Employee should avoid outside employment or activities that would have a negative impact on his or her job performance with the Company, or which are likely to conflict with the Employee's job or his or her obligations to the Company.

E. ***Business Opportunities; Competitive Interests; Corporate Opportunities***

No Employee may enter into any contract or arrangement, own any interest or be a director, officer or consultant in or for an entity which enters into any contract or arrangement (except for the ownership of non-controlling interests in publicly-traded entities) with the Company for the providing of services to the Company unless and until the material facts as to the relationship or interest and the contract or transaction are fully disclosed to the Company's Compliance Officer and approved by the Board of Directors. If approved by the Board of Directors, the Company's Compliance Officer shall provide written confirmation of the approval of said contract or transaction.

Each Employee owes a duty to the Company to advance its legitimate interests when the opportunity arises to do so. The Employee should refrain from and shall be prohibited from: (i) taking for the Employee's or for Employee's personal benefit opportunities that could advance the interests of the Company or benefit the Company when such opportunities are discovered through the use of Company property, information or position; (ii) using Company property, information or position for personal gain; or (iii) competing with the Company.

II. <u>Dealing With Suppliers, Customers And Other Employees</u>

The Company obtains and keeps its business because of the quality of its operations. Conducting business, however, with another Employee, supplier or customer can pose ethical or even legal problems. The following guidelines are intended to help all Employees make the appropriate decision in potentially difficult situations.

A. ***Bribes and Kickbacks***

No Employee may ever accept or pay bribes, kickbacks or other types of unusual payments from or to any organization or individual seeking to do business with, doing business with or competing with the Company.

B. ***Gifts***

An Employee may accept gifts or entertainment of nominal value as part of the normal business process if public knowledge of the Employee's acceptance could cause the Company no

conceivable embarrassment. Even a nominal gift and/or entertainment should not be accepted if it might appear to an observer that the gift and/or entertainment would influence the Employee's business decisions. The term "nominal value" applies to the amount of the gift and/or its frequency; i.e., frequent gifts, even if of nominal value, are unacceptable. The term "entertainment" includes, but is not limited to, meals, charitable and sporting events, parties, plays and concerts. If you have any questions about the acceptance of entertainment or gifts, ask the Company's Compliance Officer or if it involves the Compliance Officer, the Chief Executive Officer for advice.

C. ***Travel and Entertainment Expenses***

An Employee must comply with the Company's policy on travel and entertainment expenses as set forth in the Company's policies and procedures, as the same may be amended or supplemented from time to time.

D. ***Relations with Government Personnel***

The Company will not offer, give or reimburse expenses for entertainment or gratuities (including transportation, meals at business meetings or tickets to sporting or other events) to government officials or to Employees who are prohibited from receiving such by applicable government regulations.

E. ***Payments to Agents, Consultants, Distributors, Contractors***

Agreements with agents, sales representatives, distributors, contractors and consultants should be in writing and should clearly and accurately set forth the services to be performed, the basis for earning the commission or fee involved and the applicable rate or fee. Payments should be reasonable in amount and not excessive in light of the practice in the trade and commensurate with the value of services rendered.

F. ***Fair Dealing***

Each Employee should endeavor to deal fairly with the Company's customers, suppliers, competitors and other Employees.

III. Books and Records

False or misleading entries shall not be made in any reports, ledgers, books or records of the Company nor shall any misrepresentation be made regarding the content thereof. No Employee may engage in an arrangement that in any way may be interpreted or construed as misstating or otherwise concealing the nature or purpose of any entries in the books and records of the Company. No payment or receipt on behalf of the Company may be approved or made with the intention or understanding that any part of the payment or receipt is to be used for a purpose other than that described in the documents supporting the transaction.

IV. Competitive Practices

As a vigorous competitor in the marketplace, the Company seeks economic knowledge about its competitors; however, it will not engage nor will any Employee cause it to engage in illegal acts to acquire a competitor's trade secrets, financial data, information about company facilities, technical developments or operations.

V. Political Activities & Contributions

The Company encourages each of its Employees to be good citizens and to participate in the political process. Employees should, however, be aware that: (1) federal law and the statutes of some states in the U.S. prohibit the Company from contributing, directly or indirectly, to political candidates, political parties or party officials; and (2) An Employee who participates in partisan political activities should ensure that the Employee does not leave the impression that the Employee speaks or act for the Company.

VI. Compliance with Laws, Rules and Regulations

The Company proactively promotes compliance by all Employees with applicable laws, rules and regulations of any governmental unit, agency or divisions thereof and the rules and regulations of the American Stock Exchange, The NASD Stock Market and/or any exchange upon which the Company's stock may be traded. The Company requires its Employees to abide by the provisions of applicable law on trading on inside information and all Employees are directed to refrain from trading in the Company's stock based on inside information. The Company requires its Employees to abide by applicable law and the Company's procedures with respect to periods of time within which all or some cross-section of the Company's Employees will be prevented from trading in the Company' stock. The Company requires each Employee to abide by applicable law and the Company's policies with respect to disclosures of material non-public information (Regulation FD).

VII. Protection of Employees from Reprisal for Whistleblowing ("Whistleblowing Policy")

A. *Purpose*

To encourage Employees to report Alleged Wrongful Conduct.

To prohibit supervisory personnel from taking Adverse Personnel Action against an Employee as a result of the Employee's good faith disclosure of Alleged Wrongful Conduct to a Designated Company Officer or Director or to the Company's Audit Committee. An Employee who discloses and subsequently suffers an adverse Personnel Action as a result is subject to the protection of this Whistleblowing Policy.

B. *Applicability*

An Employee, who discloses Alleged Wrongful Conduct, as defined in this Whistleblowing Policy, and, who, as a result of the disclosure, is subject to an Adverse Personnel Action.

C. *Whistleblowing Policy*

Each Employee is encouraged promptly to report Alleged Wrongful Conduct. No Adverse Personnel Action may be taken against an Employee in Knowing Retaliation for any lawful disclosure of information to a Designated Company Officer or Director or to the Company's Audit Committee, which information the Employee in good faith believes evidences: (i) a violation of any law; (ii) fraudulent or criminal conduct or activities; (iii) questionable accounting or auditing matters or matters; (iv) misappropriation of Company funds; or (v) violations of provisions of this Code (such matters being collectively referred to herein as "Alleged Wrongful Conduct").

No supervisor, officer, director, department head or any other Employee with authority to make or materially influence significant personnel decisions shall take or recommend an Adverse Personnel Action against an Employee in Knowing Retaliation for disclosing Alleged Wrongful Conduct to a Designated Company Officer or Director or to the Company's Audit Committee.

D. *Definitions*

In addition to other terms as defined above, the terms set forth on Exhibit A attached hereto shall have the meanings set forth thereon for purposes of this Whistleblowing Policy.

E. *Making a Disclosure*

An Employee who becomes aware of Alleged Wrongful Conduct is encouraged to make a Disclosure to a Designated Company Officer or Director or to the Company's Audit Committee as soon as possible.

F. *Legitimate Employment Action*

This Whistleblowing Policy may not be used as a defense by an Employee against whom an Adverse Personnel Action has been taken for legitimate reasons or cause. It shall not be a violation of this Whistleblowing Policy to take Adverse Personnel Action against an Employee whose conduct or performance warrants that action separate and apart from the Employee making a disclosure.

G. *Whistleblowing Statutes*

An Employee's protection under this Whistleblowing Policy is in addition to any protections such Employee may have pursuant to any applicable state or federal law and this Whistleblowing Policy shall not be construed as limiting any of such protections.

VIII. Audit Committee Procedures - Receipt, Retention and Treatment of Complaints Regarding Accounting, Internal Accounting Controls or Auditing Matters

Pursuant to the requirements of the Sarbanes-Oxley Act of 2002, the Company's Audit Committee (and in absence of an Audit Committee, the Company's Board of Directors) has established the following procedures for the receipt, retention and treatment of complaints by an Employee regarding the Company's accounting, internal accounting controls or auditing matters.

A. ***Purpose***

To promote and encourage Company Employees to report complaints, problems or questionable practices relative to accounting, internal accounting controls or auditing matters (collectively referred to herein as "Accounting Concerns").

B. ***Applicability***

All Employees.

C. ***Procedures***

Any Employee who has, knows of or has reason to know or suspect the existence of any Accounting Concern is encouraged to report such Accounting Concern, promptly and in writing, to the Company's Compliance Officer and the Audit Committee (and in the absence of the Audit Committee, the Company's Board of Directors) at the following address:

Compliance Officer
Elite Pharmaceuticals, Inc.
165 Ludlow Avenue
Northvale, NJ 06830

with a copy to:

Chairman of the Board of Directors
Elite Pharmaceuticals, Inc.
165 Ludlow Avenue
Northvale, NJ 06830

Submissions by an Employee of Accounting Concerns may be signed by the Employee or may be anonymous. Submissions by an Employee of Accounting Concerns should be sufficiently detailed so as to provide the necessary information to the Company's Audit Committee as to the nature of the Accounting Concerns, the violation or potential violation of any federal or state law or regulation or the nature of any questionable accounting or auditing practice or matter. Employees are encouraged to include as much factual data as possible in any submissions of Accounting Concerns and an Employee shall not utilize the submission of an Accounting Concern for the sole purpose of harassing another Employee. Submissions by an Employee of Accounting Concerns shall be copied by the Compliance Officer and retained in a file entitled "Accounting Concerns Report File" to be kept separate from the files of the Company's Accounting Department.

The Chairman of the Audit Committee (or in the absence of an Audit Committee, the Chairman of the Board of Directors) shall review and investigate or cause to be investigated each submission by an Employee of Accounting Concerns that suggests any violation of Company policies, violation of any federal or state laws or regulations or any questionable accounting or auditing practice or matter. The Chairman of the Audit Committee (or in the absence of an Audit Committee, the Chairman of the Board of Directors) may utilize the services of the Company's

outside legal counsel in any such investigations. In the event the Chairman of the Audit Committee (or in the absence of an Audit Committee, the Chairman of the Board of Directors) shall determine that any Accounting Concern is of sufficient veracity and significance so as to mandate any action by the Company, the Chairman of the Audit Committee (or in the absence of an Audit Committee, the Chairman of the Board of Directors) shall report the Accounting Concern to the Audit Committee and, if necessary, to the Company's Board of Directors with a recommendation as to specific action to be taken. In extreme cases where an Accounting Concern has been reported that involves a violation or potential violation of federal or state laws or regulations and the Chairman of the Audit Committee (or in the absence of an Audit Committee, the Chairman of the Board of Directors) has determined that such report is accurate or that sufficient evidence exists to create a significant concern as to whether such violation has occurred or will occur, the Chairman of the Audit Committee (or in the absence of an Audit Committee, the Chairman of the Board of Directors) may report such Accounting Concern to the appropriate government authority.

D. *Protections*

An Employee who submits reports of Accounting Concerns shall be entitled to the protection of the Whistleblowing Policy set forth above.

IX. Public Company Reporting

As a public company, it is important that the Company's filings with the SEC and other public disclosures of information be complete, fair, accurate and timely. An Employee of the Company may be called upon to provide necessary information to ensure that the Company's public reports are complete, fair and accurate. The Company expects each officer, director and other Employee to take this responsibility seriously and to provide prompt, complete, fair and accurate responses to inquiries with respect to the Company's public disclosure requirements. With respect to the officers, directors and other Employees who may be participating in the preparation of reports, information, press releases, forms or other information to be publicly disclosed through filings with the SEC or as mandated by the SEC, such officers, directors and other Employees are expected to use their diligent efforts to ensure that such reports, press releases, forms or other information are complete, fair, accurate and timely.

X. Compliance and Discipline

All Employees are required to comply with this Code. An Employee is expected to report violations of this Code and assist the Company, when necessary, in investigating violations.

Failure to comply with this Code will result in disciplinary action that may include suspension, termination, referral for criminal prosecution and/or reimbursement to the Company for any losses or damages resulting from the violation. The Company reserves the right to terminate any Employee immediately for a single violation of this Code.

An Employee may be asked from to time to reaffirm the Employee's understanding of and willingness to comply with this Code by signing an appropriate certificate (see Appendix A).

XI. Adoption, Amendment and Waiver

A. *Adoption and Amendment*

This Code has been adopted by the Company's Board of Directors and may be changed, altered or amended at any time. The interpretation of any matter with respect to this Code by the Board of Directors shall be final and binding.

B. *Waiver*

Waivers of the provisions of this Code may be granted or withheld from time to time by the Company in its sole discretion. Waivers are only effective if set forth in writing after full disclosure of the facts and circumstances surrounding the waiver. Waivers for the benefit of directors and executive officers must be approved by the Board of Directors and will be publicly disclosed by the Company. All other waivers may be approved by the Compliance Officer and may be publicly disclosed by the Company.

NO EMPLOYMENT CONTRACT

Nothing contained herein shall be construed as limiting the Company's right to terminate an Employee immediately for any reason. This Code does not provide any guarantees of continued employment, nor does it constitute an employment contract between the Company and any Employee.

APPENDIX A

EMPLOYEE STATEMENT

I acknowledge having received a copy of the Company's Code of Business Conduct and Ethics. I have read it completely and I understand that the Code applies to me. I understand the Code does not constitute an employment contract and I agree to comply fully with each of the provisions of the Code, including such changes to the Code as the Company may announce from time to time. I have reviewed with my supervisor or the Compliance Officer any matters concerning ownership or other activities which are required to be disclosed to the Company by the Code.

Employee Name _____

Employee Signature _____

Date _____

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-239847) and Form S-8 (Nos. 333-280649, 333-278317, 333-278318, 333-197694, 333-163907, 333-132140, and 333-118524) of our report dated June 29, 2026, with respect to the consolidated financial statements of Elite Pharmaceuticals, Inc., included in this Annual Report on Form 10-K for the year ended March 31, 2026.

/s/ Forvis Mazars, LLP

Iselin, New Jersey
June 29, 2026

Exhibit 31.1

CERTIFICATION BY PRINCIPAL EXECUTIVE OFFICER

I, Nasrat Hakim, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended March 31, 2026 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, 2026

By: ***/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, Carter Ward, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended March 31, 2026 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, 2026

By: ***/s/ Carter Ward***
Carter Ward
Chief Financial Officer, Treasurer and Secretary
(Principal Accounting Officer and Principal 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, 2026 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, 2026

By: ***/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, 2026 filed with the Securities and Exchange Commission (the "Report"), I, Carter Ward, Chief Financial 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-Q fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: June 29, 2026

By: ***/s/ Carter Ward***
Carter Ward
Chief Financial Officer
(Principal Accounting Officer and Principal 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.