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

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2023

OR

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

FOR THE TRANSITION PERIOD FROM _____ TO _____

COMMISSION FILE NUMBER: 001-15697

ELITE PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

(201) 750-2646

(Registrant's telephone number, including area code)

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

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

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No X

Indicate the number of shares outstanding of each of the issuer's classes of Common Stock, as of the latest practicable date: 1,014,015,081 shares of Common Stock were issued, and 1,013,915,081 shares of Common Stock were outstanding as of August 14, 2023.

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2023	March 31, 2023
ASSETS		
Current assets:		
Cash	$ 9,076,659	$ 7,832,247
Accounts receivable, net of allowance for expected credit losses of $100,000 and $0 as of June 30, 2023 and March 31, 2023, respectively	6,201,448	3,094,549
Inventory	11,168,431	9,550,716
Prepaid expenses and other current assets	998,058	1,032,785
Total current assets	**27,444,596**	**21,510,297**
Property and equipment, net of accumulated depreciation of $14,914,617 and $14,586,335, respectively	10,097,876	10,426,158
Intangible assets, net of accumulated amortization of $-0-	6,341,228	6,341,228
Operating lease - right-of-use asset	7,528	13,062
Deferred income tax asset	2,171,821	2,171,821
Other assets:		
Restricted cash - debt service for NJEDA bonds	415,430	412,434
Security deposits	21,018	21,018
Total other assets	**436,448**	**433,452**
Total assets	**$ 46,499,497**	**$ 40,896,018**
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,874,925	$ 2,446,810
Accrued expenses	5,929,353	5,047,726
Deferred revenue, current portion	13,333	13,333
Bonds payable, current portion, net of bond issuance costs	110,822	110,822
Loans payable, current portion	140,454	200,032
Related party loans payable (Note 7)	4,000,000	—
Lease obligation - operating lease, current portion	8,586	14,914
Total current liabilities	12,077,473	7,833,637
Long-term liabilities:		
Deferred revenue, net of current portion	15,556	18,890
Bonds payable, net of current portion and bond issuance costs	1,032,568	1,029,018
Loans payable, net of current portion and loan costs	2,545,753	2,532,502
Derivative financial instruments - warrants	711,078	521,711
Total long-term liabilities	4,304,955	4,102,121
Total liabilities	**16,382,428**	**11,935,758**
Shareholders' equity:		
Common stock; par value $0.001; 1,445,000,000 shares authorized; 1,014,015,081 shares issued and 1,013,915,081 shares outstanding as of June 30, 2023; 1,014,015,081 shares issued and 1,013,915,081 shares outstanding as of March 31, 2023	1,014,019	1,014,019
Additional paid-in capital	164,765,980	164,750,980
Treasury stock; 100,000 shares as of June 30, 2023 and March 31, 2023, respectively, at cost	(306,841)	(306,841)
Accumulated deficit	(135,356,089)	(136,497,898)
Total shareholders' equity	**30,117,069**	**28,960,260**
Total liabilities and shareholders' equity	**$ 46,499,497**	**$ 40,896,018**

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

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

	For the Three Months Ended June 30,

	2023	2022
Revenue:		
Manufacturing fees	$ 7,909,237	$ 6,327,141
Licensing fees	1,070,839	1,345,767
Total revenue	8,980,076	7,672,908
Cost of manufacturing	4,229,521	3,675,061
Gross profit	4,750,555	3,997,847
Operating expenses:		
Research and development	1,143,545	955,443
General and administrative	1,661,704	1,718,104
Non-cash compensation through issuance of stock options	15,000	5,322
Depreciation and amortization	328,282	296,294
Total operating expenses	3,148,531	2,975,163
Income from operations	1,602,024	1,022,684
Other income (expense):		
Change in fair value of derivative instruments	(189,367)	(500,143)
Interest expense and amortization of debt issuance costs	(119,412)	(216,787)
Interest income	3,516	129
Other expense, net	(305,263)	(716,801)
Income before income taxes	1,296,761	305,883
Income tax expense	(154,952)	—
Net income attributable to common shareholders	$ 1,141,809	$ 305,883
Basic net income per share attributable to common shareholders	$ 0.00	$ 0.00
Diluted net income per share attributable to common shareholders	$ 0.00	$ 0.00
Basic weighted average Common Stock outstanding	1,013,915,081	1,011,381,988
Diluted weighted average Common Stock outstanding	1,014,572,821	1,011,381,988

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

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

	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 April 1, 2023	—	$ —	1,013,915,081	$ 1,014,019	$ 164,750,980	100,000	$ (306,841)	$ (136,497,898)	$ 28,960,260
Net income	—	—	—	—	—	—	—	1,141,809	1,141,809
Non-cash compensation through the issuance of employee stock options	—	—	—	—	15,000	—	—	—	15,000
Balance at June 30, 2023	—	$ —	1,013,915,081	$ 1,014,019	$ 164,765,980	100,000	$ (306,841)	$ (135,356,089)	$ 30,117,069

	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 April 1, 2022	—	—	1,011,381,988	$ 1,011,385	$ 164,577,227	100,000	$ (306,841)	$ (140,059,744)	$ 25,222,027
Net income	—	—	—	—	—	—	—	305,883	305,883
Non-cash compensation through the issuance of employee stock options	—	—	—	—	5,322	—	—	—	5,322
Balance at June 30, 2022	—	$ —	1,011,381,988	$ 1,011,385	$ 164,582,549	100,000	$ (306,841)	$ (139,753,861)	$ 25,533,232

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

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

(UNAUDITED)

	For the Three Months Ended June 30,	
	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	$ 1,141,809	$ 305,883
Adjustments to reconcile net income to net cash used in operating activities:		
Depreciation and amortization	328,282	296,294
Bad debt expense	100,000	—
Amortization of operating leases - right-of-use assets	5,534	51,013
Change in fair value of derivative financial instruments - warrants	189,367	500,143
Non-cash compensation through the issuance of employee stock options	15,000	5,322
Non-cash rent expense and lease accretion	192	602
Change in operating assets and liabilities:		
Accounts receivable	(3,206,899)	(907,196)
Inventory	(1,617,715)	(875,993)
Prepaid expenses and other current assets	34,727	(180,974)
Accounts payable, accrued expenses and other current liabilities	309,550	299,968
Deferred revenue	(3,334)	(3,337)
Lease obligations - operating leases	(6,328)	(49,241)
Net cash used in operating activities	(2,709,815)	(557,516)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	—	(94,597)
Net cash used in investing activities	—	(94,597)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from loans payable	—	12,000,000
Proceeds from related party loans payable	4,000,000	—
Loan payments	(42,777)	(103,536)
Net cash provided by financing activities	3,957,223	11,896,464
Net change in cash and restricted cash	1,247,408	11,244,351
Cash and restricted cash, beginning of period	8,244,681	8,940,396
Cash and restricted cash, end of period	$ 9,492,089	$ 20,184,747
Supplemental disclosure of cash and non-cash transactions:		
Cash paid for interest	$ 119,412	$ 216,787
Cash paid for income taxes	$ 127,522	$ —

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

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

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 unaudited condensed consolidated financial statements of the Company are presented in conformity with accounting principles generally accepted in the United States of America ("GAAP") and pursuant to the rules and regulations of the SEC. The unaudited condensed 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. Certain information or footnote disclosures normally included in condensed financial statements prepared in accordance with GAAP have been condensed or omitted, pursuant to the rules and regulations of the SEC for interim financial reporting. Accordingly, they do not include all the information and footnotes necessary for a comprehensive presentation of financial position, results of operations, or cash flows. In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, consisting of a normal recurring nature, which are necessary for a fair presentation of the financial position, operating results and cash flows for the periods presented. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the Company's Form 10-K as filed with the SEC on June 29, 2023. The interim results for the three months ended June 30, 2023 are not necessarily indicative of the results to be expected for the fiscal year ending March 31, 2024 or for any future periods.

Segment Information

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

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

The Company has determined that its reportable segments are products whose marketing approvals were secured via an Abbreviated New Drug 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.

There are currently no intersegment revenues. Asset information by operating segment is not presented below since the chief operating decision maker does not review this information by segment. The reporting segments follow the same accounting policies used in the preparation of the Company's condensed unaudited consolidated financial statements. Please see Note 15 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 Contacts with Customers* ("ASC 606"), the Company recognizes revenue when the customer obtains control of promised goods or services, in an amount that reflects the consideration which is expected to be received in exchange for those goods or services. The Company recognizes revenues following the five-step model prescribed under ASC 606: (i) identify contract(s) with a customer; (ii) identify the performance obligation(s) in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation(s) in the contract; and (v) recognize revenues when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Sales, value add, and other taxes collected on behalf of third parties are excluded from revenue.

Nature of goods and services

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

a) Manufacturing Fees

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

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

b) License Fees

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

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

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

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

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

When determining the transaction price of a contract, an adjustment is made if payment from a customer occurs either significantly before or significantly after performance, resulting in a significant financing component. Applying the practical expedient in ASC 606-10-32-18, the Company does not assess whether a significant financing component exists if the period between when the Company performs its obligations under the contract and when the customer pays is one year or less. None of the Company's contracts contained a significant financing component as of June 30, 2023.

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

c) Direct Sales

The Company began direct sales of products under the Company's own label on April 1, 2023. License agreements will remain in place for select products. With this transition, however, a large portion of the manufacturing and license fees now reported will be replaced with revenues from direct sales of pharmaceutical products to distributors for pharmacies and institutions.

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. The table also includes a reconciliation of the disaggregated revenue with the reportable segments:

	For the Three Months Ended June 30,	
	2023	**2022**
ANDA:		
Manufacturing fees	$ 7,909,237	$ 6,327,141
Licensing fees	1,070,839	1,345,767
Total ANDA revenue	8,980,076	7,672,908
Total revenue	$ 8,980,076	$ 7,672,908

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

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 June 30, 2023, and March 31, 2023, the Company had $415,430 and $412,434, of restricted cash, respectively, related to debt service reserve in regard to the New Jersey Economic Development Authority ("NJEDA") bonds (see Note 5).

Accounts Receivable and Allowance for Expected Credit Losses

Accounts receivable are comprised of balances due from customers, net of estimated allowances for expected credit losses. 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, which was adopted by the Company on February 1, 2023, as discussed below within Recently Adopted Accounting Pronouncements. 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.

Prior to April 1, 2023, trade receivables were presented net of allowance for expected credit losses based on the credit risk of specific clients, past collection history, and management's evaluation of other risks. Expected credit losses stemming from unbilled receivables expected to be billed between March 31, 2024 and March 31, 2028 include additional risk premiums estimated based on factors such as projected inflation, projected decreases in GDP, and projected unemployment.

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. A significant amount of judgment is involved in determining if an indicator of impairment has occurred. Such indicators may include, among others and without limitation: a significant decline in the Company's expected future cash flows; a sustained, significant decline in the Company's stock price and market capitalization; a significant adverse change in legal factors or in the business climate of the Company's segments; unanticipated competition; and slower growth rates.

During the year ended March 31, 2023, the Company determined indicators of impairment occurred and recorded impairment expense of $292,807 on its ANDAs and patents. There were no such impairment recorded during the period ended June 30, 2023.

The following table summarizes the Company's intangible assets as of and for the periods ended June 30, 2023 and March 31, 2023:

	June 30, 2023				
	Estimated Useful Life	Gross Carrying Amount	Impairment losses	Accumulated Amortization	Net Book Value
Patent application costs	*	$ 289,039	$ —	$ —	$ 289,039
ANDA acquisition costs	Indefinite	6,052,189	—	—	6,052,189
		$ 6,341,228	$ —	$ —	$ 6,341,228

	March 31, 2023				
	Estimated Useful Life	Gross Carrying Amount	Impairment losses	Accumulated Amortization	Net Book Value
Patent application costs	*	$ 465,684	$ (176,645)	$ —	$ 289,039
ANDA acquisition costs	Indefinite	6,168,351	(116,162)	—	6,052,189
		$ 6,634,035	$ (292,807)	$ —	$ 6,341,228

Research and Development

Research and development expenditures are charged to expenses as incurred.

Contingencies

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

Income Taxes

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

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

The Company operates in multiple tax jurisdictions within the United States of America. The Company remains subject to examination in all tax jurisdiction until the applicable statutes of limitation expire. As of June 30, 2023, a summary of the tax years that remain subject to examination in our major tax jurisdictions are: United States – Federal, 2016 and forward. The Company did not record unrecognized tax positions for the three months ended June 30, 2023.

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.

The exercise price is subject to adjustment for any issuances or deemed issuances of Common Stock or Common Stock equivalents at an effective price below the then exercise price. Such exercise price adjustment feature prohibits the Company from being able to conclude the warrants are indexed to its own stock and thus such warrants are classified as liabilities and measured initially and subsequently at fair value. The Series J Warrants also provide for other standard adjustments upon the happening of certain customary events.

Stock-Based Compensation

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

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

The Company records earned but unissued stock-based compensation in accrued expenses.

Sale of ANDA

During the quarter ended December 31, 2022, the Company entered into an agreement with Pyros Pharmaceuticals, Inc. ("Pyros") pursuant to which the Company sold to Pyros its rights in and to the Company's approved abbreviated new drug applications (ANDAs) for its generic Sabril drug. The Company sold its rights to Pyros for $1,000,000, which was recorded as gain on sale of ANDA during the year ended March 31, 2023. There is no further action required by the Company regarding the rights which would affect future periods.

In conjunction with the sale of its Product to Pyros, the Company executed a Manufacturing and Supply agreement (the "Pyros Agreement") with Pyros. Under the terms of the Pyros Agreement, the Company will receive an agreed-upon price per drug for the manufacturing and packaging of Sabril over a term of three years. Revenue per the Pyros Agreement will be recognized as control of the manufactured and supplied drugs is transferred to Pyros (at the time of delivery).

Earnings Per Share Attributable to Common Shareholders'

The Company follows ASC 260, *Earnings Per Share*, which requires presentation of basic and diluted earnings per share ("EPS") on the face of the income statement for all entities with complex capital structures and requires a reconciliation of the numerator and denominator of the basic EPS computation to the numerator and denominator of the diluted EPS computation. In the accompanying financial statements, basic earnings per share is computed by dividing net income by the weighted average number of shares of Common Stock outstanding during the period. The computation of diluted net income per share does not include the conversion of securities that would have an antidilutive effect.

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

	For the Three Months Ended June 30,	
	2023	**2022**
Numerator		
Net income - basic[1]	$ 1,141,809	$ 305,883
Effect of dilutive instrument on net income	—	—
Net income - basic and diluted	$ 1,141,809	$ 305,883
Denominator		
Weighted average shares of Common Stock outstanding - basic	1,013,915,081	1,011,381,988
Dilutive effect of stock options and convertible securities	657,740	—
Weighted average shares of Common Stock outstanding - diluted	1,014,572,821	1,011,381,988
Net income per share		
Basic	$ 0.00	$ 0.00
Diluted	$ 0.00	$ 0.00

Fair Value of Financial Instruments

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

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

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

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

Measured on a Recurring Basis

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

	Amount at Fair Value	Fair Value Measurement		
		Level 1	Level 2	Level 3
Balance as of April 1, 2023	$ 521,711	$ —	$ —	$ 521,711
Change in fair value of derivative instruments	189,367	—	—	189,367
Balance as of June 30, 2023	$ 711,078	$ —	$ —	$ 711,078

	Amount at Fair Value	Fair Value Measurement		
		Level 1	Level 2	Level 3
Balance as of April 1, 2022	$ 936,837	$ —	$ —	$ 936,837
Change in fair value of derivative instruments	500,143	—	—	500,143
Balance as of June 30, 2022	$ 1,436,980	$ —	$ —	$ 1,436,980

[1] No amounts are included in the calculation because their effects are anti-dilutive

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

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

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

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

Financial Instruments — Credit Losses (ASU 2016-13)

In June 2016, the FASB issued ASU 2016-13, Financial Instruments - Credit Losses ("CECL"). The amendments in this update introduce a new accounting model to measure credit losses for financial assets measured at amortized cost. The FASB has also issued additional ASUs to clarify the scope and provide additional guidance for ASU 2016-13. Credit losses for financial assets measured at amortized cost should be determined based on the total current expected credit losses over the life of the financial asset or group of financial assets. In effect, the financial asset or group of financial assets should be presented at the net amount expected to be collected. Credit losses will no longer be recorded under the current incurred loss model for financial assets measured at amortized cost. The amendments also modify the accounting for available-for-sale debt securities whereby credit losses will be recorded through an allowance for credit losses rather than a write-down to the security's cost basis, which allows for reversals of credit losses when estimated credit losses decline. Credit losses for available-for-sale debt securities should be measured in a manner similar to current GAAP.

The amendments were effective on April 1, 2023 for the Company, and must be applied using a modified retrospective approach with a cumulative-effect adjustment through retained earnings as of the beginning of the fiscal year upon adoption as required. While the standard modifies the measurement of the allowance for credit losses, it does not alter the credit risk of our trade or unbilled receivables.

The impact of applying the CECL methodology upon adoption effective on April 1, 2023 was immaterial to the Company's consolidated financial statements.

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.

The Company has historical collections of customer payments averaging approximately 99.96% as of June 30, 2023. The Company recorded revenue during the three months ended June 30, 2023 of approximately $9.0 million and recorded an estimated allowance of $100,000, which is approximately 1.2% of total revenues during the three months ended June 30, 2023. The Company estimated the allowance using considerations such as customer collections, and estimated credit losses. The Company believes the 1.2% credit allowance is appropriate given its historical customer collections.

Treasury Stock

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

Recently Issued Accounting Pronouncements

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

NOTE 2. INVENTORY

Inventory consisted of the following:

	June 30, 2023	March 31, 2023
Finished goods	$ 7,808,657	$ 2,352,330
Work-in-progress	90,922	1,791,311
Raw materials	3,268,852	5,407,075
Inventory	$ 11,168,431	$ 9,550,716

NOTE 3. PROPERTY AND EQUIPMENT, NET

Property and equipment consisted of the following:

	June 30, 2023	March 31, 2023
Land, building and improvements	$ 10,771,997	$ 10,768,181
Laboratory, manufacturing, warehouse and transportation equipment	13,354,863	13,364,512
Office equipment and software	373,601	395,563
Furniture and fixtures	512,032	484,237
Property and equipment, gross	25,012,493	25,012,493
Less: Accumulated depreciation	(14,914,617)	(14,586,335)
Property and equipment, net	$ 10,097,876	$ 10,426,158

Depreciation expense was $328,282 and $292,748 for the three months ended June 30, 2023 and 2022, respectively.

NOTE 4. ACCRUED EXPENSES

As of June 30, 2023 and March 31, 2023, the Company's accrued expenses consisted of the following:

	June 30, 2023	March 31, 2023
Salaries and fees payable in common stock	4,470,001	4,125,000
Income tax	564,985	414,989
Consultant contract fees	193,333	193,333
Audit fees	125,000	125,000
Director dues	107,500	70,000
Legal and professional expense	90,000	—
Employee bonuses	30,000	—
Other accrued expenses	348,534	119,404
Total accrued expenses	$ 5,929,353	$ 5,047,726

NOTE 5. NJEDA BONDS

In relation to the Series A Notes, the Company is required to maintain a debt service reserve. The debt service reserve is classified as restricted cash on the accompanying unaudited consolidated balance sheets. The NJEDA Bonds require the Company to make an annual principal payment on September 1st based on the amount specified in the loan documents and semi-annual interest payments on March 1st and September 1st, equal to interest due on the outstanding principal. The annual interest rate on the Series A Note is 6.5%. The NJEDA Bonds are collateralized by a first lien on the Company's facility and equipment acquired with the proceeds of the original and refinanced bonds.

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

	June 30, 2023	March 31, 2023
Gross bonds payable		
NJEDA Bonds - Series A Notes	$ 1,245,000	$ 1,245,000
Less: Current portion of bonds payable (prior to deduction of bond offering costs)	(125,000)	(125,000)
Long-term portion of bonds payable (prior to deduction of bond offering costs)	$ 1,120,000	$ 1,120,000
Bond offering costs	$ 354,454	$ 354,454
Less: Accumulated amortization	(252,842)	(249,294)
Bond offering costs, net	$ 101,612	$ 105,160
Current portion of bonds payable - net of bond offering costs		
Current portions of bonds payable	$ 125,000	$ 125,000
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	$ 110,822	$ 110,822
Long term portion of bonds payable - net of bond offering costs		
Long term portion of bonds payable	$ 1,120,000	$ 1,120,000
Less: Bond offering costs to be amortized subsequent to the next 12 months	(87,432)	(90,982)

Long term portion of bonds payable, net of bond offering costs	$ 1,032,568	$ 1,029,018

Amortization expense was $3,548 and $3,546 for the three months ended June 30, 2023 and 2022, respectively. Interest payable was $6,744 as of June 30, 2023 and March 31, 2023. Interest expense was $20,232 and $22,101 for the three months ended June 30, 2023 and 2022, respectively.

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

Years ending March 31,	Amount
2024	$ 125,000
2025	130,000
2026	140,000
2027	150,000
Thereafter	700,000
	$ 1,245,000

NOTE 6. LOANS PAYABLE

On April 2, 2022, the Company and Elite Labs entered into a Loan and Security Agreement (the "EWB Loan Agreement") with East West Bank ("EWB"). Pursuant to the EWB Loan Agreement, the Company and Elite Labs received one term loan for a principal amount of $12,000,000 (the "EWB Term Loan") and a revolving line of credit up to $2,000,000 (the "EWB Revolver," together with the "EWB Term Loan," the EWB Loans"), each of which shall be used for working capital. The EWB Term Loan bears interest at a rate of 9.73% (1.73% plus the prime rate ("Prime")) and is repayable over five years, maturing on May 1, 2027. The EWB Revolver bears interest at a rate of (8.87% (0.87% plus Prime)) and matures on May 1, 2027. The total transaction costs associated with the EWB Term Loan incurred as of March 31, 2023, were $40,120, which are being amortized on a monthly basis over five years, beginning in April 2022. The EWB Loans are secured by a security interest in the personal property of the Company and Elite Labs. The EWB Loan Agreement contains customary representations, warranties and covenants. These covenants include, but are not limited to, maintaining maximum leverage ratios of 3.50 to 1.00, minimum liquidity of $5,000,000, minimum cash of $1,000,000, a fixed charge coverage ratio of 1.25 to 1.00 and restrictions on mergers or sales of assets and debt borrowings. As of March 31, 2023, the principal and interest on the EWB Term Loan has been paid in full by the Company and the EWB Loan Agreement is terminated.

In place of the EWB Term Loan, the Company has entered into a collateralized promissory note with individual lenders with rates comparable to the EWB Term Loan but with less restrictive covenants (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. The Promissory Note has an interest rate of 9% for the first year and 10% for an optional second year and the proceeds will be used for working capital and other business purposes.

Loans payable consisted of the following:

	June 30, 2023	March 31, 2023
Mortgage loan payable 4.75% interest and maturing June 2032	$ 2,471,304	$ 2,472,923
Equipment and insurance financing loans payable, between 7.10% and 12.02% interest and maturing between September 2023 and October 2025	214,903	259,611
Less: Current portion of loans payable	(140,454)	(200,032)
Long-term portion of loans payable	$ 2,545,753	$ 2,532,502

The interest expense associated with the loans and mortgage payable was $77,238 and $177,579 for the three months ended June 30, 2023 and 2022, respectively.

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

Years ending March 31,	Amount
2024 (excluding the three months ended June 30, 2023)	$ 140,454
2025	380,210
2026	317,537
2027	292,652
2028	297,245
2029 and thereafter	1,258,109
Total remaining principal balance	$ 2,686,207

NOTE 7. RELATED PARTY LOANS

The Company has entered into a collateralized promissory note with individual lenders with rates comparable to the EWB Term Loan but with less covenants (the "Hakim Promissory Note"). 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, CEO and Chairman of the Board of Directors, pursuant to which the Company borrowed funds in the aggregate principal amount of $3,000,000. The Hakim Promissory Note has an interest rate of 9% for the first year and 10% for an optional second year and the proceeds will be used for working capital and other business purposes. The original maturity date of the Hakim Promissory Note is June 2, 2024, with an optional second year extension. The second year extension must be exercised by both parties 60 days prior to the original maturity date. As of the date of this filing, the Company does not expect to exercise the second year extension.

On July 1, 2022, the 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 total transaction costs associated with the EWB Mortgage Loan incurred as of June 30, 2023, 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 the date of this filing, the Company was in compliance with each financial covenant.

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 is June 30, 2024, with an optional second year extension. The second year extension must be exercised by both parties 60 days prior to the original maturity date. As of the date of this filing, the Company does not expect to exercise the second year extension.

NOTE 8. DEFERRED REVENUE

Deferred revenues in the aggregate amount of $28,889 as of June 30, 2023, were comprised of a current component of $13,333 and a long-term component of $15,556. Deferred revenues in the aggregate amount of $32,223 as of March 31, 2023, were comprised of a current component of $13,333 and a long-term component of $18,890. These line items represent the unamortized amounts of a $200,000 advance payment received for a TAGI Pharma licensing agreement with a fifteen-year term beginning in September 2010 and ending in August 2025. These advance payments were recorded as deferred revenue when received and are earned, on a straight-line basis over the life of the licenses. The current component is equal to the amount of revenue to be earned during the 12-month period immediately subsequent to the balance sheet date and the long-term component is equal to the amount of revenue to be earned thereafter.

NOTE 9. COMMITMENTS AND CONTINGENCIES

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

Operating Leases

The Company entered into an operating lease for a portion of a one-story warehouse, located at 135 Ludlow Avenue, Northvale, New Jersey (the "Ludlow Ave. lease") which began in 2010. On June 30, 2021, the Company exercised a renewal option, with such option including a term that begins on January 1, 2022 and expires on December 31, 2026. The Ludlow Ave. lease was terminated on July 1, 2022, when the Company purchased the underlying property.

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 has a term of three years, ending on October 31, 2023.

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

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

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

Lease	Classification	As of June 30, 2022
Assets		
Operating	Operating lease – right-of-use asset	$ 7,528
Total leased assets		$ 7,528
Liabilities		
Current		
Operating	Lease obligation – operating lease	$ 8,586
Long-term		
Operating	Lease obligation – operating lease, net of current portion	—
Total lease liabilities		$ 8,586

Rent expense is recorded on the straight-line basis. Rent expense under the 135 Ludlow Ave. modified lease for the three months ended June 30, 2023 and 2022 was $0 and $58,248, respectively. Rent expense under the Pompano Office Lease for the three months ended June 30, 2023 and 2022 was $6,519 and $6,330, respectively. Rent expense is recorded in general and administrative expense in the unaudited condensed consolidated statements of operations.

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

Years ending March 31,	Amount
2024 (excluding the three months ended June 30, 2023)	$ 8,694
Total future minimum lease payments	8,694
Less: interest	(108)
Present value of lease payments	$ 8,586

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

Lease Term and Discount Rate	June 30, 2023
Remaining lease term (years)	
Operating leases	0.3
Discount rate	
Operating leases	6%

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 June 30, 2023 and March 31, 2023.

On April 28, 2017, the Company entered into an Exchange Agreement with Hakim, the Chairman of the Board, President, and Chief Executive Officer of the Company, pursuant to which the Company issued to Hakim 24.0344 shares of its Series J Preferred and warrants to purchase an aggregate of 79,008,661 shares of its Common Stock (the "Series J Warrants" and, along with the Series J Preferred issued to Hakim, the "Securities") in exchange for 158,017,321 shares of Common Stock owned by Hakim. The fair value of the Series J Warrants was determined to be $6,474,674 upon issuance at April 28, 2017.

The Series J Warrants are exercisable for a period of 10 years from the date of issuance, commencing April 28, 2020. The initial exercise price is $0.1521 per share and the Series J Warrants can be exercised for cash or on a cashless basis. The exercise price is subject to adjustment for any issuances or deemed issuances of Common Stock or Common Stock equivalents at an effective price below the then exercise price. Such exercise price adjustment feature prohibits the Company from being able to conclude the warrants are indexed to its own stock and thus such warrants are classified as liabilities and measured initially and subsequently at fair value. The Series J Warrants also provide for other standard adjustments upon the happening of certain customary events.

The fair value of the Series J Warrants was calculated using a Black-Scholes model instead of a Monte Carlo Simulation because the probability with the shareholder approval provisions was no longer a factor. The following assumptions were used in the Black-Scholes model to calculate the fair value of the Series J Warrants:

	June 30, 2023	March 31, 2023
Fair value of the Company's Common Stock	$ 0.0383	$ 0.0290
Volatility	72.21%	74.37%
Initial exercise price	$ 0.1521	$ 0.1521
Warrant term (in years)	3.8	4.1
Risk free rate	4.01%	3.55%

The changes in warrants (Level 3 financial instruments) measured at fair value on a recurring basis for the three months ended June 30, 2023 were as follows:

Balance at March 31, 2023	$ 521,711
Change in fair value of derivative financial instruments - warrants	189,367
Balance at June 30, 2023	$ 711,078

NOTE 12. SHAREHOLDERS' EQUITY

Lincoln Park Capital Transaction - July 8, 2020 Purchase Agreement

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

The Company did not issue any shares of its Common Stock pursuant to the 2020 LPC Purchase Agreement during the three months ended June 30, 2023 and 2022. In

addition, there were no shares issued to Lincoln Park as additional commitment shares, pursuant to the 2020 LPC Agreement. The 2020 LPC Purchase Agreement will expire on August 1, 2023.

Summary of Common Stock Activity

During the three months ended June 30, 2023 and 2022, the Company did not issue any shares of Common Stock.

NOTE 13. STOCK-BASED COMPENSATION

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

Stock-based Director Compensation

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

During the three months ended June 30, 2023, the Company accrued director's fees totaling $37,500, which will be paid via cash payments totaling $7,500 and the issuance of shares of Common Stock.

Stock-based Employee/Consultant Compensation

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

During the three months ended June 30, 2023, the Company accrued salaries totaling $170,000 owed to the Company's President, Chief Executive Officer and certain other employees which will be paid via the issuance of shares of Common Stock. As of June 30, 2023, the total obligation of $4,725,000 is outstanding.

Options

Under its 2014 Stock Option Plan and prior options plans, the Company may grant stock options to officers, selected employees, as well as members of the Board of Directors and advisory board members. All options have generally been granted at a price equal to or greater than the fair market value of the Company's Common Stock at the date of the grant. Generally, options are granted with a vesting period of up to three years and expire ten years from the date of grant. A summary of the activity of Company's 2014 Stock Option Plan for the three months ended June 30, 2023 is as follows:

	Shares Underlying Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at March 31, 2023	15,370,000	$ 0.07	7.4	$ —
Outstanding at June 30, 2023	15,370,000	$ 0.05	7.2	$ —
Exercisable at June 30, 2023	4,182,000	$ 0.08	2.0	$ —

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 June 30, 2023 and March 31, 2023 of $0.04 and $0.03, respectively. As of June 30, 2023, there was $184,722 in unrecognized stock based compensation expense that will be recognized over a 1.3 year period.

NOTE 14. CONCENTRATIONS AND CREDIT RISK

Revenues

Five customers accounted for approximately 76% of the Company's revenues for the three months ended June 30, 2023. These five customers accounted for approximately 21%, 16%, 15%, 14%, and 10% of revenues each, respectively.

One customer accounted for approximately 85% of the Company's revenues for the three months ended June 30, 2022.

Accounts Receivable

Three customers accounted for approximately 56% of the Company's accounts receivable as of June 30, 2023. These three customers accounted for approximately 22%, 21%, and 13% of accounts receivable each, respectively.

One customer accounted for approximately 96% the Company's accounts receivable as of March 31, 2023.

Purchasing

One supplier accounted for approximately 39% of the Company's purchases of raw materials for the three months ended June 30, 2023.

Two suppliers accounted for approximately 66% of the Company's purchases of raw materials for the three months ended June 30, 2022. These two suppliers accounted for approximately 56% and 10% of purchases each, respectively.

NOTE 15. SEGMENT RESULTS

FASB ASC 280-10-50 requires use of the "management approach" model for segment reporting. The management approach is based on the way a company's management organized segments within the company for making operating decisions and assessing performance. Reportable segments are based on products and services, geography, legal structure, management structure, or any other manner in which management disaggregates a company.

The Company has determined that its reportable segments are ANDAs for generic products and NDAs for branded products. The Company identified its reporting segments based on the marketing authorization relating to each and the financial information used by its chief operating decision maker to make decisions regarding the allocation of resources to and the financial performance of the reporting segments.

Asset information by operating segment is not presented below since the chief operating decision maker does not review this information by segment. The reporting segments follow the same accounting policies used in the preparation of the Company's unaudited condensed consolidated financial statements.

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

	For the Three Months Ended June 30,	
	2023	2022
Operating Income by Segment		
ANDA	$ 7,725,635	$ 8,068,073
Operating income by Segment	$ 7,725,635	$ 8,068,073

The table below reconciles the Company's operating income by segment to income before income taxes as reported in the Company's unaudited condensed consolidated statements of operations.

	For the Three Months Ended June 30,	
	2023	2022
Operating income by segment	$ 7,725,635	$ 8,068,073
Corporate unallocated costs	(2,606,661)	(2,288,461)
Interest income	3,516	129
Interest expense and amortization of debt issuance costs	(119,412)	(126,376)
Depreciation and amortization expense	(328,282)	(908,297)
Significant non-cash items	(469,021)	(652,281)
Change in fair value of derivative instruments	(189,367)	1,523,394
Income before income taxes	$ 4,016,408	$ 5,616,181

NOTE 16. RELATED PARTY AGREEMENTS WITH MIKAH PHARMA, LLC

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.

NOTE 17. INCOME TAXES

The Company's effective tax rate was 11.5% and income tax expense for the three months ended June 30, 2023 was $154,952. The Company's effective tax rate was 0.00% and income tax expense was $— for the three months ended June 30, 2022. The Company has evaluated its deferred tax assets, specifically its net operating loss carryovers, for realizability and has provided a valuation allowance on the majority of its deferred tax assets. The change in valuation allowance is the reason that the effective tax rate and income tax expense are different than the statutory rate of 21%.

NOTE 18. SUBSEQUENT EVENTS

The Company has evaluated subsequent events from the balance sheet date through August 14, 2023 and note no material subsequent events were identified.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations for the three months ended June 30, 2023 and 2022 should be read in conjunction with our unaudited condensed consolidated financial statements and the notes to those statements that are included elsewhere in this report. Our discussion includes forward-looking statements based upon current expectations that involve risks and uncertainties, such as our plans, objectives, expectations and intentions. Actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of a number of factors, including those set forth under Item 1A. Risk Factors appearing in our Annual Report on Form 10-K for the year ended March 31, 2023. We use words such as "anticipate," "estimate," "plan," "project," "continuing," "ongoing," "expect," "believe," "intend," "may," "will," "should," "could," and similar expressions to identify forward-looking statements.

Unless expressly indicated or the context requires otherwise, the terms "Elite", the "Company", "we", "us", and "our" refer to Elite Pharmaceuticals, Inc. and subsidiary.

Background

Elite Pharmaceuticals, Inc., a Nevada corporation (the "Company", "Elite", "Elite Pharmaceuticals", the "registrant", "we", "us" or "our") was incorporated on October 1,

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

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

We occupy manufacturing, warehouse, laboratory and office space at 165 Ludlow Avenue and 135 Ludlow Avenue in Northvale, NJ (the "Northvale Facility"). The Northvale Facility operates under Current Good Manufacturing Practice and is a United States Drug Enforcement Agency registered facility for research, development and manufacturing. We are also party to an operating lease for office space at Pompano Beach, Florida (the "Pompano Office Lease").

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

Our focus is on the development of various types of drug products, including generic drug products which require ANDAs as well as branded drug products which require New Drug Applications ("NDAs") under Section 505(b)(1) or 505(b)(2) of the Drug Price Competition and Patent Term Restoration Act of 1984.

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

Recent Developments

Pyros Agreement

During the quarter ended December 31, 2022, the Company entered into an agreement with Pyros Pharmaceuticals, Inc. ("Pyros") pursuant to which the Company sold to Pyros its rights in and to the Company's approved abbreviated new drug applications (ANDAs) for its generic Sabril drug. The Company sold its rights to Pyros for $1,000,000, which was recorded as gain on sale of ANDA during the year ended March 31, 2023. There is no further action required by the Company regarding the rights which would affect future periods.

In conjunction with the sale of its Product to Pyros, the Company executed a Manufacturing and Supply agreement (the "Pyros Agreement") with Pyros. Under the terms of the Pyros Agreement, the Company will receive an agreed-upon price per drug for the manufacturing and packaging of Sabril over a term of three years. Revenue per the Pyros Agreement will be recognized as control of the manufactured and supplied drugs is transferred to Pyros (at the time of delivery).

Notice of Termination of License, Supply and Distribution Agreement

On September 14, 2022, the Company has provided written notice pursuant to the License, Supply and Distribution Agreement between the Company and Elite Laboratories, Inc. and Epic Pharma, Inc. dated November 21, 2020 ("the Epic Agreement") that the Company and Elite Laboratories, Inc. are now providing notice of termination of the Epic Agreement, with such termination to be effective March 31, 2023.

Commercial Products

We own, license, contract manufacture or have contractual rights to receive royalties from the following products currently approved for commercial sale:

Product	Branded Product Equivalent	Therapeutic Category	Launch Date
Phentermine HCl 37.5mg tablets	Adipex-P®	Bariatric	April 2011
Phendimetrazine Tartrate 35mg tablets	Bontril®	Bariatric	November 2012
Phentermine HCl 15mg and 30mg capsules	Adipex-P®	Bariatric	April 2013
Naltrexone HCl 50mg tablets	Revia®	Addiction Treatment	September 2013
Isradipine 2.5mg and 5mg capsules	N/A	Cardiovascular	January 2015
Trimipramine Maleate Immediate Release 25mg, 50mg and 100mg capsules	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	Adderall®	Central Nervous System Stimulant	April 2019
Dantrolene Sodium Capsules 25mg, 50mg and 100mg	Dantrium®	Muscle Relaxant	June 2019
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, Amphetamine Sulfate Extended Release 5mg, 10mg, 15mg, 20mg, 25mg, and 30mg capsules	Adderall XR®	Central Nervous System Stimulant	March 2020
Loxapine Succinate 5mg, 10mg, 25mg and 50gm capsules	Loxapine®	Antipsychotic	May 2021

Products Under FDA Review

SequestOx™ - Immediate Release Oxycodone with sequestered Naltrexone

SequestOx™ is our abuse-deterrent candidate for the management of moderate to severe pain where the use of an opioid analgesic is appropriate. SequestOx™ is an immediate-release Oxycodone Hydrochloride containing sequestered Naltrexone which incorporates 5mg, 10mg, 15mg, 20mg and 30mg doses of oxycodone into capsules.

In January 2016, the Company submitted a 505(b)(2) New Drug Application for SequestOx™, after receiving a waiver of the $2.3 million filing fee from the FDA. In March 2016, the Company received notification of the FDA's acceptance of this filing and that such filing has been granted priority review by the FDA with a target action under the Prescription Drug User Fee Act ("PDUFA") of July 14, 2016.

On July 15, 2016, the FDA issued a Complete Response Letter, or CRL, regarding the NDA. The CRL stated that the review cycle for the SequestOx™ NDA is complete and the application is not ready for approval in its present form.

On July 7, 2017, the Company reported topline results from a pivotal bioequivalence fed study for or SequestOx™. The mean Tmax (the amount of time that a drug is present at the maximum concentration in serum) of SequestOx™ was 4.6 hr. with a range of 0.5 hr. to 12 hr. and the mean Tmax of the comparator, Roxicodone®, was 3.4 hr. with a range of 0.5 hr. to 12 hr. A key objective for the study was to determine if the reformulated SequestOx™ had a similar Tmax to the comparator when taken with a high fat meal.

Based on these results, the Company paused clinical trials for this formulation of SequestOx™. On January 30, 2018, the Company reported positive topline results from a pilot study conducted for a modified SequestOx™ wherein, based on the results of this pilot study, the modified SequestOx™ formulation is expected to achieve bioequivalence with a Tmax range equivalent to the reference product when conducted in a pivotal trial under fed conditions. The Company has provided the pilot data to the FDA, requesting clarification as to the requirements for resubmission of the NDA. The FDA has provided guidance for repeated bio-equivalence studies in order to bridge the new formulation to the original SequestOx™ studies and also extended our filing fee waiver until July 2023. Due to the prohibitive cost of such repeated bio-equivalence studies and the uncertain commercial viability given the regulatory and competitive landscape, the Company has paused development of this product 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 a generic antimetabolite ANDA and a generic dopamine agonist ANDA and these products are under review by the FDA. The Company also submitted an ANDA for pain management and intends to provide supplemental data in Q3 2023 to complete the filing.

Approved Products Not Yet Commercialized

Acetaminophen and Codeine Phosphate

The Company received approval on September 10, 2019 from the FDA of an ANDA for a generic version of Tylenol® with Codeine (acetaminophen and codeine phosphate) 300mg/7.5mg, 300mg/15mg, 300mg/30mg and 300mg/60mg tablets. Acetaminophen with codeine is a combination medication indicated for the management of mild to moderate pain, where treatment with an opioid is appropriate and for which alternative treatments are inadequate. Acetaminophen with codeine products have annual U.S. sales of approximately $45 million according to IQVIA (formerly QuintilesIMS Health Data). The Company is not pursuing licensing deals for any opioids at this time until the market changes. The Company will wait for the market to stabilize before pursuing these opportunities.

Doxycycline Hyclate Tablets

The Company received approval in April 2022 from the FDA of an ANDA for a generic version of an antibiotic product. According to QVIA (formerly QuintilesIMS Health) data, the branded product for this antibiotic and its equivalents had total annual U.S. sales of approximately $85 million for the twelve months ending September 30, 2019. The product is jointly owned by Elite and Praxgen Pharmaceuticals LLC, formerly SunGen Pharma LLC, ("Praxgen").

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.

Critical Accounting Policies and Estimates

The preparation of the unaudited condensed consolidated financial statements and related disclosures in conformity with GAAP, and our discussion and analysis of the Company's financial condition and operating results require our management to make judgments, assumptions and estimates that affect the amounts reported in the Company's unaudited condensed consolidated financial statements and accompanying notes. Management bases its estimates on historical experience and on various other assumptions it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates and such differences may be material.

There were no significant changes during the three months ended June 30, 2023 to the items that we disclosed as our significant accounting policies and estimates described in "Note 1, Summary of Significant Accounting Policies" to the Company's financial statements as contained in the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2023.

Results of Operations

The following set forth our results of operations for the periods presented. The period-to-period comparison of financial results is not necessarily indicative of future results.

Three months ended June 30, 2023 compared to the three months ended June 30, 2022

Revenue, Cost of revenue and Gross profit:

	For the Three Months Ended June 30,		Change	
	2023	2022	Dollars	Percentage
Manufacturing fees	$ 7,909,237	$ 6,327,141	$ 1,582,096	25%
Licensing fees	1,070,839	1,345,767	(274,928)	(20)%
Total revenue	8,980,076	7,672,908	1,307,168	17%
Cost of manufacturing	4,229,521	3,675,061	554,460	15%
Gross profit	$ 4,750,555	$ 3,997,847	$ 752,708	19%
Gross profit - percentage	53%	52%		

Total revenues for the three months ended June 30, 2023 increased by $1.3 million or 17%, to $9.0 million, as compared to $7.7 million, for the corresponding period of the prior year, primarily due to increased sales of Amphetamine ER Capsules and Phentermine as compared to the comparable period of the prior fiscal year.

Manufacturing fees increased by $1.6 million, or 25%, primarily due to increased sales of Amphetamine ER Capsules during the three months ended June 30, 2023 as compared to the comparable period of the prior fiscal year.

Licensing fees decreased by $0.3 million, or 20%. This decrease is primarily due to licensing fees decreasing from the sales of Amphetamine IR Tablets, Naltrexone Tablets, and Isradipine during the three months ended June 30, 2023 as compared to the comparable period of the prior fiscal year.

Cost of revenue consists of manufacturing and assembly costs. Our cost of revenue increased by $0.6 million or 15%, to $4.2 million as compared to $3.7 million for the corresponding period in the prior fiscal year. This increase was due to an increased volume of products sold during the three months ended June 30, 2023, as compared to the comparable period of the prior fiscal year, as well as a decrease in licensing fees revenues as noted.

Our gross profit margin was 53% during the three months ended June 30, 2023 as compared to 52% during the comparable period of the prior fiscal year. The increase in gross profit margin is due to manufacturing efficiencies achieved in relation to increased production volumes.

Operating expenses:

	For the Three Months Ended June 30,		Change	
	2023	2022	Dollars	Percentage
Operating expenses:				
Research and development	$ 1,143,545	$ 955,443	$ 188,102	20%
General and administrative	1,661,704	1,718,104	(56,400)	(3)%
Non-cash compensation	15,000	5,322	9,678	182%
Depreciation and amortization	328,282	296,294	31,988	11%
Total operating expenses	$ 3,148,531	$ 2,975,163	$ 173,368	6%

Operating expenses consist of research and development costs, general and administrative costs, non-cash compensation and depreciation and amortization expenses. Operating expenses for the three months ended June 30, 2023 increased by $0.2 million, or 6%, to $3.1 million as compared to $3.0 million for the corresponding period in the prior fiscal year, largely due to an increase in research and development of $0.2 million.

Research and development costs during the three months ended June 30, 2023 were $1.1 million, an increase of $0.2 million, or 20%, from approximately $1.0 million of such costs for the comparable period of the prior year. The increase was a result of the timing and nature of product development activities during the three months ended June 30, 2023 as compared to the comparable period of the prior fiscal year.

General and administrative expenses for the three months ended June 30, 2023 were $1.7 million, which was virtually unchanged from $1.7 million in such costs for the comparable period of the prior fiscal year.

Non-cash compensation expense for the three months ended June 30, 2023 and June 30, 2022 was less than $0.1 million.

Depreciation and amortization expenses from the three months ended June 30, 2023 were $0.3 million, which was virtually unchanged from $0.3 million in such costs for the comparable period of the prior fiscal year.

As a result of the foregoing, our income from operations during the three months ended June 30, 2023 was $1.6 million, compared to income from operations of $1.0 million for the comparable period of the prior fiscal year.

Other income (expense):

	For the Three Months Ended June 30,		Change	
	2023	2022	Dollars	Percentage
Other income (expense):				
Change in fair value of derivative instruments	$ (189,367)	$ (500,143)	$ 310,776	(62)%
Interest expense and amortization of debt issuance costs	(119,412)	(216,787)	97,375	(45)%
Interest income	3,516	129	3,387	2,626%
Other (expense) income, net	$ (305,263)	$ (716,801)	$ 411,538	(57)%

Other income (expense) for the three months ended June 30, 2023 was $0.3 million, a decrease of $0.4 million from $0.7 million for the comparable period of the prior fiscal year. The decrease was due to decreased income relating to changes in the fair value of our outstanding derivative warrants and increased interest expense and amortization of debt issuance costs during the three months ended June 30, 2023. Please note that the change in the fair value of derivative instruments is determined in large part by the change in the closing price of the Company's Common Stock as of the end of the period, as compared to the closing price at the beginning of the period, with a strong inverse relationship between the fair value of our derivatives instruments and decreases in the closing price of the Company's Common Stock. Please see Note 12 to the Unaudited Condensed Consolidated Financial Statements above. The decrease in interest expense is due in large part to the Company paying off the principal balance of the EWB loan during the fiscal year ended March 31, 2023, resulting in no interest on the EWB loan incurred for the three months ended June 30, 2023.

As a result of the foregoing, our net income before the net benefit from sale of net operating loss credits for the three months ended June 30, 2023 was $1.3 million, compared to net income of $0.3 million for the comparable period of the prior fiscal year.

Liquidity and Capital Resources

Capital Resources

	June 30, 2023	March 31, 2023	Change
Current assets	$ 27,444,596	$ 21,510,297	$ 5,934,299
Current liabilities	$ 12,077,473	$ 7,833,637	$ 4,243,836
Working capital	$ 15,367,123	$ 13,676,660	$ 1,690,463

Our working capital (total current assets less total current liabilities) increased by $1.7 million from $13.7 million as of March 31, 2023 to $15.4 million as of June 30, 2023, with such increase being primarily related to the increase in finished goods inventory and accounts receivable, associated with increased customer orders during the three months ended June 30, 2023.

Summary of Cash Flows:

	For the Three Months Ended June 30,

	2023	2022
Net cash used in operating activities	$ (2,709,815)	$ (557,516)
Net cash used in investing activities	$ —	$ (94,597)
Net cash provided by financing activities	$ 3,957,223	$ 11,896,464

Net cash used in operating activities for the three months ended June 30, 2023 was $2.7 million, which included, without limitation, net income of $1.1 million, increased by depreciation and other non-cash expenses totaling $0.6 million and reduced by increases in accounts receivable and inventory totaling $4.8 million.

Net cash provided by financing activities was $4.0 million for the three months ended June 30, 2023 which consisted primarily of proceeds from related party loans payable totaling $4.0 million.

Caskey Promissory Note

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 is June 30, 2024, with an optional second year extension. The second year extension must be exercised by both parties 60 days prior to the original maturity date. As of the date of this filing, the Company does not expect to exercise the second year extension.

Hakim Promissory Note

The Company has entered into a collateralized promissory note with individual lenders with rates comparable to the EWB Term Loan but with less restrictive covenants (the "Hakim Promissory Note"). 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, CEO and Chairman of the Board of Directors, pursuant to which the Company borrowed funds in the aggregate principal amount of $3,000,000. The Hakim Promissory Note has an interest rate of 9% for the first year and 10% for an optional second year and the proceeds will be used for working capital and other business purposes. The original maturity date of the Hakim Promissory Note is June 2, 2024, with an optional second year extension. The second year extension must be exercised by both parties 60 days prior to the original maturity date. As of the date of this filing, the Company does not expect to exercise the second year extension.

East West Bank

On April 2, 2022, the Company and Elite Labs entered into a Loan and Security Agreement (the "EWB Loan Agreement") with East West Bank ("EWB"). Pursuant to the EWB Loan Agreement, the Company and Elite Labs received one term loan for a principal amount of $12,000,000 (the "EWB Term Loan") and a revolving line of credit up to $2,000,000 (the "EWB Revolver," together with the "EWB Term Loan," the EWB Loans"), each of which shall be used for working capital. As of March 31, 2023, the principal and interest on the EWB Term Loan has been paid in full by the Company and the EWB Loan Agreement is terminated.

On July 1, 2022, the 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 June 30, 2023, 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 June 30, 2023, the Company was in compliance with each financial covenant.

Lincoln Park Capital – July 8, 2020 Purchase Agreement

On July 8, 2020, the Company entered into a purchase agreement (the "2020 LPC Purchase Agreement"), and a registration rights agreement, with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which Lincoln Park has committed to purchase up to $25.0 million of the Company's Common Stock, $0.001 par value per share, from time to time over the term of the 2020 LPC Purchase Agreement, at the Company's direction. The 2020 LPC Purchase Agreement expired on August 1, 2023.

During the three months ended June 30, 2023 and 2022, the Company did not issue any shares of Common Stock to Lincoln Park.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, we are not required to provide the information required by this Item.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act, refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. As required by Rules 13a-15(b) and 15d-15(b) of the Exchange Act, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective as of June 30, 2023 at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

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

Internal control over financial reporting may not prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are achieved. Further, the design of a control system must be balanced against resource constraints,

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

Management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting. Management has used the framework set forth in the report entitled "Internal Control—Integrated Framework (2013)" published by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of our internal control over financial reporting. Based on its evaluation, management has concluded that our internal control over financial reporting was effective as of June 30, 2023 at the reasonable assurance level.

Changes in Internal Controls Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) and Rule 15d-15(f) under the Exchange Act) during the period covered by this Quarterly Report.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Pending Litigation

We may be subject from time to time to various claims and legal actions arising during the ordinary course of our business. We believe that there are currently no claims or legal actions that would reasonably be expected to have a material adverse effect on our results of operations, financial condition or cash flows.

ITEM 1A. RISK FACTORS

There have been no material changes in the risk factors described in our Annual Report on Form 10-K for the fiscal year ended March 31, 2023, except as set forth below:

If we are unable to establish and maintain sales and marketing capabilities or enter into agreements with third parties to market and sell our products, we may not be successful in commercializing our products which could have a material adverse effect on our business and financial condition.

To achieve commercial success for an approved product through direct sales, we must establish and maintain a sales and marketing organization or outsource sales and marketing services to third parties. There are risks involved with establishing and maintaining our own sales and marketing capabilities and entering into arrangements with third parties to perform these services for any of our products. For example, recruiting and training a sales force is expensive and time consuming and could delay commercialization activities. If commercialization of a product for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to successfully commercialize our products through direct sales include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- inability of marketing personnel to develop effective marketing materials;
- the inability of sales personnel to obtain access to adequate numbers of potential customers;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- the costs associated with training sales personnel on legal compliance matters and monitoring their actions;
- liability for sales personnel failing to comply with the applicable legal requirements, including the prohibition on off label promotion; and,
- unforeseen costs and expenses associated with establishing and maintaining our own sales and marketing organization.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

During the fiscal quarter ended June 30, 2023, 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 6. EXHIBITS

Exhibit No.	Description

31.1	Certification of Chief Executive 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**
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.
** Furnished herewith.

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.

August 14, 2023

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

Exhibit 31.1

CERTIFICATION BY PRINCIPAL EXECUTIVE OFFICER, PRINCIPAL FINANCIAL OFFICER AND PRINCIPAL ACCOUNTING OFFICER

I, Nasrat Hakim, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 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: August 14, 2023

/s/ Nasrat Hakim

Nasrat Hakim
Chief Executive Officer, President and
Chairman of the Board of Directors
(Principal Executive Officer, Principal Financial Officer, and Principal Accounting 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 Quarterly Report of Elite Pharmaceuticals, Inc. (the "Registrant") on Form 10-Q for the quarter ended June 30, 2023 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-Q fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: August 14, 2023

/s/ Nasrat Hakim

Nasrat Hakim
Chief Executive Officer, President and
Chairman of the Board of Directors
(Principal Executive Officer, Principal Financial Officer, and Principal Accounting 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.