

ELITE PHARMACEUTICALS INC /NV/

FORM 10-Q (Quarterly Report)

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED December 31, 2024

OR

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

Commission File Number 001-15697

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

Nevada
(State or other jurisdiction of
incorporation or organization)

22-3542636
(I.R.S. Employer
Identification No.)

165 Ludlow Avenue
Northvale, New Jersey
(Address of principal executive offices)

07647
(Zip Code)

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

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

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The number of shares outstanding of each of the registrant's classes of common stock, as of February 13, 2025:
Common Stock - 1,068,273,108 shares

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PART I - FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

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

	December 31, 2024	March 31, 2024
ASSETS		
Current assets:		
Cash	\$ 8,293,068	\$ 7,106,262
Accounts receivable, net of allowance for expected credit losses of \$220,000 and \$236,000 respectively	18,454,012	19,453,301
Inventory	20,157,890	12,930,464
Prepaid expenses and other current assets	1,144,707	524,162
Total current assets	48,049,677	40,014,189
Property and equipment, net of accumulated depreciation of \$16,738,308 and \$15,906,853 respectively	9,863,527	10,175,293
Intangible assets	7,241,228	6,341,228
Finance lease - right-of-use asset	1,890,967	2,079,658
Operating lease - right-of-use asset	2,110,917	2,355,201
Deferred income tax asset	20,689,381	22,160,895
Other assets:		
Restricted cash - debt service for NJEDA bonds	449,216	432,832
Security deposits	461,551	94,240
Total other assets	910,767	527,072
Total assets	\$ 90,756,464	\$ 83,653,536
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 5,840,356	\$ 2,714,306
Accrued expenses	3,719,013	5,301,747
Deferred revenue, current portion	8,889	13,333
Bonds payable, current portion, net of bond issuance costs	125,822	115,822
Loans payable, current portion	164,177	180,399
Related party loans payable (Note 7)	4,000,000	4,000,000
Lease obligation - finance lease, current portion	373,178	312,739
Lease obligation - operating lease, current portion	457,397	411,418
Total current liabilities	14,688,832	13,049,764
Long-term liabilities:		
Deferred revenue, net of current portion	—	5,556
Bonds payable, net of current portion and bond issuance costs	783,836	913,203
Loans payable, net of current portion and loan costs	2,268,612	2,366,487
Lease obligation - finance lease, net of current portion	1,327,602	1,480,317
Lease obligation - operating lease, net of current portion	1,676,900	1,957,383
Derivative financial instruments - warrants	33,565,024	6,298,008
Total long-term liabilities	39,621,974	13,020,954
Total liabilities	54,310,806	26,070,718
Commitments and Contingencies (Note 8)		
Shareholders' equity:		
Common Stock; par value \$0.001; 1,445,000,000 shares authorized; 1,068,373,108 shares issued as of both December 31, 2024 and March 31, 2024; 1,068,273,108 shares outstanding as of both December 31, 2024 and March 31, 2024	1,068,377	1,068,377
Additional paid-in capital	173,385,785	173,210,549
Treasury stock; 100,000 shares as of both December 31, 2024 and March 31, 2024, at cost	(306,841)	(306,841)
Accumulated deficit	(137,701,663)	(116,389,267)
Total shareholders' equity	36,445,658	57,582,818
Total liabilities and shareholders' equity	\$ 90,756,464	\$ 83,653,536

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 December 31,		For the Nine Months Ended December 31,	
	2024	2023	2024	2023
Revenue:				
Manufacturing fees	\$ 13,738,131	\$ 14,791,110	\$ 50,407,239	\$ 36,208,217
Licensing fees	626,117	747,690	1,640,417	2,467,844
Total revenue	14,364,248	15,538,800	52,047,656	38,676,061
Cost of manufacturing	8,244,907	8,497,727	29,256,109	20,437,354
Gross profit	6,119,341	7,041,073	22,791,547	18,238,707
Operating expenses:				
Research and development	1,793,803	1,403,790	5,923,424	5,165,684
General and administrative	2,724,616	1,711,275	6,967,514	4,906,187
Non-cash compensation through issuance of stock options	70,578	49,815	175,236	107,592
Depreciation and amortization	432,534	343,537	1,278,564	999,059
Total operating expenses	5,021,531	3,508,417	14,344,738	11,178,522
Income from operations	1,097,810	3,532,656	8,446,809	7,060,185
Other (expense) income:				
Change in fair value of derivative financial instruments - warrants	(11,729,368)	(2,417,772)	(27,267,016)	(5,075,489)
Change in fair value of stock-based liabilities	—	(2,854,556)	—	(4,921,376)
Interest expense and amortization of debt issuance costs	(77,607)	(121,628)	(583,524)	(371,478)
Gain from settlement agreements	—	1,761,792	—	1,761,792
Interest income	5,092	5,249	16,384	16,085
Other income	51,308	—	63,308	—
Other expense, net	(11,750,575)	(3,626,915)	(27,770,848)	(8,590,466)
Loss before income taxes	(10,652,765)	(94,259)	(19,324,039)	(1,530,281)
Income tax (expense) benefit	(239,175)	800,613	(1,988,357)	18,313,045
Net (loss) income	\$ (10,891,940)	\$ 706,354	\$ (21,312,396)	\$ 16,782,764
Basic net (loss) income per share	\$ (0.01)	\$ 0.00	\$ (0.02)	\$ 0.02
Diluted net (loss) income per share	\$ (0.01)	\$ 0.00	\$ (0.02)	\$ 0.02
Basic weighted average common stock outstanding	1,068,273,108	1,014,768,071	1,068,273,108	1,014,265,162
Diluted weighted average common stock outstanding	1,068,273,108	1,024,448,445	1,068,273,108	1,019,511,813

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 Capital	Treasury Stock		Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Shares	Amount		Shares	Amount		
Balance as of March 31, 2024	—	\$ —	1,068,373,108	\$1,068,377	\$173,210,549	100,000	\$(306,841)	\$(116,389,267)	\$ 57,582,818
Net income	—	—	—	—	—	—	—	615,773	615,773
Non-cash compensation through the issuance of employee stock options	—	—	—	—	52,329	—	—	—	52,329
Balance at June 30, 2024	<u>—</u>	<u>\$ —</u>	<u>1,068,373,108</u>	<u>\$1,068,377</u>	<u>\$173,262,878</u>	<u>100,000</u>	<u>\$(306,841)</u>	<u>\$(115,773,494)</u>	<u>\$ 58,250,920</u>
Net loss	—	—	—	—	—	—	—	(11,036,229)	(11,036,229)
Non-cash compensation through the issuance of employee stock options	—	—	—	—	52,329	—	—	—	52,329
Balance at September 30, 2024	<u>—</u>	<u>\$ —</u>	<u>1,068,373,108</u>	<u>\$1,068,377</u>	<u>\$173,315,207</u>	<u>100,000</u>	<u>\$(306,841)</u>	<u>\$(126,809,723)</u>	<u>\$ 47,267,020</u>
Net loss	—	—	—	—	—	—	—	(10,891,940)	(10,891,940)
Non-cash compensation through the issuance of employee stock options	—	—	—	—	70,578	—	—	—	70,578
Balance at December 31, 2024	<u>—</u>	<u>\$ —</u>	<u>1,068,373,108</u>	<u>\$1,068,377</u>	<u>\$173,385,785</u>	<u>100,000</u>	<u>\$(306,841)</u>	<u>\$(137,701,663)</u>	<u>\$ 36,445,658</u>

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 Capital	Treasury Stock		Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Shares	Amount		Shares	Amount		
Balance as of March 31, 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	<u>—</u>	<u>\$ —</u>	<u>1,013,915,081</u>	<u>\$1,014,019</u>	<u>\$164,765,980</u>	<u>100,000</u>	<u>\$(306,841)</u>	<u>\$(135,356,089)</u>	<u>\$ 30,117,069</u>
Net income	—	—	—	—	—	—	—	14,934,601	14,934,601
Non-cash compensation through the issuance of employee stock options	—	—	—	—	42,777	—	—	—	42,777
Balance at September 30, 2023	<u>—</u>	<u>\$ —</u>	<u>1,013,915,081</u>	<u>\$1,014,019</u>	<u>\$164,808,757</u>	<u>100,000</u>	<u>\$(306,841)</u>	<u>\$(120,421,488)</u>	<u>\$ 45,094,447</u>
Shares issued in satisfaction of accrued director salaries	—	—	1,642,971	1,643	250,224	—	—	—	251,867
Shares issued in satisfaction of accrued consultant fees	—	—	2,223,147	2,223	309,015	—	—	—	311,238
Net income	—	—	—	—	—	—	—	706,354	706,354
Non-cash compensation through the issuance of employee stock options	—	—	—	—	49,815	—	—	—	49,815
Balance at December 31, 2023	<u>—</u>	<u>\$ —</u>	<u>1,017,781,199</u>	<u>\$1,017,885</u>	<u>\$165,417,811</u>	<u>100,000</u>	<u>\$(306,841)</u>	<u>\$(119,715,134)</u>	<u>\$ 46,413,721</u>

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 Nine Months Ended December 31,	
	2024	2023
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net (loss) income	\$ (21,312,396)	\$ 16,782,764
Adjustments to reconcile net (loss) income to net cash provided by (used in) operating activities:		
Depreciation and amortization	936,007	992,136
Provision for losses on accounts receivable	(15,943)	194,600
Amortization of operating leases - right-of-use assets	323,281	18,153
Amortization of finance leases - right-of-use assets	342,557	6,923
Amortization of debt discount - bonds offering costs	10,633	—
Loss on asset disposal	121,481	—
Change in fair value of derivative financial instruments - warrants	27,267,016	5,075,489
Non-cash compensation accrued	—	563,105
Gain on settlement of Common Stock to consultant	—	(1,761,792)
Change in fair value of stock-based liabilities	—	4,921,376
Deferred tax expense (benefit)	1,471,514	(18,061,782)
Non-cash compensation through the issuance of employee stock options	175,236	107,592
Change in operating assets and liabilities:		
Accounts receivable	1,015,232	(13,109,665)
Inventory	(7,227,426)	(4,774,325)
Prepaid expenses and other current assets	(422,088)	27,149
Security deposits	(367,311)	13,759
Accounts payable	3,126,050	25,490
Accrued expenses	(1,582,734)	3,677,335
Deferred revenue	(10,000)	(10,001)
Lease obligations - operating leases	(313,501)	(20,005)
Interest expense on finance lease liability	—	(2,915)
Net cash provided by (used in) operating activities	3,537,608	(5,334,614)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(870,972)	(406,007)
Purchase of intangible assets	(900,000)	—
Proceeds from disposition of property and equipment	125,250	—
Net cash used in investing activities	(1,645,722)	(406,007)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payment of bond principal	(130,000)	(125,000)
Proceeds from related party loans payable	—	4,000,000
Payments on principal on finance lease obligations	(246,142)	—
Loan payments	(312,554)	(134,850)
Net cash (used in) provided by financing activities	(688,696)	3,740,150
Net change in cash and restricted cash	1,203,190	(2,000,471)
Cash and restricted cash, beginning of period	7,539,094	8,244,681
Cash and restricted cash, end of period	<u>\$ 8,742,284</u>	<u>\$ 6,244,210</u>
Supplemental disclosure of cash and non-cash transactions:		
Cash paid for interest	\$ 503,593	\$ 119,412
Cash paid for income taxes	\$ 740,262	\$ 292,000
Finance directors and officers insurance premium	\$ 198,457	\$ —
Recognition of finance lease right of use asset and lease liabilities entered into	\$ 153,870	\$ 272,620
Recognition of operating lease right of use asset and lease liabilities entered into	\$ 78,997	\$ —
Stock issued in satisfaction of accrued directors salaries and consultant fees	\$ —	\$ 563,105
Reconciliation of cash and restricted cash		
Cash	\$ 8,293,068	\$ 5,816,211
Restricted cash - debt service for NJEDA bonds	449,216	427,999
Total cash and restricted cash shown in statement of cash flows	<u>\$ 8,742,284</u>	<u>\$ 6,244,210</u>

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 July 1, 2024. The interim results for the nine months ended December 31, 2024 are not necessarily indicative of the results to be expected for the fiscal year ending March 31, 2025 or for any future periods.

Reclassification

Certain items in prior condensed consolidated financial statements have been reclassified to conform to the current presentation. The presentation of the condensed consolidated statements of cash flows has been modified to separately present the change in the security deposits for the nine months ended December 31, 2023. Additionally, the presentation of Note 4 has been modified to separately disclose accrued interest related to the Company’s related party loan. These reclassifications had no effect on the reported results of operations.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make certain estimates and assumptions. These estimates and assumptions affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, as well as reported amounts of revenues and expenses during the reporting period. Such management estimates and assumptions include, but are not limited to, standalone selling price for each distinct performance obligation included in customer contracts with multiple performance obligations, the period of benefit for deferred commissions, valuation of intangible assets, the useful life of property and equipment and identifiable intangible assets, stock-based compensation expense and income taxes. Actual results could differ from those estimates.

Segment Information

Financial Accounting Standards Board (“FASB”) Accounting Standards Codification 280 (“ASC 280”), Segment Reporting, establishes standards for reporting information about operating segments. Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, 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.

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

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. The Company paused further development of NDAs and has not engaged in business activities. Accordingly, during the three and nine months ended December 31, 2024 and 2023, the Company has only engaged in business activities in a single operating segment.

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 consolidated financial statements. Please see Note 13 for further details.

Revenue Recognition

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

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

Nature of goods and services

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

a) Manufacturing Fees

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

The Company recognizes 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 December 31, 2024.

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

c) Sale of product under the Elite label

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 have been replaced with revenues from sales of Elite labeled pharmaceutical products to distributors for pharmacies and institutions.

The Company recognizes revenue when the customer obtains control of the Company's product based on the contractual shipping terms, at which time the performance obligation is deemed to be completed. The Company is primarily responsible for fulfilling the promise to deliver the product and bears risk of loss while the inventory is in-transit to the purchaser. Revenue is measured as the amount of consideration earned from the sale of Elite labeled pharmaceutical products are recorded at their net realizable value which consists of gross amounts invoiced reduced by contractual reductions, including, without limitation, chargebacks, discounts and program rebates, as applicable.

The Company provides for chargebacks to wholesalers for sales to various end-customers to include, but not limited to, hospitals, group purchasing organizations, and pharmacies. Chargebacks represent the difference between the price the wholesaler pays and the price that the end-customer pays for a product. The company's estimate for chargebacks is developed based upon management's assumption of anticipated product returns, other rebates, as well as historical information.

Disaggregation of revenue

In the following table, revenue is disaggregated by type of revenue generated by the Company. The Company recognizes revenue at a point in time for all performance obligations. During the nine months ended December 31, 2024 and 2023, the Company had paused further development of NDAs and has not engaged in business activities in that segment. Accordingly, during the nine months ended December 31, 2024 and 2023, the Company has only engaged in business activities in a single operating segment. The table also includes a reconciliation of the disaggregated revenue with the reportable segment:

	For the Three Months Ended December		For the Nine Months Ended December 31,	
	31,		2024	2023
	2024	2023	2024	2023
ANDA:				
Manufacturing fees	\$ 13,738,131	\$ 14,791,110	\$ 50,407,239	\$ 36,208,217
Licensing fees	626,117	747,690	1,640,417	2,467,844
Total revenue	<u>\$ 14,364,248</u>	<u>\$ 15,538,800</u>	<u>\$ 52,047,656</u>	<u>\$ 38,676,061</u>

Selected information on reportable segments and reconciliation of operating income by segment to income from operations before income taxes are disclosed within Note 13.

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Restricted Cash

As of December 31, 2024, and March 31, 2024, the Company had \$449,216 and \$432,832, of restricted cash, respectively, related to debt service reserve in regard to the New Jersey Economic Development Authority (“NJEDA”) bonds (see Note 5).

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.

There were no such impairments recorded during the nine months ended December 31, 2024 and 2023. The Company notes that none of its patents relate to any of the Company’s revenue producing activities.

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

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The following table summarizes the Company's intangible assets as of December 31, 2024 and March 31, 2024:

December 31, 2024						
	Estimated Useful Life	Gross Carrying Amount	Additions	Impairment losses	Accumulated Amortization	Net Book Value
Patent application costs	*	\$ 289,039	\$ —	\$ —	\$ —	\$ 289,039
ANDA acquisition costs	Indefinite	6,052,189	900,000	—	—	6,952,189
		<u>\$ 6,341,228</u>	<u>\$ 900,000</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 7,241,228</u>
March 31, 2024						
	Estimated Useful Life	Gross Carrying Amount	Additions	Impairment losses	Accumulated Amortization	Net Book Value
Patent application costs	*	\$ 289,039	\$ —	\$ —	\$ —	\$ 289,039
ANDA acquisition costs	Indefinite	6,052,189	—	—	—	6,052,189
		<u>\$ 6,341,228</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 6,341,228</u>

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

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.

Due to temporary differences in the timing of recognition of items included in income for accounting and tax purposes, deferred tax assets or liabilities are recorded to reflect the impact arising from these differences on future tax payments. 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 December 31, 2024, a summary of the tax years that remain subject to examination in our major tax jurisdictions are: United States – Federal, 2020 and forward. The Company did not record unrecognized tax positions for the nine months ended December 31, 2024.

(Loss) Income Per Share Attributable to Common Shareholders'

The Company follows ASC 260, *Earnings Per Share*, which requires presentation of basic and diluted (loss) income 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 (loss) income per share is computed by dividing net (loss) income by the weighted average number of shares of Common Stock outstanding during the period.

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As the Company was in a net loss position for the three and nine months ended December 31, 2024, the potential dilution from the warrants converting into 79,008,661 shares of Common Stock and the stock options converting into 15,760,000 shares of Common Stock for these periods have been excluded from the number of shares used in calculating diluted net (loss) income per share as their inclusion would have been antidilutive.

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

	For the Three Months Ended December 31,		For the Nine Months Ended December 31,	
	2024	2023	2024	2023
Numerator				
Net (loss) income - basic	\$ (10,891,940)	\$ 706,354	\$ (21,312,396)	\$ 16,782,764
Effect of dilutive instrument on net income	—	—	—	—
Net (loss) income - diluted	<u>\$ (10,891,940)</u>	<u>\$ 706,354</u>	<u>\$ (21,312,396)</u>	<u>\$ 16,782,764</u>
Denominator				
Weighted average shares of common stock outstanding - basic	1,068,273,108	1,014,768,071	1,068,273,108	1,014,265,162
Dilutive effect of stock options and convertible securities	—	9,680,374	—	5,246,651
Weighted average shares of common stock outstanding - diluted	<u>1,068,273,108</u>	<u>1,024,448,445</u>	<u>1,068,273,108</u>	<u>1,019,511,813</u>
Net (loss) income per share				
Basic	\$ (0.01)	\$ 0.00	\$ (0.02)	\$ 0.02
Diluted	<u>\$ (0.01)</u>	<u>\$ 0.00</u>	<u>\$ (0.02)</u>	<u>\$ 0.02</u>

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.

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Measured on a Recurring Basis

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

	Amount at Fair Value	Fair Value Measurement		
		Level 1	Level 2	Level 3
Balance as of March 31, 2024	\$ 6,298,008	\$ —	\$ —	\$ 6,298,008
Change in fair value of derivative financial instruments - warrants	27,267,016	—	—	27,267,016
Balance as of December 31, 2024	<u>\$ 33,565,024</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 33,565,024</u>

	Amount at Fair Value	Fair Value Measurement		
		Level 1	Level 2	Level 3
Balance as of March 31, 2023	\$ 521,711	\$ —	\$ —	\$ 521,711
Change in fair value of derivative financial instruments - warrants	5,075,489	—	—	5,075,489
Balance as of December 31, 2023	<u>\$ 5,597,200</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 5,597,200</u>

See Note 10 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, and related party loans payable approximates fair value.

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

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

Recently Issued Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09 (Topic 740), Improvements to income tax disclosures, which enhances the disclosure requirements for the income tax rate reconciliation, domestic and foreign income taxes paid, requiring disclosure of disaggregated income taxes paid by jurisdiction, unrecognized tax benefits, and modifies other income tax-related disclosures. The amendments are effective for annual periods beginning after December 15, 2024. Early adoption is permitted and should be applied prospectively. The Company is currently evaluating the effect of adopting this guidance on its condensed consolidated financial statements.

In November 2023, the FASB issued ASU 2023-07, "Segment Reporting (Topic 280): Improvements to Reportable Segments," which aims to improve financial reporting by requiring disclosure of incremental segment information on an annual and interim basis for all public entities to enable investors to develop more decision-useful financial analyses. Currently, Topic 280 requires that a public entity disclose certain information about its reportable segments. Topic 280 also requires other specified segment items and amounts to be disclosed under certain circumstances. The amendments in this ASU do not change or remove those disclosure requirements and do not change how a public entity identifies its operating segments, aggregates those operating segments, or applies the quantitative thresholds to determine its reportable segments. This ASU is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company does not expect that the requirements of ASU 2023 – 07 will have a material impact on its condensed consolidated financial statements.

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

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

NOTE 2. INVENTORY

Inventory consisted of the following:

	December 31, 2024	March 31, 2024
Finished goods	\$ 7,310,110	\$ 4,465,970
Work-in-progress	2,700,935	1,804,426
Raw materials	10,146,845	6,660,068
Inventory	<u>\$ 20,157,890</u>	<u>\$ 12,930,464</u>

NOTE 3. PROPERTY AND EQUIPMENT, NET

Property and equipment consisted of the following:

	December 31, 2024	March 31, 2024
Land, building and improvements	\$ 11,649,918	\$ 11,061,149
Laboratory, manufacturing, warehouse and transportation equipment	14,021,898	14,090,978
Office equipment and software	373,601	373,601
Furniture and fixtures	556,418	556,418
Property and equipment, gross	<u>26,601,835</u>	<u>26,082,146</u>
Less: Accumulated depreciation	(16,738,308)	(15,906,853)
Property and equipment, net	<u>\$ 9,863,527</u>	<u>\$ 10,175,293</u>

Depreciation expense was \$313,060 and \$336,614 for the three months ended December 31, 2024 and 2023, respectively, and \$936,007 and \$992,136 for the nine months ended December 31, 2024 and 2023, respectively.

NOTE 4. ACCRUED EXPENSES

As of December 31, 2024 and March 31, 2024, the Company's accrued expenses consisted of the following:

	December 31, 2024	March 31, 2024
Co-development profit split	\$ 1,858,629	\$ 3,684,587
Employee bonuses	619,374	206,225
Income tax	505,908	485,327
Legal and professional expense	73,510	90,000
Audit fees	50,000	125,000
Director dues	22,500	22,500
Consultant contract fees	—	20,000
Salaries and fees payable	170,579	—
Accrued interest - related parties	100,000	90,000
Other accrued expenses	318,513	578,108
Total accrued expenses	<u>\$ 3,719,013</u>	<u>\$ 5,301,747</u>

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NOTE 5. NJEDA BONDS

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

In relation to the Series A Notes, the Company is required to maintain a debt service reserve. The debt service reserve is classified as restricted cash on the accompanying condensed 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:

	December 31, 2024	March 31, 2024
Gross bonds payable		
NJEDA Bonds - Series A Notes	\$ 990,000	\$ 1,120,000
Less: Current portion of bonds payable (prior to deduction of bond offering costs)	(140,000)	(130,000)
Long-term portion of bonds payable (prior to deduction of bond offering costs)	\$ 850,000	\$ 990,000
Bond offering costs		
Bond offering costs	\$ 354,454	\$ 354,454
Less: Accumulated amortization	(274,112)	(263,479)
Bond offering costs, net	\$ 80,342	\$ 90,975
Current portion of bonds payable - net of bond offering costs		
Current portions of bonds payable	\$ 140,000	\$ 130,000
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	\$ 125,822	\$ 115,822
Long term portion of bonds payable - net of bond offering costs		
Long term portion of bonds payable	\$ 850,000	\$ 990,000
Less: Bond offering costs to be amortized subsequent to the next 12 months	(66,164)	(76,797)
Long term portion of bonds payable, net of bond offering costs	\$ 783,836	\$ 913,203

Amortization expense was \$3,544 and \$3,540 for the three months ended December 31, 2024 and 2023, respectively, and \$10,633 and \$10,636 for the nine months ended December 31, 2024 and 2023, respectively. Interest payable was \$21,450 and \$6,067 as of December 31, 2024 and March 31, 2024, respectively. Interest expense was \$16,088 and \$18,200 for the three months ended December 31, 2024 and 2023, respectively, and \$51,783 and \$57,985 for the nine months ended December 31, 2024 and 2023, respectively.

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

Years ending March 31,	Amount
Remainder of 2025	\$ —
2026	140,000
2027	150,000
2028	160,000
2029	170,000
Thereafter	370,000
	\$ 990,000

NOTE 6. LOANS PAYABLE

Loans payable consisted of the following:

	December 31, 2024	March 31, 2024
Mortgage loan payable 4.75% interest and maturing June 2032	\$ 2,355,991	\$ 2,418,426
Equipment and insurance financing loans payable, between 5.99% and 12.02% interest and maturing between April 2025 and October 2025	76,798	128,460
Less: Current portion of loans payable	(164,177)	(180,399)
Long-term portion of loans payable	\$ 2,268,612	\$ 2,366,487

The interest expense associated with the loans payable was \$31,089 and \$30,384 for the three months ended December 31, 2024 and 2023, respectively, and \$99,104 and \$101,478 for the nine months ended December 31, 2024 and 2023, respectively.

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

Future principal balances

Years ending March 31,	Amount
Remainder of 2025	\$ 66,306
2026	120,747
2027	92,772
2028	94,433
2029	98,447
Thereafter	1,960,084
Total remaining principal balance	<u>\$ 2,432,789</u>

NOTE 7. RELATED PARTY LOANS PAYABLE

The Company has entered into a collateralized promissory note with individual lenders with rates comparable to the EWB Term Loan but with fewer 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 were used for working capital and other business purposes. The original maturity date of the Hakim Promissory Note was June 2, 2024, with an optional second year extension. The second year extension was exercised pursuant to the terms of the Hakim Promissory Note.

For the three and nine months ended December 31, 2024, interest expense on the Hakim Promissory Note totaled \$75,000 and \$217,500 respectively, and is recorded on the Condensed Consolidated Balance Sheets in accrued expenses and on the Condensed Consolidated Statements of Operations in interest expense and amortization of debt issuance costs.

For the three and nine months ended December 31, 2023, interest expense totaled \$67,500, and \$202,500, respectively, and is recorded on the Condensed Consolidated Balance Sheets in accrued expenses and on the Condensed Consolidated Statements of Operations in interest expense and amortization of debt issuance costs.

On June 30, 2023, the Company entered into a collateralized promissory note with Davis Caskey (the “Caskey Promissory Note”). The Caskey Promissory Note has a principal balance of \$1,000,000 and an interest rate of 9% for the first year and 10% for an optional second year. The Caskey Promissory Note is subject to the same covenants as are contained in the Hakim Promissory Note. The proceeds will be used for working capital and other business purposes. The original maturity date of the Caskey Promissory Note was June 30, 2024, with an optional second year extension. The second year extension was exercised pursuant to the terms of the Caskey Promissory Note.

For the three and nine months ended December 31, 2024, interest expense on the Caskey Promissory Note totaled \$25,000 and \$72,500 respectively, and is recorded on the Condensed Consolidated Balance Sheets in accrued expenses and on the Condensed Consolidated Statements of Operations in interest expense and amortization of debt issuance costs.

For the three and nine months ended December 31, 2023, interest expense totaled \$22,500, and \$67,500, respectively, and is recorded on the Condensed Consolidated Balance Sheets in accrued expenses and on the Condensed Consolidated Statements of Operations in interest expense and amortization of debt issuance costs.

NOTE 8. 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.

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On August 17, 2023, Elite filed a paragraph IV certification with its ANDA to generic Oxycontin and after Elite got acceptance of the ANDA by the FDA on September 19, 2023, Elite sent the patentee and NDA holder a Notice Letter as required under the Hatch-Waxman Act. On November 14, 2023, a patent infringement suit was filed in the District Court of New Jersey by Purdue Pharma. Elite has obtained several agreements with Purdue to stay the litigation, with the latest being a stipulation and proposed order submitted by the participants on January 30, 2025 staying the proceedings for 30 days. Elite's launch of a generic Oxycontin will depend on the approval by the FDA and the outcome of various litigation involving Purdue or the expiry of the patents listed on the Orange Book. As of December 31, 2024, the results of such proceedings cannot be predicted with certainty and are neither probable nor estimable.

Operating Leases

In October 2020, the Company entered into an operating lease for office space in Pompano Beach, Florida (the "Pompano Office Lease"). The Pompano Office Lease is for approximately 1,275 square feet of office space, with the Company taking occupancy on November 1, 2020. The Pompano Office Lease had a term of three years, ending on October 31, 2023. The Pompano Office Lease was extended for one additional year to October 31, 2024. Accordingly, the Pompano Office Lease expired at the end of the renewal term on October 31, 2024.

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

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

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

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

Finance Leases

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

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

In February 2024, the Company entered into a finance lease for equipment (the "February 2024 Equipment Lease"). The February 2024 Equipment Lease is related to manufacturing equipment with an acquisition cost of \$455,000, with the Company taking ownership of the asset during February 2024. The February 2024 Equipment Lease has a term of five years, ending in February 2029. The Company will retain ownership of the equipment at lease termination.

In March 2024, the Company entered into three separate finance leases for manufacturing assets (the "March 2024 Equipment Leases"). The March 2024 Equipment Leases are related to manufacturing equipment and vault installed at the Company's facility located at 144 Ludlow Avenue, Northvale NJ with an aggregate acquisition cost of \$1,100,000. Each of the separate leases included in the March 2024 Equipment Leases have a term of five years, ending in March 2029. The Company will retain ownership of all related assets at lease termination.

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

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

separately.

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

Lease	Classification	December 31, 2024	March 31, 2024
Assets			
Finance	Finance lease – right-of-use asset	\$ 1,890,967	\$ 2,079,658
Operating	Operating lease – right-of-use asset	2,110,917	2,355,201
Total leased assets		<u>\$ 4,001,884</u>	<u>\$ 4,434,859</u>
Liabilities			
Current			
Finance	Lease obligation – finance lease	\$ 373,178	\$ 312,739
Operating	Lease obligation – operating lease	457,397	411,418
Long-term			
Finance	Lease obligation – finance lease, net of current portion	1,327,602	1,480,317
Operating	Lease obligation – operating lease, net of current portion	1,676,900	1,957,383
Total lease liabilities		<u>\$ 3,835,077</u>	<u>\$ 4,161,857</u>

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

Lease	For the Three Months Ended December 31,		For the Nine Months Ended December 31,	
	2024	2023	2024	2023
Ludlow-144	\$ 152,602	\$ —	\$ 455,632	\$ —
Pompano-2311	2,696	7,565	18,870	20,603
NBV-610	7,303	—	7,303	—

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

Years ending March 31,	Operating Lease Amount	Financing Lease Amount	Total
Remainder of 2025	\$ 162,079	\$ 129,734	\$ 291,813
2026	653,092	517,241	1,170,333
2027	667,307	484,151	1,151,458
2028	666,207	479,337	1,145,544
2029	440,159	438,045	878,204
Thereafter	—	13,740	13,740
Less: interest	(454,547)	(361,468)	(816,015)
Present value of lease payments	<u>\$ 2,134,297</u>	<u>\$ 1,700,780</u>	<u>\$ 3,835,077</u>

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

Lease Term and Discount Rate	For the Nine Months Ended December 31,	
	2024	2023
Remaining lease term (years)		
Operating leases	3.9	0.8
Finance leases	4.1	4.9
Discount rate		
Operating leases	10.0%	6.0%
Finance leases	9.5%	12.5%

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NOTE 9. 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 10. 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 December 31, 2024 and March 31, 2024.

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 24,034 shares of its Series J Preferred and warrants to purchase an aggregate of 79,008,661 shares of its Common Stock (the “Series J Warrants” and, along with the Series J Preferred issued to Hakim, the “Securities”) in exchange for 158,017,321 shares of Common Stock owned by Hakim. The fair value of the Series J Warrants was determined to be \$6,474,674 upon issuance at April 28, 2017.

The Series J Warrants are exercisable for a period of 10 years from the date of issuance, commencing April 28, 2020. The initial exercise price is \$0.1521 per share and the Series J Warrants can be exercised for cash or on a cashless basis, including a provision within that provides the holder a choice of net cash settlement or settlement in shares upon a cashless exercise. The net cash settlement amount is the cash value obtained by subtracting the then exercise price from the closing price of the Company’s Common Stock (provided such closing price is higher than the exercise price) and multiplying the difference by the number of shares exercised. As this event is at the holder’s option, it is considered outside of the Company’s control. As a result of the net cash settlement at the option of the holder, such warrants are classified as liabilities and measured initially and subsequently at fair value.

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

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

	December 31, 2024	March 31, 2024
Fair value of the Company’s Common Stock	\$ 0.5411	\$ 0.1543
Volatility	82.90%	72.90%
Initial exercise price	\$ 0.1521	\$ 0.1521
Warrant term (in years)	2.3	3.1
Risk free rate	4.25%	4.40%

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

Balance at March 31, 2023	\$ 521,711
Change in fair value of derivative financial instruments - warrants	5,776,297
Balance at March 31, 2024	\$ 6,298,008
Change in fair value of derivative financial instruments - warrants	27,267,016
Balance at December 31, 2024	<u>\$ 33,565,024</u>

NOTE 11. STOCK-BASED COMPENSATION

Part of the compensation paid by the Company to employees consists of the granting of options to purchase Common Stock.

Stock-based Director Compensation

The Company’s Director compensation policy, instituted in October 2009, further revised in January 2016, and ceased issuance in November 2023, 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.

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As of December 31, 2024, there was no common stock owed to Directors as the amount outstanding was paid during fiscal year 2024.

As of December 31, 2023, the Company accrued director's fees totaling \$22,500, which will be paid via cash payments totaling \$22,500 and the issuance of shares of Common Stock, 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.

Balance of common stock owed at April 1, 2023	\$	60,000
Awarded shares		—
Change in fair value of stock-based liabilities		191,867
Issuance of common stock on November 22, 2023		(251,867)
Balance of common stock owed at December 31, 2023	\$	<u>—</u>

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.

As of December 31, 2024, the Company accrued no additional salaries owed to the Company's President, Chief Executive Officer and certain other employees.

Balance of common stock owed at April 1, 2023	\$	4,278,333
Awarded shares		—
Change in fair value of stock-based liabilities		4,729,509
Common stock issued		(311,238)
Settlement of non-cash liability		(1,761,792)
Balance of common stock owed at December 31, 2023	\$	<u>6,934,812</u>

On November 6, 2023, the Company entered into a Settlement Agreement with a former executive who was terminated on February 7, 2022. The employment agreement with the former executive included annual compensation of \$250,000 which was to be paid via the issuance of shares of Common Stock. At the date of the former executive's termination an aggregate of 14,892,580 shares of Common Stock (the "Deferred Shares") were due to the former executive, with such number of shares representing an aggregate of \$1,000,000 in compensation earned pursuant to the relevant employment agreement at an annual rate of \$250,000. Pursuant to the Settlement Agreement, the former executive irrevocably elected to relinquish all rights and claims to the Deferred Shares. The Company is released of any obligation to issue the Deferred Shares and further acknowledges that no Deferred Shares will be issued to or received by the former employee. The price of the Company's Common Stock on November 6, 2023 was \$0.1183 per share and the value of the Deferred Shares on this date was \$1,761,792. The Company recorded other income from gain on settlement agreement for this amount on the unaudited Condensed Consolidated Statements of Operations.

On December 29, 2023, the Company issued 2,223,147 shares of Common Stock in satisfaction of accrued consultant fees.

Options

Under its 2014 Equity Incentive Plan and its 2024 Equity Incentive Plan, the Company did grant and may grant stock options to officers, selected employees, as well as members of the Board of Directors and advisory board members. On July 1, 2024 the Company restated the 2014 Equity Incentive Plan to increase the shares reserved under the option plan by 12,730,000. Under the 2024 Equity Incentive Plan, 80,000,000 options are available for grant. All options have generally been granted at a price equal to or greater than the fair market value of the Company's Common Stock at the date of the grant. Generally, options are granted with a vesting period of up to three years and expire ten years from the date of grant.

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

The grant date fair value of option awards is determined using the Black Scholes option-pricing model. No options were issued the nine months ended December 31, 2024 and 2023.

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

	Shares Underlying Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at March 31, 2024	15,730,000	\$ 0.05	8.8	\$ 1,626,748
Granted	90,000	0.21	—	\$ —
Expired and Forfeited	(60,000)	0.09	—	\$ —
Outstanding at December 31, 2024	15,760,000	\$ 0.05	8.0	\$ 7,696,223
Exercisable at December 31, 2024	6,546,668	\$ 0.06	7.7	\$ 3,177,814

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 December 31, 2024 of \$0.54 for those awards with strike prices lower than the quoted price of the Company's Common Stock as of December 31, 2024. As of December 31, 2024, there was \$280,495 in unrecognized stock based compensation expense that will be recognized over a weighted average 1.48 year period.

NOTE 12. CONCENTRATIONS AND CREDIT RISK

Revenues

Two customers accounted for approximately 64% of the Company's revenues for the nine months ended December 31, 2024. These two customers accounted for approximately 41% and 23%, of revenues each, respectively.

Two customers accounted for approximately 57% of the Company's revenues for the nine months ended December 31, 2023. These two customers accounted for approximately 30% and 27%, of revenues each, respectively.

Accounts Receivable

Two customers accounted for approximately 76% of the Company's accounts receivable as of December 31, 2024. These two customers accounted for approximately 47% and 29% of accounts receivable each, respectively.

Two customers accounted for approximately 77% of the Company's accounts receivable as of December 31, 2023. These two customers accounted for approximately 45% and 32% of accounts receivable each, respectively.

Purchasing

Three suppliers accounted for approximately 71% of the Company's purchases of raw materials for the nine months ended December 31, 2024. These three suppliers accounted for approximately 39%, 16%, and 16%, of purchasing each, respectively.

Two supplier accounted for approximately 43% of the Company's purchases of raw materials for the nine months ended December 31, 2023. These two customers accounted for approximately 30% and 13%, of purchasing each, respectively.

NOTE 13. 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 historically 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. During fiscal years ended March 31, 2024 and 2023, the Company had paused further development of NDAs and has not engaged in business activities in that segment. Accordingly, during the nine months ended December 31, 2024 and 2023, the Company has only engaged in business activities in a single operating segment.

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 consolidated financial statements.

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

	For the Three Months Ended December 31,		For the Nine Months Ended December 31,	
	2024	2023	2024	2023
Operating Income by Segment				
ANDA	\$ 4,325,538	\$ 5,637,283	\$ 16,868,123	\$ 13,073,023
Operating income by Segment	<u>\$ 4,325,538</u>	<u>\$ 5,637,283</u>	<u>\$ 16,868,123</u>	<u>\$ 13,073,023</u>

The Company notes that there was no revenue related to the NDA segment for the three and nine months ended December 31, 2024 and 2023.

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

	For the Three Months Ended December 31,		For the Nine Months Ended December 31,	
	2024	2023	2024	2023
Operating income by segment	\$ 4,325,538	\$ 5,637,283	\$ 16,868,123	\$ 13,073,023
Corporate unallocated costs	(2,724,616)	(1,711,275)	(6,967,514)	(4,906,187)
Interest income	5,092	5,249	16,384	16,085
Interest expense and amortization of debt issuance costs	(77,607)	(121,628)	(583,524)	(371,478)
Depreciation and amortization expense	(432,534)	(343,537)	(1,278,564)	(999,059)
Significant non-cash items	(70,578)	(49,815)	(175,236)	(107,592)
Change in fair value of derivative instruments	(11,729,368)	(2,417,772)	(27,267,016)	(5,075,489)
Change in fair value of stock-based liabilities	—	(2,854,556)	—	(4,921,376)
Gain from settlement agreements	—	1,761,792	—	1,761,792
Other income	51,308	—	63,308	—
Loss before income taxes	<u>\$ (10,652,765)</u>	<u>\$ (94,259)</u>	<u>\$ (19,324,039)</u>	<u>\$ (1,530,281)</u>

NOTE 14. RELATED PARTY AGREEMENTS

Mikah Pharma, LLC Agreements

In May 2020, Praxgen (formerly known as SunGen Pharma LLC), pursuant to an asset purchase agreement, assigned its rights and obligations under the Praxgen Agreement for Amphetamine IR and Amphetamine ER to Mikah Pharma LLC ("Mikah"). The ANDAs for Amphetamine IR and Amphetamine ER are now registered under Elite's name. Mikah will now be Elite's partner with respect to Amphetamine IR and ER and will assume all the rights and obligations for these products from Praxgen. Mikah was founded in 2009 by Nasrat Hakim, a related party and the Company's President, Chief Executive Officer and Chairman of the Board.

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

As of December 31, 2024, the Company owes an aggregate of \$1,858,629 to Mikah in accordance with the agreements, with such amount being recorded as an accrued expense on the unaudited condensed consolidated balance sheets.

NOTE 15. INCOME TAXES

The determination of income tax expense in the accompanying unaudited condensed consolidated statements of income is based on the effective tax rate for the year, adjusted for the impact of any discrete items which are accounted for in the period in which they occur. The Company's income tax (expense)/benefit was \$(239,175) and \$800,613 for the three months ended December 31, 2024 and 2023, respectively. The Company's income tax (expense)/benefit was \$(1,988,357) and \$18,313,045 for the nine months ended December 31, 2024 and 2023, respectively.

NOTE 16. SUBSEQUENT EVENTS

On February 9, 2025, the FDA notified the Company of its approval of the Company's newly constructed facility at 144 Ludlow Avenue, Northvale NJ as a commercial packaging site.

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 Nine Months Ended December 31, 2024 and 2023 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, 2024. 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, and the manufacture of generic pharmaceuticals. Our strategy includes developing generic versions of controlled-release drug products with high barriers to entry.

We occupy manufacturing, warehouse, laboratory and office space at 135, 144 and 165 Ludlow Avenue in Northvale, NJ (the “Northvale Facility”). The Northvale Facility operates under Current Good Manufacturing Practice 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 North Bay Village, Florida (the “NBV 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 products co-developed with partners; (iv) commercial exploitation of our products either by sales under our own label, license and the collection of royalties, or through the manufacture of our formulations; and (v) development of new products for sale under our own label, and the expansion of our licensing agreements with other pharmaceutical companies, including co-development projects, joint ventures and other collaborations.

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

On May 20, 2024, the Company reported that it received approval from the FDA for a generic version of Methotrexate Sodium 2.5mg tablets (“Generic Methotrexate”). Methotrexate Sodium belongs to a class of drugs known as antimetabolites and will be sold under the Elite Laboratories Inc. label. Generic Methotrexate was launched commercially on August 27, 2024.

On June 17, 2024, the Company entered into an asset purchase agreement with Nostrum Laboratories Inc. (the “Nostrum Asset Purchase Agreement”), pursuant to which the Company acquired all rights in and to the approved ANDAs as well as royalty free, non-exclusive perpetual licenses to use the manufacturing technology, proprietary information, processes, techniques, protocols, methods, know-how and improvements necessary to manufacture the following products:

- Hydrocodone Bitartrate and Acetaminophen tablets
- Oxycodone Hydrochloride and Acetaminophen tablets
- Methodone Hydrochloride tablets

As of the date of filing of this Quarterly report on Form 10-Q, Oxycodone Hydrochloride and Acetaminophen tablets and Methodone Hydrochloride tablets have not yet been commercially launched.

On October 7, 2024, the Company announced the commercial launch of Acetaminophen and Codeine Phosphate 300mg/15mg, 300mg/30mg and 300mg/60mg tablets (“APAP Codeine Tablets”). APAP Codeine Tablets are indicated for the management of mild to moderate pain, where treatment with and opioid is appropriate and for which alternate treatments are inadequate. APAP Codeine Tablets are marketed and sold under the Elite Laboratories label.

On October 10, 2024, the Company announced the Israeli Ministry of Health approval of Elite’s generic version of Adderall®, an immediate-release mixed salt of a single entity amphetamine product (Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, Amphetamine Sulfate) with strengths of 10mg, 20mg and 30mg tablets. The product is a central nervous system stimulant indicated for the treatment of attention deficit hyperactivity disorder (ADHD) and narcolepsy. The Company will supply the product to Dexcel Pharma (Akiva, Israel), the Company’s exclusive distributor for the Israel market. As of the date of filing of this quarterly report on Form 10-Q, these products have not yet been commercially launched.

On November 18, 2024, the Company reported that it received approval from the FDA for a generic version of Vyvanse® (Lisdexamphetamine Dimesylate) with strengths of 10mg, 20mg, 30mg, 40mg, 50mg, 60mg, and 70mg capsules. This product is for treatment of attention deficit hyperactivity disorder (“ADHD”) and is marketed and sold under the Elite Laboratories Inc. brand label. The Company announced the commercial launch of this product on December 26, 2024.

On December 2, 2024, the Company announced the commercial launch of Elite’s generic version of Norco® (Acetaminophen and Hydrocodone Bitartrate) 325mg/2.5mg, 325mg/5mg, 325mg/7.5mg and 325mg/10mg tablets.

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 (“Phentermine 37.5mg”)	Adipex-P®	Bariatric	April 2011
Phendimetrazine Tartrate 35mg tablets (“Phendimetrazine 35mg”)	Bontril®	Bariatric	November 2012
Phentermine HCl 15mg and 30mg capsules (“Phentermine 15mg” and “Phentermine 30mg”)	Adipex-P®	Bariatric	April 2013
Naltrexone HCl 50mg tablets (“Naltrexone 50mg”)	Revia®	Pain	September 2013
Isradipine 2.5mg and 5mg capsules (“Isradipine 2.5mg” and “Isradipine 5mg”)	N/A	Cardiovascular	January 2015
Trimipramine Maleate Immediate Release 25mg, 50mg and 100mg capsules (“Trimipramine 25mg”, “Trimipramine 50mg”, “Trimipramine 100mg”)	Surmontil®	Antidepressant	May 2017
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, Amphetamine Sulfate Immediate Release 5mg, 7.5mg, 10mg, 12.5mg, 15mg, 20mg and 30mg tablets (“Amphetamine IR 5mg”, “Amphetamine IR 7.5mg”, “Amphetamine IR 10mg”, “Amphetamine IR 12.5mg”, “Amphetamine IR 15mg”, “Amphetamine IR 20mg” and “Amphetamine IR 30mg”)	Adderall®	Central Nervous System (“CNS”) Stimulant	April 2019
Dantrolene Sodium Capsules 25mg, 50mg and 100mg (“Dantrolene 25mg”, “Dantrolene 50mg”, “Dantrolene 100mg”)	Dantrium®	Muscle Relaxant	June 2019
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, Amphetamine Sulfate Extended Release 5mg, 10mg, 15mg, 20mg, 25mg, and 30mg capsules (“Amphetamine ER 5mg”, “Amphetamine ER 10mg”, “Amphetamine ER 15mg”, “Amphetamine ER 20mg”, “Amphetamine ER 25mg”, and “Amphetamine ER 30mg”)	Adderall XR®	Central Nervous System (“CNS”) Stimulant	March 2020
Loxapine Succinate 5mg, 10mg, 25mg and 50gm capsules (“Loxapine 5mg”, “Loxapine 10mg”, “Loxapine 25mg”, and Loxapine 50mg”)	Loxapine®	Antipsychotic	May 2021
Methotrexate Sodium 2.5mg tablets (“Methotrexate 2.5mg”)	Otrexup PF®	Antimetabolite	August 2024
Acetaminophen and Codeine Phosphate 300mg/15mg, 300mg/30mg and 300mg/60mg tablets (“APAP Codeine Tablets”).	Tylenol® with Codeine	Pain	October 2024
Acetaminophen and Hydrocodone Bitartrate 325mg/2.5mg, 325mg/5mg, 325mg/7.5mg, and 325mg/10mg tablets (“APAP Hydrodocone Tablets”)	Norco®	Pain	December 2024
Lisdexamphetamine Dimesylate 10mg, 20mg, 30mg, 40mg, 50mg 60mg and 70mg capsules (“Lisdex Capsules”)	Vyvanse®	ADHD	December 2024

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 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 the following ANDA's which have been accepted for review by the FDA:

- Generic dopamine agonist accepted for review in December 2022
- Generic opiate analgesic for pain management accepted for review in September 2023

Approved Products Not Yet Commercialized

Doxycycline Hyclate Tablets

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

Oxycodone Hydrochloride and Acetaminophen Tablets

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

Methadone Hydrochloride Tablets

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

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

Discontinued and Transferred Products

As part of standard operating practices, the Company, from time to time, as relevant, conducts evaluations of all ANDAs owned, consisting, without limitation, of ANDAs acquired or approved prior to the fiscal year ended March 31, 2024 ("Fiscal 2024") and ANDAs acquired or approved during the quarterly period ending December 31, 2024. Such evaluations include, without limitation, costs and benefits relating to each ANDA owned, with such costs including those fees required under the FDA's Generic Drug User Fee Amendment which is significantly influenced by the number of ANDAs owned, and other costs and benefits taking into consideration various specific market factors for each ANDA. Those ANDAs with a cost/benefit profile not consistent with management criteria for continuation are identified for disposition and effort is made to determine the optimal course of action to achieve disposition of the ANDA.

The Company did not transfer or discontinue any ANDAs during the quarterly period ending December 31, 2024 or Fiscal 2024.

Critical Accounting 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. We have identified below the critical accounting policies, which are assumptions made by management about matters that are highly uncertain and that are of critical importance in the presentation of our financial position, results of operations and cash flows. Due to the need to make estimates about the effect of matters that are inherently uncertain, materially different amounts could be reported under different conditions or using different assumptions. On a regular basis, we review our critical accounting policies and how they are applied in the preparation of our financial statements.

Revenue Recognition - The Company generates revenue from manufacturing and sales of generic pharmaceuticals bearing either the Elite label, which are sold to pharmaceutical distributors or the label of a licensing partner, which Elite sells directly to such licensing partner, and licensing fees. Revenues earned from the sale of Elite label products are recorded at their net realizable value which consists of gross amounts invoiced reduced by contractual reductions, including, without limitation, chargebacks, discounts and program rebates, as applicable. 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.

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 immediate and controlled-release products marketed under the Elite label, or manufactured on a contract basis for third parties. 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.

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.

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

The allowance for expected credit losses is based on the probability of future collection under the current expected credit 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 April 1, 2023. 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 rate, 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 to be uncollectible. Subsequent recoveries are credited to the allowance. Changes in the allowance are recorded as adjustments to credit losses in the period incurred. Expected credit losses stemming from unbilled receivables expected to be billed between December 31, 2024 and December 31, 2028 included additional risk premiums estimated based on factors such as projected inflation, projected decreases in GDP, and projected unemployment.

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 the enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. Where applicable, the Company records a valuation allowance to reduce any deferred tax assets that it determines will not be realizable in the future.

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

The Company operates in multiple tax jurisdictions within the United States of America. The Company remains subject to examination in all tax jurisdictions until the applicable statutes of limitation expire. As of December 31, 2024, a summary of the tax years that remain subject to examination in our major tax jurisdictions are: United States of America – Federal, 2020 and forward, and State, 2019 and forward. The Company did not record unrecognized tax positions for the nine months ended December 31, 2024.

New Accounting Pronouncements

For a description of recent accounting standards, including the expected dates of adoption and estimated effects, if any, on our financial statements, see “Note 1. Summary of Significant Accounting Policies: Recently Issued Accounting Pronouncements” in Part II, Item 1 of this Form 10-Q.

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 December 31, 2024 compared to the three months ended December 31, 2023

Revenue, Cost of manufacturing and Gross profit:

	For the Three Months Ended December 31,		Change	
	2024	2023	Dollars	Percentage
Manufacturing fees	\$ 13,738,131	\$ 14,791,110	\$ (1,052,979)	(7)%
Licensing fees	626,117	747,690	(121,573)	(16)%
Total revenue	14,364,248	15,538,800	(1,174,552)	(8)%
Cost of manufacturing	8,244,907	8,497,727	(252,820)	(3)%
Gross profit	\$ 6,119,341	\$ 7,041,073	\$ (921,732)	(13)%
Gross profit - percentage	43%	45%		

Total revenues for the three months ended December 31, 2024 decreased by \$1.2 million or 8%, to \$14.4 million, as compared to \$15.5 million, for the corresponding period of the prior year, primarily due to decreased sales of the Elite label products during the current quarter in comparison to the comparable quarter of the prior fiscal year achieved as a result of decreased shipments during the extended holiday period in the current fiscal year that occurred as a result of the mid-week December and New Years holidays and allocation of manufacturing/marketing resources to the commercial launch of Lisdex Capsules, which had its full launch in January 2025.

Manufacturing fees revenue for the three months ended December 31, 2024 decreased by \$1.1 million, or 7%, primarily due to decreased sales of the Elite label products during the current fiscal year in comparison to the comparable quarter of the prior fiscal year achieved as a result of decreased shipments during the extended holiday period in the current fiscal year that occurred as a result of the mid-week December and New Years holidays and allocation of manufacturing/marketing resources to the commercial launch of Lisdex Capsules.

Licensing fees revenue for the three months ended December 31, 2024 decreased by \$0.1 million, or 16%, primarily due to the Company's transitioning away from licensing products to third parties to marketing of the Elite label, which does not result in revenues from licensing fees.

Cost of manufacturing consists of manufacturing and assembly costs. Our cost of manufacturing decreased by \$0.3 million or 3% primarily due to these costs being positively correlated to manufacturing revenues as well as product lines having varying gross profit margins. Changes in the mix of product line revenues result in variances in overall cost of manufacturing as a percentage of overall revenues.

Our gross profit margin was 43% during the three months ended December 31, 2024 as compared to 45% during the comparable period of the prior fiscal year. The decrease is due to the fixed cost component of manufacturing costs being allocated to a lower revenue base combined with a product line mix with a higher proportion of lower margin product lines as compared to the product line mix relating to sales in the comparable period of the prior fiscal year.

Operating expenses:

	For the Three Months Ended December 31,		Change	
	2024	2023	Dollars	Percentage
Operating expenses:				
Research and development	\$ 1,793,803	\$ 1,403,790	\$ 390,013	28%
General and administrative	2,724,616	1,711,275	1,013,341	59%
Non-cash compensation	70,578	49,815	20,763	42%
Depreciation and amortization	432,534	343,537	88,997	26%
Total operating expenses	\$ 5,021,531	\$ 3,508,417	\$ 1,513,114	43%

Operating expenses for the three months ended December 31, 2024 increased by \$1.5 million, or 43%, to \$5.0 million as compared to \$3.5 million for the corresponding period in the prior fiscal year, largely due to increases in general and administrative costs of \$1.0 million and research and development costs of \$0.4 million.

Research and development costs during the three months ended December 31, 2024 were \$1.8 million, an increase of \$0.4 million, or 28%, from approximately \$1.4 million of such costs for the comparable period of the prior year. The increase was the result of the number, timing and nature of product development activities conducted during the three months ended December 31, 2024 as compared to the comparable period of the prior fiscal year.

General and administrative expenses for the three months ended December 31, 2024 were \$2.7 million, an increase of \$1.0 million or approximately 59% from the comparable period of the prior fiscal year, largely due to increased human resource costs resulting from increased headcounts as well as increased costs of regulatory, financial and tax reporting compliance as compared to the comparable period of the prior year.

Non-cash compensation expense for the three months ended December 31, 2024 and 2023 was less than \$0.1 million.

Depreciation and amortization expenses from the three months ended December 31, 2024 were \$0.4 million, which increased by \$0.1 million or 26% for the corresponding period of the prior fiscal year as a result of additional capital expenditures and ASC 842 finance leases acquired as compared with 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 December 31, 2024 was \$1.1 million, compared to income from operations of \$3.5 million for the comparable period of the prior fiscal year.

Other (expense) income:

	For the Three Months Ended December 31,		Change	
	2024	2023	Dollars	Percentage
Other (expense) income:				
Change in fair value of derivative financial instruments - warrants	\$ (11,729,368)	\$ (2,417,772)	\$ (9,311,596)	385%
Change in fair value of stock-based liabilities	—	(2,854,556)	2,854,556	(100)%
Interest expense and amortization of debt issuance costs	(77,607)	(121,628)	44,021	(36)%
Gain from settlement agreements	—	1,761,792	(1,761,792)	(100)%
Interest income	5,092	5,249	(157)	(3)%
Other income	51,308	—	51,308	— %
Other (expense) income, net	<u>\$ (11,750,575)</u>	<u>\$ (3,626,915)</u>	<u>\$ (8,123,660)</u>	<u>224%</u>

Other (expense) income for the three months ended December 31, 2024 was a net other (expense) of \$11.8 million, an increase of \$8.1 million from a net other (expense) of \$3.6 million for the comparable period of the prior fiscal year. The increase was primarily due to an increase of \$9.3 million in other expenses relating to the change in fair value of derivative financial instruments. The change in the fair value of derivative instruments and stock-based liabilities is determined in large part by the change in the closing price of the Company's Common Stock as of the end of the period, as compared to the closing price at the beginning of the period, with a strong inverse relationship between the other income expense recorded from changes in the fair value of our derivatives instruments and stock-based liabilities and changes in the closing price of the Company's Common Stock. This increase was offset by other income (expense) recorded in the period ended December 31, 2023, which included the following two line items that did not occur during the period ended December 31, 2024: expense of \$2.9 million from change in fair value of stock based liabilities and gain from settlement agreements of \$1.8 million. The change in fair value of stock based liabilities relates to stock based compensation policies that were discontinued at the end of the fiscal year ended March 31, 2023. The gain from settlement agreements is a one-time event that occurred during the period ended December 31, 2023, but not in the period ended December 31, 2024. Taken together, these two items from the prior fiscal year contributed a net \$1.1 million in other expenses, which were a component of the overall increase in net other expenses of \$8.1 million.

As a result of the foregoing, our net loss before income taxes for the three months ended December 31, 2024 was \$10.7 million, compared to net loss before income taxes of \$0.1 million for the comparable period of the prior fiscal year.

Income Taxes:

The Company recorded tax (expense)/benefit of approximately (2.2)% and 849.4% of loss before income taxes, for the three months ended December 31, 2024 and 2023, respectively. The decrease of the effective tax rate for the current period as compared to the prior period is primarily due to the release of the valuation allowance on the Company's deferred tax assets as of December 31, 2023 and the nondeductible fair market value change in the Company's warrant derivative liabilities.

Nine months ended December 31, 2024 compared to the nine months ended December 31, 2023

Revenue, Cost of revenue and Gross profit:

	For the Nine Months Ended December 31,		Change	
	2024	2023	Dollars	Percentage
Manufacturing fees	\$ 50,407,239	\$ 36,208,217	\$ 14,199,022	39%
Licensing fees	1,640,417	2,467,844	(827,427)	(34)%
Total revenue	52,047,656	38,676,061	13,371,595	35%
Cost of manufacturing	29,256,109	20,437,354	8,818,755	43%
Gross profit	\$ 22,791,547	\$ 18,238,707	\$ 4,552,840	25%
Gross profit - percentage	44%	47%		

Total revenues for the nine months ended December 31, 2024 increased by \$13.4 million or 35%, to \$52.0 million, as compared to \$38.7 million, for the corresponding period of the prior year. This increase was primarily driven by manufacturing fees revenue which increased by \$14.2 million, or 39%, as compared to the corresponding period of the prior year. This increase is due to increased sales of the Elite label products during the current fiscal year in comparison to the comparable period of the prior fiscal year. The Elite label products were launched during the prior fiscal year and the current fiscal year represents their second year in the market. The additional twelve months of marketing the Elite label products has had a positive impact on sales, on a cumulative basis when compared to the sales achieved in the comparable period of the prior year.

Licensing fees revenue decreased by \$0.8 million, or 34%. This decrease is primarily due to the expiration of the marketing alliance agreements between the Company and Lannett Company, Inc. dated March 6, 2019 and April 9, 2019 (the "Lannett Agreements") on March 31, 2023. License fees earned during the nine months ended December 31, 2023 included residual amounts earned in relation to the expired Lannett Agreements. License fees earned during the nine months ended December 31, 2024 did not include such residual amounts. In addition, the Company is transitioning away from licensing products to third parties to marketing of the Elite label, which does not result in revenues from licensing fees.

Cost of manufacturing consists of manufacturing and assembly costs. Our cost of revenue increased by \$8.8 million or 43%, to \$29.3 million as compared to \$20.4 million for the corresponding period in the prior fiscal year. This increase was due to an increased volume of products sold during the nine months ended December 31, 2024, as compared to the comparable period of the prior fiscal year, as noted above.

Our gross profit margin was 44% during the nine months ended December 31, 2024 as compared to 47% during the comparable period of the prior fiscal year. The decrease is due to increased labor costs resulting from manufacturing personnel overtime hours incurred to ensure production and supply of our products in response to increased demand. In addition, during the nine months ended December 31, 2024, manufacturing fees represented a higher proportion of total revenue, as compared to licensing fees. Manufacturing fees generate lower gross profit margins as compared to licensing fees, due to it having a related cost of manufacturing, which is not associated with licensing fees. The Company is in the process of expanding its manufacturing facilities and capacity to achieve utilization rates that will yield higher volumes at standard labor rates.

Operating expenses:

	For the Nine Months Ended December 31,		Change	
	2024	2023	Dollars	Percentage
Operating expenses:				
Research and development	\$ 5,923,424	\$ 5,165,684	\$ 757,740	15%
General and administrative	6,967,514	4,906,187	2,061,327	42%
Non-cash compensation	175,236	107,592	67,644	63%
Depreciation and amortization	1,278,564	999,059	279,505	28%
Total operating expenses	<u>\$ 14,344,738</u>	<u>\$ 11,178,522</u>	<u>\$ 3,166,216</u>	<u>28%</u>

Operating expenses for the nine months ended December 31, 2024 increased by \$3.2 million, or 28%, to \$14.3 million as compared to \$11.2 million for the corresponding period in the prior fiscal year, largely due to an increase in research and development of \$0.8 million and general and administrative expenses of \$2.1 million.

Research and development costs during the nine months ended December 31, 2024 were \$5.9 million, an increase of \$0.8 million, or 15%, from approximately \$5.2 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 nine months ended December 31, 2024 as compared to the comparable period of the prior fiscal year.

General and administrative expenses for the nine months ended December 31, 2024 were \$7.0 million as compared to \$4.9 million for the corresponding period in the prior fiscal year, an increase of \$2.1 million or approximately 42%, largely due to increased human resource costs resulting from increased headcounts as well as increased costs of regulatory, financial and tax reporting compliance as compared to the comparable period of the prior year.

Non-cash compensation expense for the nine months ended December 31, 2024 was \$0.2 million as compared to \$0.1 million for the comparable period of the prior fiscal year, an increase of \$0.07 million or approximately 63%, with such increase being attributed to the issuance to employees of options to purchase Common Stock.

Depreciation and amortization expenses from the nine months ended December 31, 2024 were \$1.3 million as compared to \$1.0 million for the corresponding period of the prior fiscal year, an increase of \$0.3 million or 28%, due to additional capital expenditures and ASC 842 finance leases acquired as compared to the corresponding period from the prior fiscal year.

As a result of the foregoing, our income from operations during the nine months ended December 31, 2024 was \$8.4 million, compared to income from operations of \$7.1 million for the comparable period of the prior fiscal year.

Other (expense) income:

	For the Nine Months Ended December 31,		Change	
	2024	2023	Dollars	Percentage
Other (expense) income:				
Change in fair value of derivative financial instruments - warrants	\$ (27,267,016)	\$ (5,075,489)	\$ (22,191,527)	437%
Change in fair value of stock-based liabilities	—	(4,921,376)	4,921,376	(100)%
Interest expense and amortization of debt issuance costs	(583,524)	(371,478)	(212,046)	57%
Interest income	16,384	16,085	299	2%
Other income	63,308	—	63,308	—%
Gain from settlement agreement	—	1,761,792	(1,761,792)	100%
Other (expense) income, net	<u>\$ (27,770,848)</u>	<u>\$ (8,590,466)</u>	<u>\$ (19,180,382)</u>	<u>223%</u>

Other (expense) income for the nine months ended December 31, 2024 was a net other expense of \$27.8 million, an increase of \$19.2 million from a net other expense of \$8.6 million for the comparable period of the prior fiscal year. The increase was primarily due to an increase of \$22.2 million in other expenses relating to the change in fair value of derivative financial instruments. The change in the fair value of derivative instruments and stock-based liabilities is determined in large part by the change in the closing price of the Company's Common Stock as of the end of the period, as compared to the closing price at the beginning of the period, with a strong inverse relationship between the other income expense recorded from changes in the fair value of our derivatives instruments and stock-based liabilities and changes in the closing price of the Company's Common Stock. The increase was offset by other income (expense) recorded in the period ended December 31, 2023, which included the following two line items that did not occur during the period ended December 31, 2024: expense of \$4.9 million from change in fair value of stock based liabilities and gain from settlement agreements of \$1.8 million. The change in fair value of stock based liabilities relates to stock based compensation policies that were discontinued at the end of the fiscal year ended March 31, 2023. The gain from settlement agreements is a one-time event that occurred during the period ended December 31, 2023, but not in the period ended December 31, 2024. Taken together, these two items from the prior fiscal year contributed a net \$3.2 million in other expenses, which were a component of the overall increase in net other expenses of \$19.2 million.

As a result of the foregoing, our net loss before income taxes for the nine months ended December 31, 2024 was \$19.3 million, compared to net loss before income taxes of \$1.5 million for the comparable period of the prior fiscal year.

Income Taxes:

The Company recorded tax (expense)/benefit of approximately (10.3)% and 1,196.7% of loss before income tax expense, for the nine months ended December 31, 2024 and 2023, respectively. The decrease of the effective tax rate for the current period as compared to the prior period is primarily due to the release of the valuation allowance on the Company's deferred tax assets as of December 31, 2023 and the nondeductible fair market value change in the Company's warrant derivative liabilities.

Liquidity and Capital Resources

Capital Resources

	December 31, 2024	March 31, 2024	Change
Current assets	\$ 48,049,677	\$ 40,014,189	\$ 8,035,488
Current liabilities	\$ 14,688,832	\$ 13,049,764	\$ 1,639,068
Working capital	\$ 33,360,845	\$ 26,964,425	\$ 6,396,420

Our working capital (total current assets less total current liabilities) increased by \$6.4 million from \$27.0 million as of March 31, 2024 to \$33.4 million as of December 31, 2024, with such increase being primarily related to the increase in finished goods inventory and accounts receivable, associated with increased customer orders during the nine months ended December 31, 2024.

Summary of Cash Flows:

	For the Nine Months Ended December 31,	
	2024	2023
Net cash provided by (used in) operating activities	\$ 3,537,608	\$ (5,334,614)
Net cash used in investing activities	\$ (1,645,722)	\$ (406,007)
Net cash (used in) provided by financing activities	\$ (688,696)	\$ 3,740,150

Net cash provided by operating activities for the nine months ended December 31, 2024 was \$3.5 million compared to net cash used in operating activities of \$5.3 million for the corresponding period of the prior year. Net cash provided by operating activities included, without limitation, net loss of \$21.3 million, increased by the change in the change in fair value of derivative financial instruments - warrants of \$27.3 million, deferred tax expenses of \$1.5 million, and other non-cash expenses of \$1.9 million, and reduced by increases in operating assets and liabilities totaling \$5.8 million. Net cash used in operating activities during the prior fiscal year included, without limitation, net income of \$16.8 million, increased by depreciation and other non-cash expenses totaling \$10.1 million and reduced by increases in accounts receivable and inventory totaling \$17.9 million.

Net cash used in investing activities for the nine months ended December 31, 2024 was \$1.6 million compared to net cash used in investing activities of \$0.4 million for the corresponding period of the prior year. Net cash used in investing activities was comprised of purchases of property and equipment of approximately \$0.9 million and purchases of intangible assets consisting of ANDA products of approximately \$0.9 million. Net cash used in investing activities during the prior fiscal year was comprised of purchases of property and equipment of approximately \$0.4 million.

Net cash used in financing activities was \$0.7 million for the nine months ended December 31, 2024 compared to net cash provided by financing activities of \$3.7 million for the corresponding period of the prior year. Net cash used in financing activities consisted primarily of payments of bond and loan principal totaling \$0.4 million and payments on principal on finance lease obligations of \$0.2 million. Net cash provided by financing activities of \$3.7 million during the prior fiscal year was due to \$4.0 million in proceeds from related party loan, offset by \$0.3 million in other debt repayments.

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 fewer restrictive covenants. These covenants include filing timely tax returns and financial statements, and an agreement not to sell, lease, or transfer a substantial portion of the Company's assets during the term of the 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"). The Hakim Promissory Note has an interest rate of 9% for the first year and 10% for an optional second year and the proceeds were used for working capital and other business purposes. The original maturity date of the Hakim Promissory Note was June 2, 2024, with an optional second year extension. The second year extension of the Hakim Promissory Note was agreed to by both parties, with the maturity date being extended to June 2, 2025.

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 were used for working capital and other business purposes. The original maturity date of the Caskey Promissory Note was June 30, 2024, with both parties agreeing to the optional second year extension, as provided in the Caskey Promissory Note. The Caskey Promissory Note has a current maturity date of June 30, 2025.

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, 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 December 31, 2024, 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 December 31, 2024, and through the date of filing of this quarterly report on Form 10-Q, the Company is not aware of the existence of any violations of financial covenants included in the EWB Mortgage Loan.

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 and nine months ended December 31, 2024 and 2023, the Company did not issue any shares of Common Stock to Lincoln Park.

NJEDA Bonds

On August 31, 2005, the Company successfully completed a refinancing of a prior 1999 bond issue through the issuance of new tax-exempt bonds (the “Bonds”). The refinancing involved borrowing \$4,155,000, evidenced by a 6.5% Series A Note in the principal amount of \$3,660,000 maturing on September 1, 2030 and a 9% Series B Note in the principal amount of \$495,000 maturing on September 1, 2012. The net proceeds, after payment of issuance costs, were used (i) to redeem the outstanding tax-exempt Bonds originally issued by the Authority on September 2, 1999, (ii) refinance other equipment financing and (iii) for the purchase of certain equipment to be used in the manufacture of pharmaceutical products. As of March 31, 2016, all of the proceeds were utilized by the Company for such stated purposes.

Interest is payable semi-annually on March 1 and September 1 of each year. The Bonds are collateralized by a first lien on the Company’s facility and equipment acquired with the proceeds of the original and refinanced Bonds. The related Indenture requires the maintenance of a Debt Service Reserve Fund of \$366,000 in relation to the Series A Notes.

Bond issue costs of \$354,454 were paid from the bond proceeds and are being amortized over the life of the bonds. Amortization of bond issuance costs amounted to \$10,633 for the nine months ended December 31, 2024.

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

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

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

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 not effective as of December 31, 2024 to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms and such information is accumulated and communicated to management as appropriate to allow timely decisions regarding required disclosures.

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, the Company has concluded that due to the material weaknesses in our internal control over financial reporting noted below, our disclosure controls and procedures were not effective as of December 31, 2024 at the reasonable assurance level.

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

Remediation efforts to address material weaknesses in internal controls over financial reporting

We intend to revise the existing control environment documentation, designing and implementing controls, policies and procedure documentation that is consistent with our current personnel, resources and capabilities, with significant focus on controls relating to financial oversight, management, analysis and reporting of operations emanating from the Company’s manufacturing, marketing and distribution of its Elite Laboratory label product line. Please note that these material weaknesses cannot be considered remediated until the applicable remedial controls operate for a sufficient period of time, allowing management, through testing, to reach a conclusion on such controls design and operational effectiveness.

Changes in Internal Controls Over Financial Reporting

There have been no changes in our internal controls over financial reporting during the nine months ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Pending Litigation

Elite filed a paragraph IV certification with its ANDA to generic Oxycontin and after Elite got acceptance of the ANDA by the FDA Elite sent the patentee and NDA holder a Notice Letter. This was followed by a patent infringement suit filed by Purdue Pharma in which fifteen patents were asserted in Purdue's Complaint. The parties submitted stipulations and proposed orders on January 12, 2024 and July 12, 2024 staying all matters for six months with the possibility of further extensions subject to the court's approval and based on the circumstances of the pending Accord I and Accord II case. The parties submitted a stipulation and proposed order on September 24, 2024 staying all matters until the Federal Circuit's decision in the pending the Accord I appeal.

Purdue has already asserted claims of infringement of certain patents against Accord Healthcare Inc. In *Purdue Pharma L.P., et al. v. Accord Healthcare Inc.*, Civil Action No. 20-1362(RGA) in the District of Delaware ("the *Accord I* case"), the district court found the asserted claims invalid due to obviousness; that decision was affirmed by the Federal Circuit on December 30, 2024. Purdue is considering whether to seek Supreme Court review of the recent Federal Circuit decision in the *Accord I* case. In another patent infringement case against Accord ("the *Accord II* case"), the district court found the asserted claims of another patent invalid due to obviousness.

The parties submitted a stipulation and proposed order on January 30, 2025 staying the proceedings for 30 days to enable the parties to meet and confer regarding the impact of the Accord I and Accord II decisions on this case.

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, 2024.

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 December 31, 2024, 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	<u>Certification of Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a) and Rule 15d-14(a)*</u>
31.2	<u>Certification of Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a) and Rule 15d-14(a)*</u>
32.1	<u>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**</u>
32.2	<u>Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**</u>
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.

February 13, 2025

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

February 13, 2025

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

CERTIFICATION BY PRINCIPAL EXECUTIVE OFFICER

I, Nasrat Hakim, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended December 31, 2024 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: February 13, 2025

By: /s/ Nasrat Hakim

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

CERTIFICATION BY PRINCIPAL FINANCIAL OFFICER

I, Carter Ward, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended December 31, 2024 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: February 13, 2025

By: /s/ Carter Ward

Carter Ward
Chief Financial Officer
(Principal Accounting and Financial Officer)

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

In connection with the Quarterly Report of Elite Pharmaceuticals, Inc. (the “Registrant”) on Form 10-Q for the quarter ended December 31, 2024 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: February 13, 2025

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

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

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

**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 December 31, 2024 filed with the Securities and Exchange Commission (the “Report”), I, Carter Ward, Chief Financial Officer of the Registrant, certify, pursuant to 18 U.S. C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: February 13, 2025

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

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

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