MASCO CORP /DE/
Form 10-Q
October 31, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF

THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2012

Commission file number: 1-5794

Masco Corporation

(Exact name of Registrant as Specified in its Charter)

Delaware	**38-1794485**
(State or Other Jurisdiction of	**(IRS Employer**

Incorporation) **Identification No.)**

21001 Van Born Road,

Taylor, Michigan **48180**
(Address of Principal Executive Offices) **(Zip Code)**

(313) 274-7400

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

Large accelerated filer x Accelerated filer ¨

Non-accelerated filer ¨ (Do not check if a smaller reporting company) Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date.

Class	**Shares Outstanding at October 26, 2012**
Common stock, par value $1.00 per share	357,100,000

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MASCO CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

September 30, 2012 and December 31, 2011

(In Millions, Except Share Data)

	September 30, 2012	December 31, 2011
ASSETS		
Current assets:		
Cash and cash investments	$ 1,166	$ 1,656
Receivables	1,156	914
Prepaid expenses and other	83	70
Assets held for sale	20	20
Inventories:		
Finished goods	449	390
Raw material	290	280
Work in process	91	99
	830	769
Total current assets	3,255	3,429
Property and equipment, net	1,484	1,567
Goodwill	1,891	1,891
Other intangible assets, net	193	196
Other assets	191	209
Assets held for sale	2	5
Total assets	$ 7,016	$ 7,297
LIABILITIES		
Current liabilities:		
Notes payable	$ 207	$ 803
Accounts payable	866	770
Accrued liabilities	884	782
Liabilities held for sale	10	8
Total current liabilities	1,967	2,363
Long-term debt	3,422	3,222
Deferred income taxes and other	953	970
Total liabilities	6,342	6,555
Commitments and contingencies		
EQUITY		
Masco Corporation s shareholders equity:		
Common shares, par value $1 per share		
Authorized shares: 1,400,000,000; issued and outstanding: 2012 348,900,000; 2011 347,900,000	349	348
Preferred shares authorized: 1,000,000; issued and outstanding: 2012 None; 2011 None		
Paid-in capital	34	65

Accumulated deficit retained earnings	(15)	38
Accumulated other comprehensive income	99	76
Total Masco Corporation s shareholders equity	467	527
Noncontrolling interest	207	215
Total equity	674	742
Total liabilities and equity	$ 7,016	$ 7,297

See notes to condensed consolidated financial statements.

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MASCO CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

For the Three and Nine Months Ended September 30, 2012 and 2011

(In Millions Except Per Common Share Data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Net sales	$ 1,976	$ 1,978	$ 5,855	$ 5,729
Cost of sales	1,476	1,483	4,345	4,277
Gross profit	500	495	1,510	1,452
Selling, general and administrative expenses	398	380	1,186	1,210
Charge for litigation settlements, net	1	1	74	6
Operating profit	101	114	250	236
Other income (expense), net:				
Interest expense	(62)	(63)	(194)	(190)
Other, net	6	22	23	75
	(56)	(41)	(171)	(115)
Income from continuing operations before income taxes	45	73	79	121
Income taxes	14	4	48	55
Income from continuing operations	31	69	31	66
Loss from discontinued operations	(7)	(20)	(30)	(31)
Net income	24	49	1	35
Less: Net income attributable to noncontrolling interest	9	13	28	37
Net income (loss) attributable to Masco Corporation	$ 15	$ 36	$ (27)	$ (2)
Income (loss) per common share attributable to Masco Corporation:				
Basic:				
Income from continuing operations	$ .06	$ .16	$	$ .08
Loss from discontinued operations	(.02)	(.06)	(.08)	(.09)
Net income (loss)	$ .04	$ .10	$ (.08)	$ (.01)
Diluted:				
Income from continuing operations	$ .06	$ .16	$	$ .08
Loss from discontinued operations	(.02)	(.06)	(.08)	(.09)
Net income (loss)	$ .04	$ .10	$ (.08)	$ (.01)
Amounts attributable to Masco Corporation:				
Income from continuing operations	$ 22	$ 56	$ 3	$ 29

Loss from discontinued operations	(7)	(20)	(30)	(31)
Net income (loss)	$ 15	$ 36	$ (27)	$ (2)

See notes to condensed consolidated financial statements.

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MASCO CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS) (Unaudited)

For the Three and Nine Months Ended September 30, 2012 and 2011

(In Millions)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Net income	$ 24	$ 49	$ 1	$ 35
Other comprehensive income (loss), net of tax:				
Cumulative translation adjustment	42	(72)	15	8
Unrealized gain (loss) on interest rate swaps	1	(17)	1	(17)
Unrealized (loss) on marketable securities				(38)
Unrecognized pension prior service cost and net loss, net	3	3	11	8
Other comprehensive income (loss)	46	(86)	27	(39)
Total comprehensive income (loss)	70	(37)	28	(4)
Less: Comprehensive income (loss) attributable to the noncontrolling interest	17	(2)	32	40
Comprehensive income (loss) attributable to Masco Corporation	$ 53	$ (35)	$ (4)	$ (44)

See notes to condensed consolidated financial statements.

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MASCO CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

For the Nine Months Ended September 30, 2012 and 2011

(In Millions)

	Nine Months Ended September 30,	
	2012	2011
CASH FLOWS FROM (FOR) OPERATING ACTIVITIES:		
Cash provided by operations	$ 191	$ 210
Increase in receivables	(245)	(245)
Increase in inventories	(58)	(118)
Increase in accounts payable and accrued liabilities, net	202	248
Net cash from operating activities	90	95
CASH FLOWS FROM (FOR) FINANCING ACTIVITIES:		
Issuance of Notes, net of issuance costs	396	
Cash dividends paid	(80)	(80)
Retirement of Notes	(791)	(58)
Dividend payment to noncontrolling interest	(40)	(18)
Payment for settlement of swaps	(25)	
Purchase of Company common stock	(8)	(30)
Payment of debt		(3)
Credit Agreement costs		(1)
Net cash for financing activities	(548)	(190)
CASH FLOWS FROM (FOR) INVESTING ACTIVITIES:		
Capital expenditures	(80)	(106)
Proceeds from disposition of:		
Marketable securities		49
Other financial investments	35	43
Businesses	1	
Property and equipment	25	19
Purchases of other financial investments	(2)	(7)
Other, net	(21)	(7)
Net cash for investing activities	(42)	(9)
Effect of exchange rate changes on cash and cash investments	10	(1)
CASH AND CASH INVESTMENTS:		
Decrease for the period	(490)	(105)
At January 1	1,656	1,715
At September 30	$ 1,166	$ 1,610

See notes to condensed consolidated financial statements.

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MASCO CORPORATION

CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY (unaudited)

For The Nine Months Ended September 30, 2012 and 2011

(In Millions)

	Total	Common Shares ($1 par value)	Paid-In Capital	(Accumulated Deficit) Retained Earnings	Accumulated Other Comprehensive Income	Noncontrolling Interest
Balance, January 1, 2011	**$ 1,582**	**$ 349**	**$ 42**	**$ 720**	**$ 273**	**$ 198**
Total comprehensive income (loss)	(4)			(2)	(42)	40
Shares issued		2	(2)			
Shares retired:						
Repurchased	(30)	(2)	(28)			
Surrendered (non-cash)	(8)	(1)	(7)			
Cash dividends declared	(80)			(80)		
Dividend payment to noncontrolling interest	(18)					(18)
Stock-based compensation	45		45			
Balance, September 30, 2011	$ 1,487	$ 348	$ 50	$ 638	$ 231	$ 220
Balance, January 1, 2012	**742**	**348**	**65**	**38**	**76**	**215**
Total comprehensive income (loss)	28			(27)	23	32
Shares issued		3	(3)			
Shares retired:						
Repurchased	(8)	(1)	(7)			
Surrendered (non-cash)	(8)	(1)	(7)			
Cash dividends declared	(80)		(54)	(26)		
Dividend payment to noncontrolling interest	(40)					(40)
Stock-based compensation	40		40			
Balance, September 30, 2012	$ 674	$ 349	$ 34	$ (15)	$ 99	$ 207

See notes to consolidated financial statements.

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MASCO CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

A. In the opinion of the Company, the accompanying unaudited condensed consolidated financial statements contain all adjustments, of a normal recurring nature, necessary to present fairly its financial position as at September 30, 2012 and the results of operations for the three months and nine months ended September 30, 2012 and 2011 and cash flows for the nine months ended September 30, 2012 and 2011. The condensed consolidated balance sheet at December 31, 2011 was derived from audited financial statements.

Certain prior-year amounts have been reclassified to conform to the 2012 presentation in the condensed consolidated financial statements. The results of operations related to the 2011 discontinued operations have been separately stated in the accompanying condensed consolidated statements of income for the three months and nine months ended September 30, 2012 and 2011. In the Company s condensed consolidated statements of cash flows for the nine months ended September 30, 2012 and 2011, cash flows from discontinued operations are not separately classified.

Recently Issued Accounting Pronouncements. On January 1, 2012, the Company adopted new accounting guidance requiring more prominent presentation of other comprehensive income items in the Company s consolidated financial statements. The adoption of this new guidance did not have an impact on the Company s financial position or its results of operations.

B. Selected financial information for the discontinued operations, during the period owned by the Company, was as follows, in millions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Net Sales	$ 23	$ 28	$ 64	$ 71
Operating loss from discontinued operations	$ (3)	$ (5)	$ (10)	$ (16)
Impairment of assets	(3)	(7)	(3)	(7)
Loss on disposal of discontinued operations, net			(3)	
Loss before income tax	(6)	(12)	(16)	(23)
Income taxes	1	8	14	8
Loss from discontinued operations	$ (7)	$ (20)	$ (30)	$ (31)

The unusual relationship between income taxes and loss before income tax in 2012 results primarily from the increase in the deferred tax liability associated with the abandonment of tax basis in indefinite-lived intangibles due to the disposition of certain discontinued operations.

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MASCO CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) (continued)

C. The changes in the carrying amount of goodwill for the nine months ended September 30, 2012, by segment, were as follows, in millions:

	Gross Goodwill At Sep. 30, 2012	Accumulated Impairment Losses	Net Goodwill At Sep. 30, 2012
Cabinets and Related Products	$ 589	$ (408)	$ 181
Plumbing Products	541	(340)	201
Installation and Other Services	1,806	(762)	1,044
Decorative Architectural Products	294	(75)	219
Other Specialty Products	980	(734)	246
Total	$ 4,210	$ (2,319)	$ 1,891

	Gross Goodwill At Dec. 31, 2011	Accumulated Impairment Losses	Net Goodwill At Dec. 31, 2011	Other (A)	Net Goodwill At Sep. 30, 2012
Cabinets and Related Products	$ 589	$ (408)	$ 181	$	$ 181
Plumbing Products	541	(340)	201		201
Installation and Other Services	1,806	(762)	1,044		1,044
Decorative Architectural Products	294	(75)	219		219
Other Specialty Products	980	(734)	246		246
Total	$ 4,210	$ (2,319)	$ 1,891	$	$ 1,891

(A) Other principally includes the effect of foreign currency translation.

Other indefinite-lived intangible assets were $174 million at both September 30, 2012 and December 31, 2011, and principally included registered trademarks. The carrying value of the Company s definite-lived intangible assets was $19 million (net of accumulated amortization of $55 million) at September 30, 2012 and $22 million (net of accumulated amortization of $54 million) at December 31, 2011, and principally included customer relationships and non-compete agreements.

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MASCO CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) (continued)

D. Depreciation and amortization expense was $154 million and $188 million, including accelerated depreciation (relating to business rationalization initiatives) of $12 million and $28 million, for the nine months ended September 30, 2012 and 2011, respectively.

E. The Company has maintained investments in available-for-sale securities and a number of private equity funds, principally as part of its tax planning strategies, as any gains enhance the utilization of any current and future tax capital losses. Financial investments included in other assets were as follows, in millions:

	September 30, 2012	December 31, 2011
Auction rate securities	$ 22	$ 22
Total recurring investments	22	22
Private equity funds	71	86
Other investments	4	4
Total non-recurring investments	75	90
Total	$ 97	$ 112

The Company s investments in available-for-sale securities at September 30, 2012 and December 31, 2011 were as follows, in millions:

	Cost Basis	Pre-tax Unrealized Gains	Pre-tax Unrealized Losses	Recorded Basis
September 30, 2012	$ 19	$ 3	$	$ 22
December 31, 2011	$ 19	$ 3	$	$ 22

Recurring Fair Value Measurements. Financial investments measured at fair value on a recurring basis at each reporting period and the amounts for each level within the fair value hierarchy were as follows, in millions:

	Sep. 30, 2012	Fair Value Measurements Using Quoted Market Prices (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Auction rate securities	$ 22			$ 22
Total	$ 22	$	$	$ 22

	Dec. 31, 2011	Fair Value Measurements Using Quoted Market Prices (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Auction rate securities	22	$	$	22
Total	$ 22	$	$	$ 22

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MASCO CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) (continued)

Note E continued:

The fair value of the auction rate securities held by the Company have been estimated, on a recurring basis, using a discounted cash flow model (Level 3 input). The significant inputs in the discounted cash flow model used to value the auction rate securities include expected maturity of auction rate securities, discount rate used to determine the present value of expected cash flows and the assumptions for credit defaults, since the auction rate securities are backed by credit default swap agreements.

The following table summarizes the changes in Level 3 financial assets measured at fair value on a recurring basis for the nine months ended September 30, 2012 and the year ended December 31, 2011, in millions:

	September 30, 2012 Auction Rate Securities	December 31, 2011 Auction Rate Securities
Fair value at beginning of period	$ 22	$ 22
Total losses included in earnings		
Unrealized (losses)		
Purchases		
Settlements		
Transfer from Level 3 to Level 2		
Fair value at period end	$ 22	$ 22

Non-Recurring Fair Value Measurements. Financial investments measured at fair value on a non-recurring basis during the nine-month period ended September 30, 2012 and the amounts for each level within the fair value hierarchy were as follows, in millions:

		Fair Value Measurements Using Significant			
	Sep. 30, 2012	Quoted Market Prices (Level 1)	Other Observable Inputs (Level 2)	Significant Total Inputs (Level 3)	Gains (Losses)
Private equity funds	$ 2			$ 2	$ (2)
Total	$ 2	$	$	$ 2	$ (2)

The remaining private equity investments at September 30, 2012, with an aggregate carrying value of $69 million, were not reviewed for impairment, as there were no indicators of impairment or identified events or changes in circumstances that would have a significant adverse effect on the fair value of the investment.

During the nine-month period ended September 30, 2011, the Company did not measure any financial investments at fair value on a non-recurring basis, as there was no other-than-temporary decline in the estimated value of private equity funds.

The Company did not have any transfers between Level 1 and Level 2 financial assets in the third quarter or in the first nine months of 2012 or 2011.

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MASCO CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) (continued)

Note E concluded:

Realized Gains (Losses). Income (loss) from financial investments, net, included in other, net, within other income (expense), net, was as follows, in millions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Realized gains - distributions from private equity funds	$ 2	$ 19	$ 20	$ 28
Realized gains - sale of TriMas Corporation common stock				41
Total income from financial investments	$ 2	$ 19	$ 20	$ 69
Impairment charges - private equity funds	$	$	$ (2)	$

The fair value of the Company s short-term and long-term fixed-rate debt instruments is based principally upon quoted market prices for the same or similar issues or the current rates available to the Company for debt with similar terms and remaining maturities. The aggregate estimated market value of short-term and long-term debt at September 30, 2012 was approximately $3.9 billion, compared with the aggregate carrying value of $3.6 billion. The aggregate estimated market value of short-term and long-term debt at December 31, 2011 was approximately $4.0 billion, compared with the aggregate carrying value of $4.0 billion.

F. The Company is exposed to global market risk as part of its normal daily business activities. To manage these risks, the Company enters into various derivative contracts. These contracts include interest rate swap agreements, foreign currency exchange contracts and contracts intended to hedge the Company s exposure to copper and zinc. The Company reviews its hedging program, derivative positions and overall risk management on a regular basis.

Interest Rate Swap Agreements. In March 2012, in connection with the issuance of $400 million of debt, the Company terminated the interest rate swap hedge relationships that it entered into in August 2011. These interest rate swaps were designated as cash flow hedges and effectively fixed interest rates on the forecasted debt issuance to variable rates based on 3-month LIBOR. Upon termination, the ineffective portion of the cash flow hedges of approximately $2 million loss was recognized in the Company s consolidated statement of income in other, net. The remaining loss of approximately $23 million from the termination of these swaps is being amortized as an increase to interest expense over the remaining term of the debt, through March 2022. At September 30, 2012, the balance remaining was $22 million.

At December 31, 2011, the interest rate swaps were considered 100 percent effective; therefore, the market valuation loss of $23 million was recorded in other comprehensive income in the Company s statement of shareholders equity with a corresponding increase to accrued liabilities in the Company s condensed consolidated balance sheet at December 31, 2011.

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MASCO CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) (continued)

Note F continued:

The Company recognized a net decrease in interest expense of $4 million (including additional expense of $1 million related to the cash flow hedge terminated in March 2012) and $8 million, respectively, for the nine months ended September 30, 2012 and 2011. These decreases to interest expense are related to the amortization of net gains resulting from the terminations (in 2012, 2008 and 2004) of the interest rate swap agreements.

Foreign Currency Contracts. The Company s net cash inflows and outflows exposed to the risk of changes in foreign currency exchange rates arise from the sale of products in countries other than the manufacturing source, foreign currency denominated supplier payments, debt and other payables, and investments in subsidiaries. To mitigate this risk during 2012 and 2011, the Company, including certain European operations, entered into foreign currency forward contracts and foreign currency exchange contracts.

Gains (losses) related to foreign currency forward and exchange contracts are recorded in the Company s consolidated statements of income in other income (expense), net. In the event that the counterparties fail to meet the terms of the foreign currency forward contracts, the Company s exposure is limited to the aggregate foreign currency rate differential with such institutions.

Metal Contracts. During 2012 and 2011, the Company entered into several contracts to manage its exposure to increases in the price of copper and zinc. Gains (losses) related to these contracts are recorded in the Company s consolidated statements of income in cost of goods sold.

The pre-tax gain (loss) included in the Company s consolidated statements of income is as follows, in millions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Foreign Currency Contracts				
Exchange Contracts	$ (4)	$ 8	$	$ 1
Forward Contracts	(1)	2	(2)	3
Metal Contracts	2	(10)	3	(11)
Total gain (loss)	$ (3)	$	$ 1	$ (7)

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MASCO CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) (continued)

Note F concluded:

The Company presents its derivatives, net by counterparty due to the right of offset under master netting arrangements in current assets or current liabilities in the consolidated balance sheet. The notional amounts being hedged and the fair value of those derivative instruments, on a gross basis, are as follows, in millions:

	At September 30, 2012		
	Notional Amount	Assets	Liabilities
Foreign Currency Contracts			
Exchange Contracts	$ 168		
Current assets		$ 1	$
Current liabilities		1	(3)
Forward Contracts	84		
Current liabilities		1	(1)
Metal Contracts	38		
Current assets		1	(1)
Total		$ 4	$ (5)

	At December 31, 2011		
	Notional Amount	Assets	Liabilities
Foreign Currency Contracts			
Exchange Contracts	$ 108		
Current assets		$ 8	$
Forward Contracts	76		
Current assets		1	
Current liabilities		1	2
Metal Contracts	67		
Current assets		2	
Current liabilities			4
Total			

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Three customers accounted for substantially all the Company’s revenues for the nine months ended December 31, 2018. These three customers accounted for approximately 63%, 17% and 16% of revenues each, respectively. The same three customers accounted for approximately 58%, 21% and 7% of revenues for the three months ended December 31,

2018.

Three customers accounted for substantially all the Company's revenues for the nine months ended December 31, 2017. These three customers accounted for approximately 55%, 12% and 24% of revenues each, respectively. The same three customers accounted for approximately 53%, 21% and 17% of revenues for the three months ended December 31, 2017.

Accounts Receivable

Three customers accounted for substantially all the Company's accounts receivable as of December 31, 2018. These three customers accounted for approximately 45%, 41% and 11% of accounts receivable each, respectively.

Four customers accounted for substantially all the Company's accounts receivable as of March 31, 2018. These four customers accounted for approximately 52%, 14%, 12%, and 11% of accounts receivable each, respectively.

Purchasing

Four suppliers accounted for more than 75% of the Company's purchases of raw materials for the nine months ended December 31, 2018. Included in these four suppliers are three suppliers that accounted for approximately 40%, 16% and 15% of purchases each, respectively.

Seven suppliers accounted for more than 69% of the Company's purchases of raw materials for the nine months ended December 31, 2017. Included in these

seven suppliers are two suppliers that accounted for approximately 31% and 9% of purchases each, respectively.

NOTE 15. SEGMENT RESULTS

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

The Company has determined that its reportable segments are Abbreviated New Drug Applications for generic products and New Drug Applications ("NDA") 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.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

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

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

	For the Three Months Ended December 31,		For the Nine Months Ended December 31,	
	2018	2017	2018	2017
Operating Income (Loss) by Segment				
ANDA	$(582,822)	$(322,063)	$(1,129,324)	$(1,417,044)
NDA	(744,393)	(893,029)	(1,250,420)	(2,257,718)
	$(1,327,215)	$(1,215,092)	$(2,379,744)	$(3,674,762)

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

	For the Three Months Ended December 31,		For the Nine Months Ended December 31,	
	2018	2017	2018	2017
Operating loss by segment	$(1,327,215)	$(1,215,092)	$(2,379,744)	$(3,674,762)
Corporate unallocated costs	(667,002)	(335,800)	(3,111,346)	(1,286,318)

Interest income	1,733	4,461	4,570	12,862
Interest expense and amortization of debt issuance costs	(89,897)	(92,458)	(279,037)	(245,730)
Depreciation and amortization expense	(321,164)	(232,358)	(891,390)	(567,554)
Significant non-cash items	(321,749)	(275,711)	(766,016)	(901,469)
Change in fair value of derivative instruments	380,976	605,448	807,347	4,767,884
Loss from operations	$(2,344,318)	$(1,541,510)	$(6,615,616)	$(1,895,087)

NOTE 16. COLLABORATIVE AGREEMENT WITH EPIC PHARMA LLC

On June 4, 2015, the Company entered into the 2015 Epic License Agreement, which provides for the exclusive right to market, sell and distribute, by Epic of SequestOx™, an abuse deterrent opioid which employs the Company's proprietary pharmacological abuse-deterrent technology. Epic will be responsible for payment of product development and pharmacovigilance costs, sales, and marketing of SequestOx™, and Elite will be responsible for the manufacture of the product. Under the 2015 Epic License Agreement, Epic will pay Elite non-refundable payments totaling $15 million, with such amount representing the cost of an exclusive license to ELI-200, the cost of developing the product and certain filings and a royalty based on an amount equal to 50% of profits derived from net product sales as defined in the 2015 Epic License Agreement. The initial term of the exclusive right to product development sales and distribution is five years ("Epic Exclusivity Period"); the license is renewable upon mutual agreement at the end of the initial term.

In June 2015, Elite received non-refundable payments totaling $5 million from Epic for the exclusive right to product development sales and distribution of SequestOx™ pursuant to the Epic Collaborative Agreement, under which it agreed to not permit marketing or selling of SequestOx™ within the United States of America to any other party. These

nonrefundable payments represent consideration for certain exclusive rights to ELI-200 and will be recognized ratably over the Epic Exclusivity Period. The Company determined that the performance obligations within the 2015 Epic License Agreement included the transfer of the license and the performance of the research and development services; the license is not distinct because the customer cannot obtain value from the license without the research and development services that the Company is uniquely able to perform.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

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In addition, in January 2016, a New Drug Application for SequestOx™ was filed, thereby earning the Company a non-refundable $2.5 million milestone, pursuant to the 2015 Epic License Agreement. Accordingly, the Company has recognized the $2.5 million milestone, which was paid by Epic and related to this deliverable as income during the year ended March 31, 2016.

To date, the Company received payments totaling $7.5 million pursuant to the 2015 Epic License Agreement, with all amounts being non-refundable. An additional $7.5 million is due upon approval by the FDA of the NDA filed for SequestOx™, and license fees based on commercial sales of SequestOx™. Revenues relating to these additional amounts due under the 2015 Epic License Agreement will be recognized as the defined elements are completed and collectability is reasonably assured.

Please note that 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. Based on subsequent meetings and communications with the FDA, the Company believes that there is a clear path forward to address the issues cited in the CRL. The Company believes that the meeting minutes, received from the FDA on January 23, 2017, supported a plan to address the issues cited by the FDA in the CRL by modifying the SequestOx™ formulation. Such plan includes, without limitation, conducting

bioequivalence and bioavailability fed and fasted studies, comparing the modified formulation to the original formulation. the Company modified the SequestOx™ formulation and, on January 30, 2018 reported positive topline results from a pilot study indicating the likelihood of achieving the required bioequivalence in a pivotal trial under fed conditions. The Company has provided the pilot data to the FDA, requesting clarification as to 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 December 2019.

The 2015 Epic License Agreement expires on June 4, 2020, and Epic has previously advised the Company of their desire to extend this agreement. While discussions are ongoing, they are directly correlated to the regulatory status of SequestOx™. Furthermore, there can be no assurances that the parties will reach mutual agreement to extend the term of this agreement and no assurances that the terms and conditions of the agreement will be similar in all material aspects in the event that the agreement is extended by mutual consent of the parties. Non-receipt by the Company of the remaining $7.5 million milestone will have a material adverse effect on the Company’s financial condition.

NOTE 17. COLLABORATIVE AGREEMENT WITH SUNGEN PHARMA LLC

On August 24, 2016, the Company entered into the SunGen Agreement. The SunGen Agreement, as amended, provides that Elite and SunGen Pharma LLC will engage in the research, development, sales, and marketing of eight generic pharmaceutical products. Two of the products are classified as CNS stimulants (the “CNS Products”), two of the products are classified as beta blockers (the “Beta Blocker Products”) and the remaining four products consist of antidepressants, antibiotics and antispasmodics.

Under the terms of the SunGen Agreement, Elite and SunGen will share in the responsibilities and costs in the development of these products and will share substantially in the profits from sales of the Products. Upon approval, the know-how and intellectual property rights to the products will be owned jointly by Elite and SunGen. SunGen shall have the exclusive right to market and sell the Beta Blocker Products using SunGen's label and Elite shall have the exclusive right to market and sell the CNS Products using Elite's label. Elite will manufacture and package all four products on a cost-plus basis.

On December 1, 2016 and July 24, 2017, Elite Labs and SunGen executed an amendment to the parties' 2016 Development and License Agreement (the "*Amended Agreement*"), to undertake and engage in the research, development, sales and marketing of four additional generic pharmaceutical products bringing the total number of products under the amended agreement to eight. The product classes for the additional four products include antidepressants, antibiotics, and antispasmodics.

Under the terms of the Amended Agreement, Elite and SunGen will share in the responsibilities and costs in the development of these products and will share substantially in the profits from sales of the products. Upon approval, the know-how and intellectual property rights to the products will be owned jointly by Elite and SunGen. Three products will be owned jointly by Elite and SunGen; three shall be owned by SunGen while Elite shall have the marketing rights once the products are approved by the FDA; and two shall be owned by Elite while SunGen shall have the marketing rights once the products are approved by the FDA. Elite will manufacture and package all eight products on a cost-plus basis.

On February 8, 2018, the Company filed an ANDA with the FDA for a generic version of an immediate release central nervous system ("*CNS*") stimulant. The ANDA represents the first filing for a product co-developed with SunGen under the SunGen

Agreement. This product, a generic version of Adderall®, an immediate-release mixed salt of a single entity amphetamine product (Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, Amphetamine Sulfate), with strengths of 5mg, 7.5mg. 10mg, 12.5mg, 15mg, 20mg, and 30mg tablets. The product is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) and Narcolepsy.

On May 24, 2018, the Company filed an ANDA with the FDA for a generic version of an extended release CNS stimulant. The ANDA represents the second filing for a product co-developed with SunGen under the SunGen Agreement.

On January 3, 2019, the Company filed and ANDA with the FDA for a generic version of an antibiotic product. This is the third ANDA that Elite co-developed and filed with SunGen under the SunGen Agreement.

There can be no assurances that any of these products, including the two products for which ANDAs have already been filed, will receive marketing authorization and achieve commercialization within a reasonable time period, or at all. In addition, even if marketing authorization is received, and as applies to the ANDA for which marketing approval has already been received, there can be no assurances that there will be future revenues of profits, or that any such future revenues or profits would be in amounts that provide adequate return on the significant investments made to secure these marketing authorizations.

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NOTE 18. RELATED PARTY TRANSACTION AGREEMENTS WITH EPIC PHARMA LLC

The Company has entered into two agreements with Epic which constitute agreements with a related party due to the management of Epic including a member on our Board of Directors at the time such agreements were executed.

On June 4, 2015, the Company entered into the 2015 Epic License Agreement (please see Note 16 above). The 2015 Epic License Agreement includes milestone payments totaling $10 million upon the filing with and approval of an NDA with the FDA. The Company has determined these milestones to be substantive, with such assessment being made at the inception of the 2015 Epic License Agreement, and based on the following:

The Company’s performance is required to achieve each milestone; and

The milestones will relate to past performance, when achieved; and

The milestones are reasonable relative to all of the deliverables and payment terms within the 2015 Epic License Agreement

After marketing authorization is received from the FDA, Elite will receive a license fee which is based

on profits achieved from the commercial sales of ELI-200. On January 14, 2016, the Company filed an NDA with the FDA for SequestOx™, thereby earning a $2.5 million milestone pursuant to the 2015 Epic License Agreement. The Company has received payment of this amount from Epic. An additional $7.5 million is due upon approval by the FDA of the NDA filed for SequestOx™. Please note that 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 December 21, 2016, the Company met with the FDA for an end-of-review meeting to discuss steps that it could take to obtain approval of SequestOx™. Based on this and the meeting minutes received from the FDA on January 23, 2017, the Company formulated a plan to address the issues cited by the FDA in the CRL, with such plan including, without limitation, modifying the SequestOx™ formulation, conducting bioequivalence and bioavailability fed and fasted studies, comparing the modified formulation to the original formulation. On July 7, 2017, the Company reported topline results from a pivotal bioequivalence fed study for SequestOx™. This study resulted in a mean Tmax of 4.6 hours, with a range of 0.5 hour to 12 hours and a mean Tmax of the comparator, Roxicodone® of 3.4 hours with a range of 0.5 hour to 12 hours. A key objective of this 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 will pause, not proceed, with the rest of the clinical trials, and seek clarity from the FDA before deciding on the next steps for immediate release SequestOx™. 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, and accordingly, there can be no assurances that the Company will earn and receive the additional $7.5 million or future license fees. If the Company does not receive these payments or fees, it will materially and adversely affect our financial condition. In addition, even if marketing authorization is received, there can be no assurances that there will be future revenues of profits, or that any such future revenues or profits would be in amounts that provide adequate return on the significant investments made to secure

this marketing authorization.

On October 2, 2013, Elite executed the Epic Pharma Manufacturing and License Agreement (the “Epic Generic Agreement”). The Epic Generic Agreement, which expired on October 2, 2018 granted rights to Epic to manufacture twelve generic products whose ANDA’s are owned by Elite, and to market, in the United States and Puerto Rico, six of these products on an exclusive basis, and the remaining six products on a non-exclusive basis. These products were to be manufactured at Epic, with Epic being responsible for the manufacturing site transfer supplements that are a prerequisite to each product being approved for commercial sale. In addition, Epic was to be responsible for all regulatory and pharmacovigilance matters, as well as all marketing and distribution activities. Elite has no further obligations or deliverables under the Epic Generic Agreement.

Pursuant to the Epic Generic Agreement, Elite was to receive $1.8 million, payable in increments that require the commercialization of all six exclusive products if the full amount is to be received, plus license fees equal to a percentage that is not less than 50% and not greater than 60% of profits achieved from commercial sales of the products, as defined in the Epic Generic Agreement. The Epic Generic Agreement expired on October 2, 2018 with Epic launching four of the six exclusive products and Elite collecting $1.0 million of the total $1.8 million fee.

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The 2015 Epic License Agreement contains license fees that will be earned and payable to the Company, after the FDA has issued marketing authorization(s) for the related product(s). License fees are based on commercial sales of the products achieved by Epic and calculated as a percentage of net sales dollars realized from such commercial sales. Net sales dollars consist of gross invoiced sales less those costs and deductions directly attributable to each invoiced sale, including, without limitation, cost of goods sold, cash discounts, Medicaid rebates, state program rebates, price adjustments, returns, short date adjustments, charge backs, promotions, and marketing costs. The rate applied to the net sales dollars to determine license fees due to the Company is equal to an amount negotiated and agreed to by the parties to each agreement, with the following significant factors, inputs, assumptions, and methods, without limitation, being considered by either or both parties:

Assessment of the opportunity for each product in the market, including consideration of the following, without limitation: market size, number of competitors, the current and estimated future regulatory, legislative, and social environment for abuse deterrent opioids and the other generic products to which the underlying contracts are relevant;

Assessment of various avenues for monetizing SequestOx™ including the various combinations of sites of manufacture and marketing options;

Elite’s resources and capabilities with regards to the concurrent development of abuse deterrent opioids and expansion of its generic business segment, including financial and operational resources required to achieve manufacturing site transfers for twelve approved ANDA’s;

Capabilities of each party with regards to various factors, including, one or more of the following: manufacturing, marketing, regulatory and financial resources, distribution capabilities, ownership structure, personnel, assessments of operational efficiencies and entity stability, company culture and image;

Stage of development of SequestOx™ and manufacturing site transfer and regulatory requirements relating to the commercialization of the generic products at the time of the discussions/negotiations, and an assessment of the risks, probability, and time frames for achieving marketing authorizations from the FDA for each product.

Assessment of consideration offered; and

Comparison of the above factors among the various entities with whom the Company was engaged in discussions relating to the commercialization of SequestOx™ and the manufacture/marketing of the twelve generics related to the Epic Generic Agreement.

This transaction is not to be considered as an arms-length transaction.

Please also note that, effective April 7, 2016, all Directors on the Company's Board of Directors that were also owners/managers of Epic had resigned as Directors of the Company and all current members of the Company's Board of Directors have no relationship to Epic. Accordingly, Epic no longer qualifies as a party that is related to the Company.

NOTE 19. MANUFACTURING, LICENSE AND DEVELOPMENT AGREEMENTS

The Company has entered into the following active agreements:

License agreement with Precision Dose, dated September 10, 2010 (the "Precision Dose License Agreement");

Master Development and License Agreement with SunGen Pharma LLC, dated August 24, 2016, as amended (the "SunGen Agreement"); and

Strategic Marketing Alliance with Glenmark Pharmaceuticals, Inc. USA dated May 29, 2018 (the “Glenmark Alliance”).

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(UNAUDITED)

The Precision Dose Agreement provides for the marketing and distribution, by Precision Dose and its wholly owned subsidiary, TAGI Pharma, of Phentermine 37.5mg tablets (launched in April 2011), Phentermine 15mg capsules (launched in April 2013), Phentermine 30mg capsules (launched in April 2013), Hydromorphone 8mg tablets (launched in March 2012), Naltrexone 50mg tablets (launched in September 2013) and certain additional products that require approval from the FDA which has not been received. Precision Dose will have the exclusive right to market these products in the United States and Puerto Rico and a non-exclusive right to market the products in Canada. Pursuant to the Precision Dose License Agreement, Elite received $200k at signing, and is receiving milestone payments and a license fee which is based on profits achieved from the commercial sale of the products included in the agreement.

Revenue from the $200k payment made upon signing of the Precision Dose Agreement is being recognized over the life of the Precision Dose Agreement.

The milestones, totaling $500k (with $405k already received), consist of amounts due upon the first shipment of each identified product, as follows: Phentermine 37.5mg tablets ($145k), Phentermine 15 & 30mg capsules ($45k), Hydromorphone 8mg ($125k), Naltrexone 50mg ($95k) and the balance of $95k due in relation to the first shipment of generic products which still require marketing authorizations from the FDA, and to which there can be no

assurances of such marketing authorizations being granted and accordingly there can be no assurances that the Company will earn and receive these milestone amounts. These milestones have been determined to be substantive, with such determination being made by the Company after assessments based on the following:

- The Company's performance is required to achieve each milestone; and
- The milestones will relate to past performance, when achieved; and
- The milestones are reasonable relative to all of the deliverables and payment terms within the Precision Dose License Agreement.

The license fees provided for in the Precision Dose Agreement are calculated as a percentage of net sales dollars realized from commercial sales of the related products. Net sales dollars consist of gross invoiced sales less those costs and deductions directly attributable to each invoiced sale, including, without limitation, cost of goods sold, cash discounts, Medicaid rebates, state program rebates, price adjustments, returns, short date adjustments, charge backs, promotions, and marketing costs. The rate applied to the net sales dollars to determine license fees due to the Company is equal to an amount negotiated and agreed to by the parties to the Precision Dose License Agreement, with the following significant factors, inputs, assumptions, and methods, without limitation, being considered by either or both parties:

- Assessment of the opportunity for each generic product in the market, including consideration of the following, without limitation: market size, number of competitors, the current and estimated future regulatory, legislative, and social environment for each generic product, and the maturity of the market;
- Assessment of various avenues for monetizing the generic products, including the various combinations of sites of manufacture and marketing options;
- Capabilities of each party with regards to various factors, including, one or more of the following: manufacturing resources, marketing resources, financial resources, distribution capabilities, ownership structure,

personnel, assessment of operational efficiencies and stability, company culture and image;

Stage of development of each generic product, all of which did not have FDA approval at the time of the discussions/negotiations and an assessment of the risks, probability, and time frame for achieving marketing authorizations from the FDA for the products;

Assessment of consideration offered by Precision and other entities with whom discussions were conducted; and

Comparison of the above factors among the various entities with whom the Company was engaged in discussions relating to the commercialization of the generic products.

The SunGen Agreement provides for the research, development, sales and marketing of eight generic pharmaceutical products. Two of the products are classified as CNS stimulants (the “CNS Products”), two of the products are classified as beta blockers and the remaining four products consist of antidepressants, antibiotics and antispasmodics. To date, the Company has filed ANDAs with the FDA for the two CNS Products identified in the SunGen Agreement.

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(UNAUDITED)

Under the terms of the SunGen Agreement, Elite and SunGen will share in the responsibilities and costs in the development of these products and will share substantially in the profits from sales. Upon approval, the know-how and intellectual property rights to the products will be owned jointly by Elite and SunGen. Three of the eight products will be jointly owned, three products will be owned by SunGen, with Elite having exclusive marketing rights and the remaining two products will be owned by Elite, with SunGen having exclusive marketing rights. Elite will manufacture and package all eight products on a cost-plus basis.

The Glenmark Alliance, provides for the manufacture by Elite and marketing by Glenmark of identified generic products under license from Elite. In addition to the purchase prices for the products, Elite will receive license fees well in excess of 50% of gross profits. Gross profit is defined as net sales less the price paid to Elite for the products, distribution fees (less than 10%) and shipping costs. Glenmark will have semi-exclusive marketing rights to the ANDA approved generic product, phendimetrazine 35mg tablets, and exclusive marketing rights to generic Methadone HCl. Collectively, the brand products and their generic equivalents had total annual sales of approximately $33.6 million in 2017, according to Quintiles IMS Health data. The Agreement has an initial term of three years and automatically renews for one-year periods absent prior written notice of non-renewal. In addition to customary termination provisions, the Agreement permits Glenmark to terminate with regard to a product on at least three months' prior written notice if it determines to stop

marketing and selling such product, and it permits Elite to terminate with regard to a product if at any time after the first twelvemonths from the first commercial sale, the average license fee paid by Glenmark for such product is less than $100,000 for a six-month sales period.

NOTE 20. RELATED PARTY AGREEMENTS WITH MIKAH PHARMA LLC

Pursuant to an asset acquisition**,** on May 17, 2017, Elite Labs, executed an assignment agreement with Mikah, pursuant to which the Company acquired all rights, interests, and obligations under a supply and distribution agreement (the “Reddy’s Distribution Agreement”) with Dr. Reddy’s Laboratories, Inc. (“Dr. Reddy’s”) originally entered into by Mikah on May 7, 2017 and relating to the supply, sale and distribution of generic Trimipramine Maleate Capsules 25mg, 50mg and 100mg (“Trimipramine”).

On May 22, 2017, the Company executed an assignment agreement with Mikah, pursuant to which the Company acquired all rights, interests and obligations under a manufacturing and supply agreement with Epic originally entered into by Mikah on June 30, 2015 and relating to the manufacture and supply of Trimipramine (the “Epic Trimipramine Manufacturing Agreement”). Pursuant to this agreement, Epic manufactured Trimipramine under license from Elite. In September 2018, Elite successfully transferred manufacturing of Trimipramine to the Northvale Facility, resulting in the irrelevance of the Epic Trimipramine Manufacturing Agreement. Trimipramine is currently manufactured by Elite.

Mikah is owned by Nasrat Hakim, the CEO, President and Chairman of the Board of the Company.

The Reddy's Distribution Agreement was concluded by mutual consent in August 2018.

Trimipramine is one of the products included in the Glenmark Strategic Alliance and is currently marketed and distributed by Glenmark.

NOTE 21. SUBSEQUENT EVENTS

The Company has evaluated subsequent events from the balance sheet date through February 11, 2019, the date the accompanying financial statements were issued. The following are material subsequent events.

Sale of New Jersey State Net Operating Losses

In January 2019, Elite Laboratories Inc., a wholly owned subsidiary of Elite Pharmaceuticals Inc. received final approval from the New Jersey Economic Development Authority for the sale of net tax benefits of $296,883, relating to NJ net operating losses and net tax benefits of $376,133, relating to R&D tax credits. The Company sold the net tax benefits approved for sale at a transfer price equal to ninety-two cents for every benefit dollar, equating to net proceeds of $619,175.

Filing of ANDA for generic version of an antibiotic

On January 3, 2019, the Company filed an ANDA for a generic version of an antibiotic. This is the third ANDA that Elite has co-developed and filed pursuant to the SunGen Agreement. According to QVIA (formerly QuintilesIMS Heath) data, the branded product for this antibiotic and its equivalents had total annual U.S. sales of approximately $94 million for the twelve months ended September 30, 2018.

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

THREE AND NINE MONTHS ENDED DECEMBER 31, 2018 (UNAUDITED)

COMPARED TO THE

THREE AND NINE MONTHS ENDED DECEMBER 31, 2017 (UNAUDITED)

The following discussion of our financial condition and results of operations for the three and nine months ended December 31, 2018 and 2017 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, 2018, as filed on June 14, 2018 with the SEC. 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

We are a specialty pharmaceutical company principally engaged in the development and manufacture of oral, controlled-release products, using proprietary know-how and technology, particularly as it relates to abuse resistant products and the manufacture of generic pharmaceuticals. Our strategy includes improving off-patent drug products for life cycle management, developing generic versions of controlled-release drug products with high barriers to entry and the development of branded and generic products that utilize our proprietary and patented abuse resistance technologies.

We occupy manufacturing, warehouse, laboratory and office space at 165 Ludlow Avenue and 135 Ludlow Avenue in Northvale, NJ (the “Northvale Facility”). The Northvale Facility operates under Current Good Manufacturing Practice (“cGMP”) and is a United States Drug Enforcement Agency (“DEA”) registered facility for research, development and manufacturing.

Strategy

We focus our efforts on the following areas: (i) development of our pain management products; (ii) manufacturing of a line of generic pharmaceutical products with approved Abbreviated New Drug Application’s (“ANDAs”); (iii) development of additional generic pharmaceutical products; (iv) development of the other products in our pipeline including the products with our partners; (v) commercial exploitation of our products either by license and the collection of royalties, or through the manufacture of our formulations; and (vi) development of new products and the expansion of our licensing agreements with other pharmaceutical companies, including co-development projects, joint ventures and other collaborations.

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

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

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Commercial Products

We own, license or contract manufacture the following products currently being sold commercially:

Product	Branded Product Equivalent	Therapeutic Category	Launch Date
Phentermine HCl 37.5mg tablets ("Phentermine 37.5mg")	Adipex-P®	Bariatric	April 2011
Hydromorphone HCl 8mg tablets ("Hydromorphone 8mg")	Dilaudid®	Pain	March 2012
Phendimetrazine Tartrate 35mg tablets ("Phendimetrazine 35mg")	Bontril®	Bariatric	November 2012
Phentermine HCl 15mg and 30mg capsules ("Phentermine 15mg" and "Phentermine 30mg")	Adipex-P®	Bariatric	April 2013
Naltrexone HCl 50mg tablets ("Naltrexone 50mg")	Revia®	Pain	September 2013
Isradipine 2.5mg and 5mg capsules ("Isradipine 2.5mg" and "Isradipine 5mg")	n/a	Cardiovascular	January 2015
Oxycodone HCl Immediate Release 5mg, 10mg, 15mg, 20mg and 30mg tablets ("OXY IR 5mg", "Oxy IR 10mg", "Oxy IR 15mg", "OXY IR 20mg" and "Oxy IR 30mg")	Roxycodone®	Pain	March 2016
Trimipramine Maleate Immediate Release 25mg, 50mg and 100mg capsules ("Trimipramine 25mg" "Trimipramine 50mg", "Trimipramine 100mg")	Surmontil®	Antidepressant	May 2017
Brompheniramine/Pseudoephedrine Immediate Release capsules (formerly known as Lodrane D ® Immediate Release capsules)	n/a	OTC Allergy	September 2011
Hydroxyzine HCl 10mg, 25mg and 50mg tablets ("Hydroxyzine 10mg" and "Hydroxyzine 25mg" and "Hydroxyzine 50mg")	Atarax®, Vistaril®	Antihistamine	April 2015
Methadone HCl 5mg and 10mg tablets ("Methadone 5mg" and "Methadone 10mg")	Dolophine®	Pain	November 2018

Note: Phentermine 15mg and Phentermine 30mg are collectively and individually referred to as "Phentermine Capsules". Isradipine 2.5mg and Isradipine 5mg are collectively and individually referred to as "Isradipine Capsules". Hydroxyzine 10mg, Hydroxyzine 25mg and Hydroxyzine 50mg are collectively and individually referred to as "Hydroxyzine". In January 2019, the Company transferred the ANDAs for Hydroxyzine to Epic Pharma LLC. Oxy IR 5mg, Oxy IR 10mg, Oxy IR

15mg Oxy IR 20mg and Oxy IR 30mg are collectively and individually referred to as "Oxy IR". Trimipramine 25mg, Trimipramine 50mg, and Trimipramine 100mg are collectively and individually referred to as "Trimipramine". Methadone 5mg and Methadone 10mg are collectively and individually referred to as "Methadone". Brompheniramine/Pseudoephedrine Immediate Release Capsules are referred to as "Brom/Pseud Capsules".

Phentermine 37.5mg

The approved ANDA for Phentermine 37.5mg was acquired pursuant to an asset purchase agreement with Epic Pharma LLC ("Epic") dated September 10, 2010 (the "Phentermine Purchase Agreement").

Sales and marketing rights for Phentermine 37.5mg are included in the licensing agreement between the Company and Precision Dose Inc. ("Precision Dose") dated September 10, 2010 (the "Precision Dose License Agreement"). Please see the section below titled "Precision Dose License Agreement" for further details of this agreement.

The first shipment of Phentermine 37.5mg was made to Precision Dose's wholly owned subsidiary, TAGI Pharmaceuticals Inc. ("TAGI"), pursuant to the Precision Dose License Agreement, with such initial shipment triggering a milestone payment under this agreement. Phentermine 37.5mg is currently being manufactured by Elite and distributed by TAGI under the Precision Dose License Agreement.

Hydromorphone 8mg

The approved ANDA for Hydromorphone 8mg was acquired pursuant to an asset purchase agreement

with Mikah Pharma LLC (“Mikah Pharma”) dated May 18, 2010 (the “Hydromorphone Purchase Agreement”). Transfer of the manufacturing process of Hydromorphone 8mg to the Northvale Facility, a prerequisite of the Company’s commercial launch of the product, was approved by the United States Food and Drug Administration (the “FDA”) on January 23, 2012.

Sales and marketing rights for Hydromorphone 8mg are included in the Precision Dose License Agreement. Please see the section below titled “Precision Dose License Agreement” for further details of this agreement. The first shipment of Hydromorphone 8mg was made to TAGI, pursuant to the Precision Dose License Agreement, in March 2012, with such initial shipment triggering a milestone payment under this agreement. Hydromorphone 8mg is currently being manufactured by Elite and distributed by TAGI under the Precision Dose License Agreement.

Phendimetrazine Tartrate 35mg

The ANDA for Phendimetrazine 35mg was acquired by Elite as part of the asset purchase agreement between the Company and Mikah Pharma, dated August 1, 2013 (the "Mikah ANDA Purchase"). Please see "Thirteen Abbreviated New Drug Applications" below for more information on this agreement. The Northvale Facility was already an approved manufacturing site for this product as of the date of the Mikah ANDA Purchase. Prior to the acquisition of this ANDA, Elite had been manufacturing this product on a contract basis pursuant to a manufacturing and supply agreement with Mikah Pharma, dated June 1, 2011.

Phendimetrazine 35mg is currently a commercial product being manufactured by Elite and distributed by Glenmark Pharmaceutical, Inc. USA ("Glenmark"), pursuant to the Glenmark Strategic Alliance, on a non-exclusive basis, and by Elite. Please see the section below titled "*Strategic Marketing Alliance with Glenmark Pharmaceuticals, Inc. USA"* for further details of this agreement.

On January 2, 2018, the Company announced that it received approval of its ANDA from the FDA for Phendimetrazine Tartrate Tablets USP, 35mg. This product approval is from an ANDA that the Company filed approximately six years ago. This approval resulted in the Company having a second, approved ANDA for this product. The Company has been selling this product pursuant to the marketing authorization achieved from the first approved ANDA. The Company is currently considering strategic options for utilization of this approved ANDA, with such options including, without limitation, divestiture.

Phentermine 15mg and Phentermine 30mg

Phentermine 15mg capsules and Phentermine 30mg capsules were developed by the Company, with Elite receiving approval of the related ANDA in September 2012.

Sales and marketing rights for Phentermine 15mg and Phentermine 30mg are included in the Precision Dose License Agreement. Please see the section below titled “Precision Dose License Agreement” for further details of this agreement.

The first shipments of Phentermine 15mg and Phentermine 30mg were made to TAGI, pursuant to the Precision Dose License Agreement, in April 2013, with such initial shipments triggering a milestone payment under this agreement. Phentermine 15mg and Phentermine 30mg are currently being manufactured by Elite and distributed by TAGI under the Precision Dose License Agreement.

Naltrexone 50mg

The approved ANDA for Naltrexone 50mg was acquired by the Company pursuant to an asset purchase agreement between the Company and Mikah Pharma dated August 27, 2010 (the “Naltrexone Acquisition Agreement”) for aggregate consideration of $200,000.

Sales and marketing rights for Naltrexone 50mg are included in the Precision Dose License Agreement. Please see the section below titled “Precision Dose License Agreement” for further details of this agreement.

The first shipment of Naltrexone 50mg was made to TAGI, pursuant to the Precision Dose License Agreement, in September 2013, with such initial shipment triggering a milestone payment under this agreement. Naltrexone 50mg is currently being manufactured by Elite and distributed by TAGI under the Precision Dose License Agreement

Isradipine 2.5 mg and Isradipine 5mg

The approved ANDAs for Isradipine 2.5mg and Isradipine 5mg were acquired by Elite as part of the Mikah ANDA Purchase.

Sales and marketing rights for Isradipine 2.5mg and Isradipine 5mg were included in the Epic Manufacturing and License Agreement until the expiry of this agreement in October 2018. Please see the section below titled "Manufacturing and License Agreement with Epic Pharma LLC" for further details of this agreement.

Sales and marketing rights for Isradipine 2.5mg and Isradipine 5mg are currently included the Glenmark Strategic Alliance. Please see the section below titled "*Strategic Marketing Alliance with Glenmark Pharmaceuticals, Inc. USA"* for further details of this agreement.

The first shipments of Isradipine 2.5mg and Isradipine 5mg were made in January 2015 to Epic, pursuant to the now expired Epic Manufacturing and License Agreement.

Isradipine 2.5mg and Isradipine 5mg are currently being manufactured by Elite.

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

We received notification from Epic in October 2015 of the approval by the FDA of Epic's ANDA for Oxy IR. This product was an Identified IR Product in the Epic Strategic Alliance Agreement Dated March 18, 2009 (the "Epic Strategic Alliance"). Oxy IR was developed at the Northvale Facility pursuant to the Epic Strategic Alliance, in which we are entitled to a Product Fee of 15% of Profits as defined in the Epic Strategic Alliance. The first commercial sale of Oxy IR occurred in March 2016, and sales by Epic of this product are ongoing.

Trimipramine 25mg, Trimipramine 50mg, and Trimipramine 100mg

Through Elite Labs, Elite acquired an approved and currently marketed ANDA for Trimipramine Maleate Capsules ("Trimipramine") 25, 50 and 100 mg, from Mikah Pharma. Trimipramine is currently manufactured by Elite and marketed by Glenmark pursuant to the Glenmark Strategic Alliance. Trimipramine is a generic version of Surmontil®, a tricyclic antidepressant. Surmontil® and generic Trimipramine have total US sales of approximately $2 million in 2016 according to IMS Health Data. The ANDA purchased by Elite is currently the only marketed generic Trimipramine product.

Methadone 5mg and Methadone 10mg

Methadone 5mg and Methadone 10mg tablets were developed by us, with Elite receiving approval of the related ANDA in August 2018.

Sales and marketing rights for Methadone are included in the Glenmark Strategic Alliance. Please see the section below titled "*Strategic Marketing Alliance with Glenmark Pharmaceuticals, Inc. USA"* for further details of this agreement.

The first shipments of Methadone were made to Glenmark in November 2018. Methadone is currently manufactured by Elite and distributed by Glenmark under the Glenmark Strategic Alliance.

Hydroxyzine 10mg, Hydroxyzine 25mg and Hydroxyzine 50mg

The approved ANDAs for Hydroxyzine 10mg, Hydroxyzine 25mg and Hydroxyzine 50mg were acquired by Elite as part of the Mikah ANDA Purchase.

Sales and marketing rights for Hydroxyzine 10mg, Hydroxyzine 25mg and Hydroxyzine 50mg were included in the Epic Manufacturing and License Agreement, which expired in October 2018. The first shipment of Hydroxyzine 10mg, Hydroxyzine 25mg and Hydroxyzine 50mg were made by Epic, pursuant to the Epic Manufacturing and License Agreement, in April 2015. In January 2019, Elite transferred these ANDAs to Epic.

Brompheniramine/Pseudoephedrine Immediate Release Capsules

On September 27, 2011, the Company, along with ECR Pharmaceuticals ("ECR"), launched Brom/Pseud Capsules under the brand name, Lodrane D®, an immediate release formulation of brompheniramine maleate and pseudoephedrine HCl, an effective,

low-sedating antihistamine combined with a decongestant.

Brom/Pseud Capsules are marketed under the Over-the-Counter Monograph (the “OTC Monograph”) and accordingly, under the Code of Federal Regulations can be lawfully marketed in the US without prior approval of the FDA. Within the past few years, the FDA has revised its enforcement policies, significantly limiting the circumstances under which these unapproved products may be marketed. If the FDA determines that a company is distributing an unapproved product that requires approval, the FDA may take enforcement action in a variety of ways, including, without limitation, product seizures and seeking a judicial injunction against distribution.

Elite manufactures this product, but there have been several mergers and successor entities effecting the marketing of this product and transfer of brand name ownership since this product was originally launched. Marketing of this product under the Lodrane D® was last conducted by Valeant Pharmaceuticals International Inc. (“Valeant”), but Elite has received no new orders for this product during the current fiscal year and does not anticipate any further orders from Valeant for this product.

Filed products under FDA review

SequestOx™ - Immediate Release Oxycodone with sequestered Naltrexone

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

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

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

On December 21, 2016, the Company met with the FDA for an end-of-review meeting to discuss steps that it could take to obtain approval of SequestOx™. Based on this and the meeting minutes received from the FDA on January 23, 2017, the Company formulated a plan to address the issues cited by the FDA in the CRL, with such plan including, without limitation, modifying the SequestOx™ formulation, conducting bioequivalence and bioavailability fed and

fasted studies, comparing the modified formulation to the original formulation.

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 hours with a range of 0.5 hour to 12 hours and the mean Tmax of the comparator, Roxicodone®, was 3.4 hours with a range of 0.5 hour to 12 hours. 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. Elite will pause, not proceed with the rest of the clinical trials, and seek clarity from FDA before deciding on the next steps for immediate release SequestOx™. The Company will continue to pursue extended release products with its proprietary abuse deterrent technology.

On January 30, 2018, the Company reported positive topline results from a pilot study conducted for SequestOx™. An objective of the study was to assess whether the reformulated SequestOx could achieve a Tmax comparable to the reference drug, Roxicodone, when dosed with the standard high fat meal specified by FDA. As opposed to the earlier formulation, based on these pilot results, the modified SequestOx™ 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 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 December 2019.

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, and accordingly, there can be no assurances that the Company will earn and receive the additional $7.5 million or future license fees (see "*Licensing, Manufacturing and Development Agreements; Sales and Distribution Licensing Agreement with Epic Pharma LLC for SequestOx™*" below). If the Company does not receive these payments or fees, it will materially and adversely affect our financial condition. 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.

Acetaminophen and codeine phosphate (generic version of Tylenol® with Codeine) 300mg/7.5mg, 300mg/15mg, 300mg/30mg, and 300mg/60mg tablets

On September 18, 2018, the Company filed an ANDA with the FDA for a generic version of Tylenol® with Codeine (acetaminophen and codeine phosphate) 300mg/7.5mg, 300mg/15mg, 300mg/30mg and 300mg/60mg tablets. The Company awaits the FDA's response.

Oxycodone Hydrochloride extended release (generic version of Oxycontin®)

On September 20, 2017, the Company filed an ANDA with the FDA for generic version of Oxycontin® (extended release Oxycodone Hydrochloride). OxyContin® is approved for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. OxyContin® is formulated such that the tablets provide physical abuse deterrent properties. IMS reported approximately $2.3 billion in revenue for OxyContin® and its equivalents in 2016. The FDA requested additional information relating to this filing.

The Company's response to the FDA's request is in progress.

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Generic version of extended release Central Nervous System stimulant

On May 24, 2018, the Company filed an ANDA with the FDA for a generic version of an extended release CNS stimulant. The ANDA represents the second filing for a product co-developed with SunGen under the SunGen Agreement. According to IMS Health data, the branded product and its equivalents had total U.S. sales of approximately $1.6 billion for the twelve months ended September 30, 2017. The Company has not yet received a response from the FDA on this filing.

Under the terms of the SunGen Agreement, the product will be owned jointly by the Company and SunGen. Elite shall have exclusive rights to market and sell the product under its own label. Elite will also manufacture and package the product on a cost-plus basis.

Please see the section below titled “Master Development and License Agreement with SunGen Pharma LLC” for further details on the SunGen Agreement.

There can be no assurances that any of these products will receive marketing authorization and achieve commercialization within this time period, or at all. In addition, even if marketing authorization is received, there can be no assurances that there will be future revenues of profits, or that any such future revenues or profits would be in amounts that provide adequate return on the significant investments made to secure these marketing authorizations.

Generic version of an antibiotic product

On January 3, 2019, filed an ANDA with the FDA for a generic version of an antibiotic product.

Approved Products Not Yet Commercialized

Oxycodone Hydrochloride and Acetaminophen, USP CII 5mg/325mg, 7.5mg/325mg and 10mg/325mg tablets

On July 3, 2018, the Company received approval by the FDA of its ANDA filed for generic Percocet® (Oxycodone Hydrochloride and Acetaminophen, USP CII) 5mg/325mg, 7.5mg/325mg and 10mg/325mg tablets. This product is indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Based on Quintiles IMS Health data for the twelve months ending May 31, 2018, the retail sales for the brand and generic products were approximately $500 million. The Company is evaluating marketing options for this product.

Hydrocodone bitartrate and acetaminophen tablets USP CII (generic version of Norco)

On November 20, 2018, the FDA approved the Company's ANDA for a generic version of Norco (hydrocodone bitartrate and acetaminophen tablets, USP CII) 2.5mg/325mg, 5mg/325mg, 7.5mg/325mg and 10mg/325mg tablets. Norco is a combination medication and is used to help relieve moderate to moderately severe pain. The combination products of hydrocodone and acetaminophen have total annual US sales of approximately $700 million, according to IMS Health Data.

Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, Amphetamine Sulfate (generic version of Adderall)

On December 10, 2018, the Company received approval from the FDA for a generic version of Adderall®, an immediate-release mixed salt of a single entity Amphetamine product (Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, Amphetamine Sulfate) with strengths of 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 20 mg, and 30 mg tablets. The product is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) and Narcolepsy. It was co-developed with SunGen and is included in the Master Development and License Agreement with SunGen Pharma LLC. Please see the section below titled "*Master Development and License Agreement with SunGen Pharma LLC* for further details on this agreement.

In addition to the above, we currently own two different approved ANDAs, all of which were acquired as part of the Mikah ANDA Purchase. Each approved ANDA requires manufacturing site transfers as a prerequisite to commencement of commercial manufacturing and distribution. The products relating to each approved ANDA were included in the Epic Manufacturing and License Agreement which expired in October 2018 without such manufacture site transfers to Epic being achieved. Transfer of commercial manufacturing to the Northvale Facility is in progress.

Asset Acquisition Agreements

Generic Phentermine Capsules

On September 10, 2010, together with our wholly owned subsidiary, Elite Laboratories, Inc., executed a purchase agreement (the "Phentermine Purchase Agreement") with Epic for the purpose of acquiring from Epic, an ANDA for a generic phentermine product (the "Phentermine ANDA"), with such being filed with the FDA at the time the Phentermine Purchase Agreement was executed. On February 4, 2011, the FDA approved the Phentermine ANDA. The acquisition of the Phentermine ANDA closed on March 31, 2011 and Elite paid the full acquisition price of $450,000 from the purchase agreement with Epic Pharma.

This product is being marketed and distributed by Precision Dose and its wholly owned subsidiary, TAGI, pursuant to the Precision Dose License Agreement, a description of which is set forth below.

Generic Hydromorphone HCl Product

On May 18, 2010, we executed an asset purchase agreement with Mikah Pharma (the "Hydromorphone Purchase Agreement"). Pursuant to the Hydromorphone Purchase Agreement, the Company acquired from Mikah Pharma an approved ANDA for Hydromorphone 8 mg for aggregate consideration of $225,000, comprised of an initial payment of $150,000, which was made on May 18, 2010. A second payment of $75,000 was due to be paid to Mikah Pharma on June 15, 2010, with the Company having the option to make this payment in cash or by issuing to Mikah Pharma 937,500 shares of our

common stock. We elected and did issue 937,500 shares of Common Stock during the quarter ended December 31, 2010, in full payment of the $75,000 due to Mikah Pharma pursuant to the Hydromorphone Purchase Agreement dated May 18, 2010.

This product is currently being marketed and distributed by Precision Dose and its wholly owned subsidiary, TAGI, pursuant to the Precision Dose License Agreement, a description of which is set forth below.

Generic Naltrexone Product

On August 27, 2010, we executed an asset purchase with Mikah Pharma (the "Naltrexone Acquisition Agreement"). Pursuant to the Naltrexone Acquisition Agreement, Elite acquired from Mikah Pharma the ANDA number 75-274 (Naltrexone Hydrochloride Tablets USP, 50 mg), and all amendments thereto, that have to date been filed with the FDA seeking authorization and approval to manufacture, package, ship and sell the products described in this ANDA within the United States and its territories (including Puerto Rico) for aggregate consideration of $200,000. In lieu of cash, Mikah Pharma agreed to accept product development services to be performed by us. This product is being marketed and distributed by Precision Dose and its wholly owned subsidiary, TAGI, pursuant to the Precision Dose License Agreement, a description of which is set forth below.

Thirteen Abbreviated New Drug Applications

On August 1, 2013, Elite executed the Mikah ANDA Purchase with Mikah Pharma and acquired a total of thirteen ANDAs, consisting of twelve ANDAs approved by the FDA and one ANDA under active review with the FDA, and all amendments thereto (the "Mikah Thirteen ANDA Acquisition") for aggregate consideration of $10,000,000, payable

pursuant to a secured convertible note due in August 2016.

Each of the products referenced in the twelve approved ANDAs require manufacturing site approval with the FDA. We believe that the site transfers qualify for Changes Being Effected in 30 Days ("CBE 30") review, with one exception, which would allow for the product manufacturing transfer on an expedited basis. However, we can give no assurances that all will qualify for CBE 30 review, or on the timing of these transfers of manufacturing site, or on the approval by the FDA of the transfers of manufacturing site.

As of the date of filing of this Quarterly Report on Form 10-Q, the following products included in the Mikah Purchase Agreement have successfully achieved manufacturing site transfers:

Phendimetrazine 35mg

Isradipine 2.5mg and Isradipine 5mg

Hydroxyzine 10mg, Hydroxyzine 25mg and Hydroxyzine 50mg

These products were initially manufactured and marketed pursuant to the Epic Pharma Manufacturing and License Agreement, which expired in October 2018. Phendimetrazine and Isradipine are currently being marketed on a semi-exclusive and exclusive basis, respectively pursuant to the Glenmark Strategic Alliance. Hydroxyzine was transferred to Epic in January 2019 for aggregate cash consideration of $450,000.

Trimipramine

In May 2017, through Elite Labs, we acquired from Mikah Pharma an FDA approved ANDA for Trimipramine for aggregate consideration of $1,200,000. In conjunction with this acquisition, we also acquired from Mikah Pharma all rights, interests, and obligations under a supply and distribution agreement with Dr. Reddy's Laboratories, Inc. relating to the supply, sale and distribution of generic Trimipramine, and under a manufacturing and supply agreement with Epic Pharma relating to the manufacture and supply of Trimipramine. The agreement with Dr. Reddy's Laboratories, Inc. was concluded by mutual consent and Trimipramine is currently marketed pursuant to the Glenmark Strategic Alliance.

Please see Note 20: Related Party Agreements with Mikah Pharma LLC to the Financial Statements above.

Licensing, Manufacturing and Development Agreements

Sales and Distribution Licensing Agreement with Epic Pharma LLC for SequestOx™

On June 4, 2015, we executed an exclusive License Agreement (the "2015 SequestOx™ License Agreement") with Epic, to market and sell in the U.S., SequestOx™, an immediate release oxycodone with sequestered naltrexone capsule, owned by us. Epic will have the exclusive right to market ELI-200 and its various dosage forms as listed in Schedule A of the Agreement. Epic is responsible for all regulatory and pharmacovigilance matters related to the products. Pursuant to the 2015 SequestOx™ License Agreement, Epic will pay us non-refundable payments totaling $15 million, with such amount representing the cost of an exclusive license to SequestOx™, the cost of developing the product, the filing of an NDA with the FDA and the receipt of the approval letter for the NDA from the FDA. As of the date of filing of this annual report on Form 10-K, the Company has received $7.5 million of the $15 million in non-refundable payments due pursuant to the 2015 SequestOx™ License Agreement, with such amount consisting of $5 million being due and owing on the execution date of the 2015 SequestOx™ License Agreement, and $2.5 million being earned as of January 14, 2016, the date of Elite's filing of an NDA with the FDA for the relevant product. Both of these non-refundable fees (i.e., the $5 million fee and the $2.5 million fee), have been paid by Epic.

The remaining $7.5 million in non-refundable payments due pursuant to the 2015 SequestOx™ License Agreement is due on the FDA's approval of SequestOx™ for commercial sale in the United States of America (please see the paragraph below for further details). In addition, we will receive a license fee computed as a percentage (50%) of net sales of the products as defined in the 2015 SequestOx™ License Agreement and is entitled to multi-million-dollar minimum annual license fees we will manufacture the product for sale by Epic on a cost-plus basis and both parties agree to execute a separate Manufacturing and Supply Agreement. The license fee is payable quarterly for the term of the 2015 SequestOx™ License Agreement. The term of the 2015 SequestOx™ License Agreement is five years and may be extended for an additional five years upon mutual agreement of the parties. Elite can terminate the 2015 SequestOx™ License Agreement on 90 days' written notice in the

event that Epic does not pay us certain minimum annual license fees over the initial five-year term of the 2015 SequestOx™ License Agreement. Either party may terminate this 2015 SequestOx™ License Agreement upon a material breach and failure to cure that breach by the other party within a specified period.

Please note that 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. Based on subsequent meetings and communications with the FDA, the Company believes that there is a clear path forward to address the issues cited in the CRL. The Company believes that the meeting minutes, received from the FDA on January 23, 2017, supported a plan to address the issues cited by the FDA in the CRL by modifying the SequestOx™ formulation. Such plan includes, without limitation, conducting bioequivalence and bioavailability fed and fasted studies, comparing the modified formulation to the original formulation. the Company modified the SequestOx™ formulation and, on January 30, 2018 reported positive topline results from a pilot study indicating the likelihood of achieving the required bioequivalence in a pivotal trial under fed conditions. The Company is reviewing these results with the FDA and discussing pharmacokinetic study requirements for a re-submission of the NDA.

The 2015 Epic License Agreement expires on June 4, 2020, and Epic has previously advised the Company of their desire to extend this agreement. While discussions are ongoing, they are directly correlated to the regulatory status of SequestOx™. Furthermore, there can be no assurances that the parties will reach mutual agreement to extend the term of this agreement and no assurances that the terms and conditions of the agreement will be similar in all material aspects in the event that the agreement is extended by mutual consent of the parties. Non-receipt by the Company of the remaining $7.5 million milestone will have a material adverse effect on the Company’s financial condition.

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Manufacturing and License Agreement with Epic Pharma LLC

On October 2, 2013, we executed the Epic Pharma Manufacturing and License Agreement (the "Epic Manufacturing and License Agreement"), which expired on October 2, 2018.

Pursuant to this now expired agreement, the Company granted Epic certain rights to manufacture, market and sell in the United States and Puerto Rico the twelve approved ANDAs acquired by us pursuant to the Mikah Thirteen ANDA Acquisition. Of the twelve approved ANDAs, Epic had exclusive rights to market six products as listed in Schedule A of the Epic Manufacturing and License Agreement, and non-exclusive rights to market six products as listed in Schedule D of the Epic Manufacturing and License Agreement. Epic manufactured those products for which manufacturing site transfer was achieved and Epic was responsible for all regulatory and pharmacovigilance matters related to the products. The Company received a license fee and milestone payments, as provided for in this agreement. Upon expiration of this agreement, Epic ceased having rights to manufacture and market any of the products included therein. The Company has already successfully transferred manufacturing of Isradipine to the Northvale Facility and is in the process of transferring manufacturing of several of the other products included in this agreement to the Northvale Facility. The Company is also evaluating strategic options, in addition to manufacturing site transfer for several of the products, with such options including, without limitation, divestiture.

During the life of the Epic Manufacturing and License Agreement, the Company received license fees and milestone payments. The license fee was computed as a percentage of gross profit, as defined in the agreement, which was earned by Epic as a result of

sales of the product. The milestones, which totaled $1.8 million were based upon Epic's signing and transfer of manufacturing to their manufacturing facilities. Please note that this agreement expired prior to successful transfer of manufacturing site for all products relating to the milestones, Elite received an aggregate of $1.0 million out of the total $1.8 million in milestones provided for in the agreement.

Trimipramine Acquisition

On May 16, 2017, we executed an asset purchase agreement with Mikah Pharma, and acquired from Mikah Pharma (the "Trimipramine Acquisition") an FDA approved ANDA for Trimipramine for aggregate consideration of $1,200,000, payable pursuant to a senior secured note due on December 31, 2020 (the "Trimipramine Note"). Mikah Pharma is owned by Nasrat Hakim, the Chairman of the Board of Directors, President and Chief Executive Officer (CEO) of the Company.

The Trimipramine Note bears interest at the rate of 10% per annum, payable quarterly. All principal and unpaid interest is due and payable on December 31, 2020. Pursuant to a security agreement, repayment of the Trimipramine Note is secured by the ANDA acquired in the Acquisition.

Trimipramine Distribution Agreement with Dr. Reddy's Laboratories, Inc. and Manufacturing Agreement with Epic

On May 17, 2017, in conjunction with the Trimipramine Acquisition, the Company executed an assignment agreement with Mikah Pharma, pursuant to which the Company acquired all rights, interests, and obligations under a supply and distribution agreement (the "Reddy's Trimipramine Distribution Agreement") with Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's") originally entered into by Mikah Pharma on

May 7, 2017 and relating to the supply, sale and distribution of generic Trimipramine Maleate Capsules 25mg, 50mg and 100mg.

On May 22, 2017, the Company executed an assignment agreement with Mikah Pharma, pursuant to which the Company acquired all rights, interests and obligations under a manufacturing and supply agreement with Epic originally entered into by Mikah in 2011 and amended on June 30, 2015 and relating to the manufacture and supply of Trimipramine (the "Epic Trimipramine Manufacturing Agreement").

Under the Epic Trimipramine Manufacturing Agreement, Epic manufactured Trimipramine under license from the Company pursuant to the FDA approved and currently marketed Abbreviated New Drug Application that was acquired in conjunction with the Company's entry into these agreements.

Under the Reddy's Trimipramine Distribution Agreement, the Company supplied Trimipramine on an exclusive basis to Dr. Reddy's and Dr. Reddy's was responsible for all marketing and distribution of Trimipramine in the United States, its territories, possessions, and commonwealth. The Trimipramine was manufactured by Epic and transferred to Dr. Reddy's at cost, without markup.

The Reddy's Trimipramine Distribution Agreement was concluded by mutual consent in August 2018.

Elite successfully transferred manufacturing of Trimipramine to the Northvale Facility in September 2018, resulting in the irrelevance of the Epic Manufacturing Agreement.

Methadone Manufacturing and Supply Agreement

On June 23, 2011 and as amended on September 24, 2012, January 19, 2015, July 20, 2015 and as extended on August 9, 2016, we entered into an agreement to manufacture and supply Methadone 10mg to ThePharmaNetwork LLC (the "*Methadone Manufacturing and Supply Agreement*"). ThePharmaNetwork LLC was subsequently acquired by Alkem Laboratories Ltd ("*Alkem*") and now goes by the name Ascend Laboratories LLC ("*Ascend*") and is a wholly owned subsidiary of Alkem.

Ascend is the owner of the approved ANDA for Methadone 10mg, and the Northvale Facility is an approved manufacturing site for this ANDA. The Methadone Manufacturing and Supply Agreement provides for the manufacturing and packaging by the Company of Ascend's methadone hydrochloride 10mg tablets.

The initial shipment of Methadone 10mg pursuant to the Methadone Manufacturing and Supply Agreement occurred in January 2012.

On August 26, 2016, the Methadone Manufacturing and Supply Agreement was amended and extended through December 31, 2017 and expired. We made our final shipments of Methadone to Ascend during the quarter ended June 30, 2018.

Precision Dose License Agreement

On September 10, 2010, we executed a License Agreement with Precision Dose (the "Precision Dose

License Agreement") to market and distribute Phentermine 37.5mg, Phentermine 15mg, Phentermine 30mg, Hydromorphone 8mg, Naltrexone 50mg, and certain additional products that require approval from the FDA, through its wholly-owned subsidiary, TAGI, in the United States, Puerto Rico and Canada. Phentermine 37.5mg was launched in April 2011. Hydromorphone 8mg was launched in March 2012. Phentermine 15mg and Phentermine 30mg were launched in April 2013. Naltrexone 50mg was launched in September 2013. Precision Dose will have the exclusive right to market these products in the United States and Puerto Rico and a non-exclusive right to market the products in Canada. Pursuant to the Precision Dose License Agreement, Elite will receive a license fee and milestone payments. The license fee will be computed as a percentage of the gross profit, as defined in the Precision Dose License Agreement, earned by Precision Dose as a result of sales of the products. The license fee is payable monthly for the term of the Precision Dose License Agreement. The milestone payments will be paid in six installments. The first installment was paid upon execution of the Precision Dose License Agreement. The remaining installments are to be paid upon FDA approval and initial shipment of the products to Precision Dose. The term of the Precision Dose License Agreement is 15 years and may be extended for 3 successive terms, each of 5 years.

Master Development and License Agreement with SunGen Pharma LLC

On August 24, 2016, as amended we entered into an agreement with SunGen Pharma LLC ("SunGen") (the "SunGen Agreement") to undertake and engage in the research, development, sales and marketing of eight generic pharmaceutical products. Two of the products are classified as CNS stimulants (the "CNS Products"), two of the products are classified as beta blockers and the remaining four products consist of antidepressants, antibiotics and antispasmodics.

Under the terms of the SunGen Agreement, Elite and SunGen will share in the responsibilities and costs in

the development of these products and will share substantially in the profits from sales. Upon approval, the know-how and intellectual property rights to the products will be owned jointly by Elite and SunGen. Three of the eight products will be jointly owned, three products will be owned by SunGen, with Elite having exclusive marketing rights and the remaining two products will be owned by Elite, with SunGen having exclusive marketing rights. Elite will manufacture and package all eight products on a cost-plus basis.

On May 24, 2018, the Company filed an ANDA with the FDA for a generic version of an extended release CNS stimulant. The ANDA represents the second filing for a product co-developed with SunGen under the SunGen Agreement. According to IMS Health data, the branded product and its equivalents had total U.S. sales of approximately $1.6 billion for the twelve months ended September 30, 2017. The Company has not yet received a response from the FDA on this filing.

On December 10, 2018, the Company received approval from the FDA for a generic version of Adderall®, an immediate-release mixed salt of a single entity amphetamine product (Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, Amphetamine Sulfate) with strengths of 5mg, 7.5mg, 10mg, 12.5mg, 15mg, 20mg and 30mg tablets. The product is a central nervous system stimulant and is indicated for the treatment of Attention Deficit Hyperactivity Disorder (“ADHD”) and Narcolepsy. According to QVIA (formerly QuintilesIMS Health) data, the branded product and its equivalents had total U.S. sales of $365 million for the twelve months ending September 30, 2018. This product is jointly owned by the Company and SunGen, pursuant to the SunGen Agreement.

On January 3, 2019, the Company filed an ANDA for a generic version of an antibiotic. This is the third ANDA that Elite has co-developed and filed pursuant to the SunGen Agreement. According to QVIA (formerly QuintilesIMS Heath) data, the branded product for this antibiotic and its equivalents had total annual U.S. sales of approximately $94 million for the twelve months ended September 30, 2018.

There can be no assurances that any of these products will receive marketing authorization and achieve commercialization within this time period, or at all. In addition, even if marketing authorization is received, there can be no assurances that there will be future revenues of profits, or that any such future revenues or profits would be in amounts that provide adequate return on the significant investments made to secure these marketing authorizations.

Strategic Marketing Alliance with Glenmark Pharmaceuticals, Inc. USA

On May 29, 2018, we entered into a license, manufacturing and supply agreement with Glenmark Pharmaceuticals Inc. USA (“Glenmark”) to market the two Elite generic products described below in the United States with the option to add products in the future (the “Glenmark Alliance”).

Pursuant to the Glenmark Alliance, Glenmark will purchase the products from Elite and then sell and distribute them. In addition to the purchase prices for the products, Elite will receive license fees well in excess of 50% of gross profits. Gross profits are defined as net sales less the price paid to Elite for the products, distribution fees (less than 10%) and shipping costs. Glenmark will have semi-exclusive marketing rights to the ANDA approved generic product, phendimetrazine 35mg tablets, and exclusive

marketing rights to Methadone 5mg and 10mg, products that were approved by the FDA on August 3, 2018. Collectively, the brand products and their generic equivalents had total annual sales of approximately $33.6 million in 2017, according to Quintiles IMS Health data. The Agreement has an initial term of three years and automatically renews for one-year periods absent prior written notice of non-renewal. In addition to customary termination provisions, the Agreement permits Glenmark to terminate with regard to a product on at least three months' prior written notice if it determines to stop marketing and selling such product, and it permits Elite to terminate with regard to a product if at any time after the first twelvemonths from the first commercial sale, the average license fee paid by Glenmark for such product is less than a defined minimum amount.

Products Under Development

Elite's research and development activities are primarily focused on developing its proprietary abuse deterrent technology and the development of a range of abuse deterrent opioid products that utilize this technology or other approaches to abuse deterrence.

Elite's proprietary abuse-deterrent technology utilizes the pharmacological approach to abuse deterrence and consists of a multi-particulate capsule which contains an opioid agonist in addition to naltrexone, an opioid antagonist used primarily in the management of alcohol dependence and opioid dependence. When this product is taken as intended, the naltrexone is designed to pass through the body unreleased while the opioid agonist releases over time providing therapeutic pain relief for which it is prescribed. If the multi-particulate beads are crushed or dissolved, the opioid antagonist, naltrexone, is designed to release. The absorption of the naltrexone is intended to block the euphoria by preferentially binding to same receptors in the brain as the opioid agonist and thereby reducing the incentive for abuse or misuse by recreational drug abusers.

We filed an NDA for the first product to utilize our abuse deterrent technology, Immediate Release Oxycodone 5mg, 10mg, 15mg, 20mg and 30mg with sequestered Naltrexone (collectively and individually referred to as "SequestOx™"), on January 14, 2016. Please see "Filed products under FDA review; SequestOx™ - Immediate Release Oxycodone with sequestered Naltrexone" above.

On September 20, 2017, the Company filed an ANDA with the FDA for generic version of Oxycontin® (extended release Oxycodone Hydrochloride). Please see "Filed products under FDA review; Oxycodone Hydrochloride extended release (generic version of Oxycontin®" above. Please note that there can be no assurances of this product receiving marketing authorization or achieving commercialization. In addition, even if marketing authorization is received and the product is commercialized, there can be no assurances of future revenues or profits in such amounts that would provide adequate return on the significant investments made to secure marketing authorization for this product.

On May 30, 2018, the Company filed an ANDA with the FDA for a generic version of an extended release CNS stimulant. The ANDA represents the second filing for a product co-developed with SunGen under the SunGen Agreement. Please see "Filed products under FDA review Generic version of extended release Central Nervous System stimulant" above. Please note that there can be no assurances of this product receiving marketing authorization or achieving commercialization. In addition, even if marketing authorization is received and the product is commercialized, there can be no assurances of future revenues or profits in such amounts that would provide adequate return on the significant investments made to secure marketing authorization for this product. Please also see the section below titled "Master Development and License Agreement with SunGen Pharma LLC".

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On September 18, 2018, the Company filed an ANDA for a generic version of Tylenol® with Codeine (acetaminophen and codeine phosphate) 300mg/7.5mg, 300mg/30mg and 300mg/60mg tablets. Acetaminophen with codeine is a combination medication indicated for the management of mild to moderate pain, where treatment with an opioid is appropriate and for which the alternative treatments are inadequate. Acetaminophen with codeine products have annual U.S. sales of approximately $45 million according to IQVIA (formerly QuintilesIMS Health Data).

On January 3, 2019, the Company filed an ANDA for a generic version of an antibiotic. This is the third ANDA that Elite has co-developed and filed pursuant to the SunGen Agreement. According to QVIA (formerly QuintilesIMS Heath) data, the branded product for this antibiotic and its equivalents had total annual U.S. sales of approximately $94 million for the twelve months ended September 30, 2018.

The Company believes that the abuse deterrent technology can be applied to and incorporated into a wide range of opioids used today for pain management and has, to date, identified 10 additional products for potential development. All of these products are at early stages of development, with research and development activities mainly consisting of in-house process development and laboratory studies. Extensive efficacy and safety studies, similar to those conducted for SequestOx™, Generic Oxy/APAP and Generic Hydrocodone/APAP, have not yet been conducted for these other products. As a result, costs incurred in relation to the development of these 10 products have not been material.

On June 4, 2015, the Company entered into a sales and distribution licensing agreement which included a non-refundable payment of $5 million to Elite for prior research and development activities, with such

representing the first material net cash inflows being generated by ELI-200. On January 14, 2016, the Company filed an NDA with the FDA for SequestOx™, thereby earning a non-refundable $2.5 million milestone. An additional $7.5 million non-refundable milestone is due upon the FDA's approval of Elite's NDA. Please note, as further detailed above, there can be no assurances of the Company receiving marketing authorization for SequestOx™, and accordingly, there can be no assurances that the Company will earn and receive the additional $7.5 million or future license fees. The non-receipt by the Company of these payments and or fees will materially and adversely affect our financial condition.

Please note that, while the FDA is required to review applications within certain timeframes, during the review process, the FDA frequently requests that additional information be submitted. The effect of such request and subsequent submission can significantly extend the time for the NDA review process. Until an NDA is actually approved, there can be no assurances that the information requested and submitted will be considered adequate by the FDA to justify approval. The packaging and labeling of our developed products are also subject to FDA regulation. Based on the foregoing, it is impossible to anticipate the amount of time that will be needed to obtain FDA approval to market any product. In addition, there can be no assurances of the Company filing the required application(s) with the FDA or of the FDA approving such application(s) if filed, and the Company's ability to successfully develop and commercialize products incorporating its abuse deterrent technology is subject to a high level of risk as detailed in "Item 1A-Risk Factors-Risks Related to our Business" of the Annual Report on Form 10-K filed with the SEC on June 14, 2018.

Abuse-Deterrent and Sustained Release Opioids

The abuse-deterrent opioid products utilize our patented abuse-deterrent technology that is based on a pharmacological approach. These products are combinations of a narcotic agonist formulation

intended for use in patients with pain, and an antagonist, formulated to deter abuse of the drug. Both, agonist and antagonist, have been on the market for a number of years and sold separately in various dose strengths. We have filed INDs for two abuse resistant products under development and have tested products in various pharmacokinetic and efficacy studies. We expect to continue to develop multiple abuse resistant products. Products utilizing the pharmacological approach to deter abuse such as Suboxone®, a product marketed in the United States by Reckitt Benckiser Pharmaceuticals, Inc., and Embeda®, a product marketed in the United States by Pfizer, Inc., have been approved by the FDA and are being marketed in the United States. We have developed, licensed to Epic the marketing rights to SequestOx™, immediate release Oxycodone with Naltrexone, and retain the rights to the remainder of these abuse resistant and sustained release opioid products. We may license these products at a later date to a third party who could provide funding for the remaining clinical studies and who could provide sales and distribution for the product.

We also developed controlled release technology for oxycodone under a joint venture with Elan which terminated in 2002. According to the Elan Termination Agreement, we acquired all proprietary, development and commercial rights for the worldwide markets for the products developed by the joint venture, including the sustained release opioid products. Upon licensing or commercialization of an oral controlled release formulation of oxycodone for the treatment of pain, we will pay a royalty to Elan pursuant to the Elan Termination Agreement. If we were to sell the product itself, we will pay a 1% royalty to Elan based on the product’s net sales, and if we enter into an agreement with another party to sell the product, we will pay a 9% royalty to Elan based on our net revenues from this product. We are allowed to recoup all development costs including research, process development, analytical development, clinical development and regulatory costs before payment of any royalties to Elan.

Patents

Since our incorporation, we have secured the following patents, of which two have been assigned for a fee to another pharmaceutical company. Our patents are:

PATENT	EXPIRATION DATE
U.S. patent 5,837,284 (assigned to Celgene Corporation)	November 2018
U.S. patent 6,620,439	October 2020
U.S. patent 6,926,909	April 2023
U.S. patent 8,182,836	April 2024
U.S. patent 8,425,933	April 2024
U.S. patent 8,703,186	April 2024
Canadian patent 2,521,655	April 2024
Canadian patent 2,541,371	September 2024
U.S. patent 9,056,054	June 2030
E.P. patent 1615623	April 2024

We also have pending applications for two additional U.S. patents and two foreign patents. We intend to apply for patents for other products in the future; however, there can be no assurance that any of the pending applications or other applications which we may file will be granted. We have also filed corresponding foreign applications for key patents.

Prior to the enactment in the United States of new laws adopting certain changes mandated by the General Agreement on Tariffs and Trade (“GATT”), the exclusive rights afforded by a U.S. Patent were for a period of 17 years measured from the date of grant. Under GATT, the term of any U.S. Patent granted on an application filed subsequent to June 8, 1995 terminates 20 years from the date on which the patent application was filed in the United States or the first priority date, whichever occurs first. Future patents granted on an application filed before June 8, 1995, will have a term that terminates 20 years from such date, or 17 years from the date of grant, whichever date is later.

Under the Drug Price Competition Act, a U.S. product patent or use patent may be extended for up to five years under certain circumstances to compensate the patent holder for the time required for FDA regulatory review of the product. Such benefits under the Drug Price Competition Act are available only to the first approved use of the active ingredient in the drug product and may be applied only to one patent per drug product. There can be no assurance that we will be able to take advantage of this law.

Also, different countries have different procedures for obtaining patents, and patents issued by different countries provide different degrees of protection against the use of a patented invention by others. There can be no assurance, therefore, that the issuance to us in one country of a patent covering an invention will be followed by the issuance in other countries of patents covering the same invention, or that any judicial interpretation of the validity, enforceability, or scope of the claims in a patent issued in one country will be similar to the judicial interpretation given to a corresponding patent issued in another country. Furthermore, even if our patents are determined to be valid, enforceable, and broad in scope, there can be no assurance that competitors will not be able to design around such patents and compete with us using the resulting alternative technology.

Trademarks

SequestOx™ is a trademark owned by Elite, which received a Notice of Allowance by the United States Patent and Trademark Office on December 22, 2015. We currently plan to license at least some of our products to other entities in the marketing of pharmaceuticals but may also sell products under our own brand name in which case we may register trademarks for those products.

Sources and Availability of Raw Materials; Manufacturing

A significant portion of our raw materials may be available only from foreign sources. Foreign sources can be subject to the special risks of doing business abroad, including:

greater possibility for disruption due to transportation or communication problems;

the relative instability of some foreign governments and economies;

interim price volatility based on labor unrest, materials or equipment shortages, export duties, restrictions on the transfer of funds, or fluctuations in currency exchange rates; and

uncertainty regarding recourse to a dependable legal system for the enforcement of contracts and other rights.

While we currently obtain the raw materials that we need from over 20 suppliers, some materials used in our products are currently available from only one supplier or a limited number of suppliers. The FDA requires identification of raw material suppliers in applications for approval of drug products. If raw materials were unavailable from a specified supplier, FDA approval of a new supplier could delay the manufacture of the drug involved.

We have acquired pharmaceutical manufacturing equipment for manufacturing our products. We have registered our facilities with the FDA and the DEA.

Dependence on One or a Few Major Customers

Each year we have had one or a few customers that have accounted for a large percentage of our limited revenues, therefore the termination or restructuring of a contract with a customer may result in the loss of material amount or substantially all of our revenues. We are constantly working to develop new relationships with existing or new customers, but despite these efforts we may not, at the time that any of our current contracts expire, have other contracts in place generating similar or material revenue. We have agreements with Epic, Precision Dose and Glenmark for the licensing, sales and distribution of products that we manufacture. We are currently renegotiating a licensing contract with Epic, which may result in the termination of an existing contract or an amended licensing contract that is materially different from that already in place. We receive revenues to manufacture these products and also receive a profit split or royalties based on in-market sales of the products. Please see the Risk Factors in Part II, Item 1A entitled "*We depend on a limited number of customers and any reduction, delay or cancellation of an order from these customers or the loss of any of these customers could cause our revenue to decline*."

Critical Accounting Policies and Estimates

The preparation of the unaudited condensed consolidated financial statements and related disclosures in conformity with GAAP, and our discussion and analysis of its financial condition and operating results require our management to make judgments, assumptions and estimates that affect the amounts reported in its condensed consolidated financial statements and accompanying notes. Note 1 – Summary of Significant Accounting Policies, of the Notes to Condensed Consolidated Financial Statements of this Quarterly Report on Form 10-Q describes the significant accounting policies and methods used in the preparation of our unaudited condensed consolidated financial statements. 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.

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, 2018 compared to December 31, 2017

Revenue, Cost of revenue and Gross profit:

	For the Three Months Ended December 31,		Change	
	2018	2017	Dollars	Percentage
Manufacturing fees	$2,108,487	$2,083,826	$24,661	1 %
Licensing fees	585,479	451,628	133,851	30 %
Total revenue	2,693,966	2,535,454	158,512	6 %
Cost of revenue	1,771,136	1,419,829	351,307	25 %
Gross profit	$922,830	$1,115,625	$(192,795)	-17 %
Gross profit - percentage	34 %	44 %		

Total revenues for the three-month period ended December 31, 2018 increased by $0.2 million or 6%, to $2.7 million, as compared to $2.5 million, for the corresponding period in 2017 primarily due to the launch, in November 2018, of the recently approved Methadone products being marketed pursuant to the Glenmark Strategic Alliance, and increased profit splits earned from Isradipine, Naltrexone and Phentermine.

Manufacturing fees increased by $0.02 million, or 1%, due to the methadone launch, as more fully described above.

Licensing fees increased by $0.1 million, or 30%. This increase is primarily due to the timing of in-market sales of the Company’s generic products, especially, without limitation, generic Isradipine, Phentermine and Naltrexone, as well as margins achieved by the Company’s licensed marketing partners. License fees earned are based on in-market sales and accordingly, there is a natural lag between manufacturing revenues earned by the Company and

related license fees being earned from in market sales occurring subsequent to the Company's shipment of licensed generic products to its marketing partners. In market profits achieved by the Company's marketing partners are also a factor, with a direct correlation to the license fee revenues earned by the Company.

Costs of revenue consists of manufacturing and assembly costs. Our costs of revenue increased by $0.4 million or 25%, to $1.8 million as compared to $1.4 million for the corresponding period in 2017. This increase was due in large part to manufacturing operations consisting of a greater proportion of lower margin products, as compared to the prior year. Costs of revenue consists of manufacturing and assembly costs, with there being a strong correlation with manufacturing fees, as well as the product components of such manufacturing fees.

Our gross profit margin was 34% during the three months ended December 31, 2018 as compared to 44% during the three months ended December 31, 2017. The decrease in gross margin is due to the product mix of generics manufactured during the quarter.

Operating expenses:

	For the Three Months Ended December 31,		Change	
	2018	2017	Dollars	Percentage
Operating expenses:				
Research and development	$2,454,098	$2,289,273	$164,825	7 %
General and administrative	748,151	614,994	133,157	22 %
Non-cash compensation	36,547	37,961	(1,414)	-4 %
Depreciation and amortization	321,164	232,358	88,806	38 %
Total operating expenses	$3,559,960	$3,174,586	$385,374	12 %

Operating expenses consist of research and development costs, general and administrative,

non-cash compensation and depreciation and amortization expenses. Operating expenses for the three-month period ended December 31, 2018 increased by $0.4 million, or 12%, to $3.6 million, as compared to $3.2 million for the corresponding period in 2017.

Research and development costs for the three months ended December 31, 2018 was $2.5 million, an increase of $0.2 million, or 7%, from $2.3 million of such costs for the comparable period of the prior year. The increase was a result of the timing, nature and resources utilized during the current quarter as compared to such activities and resources employed in the prior fiscal year.

General and administrative expenses for the three months ended December 31, 2018 were $0.7 million, an increase of $0.1 million or 22% from $0.6 million of such costs for the comparable period of the prior year with such increase being attributed in large part to increased costs relating to compliance with various regulatory authorities and increased FDA regulatory fees.

Non-cash compensation expense for the three months ended December 31, 2018 and 2017 was $0.04 million and $0.04 million, respectively.

Depreciation and amortization expenses for the three months ended December 31,2018 was $0.3 million, an increase of $0.1 million or 38% from $0.2 million of such costs for the comparable period of the prior year. The increase was due to acquisitions of additional fixed assets as well as additional equipment being placed into service during the current fiscal quarter.

As a result of the foregoing, our loss from operations for the three months ended December 31, 2018 was $2.6 million, compared to a loss from operations of $2.1 million for the three months ended December 31, 2017.

Other income (expense):

	For the Three Months Ended December 31,		Change	
	2018	2017	Dollars	Percentage
Other income (expense):				
Interest expense and amortization of debt issuance costs	$(89,897)	$(92,458)	$2,561	-3 %
Change in fair value of derivative instruments	380,976	605,448	(224,472)	-37 %

Interest income	1,733	4,461	(2,728)	-61	%
Other income, net	$292,812	$517,451	$(224,639)	-43	%

Other income, net for the three months ended December 31, 2018 was a net other income of $0.3 million, a decrease in net other income of $0.2 million from the net other income of $0.5 million for the comparable period of the prior year. The decrease in other income was due to derivative income relating to changes in the fair value of our outstanding warrants during the quarter ended December 31, 2017. Please note that the change in the fair value of derivative instruments is determined in large part by the number of warrants outstanding and the change in the closing price of the Company's Common Stock as of the end of the period, as compared to the closing price at the beginning of the period, with a strong inverse relationship between the fair value of our derivatives instruments and increases in the closing price of the Company's Common Stock. The warrants related to revenues earned in relation to the change in fair value of derivative instruments for the quarter ended December 31, 2017 expired prior to the quarter ended December 31, 2018 and accordingly had no impact on other income (expense) during the current fiscal quarter.

As a result of the foregoing, our net loss for the three months ended December 31, 2018 was $2.3 million, compared to a net loss of $0.5 million for the comparable period of the prior year.

Change in value of convertible preferred share mezzanine equity:

There were no changes in the value of our convertible preferred stock, which is included in the calculation of net loss attributable to common shareholders for the three months ended December 31, 2018, and December 31, 2017.

Nine months ended December 31, 2018 compared to December 31, 2017

Revenue, Cost of revenue and Gross profit:

	For the Nine Months Ended December 31,		Change	
	2018	2017	Dollars	Percentage
Manufacturing fees	$4,456,832	$4,160,949	$295,883	7 %
Licensing fees	1,767,881	1,700,856	67,025	4 %
Total revenue	6,224,713	5,861,805	362,908	6 %
Cost of revenue	3,890,086	3,049,830	840,256	28 %
Gross profit	$2,334,627	$2,811,975	$(477,348)	-17 %
Gross profit - percentage	39 %	48 %		

Total revenues for the nine-month period ended December 31, 2018 increased by $0.4 million or 6%, to $6.2 million, as compared to $5.9 million, for the corresponding period in 2017 primarily due to increases in revenues related to the manufacture and sale of generic Naltrexone as compared to the comparable period of the prior fiscal year and the November 2018 launch of Methadone.

Manufacturing fees increased by $0.3 million, or 7%, due to an increase in fees earned from the manufacture of generic Naltrexone.

Licensing fees increased by $0.1 million, or 4%. This increase is primarily due to the timing of in-market sales of the Company’s generic products, especially, without limitation, generic Isradipine and Phentermine, as well as margins achieved by the Company’s licensed marketing partners. License fees earned are based on in-market sales and accordingly, there is a natural lag between manufacturing revenues earned by the Company and related license fees being earned from in market sales occurring subsequent to

the Company's shipment of licensed generic products to its marketing partners. In market profits achieved by the Company's marketing partners are also a factor, with a direct correlation to the license fee revenues earned by the Company.

Our costs of revenue increased by $0.8 million or 28%, to $3.9 million as compared to $3.0 million for the corresponding period in 2017. Costs of revenue consists of manufacturing and assembly costs, with there being a strong correlation with manufacturing fees, as well as the product components of such manufacturing fees.

Our gross profit margin was 38% during the nine months ended December 31, 2018 as compared to 48% during the nine months ended December 31, 2017. The decrease in gross margin is due to the product mix of generics manufactured during the period, with the current year period specifically consisting of a greater proportion of naltrexone manufacturing as compared to the prior year. .

Operating expenses:

	For the Nine Months Ended December 31,		Change	
	2018	2017	Dollars	Percentage
Operating expenses:				
Research and development	$6,236,192	$6,397,777	$(161,585)	-3 %
General and administrative	2,245,900	2,068,028	177,872	9 %
Non-cash compensation	109,641	208,719	(99,078)	-47 %
Depreciation and amortization	891,390	567,554	323,836	57 %
Total operating expenses	$9,483,123	$9,242,078	$241,045	3 %

Operating expenses consist of research and development costs, general and administrative, non-cash compensation and depreciation and amortization expenses. Operating expenses for the nine-month period ended December 31, 2018

increased by $0.2 million , or 3%, to $9.5 million, as compared to $9.2 million for the corresponding period in 2017.

Research and development costs for the nine months ended December 31, 2018 were $6.2 million, a decrease of $0.2 million or 3% from $6.9 million of such costs for the comparable period of the prior year. The decrease was due to the timing and composition of ongoing development of our abuse deterrent opioid, products under development pursuant to the SunGen Agreement and other products.

General and administrative expenses for the nine months ended December 31, 2018 were $2.2 million, an increase of $0.2 million or 9% from $2.1 million of such costs for the comparable period of the prior year with such increase being primarily due to increases in regulatory compliance costs.

Non-cash compensation expense for the nine months ended December 31, 2018 and 2017 was $0.1 million and $0.2 million, respectively. The decrease in non-cash compensation expense derives from the timing in amortization of the value of employee stock options issued over the course of the last three years.

Depreciation and amortization expenses for the nine months ended December 31,2018 was $0.9 million, an increase of $0.3 million or 57% from $0.6 million of such costs for the comparable period of the prior year. The increase was due to acquisitions of additional fixed assets as well as additional equipment being placed into service during the current fiscal year, in particular equipment required for compliance with new serialization regulations.

As a result of the foregoing, our loss from operations for the nine months ended December 31, 2018 was $7.1 million**,** compared to a loss from operations of $6.4 million for the nine months ended December 31, 2017.

Other income (expense):

	For the Nine Months Ended December 31,		Change	
	2018	2017	Dollars	Percentage
Other income (expense):				

Interest expense and amortization of debt issuance costs	$(279,037)	$(245,730)	$(33,307)	14	%
Change in fair value of derivative instruments	807,347	4,767,884	(3,960,537)	-83	%
Interest income	4,570	12,862	(8,292)	-64	%
Other income (expense), net	$532,880	$4,535,016	$(4,002,136)	-88	%

Other income, net for the nine months ended December 31, 2018 was net other income of $0.5 million, a decrease in net other income of $4.0 million from the net other income of $4.5 million for the comparable period of the prior year. The decrease in other income was due to derivative income relating to changes in the fair value of our outstanding warrants during the quarter ended December 31, 2018 totaling a decrease in other income of $4.0 million, as compared to the prior period. Please note that derivative income (expenses) is determined in large part by the number of warrants outstanding and 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 derivative revenues and increases in the closing price of the Company's Common Stock. Please also note that the warrants related to revenues earned in relation to the change in fair value of derivative instruments for the nine months ended December 31, 2017 had substantially been exercised or expired prior to the nine-month period ended December 31, 2018 and accordingly had no impact on other income (expense) during the current fiscal quarter.

As a result of the foregoing, our net loss for the nine months ended December 31, 2018 was $6.6 million, compared to $0.8 million for the comparable period of the prior year.

Change in value of convertible preferred share mezzanine equity:

There were no changes in the value of our convertible preferred stock, which is included in the calculation

of net loss attributable to common shareholders for the nine months ended December 31, 2018, and December 31, 2017.

Liquidity and Capital Resources

Capital Resources

	December 31, 2018	March 31, 2018	Change
Current assets	$ 9,431,204	$ 13,702,401	$ (4,271,197)
Current liabilities	6,940,409	5,114,704	1,825,705
Working capital	2,490,795	8,587,697	(6,096,902)

The Company considers cash and working capital balances as several of the factors the Company uses in evaluating its performance, without limitation. As of December 31, 2018, the Company had cash on hand of $3.7 million and a working capital surplus of $2.5 million. We believe that such resources, combined with the Company’s access to part or all of the remaining $36.0 million available pursuant to the $40 million equity line with Lincoln Park is sufficient to fund operations through the current operating cycle. For the nine months ended December 31, 2018, we had losses from operations totaling $7.1 million, and net other income totaling $0.5 million, resulting in a net loss of $6.6 million.

The Company does not anticipate being profitable for the fiscal year ending March 31, 2019, due in large part to its plans to conduct clinical development and commercialization activities on a range of abuse deterrent opioid products, on an accelerated and simultaneous basis. Such activities require the investment of significant amounts in clinical trials, safety and efficacy studies, bioequivalence studies, product manufacturing, regulatory expertise and filings, as well as investments in manufacturing and lab equipment and software. In order to finance these significant expenditures, the Company entered into a new purchase agreement with Lincoln Park Capital Fund, with such agreement providing the Company with an equity line totaling $40 million. We believe this amount of financing, if received, is sufficient to fund the commercialization of the abuse deterrent opioid products identified. Please see below for further details on the financing transactions with Lincoln Park.

Summary of Cash Flows:

	For the Nine Months Ended December 31,	
	2018	2017
Net cash used in operating activities	$(4,656,762)	$(3,795,644)
Net cash used in investing activities	$(19,130)	$(376,633)
Net cash (used in) provided by financing activities	$1,181,783	$823,545

Net cash used in operating activities for the nine months ended December 31, 2018 was $4.7 million, which included net losses of $6.5 million and change in fair value of derivative financial instruments – warrants of $0.8 million (non-cash). These instances of decreases in cash are offset by non-cash expenses including depreciation and amortization of $0.9 million, non-cash compensation accrued of $1.4 million, non-cash compensation from the issuance of options of $0.1 million, as well as changed in operating assets and liabilities of $0.3 million.

Net cash used in investing activities for the nine months ended December 31, 2018 was $0.02 million.

Net cash provided by financing activities was $1.2 million for the nine months ended December 31, 2018 which consist primarily from proceeds from the issuance of common stock pursuant to the 2017 LPC Purchase Agreement (see below).

Lincoln Park Capital – May 1, 2017 Purchase Agreement

On May 1, 2017, the Company entered into a purchase agreement (the "2017 LPC Purchase Agreement"), together with a registration rights agreement (the "2017 LPC Registration Rights Agreement"), with Lincoln Park.

Under the terms and subject to the conditions of the 2017 LPC Purchase Agreement, the Company has the right to sell to and Lincoln Park is obligated to purchase up to $40 million in shares of common stock, subject to certain limitations, from time to time, over the 36-month period commencing on June 5, 2017.

The Company may direct Lincoln Park, at its sole discretion and subject to certain conditions, to purchase up to 500,000 shares of Common Stock on any business day, provided that at least one business day has passed since the most recent purchase, increasing to up to 1,000,000 shares, depending upon the closing sale price of the Common Stock (such purchases, "Regular Purchases"). However, in no event shall a Regular Purchase be more than $1,000,000. The purchase price of shares of common stock related to the future funding will be based on the prevailing market prices of such shares at the time of sales. In addition, the Company may direct Lincoln Park to

purchase additional amounts as accelerated purchases under certain circumstances. Sales of shares of common stock to Lincoln Park under the 2017 LPC Purchase Agreement are limited to no more than the number of shares that would result in the beneficial ownership by Lincoln Park and its affiliates, at any single point in time, of more than 4.99% of the then outstanding shares of common stock.

In connection with the 2017 LPC Purchase Agreement, the Company issued to Lincoln Park 5,540,550 shares of common stock and the Company is required to issue up to 5,540,550 additional shares of common stock pro rata as the Company requires Lincoln Park to purchase shares under the 2017 LPC Purchase Agreement over the term of the agreement. Lincoln Park has represented to us, among other things, that it is an “accredited investor” (as such term is defined in Rule 501(a) of Regulation D under the Securities Act of 1933, as amended (the “Securities Act”)). We sold the securities in reliance upon an exemption from registration contained in Section 4(a)(2) under the Securities Act. The securities sold may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements.

The 2017 LPC Purchase Agreement and the 2017 LPC Registration Rights Agreement contain customary representations, warranties, agreements and conditions to completing future sale transactions, indemnification rights and obligations of the parties. The Company has the rights to terminate the 2017 LPC Purchase Agreement at any time, at no cost or penalty. Actual sales of shares of common stock to Lincoln Park under the 2017 LPC Purchase Agreement will depend on a variety of factors to be determined by us from time to time, including, among others, market conditions, the trading price of the common stock and determinations by us as to the appropriate sources of funding for us and our operations. There are no trading volume requirements or, other than the limitation on beneficial ownership discussed above, restrictions under the Purchase Agreement. Lincoln Park has no right to require any sales by the Company but is obligated to make purchases from the Company as directed in accordance with the 2017 LPC Purchase Agreement Lincoln Park has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of the Company’s shares.

The net proceeds received by under the 2017 LPC Purchase Agreement will depend on the frequency and prices at which the Company sells shares of common stock to Lincoln Park.

A registration statement on form S-3 was filed with the SEC on May 10, 2017 and was declared effective on June 5, 2017.

As of December 31, 2018, the Company issued 5,540,550 shares of its Common Stock as initial commitment shares and 508,304 shares of its Common Stock as additional commitment shares, both being pursuant to the 2017 LPC Purchase Agreement. In addition, as of December 31, 2018, the Company sold 35,461,033 shares of its common stock

for proceeds totaling 3,669,713 in connection with the 2017 LPC Purchase Agreement with Lincoln Park.

Exchange Agreement

On April 28, 2017, we entered into an exchange agreement (the "Exchange Agreement") with Nasrat Hakim, our Chief Executive Officer, pursuant to which we issued to Mr. Hakim 23.0344 shares of our newly designated Series J Convertible Preferred Stock ("Series J Preferred") (see Note 10 to the financial statements) and Warrants (see Note 11 to the financial statements) to purchase an aggregate of 79,008,661 shares of our Common Stock (the "Warrants" and, along with the Series J Preferred issued to Mr. Hakim, the "Securities") in exchange for 15,017,321 shares of our common stock owned by Mr. Hakim. The exchange was conducted pursuant to the exemption from registration provided by Section 3(a)(9) of the Securities Act of 1933, as amended (the "Securities Act").

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We believe that our market risk exposures are immaterial as we do not have instruments for trading purposes, and reasonable possible near-term changes in market rates or prices will not result in material near-term losses in earnings, material changes in fair values or cash flows for all instruments.

We maintain all our cash, cash equivalents and restricted cash in three financial institutions, and we perform periodic evaluations of the relative credit standing of these institutions. However, no assurances can be given that the third-party institutions will retain acceptable credit ratings or investment practices.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). In designing and evaluating our disclosure controls and procedures, our management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is 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.

As of the end of the period covered by this Quarterly Report on Form 10-Q, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of our disclosure controls and procedures as defined in Rule 13a-15(e) and 15d-15(e) of the Exchange Act. Based on the controls evaluation, our Chief Executive Officer and Chief Financial Officer concluded that as of the date of their evaluation, our disclosure controls and procedures were effective to provide reasonable assurance that (a) the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (b) such information is accumulated and communicated to our management, including our Chief Executive Officer and President and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Controls

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) and Rule 15d-15(f) under the Exchange Act) during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEDURES

Pending Litigation

There have been no material developments in any of the legal proceedings discussed in Item 3 of our Annual Report on Form 10-K for the year ended March 31, 2018.

ITEM 1A. RISK FACTORS

We depend on a limited number of customers and any reduction, delay or cancellation of an order from these customers or the loss of any of these customers could cause our revenue to decline.

Each year we have had one or a few customers that have accounted for a large percentage of our limited revenues therefore the termination of a contract with a customer may result in the loss of substantially all of our revenues. We are constantly working to develop new relationships with existing or new customers, but despite these efforts we may not, at the time that any of our current contracts expire, have other contracts in place generating similar or material revenue. We have agreements with Epic, Glenmark and Precision Dose for the sales and distribution of products that we manufacture. We receive revenues to manufacture these products and also receive a profit split or royalties based on in-market sales of the products.

In addition, since a significant portion of our revenues is derived from a relatively few customers, any financial difficulties experienced by any one of these customers, or any delay in receiving payments from any one of these customers, could have a material adverse effect on our business, results of operations, financial condition, and cash flows. The contract manufacturing agreement with Ascend expired on December 31, 2017 and was not renewed or extended, with resultant adverse effects on revenues, results of operations, financial condition and cash flows. Furthermore, one of the agreements with Epic expired in October 2018 and the other one expires in June 2020. The agreement that expired in October 2018 has not been renewed or extended and there can be no assurances of the other agreement being renewed with Epic at all, or on terms that are not materially different from those currently in effect. The non-renewal of the current agreement with Epic or the renewal of the other agreement on terms that are materially different from those currently in effect could have a material adverse effect on our business, results of operations, financial condition and cash flows.

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended March 31, 2018, and in Part II, “Item 1A. Risk Factors” in our Quarterly Reports on Form 10-Q for the quarters ended September 30, 2018 and June 30, 2018, which could materially affect our business, financial condition, or future results. The risks described herein and in our Annual and Quarterly Reports are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and operating results.

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

On November 7, 2018, Dr. Aqeel Fatmi resigned from our Board of Directors.

ITEM 6. EXHIBITS

Exhibit No.	Description
2.1	Agreement and Plan of Merger between Elite Pharmaceuticals, Inc., a Delaware corporation ("Elite-Delaware") and Elite Pharmaceuticals, Inc., a Nevada corporation ("Elite-Nevada"), incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed with the SEC on January 9, 2012.
3.1(a)	Articles of Incorporation of Elite-Nevada, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the SEC on January 9, 2012.
3.1(b)	Certificate of Incorporation of Elite-Delaware, together with all other amendments thereto, as filed with the Secretary of State of the State of Delaware, incorporated by reference to (a) Exhibit 4.1 to the Registration Statement on Form S-4 (Reg. No. 333-101686), filed with the SEC on December 6, 2002 (the "Form S-4"), (b) Exhibit 3.1 to the Company's Current Report on Form 8-K dated July 28, 2004 and filed with the SEC on July 29, 2004, (c) Exhibit 3.1 to the Company's Current Report on Form 8-K dated June 26, 2008 and filed with the SEC on July 2, 2008, and (d) Exhibit 3.1 to the Company's Current Report on Form 8-K dated December 19, 2008 and filed with the SEC on December 23, 2008.*
3.1(c)	Certificate of Designations, Preferences and Rights of Series A Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 4.5 to the Current Report on Form 8-K dated October 6, 2004, and filed with the SEC on October 12, 2004.*
3.1(d)	Certificate of Retirement with the Secretary of the State of the Delaware to retire 516,558 shares of the Series A Preferred Stock, as filed with the Secretary of State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated March 10, 2006, and filed with the SEC on March 14, 2006.*
3.1(e)	Certificate of Designations, Preferences and Rights of Series B 8% Convertible Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated March 15, 2006, and filed with the SEC on March 16, 2006.*
3.1(f)	Amended Certificate of Designations of Preferences, Rights and Limitations of Series B 8% Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated April 24, 2007, and filed with the SEC on April 25, 2007.*
3.1(g)	Certificate of Designations, Preferences and Rights of Series C 8% Convertible Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K dated April 24, 2007, and filed with the SEC on April 25, 2007.*
3.1(h)	Amended Certificate of Designations, Preferences and Rights of Series C 8% Convertible Preferred Stock, as filed with the

	Secretary of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated April 24, 2007, and filed with the SEC on April 25, 2007.*
3.1(i)	Amended Certificate of Designations of Preferences, Rights and Limitations of Series B 8% Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated September 15, 2008, and filed with the SEC on September 16, 2008.*
3.1(j)	Amended Certificate of Designations, Preferences and Rights of Series C 8% Convertible Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K dated September 15, 2008, and filed with the SEC on September 16, 2008.*
3.1(k)	Amended Certificate of Designations of Preferences, Rights and Limitations of Series D 8% Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.3 to the Current Report on Form 8-K dated September 15, 2008, and filed with the SEC on September 16, 2008.*
3.1(l)	Certificate of Designation of Preferences, Rights and Limitations of Series E Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated June 1, 2009, and filed with the SEC on June 5, 2009.*
3.1(m)	Amended Certificate of Designations of the Series D 8% Convertible Preferred Stock as filed with the Secretary of State of the State of Delaware on June 29, 2010, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K, dated June 24, 2010 and filed with the SEC on July 1, 2010.*
3.1(n)	Amended Certificate of Designations of the Series E Convertible Preferred Stock as filed with the Secretary of State of the State of Delaware on June 29, 2010, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K, dated June 24, 2010 and filed with the SEC on July 1, 2010.*

3.1(o)	Certificate of Designations of the Series G Convertible Preferred Stock as filed with the Secretary of State of the State of Nevada on April 18, 2013, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated April 18, 2013 and filed with the SEC on April 22, 2013.
3.1(p)	Certificate of Designation of the Series H Junior Participating Preferred Stock, incorporated by reference to Exhibit 2 (contained in Exhibit 1) to the Registration Statement on Form 8-A filed with the SEC on November 15, 2013.
3.1(q)	Certificate of Designations of the Series I Convertible Preferred Stock as filed with the Secretary of State of the State of Nevada on February 6, 2014, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K, dated February 6, 2014 and filed with the SEC on February 7, 2014.
3.1(r)	Certificate of Designations of the Series J Convertible Preferred Stock as filed with the Secretary of State of the State of Nevada on May 3, 2017, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K, dated April 28, 2017 and filed with the SEC on April 28, 2017.
3.2(a)	Amended and Restated By-Laws of the Company, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated March 17, 2014 and filed with the SEC on March 18, 2014.
3.2(b)	By-Laws of Elite-Delaware, as amended, incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form SB-2 (Reg. No. 333-90633) made effective on February 28, 2000 (the "Form SB-2").*
4.1	Form of specimen certificate for Common Stock of the Company, incorporated by reference to Exhibit 4.1 to the Form SB-2.*
4.2	Form of specimen certificate for Series B 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.*
4.3	Form of specimen certificate for Series C 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.*
4.4	Form of specimen certificate for Series D 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.*
4.5	Form of specimen certificate for Series E Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated June 1, 2009, and filed with the SEC on June 5, 2009.*
4.6	Form of specimen certificate for Series G Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated April 18, 2013 and filed with the SEC on April 22, 2013.
4.7	Form of specimen certificate for Series I Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated February 6, 2014 and filed with the SEC on February 7, 2014.

4.8	Rights Agreement, dated as of November 15, 2013, between the Company and American Stock Transfer & Trust Company, LLC., incorporated by reference to Exhibit 1 to the Registration Statement on Form 8-A filed with the SEC on November 15, 2013.
4.9	Form of Series H Preferred Stock Certificate, incorporated by reference to Exhibit 1 to the Registration Statement on Form 8-A filed with the SEC on November 15, 2013.
4.10	Warrant to purchase shares of Common Stock issued to Nasrat Hakim dated April 28, 2017 incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated April 28, 2017, and filed with the SEC on April 28, 2017.
10.1	Elite Pharmaceuticals, Inc. 2014 Equity Incentive Plan, incorporated by reference to Appendix B to the Company's Definitive Proxy Statement for its Annual Meeting of Shareholders, filed with the SEC on April 3, 2014.
10.2	Form of Confidentiality Agreement (corporate), incorporated by reference to Exhibit 10.7 to the Form SB-2.
10.3	Form of Confidentiality Agreement (employee), incorporated by reference to Exhibit 10.8 to the Form SB-2.
10.4	Loan Agreement, dated as of August 15, 2005, between New Jersey Economic Development Authority ("NJEDA") and the Company, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
10.5	Series A Note in the aggregate principal amount of $3,660,000.00 payable to the order of the NJEDA, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.

10.6	Series B Note in the aggregate principal amount of $495,000.00 payable to the order of the NJEDA, incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
10.7	Mortgage from the Company to the NJEDA, incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
10.8	Indenture between NJEDA and the Bank of New York as Trustee, dated as of August 15, 2005, incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
10.9	Consulting Agreement, dated as of July 27, 2007, between the Registrant and Willstar Consultants, Inc., incorporated by reference as Exhibit 10.1 to the Quarterly Report on Form 10-Q for the period ending September 30, 2007 and filed with the SEC on November 14, 2007.
10.10	Compensation Agreement, dated as of December 1, 2008, by and between the Company and Jerry I. Treppel, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated December 1, 2008 and filed with the SEC on December 4, 2008.
10.11	Strategic Alliance Agreement, dated as of March 18, 2009, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated March 18, 2009 and filed with the SEC on March 23, 2009.
10.12	Amendment to Strategic Alliance Agreement, dated as of April 30, 2009, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated April 30, 2009 and filed with the SEC on May 6, 2009.
10.13	Second Amendment to Strategic Alliance Agreement, dated as of June 1, 2009, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated June 1, 2009, and filed with the SEC on June 5, 2009.
10.14	Third Amendment to Strategic Alliance Agreement, dated as of Aug 18, 2009, by and among the Company, Epic Pharma LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q, for the period ending June 30, 2009 and filed with the SEC on August 19, 2009.
10.15	Employment Agreement, dated as of November 13, 2009, by and between the Company and Carter J. Ward, incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q, for the period ending September 30, 2009 and filed with the SEC on November 16, 2009.
10.16	Elite Pharmaceuticals Inc. 2009 Equity Incentive Plan, as adopted November 24, 2009, incorporated by reference to Exhibit 10.1 to the Registration Statement Under the Securities Act of 1933 on Form S-8, dated December 18, 2009 and filed with the SEC on December 22, 2009.
10.17	License Agreement, dated as of September 10, 2010, by and among Precision Dose Inc. and the Company, incorporated by reference to Exhibit 10.8 to the Quarterly Report on Form 10-Q, for the period

	ended September 30, 2010 and filed with the SEC on November 15, 2010 (Confidential Treatment granted with respect to portions of the Agreement).
10.18	Manufacturing and Supply Agreement, dated as of September 10, 2010, by and among Precision Dose Inc. and the Company, incorporated by reference to Exhibit 10.9 to the Quarterly Report on Form 10-Q, for the period ended September 30, 2010 and filed with the SEC on November 15, 2010 (Confidential Treatment granted with respect to portions of the Agreement).
10.19	Product Development Agreement between the Company and Hi-Tech Pharmacal Co., Inc. dated as of January 4, 2011, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated January 4, 2011 and filed with the SEC on January 10, 2011 (Confidential Treatment granted with respect to portions of the Agreement).
10.20	Manufacturing & Supply Agreement between the Company and ThePharmaNetwork, LLC, dated as of June 23, 2011, incorporated by reference to Exhibit 10.71 to the Annual Report on Form 10-K, for the period ended March 31, 2011 and filed with the SEC on June 29, 2011 (Confidential Treatment granted with respect to portions of the Agreement).
10.21	Treppel $500,000 Bridge Loan Agreement dated June 12, 2012, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on June 13, 2012.
10.22	December 5, 2012 amendment to the Treppel Bridge Loan Agreement incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on December 10, 2012.

10.23	Letter Agreement between the Company and ThePharmaNetwork LLC, dated September 21, 2012 incorporated by reference to Exhibit 10.6 to the Quarterly Report on Form 10-Q filed with the SEC on November 14, 2012 (Confidential Treatment granted with respect to portions of the Agreement).
10.24	Purchase Agreement between the Company and Lincoln Park Capital LLC dated April 19, 2013, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated April 18, 2013 and filed with the SEC on April 22, 2013.
10.25	Registration Rights Agreement between the Company and Lincoln Park Capital LLC dated April 19, 2013, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated April 18, 2013 and filed with the SEC on April 22, 2013.
10.26	August 1, 2013 Employment Agreement with Nasrat Hakim, incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K, dated August 1, 2013 and filed with the SEC on August 5, 2013.
10.27	August 1, 2013 Mikah LLC Asset Purchase Agreement, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K/A, dated August 1, 2013 and filed with the SEC on August 30, 2018. (Confidential Treatment granted with respect to portions of the Agreement).
10.28	August 1, 2013 Secured Convertible Note from the Company to Mikah Pharma LLC., incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated August 1, 2013 and filed with the SEC on August 5, 2013.
10.29	August 1, 2013 Security Agreement from the Company to Mikah Pharma LLC., incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K, dated August 1, 2013 and filed with the SEC on August 5, 2013.
10.30	October 15, 2013 Hakim Credit Line Agreement, incorporated by reference to Exhibit 10.16 to the Quarterly Report on Form 10-Q for the period ended September 30, 2013.
10.31	October 2, 2013 Manufacturing and Licensing Agreement with Epic Pharma LLC, incorporated by reference to Exhibit 10.17 to the Amended Quarterly Report on Form 10-Q/A for the period ended September 30, 2013 and filed with the SEC on October 17, 2018.
10.32	August 19, 2013, Master Services Agreement with Camargo Pharmaceutical Services, LLC, incorporated by reference to Exhibit 10.18 to the Quarterly Report on Form 10-Q for the period ended September 30, 2013 and filed with the SEC on November 14, 2013.
10.33	November 21, 2013 Unsecured Convertible Note from the Company to Jerry Treppel, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated November 26, 2013 and filed with the SEC on November 26, 2013.
10.34	February 7, 2014 Amendment to Secured Convertible Note from the Company to Mikah, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated February 7, 2014 and filed with the SEC on February 7, 2014.
10.35	February 7, 2014 Amendment to Secured Convertible Note from the Company to Jerry Treppel, incorporated by reference to Exhibit

	10.2 to the Current Report on Form 8-K, dated February 7, 2014 and filed with the SEC on February 7, 2014.
10.36	Purchase Agreement between the Company and Lincoln Park Capital LLC dated April 10, 2014, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated April 10, 2014 and filed with the SEC on April 14, 2014.
10.37	Registration Rights Agreement between the Company and Lincoln Park Capital LLC dated April 10, 2014, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated April 10, 2014 and filed with the SEC on April 14, 2014.
10.38	Employment Agreement with Dr. G. Kenneth Smith, dated October 20, 2014, incorporated by reference to Exhibit 10.82 to the Quarterly Report on Form 10-Q for the period ended September 30, 2014 and filed with the SEC on November 14, 2014.
10.39	January 19, 2015 Second Amendment to TPN-Elite Manufacturing and Supply Agreement dated June 23, 2011 and First Amendment to the TPN-Elite Manufacturing and Supply Agreement dated September 21, 2012, incorporated by reference to Exhibit 10.6 to the Quarterly Report on Form 10-Q/A for the period ended September 30, 2012, and filed with the SEC on November 17, 2016. Confidential Treatment granted with respect to portions of the Agreement.
10.40	January 28, 2015 First Amendment to the Loan Agreement between Nasrat Hakim and Elite Pharmaceuticals dated October 15, 2013, incorporated by reference to Exhibit 10.83 to the Quarterly Report on Form 10-Q for the period ended December 31, 2014 and filed with the SEC on February 17, 2015.
10.41	January 28, 2015 Termination of Development and License Agreement for Mikah-001 between Elite Pharmaceuticals, Inc. and Mikah Pharma LLC and Transfer of Payment, incorporated by reference to Exhibit 10.84 to the Quarterly Report on Form 10-Q for the period ended December 31, 2014 and filed with the SEC on February 17, 2015.

10.42	June 4, 2015 License Agreement with Epic Pharma LLC, incorporated by reference to Exhibit 10.85 to Amendment No. 1 to the Annual Report on Form 10-K for the fiscal year ended March 31, 2015 and filed with the SEC on July 11, 2016. (Confidential Treatment granted with respect to portions of the Agreement).
10.43	Amendment No. 1 to Hakim Employment Agreement, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on January 29, 2016.
10.44	August 24, 2016 Master Development and License Agreement between Elite and SunGen Pharma LLC. incorporated by reference to Exhibit 10.44 to the Quarterly Report on Form 10-Q for the period ended September 30, 2016 and filed with the SEC on November 9, 2016. (Confidential Treatment granted with respect to portions of the Agreement).
10.45	August 9, 2016 Amendment to Manufacturing and Supply Agreement between the Company and ThePharmaNetwork, LLC, dated as of June 23, 2011 incorporated by reference to Exhibit 10.45 to the Quarterly Report on Form 10-Q for the period ended September 30, 2016 and filed with the SEC on November 9, 2016.
10.46	July 20, 2015 Third Amendment to TPN-Elite Manufacturing and Supply Agreement dated June 23, 2011 incorporated by reference to Exhibit 10.46 to the Quarterly Report on Form 10-Q for the period ended September 30, 2016 and filed with the SEC on November 9, 2016. (Confidential Treatment granted with respect to portions of the Agreement).
10.47	Purchase Agreement between the Company and Lincoln Park Capital LLC dated May 1, 2017, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated May 2, 2017 and filed with the SEC on May 2, 2017.
10.48	Registration Rights Agreement between the Company and Lincoln Park Capital LLC dated May 1, 2017, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated May 2, 2017 and filed with the SEC on May 2, 2017.
10.49	April 28, 2017 Exchange Agreement between the Company and Nasrat Hakim, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated April 28, 2017 and filed with the SEC on April 28, 2017.
10.50	May 2017 Trimipramine Acquisition Agreement from Mikah Pharma, incorporated by reference to Exhibit 10.50 to the Annual Report on Form 10-K, for the period ended March 31, 2017 and filed with the SEC on June 14, 2017.
10.51	May 2017 Secured Promissory Note from the Company to Mikah Pharma, incorporated by reference to Exhibit 10.51 to the Annual Report on Form 10-K, for the period ended March 31, 2017 and filed with the SEC on June 14, 2017.
10.52	May 2017 Security Agreement between the Company to Mikah Pharma, incorporated by reference to Exhibit 10.52 to the Annual Report on Form 10-K, for the period ended March 31, 2017 and filed with the SEC on June 14, 2017.
10.53	May 2017 Assignment of Supply and Distribution Agreement between Dr. Reddy's Laboratories and Mikah Pharma, incorporated by reference to Exhibit 10.53 to the Annual Report on Form 10-K, for the period ended March 31, 2017 and filed with the SEC on

	June 14, 2017.
10.54	May 2017 Assignment of Manufacturing and Supply Agreement between Epic and Mikah Pharma, incorporated by reference to Exhibit 10.54 to the Annual Report on Form 10-K, for the period ended March 31, 2017 and filed with the SEC on June 14, 2017.
10.55	Supply and Distribution Agreement between Dr. Reddy's Laboratories and Mikah Pharma, incorporated by reference to Exhibit 10.55 to the Annual Report on Form 10-K, for the period ended March 31, 2017 and filed with the SEC on June 14, 2017. (Confidential Treatment granted with respect to portions of the Agreement).
10.56	Manufacturing and Supply Agreement between Epic and Mikah Pharma, incorporated by reference to Exhibit 10.56 to the Annual Report on Form 10-K, for the period ended March 31, 2017 and filed with the SEC on June 14, 2017. (Confidential Treatment granted with respect to portions of the Agreement).
10.57	Master Development and License Agreement for Products Between Elite Pharmaceuticals, Inc. And Sungen dated July 6, 2017, incorporated by reference to Exhibit 10.57 to the Quarterly Report on Form 10-Q for the period ended June 30, 2017 and filed with the SEC on August 9, 2017. (Confidential Treatment granted with respect to portions of the Agreement).
10.58	Second Amendment to Master Development and License Agreement for Products Between Elite Pharmaceuticals, Inc. and SunGen Pharma, LLC, incorporated by reference to Exhibit 10.58 to the Quarterly Report on Form 10-Q for the period ended June 30, 2017 and filed with the SEC on August 9, 2017. (Confidential Treatment granted with respect to portions of the Agreement).
10.59	First Amendment to Master Development and License Agreement for Products Between Elite Pharmaceuticals, Inc. And SunGen Pharma, LLC, incorporated by reference to Exhibit 10.59 to the Quarterly Report on Form 10-Q for the period ended June 30, 2017 and filed with the SEC on August 9, 2017. (Confidential Treatment granted with respect to portions of the Agreement).
10.60	May 29, 2018 License, Manufacturing and Supply Agreement with Glenmark Pharmaceuticals Inc. USA., incorporated by reference to Exhibit 10.60 to the Annual Report on Form 10-K for the fiscal year ended March 31, 2018 and filed with the SEC on June 14, 2018. (Confidential Treatment granted with respect to portions of the Agreement).

31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document

* On January 5, 2011, the Company changed its domicile from Delaware to Nevada. All corporate documents from Delaware have been superseded by Nevada corporate documents filed or incorporated by reference herein. All outstanding Delaware securities certificates are now outstanding Nevada securities certificates.

** Filed 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 11, 2019

By: /s/ Nasrat Hakim

Nasrat Hakim

Chief Executive Officer, President and Chairman of the Board of Directors

(Principal Executive Officer)

February 11, 2019

By: /s/ Carter J. Ward

Carter J. Ward

Chief Financial Officer, Treasurer and Secretary

(Principal Financial and Accounting Officer)