ELITE PHARMACEUTICALS INC /NV/
Form 424B3
July 14, 2016

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Registration No. 333-212266

PROSPECTUS

ELITE PHARMACEUTICALS, INC.

63,000,000 Shares of

Common Stock

This prospectus relates to the offer and sale of up to 63,000,000 shares of common stock, par value $0.001, of Elite Pharmaceuticals, Inc., a Nevada corporation, by Lincoln Park Capital Fund, LLC, or Lincoln Park or the selling shareholder.

The shares of common stock being offered by the selling shareholder have been or may be issued pursuant to the purchase agreement dated April 10, 2014 that we entered into with Lincoln Park. See “The Lincoln Park Transaction” in “Selling Shareholder” for a description of that agreement and “Selling Shareholder” for additional information regarding Lincoln Park. The prices at which Lincoln Park may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions.

We are not selling any securities under this prospectus and will not receive any of the proceeds from the sale of shares by the selling shareholder.

The selling shareholder may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. See “Plan of Distribution” for more information about how the selling shareholder may sell the shares of common stock being registered pursuant to this prospectus. The selling shareholder is an “underwriter” within the meaning of Section 2(a)(11) of the Securities Act of 1933, as amended.

We will pay the expenses incurred in registering the shares, including legal and accounting fees. See “Plan of Distribution”.

Our common stock is currently quoted on the Over-the-Counter Bulletin Board, or the OTCBB, under the symbol “ELTP”. On July 11, 2016, the last reported sale price of our common stock on the OTCBB was $0.36

Investment in the Common Stock involves a high degree of risk. You should consider carefully the risk factors beginning on page 6 of this prospectus as well as in any prospectus supplement related to these specific offerings before purchasing any of the shares offered by this prospectus.

We may amend or supplement this prospectus from time to time by filing amendments or supplements as required. You should read the entire prospectus and any amendments or supplements carefully before you make your investment decision.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is July 13, 2016.

ELITE PHARMACEUTICALS, INC.

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ABOUT THIS PROSPECTUS

You may only rely on the information contained in this prospectus and any prospectus supplement. We have not authorized anyone to provide you with different information. The selling shareholder is not making an offer of these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information in this prospectus or any prospectus supplement is accurate only as of the date on the front of that document. Our business, financial condition, results of operations and prospects may have changed materially since those dates.

PROSPECTUS SUMMARY

This prospectus summary highlights certain information about our company and other information contained elsewhere in this prospectus. This summary does not contain all of the information that you should consider before making an investment decision. You should carefully read the entire prospectus, any prospectus supplement, including the section entitled “Risk Factors”, before making an investment decision.

About Us

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

We are a specialty pharmaceutical company principally engaged in the development and manufacture of oral, controlled-release products, using proprietary know-how and technology, 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 own and 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

Elite is focusing its efforts on the following areas: (i) development of Elite's pain management products; (ii) manufacturing of a line of generic pharmaceutical products with approved 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.

Elite is focusing 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.

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

Commercial Products

We own, license, contract manufacture or have certain rights to profits for 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
Lodrane D ® Immediate Release capsules ("Lodrane D")	n/a	OTC Allergy	September 2011
Methadone HCl 10mg tablets ("Methadone 10mg")	Dolophine®	Pain	January 2012
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
Hydroxyzine HCl 10mg, 25mg and 50mg tablets ("Hydroxyzine 10mg" and "Hydroxyzine 25mg" and "Hydroxyzine 50mg")	Atarax®, Vistaril®	Antihistamine	April 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

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". 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".

Our principal executive offices are located at 165 Ludlow Avenue, Northvale, New Jersey 07647, and our telephone number is (201) 750-2646. We maintain a website at "http://www.elitepharma.com." Information contained on our website is not considered to be a part of, nor incorporated by reference in, this Prospectus.

About This Offering

On April 10, 2014, we entered into a purchase agreement with Lincoln Park, which we refer to in this prospectus as the Purchase Agreement, pursuant to which Lincoln Park has agreed to purchase from us up to $40,000,000 of our common stock (subject to certain limitations) from time to time over a 36-month period. Also, on April 10, 2014, we entered into a Registration Rights Agreement, or the Registration Rights Agreement, with Lincoln Park, pursuant to which we have filed with the SEC the registration statement that includes this prospectus to register for resale under the Securities Act of 1933, as amended (the "Securities Act"), or the Securities Act, the shares that have been or may be issued to Lincoln Park under the Purchase Agreement.

On July 8, 2014, we registered up to 108,000,000 shares of our Common Stock that have been or may be issued to Lincoln Park under the Purchase Agreement in a registration statement (the "Prior Registration Statement"). Through July 11, 2016, we have sold an aggregate of 79,082,073 shares of Common Stock to Lincoln Park under the Purchase Agreement for aggregate gross proceeds of approximately $21,906,602. In addition, we have issued 2,984,894 shares as a commitment fee. We do not have the right to make any additional sales to Lincoln Park under the Purchase Agreement until the SEC has declared effective the registration statement of which this prospectus forms a part. Thereafter, we may, from time to time and at our sole discretion, direct Lincoln Park to purchase up to 500,000 shares of our common stock on any business day, provided that at least one business day has passed since the most recent purchase. However, in no event shall Lincoln Park purchase more than $760,000 worth of our common stock on any single business day, plus an additional "accelerated amount" under certain circumstances. Except as described in this prospectus, there are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Lincoln Park. The purchase price of the up to 500,000 shares that may be sold to Lincoln Park under the Purchase Agreement on any business day will be based on the market price of our common stock immediately preceding the time of sale as computed under the Purchase Agreement without any fixed discount; provided that in no event will such shares be sold to Lincoln Park when our closing sale price is less than $0.10 per share, subject to adjustment as provided in the Purchase Agreement. The purchase price per share will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the business days used to compute such price. We may at any time in our sole discretion terminate the Purchase Agreement without fee, penalty or cost upon one business day's notice. Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement.

Although the Purchase Agreement provides that we may sell up to $40,000,000 of our common stock to Lincoln Park, only 63,000,000 shares of our common stock are being offered under this prospectus, which represents (i) 872,388 shares registered, remaining unissued under the Prior Registration Statement which are issuable to Lincoln Park as a commitment fee, (ii) 26,258,385 shares registered and remaining unsold under the Prior Registration Statement and issued or issuable to Lincoln Park under the Purchase Agreement and (iii) an additional 35,869,227 shares which may be issued to Lincoln Park in the future under the Purchase Agreement. If all of the 63,000,000 shares offered by Lincoln Park under this prospectus were issued and outstanding as of July 11, 2016, such shares would represent approximately 7.9% of the total number of shares of our common stock outstanding and approximately 8.2% of the total number of outstanding shares held by non-affiliates, in each case as of July 11, 2016. If we elect to issue and sell more than the 63,000,000 shares offered under this prospectus to Lincoln Park, which we have the right, but not the obligation, to do, we must first register for resale under the Securities Act any such additional shares, which could cause additional substantial dilution to our shareholders. The number of shares ultimately offered for resale by Lincoln Park is dependent upon the number of shares we sell to Lincoln Park under the Purchase Agreement.

Issuances of our common stock in this offering will not affect the rights or privileges of our existing shareholders, except that the economic and voting interests of each of our existing shareholders will be diluted as a result of any such issuance. Although the number of shares of common stock that our existing shareholders own will not decrease, the shares owned by our existing shareholders will represent a smaller percentage of our total outstanding shares after any such issuance to Lincoln Park.

For more detailed information on the transaction with Lincoln Park, please see “The Lincoln Park Transaction” in “Selling Shareholder” below.

Securities Offered

Common stock offered by the selling shareholder	63,000,000 shares
Common stock outstanding prior to this offering	730,971,084 shares
Common stock to be outstanding after giving effect to the issuance of 63,000,000 additional shares under the Purchase Agreement	792,971,084 shares
Use of Proceeds	We will receive no proceeds from the sale of shares of common stock by Lincoln Park in this offering. However, we may receive up to approximately an additional $18,093,398 under the Purchase Agreement with Lincoln Park. Any proceeds that we receive from sales to Lincoln Park under the Purchase Agreement will be used to fund the production development and commercial activities of the Company, for general and administrative expenses, to pay down liabilities and for working capital. See “Use of Proceeds.”
Risk Factors	This investment involves a high degree of risk. See “Risk Factors” for a discussion of factors you should consider carefully before making an investment decision.
Symbol on OTCBB	ELTP

SELECTED FINANCIAL DATA

The consolidated financial data presented below have been derived from our financial statements. The selected historical consolidated financial data presented below should be read in conjunction with "Management’s Discussion and Analysis of Financial Condition and Results of Operations" and "Financial Statements and Supplementary Data". The selected data in this section is not intended to replace the Consolidated Financial Statements. The information presented below is not necessarily indicative of the results of our future operations. Certain prior period amounts have been restated to reflect corrections to errors in accounting done on a prospective basis. Please see “Note 2: Restatement of Prior Financial Information” to the financial statements included herein for further discussion on prospective restatement of financial information to reflect corrections in accounting error.

	Fiscal Year Ended March 31, (dollars in thousands, except per share amounts)

	2016	**2015**	**2014**	**2013**	**2012**
		(restated)	**(restated)**	**(restated)**	**(restated)**
Consolidated Statement of Operations Data:					
Operating revenues	$12,498	$5,015	$4,601	$3,404	$2,424
Income (Loss) from Operations	(8,317)	(16,507)	(5,284)	(1,563)	(1,966)
Other Income (Expense)	7,113	21,724	(36,270)	3,259	(2,348)
Credit for Income Taxes	520	3	293	354	484
Net Income (Loss)	(683)	5,221	(41,261)	2,050	(3,830)
Change in carrying value of convertible preferred share mezzanine equity	(9,286)	23,709	(55,314)	(562)	(11,228)
Income (Loss) from continuing operations available to common shareholders	(9,969)	28,930	(96,575)	1,488	(15,058)
Earnings per share: Basic	(0.01)	0.05	(0.21)	0.00	(0.06)
Earnings per share: Diluted	(0.01)	(0.02)	(0.21)	(0.00)	(0.06)
Cash dividends declared per common share	$0.00	$0.00	$0.00	$0.00	$0.00
Consolidated Balance Sheet Data:					
Cash	11,512	7,464	6,942	369	668
Current Assets	16,714	12.331	9,925	2,543	1,498
Total assets	31,879	25,920	24,318	11,125	10,312
Current Liabilities	4,654	5,069	6,161	5,357	4,549
Working Capital	12,060	7,262	3,764	(2,814)	(3,051)
Long term obligations	16,061	20,583	38,373	8,107	12,240
Convertible preferred share mezzanine equity	44,286	35,000	60,982	6,335	8,506
Total Equity	(33,122)	(34,731)	(81,198)	(8,673)	(14,984)
Other financial data:					
Cash (used in) operating activities	(2,765)	(15,103)	(4,217)	(1,693)	(394)
Cash provided by (used in) investing activities	(1,949)	2,879	(558)	(192)	(658)
Cash provided by (used in) financing activities	8,762	12,746	11,347	1,585	(106)

The comparability of the foregoing is impacted by the change in classification of the NJEDA bond liabilities made subsequent to our repayment of all amounts in arrears during Fiscal 2015. Prior to Fiscal 2015, the entire bond liability was recorded as a current liability as a result of a notice of default being issued pursuant to our non-payment of scheduled amounts due. As these in arrears amounts were paid in Fiscal 2015, and we have remained current on all payments scheduled pursuant to the bond agreement, bond liabilities included in current liabilities consist only of those amounts due within 12 months of the balance sheet date, with all remaining amounts due being classified as non-current liabilities. Please see "Note 8: NJEDA Bonds" to the financial statements included herein for a further discussion of the bond liability.

The comparison of net income (loss) and long term obligations is significantly impacted by the change in fair value of warrant derivatives, with net income (loss) having a strong inverse correlation to the trading price of the Company's Common Stock.

SUPPLEMENTARY FINANCIAL INFORMATION

Our consolidated results of quarterly operations are shown below:

(In thousands, except per share data)	Fourth Quarter	Third Quarter	**Second Quarter**	**First Quarter**
			(restated)	**(restated)**
Fiscal year ended March 31, 2016				
Total revenues	$5,195	$2,194	$ 2,947	$ 2,163
Costs of revenues	1,036	836	1,415	1,197
Gross Profit	4,159	1,358	1,532	966
Operating Expenses	3,588	4,071	5,299	3,373
Income (Loss) from Operations	571	(2,713)	(3,767)	(2,407)
Other income (expense)	7,408	(9,520)	2,086	7,139
Income tax (credit) expense	(520)	—	—	—
Net Income	8,499	(12,233)	(1,681)	4,732
Change in carrying value of convertible preferred mezzanine equity	14,142	(24,786)	(5,071)	6,429
Net income attributable to common shareholders	22,641	(37,019)	(6,753)	11,161
Earnings per share – basic	$0.03	$(0.05)	$ (0.01)	$ 0.02
Earnings per share - Diluted	$0.00	$(0.05)	$ (0.01)	$ (0.00)

(In thousands, except per share data)	Fourth Quarter	Third Quarter	Second Quarter	First Quarter
	(restated)	(restated)	(restated)	(restated)
Fiscal year ended March 31, 2015				
Total revenues	1,234	1,363	1,256	1,162
Costs of revenues	904	700	682	729
Gross Profit	331	663	575	433
Operating Expenses	5,788	3,221	4,636	4,864
Income (Loss) from Operations	(5,457)	(2,557)	(4,061)	(4,431)
Other income (expense)	(898)	9,974	10,310	2,338
Income tax (credit) expense	(3)	—	—	—
Net Income	(6,350)	7,417	6,248	(2,094)
Change in carrying value of convertible preferred mezzanine equity	(2,715)	13,600	15,132	(2,308)
Net income attributable to common shareholders	(9,065)	21,017	21,380	(4,402)
Earnings (Loss) per share – basic	$ (0.01)	$ 0.03	$ 0.04	$ (0.01)
Earnings (Loss) per share - diluted	$ (0.01)	$ (0.01)	$ (0.01)	$ (0.01)

(In thousands, except per share data)	Fourth Quarter	Third Quarter	Second Quarter	First Quarter
	(restated)	(restated)	(restated)	(restated)
Fiscal year ended March 31, 2014				
Total revenues	1,028	1,693	1,159	722
Costs of revenues	1,046	995	617	579
Gross Profit	(18)	699	542	143
Operating Expenses	2,365	1,936	1,229	1,118
Income (Loss) from Operations	(2,384)	(1,237)	(687)	(976)
Other income (expense)	(31,652)	175	(6,887)	2,095
Income tax (credit) expense	(295)	—	2	—
Net Income	(33,741)	(1,061)	(7,576)	1,119
Change in carrying value of convertible preferred mezzanine equity	(53,056)	1	(2,061)	(197)
Net income attributable to common shareholders	(86,798)	(1,062)	(9,638)	922
Earnings (Loss) per share – basic	$ (0.16)	$ (0.00)	$ (0.02)	$ 0.00
Earnings (Loss) per share - diluted	$ (0.16)	$ (0.00)	$ (0.02)	$ (0.00)

RISK FACTORS

An investment in our company involves a high degree of risk. In addition to the other information included in this prospectus, you should carefully consider the following risk factors described in this prospectus and the risk factors that may be described in any applicable prospectus supplement. You should consider these matters in conjunction with

the other information included in this prospectus. The risks and uncertainties described in this prospectus and any applicable prospectus supplement are not the only ones facing us. Additional risks and uncertainties that we do not presently know about or that we currently believe are not material may also adversely affect our business. Our business, results of operations or financial condition could be seriously harmed, and the trading price of our common stock may decline due to any of these or other risks.

This prospectus contains statements that constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements appear in a number of places in this prospectus and include statements regarding the intent, belief or current expectations of our management, directors or officers primarily with respect to our future operating performance. Prospective purchasers of our securities are cautioned that these forward-looking statements are not guarantees of future performance and involve risks and uncertainties. Actual results may differ materially from those in the forward-looking statements due to various factors. The accompanying information contained in this prospectus, including the information set forth below, identifies important factors that could cause these differences. See "Forward-Looking Statements" below.

RISKS RELATED TO OUR BUSINESS

Our revenues and operating income/(loss) could fluctuate significantly

Our revenues and operating results may vary significantly from year-to-year and quarter-to-quarter as well as in comparison to the corresponding quarter of the preceding year. Variations my result from one or more factors, including, without limitation:

- Timing of approval of applications filed with the FDA;
- Timing of process validation, product launches and market acceptance of products launched;
- Changes in the amounts spent to research, develop, acquire, license or promote new and existing products;
- Results of clinical trial programs;
- Serious or unexpected health or safety concerns with our products, brand products which we have genericized, products currently under development or any other product candidates;
- Introduction of new products by others that render our products obsolete or noncompetitive;
- The ability to maintain selling prices and gross margin on our products;
- The cost and outcome of litigation, in the event that such occurs in relation to, without limitation, intellectual property issues, regulatory or other matters;
- The ability to comply with complex and numerous governmental regulations and regulatory authorities which oversee and regulate many aspects of our business and operations;
- Changes in coverage and reimbursement policies of health plans and other health insurers, including changes to Medicare, Medicaid and similar state programs, especially in relation to those products that are currently manufactured, under development or identified for future development by the Company;

- Increases in the cost of raw materials contained within our products;
- Manufacturing and supply interruptions, including product rejections or recalls due to failure to comply with manufacturing specifications;
- Timing of revenue recognition relating to our licensing and other agreements;
- The ability to protect our intellectual property from being acquired by other entities;
- The ability to avoid infringing the intellectual property of others;
- Our ability to manage growth and integrate acquired products and assets successfully; and
- The addit