

19-05 374-E

FOIA / PA Officer John Livornese U.S. Securities & Exchange Commission FOIA Office 100 F Street NE, Mail Stop 5100 Washington, DC 20549 RECEIVED

JUL 2 4 2018

Office of FOIA Services

July 24, 2018

Dear Mr. Livornese:

I request pursuant to the Freedom of Information Act (FOIA) 5 U.S.C. § 552. As Amended by Public Law No. 104-231,110 Stat. 3048, copies of the following agreements, based on the **File No. 1-15697 - CF#27626**, and as **FOIA Request 18-00773-E.**

Exhibit 10.1 to Form 10-Q filed on 11/14/2011 by ELITE PHARMACEUTICALS INC /DE/.

Exhibit Title: Amendment To The Master Development And License Agreement

CIK: 1053369

Sectilis will pay up to \$61 for research, copies and review fees for all of the abovementioned agreements. Please forward all releasable material for copying. My daytime telephone number is 202-558-2356. Please call me or e-mail at research@sectilis.com to discuss the total cost or estimated cost of this research/copies should the amount exceed the price indicated in this request.

Sincerely,

Stella Vasconcellos Research Assistant Sectilis LLC 6931 Arlington RD. # 580 Bethesda, MD 20814



UNITED STATES SECURITIES AND EXCHANGE COMMISSION

STATION PLACE 100 F STREET, NE WASHINGTON, DC 20549-2465

Office of FOIA Services

August 16, 2018

Ms. Stella Vasconcellos Sectilis LLC 6931 Arlington Rd. # 580 Bethesda, MD 20814

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552

Request No. 18-05374-E

Dear Ms. Vasconcellos:

This letter is in response to your request, dated and received in this office on July 24, 2018, for access to Exhibit 10.1 to Form 10-Q filed on November 14, 2011 by Elite Pharmaceuticals Inc /DE/.

In connection with a previous request, access was granted to the subject exhibit. Therefore, we have determined to release the same exhibit (copy enclosed) to you. No fees have been assessed in this instance.

If you have any questions, please contact me at reidk@sec.gov or (202) 551-3504. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Lizzette Katilius as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

Kay Reid

Kay Reid FOIA Lead Research Specialist

Enclosures

Confidential Treatment

RECEIVED
NOV 15 2011
OFFICE OF THE SECRETARY

[Double underscore version]

AMENDMENT TO

THE MASTER DEVELOPMENT AND LICENSE AGREEMENT FOR MORPHINE SULFATE ODT BETWEEN ELITE PHARMACEUTICALS, INC. AND MIKAH PHARMA, LLC

This Amendment, dated as of November 1, 2011 (the "Amendment"), by and between Elite Pharmaceuticals, Inc. and Elite Laboratories, Inc. (a subsidiary of Elite Pharmaceuticals, Inc.), both corporations organized under the laws of the State of Delaware, with offices at 165 Ludlow Avenue, Northvale, New Jersey ("Elite"), and Mikah Pharma, LLC, a Delaware limited liability company with its offices at 20 Kilmer Drive, Hillsborough, New Jersey 08844 ("Mikah") relating to that Master Development and License Agreement For Morphine Sulfate ODT (the "Agreement"), dated August 27, 2010, by and between Elite and Mikah;

- **A.** WHEREAS Elite and Mikah desire to amend the Agreement on the terms and subject to the conditions contained herein: and
- **B.** WHEREAS, capitalized terms used herein and not otherwise defined shall have the meaning assigned to such terms in the Agreement.

NOW, THEREFORE in consideration of the mutual covenants and agreements contained herein, the sufficiency, adequacy and satisfaction of which are hereby acknowledged, Mikah and Elite hereby agree as follows:

ARTICLE 1

DEFINITIONS

1. Section 1.20 of the Agreement is hereby amended and restated in its entirety as follows:

"Net Profits" means Net Sales minus Cost of Goods Sold. Net Sales means proceeds received by Mikah and/or its Affiliates and/or from Mikah's successors and/or from unaffiliated third parties from sales, of <u>MS ODT</u> in the Territories, less returns, samples, allowances, discounts and applicable taxes, as reflected on actual customer invoices, as may be applicable. Cost of Goods Sold means the costs of supplying Product and shall be the cost of goods for the Product as supplied and invoiced by Elite to Mikah.

Confidential Treatment

ARTICLE 2

Exhibit B

1. Exhibit B, Item 4 of the Agreement is hereby amended and restated in its entirety as follows:

"Royalties of amounts equal to <u>5%</u> of Net Profits of <u>MS ODT</u> shall be paid to Elite in accordance with the terms of this Agreement, including, without limitation, Article 4 and Article 11".

ARTICLE 3

Miscellaneous

- 1. Severability. If any clause or provision of this Amendment is declared invalid or unenforceable by a court of competent jurisdiction, such provision shall be severed and the remaining provisions of the Amendment shall continue in full force and effect. The Parties shall use their best efforts to agree upon a valid and enforceable provision as a substitute for the severed provision, taking into account the intent of this Amendment.
- 2. Notices. Any notice, request or other communication required to be given pursuant to the provisions of this Amendment shall be made in accordance with the provisions of the Amendment.
- 3. Governing Law. All questions concerning the construction, validity, enforcement and interpretation of the Amendment shall be determined pursuant to the Governing Law provision of the Agreement.
- 4. Independent Parties. The relationship of the Parties under this Amendment is that of independent contractors. Neither Party shall be deemed to be the agent of the other, nor shall the Parties be deemed to be partners or joint venturers, and neither is authorized to take any action binding upon the other. Elite expressly acknowledges for itself, its employees, agents and subcontractors, that none of them are employees of Mikah and that none of them are entitled to participate in any benefit plans of Mikah. Elite further acknowledges that none of its employees, agents or subcontractors are eligible to participate in any benefit plans of Mikah, even if it is later determined that the status of any of them was that of an employee during the period of this engagement of Elite by Mikah.

(The remainder of this page has been intentionally left blank.)

Confidential Treatment

IN WITNESS WHEREOF, the Parties have caused this Amendment to be executed by their duly authorized representatives as of the day and year first above written.

MIKAH PHARMA LLC		ELITE P	ELITE PHARMACEUTICALS, INC	
By:		By:		
Name:	Nasrat Hakim	Name:	Chris C. Dick	
Title:	President and CEO	Title:	President	