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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**FORM 8-K**

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**CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): February 8, 2019**

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**SIENNA BIOPHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-38155**  
(Commission  
File Number)

**27-3364627**  
(IRS Employer  
Identification Number)

**30699 Russell Ranch Road, Suite 140**  
**Westlake Village, CA 91362**  
(Address of principal executive offices, including Zip Code)

**Registrant's telephone number, including area code: (818) 629-2256**

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

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

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**Item 8.01 Other Events**

On February 8, 2019, Sienna Biopharmaceuticals, Inc. (the “Company”) announced top-line data from its pivotal trials with SNA-001 for the reduction of light-pigmented hair and its final pivotal trial with SNA-001 in acne. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference herein.

**Item 9.01 Financial Statements and Exhibits**

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release dated February 8, 2019.</a>

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**SIENNA BIOPHARMACEUTICALS, INC.**

Date: February 8, 2019

By: /s/ Timothy K. Andrews

Timothy K. Andrews

General Counsel and Secretary



**Sienna Biopharmaceuticals' Novel Silver Photoparticle Technology SNA-001 Successfully Removes Light Hair When Used with Common Laser System**

- *SNA-001 addresses a large unmet need in laser hair removal by treating light hair using a topical solution of silver photoparticles, an ultra-efficient light absorber —*
- *If cleared, SNA-001 has potential to expand the \$3 billion U.S. laser hair removal market as an effective option for light-haired consumers —*
- *Sienna to seek strategic partner for SNA-001, and will continue to focus on Phase 3 development of SNA-120 for Psoriasis and Pruritus and its Topical by Design™ Platform —*

**WESTLAKE VILLAGE, Calif., Feb. 8, 2019** – Sienna Biopharmaceuticals, Inc. (NASDAQ:SNNA), a clinical-stage biotechnology company, today announced positive topline results from its pivotal trial of SNA-001 in conjunction with an 810 nm Diode laser, involving 65 patients. SNA-001, a topical pre-treatment to standard laser hair removal, was studied in women and men with white, gray, blonde, light red and light brown hair. The data showed SNA-001 met the primary endpoint of non-inferiority in hair reduction (-17.5 percent with SNA-001+Laser compared to -1.1 percent with vehicle+Laser following six treatment sessions). In additional analyses, SNA-001 was statistically superior compared to vehicle+Laser, demonstrating up to a 31 percent reduction of light hair from baseline<sup>1</sup>.

“SNA-001 represents an exciting growth opportunity for the aesthetics market, and a potential solution for consumers with light hair who are well aware of the ineffectiveness of laser hair removal,” said Frederick C. Beddingfield III, M.D., Ph.D., President and Chief Executive Officer of Sienna Biopharmaceuticals. “We are pleased with these results and will seek a strategic partner who can rapidly maximize the value of SNA-001. This will allow us to remain focused on our Phase 3 development of SNA-120, our TrkA<sup>2</sup> inhibitor for psoriasis and pruritus, and to unlock the full potential of our Topical by Design™ platform, from which we are creating a pipeline of drug candidates that target select pathways in specific tissues to treat a variety of chronic inflammatory and immunologic conditions.”

Available for nearly 25 years, laser hair removal is one of the most commonly performed aesthetic procedures in the world. With more than 12 million procedures performed annually in the United States<sup>3</sup>, countless

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patients have benefitted from the lasting results, except for those with light hair. Of the 53 million people who use laser treatments, waxing and other methods to remove unwanted hair, one in three are light haired<sup>4</sup>. People with white, gray, blonde and red hair, for whom lasers are ineffective, have been limited to using waxing and razors to remove their unwanted light hair, which yield temporary results and, in the case of waxing, can be costly to maintain<sup>5</sup>. Market data indicate that a safe and effective treatment for people with light hair could increase the number of laser hair removal procedures by 27 percent in the United States<sup>3</sup>.

“This represents the first major breakthrough in laser hair removal in over a decade. Sienna’s silver photoparticle technology, combined with the lasers we already have in our offices, showed a meaningful reduction in light hair – something we have never achieved before,” said Mathew Avram, M.D., J.D., Director, Massachusetts General Hospital Laser, Cosmetics & Dermatologic Surgery Associate Professor, Harvard Medical School. “If cleared by FDA, SNA-001 would allow physicians and aesthetic centers to expand their current practices by bringing in new patients with blonde, gray, white, light brown or light red hair who have resorted to waxing and shaving. Once available, I would anticipate rapid and widespread adoption of SNA-001.”

SNA-001 was also evaluated in conjunction with a 1064 Nd:YAG and 755 nm Alexandrite laser for the reduction of light hair, showing a significant reduction from baseline and providing a potential path to regulatory clearance. These results, however, were less differentiated from the vehicle+Laser group compared to the 810 nm Diode laser study results.

A third and final pivotal trial of SNA-001 in acne was also completed, demonstrating SNA-001 was non-inferior to laser therapy and providing a potential path to regulatory clearance.

#### **About SNA-001**

SNA-001 represents an advancement in medical aesthetic procedures, using silver particles applied to the skin to harness light energy from a medical laser to thermally target the hair follicle inside the pilosebaceous unit, resulting in reduction of light- and non-pigmented hair. SNA-001 is a topical, ready-to-use suspension applied to the treatment area on the skin and delivered into the pores. The silver particles are then activated by a laser to thermally target the hair follicle while sparing the surrounding tissue, a process called selective photothermolysis. The silver particles in SNA-001 are designed to work with the most common lasers already utilized in aesthetic clinics and laser centers today.

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## **About Sienna Biopharmaceuticals**

Sienna Biopharmaceuticals, Inc. is a cutting-edge biopharmaceutical company focused on bringing unconventional scientific innovations to patients whose lives remain compromised by their disease. We draw upon our knowledge and experience in immunology and inflammation as we build a unique, diversified, multi-asset portfolio of targeted therapies, with an initial focus on one of the most important immune tissues, the skin. We are leading the way with our novel technology platform, Topical by Design™, applying a scientific design process to create potent targeted pharmacologically active molecules that are specifically and selectively directed toward a target tissue and a disease pathway, and with minimal to no systemic exposure. At Sienna, we are going where it still matters for patients.

For more information, visit the Company's website at [www.SiennaBio.com](http://www.SiennaBio.com).

## **Forward-Looking Statements**

This press release contains forward-looking statements, including but not limited to statements by Sienna's Chief Executive Officer and Dr. Mathew Avram regarding Sienna's expectations for SNA-001, including the potential for regulatory clearance of SNA-001 and the commercial potential for SNA-001, as well as Sienna's expectations with respect to partnering SNA-001. Such forward-looking statements involve substantial risks and uncertainties that could cause Sienna's future results, performance, or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the pharmaceutical drug and medical device development processes, including the clinical development process, regulatory approval processes, the timing of regulatory filings, the challenges associated with manufacturing pharmaceutical drug and medical device products, Sienna's ability to successfully protect and defend its intellectual property, and other matters that could affect the sufficiency of existing cash to fund operations and the availability or commercial potential of Sienna's drug candidates. Sienna undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of the Company in general, see Sienna's most recent Annual Report on Form 10-K and any subsequent current and periodic reports filed with the Securities and Exchange Commission.

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**Contact:**

**Media**

Caroline Van Hove  
[cvanhove@siennabio.com](mailto:cvanhove@siennabio.com)  
818-575-6250

Crystal Muilenburg  
[cmuilenburg@siennabio.com](mailto:cmuilenburg@siennabio.com)  
818-584-1035

**Investors**

Sean Andrews  
[sandrews@siennabio.com](mailto:sandrews@siennabio.com)  
818-629-2244

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- 1 Observed, per-protocol analysis using the higher of the two baseline hair counts
  - 2 tropomyosin receptor kinase A
  - 3 Kalorama. World Market for Dermatological Drugs, 2015
  - 4 Sienna data on file. Promidian Primary Research, 2018.
  - 5 “Plucked: A History of Hair Removal.” NYU Press, 2014.

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Sienna Biopharmaceuticals, Inc.  
30699 Russell Ranch Road, Suite 140, Westlake Village, CA 91362  
Office 818-629-2256 | Fax 818-706-1214  
[www.SiennaBio.com](http://www.SiennaBio.com)