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

FORM 8-K

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

Date of Report (Date of earliest event reported): August 27, 2018

SIENNA BIOPHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	001-38155	27-3364627
(State or other jurisdiction of incorporation)	(Commission File Number)	(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

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. ☒

Item 8.01 Other Events

On August 27, 2018, Sienna Biopharmaceuticals, Inc. (the "Company") announced results from its first-in-human study of SNA-125 in psoriasis. A copy of the Company's press release is filed as Exhibit 99.1 to this Current Report on Form 8-K, and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits

Exhibit No.	Description
99.1	Press Release dated August 27, 2018.

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: August 27, 2018

By: /s/ Timothy K. Andrews
Timothy K. Andrews
General Counsel and Secretary

Exhibit 99.1

Sienna Biopharmaceuticals Announces Results from First-in-Human Study of SNA-125 in Psoriasis and Continued Progression to Phase 2

— Phase 1/2 study data of SNA-125 in atopic dermatitis on track to be released in fourth quarter of 2018

— SNA-125 Phase 2 studies expected to begin in second half of 2019

WESTLAKE VILLAGE, Calif., Aug. 27, 2018 – Sienna Biopharmaceuticals, Inc. (NASDAQ:SNNA), a clinical-stage medical dermatology and aesthetics company, today announced results from a first-in-human study of its investigational new chemical entity SNA-125, a JAK3/TrkA inhibitor being evaluated as a first-in-class topically administered medication to treat mild-to-moderate psoriasis.

SNA-125 was developed using Sienna's Topical by Design™ platform, which yields new chemical entities (NCEs) designed to deliver high local drug concentration in the target tissue with minimal to no systemic exposure for patients. SNA-125 selectively inhibits Janus kinase 3 (JAK3) and tropomyosin receptor kinase A (TrkA). JAK3 inhibition blocks the signaling of key cytokines, resulting in reduced severity of certain autoimmune and inflammatory diseases such as psoriasis. TrkA is the high-affinity receptor for nerve growth factor (NGF), a known mediator of neurogenic inflammation associated with psoriasis, as well as pruritus (itch).

This exploratory Phase 1/2, double-blind, within-subject vehicle-controlled study in 15 subjects, using a psoriasis microplaque model, was designed to measure an effect on inflammatory skin infiltrate thickness, local tolerability, and histology and biomarkers with two doses of SNA-125 prototype gel applied once daily for 10 days.

In this model, SNA-125, the second NCE from Sienna's Topical by Design™ platform, was well-tolerated and showed no safety signals. Neither dose of SNA-125 (0.2 or 2 percent) reduced the inflammatory skin infiltrate thickness from baseline ($p>0.8$). However, histological and biomarker analyses showed a modest, statistically significant reduction with SNA-125 0.2 percent in epidermal thickness from baseline (-17%, $p<0.05$), as well as modulation of certain psoriasis-relevant biomarkers and gene expression profiles.

"This exploratory study, while limited, showed a modest drug effect and good tolerability with SNA-125, and provides us with directional information to help guide the design of our Phase 2 development program," said Frederick C. Beddingfield III, MD, PhD, President and Chief Executive Officer of Sienna Biopharmaceuticals. "Of course, we would have liked to have seen more robust impact in this early-stage model, but treatment with SNA-125 may take longer than ten treatments to reveal its full effect. In parallel with this study, we have developed a more optimal cream formulation to treat inflammatory skin disorders that is undergoing nonclinical testing, and we remain excited about our Phase 2 studies beginning in the second half of 2019. We look forward to additional data from our Topical by Design™ platform in the fourth quarter of 2018 – namely, our SNA-125 Phase 1/2 study in atopic dermatitis, as well as our SNA-120 Phase 2b study in pruritis associated with psoriasis, now that enrollment has been completed ahead of schedule."

Pipeline Overview

Sienna's pipeline currently includes five clinical-stage programs:

(from the Company's Topical by Design™ platform)

- SNA-125 for the treatment of atopic dermatitis; Phase 1/2 results expected in the fourth quarter of 2018
- SNA-125 Phase 2 studies expected to begin in the second half of 2019
- SNA-120 for the treatment of pruritus associated with psoriasis and the underlying psoriasis; Phase 2b top-line results now expected in the fourth quarter of 2018

(from the Company's Topical Photoparticle Therapy™ platform)

- SNA-001 for the reduction of light-pigmented hair
    - pivotal results with the 1064 nm wavelength laser expected in the fourth quarter of 2018
    - pivotal results with the 810 nm and with the 755 nm wavelength lasers expected in the first quarter of 2019
- SNA-001 for the treatment of acne
    - pivotal results with the 755 nm wavelength laser expected in the fourth quarter of 2018

About Topical by Design™

Topical by Design™ is an innovative platform, designed to enable the topical application of potent active pharmaceuticals against known biologic targets while minimizing exposure to the systemic circulation, thereby addressing the tolerability trade-offs that often make therapies unsuitable for use in larger segments of the population with less severe disease. Topical by Design™ applies a scientific design process

to transform molecules into new chemical entities by stably linking a short polyethylene glycol (PEG) polymer to a pharmacologically active molecule. Applying this technology, we have created a pipeline of drug candidates with unique pharmacological profiles to manage a variety of chronic inflammatory and immunologic conditions. Applications for the Topical by Design™ platform are currently being explored in a Phase 2b trial with SNA-120 for use in pruritus associated with psoriasis, and Phase 1/2 studies with SNA-125 for use in psoriasis and atopic dermatitis.

About Sienna Biopharmaceuticals

Sienna Biopharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on bringing innovations in biotechnology to the discovery, development and commercialization of first-in-class, targeted, topical products in medical dermatology and aesthetics. The Company's objective is to develop a unique, diversified, multi-asset pipeline of topical therapies that enhance the health, appearance and quality of life of dermatology and aesthetics patients. Sienna is led by a management team with extensive experience in product development and commercialization at several leading dermatology, aesthetics and biotechnology companies.

For more information, visit the Company's website at 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 other statements regarding Sienna's expectations for the timing of additional data readouts for its clinical trials. Such forward-looking statements involve substantial risks and uncertainties that could cause Sienna's clinical development programs, 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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