
**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): March 14, 2019

Sienna Biopharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

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

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 2.02 Results of Operations and Financial Condition.

On March 14, 2019, Sienna Biopharmaceuticals, Inc. (the “Company”) announced its financial results for the fourth quarter and full year ended December 31, 2018. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K, including the attached Exhibit 99.1, is being furnished and shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits.*

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated March 14, 2019

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.

Date: March 14, 2019

Sienna Biopharmaceuticals, Inc.

By: /s/ Timothy K. Andrews

Name: Timothy K. Andrews

Title: General Counsel and Secretary



Sienna Biopharmaceuticals Reports Fourth Quarter and Full Year 2018 Financial Results

WESTLAKE VILLAGE, Calif., Mar. 14, 2019 – Sienna Biopharmaceuticals, Inc. (Nasdaq:SNNA), a clinical-stage biopharmaceutical company, today reported the Company's financial results for the fourth quarter and full year of 2018.

"We are pleased to report the results of our 2018 fourth quarter and full year and contemplate the possibilities in 2019, particularly in light of our streamlined focus on strategic priorities and successful equity raise," said Frederick C. Beddingfield III, M.D., Ph.D., President and Chief Executive Officer of Sienna. "Our drive to bring unconventional scientific innovations to patients whose lives remain burdened by their disease without compromising safety has unlocked a pipeline of selective kinase inhibitors that target select pathways in specific tissues to treat a variety of chronic inflammatory and immunologic conditions with minimal to no systemic exposure. We are poised to begin Phase 3 enrollment for SNA-120 (pegcantratinib) later this year as a potential first-in-class, non-steroidal treatment for psoriasis and the associated pruritus. Additionally, we continue to see potential in SNA-125, our tissue-targeted JAK3/TrkA dual kinase inhibitor, for other inflammatory disorders of the skin, as well the gastrointestinal tract, the eye and the lung. Indeed, with additional funding through a business-development transaction or other means, we would plan to move SNA-125 forward with a Phase 2 trial in atopic dermatitis, as well as with a proof-of-concept study in ulcerative colitis, where the need for gut-restricted drugs with low systemic exposure is high. We are actively seeking a strategic partner for SNA-001, with positive results now in hand that provide a potential path to regulatory clearance. Our future is bright, and we look forward to translating our scientific aptitude and curiosity into new possibilities and positivity for patients who continue to suffer from autoimmune and inflammatory disorders across multiple therapeutic areas."

Business Highlights

In February 2019, Sienna closed a follow-on public offering of 9,200,000 shares of common stock at a public offering price of \$2.50 per share, which included the exercise in full by the underwriters of their option to purchase up to an additional 1,200,000 shares of common stock. Net proceeds to the Company were approximately \$21.3 million, after underwriting discounts, commissions and estimated offering expenses.

Sienna announced on Feb. 8, 2019, top-line results from three pivotal clinical trials for the reduction of light-pigmented hair and from the third and final pivotal clinical trial in acne with SNA-001, a topical, ready-to-use suspension of silver particles to be used as a pre-treatment in conjunction with the most common commercial lasers already utilized in aesthetic clinics and laser centers today. The data showed SNA-001 successfully removed light hair when used with an 810 nm Diode laser and met the primary endpoint of non-inferiority in hair reduction (-17.5% with SNA-001+Laser compared to -1.1% with vehicle+Laser following six treatment sessions). In additional analyses, SNA-001 was statistically superior compared to vehicle+Laser, demonstrating up to a 32% reduction of light hair from baseline. 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. The third and final pivotal trial of SNA-001 in acne demonstrated SNA-001 was non-inferior to laser therapy. In all of these trials, SNA-001 was well tolerated, with no unexpected, treatment-related adverse events observed. These results provide a potential path to regulatory clearance in light-pigmented hair removal and acne, and the Company is seeking a strategic partner to maximize the value of SNA-001.

Sienna announced on Dec. 3, 2018, that the Company's tissue-targeted Tropomyosin receptor kinase A (TrkA) inhibitor, SNA-120 (0.05%), demonstrated in a Phase 2b clinical trial statistically significant improvement compared to vehicle on important pre-specified endpoints of psoriasis disease severity, including the Investigator's Global Assessment (IGA) 2-grade composite, comprising a 2-grade improvement from baseline and clear (0) or almost clear (1) skin, which has been the Phase 3 primary endpoint for recent topical psoriasis drugs approved by the U.S. Food and Drug Administration (FDA). Specifically, 29% of patients achieved success on the IGA 2-grade composite, compared to 13% of subjects treated with vehicle. Additionally, 27% of subjects experienced a 75% reduction from baseline in their Psoriasis Area and Severity Index score (PASI 75), compared to 13% of subjects treated with vehicle. Subjects also experienced an approximately 60% reduction from baseline in the associated pruritus (itch), although the pruritus result did not reach statistical significance compared to vehicle. SNA-120 has been administered to more than 500 subjects for up to 12 weeks and has been well tolerated across all trials, with minimal to no demonstrated systemic bioavailability. Following an End-of-Phase 2 (EOP2) meeting with the FDA scheduled for April 2019, Sienna intends to initiate two Phase 3 pivotal clinical trials for a psoriasis indication, subject to securing sufficient capital to complete both trials, in the second half of 2019.

Sienna announced on Dec. 3 and Aug. 27, 2018, results from exploratory Phase 1/2 studies in atopic dermatitis and psoriasis, respectively, with SNA-125, the Company's dual Janus kinase 3 (JAK3)/TrkA inhibitor. In these studies, SNA-125 was well tolerated and showed no safety signals. Additionally, histological and biomarker analyses showed a modest drug effect in both atopic dermatitis and psoriasis, despite using a prototype gel formulation and treating a limited area for a short duration. Sienna intends to initiate a Phase 2 study with a more optimal cream formulation of SNA-125 first in atopic dermatitis, subject to securing sufficient capital to complete the trial.

Selected Financial Results

Total operating expenses for the three months ended Dec. 31, 2018, were approximately \$19.8 million, which includes research and development (R&D) expenses totaling approximately \$10.8 million and general and administrative (G&A) expenses totaling approximately \$9.0 million. Total operating expenses for the three months ended Dec. 31, 2017, were approximately \$14.0 million, which included R&D expenses totaling approximately \$9.5 million and G&A expenses totaling approximately \$4.5 million. The year-over-year increase in R&D expenses was due primarily to increased development costs related to SNA-120 and SNA-125, partially offset by a reduction in costs related to the pivotal trials for SNA-001. The year-over-year increase in G&A expenses was due primarily to a \$4.9 million non-cash increase in expense related to the fair value of the contingent consideration liability associated with the Company's acquisition of Creabilis plc in December 2016, partially offset by a reduction in legal fees.

Total operating expenses for the twelve months ended Dec. 31, 2018, were approximately \$76.5 million, which includes R&D expenses totaling approximately \$51.6 million and G&A expenses totaling approximately \$24.9 million. Total operating expenses for the twelve months ended Dec. 31, 2017, were approximately \$48.6 million, which included R&D expenses totaling approximately \$30.5 million and G&A expenses totaling approximately \$18.1 million. The year-over-year increase in R&D expenses was due primarily to increased development costs related to the clinical trials for SNA-120 and for SNA-125, increased manufacturing costs to support the clinical trials for SNA-120 and SNA-125 and increased costs related to early stage research activities, offset by a reduction in costs related to the pivotal trials for SNA-001. The year-over-year increase in G&A expenses was due primarily to an increase in personnel costs, an increase in expenses related to marketing research and a \$3.3 million non-cash increase in expense related to the fair value of the contingent consideration liability associated with the Company's acquisition of Creabilis plc in December 2016.

Cash burn during the three months ended Dec. 31, 2018, was approximately \$15.6 million. Cash burn during the twelve months ended Dec. 31, 2018, was approximately \$61.7 million. Sienna's cash and cash equivalents as of Dec. 31, 2018, totaled approximately \$48.5 million, which does not include the \$21.3 million in net proceeds from the Company's February 2019 follow-on public offering.

About Sienna Biopharmaceuticals

Sienna Biopharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on bringing unconventional scientific innovations to patients whose lives remain burdened by their disease. We draw upon our deep knowledge and experience in drug development across multiple therapeutic areas as we build a unique, diversified, multi-asset portfolio of therapies in immunology and inflammation that target select pathways in specific tissues, with our initial focus on one of the most important 'immune' tissues, the skin. We are leading the way with our novel proprietary technology platform, applying a scientific design process to create potent targeted pharmacologically active molecules that are directed toward a specific target tissue and a select 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.

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: SNA-120, including timing of its EOP2 meeting with the FDA as well as timing to begin two Phase 3 pivotal clinical trials; SNA-125, including its potential to treat other inflammatory disorders of the skin, the gastrointestinal tract, the eye and the lung and Sienna's ability to fund any further clinical trials of SNA-125; and SNA-001, including the potential for regulatory clearance of SNA-001 and Sienna's expectations related to partnering SNA-001. 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 regulatory approval processes, the timing of regulatory filings, the challenges associated with manufacturing pharmaceutical drug and medical device

products, Sienna's ability to raise sufficient capital to fund its development programs, 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 Sienna 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.

Sienna Biopharmaceuticals, Inc.
Consolidated Statements of Operations
(in thousands, except per share data)
(unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	\$ 10,774	\$ 9,465	\$ 51,592	\$ 30,484
General and administrative	8,995	4,525	24,906	18,087
Total operating expenses	<u>19,769</u>	<u>13,990</u>	<u>76,498</u>	<u>48,571</u>
Loss from operations	(19,769)	(13,990)	(76,498)	(48,571)
Other income (expense), net	434	2,722	3,027	(2,264)
Net loss before taxes	(19,335)	(11,268)	(73,471)	(50,835)
Income tax benefit	—	78	—	290
Net loss	<u>\$ (19,335)</u>	<u>\$ (11,190)</u>	<u>\$ (73,471)</u>	<u>\$ (50,545)</u>
Per share information:				
Net loss, basic and diluted ¹	<u>\$ (0.93)</u>	<u>\$ (0.56)</u>	<u>\$ (3.59)</u>	<u>\$ (5.19)</u>
Basic and diluted weighted average shares outstanding ²	<u>20,805</u>	<u>20,128</u>	<u>20,450</u>	<u>9,735</u>

¹ Diluted net loss per share is the same as basic net loss per share, as the effects of potentially dilutive securities are antidilutive during periods of net loss.

² As of Dec. 31, 2018, there were 21,177,123 shares of common stock outstanding.

Sienna Biopharmaceuticals, Inc.
Selected Consolidated Balance Sheet Data
(in thousands)
(unaudited)

	December 31, 2018	December 31, 2017
Cash and cash equivalents	\$ 48,526	\$ 74,467
Working capital	26,063	69,105
Total current assets	50,412	77,346
Total assets	107,306	136,847
Total current liabilities	24,349	8,241
Long-term debt, net	30,125	—
Accumulated deficit	159,368	85,897
Total stockholders' equity	26,581	91,199

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