
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): **October 21, 2019 (October 18, 2019)**

ASSERTIO THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of
Incorporation)

001-13111
(Commission File Number)

94-3229046
(IRS Employer Identification No.)

100 S. Saunders Road, Suite 300, Lake Forest, IL 60045
(Address of Principal Executive Offices; Zip Code)

(224) 419-7106
(Registrant's telephone number, including area code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:
Common Stock, \$0.0001 par value

Trading Symbol(s):
ASRT

Name of each exchange on which registered:
The Nasdaq Stock Market LLC

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 (*see* General Instruction A.2. below):

- 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 7.01 Regulation FD Disclosure

On October 21, 2019, Assertio Therapeutics, Inc. (the “Company”) issued a press release announcing that the Company's development partner received a Complete Response Letter from the FDA relating to long-acting cosyntropin. A copy of the press release is furnished as Exhibit 99.1 to this Current Report.

This information, including Exhibit 99.1 attached hereto, is being furnished pursuant to Item 7.01 of this Current Report and shall not be deemed to be “filed” for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section and will not be incorporated by reference into any registration statement filed by the Company, under the Securities Act of 1933, as amended, unless specifically identified as being incorporated therein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 [Assertio Therapeutics, Inc. Press Release issued on October 21, 2019](#)

SIGNATURES

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

ASSERTIO THERAPEUTICS, INC.

Date: October 21, 2019

By: /s/ Amar Murugan

Amar Murugan

Senior Vice President and General Counsel



Assertio Therapeutics Provides Regulatory Update on Long-Acting Cosyntropin

LAKE FOREST, Ill., (October 21, 2019) (GLOBE NEWSWIRE) -- Assertio Therapeutics, Inc. (NASDAQ: ASRT), today announced that its development partner West Therapeutic Development, LLC (West) has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) for its New Drug Application (NDA) for its injectable formulation of long-acting cosyntropin (synthetic adrenocorticotrophic hormone, or ACTH). West is seeking approval for use as a diagnostic drug in the screening of patients presumed to have adrenocortical insufficiency.

The primary focus of the CRL relates to the FDA determination that certain pharmacodynamic parameters were not adequately achieved.

“West and Assertio will work together to determine how best to address the CRL,” said Arthur Higgins, President and CEO of Assertio. “In the meantime, we continue to focus on driving robust adjusted EBITDA performance and generating strong cash flows.”

Long-acting cosyntropin is an alcohol-free formulation of a synthetic analogue of ACTH, a hormone secreted from the pituitary gland that is responsible for the stimulation of the adrenal cortex. Cosyntropin is composed of the first 24 of 39 amino acids of natural ACTH and retains the full steroidogenic activity of natural ACTH.

About Assertio Therapeutics, Inc.

Assertio Therapeutics is committed to providing responsible solutions to advance patient care in the Company’s core areas of neurology, orphan and specialty medicines. Assertio currently markets three FDA-approved products and continues to identify, license and develop new products that offer enhanced options for patients that may be underserved by existing therapies. To learn more about Assertio, visit www.assertiotx.com.

"Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995

This news release contains forward-looking statements. These statements involve inherent risks and uncertainties that could cause actual results to differ materially from those projected or anticipated, including risks related to regulatory approval and clinical development of long-acting cosyntropin, expectations regarding potential business opportunities and other risks outlined in the Company's public filings with the Securities and Exchange Commission, including the Company's most recent annual report on Form 10-K and subsequent Quarterly Reports on Form 10-Q. All information provided in this news release speaks as of the date hereof. Except as otherwise required by law, the Company undertakes no obligation to update or revise its forward-looking statements.

Investor and Media Contact:

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Source: Assertio Therapeutics, Inc.