

Assertio Therapeutics, Inc
Form 8-K
March 28, 2019

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 28, 2019 (March 28, 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)

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Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

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 8.01 Other Events

Assertio Therapeutics, Inc., a Delaware corporation (the "Company"), announced that the United States Court of Appeals for the Federal Circuit has ruled in favor of the Company with respect to the Company's patent litigation against three filers of Abbreviated New Drug Applications (ANDAs) for the NUCYNTA® franchise. The Federal Circuit's ruling affirms the decision of the United States District Court (D.N.J.), which found U.S. patent No. 7,994,364 (the "364 Patent") to be valid and infringed by the defendants. The 364 Patent covers the entire NUCYNTA franchise until December 2025. With the Federal Circuit's ruling, the Company expects market exclusivity until December 2025 for NUCYNTA ER, NUCYNTA and NUCYNTA oral solution (an unmarketed form of NUCYNTA). The Federal Circuit affirmed the District Court's ruling with regard to U.S. patent No. 8,536,130 (the "130 Patent"), which upheld the validity of the 130 Patent but found that two of the three filers of Abbreviated New Drug Applications (ANDAs) do not infringe the patent. The 130 Patent covers NUCYNTA ER until March 2029. The periods of patent exclusivity referred to above include the addition of six months of pediatric patent term extension the Company anticipates securing from the United States Food and Drug Administration.

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: March 28, 2019

By:

/s/ Amar Murugan
Amar Murugan
Senior Vice President and General Counsel