
**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

August 14, 2018

Date of Report (Date of earliest event reported)

AEVI GENOMIC MEDICINE, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

1-35112
(Commission File Number)

98-0217544
(I.R.S. Employer
Identification No.)

435 Devon Park Drive, Suite 715
Wayne, Pennsylvania 19087
(Address of principal executive offices, zip code)

(610) 254-4201
(Registrant's telephone number, including area code)

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.

On August 14, 2018, Aevi Genomic Medicine, Inc. issued a press release announcing full enrollment of Part A of its Phase 2 ASCEND clinical trial. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference into this Item 8.01.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

[99.1 Aevi Genomic Medicine, Inc. Press Release dated August 14, 2018](#)

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.

AEVI GENOMIC MEDICINE, INC.

By: /s/ Michael F. Cola
Name: Michael F. Cola
Title: President and Chief Executive Officer

Date: August 14, 2018

Aevi Genomic Medicine Announces Completion of Enrollment in Part A of Phase 2 ASCEND Trial in ADHD

- *Top Line Data for Part A expected in Q4 2018*

PHILADELPHIA, PA – (Marketwired) – August 14, 2018 – Aevi Genomic Medicine, Inc. (NASDAQ: GNMX) (the Company) today announced that it has completed enrollment in Part A (n=64) of its Phase 2 ASCEND clinical trial, which is assessing a mGluR mutation positive genetic subset of pediatric and adolescent patients with Attention Deficit Hyperactivity Disorder (ADHD), to confirm response to AEVI-001 in these patients.

“We are pleased that we have completed enrollment in Part A of our ASCEND trial” said Garry A. Neil, M.D., Chief Scientific Officer of Aevi Genomic Medicine. “This milestone brings us one step closer to evaluating the impact of AEVI-001 in mGluR+ ADHD patients and we look forward to announcing topline data for Part A of ASCEND in the fourth quarter of this year.”

About the ASCEND Clinical Trial

ASCEND is an adaptive, 6-week, double-blind parallel-group study in children and adolescents (ages 6-17 years) with ADHD with and without copy number variants (CNVs) in specific genes implicated in glutamatergic signaling and neuronal connectivity. Part A includes subjects determined to have one of eight specific gene mutation(s) implicated in glutamatergic signaling and neuronal connectivity. Part B will assess subjects who do not have CNVs in any of the specific gene mutation(s) implicated in glutamatergic signaling and neuronal connectivity. Once subjects are confirmed as eligible for each part of the study, they are randomized to one of two treatment groups (AEVI-001 or placebo) in a 1:1 ratio.

About AEVI-001

AEVI-001 is an oral non-stimulant pan selective activator/modulator of mGluRs. The molecule has excellent pharmacokinetic and metabolic profiles and crosses the blood brain barrier.

Aevi Genomic Medicine is developing AEVI-001 as a potential treatment for a sub-population of Attention Deficit Hyperactivity Disorder (ADHD) patients with genetic mutations that disrupt the mGluR network. In the US, the CDC estimates that 6.4 million children 4-17 years of age (11%) have ever been diagnosed with ADHD. Many ADHD patients remain unsatisfied with existing therapies, particularly with respect to safety, tolerability and treatment of comorbidities.

AEVI-001 is an investigational agent that has not been approved by the US FDA or any other regulatory agencies.

About Aevi Genomic Medicine, Inc.

Aevi Genomic Medicine, Inc. is dedicated to unlocking the potential of genomic medicine to translate genetic discoveries into novel therapies. Driven by a commitment to patients with pediatric onset life-altering diseases, the Company’s research and development efforts leverage an internal genomics platform and an ongoing collaboration with the Center for Applied Genomics (CAG) at The Children’s Hospital of Philadelphia (CHOP).

Forward-looking Statements

This release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and as that term is defined in the Private Securities Litigation Reform Act of 1995, which include all statements other than statements of historical fact, including (without limitation) those regarding the Company's financial position, status and timing of clinical trials, its development and business strategy, its product candidates and the plans and objectives of management for future operations. The Company intends that such forward-looking statements be subject to the safe harbors created by such laws. Forward-looking statements are sometimes identified by their use of the terms and phrases such as "estimate," "project," "intend," "forecast," "anticipate," "plan," "planning," "expect," "believe," "will," "will likely," "should," "could," "would," "may" or the negative of such terms and other comparable terminology. All such forward-looking statements are based on current expectations and are subject to risks and uncertainties. Should any of these risks or uncertainties materialize, or should any of the Company's assumptions prove incorrect, actual results may differ materially from those included within these forward-looking statements. Accordingly, no undue reliance should be placed on these forward-looking statements, which speak only as of the date made. The Company expressly disclaims any obligation or undertaking to disseminate any updates or revisions to any forward-looking statements contained herein to reflect any change in the Company's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based. As a result of these factors, the events described in the forward-looking statements contained in this release may not occur.

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