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): September 23, 2016

IONIS PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

000-19125	**33-0336973**
(Commission File No.)	(IRS Employer Identification No.)

2855 Gazelle Court
Carlsbad, CA 92010
(Address of Principal Executive Offices and Zip Code)

Registrant's telephone number, including area code: **(760) 931-9200**

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))

Item 8.01. Other Events.

On September 23, 2016, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has granted Accelerated Assessment for the nusinersen Marketing Authorization Application (MAA) for the treatment of European patients with spinal muscular atrophy (SMA).

Accelerated Assessment reduces the timeframe for the CHMP to review a MAA. Applications may be eligible for accelerated assessment if the CHMP decides the product is of major interest for public health and a therapeutic innovation. The accelerated review procedure may decrease the standard 210-day time limit for the CHMP to grant an opinion by approximately two months. Accelerated Assessment also requires the sponsor to respond in a shorter timeframe (30 days) to questions from the CHMP (the "clock-stop" periods). This is compared to the normal response time of 3-4 months. Programs granted Accelerated Assessment can be switched back to the standard assessment time frame at any time.

In August 2016, Ionis and Biogen announced that nusinersen met the primary endpoint for the pre-specified interim analysis of the ENDEAR clinical study in patients with infantile-onset SMA. Infants receiving nusinersen experienced a statistically significant improvement in the achievement of motor milestones compared to those who did not receive treatment. Nusinersen demonstrated an acceptable safety profile in the trial. Based on these results, Biogen plans to file marketing applications for nusinersen globally in the coming months. Biogen has exercised its option to develop and commercialize nusinersen globally and paid Ionis a $75 million license fee.

Nusinersen is an investigational, potentially disease-modifying therapy for the treatment of SMA. Nusinersen is an antisense oligonucleotide (ASO) that is designed to alter the splicing of SMN2, a gene that is nearly identical to SMN1, in order to increase production of fully functional SMN protein. Both the U.S. and EU regulatory agencies have granted special status to nusinersen in an effort to expedite the review process, including Orphan Drug Status and Fast Track Designation in the U.S. and Orphan Drug Designation in the EU.

Forward-looking Statement

This report includes forward-looking statements regarding the development of nusinersen. Any statement describing Ionis’ goals, expectations, financial or other projections, intentions or beliefs is a forward-looking statement and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those inherent in the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such drugs. Ionis’ forward-looking statements also involve assumptions that, if they never materialize or prove correct, could cause its results to differ materially from those expressed or implied by such forward-looking statements. Although Ionis’ forward-looking statements reflect the good faith judgment of its management, these statements are based only on facts and factors currently known by Ionis. As a result, you are cautioned not to rely on these forward-looking statements. These and other risks concerning Ionis' programs are described in additional detail in Ionis’ annual report on Form 10-K for the year ended December 31, 2015, and its most recent quarterly report on Form 10-Q, which are on file with the SEC. Copies of these and other documents are available from the Company.

SIGNATURE

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, thereunto duly authorized.

IONIS PHARMACEUTICALS, INC.

Dated: September 23, 2016

By: /s/ B. Lynne Parshall

B. LYNNE PARSHALL
Chief Operating Officer
and Director