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): November 18, 2021

Biogen Inc.

(Exact name of registrant as specified in its charter)

Delaware	**0-19311**	**33-0112644**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

225 Binney Street, Cambridge, Massachusetts 02142
(Address of principal executive offices; Zip Code)

Registrant's telephone number, including area code: **(617) 679-2000**

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:

☐ 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))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0005 par value	**BIIB**	**The Nasdaq Global Select Market**

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.

Tecfidera CHMP Update

On November 18, 2021, Biogen received an Opinion adopted by The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) at its November meeting on the ad hoc assessment relating to the therapeutic effect of monoethyl fumarate salts (MEF) within Fumaderm for the purpose of implementation of the May 5, 2021 Judgment of the General Court (Case T-611/18) annulling the EMA's non-validation decision for a generic application of Tecfidera and in connection with a number of pending applications before the CHMP which concern dimethyl fumarate. The Company, the EMA, and the European Commission have each appealed the General Court's decision as wrongly decided.

The CHMP Opinion states:

> The CHMP, having considered the matter as set out in the appended *ad hoc* assessment report, is of the opinion that taking into account the described results, including the severe methodological limitations of the clinical studies, it cannot be concluded based on these data that a clinically relevant therapeutic effect of MEF in Fumaderm has been demonstrated.
>
> Therefore, the CHMP concludes that the totality of the available data cannot establish that MEF exerts a clinically relevant therapeutic contribution within Fumaderm.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The exhibits listed below are furnished as part of this Current Report on Form 8-K

Exhibit Number	Description
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

Biogen Inc.

By: /s/ Wendell Taylor
Wendell Taylor
Chief Corporation Counsel and Assistant Secretary

Date: November 19, 2021