

**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): September 26, 2023

BIOGEN INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

0-19311
(Commission
File Number)

33-0112644
(IRS Employer
Identification No.)

225 Binney Street, Cambridge, Massachusetts 02142
(Address of Principal Executive Offices and Zip Code)

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

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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.

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

Item 8.01. Other Events.

On September 26, 2023, Biogen Inc. issued a press release announcing the completion of its acquisition of Reata Pharmaceuticals, Inc. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Cautionary Note Regarding Forward-looking Statements

This press release contains forward-looking statements, relating to: our strategy and plans; potential of, and expectations for, our commercial business and pipeline programs; capital allocation and investment strategy; clinical development programs, clinical trials, and data readouts and presentations; regulatory discussions, submissions, filings, and approvals; the potential benefits, safety, and efficacy of our and our collaboration partners' products and investigational therapies; the anticipated benefits and potential of investments; optimization of the cost structure including our "Fit for Growth" program, actions to improve risk profile and productivity of R&D pipeline, collaborations, and business development activities; our future financial and operating results; 2023 financial guidance. These forward-looking statements may be accompanied by such words as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "potential," "possible," "prospect," "will," "would," and other words and terms of similar meaning. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including: our dependence on sales from our products; uncertainty of long-term success in developing, licensing, or acquiring other product candidates or additional indications for existing products; failure to compete effectively due to significant product competition in the markets for our products; failure to successfully execute or realize the anticipated benefits of our strategic and growth initiatives; difficulties in obtaining and maintaining adequate coverage, pricing, and reimbursement for our products; our dependence on collaborators and other third parties for the development, regulatory approval, and commercialization of products and other aspects of our business, which are outside of our full control; risks associated with current and potential future healthcare reforms; risks related to commercialization of biosimilars; failure to obtain, protect, and enforce our data, intellectual property, and other proprietary rights and the risks and uncertainties relating to intellectual property claims and challenges; the risk that positive results in a clinical trial may not be replicated in subsequent or confirmatory trials or success in early stage clinical trials may not be predictive of results in later stage or large scale clinical trials or trials in other potential indications; risks associated with clinical trials, including our ability to adequately manage clinical activities, unexpected concerns that may arise from additional data or analysis obtained during clinical trials, regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates; the occurrence of adverse safety events, restrictions on use with our products, or product liability claims; risks relating to technology failures or breaches; problems with our manufacturing processes; risks relating to management and personnel changes, including attracting and retaining personnel; failure to comply with legal and regulatory requirements; the risks of doing business internationally, including currency exchange rate fluctuations; risks relating to investment in our manufacturing capacity; the direct and indirect impacts of the COVID-19 pandemic on our business; risks relating to the distribution and sale by third parties of counterfeit or unfit versions of our products; risks relating to the use of social media for our business; results of operations, and financial condition;

fluctuations in our operating results; risks related to investment in properties; the market, interest, and credit risks associated with our investment portfolio; risks relating to share repurchase programs; risks relating to access to capital and credit markets; risks related to indebtedness; change in control provisions in certain of our collaboration agreements; fluctuations in our effective tax rate; environmental risks; the risk that we may be unable to achieve the anticipated benefits of the transaction within the expected time frames or at all; the effect of the transaction on the acquired company's ability to retain and hire key personnel, its ability to maintain relationships with its customers, clients, vendors and others with whom it does business; the risk that stockholder litigation in connection with the transaction may result in significant costs of defense, indemnification and liability; and any other risks and uncertainties that are described in other reports we have filed with the SEC.

These statements speak only as of the date of this presentation. We do not undertake any obligation to publicly update any forward-looking statements.

In particular, you should consider the risks set forth in Biogen's filings with the SEC, including its Annual Report on Form 10-K for the fiscal year ended December 31, 2022, under the caption "Risk Factors", and subsequent reports on Form 10-Q. The forward-looking statements speak only as of the date made and, other than as required by law, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 [Press Release of Biogen Inc., dated September 26, 2023.](#)

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.

Date: September 26, 2023

By: /s/ Wendell Taylor

Name: Wendell Taylor

Title: Assistant Secretary



Biogen Completes Acquisition of Reata Pharmaceuticals

- Reata acquisition bolsters Biogen’s rare disease portfolio with the addition of SKYCLARYS® (omaveloxolone), the first and only FDA approved treatment for Friedreich’s ataxia in the U.S.

CAMBRIDGE, Mass., Sept. 26, 2023 (GLOBE NEWSWIRE) – [Biogen Inc.](#) (Nasdaq: BIIB) – has completed the acquisition of Reata Pharmaceuticals, Inc. (Nasdaq: RETA), a company focused on developing therapeutics that regulate cellular metabolism and inflammation in serious neurologic diseases. As a result of the transaction, Biogen has now acquired SKYCLARYS® (omaveloxolone), as well as other clinical and preclinical pipeline programs.

SKYCLARYS®, Reata Pharmaceuticals’ lead asset, was approved for the treatment of Friedreich’s ataxia (FA), a rare neuromuscular disorder, in the United States earlier this year. FA is genetic, progressive, life-shortening, debilitating, and degenerative, affecting an estimated 5,000 diagnosed patients within the United States¹. The commercial launch of SKYCLARYS® is underway in the United States and European regulatory review is ongoing. As of the closing date, over 1,000 patient start forms for SKYCLARYS® have been submitted in the United States.

“By adding a highly complementary product in an area of significant unmet medical need to our portfolio, we believe the acquisition of Reata aligns with our strategy to serve patients, drive sustainable growth and create significant shareholder value,” said Christopher A. Viehbacher, President and Chief Executive Officer at Biogen. “With the transaction now complete, we look forward to leveraging Biogen’s rare disease expertise and capabilities to work together with our Reata colleagues as one team to bring SKYCLARYS® to patients living with this devastating disease.”

Biogen anticipates significant synergies with its existing rare disease portfolio and plans to update its Full Year 2023 Financial Guidance in conjunction with its third quarter 2023 earnings release. The acquisition of Reata is expected to be slightly dilutive to Biogen’s Non-GAAP diluted Earnings Per Share (EPS) in 2023, roughly neutral in 2024, and significantly accretive beginning in 2025, inclusive of associated transaction costs. As a result of the transaction closing, Reata’s Class A common stock will no longer be listed for trading on the Nasdaq Global Market.

About SKYCLARYS® (omaveloxolone)

SKYCLARYS® (omaveloxolone) is an oral, 150 mg once-daily medication indicated for the treatment of Friedreich’s ataxia in adults and adolescents aged 16 years and older in the United States. Additionally, the company’s Marketing Authorization Application for omaveloxolone is under review in Europe by the European Medicines Agency (EMA). The European Commission has granted Orphan Drug designation in Europe to omaveloxolone for the treatment of Friedreich’s ataxia.

About Biogen

Founded in 1978, Biogen is a leading global biotechnology company that has pioneered multiple breakthrough innovations including a broad portfolio of medicines to treat multiple sclerosis, the first approved treatment for spinal muscular atrophy, and two co-developed treatments to address a defining pathology of Alzheimer’s disease. Biogen is advancing a pipeline of potential novel therapies across neurology, neuropsychiatry, specialized immunology and rare diseases and remains acutely focused on its purpose of serving humanity through science while advancing a healthier, more sustainable and equitable world.

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We routinely post information that may be important to investors on our website at www.biogen.com. Follow us on social media - [X](#), [LinkedIn](#), [Facebook](#), [YouTube](#).

Biogen Safe Harbor

This press release contains forward-looking statements, relating to: the anticipated benefits of the Reata Pharmaceuticals acquisition, our strategy and our future financial and operating results. These forward-looking statements may be accompanied by such words as “aim,” “anticipate,” “believe,” “could,” “estimate,” “expect,” “forecast,” “goal,” “intend,” “may,” “plan,” “potential,” “possible,” “prospect,” “will,” “would,” and other words and terms of similar meaning. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including: our dependence on sales from our products; uncertainty of long-term success in developing, licensing, or acquiring other product candidates or additional indications for existing products; failure to compete effectively due to significant product competition in the markets for our products; failure to successfully execute or realize the anticipated benefits of our strategic and growth initiatives; difficulties in obtaining and maintaining adequate coverage, pricing, and reimbursement for our products; our dependence on collaborators, joint venture partners, and other third parties for the development, regulatory approval, and commercialization of products and other aspects of our business, which are outside of our full control; the potential impact of the conflict in Ukraine; risks associated with current and potential future healthcare reforms; risks related to commercialization of biosimilars; failure to obtain, protect, and enforce our data, intellectual property, and other proprietary rights and the risks and uncertainties relating to intellectual property claims and challenges; the risk that positive results in a clinical trial may not be replicated in subsequent or confirmatory trials or success in early stage clinical trials may not be predictive of results in later stage or large scale clinical trials or trials in other potential indications; risks associated with clinical trials, including our ability to adequately manage clinical activities, unexpected concerns that may arise from additional data or analysis obtained during clinical trials, regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates; the occurrence of adverse safety events, restrictions on use with our products, or product liability claims; risks relating to technology failures or breaches; problems with our manufacturing processes; risks relating to management and personnel changes, including attracting and retaining personnel; failure to comply with legal and regulatory requirements; the risks of doing business internationally, including currency exchange rate fluctuations; risks relating to investment in our manufacturing capacity; the direct and indirect impacts of the ongoing COVID-19 pandemic on our business; risks relating to the distribution and sale by third parties of counterfeit or unfit versions of our products; risks relating to the use of social media for our business; results of operations and financial condition; fluctuations in our operating results;

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risks related to investment in properties; the market, interest, and credit risks associated with our investment portfolio; risks relating to share repurchase programs; risks relating to access to capital and credit markets; risks related to indebtedness; change in control provisions in certain of our collaboration agreements; fluctuations in our effective tax rate; environmental risks; and any other risks and uncertainties that are described in other reports we have filed with the U.S. Securities and Exchange Commission.

These statements speak only as of the date of this press release. We do not undertake any obligation to publicly update any forward-looking statements.

References:

1. Lynch DR, et al., Safety and Efficacy of Omaveloxolone in Friedreich Ataxia (MOXIe Study). *Ann Neurol.* 2021 Feb;89(2):212-225. doi: 10.1002/ana.25934

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