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): August 6, 2026

ANNEXON, INC.
(Exact name of registrant as specified in its charter)

Delaware	001-39402	27-5414423
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1400 Sierra Point Parkway, Bldg C, Suite 200
Brisbane, California 94005
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (650) 822-5500

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, par value $0.001 per share	ANNX	The Nasdaq Stock 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.

On August 6, 2026, Annexon, Inc. issued a press release titled "Annexon Reports First U.S. and European Patient Cohort of GBS FORWARD Study Demonstrated Rapid, Positive Clinical Responses in All Tanruprubart Treated Patients Within One Week." A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and, other than the quotes contained therein, is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated August 6, 2026, titled "Annexon Reports First U.S. and European Patient Cohort of GBS FORWARD Study Demonstrated Rapid, Positive Clinical Responses in All Tanruprubart Treated Patients Within One Week".
104.1	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.

Dated: August 6, 2026

Annexon, Inc.

By: /s/ Jennifer Lew
Jennifer Lew
Executive Vice President and Chief Financial Officer

Annexon Reports First U.S. and European Patient Cohort of GBS FORWARD Study Demonstrated Rapid, Positive Clinical Responses in All Tanruprubart Treated Patients Within One Week

Early Outcomes Reinforce the Consistency and Reproducibility of Tanruprubart Treatment Effect Previously Demonstrated in Phase 3 and Real-World Evidence Studies

Potential to Become the First Approved Targeted Therapy to Treat GBS Worldwide, Addressing the Significant Unmet Need and Over $20 Billion Estimated Annual U.S. Healthcare Burden

FORWARD Data to Support BLA Submission Targeted for Q4 2026; Tanruprubart Currently Under Review by the EMA

BRISBANE, Calif., August 6, 2026 – Annexon, Inc. (Nasdaq: ANNX), a biopharmaceutical company advancing the next generation platform of targeted immunotherapies for multiple neuroinflammatory diseases that impact nearly 10 million people worldwide, today announced early improvement in strength and clinically meaningful reduction in disability shown with tanruprubart in the first ten U.S. and European patients with Guillain-Barré syndrome (GBS) from its ongoing, open-label FORWARD study.

GBS is a life-threatening neuroinflammatory disease that can cause rapid and severe weakness or complete paralysis, often requiring intensive care and mechanical ventilation. It is the leading cause of acute neuromuscular paralysis with approximately 22,000 patients affected annually across the U.S. and Europe, and an estimated >$20 billion annual healthcare burden in the U.S. alone. In the 110 years since GBS was described, there have been no approved targeted therapies that rapidly and meaningfully impact the disease. Current standard-of-care intravenous immunoglobulin (IVIg), which is not FDA-approved, provides incomplete benefit for many patients. Indeed, despite standard of care use, mortality rates associated with GBS are up to 10%[1] generally, and nearly 25% in GBS patients over the age of 65 within one year of hospitalization. Moreover, many IVIg-treated patients frequently progress during or shortly after treatment, resulting in ventilatory support in one of four patients, prolonged intensive care unit (ICU) stays, inability to walk unassisted for months to years, and continued physical and psychological limitations, pain and severe fatigue.

Notably, initial cohort FORWARD data (n=10) showed clinically meaningful and rapid improvement in strength and reduced disability within days of a single infusion of 30 mg/kg tanruprubart. Outcomes include:

- All patients treated in the study showed rapid, clinically meaningful improvement in muscle strength within four days.
- Four patients who were bedbound early in the course of their disease walked with or without assistance between day two and eight.
- The one patient who required ventilation early in the course of disease came off the ventilator within four days.
- Five other patients all showed marked gains in function within 48 hours.
- Tanruprubart was generally well-tolerated, with most common adverse events related to GBS or complications with the disease consistent with Phase 3 results.
- Initial cohort included both male and female patients, ranging in age from 12 to 78 years old, and covered the spectrum of disease from moderate to severe. Outcomes of the FORWARD trial are consistent with outcomes demonstrated in the GBS Phase 3 study where approximately 90% of patients demonstrated rapid, clinically meaningful improvement by day 8 of treatment.

“The early results from the FORWARD study are some of the most encouraging we have seen in GBS research and reinforce the potential of tanruprubart as a transformative treatment,” said Rafid Mustafa, M.D., Associate Professor of Neurology and Vice Chair for Quality, Department of Neurology, Mayo Clinic. “We are optimistic about what this may mean for patients. Restoring strength and mobility is not simply a clinical milestone; it is a pathway back to independence, dignity, and everyday life.”

Thomas Harbo, M.D., Ph.D., Professor of Neurology, Aarhus University, and Consultant Neurologist, Aarhus University Hospital in Denmark remarked, “The speed of responses with tanruprubart are striking. Patients who may have otherwise faced an uncertain road to recovery showed remarkable improvements in strength within days, translating into enhanced function and early mobilization. Thus far, the findings reinforce the potential of tanruprubart to stop the underlying disease process rather than just supporting patients through it.”

Douglas Love, president and chief executive officer of Annexon added, “The early and marked improvements in this initial data from FORWARD are consistent with our Phase 3 and Real World Evidence findings. That consistency continues to strengthen the significant functional outcomes being achieved with our differentiated C1q-focused approach targeting neuroinflammation at its source. It also reflects our decade-long commitment to bringing disease-modifying treatments to help millions of people in need live their best lives.”

Data from FORWARD will be presented at upcoming medical conferences and are expected to support consistent clinical benefit of tanruprubart across global patient populations to supplement Annexon's planned Biologics License Application (BLA) submission targeted for Q4 2026. The Marketing Authorisation Application (MAA) for tanruprubart is currently under review by the European Medicines Agency (EMA).

[1] Doets AY, Verboon C, van den Berg B, et al. Regional variation of Guillain-Barré syndrome. Brain. 2018;141(10):2866-2877.

About the FORWARD Study

FORWARD is designed to give Western physicians and patients experience with tanruprubart, including in pediatric patients, and to support a broad intended label. The ongoing, open-label study is evaluating PK, PD, early impact on function and biomarkers, and safety of tanruprubart in adult and pediatric patients with GBS in the U.S. and Europe.

About Tanruprubart

Annexon's lead investigational therapy, tanruprubart, is a first-in-class targeted and rapid-acting agent designed to reduce inflammation and nerve damage by stopping C1q activity in the peripheral and central nervous systems. Tanruprubart is administered intravenously and has been observed to act almost immediately in blocking C1q function. The aim of an effective treatment in GBS is to rapidly stop the neuroinflammatory damage on nerve cells, allowing patients to recover sooner, regain independence and return to pre-illness activities. Tanruprubart has received both Fast Track and Orphan Drug designations from the FDA as well as orphan drug designation from the EMA for the treatment of GBS.

About Guillain-Barré Syndrome

GBS is a rare neuromuscular emergency resulting from an acute autoantibody and classical complement-mediated attack on peripheral nerves that generally occurs post-infection in otherwise healthy persons. It is an acute, rapidly progressive disease with a narrow timeframe for therapeutic intervention. GBS results in the hospitalization of more than 22,000 people annually in the U.S. and Europe. The peripheral nerve damage progresses rapidly, causing acute neuromuscular paralysis that can lead to significant morbidity, disability and mortality. Currently, there are no approved treatments for GBS in the U.S. The long-term disease burden associated with GBS has led to a multi-billion-dollar annual economic cost to the U.S. healthcare system alone. More information about the impact of GBS is available at MoveGBSForward.com.

About Annexon

Annexon Biosciences (Nasdaq: ANNX) is advancing the next generation platform of targeted immunotherapies for nearly 10 million people worldwide living with serious neuroinflammatory diseases. Our founding scientific approach focuses on C1q, the initiating molecule of a potent inflammatory pathway that when misdirected can lead to tissue damage and loss of function in a host of diseases. Our targeted therapies are designed to stop classical complement-driven neuroinflammation at its source to provide meaningful functional benefit and alter the course of disease. Annexon's mission is to deliver game-changing therapies to patients so that they can live their best lives. To learn more visit annexonbio.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "design," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "positioned," "potential," "predict," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. All statements other than statements of historical facts contained in this press release are forward-looking statements. These forward-looking statements include, but are not limited to the potential therapeutic benefit of tanruprubart; timing of and results from the FORWARD study, including expected initial data in the second half of 2026; whether data from the FORWARD study will support consistent clinical benefit of tanruprubart and the Company's expected BLA submission to the FDA in 2026. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results and events to differ materially from those anticipated, including, but not limited to, risks and uncertainties related to: the company's history of net operating losses; the company's ability to obtain necessary capital to fund its clinical programs; the potential for delays in the company's clinical trials; the potential for the company's product candidates to not receive regulatory approval, including if the FDA and comparable foreign regulatory authorities determine that the company's submission package is not sufficient or require the company to provide additional data in patients that are not feasible to obtain; the early stages of clinical development of the company's product candidates; the effects of public health crises on the company's clinical programs and business operations; the company's ability to obtain regulatory approval of and successfully commercialize its product candidates; any undesirable side effects or other properties of the company's product candidates; the company's reliance on third-party suppliers and manufacturers; the outcomes of any future collaboration agreements; and the company's ability to adequately maintain intellectual property rights for its product candidates. These and other risks are described in greater detail under the section titled "Risk Factors" contained in the company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q and the company's other filings with the Securities and Exchange Commission. Any forward-looking statements that the company makes in this press release are made pursuant to the Private Securities Litigation Reform Act of 1995, as amended, and speak only as of the date of this press release. Except as required by law, the company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

Investor Contact:

Joyce Allaire
LifeSci Advisors
jallaire@lifesciadvisors.com

Media Contact:

Beth Keshishian
917-912-7195
beth@bethkeshishian.com