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): May 27, 2026

BridgeBio Pharma, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-38959**	**84-1850815**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
3160 Porter Dr., Suite 250 **Palo Alto, CA**		**94304**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (650) 391-9740

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	BBIO	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

On May 27, 2026, BridgeBio Pharma, Inc. issued a press release titled "BridgeBio Announces FDA Acceptance and Priority Review of NDA for BBP-418 for LGMD2I/R9." A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
99.1	Press Release titled "BridgeBio Announces FDA Acceptance and Priority Review of NDA for BBP-418 for LGMD2I/R9"
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.

BridgeBio Pharma, Inc.

Date: May 27, 2026

By: /s/ Thomas Trimarchi

Thomas Trimarchi, Ph.D.
President and Chief Financial Officer

Exhibit 99.1

BridgeBio Announces FDA Acceptance and Priority Review of NDA for BBP-418 for LGMD2I/R9

- Accepted for Priority Review with PDUFA target action date of November 27, 2026, and poised to launch upon approval; being granted Priority Review by the FDA reiterates the serious unmet need for treatment options for the LGMD2I/R9 community

- If approved, BBP-418 would be the first and only therapy for individuals living with LGMD2I/R9 and would represent the first approved treatment for any form of LGMD

- BBP-418 demonstrated strong, consistent efficacy across all prespecified subgroups with treated individuals improving on every key endpoint while placebo recipients declined, reflecting both the natural progression of this devastating disease and the meaningful potential impact for those on treatment

PALO ALTO, Calif., May 27, 2026 (GLOBE NEWSWIRE) -- BridgeBio Pharma, Inc. (Nasdaq: BBIO) ("BridgeBio" or the "Company"), a commercial-stage, multi-product biopharmaceutical company focused on developing medicines for genetic conditions, today announced the FDA has accepted for filing its New Drug Application (NDA) with Priority Review for oral BBP-418 for the treatment of individuals living with limb-girdle muscular dystrophy type 2I/R9 (LGMD2I/R9). The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of November 27, 2026, and BridgeBio is poised to launch BBP-418 upon approval. The FDA also notified the Company that it is not currently planning to hold an advisory committee meeting to discuss the application.

"LGMD2I/R9 is a relentless and life-shortening disease. Patients progressively lose the ability to walk, face serious cardiovascular complications, and ultimately die from respiratory failure," said Christine Siu, Chief Executive Officer of BridgeBio Neuromuscular. "With today's acceptance of our NDA, we are one step closer to the potential FDA approval of a treatment that could potentially change the progression of this disease. The compelling data from FORTIFY give us confidence that BBP-418 can make a meaningful difference in how this disease progresses, and we will work with urgency to bring it to the patients and families who have been waiting."

In the Phase 3 FORTIFY trial, BBP-418 met all primary and secondary endpoints at the pre-specified 12-month interim analysis, showing treated individuals improving while placebo recipients declined across every key measure. These results were presented as a late-breaking oral presentation at the 2026 MDA Clinical and Scientific Conference, which are available here.

"For families living with LGMD2I/R9, every milestone reflects years of advocacy, resilience, and hope," said Kat Bryant Knudson, Founder and CEO of The Speak Foundation. "The FDA's acceptance of this application reflects not only scientific advancement, but a commitment to listening to and partnering with our community every step of the way. We are grateful for the continued commitment to patients and families who have waited far too long."

BridgeBio believes BBP-418 is positioned to become the first and only approved therapy for individuals living with LGMD2I/R9 addressing a significant unmet need in this disease and potentially representing the first approval of a therapy for any form of LGMD. Approximately 7,000 individuals currently live with LGMD2I/R9 and other addressable α-dystroglycanopathies in the U.S. and Europe. The Company is also engaging regulatory agencies to identify an expedited path to approval for BBP-418 in Europe.

BBP-418 has previously received Orphan Drug, Fast Track, and Rare Pediatric Disease Designations from the FDA and Orphan Drug Designation from the European Medicines Agency (EMA). BBP-418 received Priority Review from the FDA, highlighting the potential for BBP-418 to address unmet need in LGMD2I/R9. Consistent with Rare Pediatric Designation from the FDA, if BBP-418 is approved, BridgeBio may qualify for a Priority Review Voucher. The Company intends to initiate clinical studies of BBP-418 in LGMD2I/R9 for individuals less than 12 years of age and in LGMD2M/R13 and LGMD2U/R20 in the near future.

About Limb-Girdle Muscular Dystrophy Type 2I/R9 (LGMD2I/R9)
LGMD2I/R9 is a monogenic autosomal recessive disease caused by partial loss of function mutations in the fukutin-related protein (FKRP) gene, and FKRP mutations impair glycosylation of alpha-dystroglycan (αDG), a protein associated with stabilizing muscle cells. Clinical manifestations typically present as a skeletal myopathy affecting the lower and then upper limbs, which is commonly later accompanied by pulmonary muscle and cardiac muscle involvement. Individuals who harbor a homozygous L276I genotype typically develop disease manifestations during late childhood with progression to loss of independent ambulation (25%), assisted ventilation (10%), and cardiomyopathy (30%) in adulthood. Cardiomyopathy is progressive, with an annual loss of 0.4% of left ventricular ejection fraction (LVEF). Individuals with other *FKRP* genotypes typically have an earlier childhood onset with a more severe clinical course, rapid loss of mobility by 20 years of age, more frequent cardiac involvement (60%), and eventual pulmonary decline by 30 years of age in nearly all cases.

About BBP-418
BBP-418 is an investigational oral glycosylation substrate therapy with potential to be the first and only therapy for LGMD2I/R9. BBP-418 is designed to saturate the partially functional FKRP enzyme with substrate thereby enhancing residual FKRP function and restoring glycosylation of αDG. Through restoration of αDG glycosylation, BBP-418 may stabilize or improve muscle function, including gross motor, ambulatory, and cardiopulmonary function.

About BridgeBio
BridgeBio exists to develop transformative medicines for genetic conditions. Millions of people worldwide living with genetic conditions lack treatment options, often because drug development for small patient populations can be commercially challenging. We aim to bridge the gap between advancements in genetic science and meaningful medicines for underserved patient populations. Our decentralized, hub-and-spoke model is designed for speed, precision, and scalability. Autonomous and empowered teams focus on individual conditions, while a central hub provides the clinical, regulatory, and commercial capabilities needed to bring innovation to market. For more information, visit **bridgebio.com** and follow us on **LinkedIn**, **X**, **Facebook**, **Instagram**, **YouTube**, and **TikTok**.

BridgeBio Forward-Looking Statements

This press release contains forward-looking statements. Statements in this press release may include statements that are not historical facts and are considered forward-looking within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act), which are usually identified by the use of words such as “anticipates,” “believes,” “continues,” “estimates,” “expects,” “hopes,” “intends,” “may,” “plans,” “projects,” “remains,” “seeks,” “should,” “will,” and variations of such words or similar expressions. BridgeBio intends these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act. These forward-looking statements include express and implied statements relating to the Company’s expectations regarding the regulatory review process and potential approval for BBP-418 in LGMD2I/R9, including the FDA’s assigned target action date; the timing of a potential launch for BBP-418 and its related commercial infrastructure and personnel; the Company’s expectations regarding the potential effectiveness of BBP-418 in LGMD2I/R9; the Company’s expectations regarding the initiation and timing of clinical trials of BBP-418 in LGMD2I/R9 for individuals less than 12 years of age and in LGMD2M/2U; the potential for BBP-418 to become the first and only approved therapy for LGMD2I/R9 and potentially the first approved therapy for any form of LGMD; the anticipated regulatory pathway for BBP-418; and the potential eligibility of BBP-418 under the Rare Pediatric Disease Priority Review Voucher program. Such statements reflect the Company’s current views about the Company’s plans, intentions, expectations and strategies, which are based on the information currently available to it and on assumptions the Company has made. Although the Company believes that its plans, intentions, expectations and strategies as reflected in or suggested by those forward-looking statements are reasonable, the Company can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a number of risks, uncertainties and assumptions, including, but not limited to, initial and ongoing data from the Company’s clinical trials not being indicative of final data, the design and success of ongoing and planned clinical trials, future regulatory filings, approvals and/or sales, despite having ongoing and future interactions with the FDA or other regulatory agencies to discuss potential paths to registration for the Company’s product candidates, the FDA or such other regulatory agencies not agreeing with the Company’s regulatory approval strategies, components of the Company’s filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of data submitted, the impacts of current macroeconomic and geopolitical events, including changing conditions from hostilities in Ukraine and in Israel and the Gaza Strip, increasing rates of inflation and changing interest rates, on business operations and expectations, as well as those risks set forth in the Risk Factors section of the Company’s most recent Annual Report on Form 10-K and the Company’s other filings with the U.S. Securities and Exchange Commission. Moreover, the Company operates in a very competitive and rapidly changing environment in which new risks emerge from time to time. These forward-looking statements are based upon the current expectations and beliefs of the Company’s management as of the date of this press release, and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Except as required by applicable law, BridgeBio assumes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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