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): July 1, 2024

Longboard Pharmaceuticals, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**1-40192**	**84-5009619**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
4275 Executive Square, Suite 950 La Jolla, CA		**92037**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (858) 789-9283

N/A
(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 $0.0001 per share	LBPH	The Nasdaq Global 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. ☐

In this report, "we", "us", "our" and "Longboard" refer to Longboard Pharmaceuticals, Inc.

Item 7.01 Regulation FD Disclosure.

On July 1, 2024, we issued a press release announcing the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation for bexicaserin for the treatment of seizures associated with Developmental and Epileptic Encephalopathies (DEEs). A copy of the press release is attached hereto as Exhibit 99.1.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 7.01, including Exhibit 99.1, shall not be incorporated by reference into any filing we make with the U.S. Securities and Exchange Commission (SEC), whether before or after the date hereof, regardless of any general incorporation language in such filing.

Item 8.01 Other Events

Bexicaserin (LP352) Update

The U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation for bexicaserin (also known as LP352) for the treatment of seizures associated with Developmental and Epileptic Encephalopathies (DEEs) for patients two years of age or older.

FDA Breakthrough Therapy designation is a process designed to expedite the development and regulatory review of drugs that are intended to treat serious or life-threatening conditions and preliminary clinical evidence indicates that the drug may demonstrate a substantial improvement over available therapy on at least one clinically significant endpoint.

We plan to initiate a global Phase 3 program for bexicaserin later this year.

LP659 Update

We conducted a Phase 1 first-in-human, randomized, double blind, placebo controlled single ascending dose (SAD) study of LP659 in thirty-two healthy volunteers. Based on the data from the SAD study and additional nonclinical studies conducted, we expect to initiate a Phase 1 multiple ascending dose (MAD) study in LP659 subject to discussions with the FDA to address a partial clinical hold. We plan to release additional data on LP659 later this summer.

Bexicaserin and LP659 are investigational compounds that are not approved for marketing by the FDA or any other regulatory authority.

Forward Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Any statements in this Current Report on Form 8-K that are not historical facts may be considered "forward-looking statements," including statements regarding the Breakthrough Therapy designation and the initiation of a global Phase 3 program for bexicaserin, and the initiation of a MAD study subject to discussions with the FDA to address a partial clinical hold and plans to release additional data for LP659. Forward-looking statements are typically, but not always, identified by the use of words such as "intend", "may", "expect", "plan" and other similar terminology. Forward-looking statements are based on current expectations of management and upon what management believes to be reasonable assumptions based on information currently available to it and are subject to risks and uncertainties. Such risks and uncertainties may cause actual results to differ materially from the expectations set forth in the forward-looking statements. Such risks and uncertainties include, but are not limited to, the standard for Breakthrough Therapy designation is not the same as the standard for drug approval, the clinical evidence supporting Breakthrough Therapy designation is preliminary, and not all drugs designated as Breakthrough Therapies ultimately will be shown to have substantial improvement over available therapies; the FDA may later decide to rescind a Breakthrough Therapy designation if it determines the designation is no longer supported by subsequent data; Longboard's product candidates are in a lengthy research and development process, the timing, manner and outcome of research, development and regulatory review is uncertain, and Longboard's product candidates, including bexicaserin and LP659, may not advance in research or development or be approved for marketing; risks related to Longboard's limited operating history, financial position and need for additional capital; Longboard's need for additional managerial and financial resources to advance all of its programs, and that you and others may not agree with the manner in which Longboard allocates its resources; risks related to the development and commercialization of Longboard's product candidates; enrolling participants in clinical trials is competitive and challenging; nonclinical and clinical data is voluminous and detailed, and regulatory agencies may interpret or weigh the importance of data differently and reach different conclusions than Longboard's or others, request additional information, have additional recommendations or change their guidance or requirements before or after approval; results of

clinical trials and other studies are subject to different interpretations and may not be predictive of future results; topline or interim data may not accurately reflect the complete results of a particular study or trial and remain subject to audit, and that final data may differ materially from topline or interim data; macroeconomic events and their impact on Longboard's clinical trials and operations, the operations of Longboard's suppliers, partners, collaborators, and licensees, and capital markets; risks related to unexpected or unfavorable new data; risks related to relying on licenses or collaborative arrangements; other risks related to Longboard's dependence on third parties; competition; product liability or other litigation or disagreements with others; government and third-party payor actions, including relating to reimbursement and pricing; risks related to regulatory compliance; and risks related to Longboard's and third parties' intellectual property rights, as well as the risks detailed in Longboard's recent filings on Forms 10-K and 10-Q with the SEC. Longboard disclaims any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

Item 9.01 Financial Statements and Exhibits. (d) Exhibits.

Exhibit No.	Description
99.1	Press release dated July 1, 2024, regarding Breakthrough Therapy designation for bexicaserin
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 thereunto duly authorized.

Longboard Pharmaceuticals, Inc.

Date: July 1, 2024

By: */s/ Kevin R. Lind*

Kevin R. Lind

President and Chief Executive Officer

Exhibit 99.1

Longboard Pharmaceuticals Receives Breakthrough Therapy Designation for Bexicaserin (LP352)

- *U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation for bexicaserin for the treatment of seizures associated with Developmental and Epileptic Encephalopathies (DEEs)*

LA JOLLA, Calif., July 1, 2024 – Longboard Pharmaceuticals, Inc. (Nasdaq: LBPH), a clinical-stage biopharmaceutical company focused on developing novel, transformative medicines for neurological diseases, today announced that the FDA has granted Breakthrough Therapy designation for its investigational drug bexicaserin for the treatment of seizures associated with Developmental and Epileptic Encephalopathies (DEEs) for patients two years of age or older.

"We are thrilled to receive Breakthrough Therapy designation for bexicaserin and believe this important milestone underscores our innovative approach to potentially treating a broad range of DEE patients," stated Dr. Randall Kaye, Longboard's Chief Medical Officer. "The FDA will work closely with us to provide guidance on subsequent development of bexicaserin to help us design and conduct a development program as efficiently as possible. We are looking forward to initiating our global Phase 3 program later this year."

"I am excited about what this designation means for the DEE community. Most of those living with DEEs do not have access to novel medications, nor have they had the opportunity to participate in trials designed to collect data specific to their condition. I am thrilled that we are making strides towards advancing DEE research for the broader population and pleased that there is a move towards increased equity and access for underserved patients and families to clinical trials and potential novel treatments," stated Gabrielle Conecker, MPH, Executive Director & Co-Founder of Decoding Developmental Epilepsies, home of the International SCN8A Alliance, DEE-P Connections, and The Inchstone Project.

Breakthrough Therapy designation is a process designed to expedite the development and regulatory review of drugs that are intended to treat serious or life-threatening conditions and preliminary clinical evidence indicates that the drug may demonstrate a substantial improvement over available therapy on at least one clinically significant endpoint. A drug that receives Breakthrough Therapy designation is eligible for more intensive guidance on an efficient drug development program and organizational commitment involving senior managers from the FDA.

ABOUT LONGBOARD PHARMACEUTICALS

Longboard Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on developing novel, transformative medicines for neurological diseases. Longboard is working to advance a portfolio of centrally acting product candidates designed to be highly selective for specific G protein-coupled receptors (GPCRs). Longboard's small molecule product candidates are based on more than 20 years of GPCR research. Longboard plans to advance bexicaserin (LP352), an oral, centrally acting 5-hydroxytryptamine 2C (5-HT2C) receptor superagonist, with no observed impact on 5-HT2B and 5-HT2A receptor subtypes, into a global Phase 3 program. Earlier this year, Longboard reported positive topline data from a Phase 1b/2a clinical trial (the PACIFIC Study) evaluating bexicaserin in participants ages 12 to 65 years old with Developmental and Epileptic Encephalopathies (DEEs), including Lennox-Gastaut syndrome, Dravet syndrome and other DEEs. Longboard is also evaluating LP659, an oral, centrally acting, sphingosine-1-phosphate (S1P) receptor subtypes 1 and 5 modulator, which is in development for the potential treatment of rare neuroinflammatory conditions. Longboard recently completed a Phase 1 single-ascending dose (SAD) clinical trial for LP659 in healthy volunteers.

Bexicaserin and LP659 are investigational compounds that are not approved for marketing by the FDA or any other regulatory authority.

FORWARD-LOOKING STATEMENTS

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. In some cases, you can identify forward-looking statements by words such as "focus", "believe", "potential", "will", "optimistic", "designed to", "intended to", "eligible", "may", "working to", "plans", or the negative, plural or other tenses of these words, references to future dates or time periods, or other comparable language, and they may include, without limitation, statements about the following: bexicaserin, including its potential to treat a broad range of DEEs, its development and advancement into a global Phase 3 program, the regulatory process and Breakthrough Therapy designation, and its selectivity and novel chemistry; the DEE community; Longboard's ability to develop product candidates and deliver medicines; Longboard's focus and work; and LP659, including its potential and Longboard's Phase 1 SAD clinical trial for LP659. For such statements, Longboard claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Longboard's expectations. Factors that could cause actual results to differ materially from those stated or implied by Longboard's forward-looking statements include, but are not limited to, the following: the standard for Breakthrough Therapy designation is not the same as the standard for drug approval, the clinical evidence supporting Breakthrough Therapy designation is preliminary, and not all drugs designated as Breakthrough Therapies ultimately will be shown to have substantial improvement over available therapies; the FDA may later decide to rescind a Breakthrough Therapy designation if it determines the designation is no longer supported by subsequent data; Longboard's product candidates are in a lengthy research and development process, the timing, manner and outcome of research, development and regulatory review is uncertain, and Longboard's product candidates, including bexicaserin and LP659, may not advance in research or development or be approved for marketing; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; topline or interim data may not accurately reflect the complete results of a particular study or trial and remain subject to audit, and final data may differ materially from topline or interim data; enrolling participants in clinical trials is competitive and challenging; risks related to

unexpected or unfavorable new data; nonclinical and clinical data is voluminous and detailed, and regulatory agencies may interpret or weigh the importance of data differently and reach different conclusions than Longboard or others, request additional information, have additional recommendations or change their guidance or requirements before or after approval; risks related to Longboard's limited operating history, financial position and need for additional capital; Longboard will need additional managerial and financial resources to advance all of its programs, and you and others may not agree with the manner Longboard allocates its resources; risks related to the development and commercialization of Longboard's product candidates; risks related to relying on licenses or collaborative arrangements; other risks related to Longboard's dependence on third parties; competition; product liability or other litigation or disagreements with others; government and third-party payor actions, including relating to reimbursement and pricing; risks related to regulatory compliance; and risks related to Longboard's and third parties' intellectual property rights. Additional factors that could cause actual results to differ materially from those stated or implied by Longboard's forward-looking statements are disclosed in Longboard's filings with the Securities and Exchange Commission (SEC). These forward-looking statements represent Longboard's judgment as of the time of this release. Longboard disclaims any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

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