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 8, 2021

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: (619) 592-9775

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 $0.0001 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. ☐

Item 7.01 Regulation FD Disclosure

The press release attached as Exhibit 99.1 to this Current Report contains certain additional information related to the clinical data results discussed in Item 8.01 below.

The information contained under this Item 7.01, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or under the Securities Exchange Act of 1934, as amended, regardless of any general incorporation language in any such filing, unless Longboard expressly sets forth in such filing that such information is to be considered "filed" or incorporated by reference therein.

Item 8.01 Other Events

Successful Completion of LP352 Multiple Ascending Dose (MAD) Portion of Phase 1 Clinical Trial in Healthy Volunteers, Plans to Initiate Phase 1b/2a Clinical Trial

On September 8, 2021, we announced that we had successfully completed the LP352 MAD portion of the Phase 1 clinical trial in healthy volunteers.

The LP352 Phase 1 clinical trial (N=83) was a first-in-human, randomized, placebo-controlled, double-blind, four-part trial including single ascending dose (SAD) and MAD assessments in healthy volunteers. The primary objectives of the trial were to evaluate safety, tolerability, pharmacokinetics and pharmacodynamics of LP352. In the MAD portion (N=43) of the trial, five doses including the maximum planned dose were evaluated. The majority of adverse events (AEs) were mild to moderate, with the most common being headache. A single serious adverse event (SAE) of anxiety was reported at the maximum planned dose two days after the last dose of study drug and subsequently resolved. AEs were generally consistent with central nervous system (CNS) effects and expected effects of serotonergic drugs.

LP352 demonstrated dose and exposure-dependent increases of prolactin, suggesting proof of central 5-HT2c receptor engagement, as well as dose-dependent increases in exposure (C_{max} and AUC_{tau}).

These data have informed us on the optimal expected dose range for our upcoming Phase 1b/2a clinical trial in adult patients with developmental and epileptic encephalopathies (DEEs), which we expect to initiate in the first quarter of 2022.

About LP352

LP352 is an oral, centrally acting, next-generation 5-HT2c receptor superagonist in development for the potential treatment of seizures associated with DEEs such as Dravet syndrome, Lennox-Gastaut syndrome (LGS), tuberous sclerosis complex (TSC), CDKL5 deficiency disorder, and other epileptic disorders. LP352 is designed to modulate GABA inhibition and, as a result, suppress the central hyperexcitability that is characteristic of seizures. LP352 has demonstrated negligible observed impact on 5-HT2b and 5-HT2a receptor subtypes in the Company's preclinical studies to date. 5-HT2b and 5-HT2a receptor agonism have been associated with significant adverse effects. LP352 has novel chemistry and attributes, and was designed to be more specific and selective for the 5-HT2c receptor subtype, giving it the potential to reduce seizures in DEE patients while overcoming the known or perceived safety limitations of available drugs in the 5-HT2 class.

LP352, in any form, is an investigational compound that is not approved for use in any country.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release dated September 8, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Forward Looking Statements

Certain statements in this Current Report on Form 8-K that are not statements of historical fact 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 "expected," "potential," "plan," "anticipate," "focused on," and "look forward" and include, without limitation, statements about the following:

Longboard's clinical and preclinical programs, including plans to advance LP352 in a Phase 1b/2a clinical trial; LP352's safety, tolerability, PK and PD profile and effect on the 5-HT2c pathway; and LP352's potential to reduce seizures and overcome safety limitations of available drugs in the 5-HT2 class. 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 the forward-looking statements include, but are not limited to, the following: 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; Longboard's product candidates are in the early phase of a lengthy research and development process, the timing, manner and outcome of research, development and regulatory review is uncertain, and Longboard's product candidates may not advance in research or development or be approved for marketing; continued clinical development of LP352 is dependent on the acceptance and approval of our investigational new drug application by the U.S. Food and Drug Administration's (FDA) Division of Neurology; enrolling participants in clinical trials is competitive and challenging; the duration and severity of the coronavirus disease (COVID-19) outbreak, including but not limited to the impact on Longboard's clinical trials and operations, the operations of Longboard's suppliers, partners, collaborators, and licensees, and capital markets, which in each case remains uncertain; 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; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; topline data may not accurately reflect the complete results of a particular study or trial; risks related to relying on licenses or collaborative arrangements, including lack of control and potential disputes; the entry into or modification or termination of 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.

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: September 8, 2021

By: */s/ Kevin R. Lind*
Kevin R. Lind
President and Chief Executive Officer

Exhibit 99.1

Longboard Pharmaceuticals Successfully Completes LP352 Multiple Ascending Dose Portion of Phase 1 Clinical Trial in Healthy Volunteers, Plans to Initiate Phase 1b/2a Clinical Trial

- *Favorable safety, tolerability, pharmacokinetics and pharmacodynamics were observed*
- *Central 5-HT2c receptor engagement demonstrated by dose- and exposure-dependent increases of prolactin*
- *Company plans to initiate a Phase 1b/2a clinical trial in adult participants with developmental and epileptic encephalopathies (DEEs) in Q1 2022*

SAN DIEGO, Calif., September 8, 2021 – Longboard Pharmaceuticals, Inc. (Nasdaq: LBPH), a clinical-stage biopharmaceutical company focused on developing novel, transformative medicines for neurological diseases, announced today that the Company successfully completed the multiple ascending dose (MAD) portion of a Phase 1 clinical trial to assess the safety, tolerability, pharmacokinetics *(*PK) and pharmacodynamics (PD) of escalating doses of LP352, an oral, centrally acting, next-generation 5-HT2c receptor superagonist, in healthy volunteers. Longboard plans to advance LP352 into a Phase 1b/2a efficacy trial in adult participants with DEEs in the first quarter of 2022 in study sites across the United States.

"We are very pleased that we achieved the goals of this trial, which were to explore the safety, tolerability, PK and PD of LP352 at several dose levels and determine the optimal expected dose range for our upcoming efficacy trial. We are encouraged by the initial safety and tolerability characteristics of LP352 observed in the trial and that it appears to have a potent effect on the 5-HT2c pathway," stated Dr. Phil Perera, Longboard's Chief Medical Officer. "We believe LP352 has the potential to reduce seizures in a broad range of severe and devastating, treatment-resistant epilepsies, and we look forward to advancing the program in patients living with these debilitating disorders."

Phase 1 Trial:
The LP352 Phase 1 trial (N=83) was a first-in-human, randomized, placebo-controlled, double-blind, four-part trial including single ascending dose (SAD) and MAD assessments in healthy volunteers. The primary objectives of the trial were to evaluate safety, tolerability, PK & PD of LP352.

In the MAD portion (N=43) of the trial, five doses including the maximum planned dose were

evaluated. The majority of adverse events (AEs) were mild to moderate, with the most common being headache. A single serious adverse event (SAE) of anxiety was reported at the maximum planned dose two days after the last dose of study drug and subsequently resolved. AEs were generally consistent with central nervous system (CNS) effects and expected effects of serotonergic drugs.

LP352 demonstrated dose- and exposure-dependent increases of prolactin, suggesting proof of central 5-HT2c receptor engagement, as well as dose-dependent increases in exposure (C_{max} and AUC_{tau}).

About LP352
LP352 is an oral, centrally acting, next-generation 5-HT2c receptor superagonist in development for the potential treatment of seizures associated with DEEs such as Dravet syndrome, Lennox-Gastaut syndrome (LGS), tuberous sclerosis complex (TSC), CDKL5 deficiency disorder, and other epileptic disorders. LP352 is designed to modulate GABA inhibition and, as a result, suppress the central hyperexcitability that is characteristic of seizures. LP352 has demonstrated negligible observed impact on 5-HT2b and 5-HT2a receptor subtypes in the Company's preclinical studies to date. 5-HT2b and 5-HT2a receptor agonism have been associated with significant adverse effects. LP352 has novel chemistry and attributes, and was designed to be more specific and selective for the 5-HT2c receptor subtype, giving it the potential to reduce seizures in DEE patients while overcoming the known or perceived safety limitations of available drugs in the 5-HT2 class.

About Developmental and Epileptic Encephalopathies
DEEs refer to a group of severe epilepsies that are characterized both by seizures, which are often drug-resistant, as well as encephalopathy, which is a term used to describe significant developmental delay or even loss of developmental skills. In the DEEs, there are two factors that contribute to the developmental delay:

- Developmental encephalopathy implies that developmental delays are the direct result of the underlying cause of their epilepsy.

- In addition, some children with DEEs also have an epileptic encephalopathy due to very frequent seizures and markedly abnormal EEGs, which may substantially worsen developmental problems.

Importantly, if seizure control can be improved, the epileptic encephalopathy component of the delay may improve.

Most DEEs begin early in life, often starting in infancy. Children can have very frequent and severe seizures which may be of multiple types. Epileptic spasms, tonic or atonic seizures and myoclonic seizures, among other seizure types, can be seen. In many cases, seizures are life long, although in some instances they can abate with time with certain syndromes or specific causes.

About Longboard Pharmaceuticals
Longboard Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on developing novel, transformative medicines for neurological diseases. Longboard was formed in

January 2020 by Arena Pharmaceuticals, Inc. (Arena) 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 were discovered out of the same platform at Arena that represents a culmination of more than 20 years of GPCR research. Longboard is evaluating LP352, an oral, centrally acting, next-generation 5-hydroxytryptamine 2c receptor superagonist, with negligible observed impact on 5-HT2b and 5-HT2a receptor subtypes, in development for the potential treatment of seizures associated with developmental and epileptic encephalopathies. Longboard is also evaluating LP143, a centrally acting, full cannabinoid type 2 receptor agonist, in development for the potential treatment of neurodegenerative diseases associated with neuroinflammation caused by microglial activation, and LP659, a centrally acting, sphingosine-1-phosphate receptor subtypes 1 and 5 modulator, in development for the potential treatment of central nervous system neuroinflammatory diseases.

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 "expected," "potential," "plan," "anticipate," "focused on," and "look forward" and include, without limitation, statements about the following: Longboard's clinical and preclinical programs, including plans to advance LP352 in a Phase 1b/2a clinical trial; LP352's safety, tolerability, PK and PD profile and effect on the 5-HT2c pathway; LP352's potential to reduce seizures; the potential disease treatments of LP143 and LP659; and our focus. 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 the forward-looking statements include, but are not limited to, the following: 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; Longboard's product candidates are in the early phase of a lengthy research and development process, the timing, manner and outcome of research, development and regulatory review is uncertain, and Longboard's product candidates may not advance in research or development or be approved for marketing; continued clinical development of LP352 is dependent on the acceptance and approval of our investigational new drug application by the U.S. Food and Drug Administration's (FDA) Division of Neurology; enrolling participants in clinical trials is competitive and challenging; the duration and severity of the coronavirus disease (COVID-19) outbreak, including but not limited to the impact on Longboard's clinical trials and operations, the operations of Longboard's suppliers, partners, collaborators, and licensees, and capital markets, which in each case remains uncertain; 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; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; topline data may not accurately reflect the complete results of a particular study or trial; risks related to relying on licenses or collaborative arrangements, including lack of control and potential disputes; the entry into or modification or termination of 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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