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): December 21, 2021

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

Delaware	**001-38707**	**47-1514975**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

65 Hayden Avenue, 2nd Floor **Lexington, MA**	**02421**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 245-0399

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	**LOGC**	**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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On and effective December 21, 2021, the Board of Directors (the "Board") of LogicBio Therapeutics, Inc. ("LogicBio" or the "Company") increased the size of the Board from eight to nine directors and appointed Susan R. Kahn as a Class II director. Ms. Kahn's initial term is scheduled to expire at the Company's 2023 annual meeting of stockholders, subject to the election and qualification of her successor and her earlier death, resignation or removal. Ms. Kahn has not yet been appointed to any committees of the Board.

Ms. Kahn is entitled to receive compensation for her service as a director in accordance with the Company's non-employee director compensation policy applicable to all non-employee directors (the "Director Compensation Policy"). In accordance with the Director Compensation Policy, as a new non-employee director, Ms. Kahn was granted an option to purchase 25,000 shares of the Company's common stock at an exercise price of $2.41 per share on December 21, 2021. The initial option grant vests in equal annual installments over three years.

In addition, in accordance with the Director Compensation Policy, Ms. Kahn is entitled to receive an annual cash retainer of $35,000 for serving on the Board, and an annual equity grant of an option to purchase 12,500 shares of the Company's common stock. Pursuant to the Director Compensation Policy, annual option awards granted to non-employee directors vest in full on the earlier of (1) the first anniversary of the applicable grant date, and (2) the day prior to the date of the next annual meeting of the Company's stockholders following the grant date.

Pursuant to the Director Compensation Policy, the initial and annual equity awards granted to non-employee directors under the Director Compensation Policy vest in full upon a change in control and, in each case, are subject to Ms. Kahn's continued service through the applicable vesting date.

The Company has also entered into an indemnification agreement with Ms. Kahn in connection with her service as a member of the Board. The indemnification agreement is substantially in the form filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2021, as filed with the U.S. Securities and Exchange Commission (the "SEC") on November 15, 2021 and is incorporated herein by reference.

Ms. Kahn does not have a material direct or indirect interest in any transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K. Additionally, there are no arrangements or understandings between Ms. Kahn and any other person regarding her election to the Board.

Item 7.01 Regulation FD Disclosure.

On December 22, 2021, the Company issued the press release furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

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

Item 8.01 Other Events.

Phase 1/2 SUNRISE Clinical Trial Updates

As previously disclosed, LogicBio is currently conducting the Phase 1/2 SUNRISE clinical trial evaluating LB-001, the Company's investigational, single-administration, genome editing therapy based on its proprietary GeneRide™ platform, in pediatric patients with methylmalonic acidemia ("MMA"). The SUNRISE trial is designed to enroll up to eight patients across two age groups (six months to two years old, and three to twelve years old) and evaluate LB-001 at two dose levels (5×10^{13} vg/kg and 1×10^{14} vg/kg).

On December 22, 2021, the Company announced certain updates with respect to the SUNRISE trial. First, the Company announced that the serious adverse event ("SAE") experienced by the third patient dosed in the SUNRISE trial, which was previously disclosed by the Company in November 2021, has been completely resolved and all laboratory parameters that were abnormal at the time the SAE was observed have returned to normal.

The Company also announced that it expects to dose two additional patients in the SUNRISE trial in the near term, one patient in the older age group at the higher dose, and another patient in the lower age group at the lower dose. The Company further announced that it plans to report additional interim data from the SUNRISE trial in the second quarter of 2022 in lieu of reporting additional interim data from SUNRISE by the end of 2021. The Company believes that this updated timing for announcement of additional interim data will allow it to amass a more robust and meaningful data set.

Nomination of New GeneRide Development Candidate for the Treatment of Hereditary Tyrosinemia Type 1

In accordance with its previously announced guidance, on December 22, 2021, LogicBio also announced the nomination of a new development candidate, LB-401, for the treatment of hereditary tyrosinemia type 1 ("HT1"). This development candidate is based on the Company's GeneRide genome editing platform. HT1 is a rare, genetic disorder characterized by elevated blood levels of the amino acid tyrosine that affects 1 in 100,000 to 120,000 newborns worldwide. This condition is caused by a shortage of the enzyme fumarylacetoacetate hydrolase ("FAH"), one of the enzymes required for the multi-step process that breaks down tyrosine.

In preclinical studies presented at the 2021 ESGCT Annual Meeting ("ESGCT") in October 2021, HT1 models with acute liver damage showed that GeneRide-edited hepatocytes substantially repopulated the entire liver within four weeks post-administration, replacing the diseased hepatocytes with corrected hepatocytes. HT1 mice that received the GeneRide-FAH vector were no longer reliant on the current standard of care for the disease, and demonstrated restored normal body growth, liver function, and undetectable succinyl acetone levels.

Cautionary Note Regarding Forward-Looking Statements.

Statements in this Current Report on Form 8-K regarding the Company's strategy, plans, prospects, expectations, beliefs, intentions and goals are forward-looking statements, including but not limited to statements regarding validation of previous research; the anticipated timing of announcing interim clinical data; and the anticipated number and ages of patients that we expect to enroll and/or dose in the near term. The terms "believe," "expect," "plans" and similar references are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement, including the risk that existing preclinical data may not be predictive of the results of ongoing or later preclinical and/or clinical results; the risk that we will not be able to generate sufficient clinical data or enroll our clinical trial in a timely manner or at all; the potential direct or indirect impact of the COVID-19 pandemic on our business, operations, and the markets and communities in which we and our partners, collaborators and vendors operate; manufacturing risks; risks associated with management and key personnel changes and transitional periods; the actual funding required to develop and commercialize product candidates, including for safety, tolerability, enrollment, manufacturing or economic reasons; the timing and content of decisions made by regulatory authorities; the actual time it takes to initiate and complete preclinical and clinical studies; the competitive landscape; changes in the economic and financial conditions of LogicBio; and LogicBio's ability to obtain, maintain and enforce patent and other intellectual property protection for LB-001 and any other product candidates. Other risks and uncertainties include those identified under the heading "Risk Factors" in LogicBio's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 and other filings that LogicBio may make with the U.S. Securities and Exchange Commission in the future. These forward-looking statements (except as otherwise noted) speak only as of the date of this Current Report on Form 8-K, and the Company does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Exhibit Description
99.1	Press Release issued by LogicBio Therapeutics, Inc. on December 22, 2021.
104	Cover Page Interactive Data File (embedded with 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.

Date: December 22, 2021

LOGICBIO THERAPEUTICS, INC.

By: /s/ Cecilia Jones
Name: Cecilia Jones
Title: Chief Financial Officer

LogicBio Therapeutics Provides Business Updates

- SUNRISE Phase 1/2 interim data expected to be announced in 2Q 2022 -

- New GeneRide™ development candidate nominated for the treatment of hereditary tyrosinemia type 1 -

- Susan R. Kahn, leading advocate for patients and families impacted by rare genetic diseases, appointed to Board of Directors -

LEXINGTON, Mass., December 22, 2021 — LogicBio Therapeutics, Inc. (Nasdaq: LOGC), a clinical-stage genetic medicine company, today provided updates around its SUNRISE Phase 1/2 clinical trial and development pipeline, and announced the appointment of Susan R. Kahn to its Board of Directors.

SUNRISE Phase 1/2 Clinical Trial Update

SUNRISE is a first-in-human, open-label, multi-center, Phase 1/2 clinical trial designed to assess the safety and tolerability of an intravenous infusion of LB-001, the company's investigational, single-administration genome editing therapy, in pediatric patients with methylmalonic acidemia (MMA). SUNRISE is designed to enroll up to eight patients across two age groups (six months to two years old, and three to twelve years old) and evaluate LB-001 at two dose levels (5×10^{13} vg/kg and 1×10^{14} vg/kg).

In October, LogicBio announced early data from the SUNRISE trial demonstrating the first-ever *in vivo* genome editing in children. These early data showed measurable levels of albumin-2A, a technology-related biomarker indicating site-specific gene insertion and protein expression. In November, the company disclosed that the third patient dosed in SUNRISE, who received 5×10^{13} vg/kg of LB-001 and was in the lower age group, experienced a serious adverse event (SAE). This SAE has been completely resolved and all laboratory parameters that were abnormal at the time the SAE was observed have returned to normal. The SUNRISE trial is continuing in accordance with the protocol and additional safety measures implemented following the occurrence of the SAE. The company plans to report additional interim data from the SUNRISE trial in the second quarter of 2022.

"We believe reporting interim data from SUNRISE in the second quarter of 2022 instead of by year-end 2021 will allow us to amass a more robust and meaningful data set," said Fred Chereau, president and chief executive officer of LogicBio. "Safety is our top priority, and we are pleased that the patient who experienced the SAE is now fully recovered. We expect to dose two additional patients in the near term, one patient in the older age group at the higher dose, and another patient in the lower age group at the lower dose."

Nomination of New GeneRide Development Candidate for the Treatment of Hereditary Tyrosinemia Type 1

In accordance with its previously announced guidance, LogicBio also announced the nomination of a new development candidate, LB-401, for the treatment of hereditary tyrosinemia type 1 (HT1). This development candidate is based on the company's GeneRide genome editing platform. HT1 is a rare, genetic disorder characterized by elevated blood levels of the amino acid tyrosine. This condition is caused by a shortage of the enzyme fumarylacetoacetate hydrolase (FAH), one of the enzymes required for the multi-step process that breaks down tyrosine.

In preclinical studies presented at the 2021 ESGCT Annual Meeting (ESGCT) in October, HT1 models with acute liver damage showed that GeneRide-edited hepatocytes substantially repopulated the entire liver within four weeks post-administration, replacing the diseased hepatocytes with corrected hepatocytes. HT1 mice that received the GeneRide-FAH vector were no longer reliant on the current standard of care for the disease, and demonstrated restored normal body growth, liver function, and undetectable succinyl acetone levels.

“We are excited to explore the potential of our GeneRide platform in HT1, a devastating rare disease that can present within the first months of patients’ lives,” said Mariana Nacht, Ph.D., chief scientific officer of LogicBio. “The preclinical data presented at ESGCT for this indication validate our confidence in leveraging the selective advantage observed in our GeneRide platform to deliver corrected hepatocytes that drive improved disease markers.”

Susan R. Kahn Appointed to Board of Directors

The company also announced today the appointment of Susan R. Kahn to its Board of Directors. From September 2007 to November 2021, Ms. Kahn was the executive director of the National Tay-Sachs & Allied Diseases Association (NTSAD), a highly regarded patient advocacy group for children and adults affected by rare genetic diseases. Previously, she was at Genzyme Genetics, where she led initiatives to develop and execute new business opportunities, acquisition and partnering strategies, new product and technology assessments, and technology licensing. Before that, Ms. Kahn worked at Chiron Diagnostics in roles of increasing responsibility, including roles in business development and finance. She earned an A.B. in applied mathematics-economics from Brown University and an M.B.A. from the Tuck School of Business at Dartmouth**.**

“Sue is a leading advocate for those impacted by rare genetic diseases. Her passion for these patients and their families aligns perfectly with our mission at LogicBio,” said Mr. Chereau. “I am thrilled to welcome Sue to our Board and am excited to leverage her expertise and thought leadership in the advocacy space as we continue to advance our mission to deliver the hope of genetic medicine to people impacted by devastating, early onset diseases.”

“I am excited to join the LogicBio Board at what I believe is a pivotal time for the company,” said Ms. Kahn. “Having spent the last fourteen years supporting patients and families affected by rare genetic diseases, I look forward to helping LogicBio deliver much-needed treatment options to patients.”

About LogicBio Therapeutics

LogicBio Therapeutics is a clinical-stage genetic medicine company pioneering genome editing and gene delivery platforms to address rare and serious diseases from infancy through adulthood. The company’s genome editing platform, GeneRide™, is a new approach to precise gene insertion harnessing a cell’s natural DNA repair process potentially leading to durable therapeutic protein expression levels. The company’s gene delivery platform, sAAVy™, is an adeno-associated virus (AAV) capsid engineering platform designed to optimize gene delivery for treatments in a broad range of indications and tissues. The company is based in Lexington, MA. For more information, visit www.logicbio.com, which does not form a part of this release.

About the SUNRISE Trial

The SUNRISE trial is an open-label, multi-center, Phase 1/2 clinical trial designed to assess the safety, tolerability and preliminary efficacy of a single intravenous infusion of LB-001 in pediatric patients with methylmalonic acidemia (MMA) characterized by methylmalonyl-CoA mutase gene (MMUT) mutations. Seven leading centers in the United States and one in Saudi Arabia are expected to participate in the trial. With the aim of evaluating LB-001 at an early age, the SUNRISE trial is designed to enroll up to eight patients with ages ranging from six months to twelve years and evaluate a single administration of LB-001 at two dose levels (5×10^{13} vg/kg and 1×10^{14} vg/kg).

About LB-001

LB-001 is an investigational, first-in-class, single-administration, genome editing therapy for early intervention in methylmalonic acidemia (MMA) using LogicBio's proprietary GeneRide™ drug development platform. GeneRide technology utilizes a natural DNA repair process called homologous recombination that enables precise editing of the genome without the need for exogenous nucleases and promoters that have been associated with an increased risk of immune response and cancer. LB-001 is designed to non-disruptively insert a corrective copy of the methylmalonyl-CoA mutase (MMUT) gene into the albumin locus to drive lifelong therapeutic levels of MMUT expression in the liver, the main site of MMUT expression and activity. LB-001 is delivered to hepatocytes intravenously via liver-targeted, engineered recombinant adeno-associated virus vector (rAAV-LK03). Preclinical studies found that LB-001 was safe and demonstrated transduction of hepatocytes, site-specific genomic integration, and transgene expression. LB-001–corrected hepatocytes in a mouse model of MMA demonstrated preferential survival and expansion (selective advantage), thus contributing to a progressive increase in hepatic MMUT expression over time. LB-001 resulted in improved growth, metabolic stability, and survival in MMA mice. The U.S. Food and Drug Administration (FDA) granted fast track designation, rare pediatric disease designation and orphan drug designation for LB-001 for the treatment of MMA. In addition, the European Medicines Agency (EMA) granted orphan drug designation for LB-001 for the treatment of MMA.

About Methylmalonic Acidemia (MMA)

Methylmalonic acidemia (MMA) is a rare and life-threatening genetic disorder affecting approximately 1 in 50,000 newborns in the United States. In the most common form of MMA, a mutation in a gene called methylmalonyl-CoA mutase (MMUT) prevents the body from properly processing certain fats and proteins. As a result, toxic metabolites accumulate in the liver, in muscle tissue and in the brain. Symptoms include vomiting, lethargy, seizures, developmental delays and organ damage. There is no approved medical therapy addressing the underlying cause of the disease. To manage the symptoms, patients go on a severely restrictive, low-protein, high-calorie diet, often through a feeding tube. Even with aggressive management, these patients often experience life-threatening metabolic crises that can require recurrent hospitalizations and cause permanent neurocognitive damage. Because of this risk for irreversible damage, early intervention is critical and newborns are screened for MMA in every state in the United States.

About Hereditary Tyrosinemia Type 1 (HT1)

Hereditary tyrosinemia type 1 (HT1) affects 1 in 100,000 to 120,000 newborns worldwide. In the most common form, it is characterized by elevated blood levels of the amino acid tyrosine, a building block of most proteins. This condition is caused by a shortage of the enzyme fumarylacetoacetate hydrolase (FAH), one of the enzymes required for the multi-step process that breaks down tyrosine. This enzyme shortage is caused by mutations in the FAH gene. Symptoms usually appear in the first few months of life and include failure to thrive, diarrhea, vomiting, jaundice, cabbage-like odor, and increased tendency to bleed (particularly nosebleeds). HT1 can lead to liver and kidney failure, softening and weakening of the bones, problems affecting the nervous system, and an increased risk of liver cancer.

Forward-Looking Statements

Statements in this press release regarding LogicBio's strategy, plans, prospects, expectations, beliefs, intentions and goals are forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, as amended, including but not limited to statements regarding validation of previous research; the potential of the GeneRide™ platform in hereditary tyrosinemia type 1 or generally; the anticipated timing of announcing interim clinical data; the anticipated number and ages of patients that we expect to enroll and/or dose in the near term; and delivering treatment options to patients. The terms "believe," "expect," "look forward," "plans," "potential" and similar references are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement, including the risk that existing preclinical data may not be predictive of the results of ongoing or later preclinical and/or clinical results; the risk that we will not be able to generate sufficient clinical data or enroll our clinical trial in a timely manner or at all; the potential direct or indirect impact of the COVID-19 pandemic on our business, operations, and the markets and communities in which we and our partners, collaborators and vendors operate; manufacturing risks; risks associated with management and key personnel changes and transitional periods; the actual funding required to develop and commercialize product candidates, including for safety, tolerability, enrollment, manufacturing or economic reasons; the timing and content of decisions made by regulatory authorities; the actual time it takes to initiate and complete preclinical and clinical studies; the competitive landscape; changes in the economic and financial conditions of LogicBio; and LogicBio's ability to obtain, maintain and enforce patent and other intellectual property protection for LB-001 and any other product candidates. Other risks and uncertainties include those identified under the heading "Risk Factors" in LogicBio's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 and other filings that LogicBio may make with the U.S. Securities and Exchange Commission in the future. These forward-looking statements (except as otherwise noted) speak only as of the date of this press release, and LogicBio does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this press release.

Investor Contacts:

Stephen Jasper
Gilmartin Group
(858) 525-2047
stephen@gilmartinir.com

Media Contacts:

Adam Daley
Berry & Company Public Relations
W:212-253-8881
C: 614-580-2048
adaley@berrypr.com