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): January 10, 2020

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.)**

99 Erie St. **Cambridge, MA**	**02139**
(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**	**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.

On January 10, 2020, LogicBio Therapeutics, Inc. (the "Company") announced the submission of an investigational new drug application to the U.S. Food and Drug Administration for LB-001 in methylmalonic acidemia and provided other business updates. A copy of this press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

On January 10, 2020, the Company also announced a research collaboration with Takeda Pharmaceutical Company Limited to further developLB-301 in Crigler-Najjar syndrome. A copy of this press release is attached to this Current Report on Form 8-K as Exhibit 99.2 and is incorporated herein by reference.

Except as shall be expressly set forth by specific reference, the information contained or incorporated by reference in this Item 7.01 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 under that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by LogicBio Therapeutics, Inc. on January 10, 2020.
99.2	Press Release issued by LogicBio Therapeutics, Inc. on January 10, 2020.

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.

LOGICBIO THERAPEUTICS, INC.

By: /s/ Bryan Yoon
Bryan Yoon
Chief Administrative Officer and General Counsel

Date: January 10, 2020

Exhibit 99.1

LogicBio Therapeutics Announces Submission of Investigational New Drug Application (IND) for LB-001 for Methylmalonic Acidemia (MMA) and Highlights Key Corporate Milestones

– Filed IND for lead GeneRide™ candidate LB-001 in pediatric MMA patients –
– Phase 1/2 trial initiation planned for H1 2020, with preliminary data in H2 2020 –
– Established research collaboration with Takeda for GeneRide in Crigler-Najjar Syndrome (CN) –

CAMBRIDGE, Mass., January 10, 2020 – LogicBio Therapeutics, Inc. (Nasdaq:LOGC), a genome editing company focused on developing medicines to durably treat rare diseases in pediatric patients, today announced it has submitted an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) to initiate a Phase 1/2 trial of LB-001, a recombinant adeno-associated viral vector with human methylmalonyl-COA mutase (*MMUT)* gene for the treatment of methylmalonic acidemia (MMA). LB-001 leverages LogicBio's proprietary, promoterless, nuclease-free genome editing technology, GeneRide™, and has previously received both orphan drug and rare pediatric disease designations from the FDA.

LogicBio intends to disclose additional details regarding the planned Phase 1/2 trial, including trial size, endpoints, and timelines, once the FDA accepts the IND. LogicBio plans to initiate a Phase 1/2 trial in pediatric MMA patients in the first half of 2020, with preliminary data expected in the second half of 2020.

"We founded LogicBio with the mission of bringing genetic medicines to children with rare diseases. Both the IND submission and the nomination of our second indication represent significant steps in advancing our goal," said Fred Chereau, CEO of LogicBio. "MMA and CN are devastating early onset diseases with no approved pharmacological therapies, and we are committed to developing novel medicines based on our GeneRide platform for pediatric patients. We look forward to a transformational year for LogicBio as we work to advance our programs, validate our platform, and expand our pipeline."

Today, LogicBio also highlighted key recent and upcoming milestones.

- **Established collaboration with Takeda to leverage the GeneRide platform in a second indication, Crigler-Najjar Syndrome.** LogicBio and Takeda will further research and develop LB-301, an investigational pediatric genome editing therapy based on LogicBio's GeneRide technology for the treatment of CN. The LB-301 construct, utilizing the modularity of GeneRide, is expected to share several components with LB-001 to facilitate development. Those components include: LK-03 as the capsid; the albumin gene as the target genetic locus for integration; and a 2A peptide sequence to facilitate polycistronic expression and serving as a circulating biomarker. A separate press release with more details can be found on LogicBio's investor relations website at investor.logicbio.com.
- **Initiated Retrospective Natural History Study in MMA.** This study is designed to evaluate disease progression in pediatric patients (born since 2010) with severe MMA, with the aim of informing LogicBio's future development in MMA and its discussions with regulatory agencies.
- **Reported positive data on Next Generation Capsid Development program at European Society of Gene and Cell Therapy Annual Meeting.** Data were presented from a set of novel, synthetic adeno-associated virus (AAV) capsid candidates tested against references AAV2, AAV8, and LK-03. All capsids showed selective tropism and more potent transduction and gene expression than the reference capsids in human hepatocytes of a chimeric FRG mouse model. LogicBio, working in partnership with the Children's Medical Research Institute, intends to advance this research and present additional findings at a scientific conference in 2020.

- **Doubling available lab and office space to support GeneRide platform development and capabilities expansion.**LogicBio expects to move into new headquarters in Lexington, Mass. in the spring of 2020. LogicBio will be adding vivarium space, internal development capabilities, and will increase its capacity for in-house manufacturing of preclinical material. The expanded lab space will support the continued advancement of a robust pipeline that builds on the modular GeneRide construct. The new facilities will also support continued growth of the capsid program, which aims to develop and license new state-of-the-art viral vectors.

About Methylmalonic Acidemia

Primarily caused by mutations in the*MMUT* gene, methylmalonic acidemia is a rare, life-threatening, autosomal recessive disease for which there are no approved therapies. The disease, which starts in the first month of life, prevents the body from properly processing certain fats and proteins, resulting in a toxic accumulation of metabolites that can cause life-threatening decompensations in infants and children. This buildup can lead to significant morbidity and mortality, including infections, neurodevelopmental disabilities and chronic kidney disease. The incidence of MMA in the United States is reported to be 1 in 50,000 births. LogicBio estimates the number of MMA patients with the genetic deficiency targeted by LB-001 to be 3,400 to 5,100 patients in key global markets, of which 1,000 to 1,500 patients are in the United States.

About LB-001

LB-001 is an investigational pediatric genome editing therapy based on LogicBio's GeneRide™ technology. GeneRide enables site-specific integration and lifelong expression of therapeutic transgenes, without the use of exogenous promoters or nucleases. LB-001 is designed to incorporate a functioning version of the faulty *MMUT* gene into the genome of MMA patients. LogicBio has demonstrated preclinicalproof-of-concept of GeneRide in multiple animal models of the disease, improving survival and reversing disease pathology. In preclinical MMA models, LogicBio has shown that cells into which GeneRide has inserted a transgene demonstrate a selective survival advantage over cells not expressing the transgene. LB-001 has received both orphan drug and rare pediatric disease designations from the U.S. Food and Drug Administration.

About LogicBio Therapeutics

LogicBio Therapeutics is a genome editing company focused on developing medicines to durably treat rare diseases in pediatric patients with significant unmet medical needs using GeneRide™, its proprietary technology platform. GeneRide enables the site-specific integration of a therapeutic transgene in a nuclease-free and promoterless approach by relying on the native process of homologous recombination to drive potential lifelong expression. Headquartered in Cambridge, Mass., LogicBio is committed to developing medicines that will transform the lives of pediatric patients and their families.

For more information, please visit www.logicbio.com.

Forward Looking Statements

This press release contains "forward-looking" statements within the meaning of the federal securities laws. These are not statements of historical facts and are based on management's beliefs and assumptions and on information currently available. They are subject to risks and uncertainties that could cause the actual results and the implementation of the Company's plans to vary materially,

including the risks associated with the initiation, cost, timing, progress and results of the Company's current and future research and development activities and preclinical studies and potential future clinical trials. These risks are discussed in the Company's filings with the U.S. Securities and Exchange Commission (SEC), including, without limitation, the Company's Annual Report on Form 10-K filed on April 1, 2019 with the SEC, and the Company's subsequent Quarterly Reports on Form 10-Q and other filings with the SEC. Except as required by law, the Company assumes no obligation to update these forward-looking statements publicly, even if new information becomes available in the future.

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Exhibit 99.2

LogicBio Therapeutics Announces Collaboration with Takeda to Develop New Genome Editing Candidate LB-301 for the Treatment of Crigler-Najjar Syndrome

– LB-301 is a recombinant AAV vector with a *UGT1A1* gene leveraging GeneRide™ genome editing platform for the treatment of Crigler-Najjar syndrome –

– The collaboration agreement grants Takeda an exclusive option to negotiate an exclusive, worldwide license to LogicBio's LB-301 program –

– Crigler-Najjar syndrome is the second indication to be pursued using GeneRide™ platform –

CAMBRIDGE, Mass., January 10, 2020 – LogicBio Therapeutics, Inc. (Nasdaq:LOGC), a genome editing company focused on developing medicines to durably treat rare diseases in pediatric patients today announced a research collaboration with Takeda Pharmaceutical Company Limited (Takeda) to further develop LB-301, an investigational therapy using LogicBio's proprietary, promoterless, nuclease-free genome editing technology, GeneRide™, for the treatment of Crigler-Najjar syndrome. LB-301 is a recombinant adeno-associated viral (AAV) vector with a uridinedisphosphate-glucuronosyltransferase-1 (*UGT1A1*) gene. The collaboration will bring together LogicBio's propriety platform for genome editing and Takeda's expertise in researching and developing gene therapies.

"LogicBio's innovative, site-specific, genome editing platform has the potential to overcome the limitations that make it challenging to apply conventional gene editing and gene transfer in pediatric patients," said Dan Curran, Head, Rare Diseases Therapeutic Area Unit at Takeda. "We see GeneRide™ as a promising approach to explore as part of our aspiration to develop transformative – or even potentially curative – therapies to patients living with rare diseases."

"We are thrilled to be working with Takeda to advance our GeneRide™ platform in a second indication," said Fred Chereau, CEO of LogicBio. "Their insights and expertise in rare diseases drug development is expected to significantly accelerate the development of a much-needed therapy for this devastating pediatric disease. This collaboration recognizes GeneRide™ as a promising approach for bringing the transformational power of genome editing to children with an array of relentless, progressive pediatric diseases."

Under the agreement, LogicBio and Takeda will collaborate to further research and develop LB-301. Takeda will provide funding for the research program under the collaboration agreement and will have an exclusive option to negotiate an exclusive, worldwide license to LogicBio's LB-301 program.

Crigler-Najjar syndrome is a rare monogenic pediatric disease caused by a deficiency in theliver-specific *UGT1A1* gene, resulting in severely high levels of unconjugated bilirubin in the blood starting at birth, with lifelong risk of permanent neurological damage and death. Current clinical practice consists of daily, intense phototherapy treatment for approximately 12 hours, but this treatment becomes less effective with age, ultimately leaving liver transplantation as the only therapeutic option for survival.

LogicBio has demonstrated that a murine GeneRide™ construct of LB-301 can correct the gene deficiency in an animal model of Crigler-Najjar syndrome. The introduction of a *UGT1A1* gene into the albumin locus in mouse liver cells resulted in normalization of bilirubin levels and long-term survival of mice deficient in *UGT1A1* from fewer than 20 days to at least one year. The results from this research were published in *EMBO Molecular Medicine* (Porro et al., 2017).

About LB-301

LB-301 is an investigational pediatric genome editing therapy based on LogicBio's GeneRide™ technology. GeneRide™ enables site-specific integration and lifelong expression of therapeutic transgenes, without the use of exogenous promoters or nucleases. LB-301 is designed to incorporate a functioning version of the faulty uridine disphosphate-glucuronosyltransferase-1 (*UGT1A1*) gene into the genome of Crigler-Najjar patients. LogicBio has demonstrated preclinical proof-of-concept of GeneRide™ in multiple animal models of the disease, improving survival and reversing disease pathology.

About LogicBio Therapeutics

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Forward Looking Statements

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