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): August 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.)**

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**	**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 2.02 Results of Operations and Financial Condition.

On August 10, 2020, LogicBio Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarterly period ended June 30, 2020. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 7.01 Regulation FD.

On August 10, 2020, the Company issued a press release announcing the clearance of its investigational new drug application to support the initiation of the SUNRISE Phase 1/2 clinical trial on LB-001 in pediatric patients with methylmalonic acidemia along with certain details regarding the SUNRISE trial. 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.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.2 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act and shall not be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

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

Exhibit 99.1

LogicBio Therapeutics Reports Second Quarter 2020 Financial Results and Provides Business Updates

– FDA Clears IND Application for LB-001 for the Treatment of Methylmalonic Acidemia in Pediatric Patients –

LEXINGTON, Mass., August 10, 2020 – LogicBio Therapeutics, Inc. (Nasdaq:LOGC) (LogicBio or the Company), a company dedicated to extending the reach of genetic medicine with pioneering targeted delivery platforms, today reported financial results for the quarter ended June 30, 2020, provided a business update and announced the U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) application for LB-001 for the treatment of methylmalonic acidemia in pediatric patients. LogicBio released a separate press release this morning providing further details on the planned Phase 1/2 clinical design for LB-001.

"We are thrilled to have received clearance to move forward with this first-in-human clinical trial with our lead product candidate, LB-001, for the treatment of methylmalonic acidemia, a life-threatening congenital genetic disease with no current therapeutic treatment options. This represents a significant milestone in our goal of bringing a treatment to MMA patients as well as for our GeneRide platform. We have maintained continuous dialogue with the centers of excellence that are planned to participate in the Phase 1/2 clinical trial, and we look forward to activating these sites as quickly as possible," said Fred Chereau, CEO of LogicBio. "We have instituted systems attempting to mitigate COVID-19 dynamics on our study start-up process and, based on our best estimates, we plan to enroll our first patient in early 2021."

Commenting on the Next Generation Capsid Program, Mr. Chereau said, "We are very excited about the recent advances in our novel capsid program, which has generated liver-tropic capsids intended for use in gene editing technologies such as GeneRide and other gene therapy approaches. We are focused on executing across all of our programs and look forward to sharing further details on our novel capsids in early 2021."

Appointment of Daniel Gruskin, M.D. to SVP, Head of Clinical Development

Daniel Gruskin, M.D. was appointed as SVP, head of clinical development in August 2020. Dr. Gruskin has served as interim head of clinical development of LogicBio since June 2020. In April 2020, Dr. Gruskin started consulting with the Company as a special advisor. Previously, Dr. Gruskin served in roles of increasing responsibility at Sanofi Genzyme, most recently as vice president, head of global medical affairs, rare disease, in which capacity he oversaw medical affairs, life cycle management, scientific affairs and other medical and development activities related to metabolic, rare and/or genetic diseases. Prior to his role at Sanofi Genzyme, Dr. Gruskin served as assistant professor, human genetics and pediatrics at Emory University School of Medicine, where he was also the chief of the genetics section at Children's Healthcare of Atlanta.

"Daniel has been instrumental in leading LB-001 clinical development efforts including getting the IND cleared. His deep experience in genetic medicines and metabolic diseases will serve LogicBio well as we look to execute on our goals for both the GeneRide and Next Generation Capsid platforms in search of transformative medicines," said Mr. Chereau.

Anticipated Milestones for 2020 and 2021:

- **GeneRide Platform**
  - **LB-001 for MMA**
    - **Early 2021:** First patient enrollment in Phase 1/2 trial
  - **Platform**
    - **Early 2021:** Translational model data
- **Next Gen Capsid Platform**
  - **Early 2021:** Translational model data

Second Quarter 2020 Financial Results

Three Months Ended June 30, 2020 and 2019

- **R&D Expenses:** Research and development expenses for the three months ended June 30, 2020 were $5.9 million, compared to $7.9 million for three months ended June 30, 2019. The decrease was primarily due to decreases of approximately $2.3 million in external development and manufacturing expenses for the Company's lead product candidate, LB-001, and a decrease of $0.1 million in personnel-related costs as increased headcount was offset by salary cuts related to the COVID-19 pandemic. These decreases were partially offset by an increase of $0.3 million in other research and development expenses as the Company increased its overall research and development activities related to general platform development. While there may be fluctuations on a quarterly basis, the Company expects that its research and development costs will decrease during 2020 as compared to 2019 as it has already incurred a significant proportion of the LB-001 external development and manufacturing costs needed to bring LB-001 into clinical development.
- **G&A Expenses:** General and administrative expenses were $3.0 million for the three months ended June 30, 2020, compared to $2.5 million for the three months ended June 30, 2019. The increase was primarily due to increases in corporate legal expense, D&O insurance premiums and non-capitalizable facilities expenses. The Company expects that general and administrative expenses will remain relatively consistent during 2020 as compared to 2019 although there may be fluctuations on a quarterly basis.
- **Net Loss:** Net loss was $8.2 million, or $0.35 per share, for the three months ended June 30, 2020, compared to a net loss of $10.0 million, or $0.45 per share, for the three months ended June 30, 2019.
- **Cash Position and Financial Guidance:** Cash and cash equivalents were $36.7 million as of June 30, 2020. The Company believes that its cash and cash equivalents as of June 30, 2020 will enable the Company to fund operating expenses and capital expenditure requirements into the third quarter of 2021.

About LogicBio Therapeutics

LogicBio Therapeutics is dedicated to extending the reach of genetic medicine with pioneering targeted delivery platforms.

LogicBio's proprietary genome editing technology platform, GeneRide, enables the site-specific integration of a therapeutic transgene without nucleases or exogenous promoters by harnessing the

native process of homologous recombination. LogicBio has received FDA clearance for the first-in-human clinical trial of LB-001, a wholly owned genome editing program leveraging GeneRide for the treatment of methylmalonic acidemia. Patient enrollment is expected to begin in early 2021. In addition, LogicBio has a collaboration with Takeda to research and develop LB-301, an investigational therapy leveraging GeneRide for the treatment of the rare pediatric disease Crigler-Najjar syndrome.

LogicBio is also developing a Next Generation Capsid platform for use in gene editing and gene therapies. Data presented have shown that the capsids deliver highly efficient functional transduction of human hepatocytes with improved manufacturability with low levels of pre-existing neutralizing antibodies in human samples. Top-tier capsid candidates from this effort demonstrated significant improvements over benchmark AAVs currently in clinical development. LogicBio is developing these highly potent vectors for internal development candidates and potentially for business development collaborations.

LogicBio is headquartered in Lexington, Mass. 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, including those related to the Company’s plans to initiate, advance and complete its planned SUNRISE Phase 1/2 clinical trial of LB-001 in MMA; the timing, progress and results of the Company’s research and development activities, including those related to the GeneRide technology platform and Next Generation Capsid Program; its plans for LB-301 in Crigler-Najjar; and the sufficiency of its cash and cash equivalents to fund operating expenses and capital expenditure requirements. 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. In particular, the impact of the COVID-19 pandemic on the Company’s ability to progress with its research, development, manufacturing and regulatory efforts, including the Company’s plans to initiate, advance and complete its Phase 1/2 clinical trial for LB-001 in MMA, and the value of and market for the Company’s common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the United States and in other countries, and the effectiveness of actions taken globally to contain and treat the disease. 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 March 16, 2020 with the SEC, the Company’s Quarterly Report on Form 10-Q filed on May 11, 2020, 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.

LogicBio Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
REVENUE				
Service revenue	$ 965	$ —	$ 1,986	$ —
Total revenue	965	—	1,986	—
OPERATING EXPENSES				
Research and development	5,895	7,934	13,068	$ 13,420
General and administrative	3,029	2,524	6,221	5,156
Total operating expenses	8,924	10,458	19,289	18,576
LOSS FROM OPERATIONS	(7,959)	(10,458)	(17,303)	(18,576)
OTHER INCOME (EXPENSE), NET:				
Interest income	10	411	177	854
Interest expense	(273)	—	(545)	—
Other expense, net	(5)	(1)	(11)	(1)
Total other (expense) income, net	(268)	410	(379)	853
Loss before income taxes	(8,227)	(10,048)	(17,682)	(17,723)
Income tax provision	—	—	—	(22)
Net loss	$ (8,227)	$ (10,048)	$ (17,682)	$ (17,745)
Net loss per share—basic and diluted	$ (0.35)	$ (0.45)	$ (0.76)	$ (0.79)
Weighted-average common stock outstanding—basic and diluted	23,326,018	22,479,511	23,250,910	22,396,780

LogicBio Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(In thousands)
(Unaudited)

	As of	
	June 30, 2020	December 31, 2019
Cash, cash equivalents and investments	$ 36,697	$ 50,647
Other assets	10,646	5,013
TOTAL ASSETS	$ 47,343	$ 55,660
Accounts payable, accrued expenses and other liabilities	$ 19,187	$ 13,373
Stockholders' equity	28,156	42,287
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 47,343	$ 55,660

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Exhibit 99.2

LogicBio Therapeutics Announces SUNRISE Phase 1/2 Clinical Design for LB-001 for the Treatment of Methylmalonic Acidemia in Pediatric Patients

– LogicBio's First IND Clearance Leveraging GeneRide, an In Vivo Homologous Recombination-based Genome Editing Platform –

– Enrollment to Start with Patients as Young as 3 Years Old, De-escalating Down to 6 Months old –

– Webcast and Conference Call Today at 8 a.m. ET to Discuss LB-001 Update –

LEXINGTON, Mass., August 10, 2020 – LogicBio Therapeutics, Inc. (Nasdaq:LOGC) (LogicBio or the Company), a company dedicated to extending the reach of genetic medicine with pioneering targeted delivery platforms, today announced the clinical trial design for the planned Phase 1/2 clinical trial for LB-001 in pediatric patients with methylmalonic acidemia (MMA) .

"We're pleased to announce our plans for developing LB-001 in pediatric patients with MMA. This is an important milestone for patients, their families, our company and for the genetic medicines space more broadly as we believe this is the first Investigational New Drug application (IND) clearance for an *in vivo* gene editing program harnessing homologous recombination," said Fred Chereau, CEO of LogicBio. "We have maintained a steadfast commitment to execution and the IND clearance is the first of several near-term milestones we expect to reach in our determined efforts to leverage cutting-edge medicines to address high unmet medical needs. I look forward to sharing those updates as we advance our LB-001 program."

Daniel Gruskin, M.D., SVP, head of clinical development, commented, "The effects of MMA usually appear shortly after birth and can quickly become severe and life-threatening. Early intervention in this vulnerable population is critical to combat the manifestation of irreversible clinical disease pathologies including neurological damage. That's the reason MMA is on the newborn screening panel in the United States. Our protocol allows for the first cohort to enroll patients as young as three years old and, once certain safety parameters are met, we can age de-escalate to as young as six months old. Our goal is to provide a safe and durable therapeutic with a single administration at an age when we can make a difference for these patients."

SUNRISE – Phase 1/2 Clinical Trial of LB-001 in Pediatric Methylmalonic Acidemia (MMA)

The SUNRISE trial is a multi-center, open-label, Phase 1/2 clinical trial designed to assess the safety and tolerability of a single intravenous infusion of LB-001 in pediatric patients with MMA characterized by methylmalonyl-CoA mutase gene (*MMUT*) mutations. Six leading centers in the United States are expected to participate in the SUNRISE Phase 1/2 trial. The trial is expected to enroll eight pediatric patients with ages ranging from 6 months to 12 years, initially starting with 3 to 12 year-old patients and then adding patients aged 6 months to 2 years. The SUNRISE Phase 1/2 trial will evaluate two doses of LB-001. Patients will participate in a pre-dosing observational period and will be administered a prophylactic steroid regimen. The primary endpoint of the SUNRISE trial is to assess the safety and tolerability of LB-001 at 52 weeks after a single infusion. Additional endpoints include changes in disease-related biomarkers, including serum methylmalonic acid, clinical outcomes such as growth and healthcare utilization, and the pharmacodynamic marker albumin-2A. The Company expects to enroll the first patient in early 2021.

LB-001 Webcast and Conference Call Information

LogicBio will host a webcast and conference call on Monday, August 10, 2020 at 8:00 a.m. ET. The webcast will feature an overview of recently generated preclinical data using LB-001 and the planned clinical development plan for LB-001.

The event will be broadcast live and available under the investor relations section of LogicBio's website at https://investor.logicbio.com/. The dial-in details for the call are +1 833-519-1335 or +1 602-585-9978, Conference ID: 1151546. A replay of the webcast will be available on the LogicBio website for one month following the call.

About LogicBio Therapeutics

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