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 9, 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 2.02 Results of Operations and Financial Condition.

On August 9, 2021, LogicBio Therapeutics, Inc. (the "Company") announced financial results for the quarter ended June 30, 2021 and commented on certain corporate accomplishments and plans. A copy of the Company's press release containing this information is furnished as Exhibit 99.1 to this Current Report on Form 8-K ("Report") and is incorporated herein by reference.

The information in this Report (including Items 2.02 and Exhibit 99.1) 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 of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits*.

Exhibit No.	Description
99.1	Press Release, dated August 9, 2021, issued by LogicBio Therapeutics, Inc.
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: August 9, 2021

LOGICBIO THERAPEUTICS, INC.

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

Exhibit 99.1

LogicBio Therapeutics Reports Second Quarter 2021 Financial Results and Highlights Recent Company Milestones

– First patient dosed in Phase 1/2 SUNRISE trial of LB-001, an investigational in vivo gene editing therapy, in pediatric patients with methylmalonic acidemia (MMA) –

– Company on track to announce update on SUNRISE enrollment, including dose escalation and age de-escalation in late 2021 and interim data by year-end 2021 –

– Company entered into platform-validating collaborations with Daiichi Sankyo and CANbridge Pharmaceuticals

LEXINGTON, Mass., August 9, 2021 (GLOBE NEWSWIRE) — LogicBio Therapeutics, Inc. (Nasdaq:LOGC), a clinical-stage genetic medicine company pioneering gene editing and gene delivery platforms to address rare and serious diseases from infancy through adulthood, today reported financial results for the second quarter ended June 30, 2021 and highlighted recent corporate milestones.

"LogicBio made significant progress in the first half of the year. Most importantly, we dosed the first patient in our groundbreaking Phase 1/2 SUNRISE trial, which we believe represented the first *in vivo* gene editing therapy delivered systemically to a pediatric patient," said Frederic Chereau, president and chief executive officer of LogicBio Therapeutics. "We also entered into collaborations with Daiichi Sankyo and CANbridge Pharmaceuticals, which represented a validation of the potential of our GeneRide™ and sAAVy™ platforms. The second quarter also saw us strengthen our leadership team with key executive appointments. I am confident this progress positions us well to expand our platforms and pipeline. We continue to look forward to providing an update on SUNRISE enrollment, highlighting dose escalation and age de-escalation, expected later in the year, as well as interim data from the SUNRISE trial, expected by year-end."

Anticipated Milestones for 2021:

Ph 1/2 SUNRISE Trial for LB-001 in Pediatric Patients with MMA

- **Late 2021**: Provide update on enrollment, including dose escalation and age de-escalation
- **Year-end 2021**: Announce interim clinical data

Pipeline

- **Year-end 2021**: Nomination of next development candidate

Recent Business Highlights:

First patient dosed in Phase 1/2 SUNRISE clinical trial for LB-001 for the treatment of MMA in pediatric patients

- In June, LogicBio announced it dosed its first patient in its Phase 1/2 SUNRISE clinical trial for the treatment of pediatric patients with MMA. The SUNRISE trial is initially enrolling patients 3-12 years old and will potentially enroll infants as young as 6 months once the first two patients meet certain safety parameters and a biomarker indicating genome integration and protein expression is detected.

Entered into collaborations with Daiichi Sankyo and CANbridge Pharmaceuticals

- In April, LogicBio entered into a research collaboration with Daiichi Sankyo to develop treatments for two indications based on the Company's GeneRide platform.
- In April, LogicBio entered into a strategic collaboration and option agreement with CANbridge Pharmaceuticals (CANbridge) under which LogicBio granted CANbridge a license to certain intellectual property rights, including those relating to adeno-associated virus sL65 (sL65), the first capsid produced from LogicBio's sAAVy platform, for the development and commercialization of gene therapy candidates for the treatment of Fabry and Pompe diseases. LogicBio also granted CANbridge exclusive options to license certain intellectual property rights, including those relating to sL65, for the development and commercialization of gene therapy candidates for two additional indications, and to license LB-001 for the treatment of MMA in Greater China. In addition, under the terms of the agreement, LogicBio and CANbridge will collaborate to develop the gene therapy candidates for the treatment of Fabry and Pompe diseases and, upon CANbridge's exercise of the applicable options, two additional indications, under a mutually agreed research plan.

Preclinical data presented at ASGCT

- In May, the Company presented preclinical data that highlighted the significant potential of the Company's GeneRide and sAAVy platforms at the 24th Annual American Society of Gene and Cell Therapy (ASGCT) Virtual Meeting.

Strengthened leadership team with key appointments

- In May, LogicBio announced the following appointments to its leadership team: Daniel Gruskin, M.D., as chief medical officer, Andrea Paul, as general counsel and corporate secretary, Janice Olson, as senior vice president of portfolio strategy and management, Stephen Boyer, Ph.D., as vice president of regulatory and quality affairs, and Peter Pechan, Ph.D., as vice president of gene therapy.

Second Quarter 2021 Financial Results:

- **Revenue**: Revenue for the three months ended June 30, 2021 was $0.8 million, compared to $1.0 million for the three months ended June 30, 2020. The decrease in revenue during the three months ended June 30, 2021 compared to the corresponding period in 2020 was related to winding down activities under the January 2020 Takeda agreement, which was partially offset by revenue recognized under the April 2021 CANbridge and Daiichi Sankyo agreements.

- **R&D Expenses**: Research and development expenses for the three months ended June 30, 2021 were $7.3 million, compared to $5.9 million for the three months ended June 30, 2020. The increase of approximately $1.4 million was primarily due to an increase of $0.8 million in personnel-related costs as the Company increased its headcount as well as an increase of $1.2 million in other research and development costs, primarily driven by intellectual property licensing obligations due to certain of the Company's licensors. These increases were partially offset by a decrease of $0.6 million in LB-001 external development and manufacturing costs.
- **G&A Expenses**: General and administrative expenses were $3.8 million for the three months ended June 30, 2021, compared to $3.0 million for the three months ended June 30, 2020. The increase of approximately $0.7 million was primarily driven by an increase of $0.4 million in personnel expenses, including a $0.1 million increase in stock-based compensation expense as the Company increased its headcount.
- **Net Loss**: Net loss for the three months ended June 30, 2021 was $10.5 million or $0.33 per share, compared to a net loss of $8.2 million, or $0.35 per share, for the three months ended June 30, 2020.
- **Cash Position**: As of June 30, 2021, LogicBio had cash and cash equivalents of $68.1 million as compared to $63.9 million as of March 31, 2021. The increase was driven by the upfront payments received as part of the collaborations with CANbridge and Daiichi Sankyo, and partially offset by cash used in operating activities during the quarter. As of June 30, 2021, LogicBio had 32,222,366 shares outstanding.
- **Financial Guidance**: The Company expects its cash and cash equivalents to fund its current operating plan for at least the next twelve months from the date of this press release.

About the SUNRISE Trial

The SUNRISE trial is an open-label, multi-center, Phase 1/2 clinical trial designed to assess the safety and tolerability of a single intravenous infusion of LB-001 in pediatric patients with methylmalonic acidemia (MMA) characterized by methylmalonyl-CoA mutase gene (MMUT) mutations. On June 2, 2021, the Company announced that the first patient was dosed. 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, before irreversible damage has occurred, the SUNRISE trial is initially enrolling 3-12 year old patients with the potential to include infants as young as 6 months old after meeting certain safety parameters and biomarker detection indicating genome integration and protein expression. The SUNRISE trial will enroll up to eight patients and evaluate a single administration of LB-001 at two dose levels.

About LB-001

LB-001 is an investigational, first-in-class, single-administration, gene editing therapy for early intervention in methylmalonic acidemia (MMA) using the GeneRide™ 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 exogenous promoters that are 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 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 cause permanent neurocognitive damage. Because of the need for early intervention, newborns are screened for MMA in every state in the United States.

About LogicBio Therapeutics

LogicBio Therapeutics is a clinical-stage genetic medicine company pioneering gene editing and gene delivery platforms to address rare and serious diseases from infancy through adulthood. The Company's gene 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.

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 dosing representing the first in vivo gene editing therapy delivered systemically to a pediatric patient; the expected timing of providing an update on enrollment, dose escalation and age de-escalation in the SUNRISE trial; the expected timing of announcing interim clinical data in the SUNRISE trial; being well-positioned to continue to expand our platforms and pipeline; our anticipated milestones and the timing thereof; enrolling patients as young as 6 months old in the SUNRISE trial; the potential benefits of LB-001; and the sites expected to participate in the SUNRISE trial. The terms "anticipate," "believe," "confident," "expect," "look forward," "on track," "positions us," "potential," "will" 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 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; the risk that existing preclinical data may not be predictive of the results of ongoing or later clinical trials; the risks that clinical trials may not be successful or may be discontinued or delayed for any reason; manufacturing and process development risks, including delays relating to continuously improving our manufacturing processes; 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 Annual Report on Form 10-K for the year ended December 31, 2020 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
REVENUE				
Collaboration and service revenue	$ 802	$ 965	$ 1,263	$ 1,986
Total revenue	802	965	1,263	1,986
OPERATING EXPENSES				
Research and development	7,257	5,895	13,676	13,068
General and administrative	3,765	3,029	7,824	6,221
Total operating expenses	11,022	8,924	21,500	19,289
LOSS FROM OPERATIONS	(10,220)	(7,959)	(20,237)	(17,303)
OTHER INCOME (EXPENSE):				
Interest income	4	10	10	177
Interest expense	(283)	(273)	(554)	(545)
Other expense, net	—	(5)	—	(11)
Total other expense, net	(279)	(268)	(544)	(379)
Loss before income taxes	(10,499)	(8,227)	(20,781)	(17,682)
Income tax provision	—	—	—	—
Net loss	$ (10,499)	$ (8,227)	$ (20,781)	$ (17,682)
Net loss per share—basic and diluted	$ (0.33)	$ (0.35)	$ (0.65)	$ (0.76)
Weighted-average common stock outstanding—basic and diluted	32,162,375	23,326,018	32,048,716	23,250,910

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

	As of	
	June 30, 2021	December 31, 2020
Cash and cash equivalents	$68,108	$ 70,075
Other assets	9,767	10,565
TOTAL ASSETS	$77,875	$ 80,640
Accounts payable, accrued expenses and other liabilities	33,055	19,213
Stockholders' equity	44,820	61,427
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$77,875	$ 80,640

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