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): May 16, 2022

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)**

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

n/a
(Former name, former address and formal fiscal year, 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 May 16, 2022, LogicBio Therapeutics, Inc. (the "Company") announced financial results for the quarter ended March 31, 2022 and commented on certain corporate highlights 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 Item 2.02 and Exhibit 99.1) 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"), 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.	Exhibit Description
99.1	Press Release issued by LogicBio Therapeutics, Inc. on May 16, 2022.
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: May 16, 2022

LOGICBIO THERAPEUTICS, INC.

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

LogicBio Therapeutics Reports First Quarter 2022 Financial Results and Highlights Recent Business Updates

– FDA lifted clinical hold on SUNRISE trial in pediatric patients with methylmalonic acidemia

–Interim clinical data from Phase 1/2 trial expected to be presented by end of second quarter 2022

–LogicBio to present at ASGCT 2022 Annual Meeting

LEXINGTON, Mass., May 16, 2022 — LogicBio® Therapeutics, Inc. (Nasdaq: LOGC), a clinical-stage company advancing a diversified pipeline of genetic medicines addressing rare disorders from infancy through adulthood, today reported financial results for the quarter ended March 31, 2022, and highlighted recent business updates.

"Earlier this month, we were pleased to announce that the FDA lifted the clinical hold on our LB-001 IND, allowing us to resume dosing of our SUNRISE trial," said Frederic Chereau, president and chief executive officer of LogicBio. "We are also excited to see the progression of our GeneRide® platform as well as advancements from our CMC team, including our proprietary mAAVRx™ system, which is a transfection process optimized to improve manufacturing yields and product quality. Finally, we continue to progress well with our Daiichi Sankyo and CANbridge collaborations."

Recent Business Highlights:

- In May, LogicBio announced that the U.S. Food and Drug Administration (FDA) lifted the clinical hold on the company's LB-001 Investigational New Drug Application (IND), allowing patient dosing to resume in the Phase 1/2 SUNRISE trial in pediatric patients with methylmalonic acidemia. The company expects to dose the next patient in the SUNRISE trial in the third quarter of 2022. Following the lifting of the clinical hold, the company announced that it reinstated its previous guidance and expects to present interim clinical data from the SUNRISE trial by the end of the second quarter of 2022.
- In May, LogicBio announced that it will present at the American Society of Gene & Cell Therapy (ASGCT) 2022 Annual Meeting, to be held May 16-19, 2022. The two oral and two poster presentations highlight the company's GeneRide technology in preclinical hereditary tyrosinemia type 1 models and optimized adeno-associated virus manufacturing processes.

First Quarter 2022 Financial Results:

Three Months Ended March 31, 2022 and 2021

- **Revenue:** Revenue for the quarter ended March 31, 2022 consisted of $2.8 million in collaboration and service revenue recognized under our April 2021 agreements with CANbridge Care Pharma Hong Kong Limited (CANbridge) and Daiichi Sankyo Company, Limited (Daiichi Sankyo). Revenue for the quarter ended March 31, 2021 was $0.5 million consisting solely of service revenue recognized under our January 2020 agreement with Takeda Pharmaceutical Company Limited (Takeda). The agreement with Takeda expired by its own terms in the year ended December 31, 2021.
- **R&D Expenses:** Research and development expenses for the quarter ended March 31, 2022 were $5.6 million, compared to $6.4 million for the quarter ended March 31, 2021. The decrease of approximately $0.8 million was primarily due to a decrease of $0.9 million related to LB-001 external development and manufacturing costs incurred during first quarter 2021 to start up the LB-001 SUNRISE clinical trial and manufacture appropriate clinical supply that did not re-occur during the first quarter of 2022.
- **G&A Expenses:** General and administrative expenses were $3.6 million for the quarter ended March 31, 2022, compared to $4.1 million for the quarter ended March 31, 2021. The decrease of approximately $0.4 million was primarily driven by a decrease of approximately $0.6 million in professional service fees as we brought more professional work in-house through key hires made during 2021. As such, personnel expenses increased approximately $0.3 million as we filled key open positions within the human resources, legal and business development functions.
- **Net Loss:** Net loss for the quarter ended March 31, 2022 was $6.7 million or $0.20 per share, compared to a net loss of $10.3 million, or $0.32 per share, for the quarter ended March 31, 2021.
- **Cash Position:** As of March 31, 2022, we had cash and cash equivalents of $42.7 million as compared to $53.5 million as of December 31, 2021. As of March 31, 2022, we had 32,962,733 shares outstanding.
- **Financial Guidance:** Based upon our current operating plan, we believe that our $42.7 million in cash and cash equivalents as of March 31, 2022 will enable us to fund our operating expenses and capital expenditure requirements through the first quarter of 2023.

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's proprietary system, mAAVRx™, aims to overcome one of the current limitations of AAV manufacturing by optimizing the transfection process to improve yields and product quality. 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. With the aim of evaluating LB-001 at an early age, the SUNRISE trial is designed to enroll 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) with dose escalation subject to certain conditions.

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.

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 resumption of dosing in LogicBio's SUNRISE clinical trial and timing thereof; the improvement of manufacturing yields and product quality; our expectations to continue enrollment and dosing of clinical trial subjects; our expectations on the continuation of our current collaborations; the potential of the GeneRide® platform; and the anticipated timing of announcing interim clinical data. The terms "anticipate," "progress," "expects to," "designed," "evaluate," "aim," "enables," "continue," "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 we will need to obtain the approval of each clinical trial site's institutional review board prior to resuming enrollment of our SUNRISE trial; we may encounter difficulties enrolling patients; we may encounter difficulties or delays with respect to our collaborations; 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 most recently filed periodic reports on Form 10-K and Form 10-Q and subsequent filings 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.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2022	2021
REVENUE		
Collaboration and service revenue	$ 2,816	$ 461
Total revenue	2,816	461
OPERATING EXPENSES		
Research and development	5,641	6,419
General and administrative	3,624	4,059
Total operating expenses	9,265	10,478
LOSS FROM OPERATIONS	(6,449)	(10,017)
OTHER INCOME (EXPENSE):		
Interest income	5	6
Interest expense	(218)	(271)
Total other expense, net	(213)	(265)
Net loss	$ (6,662)	$ (10,282)
Net loss per share—basic and diluted	$ (0.20)	$ (0.32)
Weighted-average common stock outstanding—basic and diluted	32,961,180	31,933,794

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

	As of	
	March 31, 2022 (Unaudited)	December 31, 2021
Cash and cash equivalents	$ 42,739	$ 53,480
Other assets	9,160	9,290
TOTAL ASSETS	$ 51,899	$ 62,770
Accounts payable, accrued expenses and other liabilities	$ 26,988	$ 32,043
Stockholders' equity	24,911	30,727
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 51,899	$ 62,770

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