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): March 4, 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 March 4, 2022, LogicBio Therapeutics, Inc. (the "Company") announced financial results for the year ended December 31, 2021 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 March 4, 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: March 4, 2022

LOGICBIO THERAPEUTICS, INC.

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

Exhibit 99.1

LogicBio Therapeutics Reports Full Year 2021 Financial Results and Provides Business Updates

LEXINGTON, Mass., March 4, 2022 — LogicBio® Therapeutics, Inc. (Nasdaq: LOGC), a clinical-stage genetic medicine company, today reported financial results for the year ended December 31, 2021, and provided business updates.

“At LogicBio, we are continuing to advance our mission to safely deliver novel genetic medicines to people impacted by devastating, early onset diseases,” said Frederic Chereau, president and chief executive officer of LogicBio. “We are pleased to report that the serious adverse event experienced by the fourth patient enrolled in our Phase 1/2 SUNRISE trial of LB-001 in pediatric patients with methylmalonic acidemia has resolved.”

Recent Business Updates:

- In January 2022, the fourth patient dosed in the Phase 1/2 SUNRISE trial experienced a drug-related serious adverse event (SAE), which was categorized as a case of thrombotic microangiopathy. The company announced today that the SAE has resolved. As previously disclosed, after reporting the SAE to the U.S. Food and Drug Administration (FDA), the Investigational New Drug Application for LB-001 was placed on clinical hold. The company is working closely with the FDA and the Data Safety Monitoring Board for SUNRISE to determine the next steps for SUNRISE and the LB-001 program.
- In December 2021, LogicBio announced the nomination of a new development candidate, LB-401, based on the company’s GeneRide™ genome editing platform, for the treatment of hereditary tyrosinemia type 1 (HT1). Preclinical studies of HT1 models with acute liver damage demonstrated that GeneRide-edited hepatocytes repopulated the entire liver within four weeks post-administration, replacing diseased hepatocytes with corrected hepatocytes.
- In December 2021, LogicBio announced the appointment of Susan R. Kahn to its Board of Directors. Ms. Kahn was previously 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.
- In October 2021, LogicBio announced clinical trial results from the company’s Phase 1/2 SUNRISE clinical trial of its product candidate, LB-001, in pediatric patients with methylmalonic acidemia demonstrating the first-ever *in vivo* genome editing in children. Early data showed measurable levels of albumin-2A, a technology-related biomarker indicating site-specific gene insertion and protein expression.

- In October 2021, the company presented new preclinical data highlighting its GeneRide genome editing technology at the European Society of Gene and Cell Therapy Virtual Congress 2021. The data highlighted selective advantage, a key feature of the GeneRide technology, in HT1 and Wilson disease.

Full Year 2021 Financial Results:

- **Revenue:** Revenue for the year ended December 31, 2021 was $5.4 million, compared to $3.5 million for the year ended December 31, 2020. The increase of approximately $1.9 million was related to collaboration and service revenue recognized under our April 2021 agreements with CANbridge Care Pharma Hong Kong Limited and Daiichi Sankyo Company, Limited, and partially offset by winding down activities under our January 2020 agreement with Takeda Pharmaceutical Company Limited.
- **R&D Expenses:** Research and development expenses for the year ended December 31, 2021 were $28.2 million, compared to $22.8 million for the year ended December 31, 2020. The increase of approximately $5.4 million was primarily due to increases of $3.8 million in personnel-related costs related to an increase in headcount associated with the progress of both our partnered and internal programs and a corresponding increase of $0.8 million in lab supplies.
- **G&A Expenses:** General and administrative expenses were $16.2 million for the year ended December 31, 2021, compared to $12.2 million for the year ended December 31, 2020. The increase of approximately $4.0 million was primarily driven by an increase of $2.1 million in personnel expenses, as we increased our headcount to support our continued research and development activities and build our corporate and administrative functions, as well as an increase of $1.3 million in fees associated with professional services due to an increase in corporate development and general corporate activities.
- **Net Loss:** Net loss for the year ended December 31, 2021 was $40.0 million or $1.24 per share, compared to a net loss of $32.6 million, or $1.29 per share, for the year ended December 31, 2020.
- **Cash Position:** As of December 31, 2021, we had cash and cash equivalents of $53.5 million as compared to $59.6 million as of September 30, 2021. As of December 31, 2021, we had 32,952,306 shares outstanding.
- **Financial Guidance:** Based upon our current operating plan, we believe that our $53.5 million in cash and cash equivalents as of December 31, 2021 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 is based in Lexington, MA. For more information, visit www.logicbio.com, which does not form a part of this release.

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 the potential of the GeneRide™ platform, its potential to lead to durable therapeutic protein expression levels, and our ability to

advance our mission to safely deliver novel genetic medicines. The terms “anticipate,” “continue to,” “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 may not be able to successfully and favorably resolved the current clinical hold on the Investigational New Drug Application of LB-001; existing preclinical data may not be predictive of the results of ongoing or later preclinical and/or clinical results; interim and preliminary data from our clinical trials may not be predictive of future results; 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; and the actual time it takes to initiate and complete preclinical and clinical studies. 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 filed with the U.S. Securities and Exchange Commission and other filings that LogicBio may make 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)

	Year Ended December 31,	
	2021	2020
REVENUE		
Collaboration and service revenue	$ 5,410	$ 3,454
Total revenue	5,410	3,454
OPERATING EXPENSES		
Research and development	28,169	22,753
General and administrative	16,226	12,212
Total operating expenses	44,395	34,965
LOSS FROM OPERATIONS	(38,985)	(31,511)
OTHER INCOME (EXPENSE), NET:		
Interest income	16	181
Interest expense	(1,070)	(1,098)
Other expense, net	(18)	(5)
Total other expense, net	(1,072)	(922)
Loss before income taxes	(40,057)	(32,433)
Income tax benefit (provision)	28	(188)
Net loss	$ (40,029)	$ (32,621)
Net loss per share—basic and diluted	$ (1.24)	$ (1.29)
Weighted-average common stock outstanding—basic and diluted	32,375,513	25,364,453

LogicBio Therapeutics, Inc.

Condensed Consolidated Balance Sheets

(In thousands)

	As of	
	December 31, 2021	**December 31, 2020**
Cash and cash equivalents	$ 53,480	$ 70,075
Other assets	9,290	10,565
TOTAL ASSETS	$ 62,770	$ 80,640
Accounts payable, accrued expenses and other liabilities	$ 32,043	$ 19,213
Stockholders' equity	30,727	61,427
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 62,770	$ 80,640

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