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): November 15, 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)**

(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 November 15, 2021, LogicBio Therapeutics, Inc. (the "Company") announced financial results for the quarter ended September 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) 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 November 15, 2021.
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: November 15, 2021

LOGICBIO THERAPEUTICS, INC.

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

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

– Early clinical results from SUNRISE trial demonstrated first-ever in vivo *genome editing in children*

– New preclinical data highlighting successful repopulation of diseased livers in mice with healthy corrected hepatocytes in two new indications

LEXINGTON, Mass., November 15, 2021 (GLOBE NEWSWIRE) — LogicBio Therapeutics, Inc. (Nasdaq:LOGC), a clinical-stage genetic medicine company, today reported financial results for the third quarter ended September 30, 2021 and highlighted recent corporate milestones.

"The recent progress we have made provides further validation of the potential of our GeneRide™ technology and brings us closer to delivering the hope of genetic medicine to people impacted by devastating diseases," said Frederic Chereau, president and chief executive officer of LogicBio Therapeutics. "We remain on track to provide interim data from our Phase 1/2 SUNRISE clinical trial in pediatric patients with methylmalonic acidemia by the end of the year. Additionally, the compelling preclinical data we recently presented at ESGCT showcase the potential applicability of our GeneRide technology in additional indications. We look forward to nominating our next development candidate by year-end."

Anticipated Upcoming Milestones:

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

- **Year-end 2021**: Announce interim clinical data

Pipeline

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

Recent Business Highlights

Announced early clinical trial results demonstrating first-ever* in vivo *genome editing in children

- In October, LogicBio announced clinical trial results demonstrating the first-ever *in vivo* genome editing in children. Early data from the company's Phase 1/2 SUNRISE clinical trial in pediatric patients with methylmalonic acidemia (MMA) showed measurable levels of albumin-2A, a technology-related biomarker indicating site-specific gene insertion and protein expression.

Preclinical data presented at ESGCT demonstrated successful repopulation of diseased livers in mice with healthy corrected hepatocytes in two new liver indications

- In October, the company presented new preclinical data highlighting GeneRide genome editing technology at the European Society of Gene and Cell Therapy (ESGCT) Virtual Congress 2021. The newly presented preclinical data further validated previous research in MMA and highlighted selective advantage, a key feature of the GeneRide technology, in two additional indications characterized by intrinsic liver damage, hereditary tyrosinemia type 1 (HT1) and Wilson disease.

Third Quarter 2021 Financial Results

- **Revenue**: Revenue for the three months ended September 30, 2021 was $2.1 million, compared to $0.9 million for the three months ended September 30, 2020. The increase of approximately $1.2 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 three months ended September 30, 2021 were $7.8 million, compared to $5.5 million for the three months ended September 30, 2020. The increase of approximately $2.3 million was primarily due to increases of $1.2 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 $0.4 million in lab supplies. In addition, LB-001 external development and manufacturing costs increased $0.5 million mainly driven by an increase in activities supporting the LB-001 development program.
- **G&A Expenses**: General and administrative expenses were $4.3 million for the three months ended September 30, 2021, compared to $3.2 million for the three months ended September 30, 2020. The increase of approximately $1.1 million was primarily driven by an increase of $0.4 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 $0.4 million in fees associated with professional services due to an increase in general corporate activities.
- **Net Loss**: Net loss for the three months ended September 30, 2021 was $10.2 million or $0.31 per share, compared to a net loss of $8.0 million, or $0.34 per share, for the three months ended September 30, 2020.
- **Cash Position**: As of September 30, 2021, we had cash and cash equivalents of $59.6 million as compared to $68.1 million as of June 30, 2021. As of September 30, 2021, we had 32,945,616 shares outstanding.
- **Financial Guidance**: Based upon our current operating plan, we believe that our $59.6 million in cash and cash equivalents as of September 30, 2021 will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2022.

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. 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, the SUNRISE trial is designed to enroll up to eight 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).

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 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.

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 validation of previous research; the potential of the GeneRide™ platform; and the anticipated timing of announcing interim clinical data and the company's next development candidate. The terms "anticipate," "look forward," "on track," "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 existing preclinical data may not be predictive of the results of ongoing or later preclinical and/or clinical 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; 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.

Investor Contacts:

Laurence Watts
Gilmartin Group
(619) 916-7620
laurence@gilmartinir.com

Stephen Jasper
Gilmartin Group
(858) 525-2047
stephen@gilmartinir.com

Media Contacts:

Adam Daley
Berry & Company Public Relations
W:212-253-8881
C: 614-580-2048
adaley@berrypr.com