UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16
of the Securities Exchange Act of 1934

Date of Report: October 18, 2021

Commission File Number: 001-39307

Legend Biotech Corporation
(Exact Name of Registrant as Specified in its Charter)

2101 Cottontail Lane
Somerset, New Jersey 08873
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

This report on Form 6-K shall be deemed to be incorporated by reference in the registration statements of Legend Biotech Corporation ("Legend Biotech") on Form F-3 (Nos. 333-257609 and 333-257625) and Form S-8 (No. 333-239478), to the extent not superseded by documents or reports subsequently filed.

Legend Biotech Provides Updates at R&D Day

Legend Biotech will present preliminary preclinical and clinical data for a range of investigational agents at its Research and Development Day (R&D Day) on October 18, 2021.

LB1908

LB1908 is an investigational autologous chimeric antigen receptor T cell (CAR-T) immunotherapy designed to eradicate tumor cells expressing Claudin18.2 (CLDN18.2), which is a tight junction protein commonly expressed on multiple cancers, including gastric cancer and pancreatic cancer.

Preclinical data for LB1908

Legend Biotech will present pre-clinical data from its LB1908 program for the treatment of advanced gastric and pancreatic cancers. Preclinical studies have shown that the antigen-binding domain of the LB1908 CAR binds to CLDN18.2 specifically with high affinity. The antitumor effects of LB1908 are target-specific in both *in vitro* and *in vivo* mouse models of human tumor xenografts. LB1908 demonstrated cytotoxicity only to cells expressing CLDN18.2, but not to human primary cells or cells expressing Claudin18.1, which is expressed in normal lung cells.

In the preclinical studies, LB1908 showed significant anti-tumor efficacy in a cell line-derived xenograft, or CDX, gastric tumor mouse model, as well as in a CDX pancreatic tumor mouse model.

Preliminary clinical data for LB1908

Legend Biotech is evaluating LB1908 in China in a Phase 1 investigator-initiated trial (IIT) (NCT04467853) assessing its safety and pharmacokinetics profile and obtaining preliminary efficacy in adult patients with advanced gastric cancer. Enrollment of this Phase 1 IIT study is ongoing.

Four patients were dosed at levels ranging from 0.5×10^6 to 3×10^6 CAR-positive viable T-cells/kg. Three patients completed the DLT observation, and no dose-limiting toxicities (DLTs) have been observed to date. The first patient has reached time point for evaluation and remained progression-free at Day 180. The preliminary efficacy data shows the anti-tumor activities of LB1908.

Legend Biotech is also pursuing submission of a US Investigational New Drug (IND) for LB1908, which is planned for H1 2022.

LB2102 SCLC target disclosed

During the R&D Day, Legend Biotech will disclose delta-like ligand 3 (DLL3) as the target of its LB2102 small cell lung cancer (SCLC) program. LB2102 is an investigational autologous CAR-T immunotherapy designed to treat adult patients with SCLC by targeting DLL3, a cell surface protein that is highly expressed in SCLC.

LB2102 is a biparatopic CAR "armored" to resist immune suppression. At the discovery stage, the LB2102 CAR demonstrated strong and specific binding to its intended target protein DLL3, with no off-target binding. Both *in vitro* and *in vivo* studies have shown robust tumoricidal effects of LB2102 in a target-dependent manner with no off-target cytotoxicity.

LB2101 HCC and NSCLC target disclosed

During the R&D Day, Legend Biotech will disclose Glypican-3 (GPC3) as the target of its LB2101 hepatocellular carcinoma (HCC) and non-small cell lung cancer (NSCLC) program. LB2101 is an investigational autologous CAR-T immunotherapy designed to treat adult patients with HCC and NSCLC by targeting GPC3, a cell surface glycoprotein that is highly expressed in HCC and NSCLC.

LB2101 is "armored" to resist immune suppression. At the discovery stage, the LB2101 CAR demonstrated strong and specific binding to its intended target protein GPC3, with no off-target binding. Both *in vitro* and *in vivo* studies have shown robust tumoricidal effects of LB2101 in a target-dependent manner with no off-target cytotoxicity.

Allogeneic CAR-T product candidate development

Legend Biotech has developed a proprietary allogeneic CAR-T technology using a non-gene-editing approach, which reduces risks of off-target activities and genotoxicity. Legend Biotech also believes that this approach to the design of allogeneic programs potentially simplifies the process for chemistry, manufacturing and controls (CMC) and improves product homogeneity. Based on this approach, Legend Biotech has developed allogeneic CAR-T, LUCAR-20S, targeting CD20. LUCAR-20S utilizes a co-expression of gene X to disrupt cell surface presentation and activity of the endogenous T-cell receptor (TCR) complex and evade immune surveillance and inhibit graft versus host disease (GvHD).

A Phase 1 study (NCT04176913) was initiated for LUCAR-20S. It is an open label, dose escalation/dose-regimen-finding study to assess the safety and pharmacokinetics of donor-derived CD20-directed CAR-T cells administered with lymphodepletion, and to obtain the preliminary efficacy in subjects who have been diagnosed with relapsed or refractory CD20 positive diffuse large B-cell lymphoma, follicular lymphoma, mantle cell lymphoma or small lymphocytic lymphoma.

Enrollment in the Phase 1 study in China is ongoing. Five subjects were dosed at levels from 10×10^6 to 300×10^6 CAR-T cells, and no DLTs or evidence of GvHD have been observed to date. The preliminary data shows antitumor activities following the infusion of LUCAR-20S.

Legend has developed a modified version (LUCAR-20SD) with an innovative armoring strategy to control host-versus-graft disease (HvG) to further improve the CAR-T persistence. An exploratory trial is being planned.

Allogeneic CAR-NK program

Legend Biotech will present its in-house chimeric antigen receptor (CAR) natural killer (NK) cell therapy platform. NK cells play a pivotal role as the body's first line of defense against virally infected cells or tumor cells. Unlike CAR-T cells, CAR-NK cells do not need priming and have a number of mechanisms to elicit responses to tumors that are not limited to direct releases of cytotoxic granules, antibody dependent cellular cytotoxicity (ADCC), CAR-mediated killing and secretion of inflammatory cytokines. NK cells can naturally recognize features only presented on tumor cells, facilitating tumor-specific elimination. NK cells engineered to express CARs can further enhance their antitumor effects.

Legend will present preliminary preclinical data demonstrating:

- Legend will present preclinical safety and efficacy data of CAR-NK cells armored with in-house engineered cytokine (LGkine).

- Legend Biotech has developed a robust NK manufacture process with the following features: robust expansion and CAR transduction process; production of highly pure CAR-NK product with strong anti-tumor activity; optimized cryopreservation process to minimize the loss of viability and functionality after thawing.

Cautionary Note Regarding Forward-Looking Statements

Statements in this report about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, constitute “forward-looking statements” within the meaning of The Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements relating to Legend Biotech’s overall strategies and objectives; Legend Biotech’s ability to achieve milestones under its collaboration with Janssen Biotech; Legend Biotech’s strategy and plans for the development, manufacturing and commercialization of ciltacabtagene autoleucel (cilta-cel), including anticipated regulatory milestones; the preclinical and clinical development strategy for product candidates and the anticipated timing of key regulatory and clinical milestones for such product candidates; the potential benefits afforded by investigational candidates; and the opportunities presented by preclinical data. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors. Legend Biotech’s expectations could be affected by, among other things, uncertainties involved in the development, manufacturing and commercialization of new pharmaceutical products; unexpected or inconsistent preclinical data; unexpected clinical trial results, including as a result of additional analysis of existing clinical data or unexpected new clinical data; unexpected regulatory actions or delays, including requests for additional safety and/or efficacy data or analysis of data, or government regulation generally; unexpected delays as a result of actions undertaken, or failures to act, by our third party partners; uncertainties arising from challenges to Legend Biotech’s patent or other proprietary intellectual property protection, including the uncertainties involved in the US litigation process; competition in general; government, industry, and general public pricing and other political pressures; the duration and severity of the COVID-19 pandemic and governmental and regulatory measures implemented in response to the evolving situation; as well as the other factors discussed in the “Risk Factors” section of the Company’s Annual Report on Form 20-F filed with the Securities and Exchange Commission on April 2, 2021. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in this report as anticipated, believed, estimated or expected. Legend Biotech specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise. In addition, caution should be exercised when interpreting results relating to a small number of patients or individually presented case studies.

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, thereunto duly authorized.

LEGEND BIOTECH CORPORATION
(Registrant)

October 18, 2021

By: /s/ Ying Huang
Ying Huang, Ph.D.
Chief Executive Officer and Chief Financial Officer