
**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**

For the Month of December 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):

Press Release Dated December 14, 2021

On December 14, 2021, Legend Biotech Corporation (the “Company”) issued a press release announcing a proposed underwritten public offering of \$300.0 million of American Depositary Shares (“ADSs”), each representing two ordinary shares, and up to an additional \$45.0 million of ADSs sold in the public offering to the underwriters pursuant to an option to purchase additional ADSs (the “Offering”). The Company is filing a copy of the press release relating to the Offering as Exhibit 99.1 hereto, which is incorporated by reference herein.

The press release was issued pursuant to, and in accordance with, Rule 134 under the Securities Act of 1933, as amended, and is neither an offer to sell nor a solicitation of an offer to buy the ordinary shares, ADSs or any other securities and shall not constitute an offer to sell or a solicitation of an offer to buy, or a sale of, the ordinary shares, ADSs or any other securities in any jurisdiction in which such offer, solicitation or sale is unlawful.

Financial Results for the Nine Months Ended September 30, 2021

The Company is furnishing this report on Form 6-K to provide its unaudited consolidated financial statements for the nine months ended September 30, 2021 and 2020 and to provide Management’s Discussion and Analysis of Financial Condition and Results of Operations with respect to such financial statements.

The unaudited condensed consolidated financial statements as of September 30, 2021 and for the nine-months ended September 30, 2021 and 2020 are attached to this Form 6-K as Exhibit 99.2. Management’s Discussion and Analysis of Financial Condition and Results of Operations is attached to this Form 6-K as Exhibit 99.3. The Company is also updating certain of its Risk Factors that were previously included in Item 3.D of its Annual Report on Form 20-F, which updated Risk Factors are attached to this Form 6-K as Exhibit 99.4.

This report on Form 6-K is hereby incorporated by reference into the Company’s Registration Statements on Form F-3 (Registration Nos. 333-257625 and 333-257609) and the Company’s Registration Statement on Form S-8 (Registration No. 333-239478).

EXHIBIT INDEX

<u>Exhibit</u>	<u>Title</u>
99.1	Press Release dated December 14, 2021
99.2	Unaudited Interim Condensed Consolidated Financial Statements as of September 30, 2021 and for the nine months ended September 30, 2021 and 2020.
99.3	Management’s Discussion and Analysis of Financial Condition and Results of Operations.
99.4	Select Updated Risk Factors.

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)

December 14, 2021

By: /s/ Ying Huang

Ying Huang, Ph.D.

Chief Executive Officer and Chief Financial Officer

Legend Biotech Corporation Announces Proposed Public Offering

SOMERSET, NJ – December 14, 2021 – Legend Biotech Corporation (NASDAQ: LEGN) (“Legend Biotech”), a global clinical-stage biopharmaceutical company engaged in the discovery and development of novel cell therapies for oncology and other indications, today announced that it intends to offer and sell \$300.0 million of American Depositary Shares (“ADSs”), each representing two ordinary shares, in an underwritten public offering. All ADSs to be sold in the proposed offering will be offered by Legend Biotech. Legend Biotech also intends to grant the underwriters a 30-day option to purchase up to an additional \$45.0 million of ADSs sold in the public offering at the public offering price, less underwriting discounts and commissions. The offering is subject to market conditions, and there can be no assurance as to whether or when the offering may be completed or the actual size or terms of the offering.

Morgan Stanley, J.P. Morgan, Jefferies, Piper Sandler & Co. and Barclays are serving as joint book-running managers for the offering. BTIG is serving as a co-manager for the offering.

The ADSs are being offered by Legend Biotech pursuant to an effective shelf registration statement that was previously filed with the Securities and Exchange Commission (“SEC”). The offering is being made only by means of a written prospectus and prospectus supplement that form a part of the registration statement. A preliminary prospectus supplement relating to and describing the terms of the offering will be filed with the SEC and will be available on the SEC’s website at www.sec.gov. A copy of the preliminary prospectus supplement can be obtained, when available, from Morgan Stanley & Co. LLC, 180 Varick Street, New York, NY 10014, Attention: Prospectus Department, or by telephone at (866) 718-1649; J.P. Morgan Securities LLC, c/o Broadridge Financial Solutions, 1155 Long Island Avenue, Edgewood, NY 11717, by telephone at 866-803-9204 or by email at prospectus-eq_fi@jpmorganchase.com; Jefferies LLC, Attention: Equity Syndicate Prospectus Department, 520 Madison Avenue, 2nd Floor, New York, NY 10022, by email at prospectus_department@jefferies.com or by phone at (877) 821-7388; Piper Sandler & Co., Attention: Prospectus Department, 800 Nicollet Mall, J12S03, Minneapolis, MN 55402, or by email at prospectus@psc.com or by telephone at 1-800-747-3924; or Barclays Capital Inc., c/o Broadridge Financial Solutions, 1155 Long Island Avenue, Edgewood, NY 11717 or by email at barclaysprospectus@broadridge.com or by telephone at (888) 603-5847.

This press release does not constitute an offer to sell or the solicitation of an offer to buy securities, and shall not constitute an offer, solicitation or sale in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of that jurisdiction.

About Legend Biotech

Legend Biotech is a global, clinical-stage biotechnology company dedicated to treating, and one day curing, life-threatening diseases. Headquartered in Somerset, New Jersey, we are developing advanced cell therapies across a diverse array of technology platforms, including autologous and allogenic chimeric antigen receptor T-cell, T-cell receptor (TCR-T), and natural killer (NK) cell-based immunotherapy. From our three R&D sites around the world, we apply these innovative technologies to pursue the discovery of safe, efficacious and cutting-edge therapeutics for patients worldwide.

We are currently engaged in a strategic collaboration to develop and commercialize our lead product candidate, ciltacabtagene autoleucel (cilta-cel), an investigational BCMA-targeted CAR-T cell therapy for patients living with multiple myeloma. Applications seeking approval of cilta-cel for the treatment of patients with relapsed or refractory multiple myeloma (RRMM) are currently under regulatory review by several health authorities around the world, including the U.S. Food and Drug Administration and the European Medicines Agency.

Cautionary Note Regarding Forward-Looking Statements

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may 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 the proposed public offering. 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, including: the uncertainties related to market conditions and the completion of the proposed public offering on the anticipated terms or at all, and other factors discussed in the “Risk Factors” section of Legend Biotech’s Annual Report on Form 20-F for the year ended December 31, 2020 filed with the SEC, as well as in Legend Biotech’s other filings with the SEC. Any forward-looking statements contained in this press release speak only as of the date hereof, and Legend Biotech specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise. Readers should not rely upon the information on this page as current or accurate after its publication date.

Investor Contacts:

Joanne Choi, Senior Manager of Investor Relations and Corporate Communications, Legend Biotech

joanne.choi@legendbiotech.com

Crystal Chen, Manager of Investor Relations and Corporate Communications, Legend Biotech

crystal.chen@legendbiotech.com

Press Contact:

Tina Carter, Corporate Communications Lead, Legend Biotech

tina.carter@legendbiotech.com or media@legendbiotech.com

LEGEND BIOTECH CORPORATION
UNAUDITED INTERIM CONDENSED CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE
INCOME FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2021 AND 2020

	Notes	Nine months ended September 30,	
		2021 (Unaudited)	2020 (Unaudited)
(US\$ in thousands, except per share data)			
REVENUE	4	50,797	34,893
Other income and gains	4	2,316	5,315
Research and development expenses		(226,843)	(165,226)
Administrative expenses		(29,797)	(13,976)
Selling and distribution expenses		(49,731)	(25,389)
Other expenses		(6,918)	(1,331)
Fair value loss of warrant liability	15	(37,400)	—
Fair value loss of convertible redeemable preferred shares	14	—	(79,984)
Finance costs		(298)	(4,169)
LOSS BEFORE TAX	5	(297,874)	(249,867)
Income tax (expense)/credit	6	(1)	4,217
LOSS FOR THE PERIOD		<u>(297,875)</u>	<u>(245,650)</u>
Attributable to:			
Equity holders of the parent		<u>(297,875)</u>	<u>(245,650)</u>
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Ordinary shares—basic and diluted	7	<u>(1.07)</u>	<u>(1.08)</u>
OTHER COMPREHENSIVE INCOME			
Other comprehensive income that may be reclassified to profit or loss in subsequent periods:			
Exchange differences:			
Exchange differences on translation of foreign operations		6,129	(799)
Net other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods		6,129	(799)
OTHER COMPREHENSIVE INCOME/(LOSS) FOR THE PERIOD, NET OF TAX		6,129	(799)
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD		<u>(291,746)</u>	<u>(246,449)</u>
Attributable to:			
Equity holders of the parent		<u>(291,746)</u>	<u>(246,449)</u>

The accompanying notes are an integral part of the unaudited interim condensed consolidated financial statements.

LEGEND BIOTECH CORPORATION

**UNAUDITED INTERIM CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION AS AT SEPTEMBER 30, 2021 AND
CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION AS AT DECEMBER 31, 2020**

	<u>Notes</u>	<u>September 30, 2021</u> <u>US\$'000</u> <u>(Unaudited)</u>	<u>December 31, 2020</u> <u>US\$'000</u>
NON-CURRENT ASSETS			
Property, plant and equipment	8	141,071	113,091
Advance payments for property, plant and equipment		1,766	224
Right-of-use assets		7,561	8,009
Other non-current assets		4,573	3,973
Intangible assets		5,432	2,852
Total non-current assets		<u>160,403</u>	<u>128,149</u>
CURRENT ASSETS			
Inventories		1,634	1,800
Trade receivables	9	1,501	74,978
Prepayments, other receivables and other assets		13,838	10,007
Financial assets measured at amortized cost	10	29,849	—
Financial assets at fair value through profit or loss	11	50,040	—
Pledged deposits	12	456	384
Time deposits	12	217,710	50,000
Cash and cash equivalents	12	338,334	455,689
Total current assets		<u>653,362</u>	<u>592,858</u>
Total assets		<u>813,765</u>	<u>721,007</u>
CURRENT LIABILITIES			
Trade and notes payables	13	11,593	5,238
Other payables and accruals		87,445	99,168
Lease liabilities		1,116	1,464
Government grants		299	283
Warrant liability	15	119,100	—
Contract liabilities		55,816	55,014
Total current liabilities		<u>275,369</u>	<u>161,167</u>
NON-CURRENT LIABILITIES			
Contract liabilities		237,219	275,071
Lease liabilities		1,865	1,909
Other non-current liabilities		991	554
Interest-bearing loans and borrowings	16	70,540	—
Government grants		1,915	2,051
Total non-current liabilities		<u>312,530</u>	<u>279,585</u>
Total liabilities		<u>587,899</u>	<u>440,752</u>
EQUITY			
Share capital	17	29	27
Reserve		225,837	280,228
Total ordinary shareholders' equity		<u>225,866</u>	<u>280,255</u>
Total equity		<u>225,866</u>	<u>280,255</u>
Total liabilities and equity		<u>813,765</u>	<u>721,007</u>

The accompanying notes are an integral part of the unaudited interim condensed consolidated financial statements.

LEGEND BIOTECH CORPORATION
UNAUDITED INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2021 AND 2020

	Attributable to equity holders of the parent					
	Share capital US\$'000	Share premium* US\$'000	Share-based Compensation reserves* US\$'000	Foreign currency translation reserve* US\$'000	Accumulated losses* US\$'000	Total (deficits)/ equity US\$'000
As January 1, 2020	20	3,908	1,976	(1,491)	(127,282)	(122,869)
Loss for the period	—	—	—	—	(245,650)	(245,650)
Other comprehensive income:						
Exchange differences on translation of foreign operations	—	—	—	(799)	—	(799)
Total comprehensive loss for the period	<u>—</u>	<u>—</u>	<u>—</u>	<u>(799)</u>	<u>(245,650)</u>	<u>(246,449)</u>
Conversion of convertible redeemable preferred shares to ordinary shares	2	240,432	—	—	—	240,434
Issuance of ordinary shares for initial public offering, net of issuance costs	4	450,081	—	—	—	450,085
Issuance of ordinary shares for initial public offering and private placement to GenScript	—	12,000	—	—	—	12,000
Equity-settled share-based compensation expense	—	—	1,696	—	—	1,696
As September 30, 2020 (Unaudited)	<u>26</u>	<u>706,421</u>	<u>3,672</u>	<u>(2,290)</u>	<u>(372,932)</u>	<u>334,897</u>
As January 1, 2021	27	708,306	6,314	(3,633)	(430,759)	280,255
Loss for the period	—	—	—	—	(297,875)	(297,875)
Other comprehensive income:						
Exchange differences on translation of foreign operations	—	—	—	6,129	—	6,129
Total comprehensive income/(loss) for the period	<u>—</u>	<u>—</u>	<u>—</u>	<u>6,129</u>	<u>(297,875)</u>	<u>(291,746)</u>
Issuance of ordinary shares relating to private placement for an institutional investor	2	218,298	—	—	—	218,300
Exercise of share options	—	5,358	(1,259)	—	—	4,099
Reclassification of vested restricted share units	—	4,016	(4,016)	—	—	—
Equity-settled share-based compensation expense	—	—	14,958	—	—	14,958
As September 30, 2021 (Unaudited)	<u>29</u>	<u>935,978</u>	<u>15,997</u>	<u>2,496</u>	<u>(728,634)</u>	<u>225,866</u>

* These reserve accounts comprise the consolidated reserve of US\$225,837,000 and reserve of US\$334,871,000 in the condensed consolidated statements of financial position as at September 30, 2021 and 2020, respectively.

The accompanying notes are an integral part of the unaudited interim condensed consolidated financial statements.

LEGEND BIOTECH CORPORATION
UNAUDITED INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2021 AND 2020

	Note	September 30, 2021 US\$'000 (Unaudited)	September 30, 2020 US\$'000 (Unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES			
Loss before tax		(297,874)	(249,867)
Adjustments for:			
Finance income	4	(548)	(2,612)
Finance costs		298	4,169
Reversal of the impairment of trade receivables	9	(22)	(9)
Loss from disposal of property, plant and equipment		977	11
Depreciation of property, plant and equipment		8,159	6,892
Amortization of intangible assets		960	165
Depreciation of right-of-use assets		1,087	1,095
Fair value loss of warrant liability	15	37,400	—
Fair value loss of convertible redeemable preferred shares	14	—	79,984
Fair value gains on financial assets at fair value change through profit or loss	4	(40)	(40)
Foreign currency exchange loss, net		2,726	1,275
Equity-settled share-based compensation expenses		14,958	1,696
Deferred government grant		(219)	—
		(232,138)	(157,241)
Decrease in trade receivables		73,499	30,000
Increase in prepayments, other receivables and other assets		(3,656)	(3,314)
Increase in other non-current assets		(600)	—
Decrease/(increase) in inventories		166	(356)
Government grant received		79	—
Increase/(decrease) in trade and notes payables		6,355	(2,187)
Increase/(decrease) in other payables and accruals		63,795	(2,810)
Increase in other non-current liabilities		437	—
Decrease in contract liabilities		(37,050)	(31,629)
Decrease of pledged deposits, net		(72)	—
Cash used in operations		(129,185)	(167,537)
Income tax paid		(1)	(13)
Finance income received		373	652
Interest on lease payments		(105)	(155)
Net cash flows used in operating activities		(128,918)	(167,053)

The accompanying notes are an integral part of the unaudited interim condensed consolidated financial statements.

LEGEND BIOTECH CORPORATION
UNAUDITED INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2021 AND 2020 (CONTINUED)

	<u>Note</u>	<u>September 30,</u> <u>2021</u> <u>US\$'000</u> <u>(Unaudited)</u>	<u>September 30,</u> <u>2020</u> <u>US\$'000</u> <u>(Unaudited)</u>
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchase of property, plant and equipment		(40,407)	(33,315)
Purchase of intangible assets		(3,555)	(710)
Proceeds from disposal of items of property, plant and equipment		26	—
Purchase of financial assets at fair value through profit or loss		(50,000)	(20,432)
Cash received from withdrawal of financial assets at fair value through profit or loss		—	19,257
Cash receipts from investment income		—	40
Purchase of financial assets measured at amortized cost	10	(29,849)	—
Addition of time deposits		(267,710)	(50,000)
Decrease in time deposits		100,000	—
Increase in pledged deposits		—	(174)
Net cash flows used in investing activities		<u>(291,495)</u>	<u>(85,334)</u>
CASH FLOWS FROM FINANCING ACTIVITIES			
Repayment of cash advances from related parties	20	—	(4)
Proceeds from convertible redeemable preferred shares		—	160,450
Proceeds from issuance of ordinary shares for Initial public offering, net of issuance costs		—	450,085
Proceeds from issuance of ordinary shares and warrant relating to private placement for an institutional investor		300,000	—
Proceeds from issuance of ordinary shares relating to private placement by GenScript		—	12,000
Payments of expenses for issuance convertible redeemable preferred shares		—	(2,514)
Proceeds from exercise of share option and restricted share units		4,099	—
Principal portion of lease payments		(997)	(1,799)
Net cash flows from financing activities		<u>303,102</u>	<u>618,218</u>
NET (DECREASE)/INCREASE IN CASH AND CASH EQUIVALENTS		<u>(117,311)</u>	<u>365,831</u>
Effect of foreign exchange rate changes, net		(44)	186
Cash and cash equivalents at beginning of period	12	<u>455,689</u>	<u>83,364</u>
CASH AND CASH EQUIVALENTS AT END OF PERIOD	12	<u><u>338,334</u></u>	<u><u>449,381</u></u>
ANALYSIS OF BALANCES OF CASH AND CASH EQUIVALENTS			
Cash and bank balances		556,500	575,370
Less: Pledged deposits		456	430
Time deposits		217,710	125,559
Cash and cash equivalents as stated in the statement of financial position	12	<u><u>338,334</u></u>	<u><u>449,381</u></u>
Cash and cash equivalents as stated in the statement of cash flows		<u><u>338,334</u></u>	<u><u>449,381</u></u>

The accompanying notes are an integral part of the unaudited interim condensed consolidated financial statements.

LEGEND BIOTECH CORPORATION
NOTES TO THE UNAUDITED INTERIM CONDENSED
CONSOLIDATED FINANCIAL STATEMENTS

1. CORPORATE INFORMATION

Legend Biotech Corporation (the “Company”) was incorporated on May 27, 2015 as an exempted company in the Cayman Islands with limited liability under the Companies Law of the Cayman Islands. The registered office address of the Company is PO Box 10240, Harbour Place, 103 South Church Street, George Town, Grant Cayman KY1-1002, Cayman Islands.

The Company is an investment holding company. The Company’s subsidiaries are principally engaged in research and development of biological products.

In the opinion of the Directors, the parent company of the Company is Genscript Biotech Corporation (“GenScript”), which was incorporated in the Cayman Islands on May 21, 2015 and listed on the main board of Hong Kong Stock Exchange since December 30, 2015.

2.1. BASIS OF PREPARATION

The unaudited interim condensed consolidated financial statements of the Company and its subsidiaries (collectively referred to as the “Group”) for the nine months ended September 30, 2021 have been prepared in accordance with International Accounting Standard 34 *Interim Financial Reporting* (“IAS34”) issued by the International Accounting Standards Board (“IASB”).

The accounting policies and basis of preparation adopted in the preparation of these unaudited interim condensed consolidated financial statements are consistent with those followed in the preparation of the Group’s financial statements for the year ended December 31, 2020, except for the adoption of new standards effective as of January 1, 2021 set out below. The Group has not early adopted any other standards, interpretation or amendments that has been issued but is not yet effective.

In the opinion of the Company’s management, the accompanying unaudited interim condensed consolidated financial statements contain all normal recurring adjustments necessary to present fairly the financial position, operating results and cash flows of the Company for each of the periods presented. The results of operations for the nine months ended September 30, 2021 are not necessarily indicative of results to be expected for any other interim periods or for the year ended December 31, 2021. The condensed consolidated statement of financial position as of December 31, 2020 was derived from the audited consolidated financial statements at that date but does not include all of the disclosures required by IFRS for annual financial statements. These unaudited condensed consolidated financial statements should be read in conjunction with the Company’s audited consolidated financial statements for the years ended December 31, 2020.

2.2. NEW STANDARDS, INTERPRETATIONS AND AMENDMENTS ADOPTED BY THE GROUP

In the nine months ended September 30, 2021, the Group has applied, for the first time, the following new and revised international financial reporting standards (“IFRS”) issued by the IASB that are mandatorily effective for the period.

Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16	Interest Rate Benchmark Reform – Phase 2
--	--

The prospective adoption of the above new and revised IFRSs does not have a material effect on the Group’s interim condensed consolidated financial statements.

LEGEND BIOTECH CORPORATION
NOTES TO THE UNAUDITED INTERIM CONDENSED
CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

3. OPERATING SEGMENT INFORMATION

IFRS 8 *Operating Segments* requires operating segments to be identified on the basis of internal reporting about components of the Group that are regularly reviewed by the chief operating decision-maker in order to allocate resources to segments and to assess their performance. The information reported to the directors of the Company, who are the chief operating decision makers, for the purpose of resource allocation and assessment of performance does not contain discrete operation segment financial information and the directors reviewed the financial results of the Group as a whole. Therefore, no further information about the operating segment is presented.

Geographic information

(a) Revenue from external customers

	Nine months ended September 30,	
	2021 US\$'000 (Unaudited)	2020 US\$'000 (Unaudited)
North America	47,804	34,893
China	2,993	—
Total	50,797	34,893

The revenue information above is based on the locations of the customers.

(b) Non-current assets

	September 30, 2021 US\$'000 (Unaudited)	December 31, 2020 US\$'000
	China	48,441
United States	103,445	78,022
Other countries	8,517	6,174
Total	160,403	128,149

The non-current asset information above is based on the locations of assets.

Information about major customer

Revenue of US\$47.8 million and US\$34.9 million for the nine months ended September 30, 2021 and 2020, respectively, was derived from sales to a single customer. Revenue of US\$3.0 million for the nine months ended September 30, 2021 was generated from transfer of an exclusive licensing of certain patents to Nanjing Probio Biotech Co., Ltd. and its affiliates (note 20).

LEGEND BIOTECH CORPORATION
NOTES TO THE UNAUDITED INTERIM CONDENSED
CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

4. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue is as follows:

	Nine months ended September 30,	
	2021	2020
	US\$'000 (Unaudited)	US\$'000 (Unaudited)
Revenue from contracts with customers		
License and collaboration revenue		
- Licensing of intellectual property	1,108	—
- Joint Steering Committee service (“JSC service”)	46,696	34,893
Others	2,993	—
Total	<u>50,797</u>	<u>34,893</u>

Revenue from the licensing of intellectual property and others are recognized at a point in time and revenue from JSC service is recognized overtime.

The following table shows the amounts of revenue recognized in the current reporting period that were included in the contract liabilities at the beginning of the reporting period and recognized from performance obligations satisfied in previous periods:

	Nine months ended September 30,	
	2021	2020
	US\$'000 (Unaudited)	US\$'000 (Unaudited)
Revenue recognized that was included in contract liabilities at the beginning of the reporting period:		
License and collaboration revenue		
- JSC service	41,000	34,893

	Nine months ended September 30,	
	2021	2020
	US\$'000 (Unaudited)	US\$'000 (Unaudited)
Revenue recognized from performance obligation satisfied in previous periods:		
License and collaboration revenue		
- Licensing of intellectual property	1,108	—
- JSC service	4,556	—
	<u>5,664</u>	<u>—</u>

LEGEND BIOTECH CORPORATION
NOTES TO THE UNAUDITED INTERIM CONDENSED
CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

4. REVENUE, OTHER INCOME AND GAINS (CONTINUED)

(i) Performance obligations

The amounts of transaction prices allocated to the remaining performance obligations (unsatisfied or partially unsatisfied) as at September 30, 2021 and December 31, 2020 are as follows:

	September 30, 2021 US\$'000 (Unaudited)	December 31, 2020 US\$'000
Amounts expected to be recognized as revenue:		
Within 1 year	55,816	55,014
1 - 2 years	55,816	55,014
2 - 3 years	55,816	55,014
3 - 4 years	55,816	55,014
After 4 years	69,771	110,029
	<u>293,035</u>	<u>330,085</u>

The amounts of transaction prices allocated to the remaining performance obligations which are expected to be recognised as revenue after one year relate to JSC service, of which the performance obligations are to be satisfied over the collaboration period, which is estimated to be 9 years from the contract inception. The amounts disclosed above do not include variable consideration which is constrained.

	Nine months ended September 30,	
	2021 US\$'000 (Unaudited)	2020 US\$'000 (Unaudited)
Other income and gains		
Government grants*	1,478	2,659
Finance income	548	2,612
Fair value gains on financial assets at fair value change through profit or loss	40	40
Others**	250	4
	<u>2,316</u>	<u>5,315</u>

* The amount represents subsidies received from local government authorities to support the Group's business. There were no unfulfilled conditions and other contingencies attached to these government grants.

** The amount mainly represents reimbursement of depositary fees that are related to the establishment and maintenance of the ADR program.

LEGEND BIOTECH CORPORATION
NOTES TO THE UNAUDITED INTERIM CONDENSED
CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

5. LOSS BEFORE TAX

The Group's loss before tax is arrived at after charging/(crediting):

	Nine months ended September 30,	
	2021 US\$'000 (Unaudited)	2020 US\$'000 (Unaudited)
Reversal for the impairment of trade receivables, net (note 9)	(22)	(9)
IPO expenses	—	1,439
Employee benefit expense:		
Wages and salaries	64,230	49,051
Pension scheme contributions (defined contribution schemes)	1,644	436
Equity-settled share-based compensation expense	14,958	1,242

6. INCOME TAX

The Group is subject to income tax on an entity basis on profits arising in or derived from the jurisdictions in which members of the Group are domiciled and operate.

Cayman Islands

Under the current laws of the Cayman Islands, the Company is not subject to tax on income or capital gains.

British Virgin Islands

Under the current laws of the British Virgin Islands ("BVI"), Legend Biotech Limited ("Legend BVI") is not subject to tax on income or capital gains. Additionally, upon payments of dividends by the Group's subsidiaries incorporated in the British Virgin Islands to their shareholders, no withholding tax will be imposed.

Hong Kong

Under the current laws of Hong Kong, the subsidiary which operates in Hong Kong is subject to a corporate income tax ("CIT") at a rate of 16.5% on the taxable income. Under the Hong Kong tax law, the subsidiary in Hong Kong are exempted from income tax on their foreign derived income and there are no withholding taxes in Hong Kong on remittance of dividends.

United States of America

Under the current laws of the United States of America ("USA"), the subsidiary which operates in the United States of America is subject to federal tax at a rate of 21% and state tax at a rate of 11.5% in New Jersey. Dividends payable by the Group's US entity, to non US resident enterprises shall be subject to 30% withholding tax, unless the respective non US resident enterprise's jurisdiction of incorporation has a tax treaty or arrangements with US that provides for a reduced withholding tax rate or an exemption from withholding tax.

Ireland

Under the current laws of Ireland, the subsidiary which operates in Ireland is subject to CIT at a rate of 12.5% on its taxable trading income. Any non-trading income is subject to CIT at a rate of 25%. Dividend withholding tax is imposed on distributions made by Irish companies at a rate of 25% with many exemptions provided.

LEGEND BIOTECH CORPORATION
NOTES TO THE UNAUDITED INTERIM CONDENSED
CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

6. INCOME TAX (CONTINUED)

Mainland China

Pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the “CIT Law”), the subsidiaries which operate in Mainland China are subject to CIT at a rate of 25% on the taxable income. The applicable income tax rate was 25%. Dividends, interests, rent or royalties payable by the Group’s PRC entities, to non PRC resident enterprises, and proceeds from any such non-resident enterprise investor’s disposition of assets (after deducting the net value of such assets) shall be subject to 10% CIT, namely withholding tax, unless the respective non PRC resident enterprise’s jurisdiction of incorporation has a tax treaty or arrangements with China that provides for a reduced withholding tax rate or an exemption from withholding tax.

	Nine months ended September 30,	
	2021 US\$'000 (Unaudited)	2020 US\$'000 (Unaudited)
Current – United States of America	—	(3,697)
Current – Elsewhere	1	(520)
Total tax expense/(credit) for the period	1	(4,217)

7. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT

The calculation of the basic loss per share amount is based on the loss for the period attributable to ordinary equity holders of the parent, and the weighted average number of ordinary shares of 277,829,268 and 226,764,437 in issue during the nine months ended September 30, 2021 and 2020, respectively.

The calculation of the diluted earnings per share amount is based on the loss for the period attributable to ordinary equity holders of the parent. The weighted average number of ordinary shares used in the calculation is the number of ordinary shares in issue during the period, as used in the basic earnings per share calculation, and the weighted average number of ordinary shares assumed to have been issued at no consideration on the deemed exercise of all dilutive potential ordinary shares into ordinary shares.

No adjustment was made to the basic loss per share amounts presented for the nine months ended September 30, 2021 and 2020 in respect of a dilution as the impact of the outstanding share options and warrant had an anti-dilutive effect on the basic loss per share amounts presented.

The calculations of basic and diluted loss per share are based on:

	Nine months ended September 30,	
	2021 US\$'000 (Unaudited)	2020 US\$'000 (Unaudited)
Losses		
Loss attributable to ordinary equity holders of the parent, used in the basic earnings per share calculation	(297,875)	(245,650)
	Number of shares Nine months ended September 30,	
	2021 (Unaudited)	2020 (Unaudited)
Shares		
Weighted average number of ordinary shares in issue during the period used in the basic earnings per share calculation	277,829,268	226,764,437

LEGEND BIOTECH CORPORATION
NOTES TO THE UNAUDITED INTERIM CONDENSED
CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

8. PROPERTY, PLANT AND EQUIPMENT

During the nine months ended September 30, 2021, the Group acquired items of property, plant and equipment with a cost of US\$40.5 million (for the nine months ended September 30, 2020: US\$35.5 million), among which, the charge from a customer under a license and collaboration agreement amounted to US\$8.0 million (for the nine months ended September 30, 2020: US\$7.9 million).

9. TRADE RECEIVABLES

	September 30, 2021 <u>US\$'000</u> (Unaudited)	December 31, 2020 <u>US\$'000</u>
Trade receivables	1,501	75,000
Less: Impairment of trade receivables	—	(22)
	<u>1,501</u>	<u>74,978</u>

The Group's trading terms with its customers are mainly on credit. The credit period is 30 to 75 days. The Group seeks to maintain strict control over its outstanding receivables and overdue balances are reviewed regularly by management. Trade receivables are non-interest-bearing. The Group has concentration of credit risk as 100% of trade receivables were due from an exclusive licensing of certain patents to Nanjing Probio Biotech Co., Ltd. and its affiliates as at September 30, 2021.

Movements in the loss allowance for impairment of trade receivables were as follows:

	<u>Total</u> <u>US\$'000</u>
At January 1, 2021	22
Impairment losses reversed	(22)
Impairment losses recognised	—
At September 30, 2021 (Unaudited)	<u>—</u>
At January 1, 2020	9
Impairment losses reversed	(9)
Impairment losses recognised	22
At December 31, 2020	<u>22</u>

10. FINANCIAL ASSETS MEASURED AT AMORTIZED COST

	September 30, 2021 <u>US\$'000</u> (Unaudited)	December 31, 2020 <u>US\$'000</u>
Financial assets measured at amortized cost	<u>29,849</u>	<u>—</u>

Financial assets measured at amortized cost was related to commercial paper issued by a financial institution with principal amount of US\$30.0 million, discounted bid yield of 0.5% per annum and one year maturity date as June 1, 2022.

LEGEND BIOTECH CORPORATION
NOTES TO THE UNAUDITED INTERIM CONDENSED
CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

11. FINANCIAL ASSETS AT FAIR VALUE THROUGH PROFIT OR LOSS

	September 30, 2021 <u>US\$'000</u> (Unaudited)	December 31, 2020 <u>US\$'000</u>
Financial assets at fair value through profit or loss	50,040	—

Financial assets at fair value through profit or loss were related to investments in wealth management products as at 30 September 2021. They were mandatorily classified as financial assets at fair value through profit or loss as their contractual cash flows are not solely payments of principal and interest.

12. CASH AND CASH EQUIVALENTS AND PLEDGED DEPOSITS

	September 30, 2021 <u>US\$'000</u> (Unaudited)	December 31, 2020 <u>US\$'000</u>
Cash and bank balances	556,500	506,073
Less: pledged deposits	(456)	(384)
time deposits	(217,710)	(50,000)
Cash and cash equivalents	338,334	455,689
Denominated in USD	326,481	451,165
Denominated in RMB	9,200	4,335
Denominated in EUR	2,653	189
Cash and cash equivalents	338,334	455,689

The cash and cash equivalents of the Group denominated in Renminbi (“RMB”) amounted to US\$9.2 million and US\$4.3 million in the condensed consolidated statements of financial position as at September 30, 2021 and December 31, 2020, respectively. The RMB is not freely convertible into other currencies, however, under Mainland China’s Foreign Exchange Control Regulations and Administration of Settlement, Sale and Payment of Foreign Exchange Regulations, the Group is permitted to exchange RMB for other currencies through banks authorized to conduct foreign exchange business.

The pledged deposit as at September 30, 2021 was pledged for credit card facilities. The pledged deposit as at December 31, 2020 was pledged for issuing bank notes payables to suppliers of the Group and for credit card facilities.

Cash at banks earns interest at floating rates based on daily bank deposit rates. The bank balances are deposited with creditworthy banks with no recent history of default. The carrying amounts of the cash and cash equivalents approximate to their fair values.

LEGEND BIOTECH CORPORATION
NOTES TO THE UNAUDITED INTERIM CONDENSED
CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

13. TRADE AND NOTES PAYABLES

	September 30, 2021 <u>US\$'000</u> (Unaudited)	December 31, 2020 <u>US\$'000</u>
Trade payables	11,593	4,911
Notes payables	—	327
	<u>11,593</u>	<u>5,238</u>

The trade payables are non-interest-bearing and are normally settled on a net 30-day term.

As at September 30, 2021 and December 31, 2020, included in the Group's trade payables are amounts due to the Group's related parties of US\$7.7 million and US\$2.1 million, respectively (note 20).

14. CONVERTIBLE REDEEMABLE PREFERRED SHARES

On March 30, 2020 and on April 16, 2020, the Company issued a total of 20,591,629 Series A convertible redeemable preferred shares (the "Series A Preference Shares") to independent third parties, at the price of US\$7.792 per share for an aggregate purchase consideration of US\$160.5 million.

The key terms of the Series A Preference Shares are summarized as follows:

(1) Dividends rights

Each Series A Preference Shares holder is entitled to dividends at the rate of 8% of the Series A original issue price per annum per share shall accrue on such Series A Preference Shares. Such dividends (i) will be declared by the board of directors and paid to the holders of Series A Preference Shares each fiscal quarter, or (ii) if not declared and, with respect to any fiscal quarter, paid to the holders of Series A Preference Shares within thirty days after such fiscal quarter, such undeclared and unpaid dividends will accrue day to day from the last day of such fiscal quarter, will be cumulative and compound annually, and will only be paid upon a redemption or liquidation event or converted into ordinary shares upon an initial public offering.

(2) Conversion rights

Optional conversion

Each Series A Preference Share is convertible, at the option of the holder, at any time after the date of issuance of such Series A Preference Share, into such number of fully paid and non-assessable ordinary shares as is determined by dividing the Series A original issue price, by a conversion price equal to the lower of (i) the conversion price at the time in effect for such Series A Preference Share and (ii) the price per share that equals the lowest net price per ordinary share received by the Company in a public offering that is not a Qualified IPO.

Automatic conversion

Each Series A Preference Share will be automatically converted upon the closing of a Qualified IPO into a number of ordinary shares as is determined by dividing the Series A original issue price by a conversion price is equal to the lower of (i) the conversion price at the time in effect for such Series A Preference Share and (ii) the price per share that equals 90% of the lowest net price per ordinary share received by the Company in the Qualified IPO.

LEGEND BIOTECH CORPORATION
NOTES TO THE UNAUDITED INTERIM CONDENSED
CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

14. CONVERTIBLE REDEEMABLE PREFERRED SHARES (CONTINUED)

(3) Redemption rights

At any time on or after the occurrence of a Trigger Event (as defined below), each investor may require the Company to redeem the Series A Preference Shares issued to the investor and require the Company to immediately pay the investor an amount equal to the redemption price, plus 8% annualized. A "Trigger Event" means the occurrence of one or more of the following events: (A) as of September 30, 2021, the Company has not consummated a qualified IPO, (B) the Company consummates a non-Qualified IPO, (C) the License Agreement (i) is terminated as a result of a material breach by any party thereto or (ii) is amended in such a way that with (or without) the passage of time would reasonably be expected to adversely affect the value of the Company or the Series A Preference Shares in any material respect and (D) there occurs or it is discovered that there is a material adverse issue with respect to the patents, know-how and all other intellectual property owned or controlled by the Company or its affiliates and licensed to a customer under a license and collaboration agreement, which is not capable of being cured within a reasonable period.

(4) Liquidation

Upon any liquidation, dissolution or winding up of the Company (collectively, a "Liquidation Event"), before any distribution or payment shall be made to the holders of any Ordinary Shares, the holders of Series A Preference Shares will be entitled to be paid out of the assets of the Company legally available for distribution for each Series A Preference Share, an amount per Series A Preference Share equal to the sum of (i) the Series A Original Issue Price, plus (ii) any accrued but unpaid Dividends on each Series A Preference Share. If, upon any such Liquidation Event, the assets of the Company will be insufficient to make payment in full to all holders of Series A Preference Shares, then such assets (or consideration) will be distributed among the holders of Series A Preference Shares at the time outstanding, ratably in proportion to the full amounts to which they would otherwise be respectively entitled.

All Series A Preferred Shares were converted into ordinary shares of the Company and all accrued but unpaid dividends were settled in the form of ordinary shares upon qualified IPO in June 2020. A fair value loss of US\$80.0 million was recorded for the nine months ended September 30, 2020 due to change in fair value upon conversion.

15. WARRANT LIABILITY

On May 13, 2021, the Company entered into a subscription agreement with an institutional investor relating to the offer and sale of 20,809,850 ordinary shares of the Company, par value US\$0.0001 per share, in a private placement at a purchase price of US\$14.41625 per ordinary share (the "PIPE Offering"). The total proceeds from the PIPE Offering is US\$300.0 million. Pursuant to the subscription agreement, the Company also agreed to issue and sell concurrently with the PIPE offering a warrant (the "Warrant") exercisable for up to an aggregate of 10,000,000 ordinary shares (such transaction together with the PIPE Offering, the "Transactions"). The Transactions have been closed on May 21, 2021 (the "Closing Date"). The Warrant is exercisable, in whole or in part, at an exercise price of US\$20.00 per ordinary share, until the two-year anniversary of the Closing Date.

The Warrant is accounted for as a financial liability because the Warrant may be net share settleable at the holder's option. The fair value of the warrant liability is assessed at US\$81.7 million and is recognized upon closing of the transaction. As of September 30, 2021, its fair value is assessed at US\$119.1 million. A fair value loss of US\$37.4 million is recorded for the nine months ended September 30, 2021 due to change in fair value.

LEGEND BIOTECH CORPORATION
NOTES TO THE UNAUDITED INTERIM CONDENSED
CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

15. WARRANT LIABILITY (CONTINUED)

The movement of the warrant liability is set out as below:

	<u>Total</u> US\$'000
At January 1, 2021	—
Issuance of the warrant liability	81,700
Fair value loss of the warrant liability	37,400
At September 30, 2021 (unaudited)	<u>119,100</u>

16. INTEREST-BEARING LOANS AND BORROWINGS

	<u>Effective interest rate (%)</u>	<u>Maturity</u>	<u>September 30, 2021</u> US\$'000 (Unaudited)
Non-current			
Loans from a collaborator	2.74	No specific maturity date	17,430
Loans from a collaborator	2.72	No specific maturity date	53,110
Total			<u>70,540</u>

Pursuant to the license and collaboration agreement entered into with a collaborator, the Company is entitled to receive funding advances from the collaborator when certain operational conditions are met. As a result, the Company took an initial funding advance amounting to US\$17.4 million on June 18, 2021, and an additional funding advance on September 17, 2021, amounting to US\$53.1 million, by reducing the same amount of other payables due to the collaborator (collectively, the "Funding Advances").

This Funding Advances are accounted for as interest-bearing borrowings funded by the collaborator, constituted by a principal and applicable interests upon such principal. The respective interest rate of each borrowing is based on the average annual London Interbank Offered Rate (LIBOR) for U.S. Dollars as reported in the Wall Street Journal on the due date, plus 250 basis points, calculated on the number of days from the date on which the Company applied such borrowings. For the initial funding advance of US\$17.4 million, interest started to accrue from June 18, 2021. For the additional funding advance of US\$53.1 million, interest started to accrue from September 17, 2021.

Pursuant to the terms of the license and collaboration agreement, the collaborator may recoup the aggregate amount of Funding Advances together with interest thereon from Company's share of pre-tax profits for the first profitable year of the collaboration program. The Company's management estimated the loan will not be recouped by the collaborator within one year, and thus the loan was classified as a long-term liability.

LEGEND BIOTECH CORPORATION
NOTES TO THE UNAUDITED INTERIM CONDENSED
CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

17. SHARE CAPITAL AND SHARE PREMIUM

Shares

	September 30, 2021 <u>US\$'000</u> (Unaudited)	December 31, 2020 <u>US\$'000</u>
Authorised:		
2,000,000,000 shares of US\$0.0001 each	200	200
Issued and fully paid:		
290,661,844 and 266,010,256 ordinary shares of US\$0.0001 each	29	27

A summary of movements in the Company's share capital and share premium is as follows:

	Number of shares in issue	Share capital <u>US\$'000</u>	Share premium <u>US\$'000</u>	Total <u>US\$'000</u>
At December 31, 2020 and January 1, 2021	266,010,256	27	708,306	708,333
Issuance of ordinary shares and warrant for an institutional investor	20,809,850	2	218,298	218,300
Exercise of share options	3,589,464	—	5,358	5,358
Vesting of RSU	252,274	—	4,016	4,016
At September 30, 2021 (Unaudited)	<u>290,661,844</u>	<u>29</u>	<u>935,978</u>	<u>936,007</u>
	Number of shares in issue	Share capital <u>US\$'000</u>	Share premium <u>US\$'000</u>	Total <u>US\$'000</u>
At December 31, 2019 and January 1, 2020	200,000,000	20	3,908	3,928
Issuance of ordinary shares for initial public offering, net of issuance costs	42,377,500	4	450,081	450,085
Issuance of ordinary shares for conversion of preferred shares	20,907,282	2	240,432	240,434
Issuance of ordinary shares for private placement by GenScript	1,043,478	—	12,000	12,000
Exercise of share options	1,681,996	1	1,885	1,886
At December 31, 2020	<u>266,010,256</u>	<u>27</u>	<u>708,306</u>	<u>708,333</u>

18. NOTES TO THE CONSOLIDATED STATEMENT OF CASH FLOWS

(a) Major non-cash transactions

For the nine months ended September 30, 2021, the Group had non-cash additions to interest-bearing loans and borrowings of US\$70.5 million which was received through the deduction of other payables to collaborator.

For the nine months ended September 30, 2021, the Group had non-cash fair value loss of US\$37.4 million of warrant liability.

For the nine months ended September 30, 2021, the Group had non-cash additions to property, plant and equipment of US\$11.3 million.

For the nine months ended September 30, 2021 and 2020, the Group had non-cash additions to right-of-use assets of US\$0.7 million and US\$0.5 million, and lease liabilities of US\$0.7 million and US\$0.5 million, in respect of lease arrangements for buildings, respectively.

For the nine months ended September 30, 2020, the Group had non-cash additions to finance costs of US\$1.5 million and other payable of US\$1.5 million, in respect of issuance costs for convertible redeemable preferred shares.

For the nine months ended September 30, 2020, the Group had non-cash fair value loss of US\$80.0 million of Series A Preferred Shares.

LEGEND BIOTECH CORPORATION
NOTES TO THE UNAUDITED INTERIM CONDENSED
CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

18. NOTES TO THE CONSOLIDATED STATEMENT OF CASH FLOWS (CONTINUED)

(b) Changes in liabilities arising from financing activities

	Convertible redeemable preferred shares US\$'000	Other payable to related parties US\$'000	Lease liabilities US\$'000
At January 1, 2021	—	—	3,373
Additions of lease liabilities	—	—	664
Changes from financing cash flows	—	—	(997)
Interest expense	—	—	105
Interest paid classified as operating cash flows	—	—	(105)
Foreign exchange movement	—	—	(59)
At September 30, 2021 (Unaudited)	<u>—</u>	<u>—</u>	<u>2,981</u>
At January 1, 2020	—	4	6,085
Decrease of lease liabilities	—	—	(413)
Changes from financing cash flows	160,450	(4)	(1,799)
Fair value loss of the Series A Preferred Shares	79,984	—	—
Conversion to ordinary shares	(240,434)	—	—
Interest expense	—	—	155
Interest paid classified as operating cash flows	—	—	(155)
Foreign exchange movement	—	—	115
At September 30, 2020 (Unaudited)	<u>—</u>	<u>—</u>	<u>3,988</u>

(c) Total cash outflow for leases

The total cash outflow for leases included in the statement of cash flows is as follows:

	Nine months ended September 30,	
	2021 US\$'000 (Unaudited)	2020 US\$'000 (Unaudited)
Right-of-use assets		
Within operating activities	105	155
Within financing activities	997	1,799
Short-term leases	121	—
	<u>1,223</u>	<u>1,954</u>

LEGEND BIOTECH CORPORATION
NOTES TO THE UNAUDITED INTERIM CONDENSED
CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

19. COMMITMENTS AND CONTINGENCIES

The Group had the following capital commitments as at September 30, 2021:

	Less than one year
	US\$'000
	(Unaudited)
Construction in progress	28,920

In September 2021, a former employee elected to enter into arbitration against Legend Biotech USA Inc. (“Legend USA”) with the American Arbitration Association, claiming such former employee was discriminated against due to her gender and wrongfully terminated in retaliation for engaging in alleged protected activity. The former employee demanded Legend USA to pay damages of approximately US\$3.0 million for alleged lost pay, lost equity, damage to reputation, emotional distress and other related losses.

Management believes that the former employee’s claims above are without merit and intends to defend vigorously. At the early stage of the process, management cannot predict the ultimate outcome of the above claims, whether in whole or in part, which may result in a loss, if any. Therefore, in the opinion of management and legal counsel, an estimate of the amount or a range of reasonably possible losses cannot be made at this time. Accordingly, no provision for any liability has been made in the financial statements.

20. RELATED PARTY TRANSACTIONS

Company	Relationship
Nanjing Genscript Biotech Co., Ltd.	Company controlled by the ultimate holding company
Jiangsu Genscript Biotech Co., Ltd.	Company controlled by the ultimate holding company
Genscript (HongKong) Ltd.	Company controlled by the ultimate holding company
Genscript USA Incorporated	Company controlled by the ultimate holding company
Genscript USA Holdings Inc	Company controlled by the ultimate holding company
Nanjing Probio Biotech Co., Ltd.	Company controlled by the ultimate holding company
CUSTOMARRAY, INC.	Company controlled by the ultimate holding company

(a) In addition to the transactions detailed elsewhere in these interim condensed consolidated financial statements, the Group had the following transactions with related parties during the period:

(i) Sale to related parties:

	Nine months ended September 30,	
	2021	2020
	US\$'000 (Unaudited)	US\$'000 (Unaudited)
Nanjing Probio Biotech Co., Ltd.	2,993	—

The sale was generated from an exclusive licensing of certain patents to Nanjing Probio Biotech Co., Ltd. and its affiliates.

(ii) Other income to related parties:

	Nine months ended September 30,	
	2021	2020
	US\$'000 (Unaudited)	US\$'000 (Unaudited)
Nanjing Genscript Biotech Co., Ltd.	7	—

The other income was the income for sublease to Nanjing Genscript Biotech Co., Ltd.

LEGEND BIOTECH CORPORATION
NOTES TO THE UNAUDITED INTERIM CONDENSED
CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

20. RELATED PARTY TRANSACTIONS (CONTINUED)

(iii) Purchases from related parties:

	Nine months ended September 30,	
	2021 US\$'000 (Unaudited)	2020 US\$'000 (Unaudited)
Nanjing Genscript Biotech Co., Ltd.	7,843	2,875
Genscript USA Incorporated	513	302
Jiangsu Genscript Biotech Co., Ltd.	154	40
Genscript USA Holdings Inc	6	—
	<u>8,516</u>	<u>3,217</u>

The transactions were made according to the terms and conditions agreed with related parties.

(iv) Management fee:

	Nine months ended September 30,	
	2021 US\$'000 (Unaudited)	2020 US\$'000 (Unaudited)
Nanjing Genscript Biotech Co., Ltd.	129	—
Genscript USA Incorporated	26	96
	<u>155</u>	<u>96</u>

The management fee was charged by related parties based on the cost of services provided.

(v) Shared services:

During the nine months ended September 30, 2021 and 2020, Nanjing Genscript Biotech Co., Ltd. provided certain accounting, legal, IT and administrative shared services to the Group for the consideration of US\$1.2 million and US\$2.6 million, respectively.

(vi) Repayment of cash advances from related parties:

	Nine months ended September 30,	
	2021 US\$'000 (Unaudited)	2020 US\$'000 (Unaudited)
Genscript (HongKong) Ltd.	—	4

The above cash advances from related parties were unsecured, interest free and repayable on demand.

LEGEND BIOTECH CORPORATION
NOTES TO THE UNAUDITED INTERIM CONDENSED
CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

20. RELATED PARTY TRANSACTIONS (CONTINUED)

(vii) Purchase of equipment

	Nine months ended	
	September 30,	
	2021	2020
	US\$'000	US\$'000
	(Unaudited)	(Unaudited)
Nanjing Genscript Biotech Co., Ltd.	—	47

The purchase of equipment was made at their respective carrying value.

(viii) Compensation fee for termination of service agreement:

	Nine months ended	
	September 30,	
	2021	2020
	US\$'000	US\$'000
	(Unaudited)	(Unaudited)
Jiangsu Genscript Biotech Co., Ltd.	2,643	—

In May 2021, pursuant to a settlement agreement between the Group and Jiangsu Genscript Biotech Co., Ltd., the Group incurred compensation charges for the termination of a service agreement related to the design and construction of a lab facility.

(b) Outstanding balances with related parties:

The Group had the following significant balances with its related parties:

(i) Due from related parties

	September 30,	December 31,
	2021	2020
	US\$'000	US\$'000
	(Unaudited)	
Trade Receivables		
Nanjing Probio Biotech Co., Ltd	1,501	—
	September 30,	December 31,
	2021	2020
	US\$'000	US\$'000
	(Unaudited)	
Other Receivables		
Nanjing Genscript Biotech Co., Ltd.	34	14
Genscript USA Incorporated	12	6
Jiangsu Genscript Biotech Co., Ltd.	1	—
	47	20

LEGEND BIOTECH CORPORATION
NOTES TO THE UNAUDITED INTERIM CONDENSED
CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

20. RELATED PARTY TRANSACTIONS (CONTINUED)

(b) Outstanding balances with related parties (continued):

(i) Due from related parties (continued)

	September 30, 2021 US\$'000 (Unaudited)	December 31, 2020 US\$'000
Prepayment		
Nanjing Probio Biotech Co., Ltd.	1,501	—

(ii) Due to related parties

	September 30, 2021 US\$'000 (Unaudited)	December 31, 2020 US\$'000
Trade Payables		
Nanjing Genscript Biotech Co., Ltd.	6,962	1,547
Genscript USA Incorporated	566	555
Jiangsu Genscript Biotech Co., Ltd.	136	1
	<u>7,664</u>	<u>2,103</u>

	September 30, 2021 US\$'000 (Unaudited)	December 31, 2020 US\$'000
Other Payables		
Jiangsu Genscript Biotech Co., Ltd.	3,788	—
Nanjing Genscript Biotech Co., Ltd.	2,782	3,736
Genscript USA Incorporated	4	—
	<u>6,574</u>	<u>3,736</u>

	September 30, 2021 US\$'000 (Unaudited)	December 31, 2020 US\$'000
Lease Liabilities		
Nanjing Genscript Biotech Co., Ltd.	321	351
Genscript USA Holdings Inc	148	582
	<u>469</u>	<u>933</u>

Except for lease liabilities with incremental borrowing rates between 2.00% and 8.89% and repayable over 5 years, other related party balances are unsecured and repayable on demand.

LEGEND BIOTECH CORPORATION
NOTES TO THE UNAUDITED INTERIM CONDENSED
CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

20. RELATED PARTY TRANSACTIONS (CONTINUED)

(c) Compensation of key management personnel of the Group:

	Nine months ended September 30,	
	2021 US\$'000 (Unaudited)	2020 US\$'000 (Unaudited)
Short-term employee benefits	1,404	1,155
Equity-settled share-based compensation expense	2,023	279
	<u>3,427</u>	<u>1,434</u>

21. FINANCIAL INSTRUMENTS BY CATEGORY

The carrying amounts of each of the categories of financial instruments as at the end of each of the reporting periods are as follows:

As at September 30, 2021

Financial assets

	Financial assets at amortized cost US\$'000 (Unaudited)	Financial assets at fair value through profit and loss US\$'000 (Unaudited)
Trade receivables	1,501	—
Financial assets included in prepayments, other receivables and other assets	709	—
Financial assets measured at amortized cost	29,849	—
Financial assets at fair value through profit and loss	—	50,040
Time deposits	217,710	—
Pledged deposits	456	—
Cash and cash equivalents	338,334	—
	<u>588,559</u>	<u>50,040</u>

Financial liabilities

	Financial liabilities at amortized cost US\$'000 (Unaudited)	Financial liabilities at fair value through profit and loss US\$'000 (Unaudited)
Trade and notes payables	11,593	—
Warrant liability	—	119,100
Financial liabilities included in other payables and accruals	19,314	—
Interest-bearing loans and borrowings	70,540	—
Lease liabilities	2,981	—
	<u>104,428</u>	<u>119,100</u>

LEGEND BIOTECH CORPORATION
NOTES TO THE UNAUDITED INTERIM CONDENSED
CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

21. FINANCIAL INSTRUMENTS BY CATEGORY (CONTINUED)

As at December 31, 2020

Financial assets

	Financial assets at amortized cost
	US\$'000
Trade receivables	74,978
Financial assets included in prepayments, other receivables and other assets	344
Time deposits	50,000
Pledged deposits	384
Cash and cash equivalents	455,689
	<u>581,395</u>

Financial liabilities

	Financial liabilities at amortized cost
	US\$'000
Trade and notes payables	5,238
Financial liabilities included in other payables and accruals	85,559
Lease liabilities	3,373
	<u>94,170</u>

22. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS

As at September 30, 2021 and December 31, 2020, the fair values of the Group's financial assets or liabilities approximated to their respective carrying amounts.

Management has assessed that the fair values of cash and cash equivalents, pledged deposits, time deposits, financial assets included in prepayments, other receivables and other assets, trade receivables, trade payables and financial liabilities included in other payables and accruals approximate to their carrying amounts largely due to the short-term maturities of these instruments.

The Group's finance department headed by the finance manager is responsible for determining the policies and procedures for the fair value measurement of financial instruments. The finance department reports directly to the finance manager. At each reporting date, the finance department analyzed the movements in the values of financial instruments and determined the major inputs applied in the valuation. The valuation was reviewed and approved by the finance manager. The valuation process and results are discussed with the directors once a year for annual financial reporting.

The fair values of the financial assets and liabilities are included at the amount at which the instrument could be exchanged in a current transaction between willing parties, other than in a forced or liquidation sale.

LEGEND BIOTECH CORPORATION
NOTES TO THE UNAUDITED INTERIM CONDENSED
CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

22. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS (CONTINUED)

The following table illustrates the fair value measurement hierarchy of the Group's financial instruments:

Assets measured at fair value:

As at September 30, 2021 (Unaudited)

	<u>Fair value measurement using</u>			<u>Total</u> US\$'000
	<u>Quoted prices in active markets (Level 1)</u> US\$'000	<u>Significant observable inputs (Level 2)</u> US\$'000	<u>Significant unobservable inputs (Level 3)</u> US\$'000	
Financial assets at fair value through profit or loss	—	50,040	—	50,040

Liability measured at fair value:

As at September 30, 2021 (Unaudited)

	<u>Fair value measurement using</u>			<u>Total</u> US\$'000
	<u>Quoted prices in active markets (Level 1)</u> US\$'000	<u>Significant observable inputs (Level 2)</u> US\$'000	<u>Significant unobservable inputs (Level 3)</u> US\$'000	
Warrant liability	—	119,100	—	119,100

The following table lists the inputs to the binominal model used for the fair value valuation of warrant liability:

	<u>September 30, 2021</u> (Unaudited)	
Underlying stock price	US\$	25.28
Volatility		81.7%
Risk free rate		0.21%
Dividend		0%

During the nine months ended September 30, 2021 and 2020, there were no transfers of fair value measurements between Level 1 and Level 2 and no transfers into or out of Level 3 for both financial assets and financial liabilities.

LEGEND BIOTECH CORPORATION
NOTES TO THE UNAUDITED INTERIM CONDENSED
CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

23. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES

The Group's principal financial instruments comprise cash and cash equivalents, pledged deposits, time deposits, financial assets measured at amortized cost, financial assets at fair value through profit or loss, prepayments, other receivables and other assets, warrant liability, financial liabilities included in other payables and accruals and interest-bearing loans and borrowings. The main purpose of these financial instruments is to raise finance for the Group's operations. The Group has various other financial assets and liabilities such as trade receivables and trade payables, which arise directly from its operations.

The main risks arising from the Group's financial instruments are foreign currency risk, credit risk and liquidity risk. The board of directors reviews and agrees policies for managing each of these risks and they are summarized below.

Foreign currency risk

The Group has transactional currency exposures. Such exposures arise from sales or purchases by operating units in currencies other than the units' functional currencies. Approximately 36% of the Group's sales were denominated in currencies other than the functional currencies of the operating units making the sale in the nine months ended September 30, 2021 (Nine months ended September 30, 2020: 25%).

As at September 30, 2021 and December 31, 2020, the Group has no outstanding foreign currency forward exchange contract. At present, the Group does not intend to seek to hedge its exposure to foreign exchange fluctuations. However, management constantly monitors the economic situation and the Group's foreign exchange risk profile and will consider appropriate hedging measures in the future should the need arise.

The following table demonstrates the sensitivity at the end of the reporting period to a reasonably possible change in the EUR and RMB exchange rate against US\$, with all other variables held constant, of the Group's loss before tax (due to changes in the fair values of monetary assets and liabilities).

	<u>Increase/ (decrease) in the rate of foreign currency</u> %	<u>Decrease/ (increase) in loss before tax</u> US\$'000 (Unaudited)
Nine months ended September 30, 2021		
If US\$ strengthens against RMB	5	193
If US\$ weakens against RMB	(5)	(193)
If US\$ strengthens against EUR	5	(1,087)
If US\$ weakens against EUR	(5)	1,087
Nine months ended September 30, 2020		
If US\$ strengthens against RMB	5	916
If US\$ weakens against RMB	(5)	(916)
If US\$ strengthens against EUR	5	(811)
If US\$ weakens against EUR	(5)	811

LEGEND BIOTECH CORPORATION
NOTES TO THE UNAUDITED INTERIM CONDENSED
CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

23. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES (CONTINUED)

Credit risk

The Group trades only with recognized and creditworthy third parties. It is the Group's policy that all customers who wish to trade on credit terms are subject to credit verification procedures. In addition, receivable balances are monitored on an ongoing basis and the Group's exposure to bad debts is not significant. For transactions that are not denominated in the functional currency of the relevant operating unit, the Group does not offer credit terms without the specific approval of the Head of Credit Control.

The credit risk of the Group's other financial assets, which comprise cash and cash equivalents, pledged deposits, time deposits, financial assets measured at amortized cost and other receivables, arises from default of the counterparty, with a maximum exposure equal to the carrying amounts of these instruments. Further quantitative data in respect of the Group's exposure to credit risk arising from trade receivables are disclosed in note 9 to the unaudited interim condensed consolidated financial statements.

Since the Group trades only with recognized and creditworthy third parties, there is no requirement for collateral. Concentrations of credit risk are managed by debtor. The Group had certain concentrations of credit risk with respect to trade receivables, which are disclosed in note 9 to the unaudited interim condensed consolidated financial statements.

Liquidity risk

The Group monitors its risk to a shortage of funds using a recurring liquidity planning tool. This tool considers the maturity of both its financial investments and financial assets (e.g., trade receivables and other financial assets) and projected cash flows from operations.

The maturity profile of the Group's financial liabilities as at the end of the reporting period, based on contractual undiscounted payments, is as follows:

As at September 30, 2021

	<u>Less than 1 year</u> <u>US\$'000</u> <u>(Unaudited)</u>	<u>Over 1 years</u> <u>US\$'000</u> <u>(Unaudited)</u>	<u>Total</u> <u>US\$'000</u> <u>(Unaudited)</u>
Trade and notes payables	11,593	—	11,593
Other payables and accruals	19,314	—	19,314
Warrant liability	119,100	—	119,100
Interest-bearing loans and borrowings	—	70,540	70,540
Lease liabilities	1,116	1,970	3,086
	<u>151,123</u>	<u>72,510</u>	<u>223,633</u>

As at December 31, 2020

	<u>Less than 1 year</u> <u>US\$'000</u>	<u>Over 1 years</u> <u>US\$'000</u>	<u>Total</u> <u>US\$'000</u>
Trade payables	5,238	—	5,238
Other payables and accruals	85,559	—	85,559
Lease liabilities	1,464	2,099	3,563
	<u>92,261</u>	<u>2,099</u>	<u>94,360</u>

LEGEND BIOTECH CORPORATION
NOTES TO THE UNAUDITED INTERIM CONDENSED
CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

23. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES (CONTINUED)

Capital management

The primary objectives of the Group's capital management are to safeguard the Group's ability to continue as a going concern and to maintain a strong credit rating and healthy capital ratios in order to support its business and maximise shareholders' value.

The Group manages its capital structure and makes adjustments to it in light of changes in economic conditions and the risk characteristics of the underlying assets. To maintain or adjust the capital structure, the Group may adjust the dividend payment to shareholders, return capital to shareholders or issue new shares. The Group is not subject to any externally imposed capital requirements. No changes were made in the objectives, policies or processes for managing capital during the reporting periods.

The Group monitors capital using a gearing ratio, which is total liabilities divided by total assets. The gearing ratios as at the end of each period were as follows:

	<u>September 30,</u> <u>2021</u> <u>US\$'000</u> <u>(Unaudited)</u>	<u>December 31,</u> <u>2020</u> <u>US\$'000</u>
Total liabilities	587,899	440,752
Total assets	813,765	721,007
Gearing ratio	<u>72%</u>	<u>61%</u>

24. APPROVAL OF THE INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

The interim condensed consolidated financial statements were approved and authorized for issue by the board of directors on December 14, 2021.

In this Management's Discussion and Analysis of Financial Condition and Results of Operations, unless otherwise indicated or the context otherwise requires, "we," "us," "our," the "Company" and "Legend Biotech" refer to Legend Biotech Corporation and its consolidated subsidiaries. References to "GenScript" refer to Genscript Biotech Corporation, our majority stockholder.

Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our interim condensed consolidated financial statements and the accompanying notes.

This Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of present and historical facts and conditions are forward-looking statements. Forward-looking statements can often be identified by words or phrases, such as "may," "will," "expect," "anticipate," "aim," "estimate," "intend," "plan," "believe," "is/are likely to," "potential," "continue" or other similar expressions. Such forward-looking statements reflect our current expectations and views of future events, but are not assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our financial needs, our operational results and other future conditions. These forward-looking statements involve various risks and uncertainties. Many important factors may adversely affect such forward-looking statements and cause actual results to differ from those in any forward-looking statement, including, without limitation, the severity and duration of the evolving COVID-19 pandemic and the resulting impact on macro-economic conditions; inconclusive clinical trial results or clinical trials failing to achieve one or more endpoints; early data not being repeated in ongoing or future clinical trials; failures to secure required regulatory approvals; disruptions from failures by third-parties on whom we rely in connection with our clinical trials; delays or negative determinations by regulatory authorities; changes or increases in oversight and regulation; increased competition; manufacturing delays or problems; inability to achieve enrollment targets; disagreements with our collaboration partners; legal challenges, including product liability claims or intellectual property disputes; commercialization factors, including regulatory approval and pricing determinations; disruptions to access to raw materials; delays or disruptions at manufacturing facilities; proliferation and continuous evolution of new technologies; dislocations in the capital markets; and other important factors described under "Risk Factors" in our Annual Report on Form 20-F filed with the Securities and Exchange Commission on April 2, 2021 (the "Annual Report") and under "Risk Factors" in any other reports that we file with the Securities and Exchange Commission. As a result of these factors, we cannot assure you that the forward-looking statements in this interim report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. In addition, even if our results of operations, financial condition and liquidity are consistent with the forward-looking statements contained in this Annual Report on Form 20-F, those results or developments may not be indicative of results or developments in subsequent periods.

Overview

We are a global, clinical-stage biopharmaceutical company engaged in the discovery and development of novel cell therapies for oncology and other indications. Our team of over 1,000 employees in the United States, China and Europe, our differentiated technology, global development and manufacturing strategy and expertise provide us with the ability to generate, test and manufacture next-generation cell therapies targeting indications with high unmet needs.

Our lead product candidate, ciltacabtagene autoleucel, or cilta-cel, is a CAR-T cell therapy we are jointly developing with our collaborator, Janssen Biotech, Inc., or Janssen, for the treatment of multiple myeloma, or MM. Clinical trial results achieved to date demonstrate that cilta-cel has the potential to deliver deep and durable anti-tumor responses in relapsed and refractory multiple myeloma, or RRMM, patients with a manageable safety profile.

In December 2017, we entered into a collaboration and license agreement with Janssen for the worldwide development and commercialization of cilta-cel. Pursuant to the Janssen Agreement, we granted Janssen a worldwide, co-exclusive (with us) license to develop and commercialize cilta-cel. We and Janssen will collaborate to develop and commercialize cilta-cel for the treatment of MM worldwide pursuant to a global development plan and global commercialization plan.

Janssen will be responsible for conducting all clinical trials worldwide with participation by our team in the United States and Greater China for cilta-cel. We will be responsible for conducting regulatory activities, obtaining pricing approval and booking sales for Greater China, while Janssen will be responsible for conducting regulatory activities, obtaining pricing approval and booking sales for the rest of the world. We and Janssen will share development, production and commercialization costs and pre-tax profits or losses equally in all countries of the world except for Greater China, for which the cost-sharing and profit/loss split will be 70% for us and 30% for Janssen.

In consideration for the licenses and other rights granted to Janssen, Janssen has paid us an upfront fee of US\$350.0 million and milestone payments totaling US\$185.0 million for the achievement of development milestone events through September 30, 2021. We have achieved an additional milestone, and received a US\$15.0 million milestone payment from Janssen in July 2021. Additionally, we are eligible to receive further milestone payments of up to US\$125.0 million for the achievement of specified manufacturing milestones and an additional US\$1,025.0 million for the achievement of specified future development, regulatory and net trade sales milestones.

Recent Business Developments

- In May 2021, a rolling submission of the Biologics License Application, or BLA, was accepted by the U.S. Food and Drug Administration, or FDA, for cilta-cel for the treatment of adults with RRMM, following the submission by Janssen. As part of the BLA acceptance, the FDA granted cilta-cel priority review and initially set the Prescription Drug User Fee Act, or PDUFA, target action date for November 29, 2021. The FDA has extended the PDUFA target date for cilta-cel by three months to February 28, 2022. The extension allows the FDA sufficient time to review information recently submitted pertaining to an updated analytical method following an FDA information request.
- In May 2021, the Marketing Authorisation Application, or MAA, submitted by Janssen was accepted by the European Medicines Agency, or EMA, for cilta-cel for the treatment of adults with RRMM. On December 13, 2021, we announced that the EMA Committee for Medicinal Products for Human Use, or CHMP, has reverted the MAA review begun under the accelerated assessment mechanism to a standard review timeline in order to allow EMA to conduct a good manufacturing practice inspection and provide a GMP certificate, which could not be accommodated in the timetable of an accelerated assessment. In addition, a submission for cilta-cel was made to the Brazilian Health Regulatory Agency by Janssen in April 2021.
- Longer term data from the CARTITUDE-1 trial of cilta-cel in 97 heavily pretreated patients with RRMM, which was presented at the 2021 ASCO and EHA Annual meetings, showed 98 percent overall response rate, 80 percent stringent complete response rate, or sCR, progression free survival rate of 66 percent and an overall survival, or OS, rate of 81 percent at the 18-month follow-up (data cutoff February 2021). Out of 61 minimal residual disease, or MRD, evaluable patients, 92 percent achieved MRD negativity status at 10-2 at a median of one month (range, 0.8-7.7 months) post infusion. The most common hematologic adverse events, or AEs, observed were neutropenia (96 percent); anemia (81 percent); thrombocytopenia (79 percent); leukopenia (62 percent); and lymphopenia (53 percent). Cytokine release syndrome, or CRS, of any grade was observed in 95 percent of patients, with a median duration of four days (range, 1-97), and median time to onset of seven days (range, 1-12). Of the 92 patients with CRS, 95 percent experienced Grade 1/2 events and CRS resolved in 91 patients (99 percent) within 14 days of onset. There was no new incidence of neurotoxicity; neurotoxicity of any grade was observed in 21 percent (n=20) of patients, with Grade 3 or higher neurotoxicity observed in 10 percent (n=10) of patients.
- First results from Cohort A of the CARTITUDE-2 study of cilta-cel in 20 patients with progressive MM after 1-3 prior lines of therapy, and who were lenalidomide refractory, which was featured at the 2021 ASCO and EHA Annual meetings, showed early and deep responses with a safety profile consistent with what has been observed in the CARTITUDE clinical development program. As of a January 2021 data cutoff, with a median follow-up of 5.8 months, overall response rate was achieved in 95% (19/20) of patients, which included stringent complete response

or complete response rate of 75%, very good partial response, or VGPR rate of 10% (VGPR or better, 85%) and partial response rate of 10%. The median time to first response was 1.0 month (range, 0.7–3.3) and the median time to best response was 1.9 months (range, 0.9–5.1). Median duration of response was not yet reached. All patients (n = 4) with minimal residual disease, or MRD, evaluable samples at the 10⁻⁵ cutoff threshold were MRD-negative at the cut-off date. With respect to safety profile, cytokine release syndrome, or CRS, occurred in 85% of patients, with 10% grade 3 or 4, and the median time to CRS onset was 7 days (range, 5–9), with a median duration of 3.5 days (range, 2–11). Neurotoxicity occurred in 20% (n=4) of patients, all of which were grade 1 or 2. The most common hematologic adverse events included neutropenia (95%; grade 3/4: 90%), thrombocytopenia (80%; grade 3/4: 35%), anemia (65%; grade 3/4: 40%), lymphopenia (60%; grade 3/4: 55%), and leukopenia (55%; all grade 3/4). One death occurred 100 days after infusion due to COVID-19 (assessed as treatment-related by investigator).

- On June 22, 2021, we announced the advancement of global manufacturing infrastructure in Belgium as part of a joint investment with Janssen, to expand global manufacturing capacity of innovative cellular therapies.
- On May 21, 2021, we completed the sale of 20,809,805 ordinary shares in a private placement at a purchase price of \$14.41625 per ordinary share (equivalent to \$28.8325 per American Depositary Share, or ADS) and the issuance of a warrant exercisable for up to an aggregate of 10,000,000 ordinary shares, exercisable for a two-year period at an exercise price of \$20.00 per ordinary share (equivalent to \$40.00 per ADS), in each case, pursuant to a subscription agreement dated May 13, 2021, with an institutional investor.
- In June 2021, the CARTITUDE clinical program expanded to include the initiation of the CARTITUDE-5 study, a Phase 3 randomized study evaluating cilta-cel in patients with newly diagnosed MM for whom autologous stem cell transplant, or ASCT, is not planned as an initial therapy. This study will evaluate bortezomib, lenalidomide and dexamethasone, or VRd, followed by cilta-cel versus VRd followed by lenalidomide and dexamethasone (Rd) maintenance therapy. CARTITUDE-5 is planned for the United States, Canada, the European Union, Australia, Israel, and Brazil.
- We expanded the ongoing Phase 2 CARTITUDE-2 study (NCT04133636) with the addition of two additional cohorts— Cohort E (high-risk NDMM, transplant not planned) and Cohort F (standard-risk NDMM).
- In September 2021, the Phase 1, open-label, multicenter clinical trial began in the United States for LB1901, an investigational autologous CD4-targeted CAR-T therapy for the treatment of adults with relapsed or refractory peripheral T-cell lymphoma or cutaneous T-cell lymphoma. The primary objectives of the trial are to characterize the safety and tolerability of LB1901 and determine the optimal dose.
- In October 2021, we and Janssen completed the enrollment of the Phase 3 CARTITUDE-4 trial, evaluating cilta-cel in patients with MM who have received 1-3 prior lines of therapy including a proteasome inhibitor and immunomodulatory agent and are refractory to lenalidomide. The purpose of this trial is to compare the efficacy of cilta-cel with standard therapy – either pomalidomide, bortezomib and dexamethasone, or PVD, or daratumumab, pomalidomide and dexamethasone, or DPd.
- On October 18, 2021, we hosted our first Research & Development Day in New York, sharing updates on our pipeline advancements, including expanded capabilities in cell therapy, and milestones in the cilta-cel clinical development program.
- On December 13, 2021, we announced new and updated results from the CARTITUDE clinical development program studying cilta-cel in the treatment of multiple myeloma, which were presented at the 63rd American Society of Hematology Annual Meeting and Exposition. In our Phase 1b/2 CARTITUDE-1 trial, longer-term results in 97 patients with RRMM continued to show a high overall response rate, or ORR, of 98 percent. After 21.7 months of follow-up, 83 percent of patients treated with cilta-cel achieved a stringent complete response, or sCR, which was higher than the 67 percent sCR rate reported at a median of approximately 1 year of follow up. Further, 95 percent of patients achieved a very good partial response, or VGPR, or better. Median progression-free survival, or PFS, and median overall survival, or OS, have not been reached, but the 2-year PFS rate was 61 percent and the 2-year OS rate was 74 percent. Of the 61 patients evaluable for minimal residual disease, or MRD, 92 percent were MRD-

negative at the 10-5 cutoff threshold. The two-year PFS rates in patients with sustained MRD negativity for at least 6 and 12 months were 91 percent and 100 percent, respectively. The longer-term data showed no new safety signals and there were no new events of cilta-cel-related neurotoxicity or movement and neurocognitive treatment emergent adverse events reported since the median approximate 1 year follow-up.

- On December 13, 2021, we also presented new results from our Phase 2 multicohort CARTITUDE-2 trial, which is evaluating cilta-cel safety and efficacy in various clinical settings for patients with multiple myeloma. Updated data from Cohort A of the trial examined the efficacy and safety of cilta-cel in 20 patients with progressive multiple myeloma after 1-3 prior lines of therapy and who are lenalidomide-refractory. At a longer median follow-up of 14.3 months, patients experienced early and deep responses with a manageable safety profile consistent with the CARTITUDE-1 trial. ORR was 95 percent, which included 85 percent of patients achieving CR or better and 90 percent achieving VGPR or better. The median time to first response was one month and the median time to best response was 2.6 months. The 6-month and 12-month PFS rates were 95 percent and 84 percent, respectively. The first data from Cohort B of the CARTITUDE-2 trial was also presented. Cohort B included 19 patients who were in early relapse after initial therapy that included a proteasome inhibitor, or PI, and immunomodulatory drug, or IMiD. Data showed early and deep responses with a manageable safety profile. At a median follow-up of 10.6 months, ORR was 95 percent, which included 79 percent of patients achieving CR or better and 90 percent of patients achieving VGPR or better. The median time to first response was one month and the median time to best response was 2.5 months. The 6-month and 12-month PFS rates were 90 percent and 84 percent, respectively. The safety profile seen in CARTITUDE-2 Cohorts A and B were consistent with data previously reported from CARTITUDE-1. CRS occurred in 95 percent of patients in Cohort A and 84 percent of patients in Cohort B, which were mostly grades 1/2 with median time to onset of 7 to 8 days and median duration of approximately 4 days.
- On December 13, 2021, we also presented new results from our Phase 2 multicohort CARTITUDE-2 trial, which is evaluating cilta-cel safety and efficacy in various clinical settings for patients with multiple myeloma. Updated data from Cohort A of the trial examined the efficacy and safety of cilta-cel in 20 patients with progressive multiple myeloma after 1-3 prior lines of therapy and who are lenalidomide-refractory. At a longer median follow-up of 14.3 months, patients experienced early and deep responses with a manageable safety profile consistent with the CARTITUDE-1 trial. ORR was 95 percent, which included 85 percent of patients achieving CR or better and 90 percent achieving VGPR or better. The median time to first response was one month and the median time to best response was 2.6 months. The 6-month and 12-month PFS rates were 95 percent and 84 percent, respectively. The first data from Cohort B of the CARTITUDE-2 trial was also presented. Cohort B included 19 patients who were in early relapse after initial therapy that included a proteasome inhibitor, or PI, and immunomodulatory drug, or IMiD. Data showed early and deep responses with a manageable safety profile. At a median follow-up of 10.6 months, ORR was 95 percent, which included 79 percent of patients achieving CR or better and 90 percent of patients achieving VGPR or better. The median time to first response was one month and the median time to best response was 2.5 months. The 6-month and 12-month PFS rates were 90 percent and 84 percent, respectively. The safety profile seen in CARTITUDE-2 Cohorts A and B were consistent with data previously reported from CARTITUDE-1. CRS occurred in 95 percent of patients in Cohort A and 84 percent of patients in Cohort B, which were mostly grades 1/2 with median time to onset of 7 to 8 days and median duration of approximately 4 days.

Impact of COVID-19 on Our Business

The COVID-19 situation is very fluid across the world where each country or the sites within a country could be impacted differently. For the nine months ended September 30, 2021, COVID-19 has had limited impact on our operations.

We are in the process of assessing the situation case by case as the pandemic evolves. In the United States, we implemented a work-from-home policy for all non-essential employees as well as segregation policies within essential personnel to minimize contact among personnel along with other precautions to minimize any potential impact. In light of vaccine rollouts and consistent with recommendations of U.S. health regulators, our Piscataway, New Jersey office re-opened in July 2021, and our Somerset, New Jersey office reopened during the third quarter of 2021, subject to a hybrid work schedule initially.

Following the guidance recently issued by FDA and EMA on conducting clinical trials in this uncertain period, we are working closely with investigators, putting patient's safety first, while working diligently to move the studies forward.

In China, the majority of IIT studies have resumed following a slow-down initiated by COVID-19 related work and local policy of quarantine after the Chinese New Year in 2020. Product manufacture and patient treatment have continued unabated.

Currently, we have not experienced any material impact to our material supply chain as a result of the global pandemic. We have established robust sourcing strategies for all necessary materials and do not expect any significant impact.

There are still uncertainties of COVID-19's future impact on our business, results of operations and financial condition, and the extent of the impact will depend on numerous evolving factors including, but not limited to: the magnitude and duration of COVID-19, the development and progress of distribution of COVID-19 vaccines and other medical treatments, the emergence and spread of variants of the disease, the speed of the anticipated recovery, and governmental and business reactions to the pandemic. If the situation materially deteriorates, our business, results of operations and financial condition could be materially and adversely affected. We will continue to monitor and assess the impact of the ongoing development of the pandemic on our financial position and operating results and respond accordingly.

Comparison of nine months ended September 30, 2021 and 2020

The following table summarizes our results of operations for the nine months ended September 30, 2021 and 2020:

	Nine Months Ended September 30,		Increase (Decrease)
	2021	2020	
(in thousands)			
Consolidated Statement of Operations Data:			
Revenue	\$ 50,797	\$ 34,893	\$ 15,904
Operating expenses:			
Research and development expenses	(226,843)	(165,226)	(61,617)
Administrative expenses	(29,797)	(13,976)	(15,821)
Selling and distribution expenses	(49,731)	(25,389)	(24,342)
Other income and gains	2,316	5,315	(2,999)
Other expenses	(6,918)	(1,331)	(5,587)
Fair value loss of warrant liability	(37,400)	—	(37,400)
Fair value loss of convertible redeemable preferred shares	—	(79,984)	79,984
Finance costs	(298)	(4,169)	3,871
Loss before tax	(297,874)	(249,867)	(48,007)
Income tax (expense)/credit	(1)	4,217	(4,218)
Loss for the period	<u>\$(297,875)</u>	<u>\$(245,650)</u>	<u>\$(52,225)</u>

Revenue

Revenue for the nine months ended September 30, 2021 was US\$50.8 million compared to US\$34.9 million for the nine months ended September 30, 2020. US\$12.9 million out of the increase of US\$15.9 million was due to two additional milestones achieved pursuant to our agreement with Janssen in the fourth quarter of 2020 and in the second quarter of 2021. The remaining \$3.0 million increase in revenue was consideration for the exclusive licensing of patents.

Milestone payments are constrained and only included as customer consideration for revenue recognition when it is highly probable that the associated milestone will be achieved, typically when the triggering event occurs. This resulted in a larger amount of revenue recognized in 2021.

We have not generated any revenue from product sales to date.

Operating Expenses

Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2021 was US\$226.8 million compared to US\$165.2 million for the nine months ended September 30, 2020. This increase of US\$61.6 million was primarily due to continuous research and development activities in cilta-cel and toward other pipeline advancements.

Administrative Expenses

Administrative expenses for the nine months ended September 30, 2021 were US\$29.8 million compared to US\$14.0 million for the nine months ended September 30, 2020. The increase of US\$15.8 million was primarily due to our expansion of supporting administrative functions to facilitate continuous research and development activities as well as activities to establish elements of a commercialization infrastructure.

Selling and Distribution Expenses

Selling and distribution expenses for the nine months ended September 30, 2021 were US\$49.7 million compared to US\$25.4 million for the nine months ended September 30, 2020. This increase of US\$24.3 million was primarily due to increased costs associated with commercial preparation activities for cilta-cel.

Other Income and Gains

Other income and gains for the nine months ended September 30, 2021 was US\$2.3 million compared to US\$5.3 million for the nine months ended September 30, 2020. The decrease of US\$3.0 million was primarily because of lower government grant and interest income earned during the nine months ended September 30, 2021, as compared to the corresponding prior year period.

Other Expenses

Other expenses for the nine months ended September 30, 2021 was US\$6.9 million compared to US\$1.3 million for the nine months ended September 30, 2020. The increase of US\$5.6 million was primarily due to higher foreign currency exchange loss, loss from disposal of assets and other expenses during the nine months ended September 30, 2021.

Fair Value Loss of Warrant Liability

Fair value loss of warrant liability for the nine months ended September 30, 2021 was caused by changes of fair value of a warrant, which was issued to an institutional investor through a private placement in May 2021. Concurrently ordinary shares were offered and sold to the same institutional investor through the same private placement. The warrant was assessed as a financial liability with a fair value of US\$119.1 million as of September 30, 2021 and a fair value loss of US\$37.4 million was recorded for the nine months ended September 30, 2021.

Fair Value Loss of Convertible Redeemable Preferred Shares

For the nine months ended September 30, 2020, we reported a one-time non-cash charge of US\$80.0 million caused by changes of fair value of Series A convertible redeemable preferred shares (Series A Preferred Shares). Upon listing on the Nasdaq Global Market, all outstanding Series A Preferred Shares were converted into our ordinary shares and all accrued but unpaid dividends were settled in the form of our ordinary shares.

Finance Costs

Finance costs for the nine months ended September 30, 2021 was US\$0.3 million compared to US\$4.2 million for the nine months ended September 30, 2020. The decrease was primarily due to finance costs related to the issuance of convertible redeemable preferred shares in 2020, which were fully converted into ordinary shares upon the completion of our initial public offering in June 2020.

Income Tax (Expense)/Credit

Income tax expense was US\$4.2 million of income tax credit for the nine months ended September 30, 2020. In 2020, the Company recognized a tax benefit for tax losses which was eligible to be carried back against prior year tax profit. There is no anticipated tax refund in 2021.

Liquidity and Capital Resources

Sources of Liquidity

To date, our operations have focused on organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and conducting preclinical studies and clinical trials. Since our inception, we have incurred significant operating losses.

To date, we have funded our operations primarily with capital contributions from GenScript, with proceeds from the sale of our Series A Preference Shares in March and April 2020, from upfront and milestone payments from Janssen, with the proceeds of our Initial Public Offering, or IPO, in June 2020, and with the proceeds from our private placement, or PIPE Offering, in May 2021.

During the nine months ended September 30, 2021, we have received US\$300.0 million from issuance of ordinary shares and warrant to an institutional investor. As of September 30, 2021, we had US\$556.0 million in cash, cash equivalents and time deposits. Other than US\$70.5 million of advance funding payable to a collaborator pursuant to the license and collaboration agreement, we had no indebtedness as of September 30, 2021.

Certain of our subsidiaries, including those registered as wholly foreign-owned enterprises in China, are required to set aside at least 10.0% of their after-tax profits to their general reserves until such reserves reach 50.0% of their registered capital. Under PRC regulations, foreign-invested enterprises may pay dividends only out of their accumulated profit, if any, as determined in accordance with PRC accounting standards and regulations. A PRC company is not permitted to distribute any profits until any losses from prior fiscal years have been offset. Profits retained from prior fiscal years may be distributed together with distributable profits from the current fiscal year. Although we do not currently require any such dividends from our PRC subsidiaries to fund our operations, should we require additional sources of liquidity in the future, such restrictions may have a material adverse effect on our liquidity and capital resources. For more information, see “Item 4.B-Business Overview—Government Regulation—PRC Regulation—Other PRC National- and Provincial-Level Laws and Regulations—Regulations Relating to Dividend Distributions” in our Annual Report.

Cash Flows

The following table shows a summary of our cash flow:

	Nine months ended September 30,	
	2021	2020
	(in thousands)	
Net cash used in operating activities	\$ (128,918)	\$ (167,053)
Net cash used in investing activities	(291,495)	(85,334)
Net cash from financing activities	303,102	618,218
Net (decrease)/increase in cash and cash equivalents	<u>\$ (117,311)</u>	<u>\$ 365,831</u>

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2021 was US\$128.9 million, primarily as a result of net loss before tax of US\$232.1 million after adjusting for non-cash items, and changes in operating assets and liabilities. Non-cash items mainly include \$37.4 million of fair value loss of warrant liability and US\$15.0 million of equity-settled share-based compensation expense. Changes in operating assets and liabilities mainly include a decrease in trade receivables of US\$73.5 million, which resulted from receipt of a milestone payment of US\$75.0 million and partially offset by an increase in trade receivables of US\$1.5 million due to transfer of license of patents; an increase of US\$63.8 million in other payables and accruals mainly due to an increase in collaboration expenses payable ; and offset by a decrease of US\$37.1 million in contract liabilities.

Net cash used in operating activities for the nine months ended September 30, 2020 was US\$167.1 million, primarily as a result of net loss before tax of US\$157.2 million after adjusting for non-cash items, and changes in operating assets and liabilities. Non-cash items are mainly from US\$80.0 million of fair value loss of convertible redeemable preferred shares. Changes in operating assets and liabilities mainly include a decrease of US\$31.6 million in contract liabilities, partially offset by a decrease in trade receivables of US\$30.0 million due to receipt of a milestone payment.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2021 was US\$291.5 million, consisting primarily of purchases of property, plant and equipment of US\$40.4 million, purchase of intangible assets of US\$3.6 million, purchase of financial assets at fair value through profit or loss of US\$50.0 million, purchase of financial assets measured at amortized cost of US\$29.8 million and purchases of time deposits of US\$267.7 million, partially offset by a decrease in time deposits of US\$100.0 million.

Net cash used in investing activities for the nine months ended September 30, 2020 was US\$85.3 million, consisting primarily of US\$33.3 million in purchases of property, plant and equipment and US\$50.0 in purchase of time deposits.

Financing Activities

Net cash from financing activities for the nine months ended September 30, 2021 was US\$303.1 million, consisting primarily of proceeds from issuance of ordinary shares and warrant to an institutional investor of US\$300.0 million in May and proceeds from exercise of share option of US\$4.1 million, partially offset by principal portion of lease payments of US\$1.0 million.

Net cash from financing activities for the nine months ended September 30, 2020 was US\$618.2 million, consisting primarily of proceeds of US\$150.5 million and US\$10.0 million from sale of Series A Preference Shares in March and April 2020 and IPO net proceeds of US\$450.1 million, partially offset by principal portion of lease payments of US\$1.8 million.

Capital Expenditure

Our capital expenditures for the nine months ended September 30, 2021 and 2020 amounted to US\$44.0 million and US\$34.0 million, respectively. These expenditures primarily consisted of property, plant, equipment and intangible assets.

Funding Requirements

We expect to incur significant expenses and operating losses for the foreseeable future as we advance the preclinical and clinical development of our research programs and product candidates, particularly as we continue the research and development of, continue or initiate clinical trials of, and seek marketing approval for, our product candidates. In particular, we expect that our research and development and general and administrative expenses will increase in connection with conducting additional clinical trials and preclinical studies for our current and future research programs and product candidates, contracting with external contract manufacturing organizations, or CMOs, to support clinical trials and preclinical studies, expanding our intellectual property portfolio, and providing general and administrative support for our operations. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to program sales, marketing, manufacturing and distribution to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of potential collaborators. Furthermore, we expect to incur additional costs associated with operating as a public company.

We do not currently have any approved products and have never generated any revenue from product sales.

Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements or other sources. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

Although consequences of the COVID-19 pandemic and resulting economic uncertainty could adversely affect our liquidity and capital resources in the future, and cash requirements may fluctuate based on the timing and extent of many factors such as those discussed below, we currently expect our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months.

Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of product discovery, preclinical studies and clinical trials;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under the Janssen Agreement and any other collaboration agreements we enter into;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under collaboration agreements, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of securing manufacturing arrangements for commercial production; and
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our product candidates.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of product candidates that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, holders of our ADSs will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our shareholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market that we would otherwise prefer to develop and market ourselves.

Quantitative and Qualitative Disclosures About Market Risk

For quantitative and qualitative disclosures about market risk that affect us, see “Quantitative and Qualitative Disclosures About Market Risk” in Item 11 of Part I of our Annual Report. There have been no material changes in from the end of the preceding year until September 30, 2021.

Off-balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements.

RISK FACTORS

The following risk factors should be read in conjunction with, and amend and supplement, those included in the Annual Report on Form 20-F filed by Legend Biotech Corporation (“we”, “our”, “us” or the “Company”) on April 2, 2021 (the “Form 20-F”). Investing in the Company’s American Depositary Shares representing its ordinary shares (“ADSs”) and its ordinary shares involves a high degree of risk. You should carefully consider the risks described below, and all other information contained in or incorporated by reference in the Form 20-F, before making an investment decision regarding the Company’s securities.

Risks Related to Our Business

We are or may become subject to a variety of privacy and data security laws, policies and contractual obligations, and our failure or failure of our third-party vendors, collaborators, contractors or consultants to comply with existing or future laws and regulations related to privacy or data security could lead to government enforcement actions, which could include civil or criminal fines or penalties, private litigation, other liabilities, and/or adverse publicity. Compliance or the failure to comply with such laws could increase the costs, could limit their use or adoption, and could otherwise negatively affect our operating results and business.

We maintain and process, and our third-party vendors, collaborators, contractors and consultants maintain and process on our behalf, sensitive information, including confidential business and personal information, including but not limited to health information in connection with our preclinical and clinical studies and our employees, and are subject to laws and regulations governing the privacy and security of such information. Failure by us, our third-party vendors, collaborators, contractors and consultants to comply with any of these laws and regulations could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

Regulatory authorities in China have implemented and are considering a number of legislative and regulatory proposals concerning data protection. On March 17, 2018, the General Office of the PRC State Council promulgated the Measures for the Management of Scientific Data (the Scientific Data Measures) which provide a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, any scientific data involving state secret, state security, social public interests, commercial secret or personal privacy may not be open and shared; where openness is indeed needed, the purpose, user’s qualification, conditions of confidentiality and other factors shall be reviewed, and the informing scope shall be strictly controlled. Further, any researcher conducting research funded, at least in part, by the PRC government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. China’s Cyber Security Law, which became effective in June 2017, created China’s national-level data protection for “network operators,” which may include all organizations in China that provide services over the internet or another information network. Numerous regulations, guidelines and other measures are expected to be adopted under the umbrella of the Cyber Security Law. Furthermore, the Opinions on Strictly Cracking Down on Illegal Securities Activities, which was issued by the General Office of the State Council and another authority on July 6, 2021, requires the speed-up of the revision of the provisions on strengthening the confidentiality and archives management related to overseas issuance and listing of securities, and improvement to the laws and regulations related to data security, cross-border data flow, and management of confidential information. China’s Data Security Laws, which was promulgated by the Standing Committee of PRC National People’s Congress, or the SCNPC, on June 10, 2021 and became effective on September 1, 2021, outlines the main system framework of data security protection. The Personal Information Protection Law promulgated by the SCNPC on August 20, 2021 and became effective on November 1, 2021, which outlines the main system framework of personal information protection and processing. Drafts of some of these measures have now been published, including the draft rules on the Measures for the Security Assessment of Personal Information and Important Data to be Transmitted Abroad published by the Cyberspace Administration of China, or the CAC, in 2017, which may, upon enactment, require security review before transferring human health-related data out of China. In addition, the draft amendment to the Measures for Cyber Security Review, or the Draft Measures, was published by the CAC on July 10, 2021 and was issued for soliciting public comment until July 25, 2021. Comparing with the current Measures for Cyber Security Review, the changes under the Draft Measures include without limitation the following aspects: (i) “data processing operators” are incorporated into the regulatory scope; (ii) the China Securities Regulatory Commission, or the CSRC, is included as one of the authorities for jointly establishing the state cyber security review working mechanism; (iii) an application for cyber security review must be made by an issuer who is a “critical information infrastructure operator” or a “data processing operator” as defined therein (each an “operator” as defined under the Draft Measures) before such issuer’s securities become listed in a foreign country if such issuer possesses personal information of more than 1 million users, (iv) the operators’ purchase of network products and services that affect or may affect national security will be subject to the

cybersecurity review, and (v) the risk of core data, material data or large volume of personal information being stolen, leaked, damaged, illegally used or cross-border transmitted and the risk of critical information infrastructure, core data, material data or large volume of personal information being influenced, controlled or used out of malevolence by the government of foreign country after relevant operators' securities being listed on a stock exchange of a foreign country shall be considered as one of the factors for evaluating the national security risks that may be brought by procurement activities, data processing activities and overseas listing. Regulations on the Security Protection of Critical Information Infrastructure, which was promulgated by the State Council of the PRC on July 30, 2021 and became effective on September 1, 2021, or the CII Protection Regulations, stipulates the obligations and liabilities of the regulators, society and critical information infrastructure operators, or the CIIOs, in protecting the security of critical information infrastructure, or the CII. According to the CII Protection Regulations, regulators supervising specific industries shall formulate detailed guidance to recognize the CII in the respective sectors, and CIIOs shall take the responsibility to protect the CII's security by performing certain prescribed obligations. For example, CIIOs are required to conduct network security test and risk assessment, report the assessment results to relevant regulatory authorities, and timely rectify the issues identified at least once a year. The draft Regulations for the Administration of Cyber Data Security, or the Draft Data Security Regulations, published by the CAC on November 14, 2021 for public comments until December 13, 2021 reiterates that a data processor who processes personal information of more than 1 million individuals shall go through the cyber security review if it intends to be listed in a foreign country, and if a data processor conducts any data processing activities that affect or may affect national security, an application for cyber security review shall also be made by such processor. And the Draft Data Security Regulations require data processors processing important data or being listed outside China shall carry out data security assessment annually by itself or through a third party data security service provider and submit assessment report to local agency of the CAC. The Draft Data Security Regulations provide a broad definition of data processing activities, including collection, storage, usage, processing, transfer, provision, publication, deletion and other activities, and the Draft Data Security Regulations also provide a broad definition of data processor as individuals and entities which autonomously determine the purpose and method during data processing activities. However, the Draft Data Security Regulations provide no further elaboration on what constitutes a situation that "affects or may affect national security" and are subject to further changes before being formally adopted and coming into effect.

As of the date of this prospectus supplement, no detailed rules or implementation of the Draft Measures or the Draft Data Security Regulations have been issued by the CAC, and the PRC governmental authorities may have wide discretion in the interpretation and enforcement of these laws and regulations. It also remains uncertain whether the future regulatory changes would impose additional restrictions on companies like us. We cannot predict the impact of the Draft Measures and/or the Draft Data Security Regulations, if any, at this stage, and we will closely monitor and assess any development in the rulemaking process. If the enacted version of the Draft Measures and/or the Draft Data Security Regulations requires any clearance of cybersecurity review and other specific actions to be completed by companies like us, we face uncertainties as to whether such clearance can be timely obtained, or at all. If we are not able to comply with the cybersecurity and data privacy requirements in a timely manner, or at all, we may be subject to government enforcement actions and investigations, fines, penalties, or suspension of our non-compliant operations, among other sanctions, which could materially and adversely affect our business and results of operations. We have been making constant efforts to comply with the relevant data protection laws and regulations in the PRC and will endeavor to comply with any update in the applicable laws, regulations or guidelines as issued by any relevant regulatory authorities in the PRC. However, we cannot assure you that we are able to comply with any applicable privacy and data security laws, regulations and guidelines in a timely manner, or at all.

In addition, certain industry-specific laws and regulations affect the collection and transfer of personal data in China. For example, the PRC State Council promulgated Regulations on the Administration of Human Genetic Resources (effective in July 2019), which require approval/filing from the Science and Technology Administration Department of the PRC State Council where human genetic resources are involved in any international collaborative project and additional approval, filing and backup for any export or cross-border transfer of the human genetic resources samples or associated data or for providing/offering access of the information on human genetic resources to foreign entities and the institutions established or actually controlled thereby. We cannot assure you that we have complied or will be able to comply with all applicable human genetic resources related regulations. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices, potentially resulting in confiscation of human genetic resources samples and associated data and administrative fines. As there are still uncertainties regarding the further enactment of new laws and regulations as well as the revision, interpretation and implementation of those existing laws and regulations, we cannot assure you that we will be able to comply with such regulations in all respects, and we may be ordered to make rectification and terminate any actions that are deemed illegal by the regulatory authorities and become subject to fines and/or other sanctions. As a result, we may be required to suspend our related businesses or face other penalties which may have material adverse effect on our business, operations and financial condition.

In May 2018, a new privacy regime, the General Data Protection Regulation, or the GDPR, took effect in the European Economic Area, or the EEA, into which we may expand our business. The GDPR governs the collection, use, disclosure, transfer or other processing of personal data of European persons. Among other things, the GDPR imposes requirements regarding the security of personal data and notification of data processing obligations to the competent national data processing authorities, changes the lawful bases on which personal data can be processed, expands the definition of personal data and requires changes to informed consent practices, as well as more detailed notices for clinical trial subjects and investigators. In addition, the GDPR increases the scrutiny of transfers of personal data from clinical trial sites located in the EEA to the United States and other jurisdictions that the European Commission does not recognize as having “adequate” data protection laws, and imposes substantial fines for breaches and violations (up to the greater of €20 million or 4% of our consolidated annual worldwide gross revenue). The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR. Further, while the United Kingdom enacted the Data Protection Act 2018 in May 2018 that supplements the GDPR and has publicly announced that it will continue to regulate the protection of personal data in the same way post-Brexit, Brexit has created uncertainty with regard to the future of regulation of data protection in the United Kingdom. Some countries also are considering or have passed legislation requiring local storage and processing of data, or similar requirements, which could increase the cost and complexity of delivering our products and services.

In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws, and federal and state consumer protection laws. Each of these constantly evolving laws can be subject to varying interpretations. For example, regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996, or HIPAA, establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. The U.S. Department of Health and Human Services, or HHS, has the discretion to impose penalties without attempting to first resolve violations. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources.

In addition, states are constantly adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements. For example, California enacted the California Consumer Privacy Act, or the CCPA, on June 28, 2018, which took effect on January 1, 2020 and has been dubbed the first “GDPR-like” law in the United States. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined and can include any of our current or future employees who may be California residents) and provide such residents new ways to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. As we expand our operations and trials (both preclinical or clinical), the CCPA may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States. Other states are beginning to pass similar laws.

Many statutory requirements, both in the United States and abroad, include obligations for companies to notify individuals of security breaches involving certain personal information, which could result from breaches experienced by us or our third-party service providers. For example, laws in all 50 U.S. states and the District of Columbia require businesses to provide notice to consumers whose personal information has been disclosed as a result of a data breach. These laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. Moreover, states have been frequently amending existing laws, requiring attention to changing regulatory requirements. We also may be contractually required to notify customers or other counterparties of a security breach. Any contractual protections we may have from our third-party service providers, contractors or consultants may not be sufficient to adequately protect us from any such liabilities and losses, and we may be unable to enforce any such contractual protections.

We expect that there will continue to be new proposed laws and regulations concerning data privacy and security, and we cannot yet determine the impact such future laws, regulations and standards may have on our business. New laws, amendments to or re-interpretations of existing laws, regulations, standards and other obligations may require us to incur additional costs and restrict our business operations. Because the interpretation and application of health-related and data protection laws, regulations, standards and other obligations are still uncertain, and often contradictory and in flux, it is possible that the scope and requirements of these laws may be interpreted and applied in a manner that is inconsistent with our practices and our efforts to comply with the evolving data protection rules may be unsuccessful. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy regulations may differ from country to country, and may vary based on whether testing is performed in the United States or in the local country and our operations or business practices may not comply with these regulations in each country.

Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. If we or our third-party vendors, collaborators, contractors and consultants fail to comply with any such laws or regulations, we may face regulatory investigations, significant fines and penalties, reputational damage or be required to change our business practices, all of which could adversely affect our business, financial condition and results of operations.

Risks Related to Doing Business in China

The approval of the China Securities Regulatory Commission or other governmental authority may be required.

On August 8, 2006, six PRC regulatory agencies, including the China Securities Regulatory Commission, or the CSRC, promulgated the Provisions on the Merger or Acquisition of Domestic Enterprises by Foreign Investors, or the M&A Rules, which became effective on September 8, 2006 and was amended on June 22, 2009. The M&A Rules, among other things, requires offshore SPVs formed for the purpose of an overseas listing and controlled by PRC companies or individuals, to obtain the CSRC approval prior to listing their securities on an overseas stock exchange. The application of this regulation remains unclear. Our PRC legal counsel has advised us that, based on their understanding of the current PRC laws, the CSRC approval was not required under the M&A Rules in the context of our initial public offering because the ownership structure of our PRC subsidiaries was established by direct investment instead of through acquisition of equity interests or assets of any PRC domestic company by foreign entities as defined under the M&A Rules.

However, we have been advised by our PRC legal counsel that there are uncertainties regarding the interpretation and application of the PRC laws and regulations, and there can be no assurance that the PRC government will ultimately take a view that is not contrary to the above opinion of our PRC legal counsel. Furthermore, the recently issued Opinions on Strictly Cracking Down on Illegal Securities Activities emphasized the need to strengthen the supervision on overseas listings by China-based companies and provided that the special provisions of the State Council on overseas issuance and listing of shares by those companies limited by shares will be revised. There are still uncertainties regarding the interpretation and implementation of these Opinions, and further explanations or detailed rules and regulations with respect to these Opinions may be issued in the future which could impose additional requirements on us.

In addition, the draft amendment to the Measures for Cyber Security Review published by the CAC on July 10, 2021 provides that an application for cyber security review must be made by an issuer who is a “critical information infrastructure operator” or a “data processing operator” as defined therein before such issuer’s securities become listed in a foreign country if such issuer possesses personal information of more than 1 million users, and that the relevant governmental authorities in the PRC may initiate cyber security review if such governmental authorities determine an operator’s cyber products or services, data processing or listing in a foreign country affect or may affect national security. The draft Regulations for the Administration of Cyber Data Security, published by the CAC on November 14, 2021 for public comments, reiterates that a data processor who processes personal information of more than 1 million individuals shall go through the cyber security review if it intends to be listed in a foreign country, and if an issuer conducts any data processing activities that affect or may affect national security, an application for cyber security review shall also be made by such processor.

We may be adversely affected by an ongoing investigation involving our majority shareholder and our former chief executive officer and Chairman. Although we and Genscript have conducted targeted internal reviews relating to the investigation, Genscript has not conducted a comprehensive internal review of all transactions it handled on behalf of us prior to our initial public offering, and there can be no assurance that the investigation will not involve us or that the Authority or other governmental authority will not pursue criminal or civil remedies against us or our directors, officers or employees in the future, including sanctions, monetary penalties and regulatory actions, which could adversely affect us.

Our majority shareholder, Genscript, and Dr. Fangliang Zhang, our former chairman and chief executive officer, and the former chairman and chief executive officer of Genscript, are currently under investigation by the Customs Anti-Smuggling Department of Zhenjiang, or the Authority, in the PRC. The Authority’s inspection included places of business in Nanjing and Zhenjiang, China, of Genscript, and certain of its subsidiaries, including our location in Nanjing. The inspections are in connection with what we believe to be an investigation relating to suspected violations of import and export regulations under the laws of the PRC, which has, to date, focused on Genscript’s import and export activity preceding our initial public offering in June 2020, at which time we were a subsidiary of Genscript and Dr. Zhang was chairman and chief executive officer of Genscript. Following a period of residential

surveillance and arrest by PRC law enforcement, Dr. Zhang was released on bail by the Authority on February 9, 2021. Two Genscript employees had also been placed under arrest. Five of our employees have been questioned by the PRC authorities about their prior roles at Genscript. One of these five employees, who was previously a Genscript employee, was briefly detained and this employee is currently released on bail. In May 2021, Dr. Zhang and the four employees of Genscript, along with two PRC subsidiaries of Genscript, were notified by the Authority that the investigation was complete, and that their respective matter had been handed over to the Zhenjiang Municipal People's Procuratorate, or the Procuratorate, for examination and possible prosecution. In July 2021, the Procuratorate returned the case to the Authority for supplementary investigation. As of the date of this prospectus supplement, the supplementary investigation is completed and the Authority has handed the case back to the Procuratorate. Whether or when the Procuratorate will pursue pressing any charges against GenScript, Dr. Zhang or Genscript employees remains undecided. To the best of our knowledge, no charges have been filed to date against Dr. Zhang, Genscript or us and the Authority has not notified us that we are a target of the Authority's investigation.

The Audit Committee of our Board of Directors engaged external counsel to conduct an internal review of our import and export transactions. The review identified no apparent issues with respect to transactions conducted since our initial public offering in June 2020. However, transactions prior to July 2020 were handled by Genscript on our behalf, which limits our ability to review such transactions. While Genscript, with the assistance of its external counsel, conducted a targeted review based on feedback from its communications with the Authority, it has not conducted a comprehensive internal review of all transactions it handled on behalf of us prior to our initial public offering. Accordingly, our ability to ascertain the risk of our exposure to the Authority's investigation is limited and there is a risk that we may become a subject of the Authority's investigation, and thereafter subject to proceedings, penalties and restrictions on our activities, which could adversely affect us.

While no charges have been filed against us or any of our officers or directors, and we understand that we are not a target of the Authority's investigation at this time, we believe that the investigation has had an adverse impact on the price of our ADSs and ordinary shares, and could continue to have such an adverse impact, particularly if charges are brought against Genscript or Dr. Zhang, if PRC authorities seek to impose restrictions on Genscript's or our activities, or if the Authority decides to investigate us, our officers, employees or directors in the context of its investigation of Genscript and Dr. Zhang or otherwise, or if any of our or Genscript's executive officers are subjected to residential surveillance, detention, arrest, charges or imprisonment. As of October 31, 2021, (i) Dr. Zhang directly owns 14.5% of the issued and outstanding ordinary shares of Genscript, plus 1.4% of ordinary shares of Genscript through his trust, (ii) Genscript, in turn, beneficially owns 58.4% of our ordinary shares, and (iii) two out of six of the members of our board of directors are employees of Genscript.

Furthermore, despite the fact that Dr. Zhang is no longer one of our executive officers or directors, Dr. Zhang may still be able to influence us and/or Genscript, and such influence, or the perception that Dr. Zhang exerts such influence over us and/or Genscript, may lead to further investigations by the Authority or other governmental authorities, and have an adverse impact on the price of our ADSs and ordinary shares. In each situation, our management's attention may be diverted, management of our operations could be adversely affected, significant expenses could be incurred, our reputation and ability to raise capital in the future may be harmed, and there could be a material adverse effect on our business, financial condition, results of operations, and prospects, especially if there is an adverse outcome.

Additionally, any investigation could damage our reputation or cause our existing collaboration partner, Janssen, and other third parties to terminate existing agreements and potential partners to seek other partners, any of which could impact our results of operations. Separately, Genscript has conveyed that in the course of the Authority's inspection of Genscript, the Authority has also identified nine imports, which Genscript handled on behalf of the Company prior to the IPO, in respect of which there may be minor non-compliance issues concerning import declarations, which are distinct from the matters that have been the focus of the Authority's investigation. Genscript has informed us that it believes that Genscript is the target of the Authority's inquiries with respect to these import declaration matters, and the Authority has not contacted us with respect to such import declaration matters.

Our business may be significantly affected by the newly enacted Foreign Investment Law and the "negative list."

On March 15, 2019, the PRC's National People's Congress promulgated the Foreign Investment Law, which took effect on January 1, 2020 and replaced three existing laws regulating foreign investment in China, namely, the PRC Equity Joint Venture Law, the PRC Cooperative Joint Venture Law and the Wholly Foreign owned Enterprise Law, together with their implementation rules and ancillary regulations. The Foreign Investment Law grants foreign invested entities the same treatment as PRC domestic entities, except for those foreign invested entities that operate in industries deemed to be either "restricted" or "prohibited" in the "negative list" published by the State Council. We are a Cayman Islands company and our PRC subsidiaries, Nanjing Legend Biotech Co., Ltd., or Legend Nanjing, and Hainan Chuanji Biotech Co., Ltd., or Legend Hainan, are currently considered to be foreign invested entities. Legend Hainan was established in October, 2021. As of the date of this prospectus supplement, Legend Hainan is not engaged in substantive business operations in the PRC.

The latest version of the “negative list,” namely, the Special Management Measures (Negative List) for the Access of Foreign Investment (2020), which was promulgated by the Ministry of Commerce (“MOFCOM”) and the National Development and Reform Commission (“NDRC”) and became effective on July 23, 2020, provides that foreign investment is prohibited in the development and application of human stem cell or gene diagnostic and therapeutic technologies. As of the date of this prospectus supplement, there has been no official interpretation of the scope of “human stem cell or gene diagnostic and therapeutic technologies” specified in the Negative List and the application of this regulation remains unclear. The Encouraged Industry Catalogue for Foreign Investment (2020), or the 2020 Encouraged Industry Catalogue, which was promulgated by the MOFCOM and the NDRC and became effective on January 27, 2021, provides that foreign investment is encouraged in the development and production of cell therapy drugs except in areas where foreign investment is prohibited. Besides, the Technical Guidelines for Clinical Trials of Immune cell Therapy Products (Trial), or Technical Guidelines for Clinical Trials, which was published by the Center for Drug Evaluation of National Medical Products Administration, or the CDE, on February 10, 2021, provides that CAR-T, as a kind of immune cell therapy products, has the nature of gene therapy products. The Technical Guidelines for Clinical Trials was issued for sponsors’ references, and is not compulsory or to identify the regulatory nature or classification of immune cell therapy products, and is subject to modifications and improvements from time to time. On December 3, 2021, the CDE published the Technical Guidelines for Non-clinical Research and Evaluation of Gene Therapy Products (Trial) (“Technical Guidelines for Gene Therapy Products”) and Technical Guidelines for Non-clinical Research of Gene Modified Cell Therapy Products (Trial) (“Technical Guidelines for Gene Modified Cell Therapy Products”), which became effective as of the date of promulgation. The Technical Guidelines for Gene Therapy Products provides that it is applicable to gene therapy products other than genetically modified cells therapy products, and genetically modified cells therapy products, such as CAR-T cell therapy products, shall refer to the Technical Guidelines for Gene Modified Cell Therapy Products, which was formulated according to the Technical Guidelines for the Research and Evaluation of Cell Therapy Products (Trial).

Legend Nanjing is engaged in the research and development of CAR-T cell therapies. We believe the CAR-T cell therapies, as they are currently being researched and developed by Legend Nanjing, do not involve the use of human stem cells or genetic diagnosis and treatment, and as such should not fall into the category of “human stem cell or gene diagnostic and therapeutic technologies” under the negative list. Moreover, relevant governmental authorities also confirmed the research and development of CAR-T cell therapies currently engaged in by Legend Nanjing complies with the requirements of foreign investment industrial policies. We have been advised by our PRC legal counsel, JunHe LLP, that Legend Nanjing has complied with PRC laws and regulations in all material respects for, and obtained all material governmental approvals and permits from PRC regulatory agencies for, the research and development of CAR-T cell therapies. However, we have been advised by our PRC legal counsel that there are uncertainties regarding the interpretation and application of the PRC laws and regulations, and there can be no assurance that the PRC government will ultimately take a view that is not contrary to our view and the opinion of our PRC legal counsel above. If our CAR-T cell therapies or other technologies that are being researched and developed by Legend Nanjing are deemed by relevant PRC regulatory agencies as falling into the category of “human stem cell or gene diagnostic and therapeutic technologies” under the negative list, Legend Nanjing would be prohibited from engaging in the research or development of such CAR-T cell therapies or other technologies. In that event, we may have to stop investing in Legend Nanjing or consider restructuring Legend Nanjing as a PRC domestic entity and our variable interest entity. Legend Nanjing may also have to forfeit its income derived from the research and development of such technologies. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

Failure to comply with PRC regulations regarding the registration or filing requirements for employee stock ownership plans or share option plans may subject the plan participants or us to fines and other legal or administrative sanctions.

Under the applicable regulations and SAFE rules, PRC citizens who participate in an employee stock ownership plan or a stock option plan in an overseas publicly listed company are required to register with SAFE and complete certain other procedures. In February 2012, SAFE promulgated the Notices on Issues concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies, or the Stock Option Rules, which replaced the Application Procedures of Foreign Exchange Administration for Domestic Individuals Participating in Employee Stock Ownership Plan or Stock Option Plans of Overseas Publicly Listed Companies issued by SAFE in March 2007. Pursuant to the Stock Option Rules, if a PRC resident participates in any stock incentive plan of an overseas publicly listed company, a qualified PRC domestic agent must, among other things, file on behalf of such participant an application with SAFE to conduct the SAFE registration with respect to such stock incentive plan and obtain approval for an annual allowance with respect to the purchase of foreign exchange in connection with the exercise or sale of stock options or stock such participant holds. Such participating PRC residents’ foreign exchange income received from the sale of stock and dividends distributed by the overseas publicly listed company must be fully remitted into a PRC collective foreign currency account opened and managed by the PRC agent before distribution to such participants. We and our PRC resident employees who have been granted stock options or other share-based incentives of ours are subject to the Stock Option Rules. However, we do not have control over our PRC resident participants and cannot compel them to comply with SAFE registrations.

Therefore, we cannot assure you that any required registration under SAFE registrations will be completed in a timely manner, or at all. If we or our PRC resident participants fail to comply with these regulations, we and/or our PRC resident participants may be subject to fines and legal sanctions. Besides, failure to complete the SAFE registrations may limit our PRC resident participants' ability to make payment under our share incentive plan or receive dividends or sales proceeds related thereto, or limit our ability to contribute additional capital into our wholly-foreign owned enterprises in China and limit our wholly-foreign owned enterprises' ability to distribute dividends to us. We also face regulatory uncertainties that could restrict our ability to adopt additional share incentive plans for our directors and employees under PRC laws.

In addition, the State Taxation Administration issued the Notice on Several Measures for Further Deepening the Reform of "Simplifying Administration and Decentralizing Powers, Combining Decentralization with Appropriate Control, and Optimizing Services" and Cultivating and Stimulating the Vitality of Market Participants, or the Notice, in October 2021, which require any enterprise that implements equity (stock) incentive plan shall submit a Report Form of Equity Incentives and other materials to the competent tax authority within 15 days of the next month after deciding to implement equity incentives or before the end of 2021 for equity incentive plans that have been implemented but not yet completed, including domestic enterprises that provide equity incentives for employees with equity of overseas enterprises. However, as the Notice is newly issued, there are still substantial uncertainties as to its interpretation and implementations in practice. Therefore, we cannot assure you that any required registration or filing under the Notice or other regulations will be completed in a timely manner, or at all. If we or our participants fail to comply with these regulations, we and/or our participants may be subject to fines and other legal sanctions.

The audit report included in Legend Biotech's Annual Report is prepared by an auditor who is not inspected by the Public Company Accounting Oversight Board, or the PCAOB and, as such, Legend Biotech's investors are deprived of the benefits of such inspection. The Holding Foreign Companies Accountable Act, or the HFCA Act, and other legislative and regulatory developments related to political tensions between the United States and China may have a material adverse impact on Legend Biotech's continued listing and trading in the U.S. and the trading prices of Legend Biotech's ADSs.

As an auditor of U.S. publicly traded companies and a PCAOB-registered accounting firm, the independent registered public accounting firm that issued the audit report included in Legend Biotech's Annual Report is required by the laws of the United States to undergo regular inspections by the PCAOB to assess its compliance with the laws of the United States and professional standards. Because our auditor is located in the PRC—a jurisdiction where the PCAOB is currently unable to conduct inspections without the approval of the Chinese authorities—our auditor is not currently inspected by the PCAOB.

PCAOB inspections are able to identify deficiencies in the inspected firms' audit procedures and quality control procedures, which may then be addressed as part of the inspection process to improve future audit quality. The lack of PCAOB inspections in China prevents the PCAOB from regularly evaluating our auditor's audits and quality control procedures. As a result, investors may be deprived of the benefits of PCAOB inspections of our auditor. The inability of the PCAOB to conduct an inspection of our auditor makes it more difficult to evaluate the effectiveness of our auditor's audit procedures or quality control procedures as compared to auditors outside of China that are subject to PCAOB inspections. Accordingly, investors may have a lower level of confidence in Legend Biotech's reported financial information and procedures and the quality of Legend Biotech's financial statements than if our auditor were subject to PCAOB inspections.

Further, U.S. legislators and regulators have in recent years voiced concerns about risks associated with investing in companies that are based in or have substantial operations in emerging markets, including China. In particular, lawmakers have highlighted the increased risks associated with companies whose independent auditors are unable to be inspected by the PCAOB. As part of this continued focus in the United States on access to audit and other information currently protected by national law, in particular China's, on December 18, 2020, the U.S. president signed the HFCA Act into law. On December 2, 2021, the SEC adopted final rules implementing the HFCA Act.

The HFCA Act requires the SEC to identify and maintain a list of U.S. listed companies whose audit reports are prepared by auditors that the PCAOB is unable to inspect or investigate completely because of restrictions imposed by the authorities in the foreign jurisdiction. The HFCA Act also requires SEC-identified public companies to (i) submit documentation establishing that the company is not owned or controlled by a governmental entity in the jurisdiction that restricts PCAOB inspections and (ii) make certain additional disclosures in their SEC filings regarding, among other things, the fact that the PCAOB is unable to inspect its audit firm, the percentage of the company's shares owned by governmental entities in such foreign jurisdiction, whether governmental entities in such foreign jurisdiction have a controlling financial interest with respect to the company, the name of any Chinese Communist Party members on the company's board of directors, and whether there are any charters of the Chinese Communist Party included in the company's organizational documents (including the text of any such charter). For issuers remaining on the SEC-identified companies list for three consecutive years, the securities of such company would be prohibited from trading on a U.S. national securities exchange, such as The Nasdaq Global Select Market, or in U.S. over-the-counter markets. On June 22, 2021, the U.S. Senate passed a bill which, if passed by the U.S. House of Representatives and signed into law, would reduce the number of consecutive non-inspection years required for triggering the prohibitions under the HFCA Act from three years to two. It is uncertain whether this proposed legislation will advance.

The SEC will begin identifying issuers based on annual reports filed in 2022 for the fiscal year ended December 31, 2021. Because Legend Biotech's Annual Report for fiscal year 2021 will include an audit report issued by our auditor, it is expected that Legend Biotech will be an SEC-identified company in fiscal year 2022, and would be required to comply with the SEC's submission and disclosure requirements for Legend Biotech's Annual Report for the fiscal year ending December 31, 2022. Legend Biotech is evaluating potential responses to the HFCA Act, including the possibility of changing its principal auditor to a firm that can be inspected by the PCAOB. Such evaluation is ongoing and until a definitive response is identified and implemented, Legend Biotech's inclusion as an SEC-identified company could cause investor uncertainty and the market price of its ADSs could be materially adversely affected. If Legend Biotech is unable to meet PCAOB inspection requirements in a timely manner, it could be delisted. If Legend Biotech's ADSs are unable to be listed on another securities exchange by then, such a delisting would substantially impair your ability to sell or purchase its ADSs when you wish to do so, and the risk and uncertainty associated with a potential delisting would have a negative impact on the price of Legend Biotech's ADSs. In addition, any actions that Legend Biotech takes in response to the HFCA Act and compliance with the requirements of the HFCA Act for so long as Legend Biotech remains an SEC-identified company, may require Legend Biotech to incur additional legal, accounting and other expenses, which may be significant.

Governmental control of currency conversion may limit our ability to utilize our revenues effectively and affect the value of your investment.

The PRC government imposes controls on the convertibility of the Renminbi into foreign currencies and, in certain cases, the remittance of currency out of China. Under our current corporate structure, our Cayman Islands holding company may rely on dividend payments from our PRC subsidiaries to fund any cash and financing requirements we may have in the future. Under existing PRC foreign exchange regulations, payments of current account items, including profit distributions, interest payments and trade and service-related foreign exchange transactions, can be made in foreign currencies without prior approval of SAFE, by complying with certain procedural requirements. Specifically, under the existing exchange restrictions, without prior approval of SAFE, cash generated from the operations of our PRC subsidiaries in China may be used to pay dividends to our company. However, approval from or registration with appropriate government authorities is required where Renminbi is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of loans denominated in foreign currencies. As a result, we need to obtain SAFE approval to use cash generated from the operations of our PRC subsidiaries to pay off their respective debt in a currency other than Renminbi owed to entities outside China, or to make other capital expenditure payments outside China in a currency other than Renminbi.

In light of the recent flood of capital outflows of China due to the weakening of RMB, the PRC government has imposed more restrictive foreign exchange policies and stepped up scrutiny of major outbound capital movement including overseas direct investment. More restrictions and substantial vetting process are put in place by SAFE to regulate cross-border transactions falling under the capital account. If any of our shareholders regulated by such policies fails to satisfy the applicable overseas direct investment filing or approval requirement timely or at all, it may be subject to penalties from the relevant PRC authorities. The PRC government may at its discretion further restrict access in the future to foreign currencies for current account transactions. If the foreign exchange control system prevents us from obtaining sufficient foreign currencies to satisfy our foreign currency demands, we may not be able to pay dividends in foreign currencies to our shareholders, including holders of the Ordinary Shares.