Legend Biotech Reports Second Quarter 2023 Results and Recent Highlights

August 15, 2023

- A supplemental Biologics License Application (sBLA) was submitted to the U.S. Food and Drug Administration (FDA) and a Type II Variation Application was submitted to the European Medicines Agency (EMA) by Janssen, seeking approval of CARVYKTI® (*ciltacabtagene autoleucel; cilta-cel)* for the earlier treatment of patients with relapsed or refractory multiple myeloma
- The FDA set the Prescription Drug User Fee Act target date for the CARVYKTI® sBLA to April 5, 2024
- The FDA granted Orphan Drug Designation for LB2102 (DLL-3) (NCT05680922), which is being evaluated for the treatment of small cell lung cancer. The US clinical trial is actively recruiting at two sites[1]
- On August 3, 2023, Legend Biotech received a payment in the amount of $15 million for the EMA's acceptance of the Type II Variation Application for CARVYKTI®, in accordance with Legend Biotech's license and collaboration agreement with Janssen (Janssen Agreement)
- On August 4, 2023, Legend Biotech earned a milestone payment of $20 million in connection with the FDA's acceptance of the sBLA, in accordance with the Janssen Agreement
- New data from the CARTITUDE-4 study (NCT04181827) of cilta-cel were featured at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting (Abstract #LBA106) and European Hematology Association (EHA) 2023 Hybrid Congress (Abstract #S100); these data were also published in *The New England Journal of Medicine*[2]
- Long-term data from the cilta-cel CARTITUDE-1 (NCT03548207) and LEGEND-2 (NCT03090659) studies were also presented at ASCO (Abstract #8009, Abstract #8010) and EHA (Abstract #S202, Abstract #P874)
- Cash and cash equivalents, deposits and investments of $1.5 billion, as of June 30, 2023, extends Legend Biotech's cash runway through 2025, strengthened by recently completed financings
- In April and May 2023, Legend Biotech entered into subscription agreements with certain institutional investors pursuant to which Legend Biotech sold an aggregate of 8,834,742 ordinary shares for aggregate gross proceeds of approximately $235 million
- In May 2023, Legend Biotech sold 5,468,750 American Depositary Shares (the "ADSs"), each representing two ordinary shares, to certain investors in a registered direct offering at a price of $64.00 per ADS for aggregate gross proceeds of $350 million
- In May 2023, an institutional investor exercised in full a warrant to purchase 10,000,000 ordinary shares of Legend Biotech at an exercise price of $20.00 per ordinary share for an aggregate exercise price of $200 million

SOMERSET, N.J.--(BUSINESS WIRE)--Aug. 15, 2023-- Legend Biotech Corporation (NASDAQ: LEGN) (Legend Biotech), a global biotechnology company developing, manufacturing and commercializing novel therapies to treat life-threatening diseases, today reported its unaudited financial results for the three and six months ended June 30, 2023.

In addition to financial performance, Legend Biotech reported on the success of its portfolio and pipeline, including the CARTITUDE clinical development program for CARVYKTI®, in collaboration with the Janssen Biotech, Inc. (Janssen).

Initial data from the CARTITUDE-4 study presented at ASCO and EHA supported recent submissions to U.S. and E.U. regulatory agencies by Janssen to expand the indication of CARVYKTI® into earlier treatment of patients (1-3 prior lines of therapy) with relapsed or refractory multiple myeloma.

"We remain committed to exploring the full potential of CARVYKTI® and are pleased with the continued growth of our development program, including two regulatory submissions made during the second quarter," said Ying Huang, Chief Executive Officer of Legend Biotech. "Following our most recent fundraising, we are well positioned to advance our pipeline and portfolio. We remain grateful to the investors who support our endeavors."

Financial Results for Quarter Ended June 30, 2023

Cash and Cash Equivalents, Time Deposits, and Short-Term Investments

As of June 30, 2023, after giving effect to the registered direct offering, private placements or warrant exercise noted above, Legend Biotech had approximately $1.5 billion of cash and cash equivalents, time deposits, and short-term investments.

Revenue

License Revenue

License revenue for the three months ended June 30, 2023 was $15.1 million due to the achievement of a milestone during the quarter,

compared to no milestones achieved during the three months ended June 30, 2022. License revenue for the six months ended June 30, 2023 was $15.1 million, compared to $50 million for the six months ended June 30, 2022. This decrease of $34.9 million was primarily driven by the nature and timing of milestones achieved as outlined in the Global Development Plan under the Janssen Agreement for cilta-cel six months ended June 30, 2023.

Collaboration Revenue

Collaboration revenue for the three and six months ended June 30, 2023 was $58.2 million and $94.4 million, respectively, compared to $11.9 million for the three and six months ended June 30, 2022. The increases of $46.3 million and $82.5 million for the three and six-month periods, respectively, were due to an increase in revenue generated from sales of CARVYKTI® in connection with the Janssen Agreement.

Operating Expenses

Collaboration cost of revenue

Collaboration cost of revenue for the three and six months ended June 30, 2023 was $32.7 million and $68.3 million, respectively, compared to $16.9 million for the three and six months ended June 30, 2022. The increases of $15.7 million and $51.3 million for the three and six months ended, respectively were a combination of Legend's portion of collaboration cost of sales in connection with collaboration revenue under the Janssen Agreement along with expenditures to support the manufacturing capacity expansion which cannot be capitalized.

Research and Development Expenses

Research and development expenses for the three and six months ended June 30, 2023 were $95.8 million and $180.7 million, respectively, compared to $68.8 million and $150.4 million for the three and six months ended June 30, 2022, respectively. The increases of $27.0 million and $30.3 million for the three and six-month periods, respectively, were primarily due to continuous research and development activities in cilta-cel, including higher patient enrollment for Phase 3 clinical trials for cilta-cel, and an increase in research and development activities for other pipeline items. The other pipeline expenses include continued investment in our solid tumor programs, which include two IND approvals that advanced into phase 1 development.

Administrative Expenses

Administrative expenses for the three and six months ended June 30, 2023 were $27.8 million and $50 million, respectively, compared to $18.1 million and $30.7 million for the three and six months ended June 30, 2022, respectively. The increases of $9.7 million and $19.3 million for the three and six-month periods, respectively, were primarily due to the expansion of supporting administrative functions to facilitate continuous business growth and continued investment in building global information technology infrastructure.

Selling and Distribution Expenses

Selling and distribution expenses for the three and six months ended June 30, 2023 were $21.4 million and $39.4 million, respectively, compared to $27.4 million and $48.7 million for the three and six months ended June 30, 2022. The decrease of $6 million and $9.4 million were primarily due to non-recurring launch expenses incurred in the first half of 2022 to support the commercialization in the U.S market.

Other Income and Gains

Other income and gains for the three and six months ended June 30, 2023 were $16.4 million and $21 million, respectively, compared to $1.9 million and $2.9 million for the three and six months ended June 30, 2022, respectively. The increase of $14.5 million in the three months ended June 30, 2023 compared to the three months ended June 30, 2022 was primarily attributable to approximately a $10.9 million increase in interest income and gain on investment, as well an increase of approximately $3.6 million in foreign currency exchange gain. The increase of $18.1 million for the six month period ended June 30, 2023 compared to the six months ended June 30, 2022 was primarily due to an increase in interest income and gain on investments.

Other Expenses

Other expenses for the three and six months ended June 30, 2023 were $0.02 million and $7.1 million, respectively, compared to $8.1 million and $9.6 million for the three and six months ended June 30, 2022. The decrease in both comparative periods was primarily due to a decrease in foreign currency exchange loss.

Finance Costs

Finance costs for the three and six months ended June 30, 2023 were $5.2 million and $10.3 million, respectively, compared to $1.6 million and $2.7 million for the three and six months ended June 30, 2022. The increase in both comparative periods was primarily due to interest on advance funding, which is interest-bearing borrowings funded by Janssen under the Janssen Agreement and constituted of principal and applicable interests upon such principal.

Fair Value Loss of Warrant Liability

Fair value loss of warrant liability for the six months ended June 30, 2023 was $85.8 million, compared to a fair value loss of $31 million for the six months ended June 30, 2022. The increase was due to the fair value loss recorded on the full exercise of the warrant, which took place on May 11, 2023.

Loss for the Period

For the three months ended June 30, 2023, net loss was $199.1 million, or $0.57 per share, compared to net loss of $193.2 million, or $0.62 per share, for the three months ended June 30, 2022. For the six months ended June 30, 2023, net loss was $311.2 million, or $0.91 per share, compared to a net loss of $225.5 million, or $0.73 per share, for the six months ended June 30, 2022.

Webcast/Conference Call Details:

Legend Biotech will host its quarterly earnings call and webcast today at 8:00am ET. To access the webcast, please visit this weblink.

A replay of the webcast will be available on Legend Biotech's website at https://investors.legendbiotech.com/events-and-presentations.

About Legend Biotech

Legend Biotech is a global 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 allogeneic chimeric antigen receptor T-cell, gamma-delta T cell 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 cutting-edge therapeutics for patients worldwide.

Learn more at https://legendbiotech.com/ and follow us on Twitter and LinkedIn.

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, constitute "forward-looking statements" within the meaning of The Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements relating to Legend Biotech's strategies and objectives; statements relating to CARVYKTI ®, including Legend Biotech's expectations for CARVYKTI ®; and statements about regulatory submissions for CARVYKTI®, and the progress of such submissions with the FDA, the EMA and other regulatory authorities; and expected results of clinical trials; Legend Biotech's expectations on advancing their pipeline and product portfolio; and the potential benefits of Legend Biotech's product candidates. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward- looking statements, although not all forward-looking statements contain these identifying words. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors. Legend Biotech's expectations could be affected by, among other things, uncertainties involved in the development of new pharmaceutical products; unexpected clinical trial results, including as a result of additional analysis of existing clinical data or unexpected new clinical data; unexpected regulatory actions or delays, including requests for additional safety and/or efficacy data or analysis of data, or government regulation generally; unexpected delays as a result of actions undertaken, or failures to act, by our third party partners; uncertainties arising from challenges to Legend Biotech's patent or other proprietary intellectual property protection, including the uncertainties involved in the U.S. litigation process; competition in general; government, industry, and general product pricing and other political pressures; the duration and severity of the COVID-19 pandemic and governmental and regulatory measures implemented in response to the evolving situation; as well as the other factors discussed in the "Risk Factors" section of Legend Biotech's Annual Report on Form 20-F filed with the Securities and Exchange Commission (SEC) on March 30, 2023 and Legend Biotech's other filings with the SEC. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in this press release as anticipated, believed, estimated or expected. Any forward-looking statements contained in this press release speak only as of the date of this press release. Legend Biotech specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

LEGEND BIOTECH CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF PROFIT OR LOSS

	Three Months Ended June 30,		Six months ended June 30,	
US$'000, except per share data	**2023 (Unaudited)**	**2022 (Unaudited)**	**2023 (Unaudited)**	**2022 (Unaudited)**
REVENUE				
License revenue	15,115	—	15,115	50,000
Collaboration revenue	58,152	11,937	94,432	11,937
Other revenue	63	34	119	74
Total revenue	73,330	11,971	109,666	62,011
Collaboration cost of revenue	(32,672)	(16,939)	(68,285)	(16,939)
Other income and gains	16,433	1,856	20,994	2,868
Research and development expenses	(95,791)	(68,827)	(180,680)	(150,375)
Administrative expenses	(27,753)	(18,050)	(49,958)	(30,707)
Selling and distribution expenses	(21,429)	(27,440)	(39,383)	(48,742)
Other expenses	(21)	(8,099)	(7,117)	(9,626)
Fair value loss of warrant liability	(105,750)	(65,900)	(85,750)	(31,000)
Finance costs	(5,185)	(1,643)	(10,298)	(2,687)
LOSS BEFORE TAX	(198,838)	(193,071)	(310,811)	(225,197)
Income tax expense	(290)	(157)	(418)	(320)
LOSS FOR THE PERIOD	(199,128)	(193,228)	(311,229)	(225,517)
Attributable to:				
Ordinary equity holders of the parent	(199,128)	(193,228)	(311,229)	(225,517)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT				
Basic	(0.57)	(0.62)	(0.91)	(0.73)
Diluted	(0.57)	(0.62)	(0.91)	(0.73)

ORDINARY SHARES USED IN LOSS PER SHARE COMPUTATION				
Basic	350,517,429	309,777,816	340,779,779	309,241,404
Diluted	350,517,429	309,777,816	340,779,779	309,241,404

LEGEND BIOTECH CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	June 30, 2023	December 31, 2022
	US$'000 (Unaudited)	US$'000 (Audited)
NON-CURRENT ASSETS		
Property, plant and equipment	110,978	105,168
Advance payments for property, plant and equipment	1,061	914
Right-of-use assets	78,497	55,590
Time deposits	4,209	—
Intangible assets	2,465	3,409
Collaboration prepaid leases	119,173	65,276
Other non-current assets	1,414	1,487
Total non-current assets	317,797	231,844
CURRENT ASSETS		
Collaboration inventories	15,196	10,354
Trade receivables	15,064	90
Prepayments, other receivables and other assets	66,573	61,755
Financial assets at fair value through profit or loss	185,756	185,603
Pledged deposits	1,246	1,270
Time deposits	95,814	54,016
Cash and cash equivalents	1,233,213	786,031
Total current assets	1,612,862	1,099,119
Total assets	1,930,659	1,330,963
CURRENT LIABILITIES		
Trade payables	21,544	32,893
Other payables and accruals	165,519	184,109
Government grants	435	451
Lease liabilities	3,558	3,563
Tax payable	10,326	9,772
Warrant liability	—	67,000
Total current liabilities	201,382	297,788
NON-CURRENT LIABILITIES		
Collaboration interest-bearing advanced funding	270,614	260,932
Lease liabilities long term	44,444	20,039
Government grants	7,036	7,659
Other non-current liabilities	152	233
Total non-current liabilities	322,246	288,863
Total liabilities	523,628	586,651
EQUITY		
Share capital	36	33
Reserves	1,406,995	744,279
Total ordinary shareholders' equity	1,407,031	744,312
Total equity	1,407,031	744,312
Total liabilities and equity	1,930,659	1,330,963

LEGEND BIOTECH CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW

	Three Months Ended June 30,		Six months ended June 30,	
US$'000	2023	2022	2023	2022
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)

LOSS BEFORE TAX	(198,838)	(193,071)	(310,811)	(225,197)
CASH FLOWS USED IN OPERATING ACTIVITIES	(95,730)	(740)	(236,783)	(79,427)
CASH FLOWS USED IN INVESTING ACTIVITIES	(123,581)	2,585	(105,651)	(229,915)
CASH FLOWS FROM FINANCING ACTIVITIES	789,890	1,009	789,604	1,034
NET INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS	570,579	2,854	447,170	(308,308)
Effect of foreign exchange rate changes, net	2,584	(864)	12	(854)
Cash and cash equivalents at beginning of the period	660,050	377,786	786,031	688,938
CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	1,233,213	379,776	1,233,213	379,776
ANALYSIS OF BALANCES OF CASH AND CASH EQUIVALENTS				
Cash and bank balances	1,334,482	788,982	1,334,482	788,982
Less: Pledged deposits	1,246	1,402	1,246	1,402
Time deposits	100,023	407,804	100,023	407,804
Cash and cash equivalents as stated in the statement of financial position	1,233,213	379,776	1,233,213	379,776
Cash and cash equivalents as stated in the statement of cash flows	1,233,213	379,776	1,233,213	379,776

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[1] ClinicalTrials.gov. DLL3-Directed Chimeric Antigen Receptor T-cells in Subjects With Extensive Stage Small Cell Lung Cancer. Available at: https://classic.clinicaltrials.gov/ct2/show/NCT05680922. Last accessed Aug 2023.

[2] San-Miguel, J, Dhakal B, Yong K, et al. Cilta-cel or Standard Care in Lenalidomide-Refractory Multiple Myeloma. *N Engl J Med*. 2023;389:335-347

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Press:
Tina Carter, Corporate Communications Lead, Legend Biotech
tina.carter@legendbiotech.com
(908) 331-5025

Investor:
Jessie Yeung, Head of Investor Relations and Public Relations, Legend Biotech
jessie.yeung@legendbiotech.com

Source: Legend Biotech Corporation