Legend Biotech Reports First Quarter 2024 Results and Recent Highlights

May 13, 2024

- *CARVYKTI® (ciltacabtagene autoleucel; cilta-cel) net trade sales of approximately $157 million*
- *EC and US FDA approved CARVYKTI® label expansion in earlier lines of treatment for adult patients with relapsed and lenalidomide-refractory multiple myeloma*
- *Legend and Johnson & Johnson enter into Master Manufacturing and Supply Services Agreement with Novartis Pharmaceuticals Corporation*
- *On April 5, Legend Biotech earned a milestone payment of $45 million in connection with FDA's approval of CARVYKTI's label expansion to treat 2L+ MM, in accordance with the Janssen Agreement**
- *Cash and cash equivalents, deposits, and short-term investments of $1.3 billion, as of March 31, 2024, which Legend believes will provide financial runway into 2026, when Legend Biotech anticipates achieving an operating profit*

SOMERSET, N.J.--(BUSINESS WIRE)--May 13, 2024-- Legend Biotech Corporation (NASDAQ: LEGN) (Legend Biotech), a global leader in cell therapy, today reported its first quarter 2024 unaudited financial results and key corporate highlights.

"Legend made great progress in the first quarter, culminating in our exciting announcements in recent weeks. We received label expansions for CARVYKTI in the U.S., Europe, and Brazil that have changed the treatment paradigm for multiple myeloma and will enable more patients to receive our transformative therapy earlier in the course of their disease," said Ying Huang, Ph.D., Chief Executive Officer of Legend Biotech. "With more patients needing access to CARVYKTI, we have increased our manufacturing capacity and have scaled up our operations to reach our goal of 10,000 annual doses by the end of 2025. The expansion of our partnership with Novartis demonstrates our commitment to ensuring every patient who needs CARVYKTI can access it."

Regulatory Updates

- The U.S. Food and Drug Administration (FDA) approved CARVYKTI® for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least one prior line of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent (IMiD) and are refractory to lenalidomide following the Oncologic Drug Advisory Committee's (ODAC) unanimous (11 to 0) vote recommending the approval of CARVYKTI®.
- The European Commission (EC) granted approval for the label expansion of CARVYKTI® for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least one prior therapy, including an immunomodulatory agent and a proteasome inhibitor, have demonstrated disease progression on the last therapy, and are refractory to lenalidomide.
- The Brazilian Health Regulatory Agency, ANVISA (Agência Nacional de Vigilância Sanitária), approved CARVYKTI® for the treatment of adult patients with multiple myeloma, who previously received a proteasome inhibitor and are refractory to lenalidomide, as well as adult patients with relapsed or refractory multiple myeloma, who previously received a proteasome inhibitor, an immunomodulatory agent and anti-CD38 antibody.

Key Business Developments

- Legend and Johnson & Johnson* entered into a Master Manufacturing and Supply Services Agreement with Novartis Pharmaceuticals Corporation to supplement our existing manufacturing capabilities and increase commercial supply of CARVYKTI®
- Published inaugural Environmental, Social & Governance (ESG) report which aligns with the Sustainable Accounting Standards Board (SASB) Biotechnology and Pharmaceutical sector standards, shares ESG data collection and disclosure roadmap, and future growth strategy for good corporate citizenship

* In December 2017, Legend Biotech entered into an exclusive worldwide collaboration and license agreement with Janssen Biotech, Inc., a Johnson & Johnson company, to develop and commercialize cilta-cel (the Janssen Agreement).

First Quarter 2024 Financial Results

- ***License Revenue***: License revenue was $12.2 million for the first quarter of 2024 and consisted of the recognition of deferred revenue in connection with the global license agreement with Novartis Pharma AG to develop, manufacture, and commercialize LB2102 and other potential CAR-T therapies selectively targeting DLL3. Legend did not recognize any license revenue for the first quarter of 2023.

- ***Collaboration Revenue***: Collaboration revenue was $78.5 million for the first quarter of 2024 compared to $36.3 million for the first quarter of 2023. The increase was primarily due to an increase in revenue generated from sales of CARVYKTI® in connection with the Janssen Agreement.
- ***Collaboration Cost of Revenue***: Collaboration cost of revenue was $49.1 million for the first quarter of 2024 compared to $35.6 million for the first quarter of 2023. The increase was primarily due to Legend Biotech's share of the cost of sales in connection with CARVYKTI® sales under the Janssen Agreement.
- ***Cost of License and Other Revenue***: Cost of license and other revenue for the three months ended March 31, 2024 was $5.6 million and consisted of costs in connection with the global license agreement with Novartis Pharma AG to develop, manufacture, and commercialize LB2102 and other potential CAR-T therapies selectively targeting DLL3. The Company did not incur any cost of license and other revenue for the three months ended March 31, 2023.
- ***Research and Development Expenses***: Research and development expenses were $101.0 million for the first quarter of 2024 compared to $84.9 million for the first quarter of 2023. The increase was primarily driven by continuous research and development activities in cilta-cel, including start up costs for clinical production in Belgium and continued investment in Legend's solid tumor programs.
- ***Administrative Expenses:*** Administrative expenses were $31.9 million for the first quarter of 2024 compared to $22.2 million for the first quarter of 2023. The increase was primarily due to the expansion of administrative functions and infrastructure to increase manufacturing capacity.
- ***Selling and Distribution Expenses***: Selling and distribution expenses were $24.2 million for the first quarter of 2024 compared to $18.0 million for the first quarter of 2023. The increase was primarily driven by costs associated with commercial activities for cilta-cel, including the expansion of the sales force and second line indication launch preparation.
- ***Net Loss***: Net loss was $59.8 million for the first quarter of 2024, compared to a net loss of $112.1 million for the first quarter of 2023.
- ***Cash Position***: Cash and cash equivalents, time deposits, and short-term investments were $1.3 billion as of March 31, 2024.

Webcast/Conference Call Details:
Legend Biotech will host its quarterly earnings call and webcast today at 8:00 am 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 X (formerly 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 its therapeutic potential; statements relating to the potential approval of CARVYKTI® for earlier lines of therapy; statements related to Legend Biotech manufacturing expectations for CARVYKTI®; 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; government, industry, and general product pricing and other political pressures; 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 on March 19, 2024. 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 March 31,	
	2024	2023
US$'000, except share and per share data	**(Unaudited)**	**(Unaudited)**
REVENUE		

License revenue	12,181	—
Collaboration revenue	78,481	36,280
Other revenue	3,329	56
Total revenue	93,991	36,336
Collaboration cost of revenue	(49,101)	(35,613)
Cost of license and other revenue	(5,638)	—
Other income and gains	64,091	8,199
Research and development expenses	(100,964)	(84,889)
Administrative expenses	(31,929)	(22,205)
Selling and distribution expenses	(24,223)	(17,954)
Other expenses	(540)	(10,734)
Fair value gain of warrant liability	—	20,000
Finance costs	(5,475)	(5,113)
LOSS BEFORE TAX	(59,788)	(111,973)
Income tax expense	(5)	(128)
LOSS FOR THE PERIOD	(59,793)	(112,101)
Attributable to:		
Ordinary equity holders of the parent	(59,793)	(112,101)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT		
Basic	(0.16)	(0.34)
Diluted	(0.16)	(0.34)
ORDINARY SHARES USED IN LOSS PER SHARE COMPUTATION		
Basic	364,010,429	330,497,072
Diluted	364,010,429	330,497,072

LEGEND BIOTECH CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	March 31, 2024	December 31, 2023
	US$'000 (Unaudited)	US$'000 (Audited)
NON-CURRENT ASSETS		
Property, plant and equipment	105,278	108,725
Advance payments for property, plant and equipment	563	451
Right-of-use assets	80,179	80,502
Time deposits	4,387	4,362
Intangible assets	3,152	4,061
Collaboration prepaid leases	166,344	151,216
Other non-current assets	1,412	1,493
Total non-current assets	361,315	350,810
CURRENT ASSETS		
Collaboration inventories	22,146	19,433
Trade receivables	3,307	100,041
Prepayments, other receivables and other assets	85,603	69,251
Financial assets at fair value through profit or loss	150,449	663
Pledged deposits	359	357
Time deposits	254,357	30,341
Cash and cash equivalents	897,571	1,277,713
Total current assets	1,413,792	1,497,799
Total assets	1,775,107	1,848,609
CURRENT LIABILITIES		
Trade payables	39,485	20,160
Other payables and accruals	136,012	132,802
Government grants	538	68
Lease liabilities	3,116	3,175
Tax payable	7,273	7,203
Contract liabilities	63,251	53,010
Total current liabilities	249,675	216,418
NON-CURRENT LIABILITIES		

Collaboration interest-bearing advanced funding	286,396	281,328
Lease liabilities long term	45,174	44,169
Government grants	6,664	7,305
Contract liabilities	23,109	47,962
Other non-current liabilities	30	56
Total non-current liabilities	361,373	380,820
Total liabilities	611,048	597,238
EQUITY		
Share capital	36	36
Reserves	1,164,023	1,251,335
Total ordinary shareholders' equity	1,164,059	1,251,371
Total equity	1,164,059	1,251,371
Total liabilities and equity	1,775,107	1,848,609

LEGEND BIOTECH CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW

	Three Months Ended March 31,	
US$'000	**2024**	**2023**
	(Unaudited)	**(Unaudited)**
LOSS BEFORE TAX	(59,788)	(111,973)
CASH FLOWS FROM/ (USED IN) OPERATING ACTIVITIES	15,518	(139,215)
CASH FLOWS FROM/ (USED IN) INVESTING ACTIVITIES	(396,148)	16,032
CASH FLOWS FROM/ (USED IN) FINANCING ACTIVITIES	831	(444)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(379,799)	(123,627)
Effect of foreign exchange rate changes, net	(343)	(2,354)
Cash and cash equivalents at beginning of the period	1,277,713	786,031
CASH AND CASH EQUIVALENTS AT END OF THE YEAR	897,571	660,050
ANALYSIS OF BALANCES OF CASH AND CASH EQUIVALENTS		
Cash and bank balances	1,156,674	670,065
Less: Pledged deposits	359	1,283
Time deposits	258,744	8,732
Cash and cash equivalents as stated in the statement of financial position	897,571	660,050
Cash and cash equivalents as stated in the statement of cash flows	897,571	660,050

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