# LianBio Reports Second Quarter 2022 Financial Results and Provides Corporate Update

August 11, 2022

- *Completed enrollment in China Phase 3 trial of mavacamten; topline data expected mid-2023*
- *Submitted mavacamten New Drug Application (NDA) in Singapore*
- *Submitted infigratinib NDA in Hong Kong*
- *Three additional registration-enabling programs to begin in China by year-end 2022*
- *Cash balance of* $349.4 *million at the end of second quarter 2022 with runway into the second half of 2024*

SHANGHAI, China and PRINCETON, N.J., Aug. 11, 2022 (GLOBE NEWSWIRE) -- LianBio (Nasdaq: LIAN), a biotechnology company dedicated to bringing innovative medicines to patients in China and other major Asian markets, today reported financial results for the second quarter ended June 30, 2022 and provided a corporate update.

“In the second quarter, LianBio achieved meaningful milestones that we believe serve as a testament to our strength in navigating the complex regulatory environments in Greater China and Asia,” said Yizhe Wang, Ph.D., Chief Executive Officer of LianBio. “We continue to grow our organization, bringing on key new team members across clinical, medical affairs, quality and commercial functions. Despite clinical site and agency disruptions due to COVID-19 lockdowns in Shanghai and other cities in China, LianBio continued to execute our key clinical development and regulatory priorities, completing enrollment in the Phase 3 EXPLORER-CN trial of mavacamten and submitting marketing applications for both mavacamten and infigratinib in Asia Pacific territories. We believe the enthusiasm for mavacamten's potential as a treatment for obstructive hypertrophic cardiomyopathy (oHCM) among both the clinical community and the world's largest oHCM population is high, and we expect to report topline results from EXPLORER-CN in mid-2023. As we work to complete the EXPLORER-CN study over the coming months to support registration in China, we turn our focus to potential launch and preparations for LianBio's next phase of evolution as a commercial-stage company. We remain on track to initiate three additional registration-enabling clinical programs in China this year, solidifying our position as a key partner in cross-border drug development. I am continually proud of our global team’s efforts to bring innovative medicines to patients in Asia.”

**Recent Business Highlights and Clinical Development Updates**

***Mavacamten progress continues in Asia with enrollment completed in China Phase 3 trial and New Drug Application submitted in Singapore***

- In May 2022, LianBio submitted an NDA to the Singapore Health Sciences Authority for mavacamten for the treatment of adults with symptomatic New York Heart Association Class II-III obstructive hypertrophic cardiomyopathy (oHCM). The submission was based on the U.S. Food and Drug Administration (FDA) approval of mavacamten.
- In August 2022, enrollment was completed in the Phase 3 EXPLORER-CN clinical trial of mavacamten in Chinese patients with oHCM.

***Infigratinib New Drug Application in 2$^{nd}$ line cholangiocarcinoma submitted in Hong Kong***

- In July 2022, LianBio submitted an NDA to the Department of Health, the Hong Kong Special Administrative Region, China, for infigratinib for the treatment of adults with previously treated, unresectable, locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement. The submission was based on the FDA approval of infigratinib.

***Development partner ReViral Ltd. acquired by Pfizer Inc.***

- In June 2022, Pfizer completed its acquisition of LianBio’s development partner ReViral and its respiratory syncytial virus therapeutic candidates, including sisunatovir. LianBio holds development and commercial rights to sisunatovir in mainland China, Hong Kong, Macau and Singapore.

***LYR-210 clinical development program refined***

- LianBio plans to conduct a Phase 3 China standalone trial to support regulatory approval in China, leveraging the results of development partner Lyra’s ongoing Phase 3 trial, which is expected to complete enrollment in mid-2023.

***Development partner Tarsus advances TP-03 into clinical trial in second indication***

- In August 2022, LianBio’s development partner Tarsus initiated a Phase 2a clinical trial of TP-03 in patients with meibomian gland disease (MGD).

***Development partner Landos Biopharma reports data from NX-13 program***

- In August 2022, Landos announced topline results from a Phase 1b clinical trial of NX-13 demonstrating NX-13 was well tolerated. Based on these data, Landos plans to initiate a Phase 2 clinical trial to evaluate the safety, efficacy and optimal dosing of NX-13 in ulcerative colitis patients.

***Business is well-positioned to achieve anticipated milestones***

- Current cash runway is projected to extend into the second half of 2024.

**Key Milestones Anticipated in 2022 and 2023**

**Mavacamten**

- LianBio expects to report topline data from the Phase 3 EXPLORER-CN trial of mavacamten in Chinese patients with symptomatic oHCM in mid-2023.

**TP-03**

- LianBio expects to initiate a Phase 3 study in Chinese patients with Demodex blepharitis in the second half of 2022. LianBio expects this study will support registration of TP-03 in China.

**NBTXR3**

- LianBio expects to begin dosing patients in Nanobiotix's global Phase 3 NANORAY-312 clinical trial of NBTXR3 for the treatment of locally advanced head and neck squamous cell carcinoma in elderly patients ineligible for cisplatin in the second half of 2022. LianBio expects this study will support registration of NBTXR3 in China and other LianBio-licensed territories in Asia.

**Infigratinib**

- Enrollment is ongoing in LianBio's Phase 2a clinical trial of infigratinib in locally advanced or metastatic gastric cancer or gastroesophageal junction adenocarcinoma with FGFR2 gene amplification and other advanced solid tumors with FGFR genomic alterations.
- LianBio expects to begin dosing Chinese patients in Helsinn's ongoing global pivotal Phase 3 PROOF-301 clinical trial of infigratinib in first-line cholangiocarcinoma (CCA) patients with FGFR2 gene fusions/translocations in the second half of 2022.

**BBP-398**

- LianBio expects to initiate a Phase 1 monotherapy clinical trial of BBP-398 in advanced solid tumors in the fourth quarter of 2022.
- LianBio also expects to initiate a Phase 1 clinical trial of BBP-398 in combination with an EGFR-inhibitor in non-small cell lung cancer in the first half of 2023.

**Second Quarter 2022 Financial Results**

**Research & Development Expenses**
Research and development expenses were $28.6 million for the second quarter of 2022 compared to $93.0 million for the second quarter of 2021, and $40.9 million for the six month period ended June 30, 2022 compared to $146.4 million for the six month period ended June 30, 2021. The decrease was primarily attributable to increased milestone payments in 2021, and was offset by higher development activities to support clinical trials and personnel-related expenses in 2022.

**General & Administrative Expenses**
General and administrative expenses were $14.6 million for the second quarter of 2022 compared to $6.5 million for the second quarter of 2021, and $30.6 million for the six month period ended June 30, 2022 compared to $13.6 million for the six month period ended June 30, 2021. The increase was primarily attributable to increases in payroll and personnel-related expenses (including share-based compensation expense) for increased employee headcount and higher expense for legal, consulting and accounting services.

**Net Loss**
Net loss was $42.4 million for the second quarter of 2022 compared to net loss of $100.4 million for the second quarter of 2021, and $70.1 million for the six month period ended June 30, 2022 compared to $162.0 million for the six month period ended June 30, 2021.

**Cash Balance**
Cash, cash equivalents, marketable securities and restricted cash at June 30, 2022 totaled $349.4 million compared to $403.2 million as of December 31, 2021. LianBio projects its current cash, cash equivalents, marketable securities, and restricted cash will be sufficient to fund its current operating plan into the second half of 2024.

**About LianBio**

LianBio is a cross-border biotechnology company on a mission to bring transformative medicines to patients in China and other Asian markets. Through partnerships with highly innovative biopharmaceutical companies around the world, LianBio is advancing a diversified portfolio of clinically validated product candidates with the potential to drive new standards of care across cardiovascular, oncology, ophthalmology, inflammatory disease and respiratory indications. LianBio is establishing an international infrastructure to position the company as a partner of choice with a platform to provide access to China and other Asian markets. For additional information, please visit the company's website at www.lianbio.com.

**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. The words "anticipate," "plan," " believe," "continue," "expect," "potential," "project," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Forward-looking statements in this press release include, but are not limited to, statements concerning the Company's plans and expectations with respect to the initiation and completion of its clinical trials, the advancement of its pipeline of therapeutic candidates, the continued growth or its organization, its ability to bring transformative medicines to patients across Asia, the availability of newits ability to navigate complex regulatory environments in-licensing opportunities Greater China and Asia, the Company's plans and expectations with respect to preparation for potential commercialization and product launch, and the timeline through which it expects to be able to fund its operating expenses and capital expenditure requirements, as well as statements regarding our partners' announced plans and expectations with respect to their planned product development activities, preclinical studies and clinical trials. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the Company's ability to successfully initiate and conduct its planned clinical trials and complete such clinical trials and obtain results on its expected timelines, or at all; the Company's plans to leverage data generated in its partners' global registrational trials and clinical development programs to obtain regulatory approval and maximize patient reach for its product candidates; the Company's ability to identify new product candidates and successfully acquire such product candidates from third parties; competition from other biotechnology and pharmaceutical companies; general market conditions; the impact of changing laws and regulations and those risks and uncertainties described in LianBio's filings with the U.S. Securities and Exchange Commission (SEC), including LianBio's Annual Report on Form 10-K for the year ended December 31, 2021 and subsequent filings with the SEC. Any forward-looking statements contained in this press release speak only as of the date hereof, and LianBio 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 this information as current or accurate after its publication date.

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**LianBio**
**Consolidated Balance Sheets**
**(In thousands, except share and per share amounts) (Unaudited)**

| | June 30, 2022 | December 31, 2021 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 134,334 | $ 228,182 |
| Marketable securities | 194,965 | 155,067 |
| Prepaid expenses and other current assets | 7,141 | 10,354 |
| Other receivable | 7,264 | 6,044 |
| Total current assets | 343,704 | 399,647 |
| Restricted cash, non-current | 20,075 | 20,000 |
| Property and equipment, net | 2,992 | 1,882 |
| Operating lease right-of-use assets | 5,003 | 4,763 |
| Other non-current assets | 39 | 51 |
| Total assets | $ 371,813 | $ 426,343 |
| **Liabilities and Shareholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,234 | $ 3,231 |
| Accrued expenses | 17,972 | 9,976 |
| Current portion of operating lease liabilities | 1,803 | 1,125 |
| Other current liabilities | 738 | 760 |
| Total current liabilities | 21,747 | 15,092 |
| Operating lease liabilities | 3,660 | 3,709 |
| Other liabilities | 208 | 206 |
| Nonrefundable research deposit | 20,000 | 20,000 |
| Total liabilities | $ 45,615 | $ 39,007 |
| Commitments and contingencies (Note 8) | | |

| | | |
|---|---|---|
| Ordinary shares, $0.000017100448 par value. Authorized 2,923,900,005 shares as of June 30, 2022; 108,353,831 shares issued and outstanding at June 30, 2022; Authorized 2,923,900,005 shares as of December 31, 2021; 107,275,458 shares issued and outstanding at December 31, 2021 | 2 | 2 |
| Additional paid-in capital | 724,176 | 713,269 |
| Accumulated other comprehensive (loss) income | (1,402) | 526 |
| Accumulated deficit | (430,352) | (360,235) |
| Total LianBio shareholders' equity | 292,424 | 353,562 |
| Non-controlling interest | 33,774 | 33,774 |
| Total shareholders' equity | 326,198 | 387,336 |
| Total liabilities and shareholders' equity | $ 371,813 | $ 426,343 |

**LianBio**
**Statements of Operations and Comprehensive Loss**
**(In thousands, except share and per share amounts) (Unaudited)**

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2022** | **2021** | **2022** | **2021** |
| **Operating expenses:** | | | | |
| Research and development | $ 28,591 | $ 93,030 | $ 40,920 | $ 146,383 |
| General and administrative | 14,551 | 6,461 | 30,639 | 13,607 |
| Total operating expenses | 43,142 | 99,491 | 71,559 | 159,990 |
| Loss from operations | (43,142) | (99,491) | (71,559) | (159,990) |
| Other income (expense): | | | | |
| Interest income, net | 553 | 106 | 833 | 139 |
| Other income (expense), net | 203 | (68) | 620 | (192) |
| Net loss before income taxes | (42,386) | (99,453) | (70,106) | (160,043) |
| Income taxes | 5 | 975 | 11 | 1,950 |
| Net loss | (42,391) | (100,428) | (70,117) | (161,993) |
| Other comprehensive (loss) income: | | | | |
| Foreign currency translation (loss) income, net of tax | (421) | 122 | (814) | 130 |
| Unrealized loss on marketable securities, net of tax | (291) | — | (1,114) | — |
| Comprehensive loss | $ (43,103) | $ (100,306) | $ (72,045) | $ (161,863) |
| Net loss per share attributable to ordinary shareholders, basic and diluted | $ (0.39) | $ (4.90) | $ (0.65) | $ (7.91) |
| Weighted-average shares outstanding used in computing net loss per share attributable to ordinary shareholders, basic and diluted | 107,922,501 | 20,477,338 | 107,600,767 | 20,477,338 |