# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 8-K

## CURRENT REPORT Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 12, 2022

# **LIANBIO**

(Exact name of registrant as specified in its charter)

**Cayman Islands** (State or other jurisdiction of incorporation) 001-40947 (Commission File Number)

98-1594670 (IRS Employer Identification No.)

08540

(Zip Code)

103 Carnegie Center Drive, Suite 309 Princeton, NJ

(Address of principal executive offices)

(Registrant's telephone number, including area code): (609) 486-2308

Not Applicable (Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

0 Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12) 0

о Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)) 0

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American depositary shares, each representing 1 ordinary share, \$0.000017100448 par value per share	LIAN	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company x

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.  $\boldsymbol{x}$ 

### Item 2.02 Results of Operations and Financial Condition.

On May 12, 2022, LianBio (the "Company") issued a press release announcing its financial results for the fiscal quarter ended March 31, 2022. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-Κ.

# Item 7.01 Regulation FD Disclosure.

On May 12, 2022, the Company posted an updated corporate presentation to its website. A copy of the corporate presentation is furnished as Exhibit 99.2 to this Current Report on Form 8-K. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.2.

The information contained in this Current Report on Form 8-K, including Exhibit 99.1 and Exhibit 99.2 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit	
N.	

No.	Description
99.1	Press release issued by LianBio, dated May 12, 2022
99.2	LianBio corporate presentation as of May 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

# 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 hereunto duly authorized.

# LIANBIO

By:

/s/ Yizhe Wang Yizhe Wang Chief Executive Officer

Date: May 12, 2022



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

- LianBio's partner, Bristol Myers Squibb, has received U.S. FDA approval of mavacamten for the treatment of patients with obstructive hypertrophic cardiomyopathy (oHCM)
  - Registrational Phase 3 EXPLORER-CN clinical trial of mavacamten in Chinese patients with symptomatic oHCM ongoing
  - LianBio's partner, Tarsus, announced positive topline data from the Phase 3 Saturn-2 clinical trial of TP-03 in patients with Demodex blepharitis

• LianBio's partner, ReViral, entered into definitive agreement to be acquired by Pfizer

- Three additional pipeline programs expected to enter into registrational Phase 3 clinical trials in China by year-end 2022
  - Cash balance of \$389.1 million at the end of first quarter 2022 with runway through mid- 2024

Shanghai and Princeton, N.J., May 12, 2022 – 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 first quarter ended March 31, 2022 and provided a corporate update.

"LianBio continues to solidify our standing as the partner of choice to bring clinically validated therapeutic candidates to Greater China and other Asian markets," said Yizhe Wang, Ph.D., Chief Executive Officer of LianBio. "Several of our partners have recently reached significant global milestones, including a U.S. FDA approval, positive pivotal trial results, and an acquisition. We congratulate our development partners on these important achievements. In China, we are committed to accelerating patient access to potentially transformative therapeutics, and we remain on track to complete enrollment in our ongoing Phase 3 EXPLORER-CN trial of mavacamten and to initiate three additional pivotal studies this year."

# Recent Business Highlights and Clinical Development Updates

#### BMS receives FDA approval for mavacamten and presents additional positive Phase 3 clinical trial results

 In April 2022, LianBio's partner Bristol Myers Squibb (BMS) presented data from two clinical trials of mavacamten at the American College of Cardiology 71<sup>st</sup> Annual Scientific Session. Data from the EXPLORER-LTE clinical trial demonstrated sustained improvements in clinically meaningful cardiovascular outcomes at weeks 48 and 84 in patients with symptomatic oHCM receiving mavacamten. Data from the Phase 3 VALOR-HCM clinical trial demonstrated the addition of mavacamten significantly reduced the need for septal reduction therapy (SRT) in patients with severely symptomatic oHCM who had been appropriate for SRT at baseline. In April 2022, BMS announced the U.S. Food and Drug Administration (FDA) approval of mavacamten for the treatment of adults with symptomatic New York Heart Association Class II-III oHCM to improve functional capacity and symptoms.

### Mavacamten development progress continues in China

- In January 2022, LianBio initiated the Phase 3 EXPLORER-CN clinical trial of mavacamten in Chinese patients with symptomatic oHCM. Patient enrollment is ongoing.
- In February 2022, the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) granted Breakthrough Therapy Designation in China for mavacamten for the treatment of patients with oHCM.
- In May 2022, LianBio announced topline results from the Phase 1 pharmacokinetic (PK) study of mavacamten in healthy Chinese volunteers. A single oral administration of mavacamten in Chinese healthy adult subjects showed no new safety signals. The data demonstrated a favorable PK, safety and tolerability profile comparable to that observed in the Phase 1 pharmacokinetic study of mavacamten conducted by LianBio's partner, MyoKardia, now a wholly owned subsidiary of BMS, in healthy volunteers in the United States.

#### TP-03 met all primary and secondary endpoints in Tarsus's second U.S. pivotal trial

- In May 2022, Tarsus announced positive topline data from the Phase 3 Saturn-2 clinical trial of TP-03 in Demodex blepharitis (DB) patients. The clinical trial met all primary and secondary endpoints and TP-03 was well-tolerated.
- Based on these data, Tarsus announced that it will submit a New Drug Application to the U.S. FDA in the second half of 2022.

# Development partner ReViral Ltd. entered into definitive agreement to be acquired by Pfizer Inc.

In April 2022, Pfizer and ReViral entered into a definitive agreement under which Pfizer will acquire ReViral and its respiratory syncytial virus therapeutic candidates, including sisunatovir.

### Formation of Scientific Advisory Board

In April 2022, LianBio formed a Scientific Advisory Board (SAB). The LianBio SAB is comprised of industry leaders in global drug development who are serving as strategic advisors to the Company.

#### Appointment to the Board of Directors

• In April 2022, LianBio appointed Wei Wei Chen to the Board of Directors. Ms. Chen brings over 17 years of experience serving as chief financial officer of companies in the consumer, retail and healthcare sectors.

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

Current cash runway is projected to extend through mid-2024.

# Key Milestones Anticipated in 2022

#### Mavacamten

• Enrollment is ongoing in the EXPLORER-CN Phase 3 clinical trial of mavacamten in Chinese patients with oHCM. LianBio expects to complete enrollment in the second half of 2022.

#### TP-03

• LianBio remains on track to initiate a Phase 3 clinical trial of TP-03 in Chinese patients with DB in the second half of 2022 to support regulatory approval in China.

### NBTXR3

LianBio expects to begin dosing Chinese patients in Nanobiotix's ongoing global pivotal 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.

#### 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 fibroblast growth factor receptor-2 (FGFR2) gene amplification and other advanced solid tumors with FGFR genomic alterations.
- LianBio expects to begin dosing Chinese patients in QED'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.

### First Quarter 2022 Financial Results

### Research & Development Expenses

Research and development expenses were \$12.3 million for the first quarter of 2022 compared to \$53.4 million for the first quarter of 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 \$16.1 million for the first quarter of 2022 compared to \$7.1 million for the first quarter of 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 \$27.7 million for the first quarter of 2022 compared to net loss of \$61.6 million for the first quarter of 2021.

#### Cash Balance

Cash, cash equivalents, marketable securities and restricted cash at March 31, 2022 totaled \$389.1 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 through mid 2024.

# About LianBio

LianBio is a cross-border biotechnology company on a mission to bring transformative medicines to historically underserved 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," "continue," "expect," "potential," "project," "target," 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, its ability to bring transformative medicines to patients across Asia, the availability of new in-licensing opportunities, 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.

# For investor inquiries, please contact:

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### For media inquiries, please contact:

Katherine Smith, CanaleComm E: katherine.smith@canalecomm.com T: (619) 849-5378

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

	March 31, 2022		December 31, 2021
Assets		-	
Current assets:			
Cash and cash equivalents	\$ 139,857	\$	228,182
Marketable securities	229,278		155,067
Related party receivable	2,062		_
Prepaid expenses and other current assets	8,973		10,354
Other receivable	 5,966		6,044
Total current assets	386,136		399,647
Restricted cash, non-current	20,000		20,000
Property and equipment, net	2,923		1,882
Operating lease right-of-use assets	4,370		4,763
Other non-current assets	50		51
Total assets	\$ 413,479	\$	426,343
Liabilities and Shareholders' Equity			
Current liabilities:			
Accounts payable	\$ 7,927	\$	3,231
Accrued expenses	14,874		9,976
Current portion of operating lease liabilities	1,374		1,125
Other current liabilities	979		760
Total current liabilities	25,154		15,092
Operating lease liabilities	3,345		3,709
Other liabilities	207		206
Nonrefundable research deposit	20,000		20,000
Total liabilities	48,706		39,007
Commitments and contingencies (Note 8)			
Shareholders' equity (deficit):			
Ordinary shares, \$0,000017100448 par value. Authorized 2,923,900,005 shares as of March 31, 2022; 107,275,458 shares issued and outstanding at March 31, 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	719,648		713,269
Accumulated other comprehensive (loss) income	(690)		526
Accumulated deficit	(387,961)		(360,235)
Total LianBio shareholders' equity	330,999		353,562
Non-controlling interest	33,774		33,774
Total shareholders' equity	364,773		387,336
Total liabilities and shareholders' equity	\$ 413,479	\$	426,343

# LianBio

# Statements of Operations and Comprehensive Loss

(In thousands, except share and per share amounts) (Unaudited)

	Three Months Ended March 31, 2021	Three Months Ended March 31, 2022
Operating expenses:		
Research and development	\$ 12,329	\$ 53,353
General and administrative	16,088	7,146
Total operating expenses	 28,417	60,499
Loss from operations	(28,417)	(60,499)
Other income (expense):		
Interest income	280	33
Other income (expense), net	417	(124)
Net loss before income taxes	 (27,720)	(60,590)
Income taxes	6	975
Net loss	(27,726)	(61,565)
Other comprehensive (loss) income:		
Foreign currency translation (loss) income, net of tax	(393)	8
Unrealized loss on marketable securities, net of tax	(823)	—
Comprehensive loss	\$ (28,942)	\$ (61,557)
Net loss per share attributable to ordinary shareholders, basic and diluted	\$ (0.26)	\$ (3.01)
Weighted-average shares outstanding used in computing net loss per share attributable to ordinary shareholders, basic and diluted	107,275,458	 20,477,338





The information herein contains statements about future expectations, plans and prospects for LianBio. All statements, other than statements of historical fact, included herein are forward-looking statements. Forward-looking statements are not statements of historical fact nor are they guarantees or assurances of future performance. Forward-looking statements are based on LianBio's expectations and assumptions and are subject to inherent uncertainties, risks and changes in circumstances that may cause actual results to materially and adversely differ from those set forth in or implied by such forward-looking statements, including those risks and uncertainties and other important factors in our subsequent filings with the Securities and Exchange Commission. LianBio undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. These forward-looking statements should not be relied upon as representing LianBio's views as of any date subsequent to the date hereof.

Certain information contained in this presentation relates to or is based on studies, publications, surveys and other data obtained from third party sources and LianBio's own internal estimates and research. While LianBio believes these third-party sources to be reliable as of the date of this presentation, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of any information obtained from third party sources. In addition, the third party information included in this presentation may involve a number of assumptions, and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, while LianBio believes its own internal research is reliable, such research has not been verified by any independent source.



We are a global biopharmaceutical company dedicated to developing and commercializing paradigm-shifting medicines for patients with unmet medical needs in Greater China and other Asian markets

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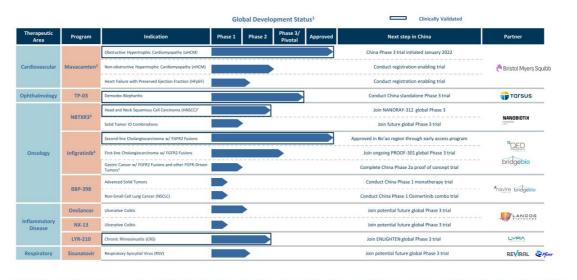




1. CapitallQ, assumes only one opportunity per company based on 10,794 total US/EU biotech companies as of July 2021. 2. Based on 857 cross-border deals from 2015-2020 per ChinaBio. 3. US-listed Chinese biotech companies include: Adagene, BeiGene, BeyondSpring, Burning Rock, Connect Biopharma, Genetron, Gracell Biotech, Hutchinson China Medical, J. Mab, Legend Biotech, and Zai Lab. Assumes pre-money IPO valuation for Adagene (\$738), Burning Rock (\$1,460), Connect Biopharma (\$758), Gracell Biotech (\$1,138), Home (\$655) and Legend Biotech (\$233) in 01-Jan-2019.



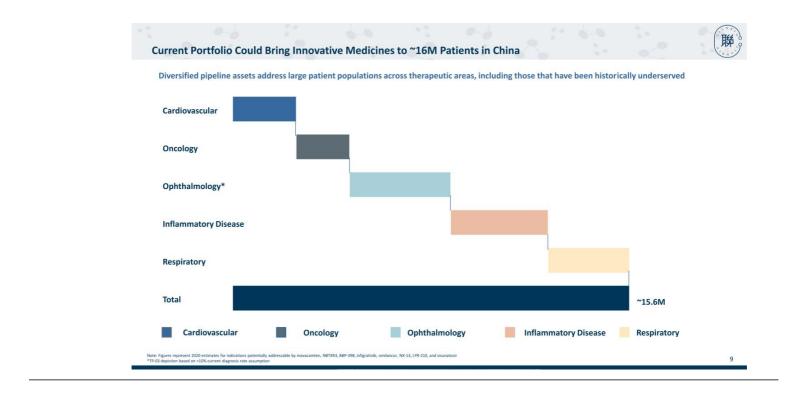
# Pipeline of Innovative Medicines – 5 Clinically Validated Therapeutic Candidates



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Establish Commercial Footprint with Lead Assets	(#2) Leverage Infrastructure	(#3) Expand Pipeline via Additional B
* All clinically validated*		
CAMZYOS Mavacamten	BBP-398	Deepen existing TA franchises
and a second	LYR-210	Strategic multi-asset partnerships
ТР-03	Sisunatovir	• Strategic multi-asset partiersnips
NBTXR3	Sisunatovir	Combination opportunities
	Omilancor	
o TRUSELTIO Infigratinib	NX-13	











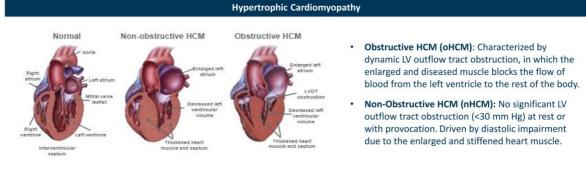
## MYOKARDIA (III Bristol Myers Squibb"

### Mavacamten for the Treatment of HCM and HFpEF

- Mavacamten is a myosin inhibitor that targets excessive contractility and impaired relaxation, myocardial energetics and compliance
- In development for the treatment of obstructive hypertrophic cardiomyopathy (oHCM), non-obstructive hypertrophic cardiomyopathy (nHCM) and heart failure with preserved ejection fraction (HFpEF)

# China Opportunity

- 1.1M 2.8M HCM patients in China (67% oHCM / 33% nHCM)
- 3.7M HFpEF patients, 10-20% of whom may potentially be addressed by mavacamten



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# **Clinical Activity Demonstrated in oHCM and nHCM**



# **Clinical Data Summary**

# oHCM:

- Phase 3 EXPLORER-HCM trial demonstrated patients on treatment experienced statistically significant and clinically meaningful improvements
  - Primary endpoint: Improvement of symptoms and functional capacity (improvement in NYHA class and peak VO2)
  - Well-tolerated; safety results were comparable to placebo; only 2% drop out rate

# nHCM:

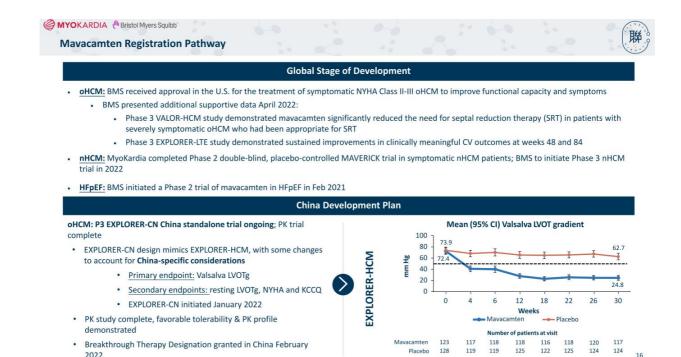
 Phase 2 MAVERICK-HCM trial demonstrated physiologic benefit with dose dependent reduction in serum levels of NT proBNP, with potentially greater benefit in more severe disease

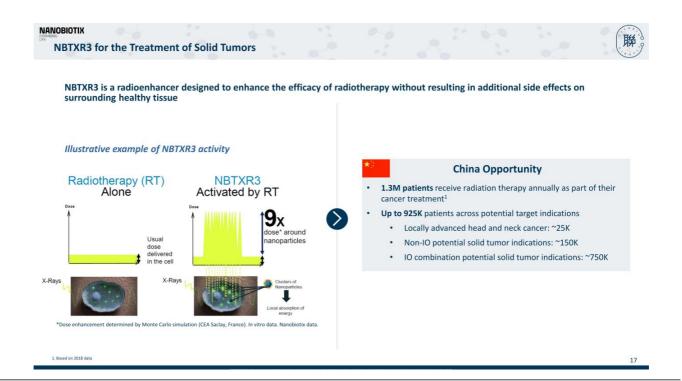
Source: Olivotto et al, Lancet 2020; Ho et al, J Am Coll Cardiol. 2020

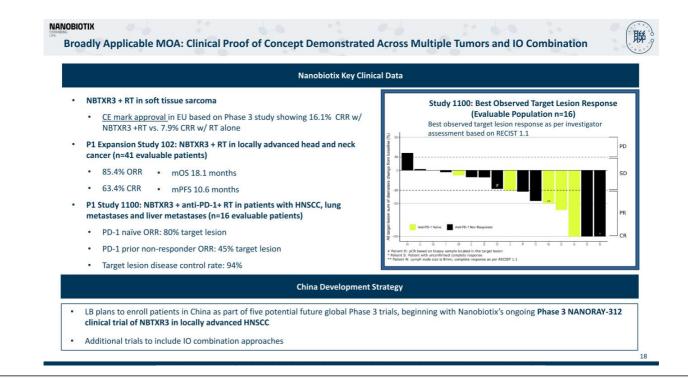
# EXPLORER-HCM

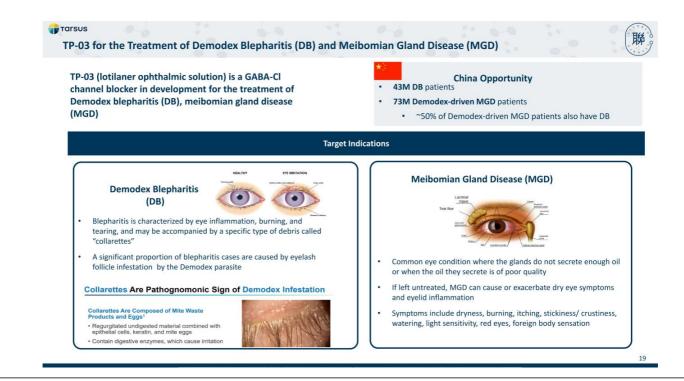
Change from Baseline to Week 30			
Primary Endpoint			
Composite functional, n (%) EITHER ≥1.5 mI/kg/min increase in pVO2 with ≥1 NYHA class improvement OR ≥3.0 mI/kg/min increase in pVO2 with no worsening of NYHA class	45 (37%)	22 (17%)	0.0005
Secondary Endpoints			
Post-exercise LVOT peak gradient, mmHg, mean (SD)	-47 (40)	-10 (30)	<0.0001
Peak VO2, mL/kg/min, mean (SD)	1.4 (3.1)	-0.1 (3.0)	0.0006
NYHA improved ≥ 1 class, n (%)	80 (65%)	40 (31%)	<0.0001
KCCQ-CSS, mean (SD)	13.6 (14.4)	4.2 (13.7)	<0.0001
HCMSQ-SoB score, mean (SD)	-2.8 (2.7)	-0.9 (2.4)	< 0.0001

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All Pre-Specified Primary and S	econdary Endpoints were	e Met in Tarsus's Saturn	-1 and Saturn-2 Pivotal	Trials
Tarsus completed two successful	pivotal trials with consisten	cy across endpoints		
	Saturn-1 N=421	Saturn-2 N=412	Combined N=833	
	(Pivotal Phase 2b/3)	(Pivotal Phase 3)	Pivotal Data	
Primary Endpoin Complete Collarette		<b>56%</b> vs. 13% (p<0.0001)	50% vs. 10%	
Clinically Meaning Collarette Cure (Grade 0 or 1)	81% vs. 23% (p<0.0001)	<b>89%</b> vs. 33% (p<0.0001)	<b>85%</b> vs 28%	

Mite Eradication Lid Erythema Cure

-

Approximately 90% of patients experienced a clinically meaningful benefit with respect to collarettes, collarette grade improvement and mites per lash

**52%** vs 14% (p<0.0001)

**31%** vs. 9% (p<0.0001)

De	Source: Tarsus Pharmaceuticals	
U.S. • Tarsus has announced plans to submit NDA for TP-03 in DB to U.S. FDA in 2H 2022	China Conduct DB PK trial (N=12) Conduct DB PS China standalone trial (N=150, 1:1 randomization)	
Phase 2a MGD trial to be initiated 1H 2022	<ul> <li><u>Co-primary endpoints:</u> collarette cure (0-2 collarettes per eyelid) at day 43, mite eradication at day 43</li> <li><u>Secondary endpoints:</u> composite cure of collarette and erythema (0-2 collarettes per eyelid and grade 0 erythema) at day 43</li> <li>Trials expected to be initiated 2H 2022</li> </ul>	

# bridgebio <sup>©</sup><u>CED</u> Infigratinib for the Treatment of FGFR-Driven Cancers

Infigratinib is an orally administered, ATP-competitive, FGFR1-3 tyrosine kinase inhibitor in development for the treatment of patients with FGFR-driven cancers

- QED received FDA approval of infigratinib for the treatment of patients with previously-treated, unresectable locally advanced or metastatic cholangiocarcinoma (CCA) harboring an FGFR2 fusion or rearrangement in May 2021
- Approval based on meaningful clinical activity demonstrated in Phase
  2 trial in chemotherapy-refractory CCA patients with FGFR2 fusions
  - BICR cORR of 23.1% (95% CI 15.6 32.2) in 2nd and later line patients
  - BICR cORR of 34.0% in true 2nd line patients
    DOR of 5.0 mos (95% CI 3.7–9.3)
  - DOR of 5.0 mos (95% CI 3.7–9.3)
     Infigratinib administered as third
  - Infigratinib administered as third-and later-line treatment resulted in meaningful PFS and ORR benefit in patients with CCA and FGFR2 fusions ~7 mos
  - Current SoC (chemo) = ~3 mos PFS in 2L CCA

Phase 2 trial of infigratinib in chemotherapy-refractory CCA patients	with FGFR2 fusions (n=108
BICR- assessed objective response rate (ORR), % (95% CI)	23.1 (15.6-32.2)
≤1 previous line of therapy (n=50)	34.0
≥2 previous lines of therapy (n=58)	7.4
BICR-assessed best overall response	
Complete Response, n (%)	1 (1.1)
Partial Response, n (%)	24 (22)
Stable Disease, n (%)	66 (61)
Unconfirmed Complete or Partial Response	12 (11)
Progressive Disease, n (%)	11 (10)
Unknown, n (%)	6 (6)
BICR-assessed confirmed or unconfirmed response, % (95% CI)	34.3 (25.4 - 44.0)
BICR-assessed disease control rate, % (95% CI)	84.3 (76.0 - 90.6)
BICR-assessed median duration of response (IQR), months (95% CI)	5.0 (3.7 - 9.3)
BICR-assessed median PFS, months (95% CI)	7.3 (5.6 - 7.6)
Median OS, months (95% CI)	12.2 (10.7 -14.9)

# QED's Development and Regulatory Status in the U.S.

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- U.S. FDA approval in 2nd line CCA received May 2021
- Ongoing global Phase 3 PROOF-301 trial in 1st line CCA
- Ongoing global Phase 3 trial in urothelial carcinoma
- In Jan 2020 received Fast Track Designation for 1st line CCA
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bridgebio <sup>©</sup> ED Infigratinib Registration Pathway and China Opportunity

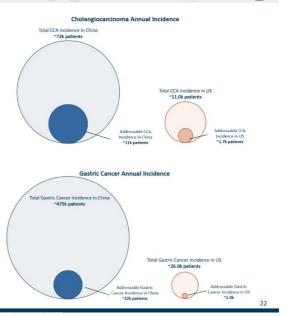


# China Opportunity

- Estimated 72,000 patients diagnosed with CCA annually in • China vs. 11,000 diagnosed in U.S.
- Estimated 480,000 patients diagnosed with GC annually in China vs. 26,350 diagnosed in U.S. •

# **China Development Strategy and Regulatory Pathway**

- LB will enroll patients in China as part of QED's ongoing global Phase 3 PROOF trial in first-line CCA
- LB initiated a Phase 2a proof of concept trial in China for . FGFR2-amplified gastric cancer and other solid tumors with FGFR alterations



Additional Pip	peline Programs	( 1 O.
bridgebio navire	<ul> <li>BBP-398 (SHP2 inhibitor) for the treatment of MAPK pathway-driven solid tumors</li> <li>Differentiated profile with a shorter-half life, attractive PK/PD and clean tox</li> <li>SHP2 inhibitors have broad potential applications across a variety of tumors and are being developed as combination therapy</li> </ul>	
THERAPEUTICS	<ul> <li>LYR-210 (implantable drug matrix) for the treatment of chronic rhinosinusitis (CRS) with 3.4M medically refractory patients in China</li> <li>Implantable drug matrix designed to consistently and locally elute mometasone furoate (steroid) to inflamed mucosal sinus tissue for up to six months with a single administration for surgically naïve patients</li> <li>Clinically validated with Ph2 statistically significant symptom improvement vs. control at 16, 20 and 24 weeks</li> </ul>	
REVIRAL Pfizer	<ul> <li>Sisunatovir (fusion inhibitor) for the treatment of respiratory syncytial virus (RSV)</li> <li>No SAEs observed across ~200 patients treated to date; no cardiac toxicity observed to date, a key issue leading to failure of prior fusion inhibitors</li> <li>Potential applicability in high-risk patient segments including pediatric, elderly patients</li> </ul>	
LANDOS	<ul> <li>Omilancor (LANCL2 agonist) for the treatment of IBD</li> <li>Oral, gut-restrictive mechanism (lack of systemic exposure) designed for a safe and convenient route of administration for treatment of moderate to severe IBD</li> <li>Rapidly growing IBD incident population in China</li> <li>NX-13 (NLRX1 agonist) for the treatment of IBD</li> </ul>	
	<ul> <li>In Ph1a safety study, NX-13 was shown to be well tolerated</li> </ul>	

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Major Validating	Milestones Highlight Stre	ength of LianBio	Business Develop	ment Engine		聯。

Partner	LianBio Partnership Date	<ul> <li>Asset Milestone Post-Partnership</li> <li>Oct 2020: MyoKardia <u>acquired by BMS for \$13.1B</u></li> <li>Apr 2022: BMS received <u>U.S. FDA approval</u> of mavacamten for patients with symptomatic oHCM</li> </ul>	
MYOKARDIA Mavacamten ( <sup>III</sup> ) Bristol Myers Squibb	Aug 2020		
REVIRAL Sisunatovir	Mar 2021	✓ Apr 2022: Reviral enters agreement to be <u>acquired by Pfizer</u> for up to \$525M	
bridgebio Dependential Infigratinib	Oct 2019	<ul> <li>May 2021: QED received <u>FDA approval</u> of infigratinib for patients with previously treated cholangiocarcinoma</li> <li>Mar 2021 &amp; 2022: Helsinn Group and QED enter into and expand <u>infigratinib strategic collaboration</u></li> </ul>	
Tarsus TP-03	Mar 2021	<ul> <li>Jun 2021: <u>Positive pivotal results</u> in Tarsus's SATURN-1 tria (P2b/3 DB) – all primary and secondary endpoints met</li> <li>May 2022: <u>Positive pivotal results</u> in Tarsus's SATURN-2 tria (P3 DB) – all primary and secondary endpoints met</li> </ul>	





A differentiated strategic collaboration that provides sourcing, development and commercial optionality

- Provides LianBio and partners optionality to access
   <u>Pfizer's established commercial infrastructure</u> with a highly compliant, secure commercial engine
- At LianBio's election and Pfizer's ROFN, we can jointly develop and commercialize certain LianBio products
- Companies are also working together to <u>source, select</u> and develop/register leading products for China
  - Pfizer will contribute up to \$70M of non-dilutive capital for in-licensing and co-development activities



# Preferential access to an <u>innovative pipeline of more</u> <u>than 20 product development candidates</u>

- BridgeBio is developing transformative medicines to treat patients who suffer from genetic diseases and cancers with clear genetic drivers. BridgeBio is advancing a broad, innovative pipeline across rare disease, oncology, dermatology, and other indications
- LianBio already holds China rights to two of BridgeBio's oncology assets, infigratinib and BBP-398

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Targeting 3 Additional Registrational Trial Initiations and Multiple Catalysts by End of 2022

Therapeutic Area	Program	Milestone / Catalyst	Anticipated Timing
Cardiovascular Mavacamten		Initiate Phase 3 EXPLORER-CN clinical trial in patients with oHCM	✓ Jan 2022
		<ul> <li>Mavacamten granted BTD for oHCM in China</li> </ul>	✓ Feb 2022
	Mavacamten	<ul> <li>U.S. FDA approval for the treatment of symptomatic oHCM (BMS)</li> </ul>	🗸 April 2022
		<ul> <li>Completion of PK trial in China, demonstrating favorable safety, tolerability and PK profile</li> </ul>	🗸 May 2022
		<ul> <li>Complete enrollment in Phase 3 EXPLORER-CN clinical trial in patients with oHCM</li> </ul>	H2 2022
Ophthalmology TP-03	70.02	<ul> <li>Saturn-2 pivotal trial readout (Tarsus)</li> </ul>	🗸 Apr 2022
	12-03	<ul> <li>Initiate Phase 3 clinical trial in patients with Demodex blepharitis in China</li> </ul>	H2 2022
Oncology Infigratinib		Global trial initiation of Phase 3 NANORAY-312 clinical trial in head and neck cancer (Nanobiotix)	🗸 Jan 2022
	NBTXR3	<ul> <li>Initiate China portion of Phase 3 NANORAY-312 clinical trial in patients with head and neck cancer</li> </ul>	H2 2022
	Infigratinib	<ul> <li>Initiate China portion of Phase 3 PROOF-301 clinical trial in patients with first line cholangiocarcinoma</li> </ul>	H2 2022

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We are a global biopharmaceutical company dedicated to developing and commercializing paradigm-shifting medicines for patients with unmet medical needs in Greater China and other Asian markets

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