TLC Reports Second Quarter 2021 Financial Results and Provides Business Update

SOUTH SAN FRANCISCO, CA and TAIPEI, Taiwan – August 12, 2021 – TLC, a clinical-stage specialty pharmaceutical company developing novel nanomedicines to target areas of unmet medical need, today announced financial results for the second quarter ended June 30, 2021 and provided a business update.

"The second quarter of 2021 was marked mainly by the timely approval of our liposomal amphotericin B product in India and the immediate partnerships for their commercialization and sales in the territory," commented George Yeh, President of TLC. "We are grateful to have the ability to be of assistance in this humanitarian crisis brought about by the COVID-19 pandemic by fulfilling an unmet need, and will continue our quest to provide best-in-class treatments in pain management, ophthalmology, oncology, as well as infectious diseases."

Clinical Pipeline Update and Upcoming Milestones

- ***All subjects have reached the 24-week timepoint in EXCELLENCE.*** The Phase III pivotal clinical trial of TLC599 in ~500 subjects is progressing smoothly, with all subject having reached the 24-week timepoint and the majority of whom having received the second injection of either TLC599 or placebo. There remains no safety concerns or serious adverse events related to treatment. The multi-center, randomized, double-blind, active comparator- and placebo-controlled pivotal study is evaluating the efficacy and safety of a single and a repeat dose of TLC599 in patients with knee osteoarthritis across 46 sites in the United States and Australia.
- ***Pivotal clinical trial of TLC590 to kick off soon.*** Following a fruitful End-of-Phase 2 meeting with the United States Food and Drug Administration (FDA), TLC has accrued additional guidelines on the design parameters for the pivotal clinical trials of TLC590 for post-operative pain and will be kicking off the next trial soon.
- ***Liposomal amphotericin B receives approval in India.*** The Central Drugs Standard Control Organization (CDSCO) of India approved the New Drug Application (NDA) of Amphotericin B Liposome for Injection 50mg (known as Ampholipad® in Taiwan and AmphoTLC™ in India). The registration allows for immediate importation per approved usage and indication to aid in the country's acute shortage of treatments for COVID-19 associated mucormycosis.
- ***Presented data on advantages of inhalable liposome formulations of antiviral drugs for lung diseases at ISAM.*** At the 23rd International Society for Aerosols in Medicine (ISAM) Congress, TLC's subsidiary, InspirMed, presented data from pharmacokinetic studies on ISPM21 (inhalable liposomal

GS-441524, main plasma metabolite of remdesivir), and ISPM19 (inhalable liposomal hydroxychloroquine) that showed significantly higher concentrations in the lungs than their conventional counterparts, suggesting feasibility of higher dosing without hepatotoxicity or nephrotoxicity as an improvement upon current treatments.

Corporate Highlights

- ***Commercialization of liposomal amphotericin B in India.*** Following the new drug registration, TLC entered non-exclusive partnerships with Zydus Healthcare Limited and Strides Pharma Science Limited to begin immediate distribution of its liposomal amphotericin B product in India.
- ***Partnership with Endo International plc*** for the commercialization of a liposomal product. TLC is eligible to receive upfront and subsequent milestone payments as well as a double-digit share of the net profits from product sales in the United States.
- ***Stock swap and restructuring.*** Details of the share swap transactions and restructuring with Woods Investment Company, along with a list of frequently asked questions, can be found on the company website (www.tlcbio.com) under Investors/Shareholder Resources/Share Swap.
- ***Expanded global intellectual property protection to 314 patents,*** with 165 patents granted and 149 applications worldwide as of June 30, 2021.

Financial Results

Operating revenue for the second quarter of fiscal 2021 was NT$160.2 million (US$5.7 million), a 1,260.2% increase compared to NT$11.8 million (US$0.4 million) in the second quarter of fiscal 2020. Operating expenses for the second quarter of fiscal 2021 was NT$251.7 million (US$9.0 million), a 6.2% decrease compared to NT$268.4 million (US$9.1 million) in the second quarter of fiscal 2020. Net loss for the second quarter of fiscal 2021 was NT$75.5 million (US$2.7 million), compared to a loss of NT$242.4 million (US$8.2 million) in the second quarter of 2020, or a net loss of NT$0.66 (US$0.02) per share for the second quarter of fiscal 2021, compared to a net loss of NT$3.28 (US$0.11) per share for the second quarter of fiscal 2020.

The Company's cash and cash equivalents were NT$696.7 million (US$25.0 million) as of June 30, 2021, compared to NT$1,342.7 million (US$47.8 million) as of December 31, 2020.

Financial Summary

Selected Consolidated Balance Sheet Data

	December 31, 2020		June 30, 2021	
	NT$000	US$000	NT$000	US$000
Cash and cash equivalents and time deposit	$1,342,667	$ 47,816	$ 696,737	$ 24,964
Total current assets	1,431,977	50,997	986,874	35,359
Total assets	1,749,461	62,303	1,330,969	47,688
Total current liabilities	348,127	12,398	327,849	11,747
Long-term borrowings	469,076	16,705	372,809	13,357
Total liabilities	886,134	31,557	775,191	27,775
Total equity	863,327	30,746	555,778	19,913

Selected Consolidated Statements of Operations Data

	Three-month periods ended June 30,				Six-month periods ended June 30,			
	2020		2021		2020		2021	
	NT$000	US$000	NT$000	US$000	NT$000	US$000	NT$000	US$000
Operating revenue	$ 11,776	$ 400	$ 160,176	$ 5,739	$ 23,750	$ 807	$ 197,794	$ 7,087
Operating expenses								
General and administrative expenses	(39,487)	(1,341)	(31,622)	(1,133)	(72,367)	(2,458)	(62,669)	(2,245)
Research and development expenses	(228,881)	(7,774)	(220,087)	(7,886)	(420,659)	(14,289)	(442,861)	(15,868)
Total operating expenses	(268,368)	(9,115)	(251,709)	(9,019)	(493,026)	(16,747)	(505,530)	(18,113)
Loss before income tax	(242,089)	(8,223)	(75,144)	(2,692)	(456,253)	(15,498)	(293,142)	(10,503)
Income tax expense	(348)	(12)	(363)	(13)	(769)	(26)	(602)	(22)
Net loss	$ (242,437)	$ (8,235)	$ (75,507)	$ (2,705)	$ (457,022)	$ (15,524)	$ (293,744)	$ (10,525)
Total other comprehensive loss	$ 1,698	$ 58	$ (13,090)	$ (469)	$ (1,808)	$ (61)	$ (21,285)	$ (762)
Total comprehensive loss	$ (240,739)	$ (8,177)	$ (88,597)	$ (3,174)	$ (458,830)	$ (15,585)	$ (315,029)	$ (11,287)
Loss per share of common stock								
Basic and diluted loss per share (in dollars)	$ (3.28)	$ (0.11)	$ (0.66)	$ (0.02)	$ (6.18)	$ (0.21)	$ (3.05)	$ (0.11)

About TLC

TLC is a clinical-stage, specialty pharmaceutical company dedicated to the research and development of novel nanomedicines that maximize the potential of its proprietary lipid-assembled drug delivery platform (LipAD®), including BioSeizer® sustained release technology and NanoX® active drug loading technology, which are versatile in the choice of active pharmaceutical ingredients and scalable in manufacturing. TLC has a diverse, wholly owned portfolio of therapeutics targeting areas of unmet medical need in pain management, ophthalmology, oncology and infectious diseases.

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements contained in this press release include, without limitation, statements regarding TLC's expectations regarding the clinical development of TLC's product and product candidates, including Ampholipad, TLC599, TLC590, ISPM21 and ISPM19, the clinical benefits of TLC's products and product candidates, the timing, scope, progress and

outcome of TLC's clinical trials and regulatory communications, the timing, scope, progress and outcome of TLC's collaborations and partnerships, the commercialization of TLC's products, how sufficient cash and equivalents will be to fund operations, the anticipated timelines for the release of clinical data and progress of TLC's manufacturing capabilities. Words such as "may," "believe," "will," "expect," "plan," "anticipate," "estimate," "intend" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are not guarantees of future performance and involve a number of risks, assumptions, uncertainties and factors, including risks that the outcome of any clinical trial is inherently uncertain and product candidates may prove to be unsafe or ineffective, or may not achieve commercial approval, and delays or disruptions on our business or clinical trials due to the COVID-19 pandemic. Other risks are described in the Risk Factors section of TLC's annual report on Form 20-F for the year ended December 31, 2020 filed with the U.S. Securities and Exchange Commission (the "SEC") as well as subsequent filings with the SEC. All forward-looking statements are based on TLC's expectations and assumptions as of the date of this press release. Actual results may differ materially from these forward-looking statements. Except as required by law, TLC expressly disclaims any responsibility to update any forward-looking statement contained herein, whether as a result of new information, future events or otherwise.

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