



TLC Reports Second Quarter 2020 Financial Results and Provides Business Update

SOUTH SAN FRANCISCO, CA and TAIPEI, Taiwan – August 5, 2020 – TLC (Nasdaq: TLC, TWO: 4152), a clinical-stage specialty pharmaceutical company developing novel nanomedicines to target areas of unmet medical need, today announced financial results for the second quarter ending June 30, 2020, and provided a business update.

“I am happy to report that we have recently reached the halfway mark in patient enrollment in our EXCELLENCE trial and are on schedule to complete enrollment by the end of this year,” commented George Yeh, President of TLC. “Other key highlights in the second quarter include positive topline results from the TLC590 trial in bunionectomy, introduction of our inhalable liposomal hydroxychloroquine to potentially treat COVID-19, and a successful round of financing in Taiwan. As TLC is a member of the healthcare industry and based in Taiwan, where there has been fewer than 500 confirmed cases of COVID-19, we are committed to alleviating the global crisis while maintaining focus on the development of our key programs, and we will continue to work closely with relevant parties to ensure their most efficacious advancement.”

Clinical Pipeline Update and Upcoming Milestones

- **50% enrollment complete in EXCELLENCE for TLC599.** The Phase III, multi-center, randomized, double-blind, placebo- and active comparator-controlled pivotal study evaluating the efficacy and safety of both a single and a repeated dose of **TLC599 for symptomatic knee osteoarthritis** has enrolled half of all 500 patients. Some patients have proceeded to receive a second injection at week 24. EXCELLENCE remains on-track to complete enrollment before the end of 2020, with topline data expected in late 2021.
- **Subgroup analyses of TLC599 Phase II data confirm robustness of response through 24 weeks.** The pattern of responsiveness seen in the overall population, with greater reductions in pain by TLC599 than with placebo, sustaining from Week 1 to Week 24, was remarkably consistent between the subgroups, which were categorized based on gender, age, Kellgren-Lawrence grade, unilateral or bilateral knee pain, baseline Visual Analog scale pain scores and baseline Western Ontario and McMaster Universities Index (WOMAC) pain scores. These findings were accepted as an abstract at **Osteoarthritis Research Society International (OARSI) 2020** and published in the *Osteoarthritis and Cartilage* journal (#722).
- **Positive results for TLC590 Phase II trial for postsurgical pain following bunionectomy.** In this randomized, double-blind, placebo- and comparator-controlled study of 150 patients, TLC590 demonstrated greater reductions in



pain than both placebo and bupivacaine through 168 hours. TLC590 achieved statistically significant pain relief over placebo and bupivacaine from 0-12, 0-24, 0-36 and 0-48 hours as measured by area under the curve on the numerical pain rating scale. TLC590 significantly delayed the time to first opioid use; total opioid consumption of TLC590 was less than placebo and bupivacaine at every time point through 168 hours. TLC590 was well-tolerated, with a safety profile comparable to bupivacaine and placebo.

- ***Introduction of inhalable liposomal hydroxychloroquine (HCQ) to potentially treat COVID-19.*** A manuscript pre-print that has been made publicly available found that TLC's sustained release, liposomal formulation of HCQ, with targeted delivery of a tiny but therapeutic dose directly to the lung, can dramatically reduce systemic and cardiac adverse events, which was cause for termination in several global clinical trials involving orally administered – and extremely high doses – of HCQ.

Corporate Highlights

- ***Completed US\$23 million financing along with a US\$12 million venture financing from Cathay Bank,*** which, along with existing cash and equivalents, we expect will provide sufficient funding for operations into EXCELLENCE's data readout.
- ***Scheduled to present at several conferences in September.*** TLC will be virtually attending and presenting at Baird's 2020 Virtual Global Healthcare Conference (September 9-10), HC Wainwright 22nd Annual Global Investment Conference (September 14-16), Cantor Virtual Global Healthcare Conference (September 15-17) and Oppenheimer Fall Healthcare Life Sciences & MedTech Summit (September 21-23). Details on presentations times will follow closer to the dates.
- ***Ampholipad™ receives approval for scale-up production.*** Production of TLC's AmBisome[®] generic can now exceed a million vials a year, a capacity capable of meeting global demands.
- ***Expanded global intellectual property protection to 234 patents*** spanning 41 countries/territories, with 149 patents granted and 85 applications worldwide as of June 30, 2020.

Financial Results

Operating revenue for the second quarter of fiscal 2020 was NT\$11.8 million (US\$0.4 million), a 42.7% decrease compared to NT\$20.6 million (US\$0.7 million) in the second quarter of fiscal 2019. Operating expenses for the second quarter of fiscal 2020 was NT\$268.4 million (US\$9.1 million), a 2.3% increase compared to NT\$262.3 million (US\$8.5 million) in the second quarter of fiscal 2019. Net loss for the second quarter



of fiscal 2020 was NT\$242.4 million (US\$8.2 million), compared to net loss of NT\$241.5 million (US\$7.8 million) in the second quarter of fiscal 2019, or a net loss of NT\$3.28 (US\$0.11) per share for the second quarter of fiscal 2020, compared to a net loss of NT\$3.79 (US\$0.12) per share for the second quarter of fiscal 2019.

The Company's cash and cash equivalents were NT\$1,234.8 million (US\$41.9 million) as of June 30, 2020, compared to NT\$1,023.9 million (US\$34.2 million) as of December 31, 2019.

Financial Summary

Selected Consolidated Balance Sheet Data

		December 31, 2019		June 30, 2020	
		NT\$000	US\$000	NT\$000	US\$000
Cash and cash equivalents	\$	1,023,874	\$ 34,232	\$ 1,234,795	\$ 41,943
Total current assets		1,095,614	36,631	1,405,944	47,756
Total assets		1,385,978	46,339	1,727,859	58,691
Total current liabilities		556,697	18,612	241,242	8,194
Long-term borrowings		55,508	1,856	451,370	15,332
Total liabilities		664,068	22,202	775,865	26,354
Total equity		721,910	24,137	951,994	32,337

Selected Consolidated Statements of Operations Data

	Three-month periods ended June 30,				Six-month periods ended June 30,			
	2019		2020		2019		2020	
	NT\$000	US\$000	NT\$000	US\$000	NT\$000	US\$000	NT\$000	US\$000
Operating revenue	\$ 20,592	\$ 664	\$ 11,776	\$ 400	\$ 178,357	\$ 5,751	\$ 23,750	\$ 807
Operating expenses								
General and administrative expenses	(38,126)	(1,230)	(39,487)	(1,341)	(78,903)	(2,544)	(72,367)	(2,458)
Research and development expenses	(224,217)	(7,230)	(228,881)	(7,774)	(453,372)	(14,620)	(420,659)	(14,289)
Total operating expenses	(262,343)	(8,460)	(268,368)	(9,115)	(532,275)	(17,164)	(493,026)	(16,747)
Loss before income tax	(240,622)	(7,759)	(242,089)	(8,223)	(352,030)	(11,352)	(456,253)	(15,498)
Income tax expense	(854)	(28)	(348)	(12)	(1,131)	(36)	(769)	(26)
Net loss	\$ (241,476)	\$ (7,787)	\$ (242,437)	\$ (8,235)	\$ (353,161)	\$ (11,388)	\$ (457,022)	\$ (15,524)
Total other comprehensive income (loss)	\$ 374	\$ 12	\$ 1,698	\$ 58	\$ 916	\$ 29	\$ (1,808)	\$ (61)
Total comprehensive loss	\$ (241,102)	\$ (7,775)	\$ (240,739)	\$ (8,177)	\$ (352,245)	\$ (11,359)	\$ (458,830)	\$ (15,585)
Loss per share of common stock								
Basic and diluted loss per share (in dollars)	\$ (3.79)	\$ (0.12)	\$ (3.28)	\$ (0.11)	\$ (5.55)	\$ (0.18)	\$ (6.18)	\$ (0.21)

About TLC

TLC (NASDAQ: TLC, TWO: 4152) 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®). TLC



believes that its deep experience with liposome science allows a combination of onset speed and benefit duration, improving active drug concentrations while decreasing unwanted systemic exposures. TLC's BioSeizer[®] technology is designed to enable local sustained release of therapeutic agents at the site of disease or injury; its NanoX[™] active drug loading technology has been proven in two approved drugs and is designed to alter the systemic exposure of a drug, potentially reducing dosing frequency and enhancing distribution of liposome-encapsulated active agents to the desired site. These technologies are versatile in the choice of active pharmaceutical ingredients, and scalable with respect to manufacturing. TLC has a diverse, wholly owned portfolio of therapeutics that target areas of unmet medical need in pain management, ophthalmology, and oncology.

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 candidates, including TLC599 and TLC590, the clinical benefits of TLC's product candidates, the timing, scope, progress and outcome of TLC's clinical trials, 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, 2019 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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