



TLC Reports Third Quarter 2020 Financial Results and Provides Business Update

SOUTH SAN FRANCISCO, CA and TAIPEI, Taiwan – October 28, 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 third quarter ending September 30, 2020, and provided a business update.

“As we journey toward the end of 2020, we are excited about the imminent enrollment completion in our EXCELLENCE trial of TLC599 for osteoarthritis pain,” commented George Yeh, President of TLC. “Moreover, we have made tremendous progress in the advancement of our anti-COVID-19 program, TLC19, which has evolved from an incubated idea to being tested in humans in an extremely short amount of time. I would also like to extend a very warm welcome back to Mr. Tom Bliss, who will serve as our new CBO and lead TLC in its commercialization and licensing efforts.”

Clinical Pipeline Update and Upcoming Milestones

- ***First patient enrollment in Phase I clinical trial of inhalable anti-COVID-19 program.*** Following approval from Australia’s Human Research Ethics Committee (HREC) and Taiwan’s Food and Drug Administration (TFDA), TLC has promptly enrolled the first patient in the Phase I randomized, vehicle-controlled, blinded study, which will evaluate the safety, tolerability, and pharmacokinetics of single ascending doses of inhaled **TLC19 (inhalable liposomal hydroxychloroquine)** in healthy volunteers. Data from this trial will serve as a basis for subsequent clinical trials in patients with COVID-19.
- ***~80% enrollment complete in EXCELLENCE,*** 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**. EXCELLENCE remains on-track to complete enrollment of all 500 patients before the end of 2020, with topline data expected in late 2021.

Corporate Highlights

- ***Appointment of Thomas H. Bliss, Jr., MBA, as Chief Business Officer.*** Mr. Bliss brings with him ample experience in licensing and business development functions from Amgen, Baxter and Johnson & Johnson, and will take the lead in TLC’s global corporate and business development efforts, with a key focus on the United States.
- ***Acceptance of Marketing Authorization Application (MAA) for Amphilipad™ in China.*** The Center for Drug Evaluation (CDE) of the China



National Medical Products Administration (NMPA) has accepted TLC's MAA for Ampholipad™, TLC's complex generic of Gilead's AmBisome® (amphotericin B liposome for injection) for the treatment of systemic fungal infections. AmBisome is currently not available in mainland China, creating a rare opportunity for Ampholipad to become available before the brand drug.

- **Presented at several global conferences.** The management team of TLC presented the latest company updates at Baird's 2020 Virtual Global Healthcare Conference, HC Wainwright 22nd Annual Global Investment Conference, Cantor Virtual Global Healthcare Conference and Oppenheimer Fall Healthcare Life Sciences & MedTech Summit.
- **Expanded global intellectual property protection to 243 patents**, with 156 patents granted and 87 applications worldwide as of September 30, 2020.

Financial Results

Operating revenue for the third quarter of fiscal 2020 was NT\$66.1 million (US\$2.3 million), a 250.9% increase compared to NT\$18.8 million (US\$0.6 million) in the third quarter of fiscal 2019. Operating expenses for the third quarter of fiscal 2020 was NT\$309.7 million (US\$10.7 million), a 56.3% increase compared to NT\$198.1 million (US\$6.4 million) in the third quarter of fiscal 2019. Net loss for the third quarter of fiscal 2020 was NT\$233.7 million (US\$8.1 million), compared to a loss of NT\$178.4 million (US\$5.7 million) in the third quarter of 2019, or a net loss of NT\$2.78 (US\$0.10) per share for the third quarter of fiscal 2020, compared to a net loss of NT\$2.80 (US\$0.09) per share for the third quarter of fiscal 2019.

The Company's cash and cash equivalents were NT\$1,015.1 million (US\$35.1 million) as of September 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		September 30, 2020	
	NT\$000	US\$000	NT\$000	US\$000
Cash and cash equivalents and time deposit	\$1,023,874	\$ 34,232	\$1,015,093	\$ 35,064
Total current assets	1,095,614	36,631	1,158,516	40,018
Total assets	1,385,978	46,339	1,486,068	51,332
Total current liabilities	556,697	18,612	285,411	9,859
Long-term borrowings	55,508	1,856	401,710	13,876
Total liabilities	664,068	22,202	763,627	26,377
Total equity	721,910	24,137	722,441	24,955



Selected Consolidated Statements of Operations Data

	Three-month periods ended September 30,				Nine-month periods ended September 30,			
	2019		2020		2019		2020	
	NT\$000	US\$000	NT\$000	US\$000	NT\$000	US\$000	NT\$000	US\$000
Operating revenue	\$ 18,837	\$ 607	\$ 66,095	\$ 2,283	\$ 197,194	\$ 6,351	\$ 89,845	\$ 3,104
Operating expenses								
General and administrative expenses	(40,226)	(1,296)	(38,166)	(1,318)	(119,129)	(3,837)	(110,533)	(3,818)
Research and development expenses	(157,901)	(5,085)	(271,541)	(9,380)	(611,273)	(19,687)	(692,200)	(23,910)
Total operating expenses	<u>(198,127)</u>	<u>(6,381)</u>	<u>(309,707)</u>	<u>(10,698)</u>	<u>(730,402)</u>	<u>(23,524)</u>	<u>(802,733)</u>	<u>(27,728)</u>
Loss before income tax	(178,301)	(5,742)	(233,576)	(8,068)	(530,331)	(17,080)	(689,829)	(23,828)
Income tax expense	(124)	(4)	(117)	(4)	(1,255)	(40)	(886)	(31)
Net loss	<u>\$ (178,425)</u>	<u>\$ (5,746)</u>	<u>\$ (233,693)</u>	<u>\$ (8,072)</u>	<u>\$ (531,586)</u>	<u>\$ (17,120)</u>	<u>\$ (690,715)</u>	<u>\$ (23,859)</u>
Total other comprehensive loss	\$ (1,675)	\$ (54)	\$ (183)	\$ (6)	\$ (759)	\$ (25)	\$ (1,991)	\$ (69)
Total comprehensive loss	<u>\$ (180,100)</u>	<u>\$ (5,800)</u>	<u>\$ (233,876)</u>	<u>\$ (8,078)</u>	<u>\$ (532,345)</u>	<u>\$ (17,145)</u>	<u>\$ (692,706)</u>	<u>\$ (23,928)</u>
Loss per share of common stock								
Basic and diluted loss per share (in dollars)	\$ (2.80)	\$ (0.09)	\$ (2.78)	\$ (0.10)	\$ (8.35)	\$ (0.27)	\$ (8.93)	\$ (0.31)

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™), 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. TLC is consistently ranked top 5% among all listed companies in Taiwan's Corporate Governance Evaluations.

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 TLC19, the clinical benefits of TLC's product candidates, the timing, scope, progress and outcome of TLC's clinical trials, including TLC599 and TLC19, 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.

TLC Contact:

Dawn Chi

Corporate Communications

dawn@tlcbio.com