TLC Reports Fiscal Year End 2020 Financial Results and Provides Business Update

SOUTH SAN FRANCISCO, CA and TAIPEI, Taiwan – February 5, 2021 – 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 fiscal year ended December 31, 2020 and provided a business update.

"In the tumultuous year that was 2020, we were fortunate enough to have achieved early patient enrollment in the Phase II clinical trial of our postsurgical pain program before COVID-19 began its spread to the United States," commented George Yeh, President of TLC. "And in the midst of the pandemic, we managed to complete full patient enrollment in the pivotal trial of our osteoarthritis pain program and continue the global expansion of Ampholipad™, all while initiating a clinical trial for inhalable liposomal hydroxychloroquine as a potential treatment for severe lung diseases such as COVID-19. We hope the application of our proprietary technologies can help to put an end to the pandemic. To resonate with the name of our pivotal trial for our osteoarthritis pain program, *EXCELLENCE,* we will continue to strive for excellence in this very important year to provide the most benefits for patients, physicians and stakeholders alike."

Clinical Pipeline Update and Upcoming Milestones

- ***Following the completion of patient enrollment, 504 patients have received their first injection of TLC599, dexamethasone sodium phosphate or normal saline in EXCELLENCE***, the Phase III pivotal clinical trial of TLC599 for symptomatic knee osteoarthritis. Majority of the patients who are due for Week 24 have received a second injection of either TLC599 or placebo. The multi-center, randomized, double-blind, active comparator- and placebo-controlled pivotal study is evaluating the efficacy and safety of a single, as well as a repeat, dose of TLC599 in patients with knee OA across 41 sites in the United States and five sites in Australia.
- ***Preparations for pivotal studies of TLC590 for postsurgical pain management are underway***, with planned End-of-Phase-2 meetings to occur in 2021 with the United States Food and Drug Administration (FDA) on the design of the clinical trials and production preparations.
- ***Published peer-reviewed manuscript in Clinical and Translational Science Journal,*** presenting the feasibility of applying TLC's inhalable liposome technology to drugs for direct delivery to – and extended release in – the lungs, as endorsed by key opinion leaders in respiratory therapies. A Phase I randomized, vehicle-controlled, blinded study evaluating the safety,

tolerability, and pharmacokinetics of TLC19 (inhalable liposomal hydroxychloroquine) in healthy volunteers is ongoing.

Corporate Highlights

- ***Completed US$15 million financing for InspirMed™ Inc.,*** a newly established subsidiary that specializes in the development of inhalable liposome formulation programs, such as TLC19, for severe acute and chronic pulmonary diseases. The strategic move to partition lung disease programs from TLC will allow TLC to maintain focus on its current pipeline of liposomal injectable formulation programs, including TLC599 and TLC590.
- ***Commercialization of Ampholipad™ advancing smoothly,*** with a non-binding term sheet for commercialization in a specified territory in Latin America recently signed and review of the formal agreement underway. In Asia, China's National Medical Products Administration is reviewing the Marketing Authorization Application of the generic liposomal amphotericin B drug. Worldwide discussions for partnership opportunities are ongoing.
- ***Held investor conference and attended JP Morgan Healthcare Conference.*** The management team of TLC presented the latest company updates during the virtual investor conference hosted by KGI Securities, as well as at JP Morgan Healthcare Conference, the largest annual biotech event in the world, which was also conducted virtually due to the COVID-19 pandemic.
- ***Expanded global intellectual property protection to 257 patents,*** with 160 patents granted and 97 applications worldwide as of December 31, 2020.

Fiscal Year End 2020 Financial Results

Operating revenue for the fiscal year 2020 was NT$101.9 million (US$3.6 million), a 51.3% decrease compared to NT$209.1 million (US$7.0 million) in the fiscal year 2019. Operating expenses for the fiscal year 2020 was NT$1,113.3 million (US$39.6 million), an 8.4% increase compared to NT$1,026.8 million (US$34.3 million) in the fiscal year 2019. Net loss for the fiscal year 2020 was NT$983.3 million (US$35.0 million), compared to a loss of NT$807.5 million (US$27.0 million) in the fiscal year 2019, or a net loss of NT$12.42 (US$0.44) per share for the fiscal year 2020, compared to a net loss of NT$12.32 (US$0.41) per share for the fiscal year 2019.

The Company's cash and cash equivalents were NT$1,342.7 million (US$47.8 million) as of December 31, 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		December 31, 2020	
	NT$000	US$000	NT$000	US$000
Cash and cash equivalents and time deposit	$1,023,874	$ 34,232	$1,342,667	$ 47,816
Total current assets	1,095,614	36,631	1,431,977	50,997
Total assets	1,385,978	46,339	1,749,461	62,303
Total current liabilities	556,697	18,612	348,127	12,398
Long-term borrowings	55,508	1,856	469,076	16,705
Total liabilities	664,068	22,202	886,134	31,557
Total equity	721,910	24,137	863,327	30,746

Selected Consolidated Statements of Operations Data

	Year ended December 31,			
	2019		2020	
	NT$000	US$000	NT$000	US$000
Operating revenue	$ 209,140	$ 6,992	$ 101,928	$ 3,630
Operating expenses				
General and administrative expenses	(166,377)	(5,562)	(145,769)	(5,191)
Research and development expenses	(860,419)	(28,767)	(967,503)	(34,455)
Total operating expenses	(1,026,796)	(34,329)	(1,113,272)	(39,646)
Loss before income tax	(803,402)	(26,861)	(982,177)	(34,978)
Income tax expense	(4,120)	(138)	(1,132)	(40)
Net loss	$ (807,522)	$ (26,999)	$ (983,309)	$ (35,018)
Total other comprehensive loss	$ (2,782)	$ (93)	$ 262	$ 9
Total comprehensive loss	$ (810,304)	$ (27,092)	$ (983,047)	$ (35,009)
Loss per share of common stock				
Basic and diluted loss per share (in dollars)	$ (12.32)	$ (0.41)	$ (12.42)	$ (0.44)

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 in the 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 and product candidates, including Ampholipad, TLC599, TLC590 and TLC19, 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 Ampholipad, 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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