



TLC Reports Fiscal Year End 2019 Financial Results and Provides Business Update

SOUTH SAN FRANCISCO, CA and TAIPEI, Taiwan – February 11, 2020 – [TLC](#) (Nasdaq: TLC, TWO: 4152), a clinical-stage specialty pharmaceutical company developing novel nanomedicines to target areas of unmet medical need in pain management, ophthalmology and oncology, today announced financial results for the fiscal year ended December 31, 2019, and provided a business update.

“We saw a monumental year for TLC in 2019, marked not only by tremendous clinical and manufacturing advancements in both our programs in pain management – TLC599 and TLC590, but also by new business development agreements, addition of internationally experienced personnel to the management team, and presentation and publication of impressive data at numerous investor conferences as well as prestigious scientific conventions,” said George Yeh, President of TLC. “With this continual momentum, we look forward to achieving more milestones in 2020, including the completion of patient enrollment in the EXCELLENCE trial and data readout from the TLC590 Phase II trial, both of which will bring us closer to the goal of mitigating the proliferation of highly addictive opioids with the availability of our non-opioid alternatives.”

Clinical Pipeline Update and Upcoming Milestones

- ***Commencement of patient enrollment in EXCELLENCE trial evaluating single and repeated administrations of [TLC599](#) for knee osteoarthritis pain.*** The Phase III pivotal study, which enrolled its first patient in November 2019, will dose about 500 patients at a 2:1:1 ratio with TLC599, dexamethasone or placebo across 45 sites in the United States and Australia. At Week 24, patients can receive a second blinded injection of TLC599 or placebo. Primary endpoint is the magnitude of pain relief by WOMAC Pain score versus placebo at Week 16 and Week 40. Patient enrollment is expected to take about one year, and all patients will be followed for 52 weeks.
- ***Commencement of patient dosing in Part 2 of Phase II trial evaluating the analgesic efficacy of [TLC590](#) following bunionectomy.*** With the first batch of patients dosed in January 2020, a total of about 150 patients will receive TLC590, bupivacaine or normal saline placebo at a ratio of 1:1:1 at the end of their bunion removal surgery. Primary endpoint is area under the curve (AUC) from 0 to 72 hours on the numerical pain rating scale.

Corporate Highlights

- ***Completed US\$27.3 million financing.*** The Company completed a cash capital offering of ordinary (common) shares in Taiwan in October 2019. The offering consisted of 10,200,000 new common shares issued at a price of NT\$82 per common share for gross proceeds of NT\$836.4 million (~US\$27.3 million).



- ***Presented at Berenberg Pain Seminar and JP Morgan Healthcare Conference.*** At the Berenberg Pain Seminar in November 2019, TLC presented recent data on TLC599 and TLC590 and discussed how they can potentially deter the spread of the opioid crisis with prominent figures in the pain management space. TLC also presented and participated in one-on-one meetings at the 38th annual JP Morgan Healthcare Conference in January 2020, marking the Company's sixth consecutive attendance at the world's largest healthcare investment symposium.
- ***Expanded global intellectual property protection to 197 patents***, with 126 patents granted and 71 applications worldwide as of December 31, 2019.

Fiscal Year End Financial Results

Operating revenue for the fiscal year 2019 was NT\$209.1 million (US\$7.0 million), a 235.6% increase compared to NT\$62.3 million (US\$2.0 million) in the fiscal year 2018. Operating expenses for the fiscal year 2019 was NT\$1,026.8 million (US\$34.3 million), a 4.7% increase compared to NT\$980.3 million (US\$32.0 million) in the fiscal year 2018. Net loss for the fiscal year 2019 was NT\$807.5 million (US\$27.0 million), compared to net loss of NT\$901.6 million (US\$29.5 million) in the fiscal year 2018, or a net loss of NT\$12.32 (US\$0.41) per share for the fiscal year 2019, compared to a net loss of NT\$14.37 (US\$0.47) per share for the fiscal year 2018.

The Company's cash and cash equivalents and time deposits with maturity over three months (which are classified as "current financial assets at amortized cost" in the Company's consolidated financial statements) were NT\$1,023.9 million (US\$34.2 million) as of December 31, 2019, compared to NT\$1,114.6 million (US\$36.4 million) as of December 31, 2018.



Financial Summary

Selected Consolidated Balance Sheet Data

	December 31, 2018		December 31, 2019	
	NT\$000	US\$000	NT\$000	US\$000
Cash and cash equivalents and time deposit	\$ 1,114,634	\$ 36,414	\$ 1,023,874	\$ 34,232
Total current assets	1,188,695	38,834	1,095,614	36,631
Total assets	1,417,921	46,322	1,385,978	46,339
Total current liabilities	344,288	11,248	556,697	18,612
Long-term borrowings	368,010	12,023	55,508	1,856
Total liabilities	748,725	24,460	664,068	22,202
Total equity	669,196	21,862	721,910	24,137

Selected Consolidated Statements of Operations Data

	Years ended December 31,			
	2018		2019	
	NT\$000	US\$000	NT\$000	US\$000
Operating revenue	\$ 62,324	\$ 2,036	\$ 209,140	\$ 6,992
Operating expenses				
General and administrative expenses	(147,743)	(4,827)	(166,377)	(5,562)
Research and development expenses	(832,575)	(27,200)	(860,419)	(28,767)
Total operating expenses	<u>(980,318)</u>	<u>(32,027)</u>	<u>(1,026,796)</u>	<u>(34,329)</u>
Loss before income tax	(900,707)	(29,426)	(803,402)	(26,861)
Income tax expense	(867)	(28)	(4,120)	(138)
Net loss	<u>\$ (901,574)</u>	<u>\$ (29,454)</u>	<u>\$ (807,522)</u>	<u>\$ (26,999)</u>
Total other comprehensive loss	<u>\$ (1,254)</u>	<u>\$ (41)</u>	<u>\$ (2,782)</u>	<u>\$ (93)</u>
Total comprehensive loss	<u>\$ (902,828)</u>	<u>\$ (29,495)</u>	<u>\$ (810,304)</u>	<u>\$ (27,092)</u>
Loss per share of common stock				
Basic and diluted loss per share (in dollars)	\$ (14.37)	\$ (0.47)	\$ (12.32)	\$ (0.41)

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 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, TLC590 and TLC178, the clinical benefits of TLC's product candidates, the timing, scope, progress and outcome of TLC's clinical trials, 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. Other risks are described in the Risk Factors section of TLC's annual report on Form 20-F for the year ended December 31, 2018 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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