TLC Reports Fourth Quarter and Full Year 2018 Financial Results and Business Update

April 1, 2019

SOUTH SAN FRANCISCO, Calif. and TAIPEI, Taiwan, April 01, 2019 (GLOBE NEWSWIRE) -- TLC (Nasdaq: TLC, TWO: 4152), a clinical-stage specialty pharmaceutical company dedicated to the development and commercialization of novel nanomedicines designed to target areas of unmet medical need in osteoarthritis, pain management, ophthalmology and oncology, today announced financial results for the fourth quarter and full year ended December 31, 2018, and provided a business update.

"We had a transformative year in 2018, highlighted by outstanding results from the Phase II clinical trial of our lead program TLC599 for knee osteoarthritis pain, commencement of the first-in-human clinical trial of TLC590 for postsurgical pain management, and completion of a U.S. public offering on Nasdaq," said TLC President George Yeh. "As we move into 2019, we expect to continue to deliver strong progress in our clinical pipeline and company operations by further advancing our lead product candidates closer to pivotal clinical stages while capitalizing on strategic opportunities with our scalable manufacturing capabilities."

Clinical Pipeline Update and Upcoming Milestones

- ***Phase II trial top-line data readout of TLC599 for knee osteoarthritis pain showed significant reductions in pain that sustained through 24 weeks.*** TLC599 demonstrated statistically significant improvements over placebo, both *through* 12, 16, 20, and 24 weeks and *at* every scheduled visit on week 1, 4, 8, 12, 16, 20, and 24. Over half of the patients treated with TLC599 maintained at least a 30% reduction in pain – over twice as many as placebo – throughout the study.

- ***Phase I/II trial top-line data readout of TLC590 for post-surgical pain showed statistically significant and clinically meaningful improvement over the standard of care through 96 hours.*** In this first-in-human study of TLC590 in patients following inguinal hernia surgery, greater levels of pain reduction were maintained through the entire 168 hours of the study. In the TLC590 group, 58.3% were opioid-free throughout the study. Among those who used opioids, time to first post-surgical use was four times that of the ropivacaine (standard of care) group, and mean total opioid consumption was 54% less.

- ***First patients dosed in Phase II trial of TLC590.*** The randomized, double-blind, comparator- and placebo-controlled two-part clinical trial will evaluate the safety, pharmacokinetics, and efficacy of TLC590 compared with ropivacaine and placebo in ~200 patients following bunionectomy. Data from Part 1 is expected mid-2019.

- ***TLC178 received clearance from the FDA to initiate Phase I/II clinical trial in pediatric rhabdomyosarcoma.*** Recruitment of pediatric patients is scheduled to commence once the optimal dose in adults is identified in an analysis scheduled for the second half of 2019.

- ***TLC178 received EMA orphan drug designation for the treatment of soft tissue sarcoma.*** The designation provides incentives and scientific advice from the EMA during product development phase and 10 years of marketing exclusivity in the EU following product approval. An orphan designation was previously granted by the US FDA, which provides 7 years of marketing exclusivity in the US following product approval.

Corporate Highlights

- ***Completed U.S. IPO.*** TLC's American Depositary Shares began trading on The Nasdaq Global Market under the ticker "TLC" on November 21, 2018, becoming the first Taiwan-based biotech company to be listed on Nasdaq. TLC has been listed on the Taipei Exchange since 2012, where it is consistently ranked in the top 5% among all listed companies in corporate governance evaluations.

- ***Appointment of new Chief Medical Officer.*** Dr. George Spencer-Green, MD, MS, joined TLC in February 2019, bringing experience from serving as VP and clinical head of Pfizer's biosimilars development program, and as medical director at the likes of Vertex Pharmaceuticals, Abbot Laboratories, and Enbrel, where he led the development of clinical programs, including Humira for rheumatoid arthritis.

- ***Received an upfront payment*** in March 2019 as part of the commercialization agreement with 3SBio Inc. TLC is eligible for further regulatory and sales milestone payments, as well as a double-digit share of the potential profits from product sales.

- ***Growing global intellectual property protection*** with 54 granted patents and 68 applications worldwide as of December

31, 2018.

Fourth Quarter and Full Year 2018 Financial Results

Operating revenue for the fourth quarter of fiscal 2018 was NT$17.4 million (US$0.6 million), a 40% increase compared to NT$12.4 million in the fourth quarter of fiscal 2017. Operating expenses for the fourth quarter of fiscal 2018 was NT$326.8 million (US$10.7 million), a 14.2% increase compared to NT$286.1 million in the fourth quarter of fiscal 2017. Net loss for the fourth quarter of fiscal 2018 was NT$306.7 million (US$10.0 million), compared to a loss of NT$262.6 million in the fourth quarter of 2017, or a net loss of NT$5.23 (US$0.17) per share for the fourth quarter of fiscal 2018, compared to a net loss of NT$4.73 per share for the fourth quarter of fiscal 2017.

Operating revenue for the fiscal year 2018 was NT$62.3 million (US$2.0 million), a 25.6% increase compared to NT$49.6 million in the fiscal year 2017. Operating expenses for the fiscal year 2018 was NT$980.3 million (US$32.0 million), a 3.4% increase compared to NT$948.1 million in the fiscal year 2017. Net loss for the fiscal year 2018 was NT$901.6 million (US$29.5 million), compared to a loss of NT$874.0 million in the fiscal year 2017, or a net loss of NT$14.37 (US$0.47) per share for the fiscal year 2018, compared to a net loss of NT$15.75 per share for the fiscal year 2017.

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$1,114.6 million (US$36.4 million) as of December 31, 2018, compared to NT$951.7 million at the end of the fourth quarter of fiscal 2017.

Financial Summary

Selected Consolidated Balance Sheet Data

	December 31, 2017	December 31, 2018	
	NT$000	**NT$000**	**US$000**
Cash and cash equivalents and time deposit	$ 951,713	$ 1,114,634	$ 36,414
Total current assets	1,051,875	1,188,695	38,834
Total assets	1,262,539	1,417,921	46,322
Total current liabilities	193,054	344,288	11,248
Long-term borrowings	66,177	368,010	12,023
Total liabilities	275,255	748,725	24,460
Total equity	987,284	669,196	21,862

Selected Consolidated Statements of Operations Data

	Three-month periods ended December 31,			Years ended December 31,		
	2017	2018		2017	2018	
	NT$000	**NT$000**	**US$000**	**NT$000**	**NT$000**	**US$000**
Operating revenue	$ 12,397	$ 17,382	$ 568	$ 49,635	$ 62,324	$ 2,036
Operating expenses						
General and administrative expenses	(37,480)	(45,613)	(1,490)	(134,869)	(147,743)	(4,827)
Research and development expenses	(248,608)	(281,176)	(9,186)	(813,252)	(832,575)	(27,200)
	(286,088)	(326,789)	(10,676)	(948,121)	(980,318)	(32,027)
Loss before income tax	(263,352)	(306,515)	(10,014)	(873,011)	(900,707)	(29,426)
Income tax expense	(261)	(187)	(6)	(951)	(867)	(28)
Net loss	($ 262,613)	($ 306,702)	($ 10,020)	($ 873,962)	($ 901,574)	($ 29,454)
Total other comprehensive loss	($ 1,401)	($ 551)	($ 18)	($ 3,520)	($ 1,254)	($ 41)
Total comprehensive loss	($ 264,014)	($ 307,253)	($ 10,038)	($ 877,482)	($ 902,828)	($ 29,495)
Loss per share of common stock						
Basic and diluted loss per share (in dollars)	($ 4.73)	($ 5.23)	($ 0.17)	($ 15.75)	($ 14.37)	($ 0.47)

About TLC

Taiwan Liposome Company, Ltd. (“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 TLC to combine onset speed and benefit duration, and improve 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 the 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. 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 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 prospectus dated November 21, 2018 filed pursuant to Rule 424(b)(4) 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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