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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 20-F

(Mark One)

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2018

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
for the transition period from _____ to _____

OR

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
Date of event requiring this shell company report

Commission file number 001-38746

台灣微脂體股份有限公司
(Exact name of Registrant as specified in its charter)

Taiwan Liposome Company, Ltd.
(Translation of Registrant's name into English)

Republic of China
(Jurisdiction of incorporation)
11F-1, No. 3 Yuanqu Street
Nangang District,
Taipei City, Taiwan 11503
Republic of China
(Address of principal executive offices)

George Yeh
President
Taiwan Liposome Company, Ltd.
11F-1, No. 3 Yuanqu Street
Nangang District,
Taipei City, Taiwan 11503
Republic of China
+886 2 2655 7377
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered, pursuant to Section 12(b) of the Act

Title of each class	Name of each exchange on which registered
American Depositary Shares (ADSs), each representing two common shares, par value NT$10 per common share	The Nasdaq Global Market
Common shares, par value NT$10 per share *	The Nasdaq Global Market *

* Not for trading, but only in connection with the registration of the American Depositary Shares.

Securities registered or to be registered pursuant to Section 12(g) of the Act:

None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:

None

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

Common shares, par value NT$10 per share: 64,045,134 as of December 31, 2018

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐	Non-accelerated filer	☒	Emerging growth company	☒

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards † provided pursuant to Section 13(a) of the Exchange Act. ☐

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐	International Financial Reporting Standards as issued by the International Accounting Standards Board ☒	Other ☐

If "Other" has been checked in response to the previous question indicate by check mark which financial statement item the registrant has elected to follow. Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

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PART I

GENERAL INFORMATION

Unless otherwise indicated or the context otherwise requires, all references in this Annual Report to the terms "TLC," "the company," "we," "us" and "our" refer to (i) Taiwan Liposome Company, Ltd., a company limited by shares organized under the laws of the Republic of China (ROC), and (ii) our subsidiaries, TLC Biopharmaceuticals, Inc., a Delaware corporation, TLC Biopharmaceuticals B.V., a private limited company organized under the laws of the Netherlands, TLC Biopharmaceuticals, (H.K.) Limited, a private limited company organized under the law of Hong Kong, TLC Biopharmaceuticals, (Shanghai) Limited, a private limited company organized under the laws of China, TLC Biopharmaceuticals Pty Ltd., a private limited company organized under the laws of Australia, and TLC Biopharmaceuticals Japan Co., Ltd, a limited company organized under the laws of Japan.

PRESENTATION OF FINANCIAL AND OTHER INFORMATION

We maintain our books and records in New Taiwan dollars, the legal currency of the ROC. *Unless otherwise specified, all monetary amounts are in United States (U.S.) dollars. All references in this Annual Report to "$," "US$," "dollars" and "USD" mean U.S. dollars and all references in this Annual Report to "NT$" mean New Taiwan dollars.* Solely for your convenience, this Annual Report contains translations of certain NT dollar amounts into U.S. dollar amounts at specified exchange rates. Except as discussed in the next two sentences, all translations from NT dollars to U.S. dollars and from U.S. dollars to NT dollars in this Annual Report were made at a rate of NT$30.61 to $1.00, the noon buying rate in The City of New York for cable transfers in NT dollars per U.S. dollar as certified for customs purposes by the Federal Reserve Bank of New York on December 31, 2018. The translation of the trading price of our common shares on the Taipei Exchange (TPEx) from NT dollars to U.S. dollars were made at a rate of NT$30.8253 to $1.00, based on the noon buying rate in The City of New York for cable transfers in NT dollars per U.S. dollar as certified for customs purposes by the Federal Reserve Bank of New York on April 22, 2019. NT dollar amounts relating to the estimated fair value per share of all share-based compensation issued to employees and consultants have been calculated based on historical exchange rates used for our accounting purposes. No representation is made that the NT dollar or U.S. dollar amounts referred to herein could have been or could be converted into U.S. dollars or NT dollars, as the case may be, at any particular rate or at all. Any discrepancies in any table between totals and sums of the amounts listed are due to rounding. Our consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standard Board (IASB), which may differ in material respects from generally accepted accounting principles in other jurisdictions, including the United States.

We have made rounding adjustments to some of the figures included in this Annual Report. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that preceded them.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act), that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by the words "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "potential," "continue" and "ongoing," or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. The forward-looking statements and opinions contained in this Annual Report on Form 20-F are based upon information available to us as of the date of this Annual Report and, while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. Forward-looking statements include statements about:

- the outcome, cost and timing of our product development activities and clinical trials;
- our plans and expected timing with respect to regulatory filings and approvals;
- our ability to fund our operations;
- our plans to develop and commercialize our product candidates and expand our development pipeline;
- our ability to enter into a transaction with respect to commercialization of our products and product candidates in China;

- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- our sales and marketing strategies and plans;
- potential market acceptance of our product candidates;
- potential regulatory developments in the United States and foreign countries;
- the performance of our third party suppliers and manufacturers;
- our ability to compete with other therapies that are or become available;
- our expectations regarding the period during which we qualify as an emerging growth company (EGC) under the Jumpstart Our Business Startups Act (JOBS Act);
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and
- our expectations regarding the terms of our patents and ability to obtain and maintain intellectual property protection for our product candidates.

You should refer to the section titled "Item 3.D. Risk Factors" for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. We claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995 for all forward-looking statements.

You should read this Annual Report and the documents that we reference in this Annual Report, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

Unless otherwise indicated, information contained in this Annual Report on Form 20-F concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity and market size estimates, is based on information from independent industry analysts, third-party sources and management estimates. Management estimates are derived from publicly available information released by independent industry analysts and third-party sources, as well as data from our internal research, and are based on assumptions made by us based on such data and our knowledge of such industry and market, which we believe to be reasonable. In addition, while we believe the market opportunity information included in this Annual Report on Form 20-F is generally reliable and is based on reasonable assumptions, such data involve risks and uncertainties and are subject to change based on various factors, including those discussed under the section of this Annual Report on Form 20-F titled "Item 3.D—Risk Factors."

PART I

Item 1. Identity of Directors, Senior Management and Advisers

Not applicable.

Item 2. Offer Statistics and Expected Timetable

Not applicable.

Item 3. Key Information

A. Selected Consolidated Financial Data

We derived the selected consolidated comprehensive income statement data for the years ended December 31, 2016, 2017 and 2018 and selected consolidated statement of financial position data as of December 31, 2017 and 2018 from our consolidated audited financial statements included elsewhere in this Annual Report on Form 20-F. The statement of financial position data as of December 31, 2016 is derived from financial statements not included in this Annual Report on Form 20-F. This data should be read together with, and is qualified in its entirety by reference to, "Item 5. Operating and Financial Review and Prospects" as well as our financial statements and notes thereto appearing elsewhere in this Annual Report on Form 20-F. Our historical results are not necessarily indicative of the results to be expected in the future.

	Year ended December 31,			
	2016	2017	2018	2018
	(in thousands, except share and per share data)			
Selected Consolidated Comprehensive Income Statement Data:				
Operating revenue[2]	NT$ 41,674	NT$ 49,635	NT$ 62,324	US$ 2,036
Operating expenses				
General and administrative expenses	(141,494)	(134,869)	(147,743)	(4,827)
Research and development expenses	(736,878)	(813,252)	(832,575)	(27,200)
Other income and expenses	5,575	21,148	26,228	857
Operating loss	(831,123)	(877,338)	(891,766)	(29,134)
Non-operating income and expenses	7,370	4,327	(8,941)	(292)
Loss before income tax	(823,753)	(873,011)	(900,707)	(29,426)
Income tax expense	(563)	(951)	(867)	(28)
Net loss	NT$ (824,316)	NT$ (873,962)	NT$ (901,574)	US$ (29,454)
Loss attributable to Owners of the parent	NT$ (824,316)	NT$ (873,962)	NT$ (901,574)	US$ (29,454)
Loss per share of common stock				
Basic and diluted loss per share (in dollars)	NT$ (14.89)	NT$ (15.75)	NT$ (14.37)	US$ (0.47)
Weighted-average shares used in computing basic and diluted loss per-share of common stock	55,361,000	55,489,000	62,719,000	62,719,000

	As of December 31,			
	2016	2017	2018	2018
	(in thousands)			
Selected Consolidated Balance Sheet Data:				
Cash and cash equivalents and time deposits	NT$ 1,798,800	NT$ 951,713	NT$ 1,114,634	US$ 36,414
Total assets	2,098,906	1,262,539	1,417,921	46,322
Total current liabilities	189,263	193,054	344,288	11,248
Total non-current liabilities[1]	106,101	82,201	404,437	13,212
Total liabilities	295,364	275,255	748,725	24,460
Capital stock	557,306	561,990	640,451	20,923
Total equity	1,803,542	987,284	669,196	21,862
Total liabilities and equity	2,098,906	1,262,539	1,417,921	46,322

(1) Included in total non-current liabilities are NT$70,050 (US$2,363), NT$66,177 (US$2,233) and NT$368,010 (US$12,023) as of December 31, 2016, 2017, and 2018, respectively, in long-term borrowings.
(2) Includes the impact of the adoption of IFRS 15, as explained in Note 3(1) of our consolidated financial statements presented herewith.

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

An investment in our American Depositary Shares (ADSs) involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information appearing elsewhere in this Annual Report, before deciding to invest in our ADSs. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and future growth prospects. In these circumstances, the market price of our ADSs could decline, and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and stock price.

Risks Related to Our Financial Condition and Need for Additional Capital

We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.

We are a clinical-stage biopharmaceutical company and are focused primarily on developing product candidates based on our proprietary lipid formulation platform, including, our primary lead product candidate, TLC599. In addition, as an early stage company, we have limited experience and have not yet demonstrated an ability to overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the pharmaceutical area.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will not demonstrate adequate effectiveness in the targeted indication or an acceptable safety profile, gain regulatory approval or become commercially viable. All of our product candidates will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We are not profitable and have incurred significant net losses in each year since our inception, including net losses of NT$873,962 and NT$901,574 (US$29,454) for fiscal years 2017 and 2018, respectively.

We have devoted substantially all our financial resources to developing our technology platforms and our product candidates, including pre-clinical development activities and clinical trials. As a result of the foregoing, we expect to continue to incur significant and increasing losses and negative cash flows for the foreseeable future. We expect to continue to incur substantial and increased expenses as we expand our development activities and advance our clinical programs, particularly with respect to our planned clinical development for TLC599, TLC399, TLC590 and TLC178, which we expect to be in late or pivotal stage clinical trials by 2020. If our product candidates are not successfully developed or commercialized because of lack of capital to fund our losses or otherwise, or if we incur insufficient revenue following marketing approval, we will not achieve profitability and our business may fail. Even if we successfully obtain regulatory approval to market our product candidates in the United States, our revenue is also dependent upon the size of the markets outside of the United States, as well as our ability to obtain market approval and achieve commercial success.

We currently do not generate significant revenue and may never be profitable.

We do not anticipate generating revenue from sales of our proprietary product candidates for the foreseeable future, if ever. Our ability to generate future revenue from branded product sales and ultimately achieve profitability depends on our success in:

- completing clinical development of TLC599, as well as advancing clinical development of our other product candidates;
- obtaining regulatory approval for TLC599, as well as our other product candidates; and
- launching and successfully commercializing any product candidates for which we receive regulatory approval, either by building our own targeted sales force or by collaborating with third parties.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to predict the timing or amount of increased expenses, when, or if, we will begin to generate revenue from branded product sales, or when, or if, we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we are required by the Food and Drug Administration (FDA) to perform studies in addition to those that we currently anticipate or if such studies are larger, take longer or are otherwise more expensive to conduct than we expect.

Even if one or more of our product candidates is approved for commercial sale, to the extent we do not engage a third-party collaborator, we anticipate incurring significant costs associated with commercializing any approved product candidate. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

If we fail to obtain additional financing, we may be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive and we have consumed substantial amounts of capital since inception. To date, we have financed our operations through government subsidies, sales related to our generic products, collaboration payments and the sale of equity securities and debt. We do not expect revenues from product sales or potential licensing transactions to be sufficient to offset our development expenses, particularly as we advance our clinical programs, including TLC599.

As of December 31, 2018, we had cash and cash equivalents of NT$807.5 million (US$26,380 thousand) and time deposits with maturity over three months of NT$307.2 million (US$10,034 thousand) (shown as “Current financial assets at amortized cost” in our consolidated financial statements). Based upon our current operating plan, we believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital requirements for at least the next 12 months. However, changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. For example, our clinical trials may encounter technical, enrollment or other difficulties that could increase our development costs more than we expect. We cannot be certain that we will have sufficient cash resources to meet such obligation if triggered without seeking additional funding or delaying or terminating certain of our then ongoing clinical development activities. In any event, we will require additional capital prior to completing pivotal clinical trials for filing for regulatory approval for, or commercialization of, TLC599, TLC399, TLC590, TLC178 or any of our other product candidates.

Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- significantly delay, scale back or discontinue the development or commercialization of our product candidates;
- seek corporate partners for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available;
- relinquish or license on unfavorable terms, our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves; or
- significantly curtail or cease operations.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing development and commercialization efforts, which will have an adverse effect on our business, operating results and prospects.

We may sell additional equity or debt securities to fund our operations, which may result in dilution to our shareholders and holders of our ADSs and impose restrictions on our business.

In order to raise additional funds to support our operations, we may sell additional equity or debt securities, which could adversely impact our existing shareholders, as well as our business. The sale of additional equity or convertible debt securities would result in the issuance of additional shares of our capital stock and dilution to all of our shareholders and holders of our ADSs. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

We have relied on Taiwan government funding, which could require us to take action with respect to our technology or patents that may not be in our best interest and which, if lost or reduced, could have an adverse effect on our research and development.

We have relied on government research grants for a portion of our funding, including grants awarded by the Institute for Information Industry (Institute) on behalf of the Taiwan Ministry of Economic Affairs, Executive Yuan of the Republic of China (MOEA) with respect to TLC399. As of December 31, 2018, we had been awarded a total of approximately NT$41.5 million (US$1.4 million) in grants pursuant to these programs. Under the terms of our government grants, we retain all right, title and interest in any research and development achievements (R&D Achievements) with respect to the applicable program, but are subject to certain limitations, including, among others, restrictions on the manufacture or use of the relevant R&D Achievement outside of Taiwan within two years after the creation of such achievement, unless otherwise approved by the MOEA or allowed under relevant regulations. Additionally, the Institute has the right to obtain non-transferable and non-exclusive use rights over the relevant R&D Achievements without additional payment if the Institute deems doing so to be in the interest of the nation or socially beneficial. The Institute and MOEA may both also require us to license the relevant R&D Achievements to a third party in the event that we either: (a) fail to implement the R&D Achievements during a reasonable period without a reasonable justification and a third party has requested a license by offering reasonable business terms but was not able to reach an agreement with us during the foregoing period or (b) we implement R&D Achievements in a manner that obstructs environmental protection, public safety or public health and is disciplined by relevant authorities, even if we determine that such actions are not in our best interest.

Funding of government grants is subject to government appropriation and all of our government contracts contain provisions making them terminable if there is a cut in government funding. The government could terminate, reduce or delay the funding under any of our grants at any time. There is no assurance that we will receive funding of any grants that we may be awarded, or that we will be able to secure additional grant funding. In the event we are not successful in obtaining any new government grants or if existing grants are not ultimately funded or extended, or we are required to repay such grants, our research and development efforts could be adversely affected. Additionally, if we obtain any new government grants, the terms of such additional grants may further restrict our research and development or intellectual property ownership flexibility.

We expect to take advantage of a Research & Development Incentive program in Australia, which could be amended or changed.

We received a financial incentive of AU$593,000 from the Australian government as part of its tax incentive program in August 2018. The research and development tax incentive is one of the key elements of the Australian government's support for Australia's innovation system and, if eligible, provides the recipient with a 43.5% refundable tax offset for research and development activities. There have been recent proposals to change the structure of the innovation and research and development funding landscape in Australia, which may impact the research and development tax incentive receivable for the 2018 financial year, including proposals to cap the total refundable payments to AU$4.0 million (US$2.8 million) on an annual basis. However, clinical trials will be specifically exempt from this cap. There can be no assurance that we will qualify and be eligible for such incentives or that the Australian government will continue to provide incentives, offset, grants and rebates on similar terms or at all.

Risks Related to Clinical Development and Regulatory Approval

We are heavily dependent on the success of TLC599, as well as TLC399, TLC590 and TLC178, which are in later stages of development than our other product candidates. We cannot give any assurance that any of TLC599, TLC399, TLC590 or TLC178 will successfully complete clinical development or receive regulatory approval, which is necessary before they can be commercialized.

Our business and future success is substantially dependent on our ability to successfully develop, obtain regulatory approval for and successfully commercialize our primary lead product candidate, TLC599, and to a lesser extent, TLC399, TLC590 and TLC178. Any delay or setback in the development of any of our product candidates, but particularly TLC599, could adversely affect our business and cause the price of our ADSs or common shares to decline. Should our planned clinical development of our more advanced product candidates fail to be completed in a timely manner or at all, we will need to rely on our other product candidates, which are at an earlier development stage and will require additional time and resources to obtain regulatory approval and proceed with commercialization. We cannot assure you that our planned clinical development for TLC599 will be completed in a timely manner, or at all, or that we will be able to obtain approval for any of our product candidates from the FDA or any foreign regulatory authority.

Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development. We have never conducted a pivotal clinical trial for our proprietary product candidates or submitted a New Drug Application (NDA) or a Biologics License Application (BLA) to the FDA or similar drug approval filings for non-generics to comparable foreign authorities.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of subsequent clinical trials.

Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. In addition to the safety and efficacy traits of any product candidate, clinical trial failures may result from a multitude of factors including flaws in trial design, dose selection, placebo effect and patient enrollment criteria. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we or any potential future collaborator may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Our future clinical trial results may not be successful.

If any product candidate is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it and our business may be materially harmed. For example, if the results of our planned pivotal clinical trials of TLC599 in osteoarthritis (OA), our ongoing and planned Phase I/II clinical trials of TLC590 in post-surgical pain, our Phase II clinical trial of TLC399 in macular edema, our ongoing Phase I/II clinical trial of TLC178 in advanced cancers or any other clinical trials for these product candidates demonstrate unexpected safety findings or do not achieve the primary efficacy endpoints, the prospects for approval of these product candidates, as well the price of our ADSs and common shares and our ability to create shareholder value would be materially and adversely affected. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in composition of the patient populations, adherence to the dosing regimen and other trial protocols and the dropout rate among clinical trial participants. For example, we could be required to use a primary endpoint in Phase III clinical trials that is different from endpoints in our Phase II clinical trials, which could result in negative or less compelling efficacy results in pivotal trials despite promising results in Phase II trials. As another example, preliminary evaluation of our Phase II trial data in TLC399 has not been able to show evidence of efficacy beyond three months, which we believe is due to the administration of rescue medication to most patients, even those who did not meet rescue criteria. Patients who receive rescue medication become unevaluable, making it difficult to assess efficacy beyond three months. We have urged trial investigators to confer with the medical monitor to ensure subjects meet rescue criteria prior to administering rescue medication; however, we cannot guarantee that such closer scrutiny will be strictly followed. It is critical for us to differentiate TLC399's duration from other products on the market, some of which already have efficacy lasting three months. We do not know whether any future clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. If we are unable to bring any of our current or future product candidates to market, our ability to create long-term shareholder value will be limited.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.

We may experience delays in clinical trials of our product candidates. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients, or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including:

- inability to raise funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA or other regulatory authorities on final trial design;
- imposition of a clinical hold for safety reasons or following an inspection of our clinical trial operations or trial or manufacturing sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective contract research organizations (CRO) and clinical trial sites;
- delays in obtaining required IRB approval at each site;
- delays in recruiting suitable patients to participate in a trial;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial to the detriment of enrollment;
- time required to add new clinical sites; or
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials.

We could also experience delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted, any data monitoring committee for such trial, or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of clinical trial operations or trial or manufacturing sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. For example, per the study protocol for our ongoing Phase II clinical trial of TLC399 in 61 planned patients with macular edema due to retinal vein occlusion (RVO) in the United States, an independent safety monitoring committee (SMC) conducted a pre-planned unblinded analysis of the study data and requested a temporary recruitment pause to make a comprehensive assessment of an optimal dose group in the trial. The optimal dose group was selected in August 2018, and we expect to resume recruitment after the study protocol amendment is implemented. We cannot assure you that the temporary pause will not last longer than we anticipate, which could potentially delay our clinical development plans for TLC399. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed. In addition, any delays in completing our clinical trials will increase our costs and slow down our product development and approval process. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval for our product candidates.

Because we have multiple product candidates in our clinical pipeline and are considering a variety of target indications, we may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must focus on research and development efforts on those product candidates and specific indications that we believe are the most promising. As a result, we may forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable

market opportunities. We may in the future spend our resources on other research programs and product candidates for specific indications that ultimately do not yield any commercially viable products. For example, one component of our business strategy is to identify additional opportunities for our extensive library of over 50 formulated discovery compounds. However, these compounds have not been proven and we cannot assure you that they will be viable candidates for preclinical development or that our estimates for the speed of development and resultant pipeline will prove accurate. In addition, the costs, time and resources required to successfully move these compounds into development may be greater than our estimates. Moreover, we have no experience to date developing product candidates at the rate that we intend to pursue. Furthermore, if we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

If the FDA does not conclude that TLC599, TLC590, TLC178 or TLC399 satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for these products under Section 505(b)(2) are not as we expect, the approval pathway for any or all of TLC599, TLC590, TLC178 or TLC399 will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in any case may not be successful.

We intend to seek FDA approval through the Section 505(b)(2) regulatory pathway for TLC599, TLC590, TLC178 and TLC399. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments, added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act (FDCA) or Section 505(b)(2). Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference.

If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur in respect of TLC599, TLC590, TLC178 or TLC399, the time and financial resources required to obtain FDA approval, and complications and risks associated with TLC599, TLC590, TLC178 and TLC399, respectively, would likely substantially increase. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway could result in new competitive products reaching the market faster than our product candidates, which could materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that TLC599, TLC590, TLC178 or TLC399 will receive the requisite approvals for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may be required to change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

Our product candidates based on our NanoX platform represent a novel approach to cancer treatment, which could result in delays in clinical development, heightened regulatory scrutiny, delays in our ability to achieve regulatory approval or commercialization, or market acceptance by physicians and patients of our product candidates.

Our product candidates developed through our NanoX platform, which is a novel drug loading vesicle of small unilamellar (single layered) liposomes employing a novel combination of counter-ions to create an ionic gradient for active drug loading, will represent a departure from more commonly used methods for cancer treatment, and therefore carry heightened development risks. To develop our NanoX platform, we must successfully demonstrate that NanoX encapsulated payloads have better toxicity profiles than the widely available treatments upon which they are based. The need to further develop or modify in any way the protocols related to our product candidates to demonstrate safety or efficacy may delay the clinical program, regulatory approval or commercialization. Unexpected safety and tolerability concerns may arise during the development process.

In addition, potential patients and their doctors may be inclined to use conventional standard-of-care treatments rather than enroll patients in any future clinical trial or use our product candidates commercially once approved. This may have a material impact on our ability to generate revenues from our product candidates. Further, given the novelty of the administration of our product candidates, hospitals and physicians may prefer traditional treatment methods, may be reluctant to adopt the use of our products or may require a substantial amount of education and training, any of which could delay or prevent acceptance of our products by physicians and patients and materially hinder successful commercialization of our product candidates.

Even though we have obtained orphan drug designation for TLC178 in STS and a Rare Pediatric Disease Designation for TLC178 in rhabdomyosarcoma (RMS), we may not be able to obtain or maintain the benefits associated with orphan drug status, including market exclusivity, or with Rare Pediatric Disease Designation.

Regulatory authorities in some jurisdictions, including the United States, Taiwan and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. The FDA and EMA has granted orphan drug status to TLC178 for the treatment of patients with STS in the United States. Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug may be entitled to a period of marketing exclusivity, which precludes the FDA, the ROC Food and Drug Administration (RFDA), or the European Medicines Agency (EMA) from approving another marketing application for the same drug for that time period. We can provide no assurance that another drug will not receive marketing approval prior to our product candidates. The applicable period is seven years in the United States and ten years in Taiwan and the European Union, which may be extended to twelve years in the European Union in the case of product candidates that have complied with an EMA-agreed upon pediatric investigation plan. The exclusivity period in the European Union can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA, the RFDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. In addition, even after a drug is granted orphan exclusivity and approved, the FDA or the RFDA can subsequently approve another drug for the same condition before the expiration of the seven or ten year exclusivity period if the FDA or the RFDA, respectively, concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In the European Union, the EMA may deny marketing approval for a product candidate if it determines such product candidate is structurally similar to an approved product for the same indication.

Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process. Also, regulatory approval for any product candidate may be withdrawn, and other product candidates may obtain approval before us and receive orphan drug exclusivity, which could block us from entering the market. Even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the candidate from competition because different drugs can be approved for the same condition before the expiration of the orphan drug exclusivity period.

TLC178 has been granted by the FDA a Rare Pediatric Disease Designation in RMS, qualifying us for a chance to receive a Priority Review Voucher that can significantly shorten the marketing application review period from over ten months to just six months; however, the receipt of any of this designation may not result in a faster development process, review or approval compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA.

Our product candidates may cause adverse events or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

Adverse events (AEs) caused by our product candidates or other potentially harmful characteristics of our product candidates could cause us, other reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval. If drug-related serious adverse events (SAEs) are observed in any of our clinical trials, our ability to obtain regulatory approval for our product candidates may be adversely affected. For example, in our ongoing Phase I clinical trial with TLC399 in five evaluable patients with macular edema due to RVO, 19 treatment-related AEs were reported, all for eye-related side effects of mild to moderate intensity, with two subjects experiencing treatment-related SAEs due to intraocular pressure elevation, a known side effect of dexamethasone sodium phosphate or other steroid treatment in this indication.

Additionally, in our ongoing Phase II clinical trial of TLC399 two patients who received a higher-concentration formulation suffered SAEs of vitreous haze. One of these patients had pre-existing cataracts and suspected vitreous hemorrhage that may have contributed to the persistent haze. These events were assessed as serious and related to study treatment. These patients underwent a vitrectomy (an out-patient procedure involving removal of the vitreous humor). Following vitrectomy, the haze was resolved in both subjects. The treatment group that the patients were a part of was not selected to go forward in this study. To date, no treatment-related SAEs have been observed in the other 29 enrolled patients.

Further, if any of our approved products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution in the form of a modified Risk Evaluation and Mitigation Strategy;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or conduct additional clinical studies;
- we could be sued and held liable for harm caused to patients; or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. For example, we cannot guarantee that our recently completed or ongoing Phase I/II or Phase II clinical trials will be sufficient to allow subsequent pivotal clinical development or that the FDA will not require additional or different clinical trials prior to initiating pivotal clinical development of TLC599 or that the required primary endpoints in pivotal clinical trials will be different than those in Phase II trials.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design, scope or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA, BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may change significantly in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market our product candidates, which would harm our business, results of operations and prospects significantly. In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could harm the commercial prospects for our product candidates. For

example, we believe that, to the extent our clinical development of TLC599 continues to focus on knee OA, any initial indication of TLC599 would be limited to the treatment of knee OA, as opposed to the treatment of OA generally. If an initial indication is limited to knee OA, we would likely need to conduct additional clinical trials in order to market TLC599 for other indications and expand its market potential.

We have not previously submitted an NDA, BLA or any similar drug approval filing to the FDA or any comparable foreign authority for any non-generic product candidate, and we cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenue will be dependent, to a significant extent, upon the size of the markets in the territories for which we gain regulatory approval. If the markets for patients or indications that we are targeting are not as significant as we estimate, we may not generate significant revenue from sales of such products, if approved.

Even if we obtain regulatory approval for our product candidates, we will still face extensive regulatory requirements and our products may face future development and regulatory difficulties.

Even if we obtain regulatory approval in the United States, the FDA may still impose significant restrictions on the indicated uses or marketing of our product candidates, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. Our product candidates, if approved, will also be subject to ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record-keeping and reporting of safety and other post-market information. The holder of an approved NDA or BLA is obligated to monitor and report AEs and any failure of a product to meet the specifications in the NDA or BLA, as applicable. The holder of an approved NDA or BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

In addition, manufacturers of drug products and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices (cGMP) and adherence to commitments made in the NDA. If we or a regulatory agency discovers previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of a product candidate, a regulatory agency may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or supplements to an NDA submitted by us;
- seize product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue.

Even if we obtain FDA approval for our product candidates in the United States, we may never obtain approval to commercialize our product candidates outside of the United States, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional non-clinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Other than our generic products, we do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. For example, if we receive marketing approval for TLC599 as a therapy for knee OA, physicians may nevertheless use our product for their patients in a manner that is inconsistent with the approved label, potentially including as an injection in other joints. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

If we fail to develop, acquire or in-license other product candidates or products, our business and prospects will be limited.

Our long-term growth strategy is to develop, acquire or in-license and commercialize a portfolio of product candidates in addition to TLC599 and our other existing product candidates. We are using our proprietary technology platform to assemble product candidates that target areas of unmet medical need in pain management, ophthalmology and oncology. Our business depends not only on our ability to successfully develop, obtain regulatory approval for and commercialize the limited number of internal product candidates we currently have in preclinical and clinical development, but to continue to generate product candidates through our platform.

Even if we are successful in continuing to build our pipeline, any additional product candidates may not be suitable for clinical development, including as a result of harmful side effects, manufacturing issues, limited efficacy or other characteristics that indicate that they are unlikely to be products that will succeed in clinical development, receive marketing approval or achieve market acceptance. If we cannot validate our technology platform by successfully developing and commercializing product candidates based on our approach, we may not be able to obtain product, licensing or collaboration revenue in future periods, which would adversely affect our business, prospects, financial condition and results of operations.

Generating new product candidates or identifying, selecting and acquiring or licensing promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual development, acquisition or license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. If we are unable to add additional product candidates to our pipeline, our long-term business and prospects will be limited.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for our preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with FDA laws and regulations regarding current good clinical practice (GCP) which are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Conference on Harmonization guidelines for all of our products in clinical development. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. While we have agreements governing activities of our CROs, we have limited influence over their actual performance. In addition, portions of the clinical trials for our product candidates are expected to be conducted outside of Taiwan, which will make it more difficult for us to monitor CROs and perform visits of our clinical trial sites and will force us to rely heavily on CROs to ensure the proper and timely conduct of our clinical trials and compliance with applicable regulations, including GCP. Failure to comply with applicable regulations in the conduct of the clinical trials for our product candidates may require us to repeat clinical trials, which would delay the regulatory approval process.

Some of our CROs have an ability to terminate their respective agreements with us if, among other reasons, it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our preclinical and clinical programs. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely completely on third parties to manufacture our preclinical and clinical drug supplies, and we intend to rely on third parties to produce commercial supplies of any approved product candidate.

If we were to experience an unexpected loss of supply of our product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, clinical trials. Although we own the equipment used by our third-party manufactures, we do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture our preclinical and clinical drug supplies, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. The facilities used by our contract manufacturers or other third-party manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit an NDA to the FDA. While we work closely with our third-party manufacturers on the manufacturing process for our product candidates, including quality audits, we generally do not control the implementation of the manufacturing process of,

and are completely dependent on, our contract manufacturers or other third-party manufacturers for compliance with cGMP regulatory requirements and for manufacture of both active drug substances and finished drug products. If our contract manufacturers or other third-party manufacturers cannot successfully manufacture material that conforms to applicable specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. For example, Evonik Corporation (Evonik), the contract manufacturer we rely on to produce TLC599 has never produced an FDA-approved therapeutic. If Evonik or our other manufacturers are unable to comply with cGMP regulation or if the FDA or other regulators do not approve their facility upon a pre-approval inspection, TLC599 or our other product candidates may not be approved or may be delayed in obtaining approval. In addition, we have no control over the ability of our contract manufacturers or other third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which could take several years and would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture our product candidates and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials, and if approved, for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a contract manufacturer or other third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenue from the sale of our product candidates.

We expect to continue to depend on contract manufacturers or other third-party manufacturers for the foreseeable future. Other than an agreement with Hospira Australia Pty Ltd with respect to TLC178, Shinlin Sinseng Pharmaceuticals, Ind. Co., Ltd (SSP) with respect to TLC590 and Evonik with respect to TLC599, we have not entered into long-term commercial supply agreements with our current contract manufacturers or with any alternate fill/finish suppliers. Although we intend to do so prior to any commercial launch of our product candidates, if approved by the FDA, in order to ensure that we maintain adequate supplies of finished drug product, we may be unable to enter into such an agreement or do so on commercially reasonable terms, which could have a material adverse impact upon our business, including delaying a product launch or subjecting our commercialization efforts to significant supply risk. Even if we are able to enter into additional long-term agreements with manufacturers for commercial supply on reasonable terms, we may be unable to do so with sufficient time prior to the launch of our product candidates, which would expose us to substantial supply risk and potentially jeopardize our launch.

Manufacturing issues may arise that could increase product and regulatory approval costs or delay commercialization.

As we scale up manufacturing of our product candidates and conduct required stability testing, product, packaging, equipment and process-related issues may require refinement or resolution in order to proceed with our planned clinical trials and obtain regulatory approval for commercial marketing. In the future, we may identify impurities, which could result in increased scrutiny by the regulatory agencies, delays in our clinical program and regulatory approval, increases in our operating expenses, or failure to obtain or maintain approval for our product candidates.

Risks Related to Commercialization of Our Product Candidates

Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, healthcare payors, patients and the medical community.

Even if we obtain regulatory approval for our product candidates, the product may not gain market acceptance among physicians, healthcare payors, patients and the medical community, which is critical to commercial success. Market acceptance of any product candidate for which we receive approval depends on a number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- acceptance by physicians, the medical community and patients of the product candidate as a safe and effective treatment and also the willingness of physicians to prescribe a drug based on an active pharmaceutical ingredient (API) that is less familiar to them than other drug API;
- the convenience of prescribing and initiating patients on the product candidate;
- the potential and perceived advantages of such product candidate over alternative treatments;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- the availability of coverage and adequate reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration;
- the prevalence and severity of adverse side effects; and
- the effectiveness of sales and marketing efforts.

For example, the steroid dexamethasone sodium phosphate, the API in TLC599, is not as commonly administered as traditional steroids for knee OA. If our product candidates are approved but fail to achieve an adequate level of acceptance by physicians, healthcare payors, patients and the medical community, we will not be able to generate significant revenue, and we may not become or remain profitable. In addition, even if any of our product candidates gain acceptance, the markets for the treatment of patients with our target indications may not be as significant as we estimate.

Guidelines and recommendations published by various organizations can reduce the use of our product candidates.

Government agencies promulgate regulations and guidelines directly applicable to us and to our product candidates. In addition, professional societies, such as the American Academy of Orthopedic Surgeons, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the healthcare and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of our product candidates or the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers could result in decreased use of our product candidates.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

Although we intend to establish a targeted sales and marketing organization to promote any approved products in the United States, we currently have no such organization or capabilities, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved, we must build sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. We may enter into strategic partnerships with third parties to commercialize our product candidates outside of the United States.

To date, we have not entered into any strategic partnerships for any of our product candidates. We face significant competition in seeking appropriate strategic partners, and these strategic partnerships can be intricate and time consuming to negotiate and document. We may not be able to negotiate strategic partnerships for territories outside of the United States on acceptable terms, or at all. For example, in January 2018, we signed a strategic alliance agreement with Jixi Biotechnology Partners (Jixi) to form a joint venture with the goal of streamlining our clinical trials, registration and commercialization processes in China; however, because Jixi was unable to obtain the requisite People's Republic of China governmental approval, we were unable to close the joint venture and in September 2018, we terminated the agreement with Jixi. We are unable to predict when, if ever, we will enter into any strategic partnerships outside of the United States because of the numerous risks and uncertainties associated with establishing strategic partnerships. To the extent that we enter into collaboration arrangements, our future collaboration partners may not dedicate sufficient resources to the commercialization of our product candidates or may otherwise fail in their commercialization due to factors beyond our control. If we are unable to establish effective collaborations to enable the sale of our product candidates in territories outside of the United States, or if our potential future collaboration partners do not successfully commercialize our product candidates in these territories, our ability to generate revenue from product sales will be adversely affected.

If we are unable to negotiate a strategic partnership or obtain additional financial resources for a product candidate, we may be forced to curtail the development of such product candidate, delay potential commercialization, reduce the scope of our sales or marketing activities or undertake development or commercialization activities at our own expense. In addition, without a partnership, we will bear all the risk related to the development of the product candidate, including in territories outside of the United States. If we elect to increase our expenditures to fund development or commercialization activities ourselves, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring TLC599 or any other product candidates to market or generate significant product revenue.

We and any collaboration partners that we may engage will be competing with many companies that currently have extensive and well-funded marketing and sales operations. If we, alone or with commercialization partners, are unable to compete successfully against these established companies, the commercial success of any approved products will be limited.

We may form or seek joint ventures, collaborations or strategic alliances or enter into additional licensing arrangements in the future but may not realize the benefits of such joint ventures, collaborations or strategic alliances. If we are unable to enter into future joint ventures, collaborations, or strategic alliances or if such arrangements are not successful, our business could be adversely affected.

We may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our clinical development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop, particularly in China. Any of these relationships may require us to incur other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex and may not ultimately prove successful. For example, in January 2018, we signed a strategic alliance agreement with Jixi to form a joint venture with the goal of streamlining our clinical trials, registration and commercialization processes in China; however, because Jixi was unable to obtain the requisite PRC governmental approval, we were unable to close the joint venture and in September 2018, we terminated the agreement with Jixi. Furthermore, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy.

Any potential future arrangements with third parties that we may enter into involving our product candidates, are subject to numerous risks, including the following:

- such third parties may have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- such third parties may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;

- such third parties may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- such third parties could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- product candidates discovered through such arrangements or any potential future collaborations with us may be viewed by such third parties or any potential future collaborators as competitive with their own product candidates or products, which may cause such third parties or collaborators to cease to devote resources to the commercialization of our product candidates;
- such third parties with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- such third parties may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and such third parties that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- such third parties may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- such arrangements may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- such third parties may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property; and
- the arrangements with such third parties may require governmental approvals, and such approvals may not be given or may be delayed.

As a result, if we are unable to enter into and maintain strategic partnerships, joint ventures or collaborations, or enter into and maintain future arrangements, joint ventures or collaborations, or if such arrangements are not successful, our business could be adversely affected. If we enter into certain arrangements or collaboration agreements and strategic partnerships or license our products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain territories for certain indications, which would harm our business prospects, financial condition, and results of operations.

Our business is subject to economic, political, regulatory and other risks associated with international operations.

As a company based in Taiwan, our business is subject to risks associated with conducting business outside of the United States. Many of our suppliers and collaborative and clinical trial relationships are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation or political instability in particular non-U.S. economies and markets;
- differing and changing regulatory requirements for drug approvals in non-U.S. countries;
- differing jurisdictions could present different issues for securing, maintaining or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property rights;

- difficulties in compliance with non-U.S. laws and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in currency exchange rates, including the euro, the New Taiwan dollar, Renminbi and the Australian dollar and currency controls;
- changes in a specific country's or region's political or economic environment, particularly in respect of the dynamic between the ROC and mainland China (PRC);
- trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;
- differing reimbursement regimes and price controls in certain non-U.S. markets;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling outside of Taiwan;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities outside of Taiwan; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

For example, we have exposure to currency fluctuations because we source our API, and other raw materials and our research and development, manufacturing, consulting and other services worldwide. Any weakening of the New Taiwan dollar against the currencies of such other jurisdictions makes the purchase of such goods and services more expensive for us. Further, potential future revenue may be derived from abroad, particularly from the United States. As a result, our business and the price of our ADSs may be affected by fluctuations in foreign exchange rates not only between the New Taiwan dollar and the U.S. dollar, but also the currencies of other countries, which may have a significant impact on our results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place.

If we are unable to differentiate TLC599, which recently completed a Phase II trial, or our other product candidates from existing generic therapies, or if the FDA or other applicable regulatory authorities approve generic products that compete with any of our product candidates, the ability to successfully commercialize those product candidates would be adversely affected.

Injectable immediate-release steroids, which are the current standard of care, are available in generic form and are therefore relatively inexpensive compared to the price we would expect to receive for TLC599. These generic steroids also have well-established market positions and familiarity with physicians, healthcare payors and patients. In particular, physicians may be less inclined to prescribe TLC599 if approved, which is based on a steroid that is not commonly used, as compared to competing products that use triamcinolone acetonide (TCA) as the API. Although we believe TLC599 has the potential for clinically meaningful differentiation in sustained pain relief as compared to immediate-release TCA and immediate-release dexamethasone sodium phosphate, as clinical development of TLC599 advances and we receive data from additional clinical trials, it is possible that the data will not support such differentiation. There are also existing generic therapies for the indications which our other product candidates are targeting. If we are unable to achieve significant differentiation for TLC599 from currently marketed steroids or for our other product candidates in respect of existing generic therapies, our opportunity for TLC599 or our other product candidates to achieve premium pricing and be commercialized successfully, if approved, would be adversely affected.

In addition to existing generic steroids, the FDA or other applicable regulatory authorities may approve generic products that could compete with our product candidates. Once an NDA, including a Section 505(b)(2) application, is approved, the product covered thereby becomes a "listed drug" which can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application (ANDA). The FDCA, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an

ANDA or other application for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use, or labeling, as our product candidate and that the generic product is bioequivalent to ours, meaning it is absorbed in the body at the same rate and to the same extent as our product candidate. These generic equivalents, which must meet the same quality standards as branded pharmaceuticals, would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product is typically lost to the generic product. Accordingly, competition from generic equivalents to our product candidates would materially adversely impact our ability to successfully commercialize our product candidates.

We face significant competition from other biopharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industry is intensely competitive and subject to rapid and significant technological change. We have competitors both in the United States and internationally, including large and specialty pharmaceutical and biotechnology companies, academic research institutions, governmental agencies and public and private research institutions. For example, the injectable OA treatment market today includes steroids, including TCA, as well as hyaluronic acid viscosupplements. Immediate-release steroids are generic, and therefore available at prices that are significantly below the price we would expect to charge for TLC599, if approved. We believe our ability to compete with immediate-release steroids and extended-release intraarticular steroids, such as ZILRETTA, will depend primarily on whether TLC599 demonstrates superior duration of pain relief and whether TLC599 proves to be safer, particularly with respect to chondrotoxicity, compared to ZILRETTA. The manufacturer of ZILRETTA recently announced that in an open-label, repeat dose Phase 3b safety trial, an analysis of X-rays taken at baseline and Week 52 showed that repeat administration of ZILRETTA had no deleterious effects on cartilage or joint structure. While the full details of these trial results have not been made available, the results may make it more difficult for us to convince healthcare providers, payors and patients that TLC599 has safety advantages over existing TCA products like ZILRETTA, and may require that we conduct additional clinical trials to support future marketing efforts. With respect to TLC399, current approved treatments for macular edema associated with RVO include intravitreal injections of anti-VEGF drugs and intravitreal steroid injections. Macular edema due to RVO is also currently treated with steroid injections in the form of dexamethasone intravitreal implants, such as Ozurdex. With respect to TLC590, numerous post-operative pain treatments exist, including local analgesics, opioids and elastomeric pumps, and we also expect to face competition from EXPAREL, which is a liposomal formulation of bupivacaine. Although there are no FDA approved products for RMS, current treatment options include vinorelbine, doxorubicin, irinotecan, topotecan and trabectedin, which are all conventional chemotherapy drugs.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products or drug delivery technologies that are more effective or less costly than our product candidates that we are currently developing or that we may develop.

We believe that our ability to successfully compete will depend on, among other things:

- the efficacy and safety of our product candidates, including as relative to marketed products and product candidates in development by third parties;
- the time it takes for our product candidates to complete clinical development and receive marketing approval;
- the ability to maintain a good relationship with regulatory authorities;
- the ability to commercialize and market any of our product candidates that receive regulatory approval;
- the price of our products, including in comparison to branded or generic competitors;

- whether coverage and adequate levels of reimbursement are available under private health insurance plans and governmental health care programs, including Medicare;
- the ability to protect intellectual property rights related to our product candidates;
- the ability to manufacture on a cost-effective basis and sell commercial quantities of any of our product candidates that receive regulatory approval; and
- acceptance of any of our product candidates that receive regulatory approval by physicians and other healthcare providers.

If our competitors market products that are more effective, safer or less expensive than our future products, if any, or that reach the market sooner than our future products, if any, we may not achieve commercial success. In addition, the biopharmaceutical industry is characterized by rapid technological change. Because we have limited research and development capabilities, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

Certain governments tend to impose strict price controls, which may adversely affect our future profitability.

In certain countries, prescription drug pricing and reimbursement is subject to governmental control. In those countries that impose price controls, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our strategic partners may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies.

Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In certain markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we or our strategic partners might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay commercial launch of the product candidate, possibly for lengthy time periods, and negatively impact the revenue that are generated from the sale of the product in that country. If reimbursement of such product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, or if there is competition from lower priced cross-border sales, our profitability will be negatively affected.

It may be difficult for us to profitably sell our product candidates if coverage and reimbursement for these products is limited by government authorities and/or third-party payor policies.

In addition to any healthcare reform measures which may affect reimbursement, market acceptance and sales of our product candidates, if approved, will depend on, in part, the extent to which our products will be covered by third-party payors, such as government health care programs, commercial insurance and managed care organizations. These third-party payors determine the extent to which new drugs will be covered as a benefit under their plans and the level of reimbursement for any covered product. It is difficult to predict at this time what third party payors will decide with respect to the coverage and reimbursement for our product candidates.

A primary trend in the U.S. healthcare industry and elsewhere has been cost containment, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products and/or biosimilars. Third-party payors decide which drugs they will pay for and establish reimbursement and co-payment levels. Government and other third-party payors are increasingly challenging the prices charged for health care products, examining the cost effectiveness of drugs in addition to their safety and efficacy, and limiting or attempting to limit both coverage and the level of reimbursement for prescription drugs. We cannot be sure that coverage will be available for our product candidates, if approved, or, if coverage is available, the level of reimbursement.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services (CMS), an agency within the U.S. Department of Health and Human Services (HHS), as CMS decides

whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors may follow CMS, but have their own methods and approval processes for determining reimbursement for new medicines. It is difficult to predict what CMS as well as other payors will decide with respect to reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products.

Reimbursement may impact the demand for, and/or the price of, any product for which we obtain marketing approval. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution.

We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new products. Further, the adoption and implementation of any future governmental cost containment or other health reform initiative may result in additional downward pressure on the price that we may receive for any approved product.

Reimbursement by a third-party payor may depend upon a number of factors including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payor. Further, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. We may not be able to provide data sufficient to gain acceptance with respect to coverage and/or sufficient reimbursement levels. We cannot be sure that coverage or adequate reimbursement will be available for our product candidates, if approved. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our future products. If reimbursement is not available, or is available only to limited levels, we may not be able to commercialize our product candidates, or achieve profitably at all, even if approved.

Legislative or regulatory healthcare reforms in the United States may make it more difficult and costly for us to obtain regulatory clearance or approval of our product candidates and to produce, market and distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our product candidates. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

- changes to manufacturing methods;
- change in protocol design;
- additional treatment arm (control);
- recall, replacement, or discontinuance of one or more of our products; and
- additional recordkeeping.

Each of these would likely entail substantial time and cost and could harm our business and our financial results.

In addition, in the United States, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. The pharmaceutical industry in the United States, as an example, has been affected by the passage of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the PPACA) which, among other things, imposed new fees on entities that manufacture or import certain branded prescription drugs and expanded pharmaceutical manufacturer obligations to provide discounts and rebates to certain government programs. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the PPACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the PPACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of any certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018 (BBA), among other things, amended the PPACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In addition, in April 2018, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the PPACA for plans sold through such marketplaces. More recently, in December 2018, CMS published a final rule permitting further collections and payments to and from certain PPACA qualified health plans and health insurance issuers under the PPACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the PPACA will impact the PPACA. Congress will likely consider other legislation to repeal or repeal and replace other elements of the PPACA. We continue to evaluate the effect that the PPACA and its possible repeal and replacement has on our business. It is uncertain the extent to which any such changes may impact our business or financial condition.

Other legislative changes have been proposed and adopted in the United States since the PPACA was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2012 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to certain providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there has been particular and increasing legislative and enforcement interest in the United States with respect to drug pricing practices in recent years, particularly with respect to drugs that have been subject to relatively large price increases over relatively short time periods. There have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. HHS has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. On January 31, 2019, the HHS Office of Inspector General, proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. Although a number of these and other proposals may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 (Right to Try Act) was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

In the future, there will likely continue to be proposals relating to the reform of the U.S. healthcare system, some of which could further limit coverage and reimbursement of drug products, including our product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Our results of operations could be adversely affected by the PPACA and by other health care reforms that may be enacted or adopted in the future.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Our operations may be directly or indirectly through our relationships with third-party payors, existing or potential customers and referral sources, including healthcare providers, subject to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our products. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

The U.S. Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, receiving or providing any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other U.S. federal healthcare programs. The U.S. Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers, among others, on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution.

The U.S. federal false claims and civil monetary penalties laws, including the False Claims Act (FCA), prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the U.S. federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the U.S. federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and significant mandatory penalties. Government enforcement agencies and private whistleblowers have investigated pharmaceutical companies for or asserted liability under the FCA for a variety of alleged promotional and marketing activities, such as providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees and other benefits to physicians to induce them to prescribe products; engaging in promotion for "off-label" uses; and submitting inflated best price information to the Medicaid Rebate Program.

The U.S. Health Insurance Portability and Accountability Act of 1996 (HIPAA) prohibits, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

The Physician Payments Sunshine Act, enacted as part of the PPACA, imposes, among other things, annual reporting requirements for covered manufacturers for certain payments and "transfers of value" provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) and their respective implementing regulations, impose, among other things, specified requirements relating to the privacy, security and transmission of individually identifiable health information held by health plans and healthcare clearinghouses, and certain healthcare providers, known as covered entities, and their business associates that create, receive, maintain or transmit individually identifiable health information for or on their behalf. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Many states have analogous state laws and regulations, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. In addition, certain states require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing. Further, certain state and local laws require the registration of pharmaceutical sales and medical representatives.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the PPACA, has among other things, amended the intent requirement of the U.S. Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. Moreover, recent health care reform legislation provides that the government may assert that a claim including items or services resulting from a violation of the U.S. Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, possible exclusion from government funded healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could substantially disrupt our operations. If the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

We are subject to U.S. and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended (FCPA), the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We engage third-party investigators, CROs, and other consultants to design and perform preclinical studies of our product candidates, and will do the same for any clinical trials. Also, once a product candidate has been approved and commercialized, we may engage third-party intermediaries to promote and sell our products abroad and/or to obtain necessary permits, licenses, and other regulatory approvals. We or our third-party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, collaborators, partners, and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage, and other collateral consequences. If any subpoenas, investigations, or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens.

The incidence and prevalence for target patient populations of our product candidates are based on estimates and third-party sources. If the market opportunities for our product candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected.

Periodically, we make estimates regarding the incidence and prevalence of target patient populations for particular diseases based on various third-party sources and internally generated analysis and use such estimates in making decisions regarding our drug development strategy, including acquiring or in-licensing product candidates and determining indications on which to focus in preclinical or clinical trials.

These estimates may be inaccurate or based on imprecise data. For example, the total addressable market opportunity will depend on, among other things, acceptance of our product candidates by the medical community and patient access, pricing and reimbursement of our product candidates. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our product candidates, or new patients may become increasingly difficult to identify or gain access to, all of which may significantly harm our business, financial condition, results of operations and prospects.

Risks Related to Our Business Operations and Industry

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the principal members of our executive team listed under "Management" located elsewhere in this Annual Report, the loss of whose services may adversely impact the achievement of our objectives. While we have entered into employment agreements or offer letters with each of our executive officers, any of them could leave our employment at any time. Recruiting and retaining other qualified employees for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. In addition, failure to succeed in clinical studies may make it more challenging to recruit and retain qualified personnel. The inability to recruit or loss of the services of any executive or key employee might impede the progress of our development and commercialization objectives.

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of December 31, 2018, we had 161 full-time employees. As our company matures, we expect to expand our employee base to increase our managerial, scientific and engineering, operational, sales, marketing, financial and other resources and to hire more consultants and contractors. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our existing or future product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and grow revenue could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage any future growth.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability.

The use of our product candidates in clinical trials, the sale of any products for which we obtain marketing approval, and the sale of any of our current generic products exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products and product candidates. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- decreased demand for our product candidates, if approved for commercial sale.

Our current clinical trial liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for our product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or

in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause the price of our ADSs or common shares to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Our internal computer systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our therapeutic development programs.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such events could cause interruptions of our operations. For instance, the loss of preclinical study or clinical trial data involving our therapeutic candidates could result in delays in our development and regulatory filing efforts and significantly increase our costs. In addition, theft or other exposure of data may interfere with our ability to protect our intellectual property, trade secrets, and other information critical to our operations. We can provide no assurances that certain sensitive and proprietary information relating to one or more of our therapeutic candidates has not been, or will not in the future be, compromised. There can be no assurances we will not experience additional unauthorized intrusions into our computer systems, or those of our CROs and other contractors and consultants, that we will successfully detect future unauthorized intrusions in a timely manner, or that future unauthorized intrusions will not result in material adverse effects on our financial condition, reputation, or business prospects. Payments related to the elimination of ransomware may materially affect our financial condition and results of operations.

Certain data breaches must also be reported to affected individuals and the government, and in some cases to the media, under provisions of HIPAA, as amended by HITECH, other U.S. federal and state law, and requirements of non-U.S. jurisdictions, including the European Union General Data Protection Regulation, and financial penalties may also apply.

Our insurance policies may not be adequate to compensate us for the potential losses arising from breaches, failures or disruptions of our infrastructure, catastrophic events and disasters or otherwise. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and defending a suit, regardless of its merit, could be costly and divert management's attention.

Furthermore, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business.

Business interruptions could delay us in the process of developing our product candidates and could disrupt our sales.

Our headquarters are located in Taipei, Taiwan. We are vulnerable to natural disasters such as earthquakes, typhoons and floods, as well as other events that could disrupt our operations. While we carry insurance for fire, flood and certain natural disasters, if we were impacted by these events this insurance may not be sufficient to compensate us for losses that may occur and our operations may be significantly interrupted regardless of insurance recovery. Any losses or damages we incur could have a material adverse effect on our business operations.

We face substantial political risks associated with doing business in the ROC and the PRC, particularly due to domestic political events and the rigid relationship between the ROC and the PRC that could negatively affect our operations and the value of your investment.

Our principal executive office and substantially all of our assets are located in the ROC and substantially all of our revenues are derived from our operations in the ROC. Accordingly, our business, financial condition and results of operations and the market price of our ADSs may be affected by changes in governmental policies, taxation, inflation or interest rates, social instability and diplomatic and social developments in or affecting the ROC.

For example, in 2006, a mass movement formed calling for the resignation of the president of the ROC over a series of alleged corruption scandals and staged dramatic protests. In addition, Taiwan has a unique international political status. Since 1949, the ROC and PRC, have been separately governed by different political parties. The PRC claims that it is the sole government in the PRC, including Taiwan, while some political parties in ROC claim ROC's independence or ROC as the

only legitimate government of the PRC, including the ROC and the PRC. There was a time when the two governments prohibited all trades, transactions and trips crossing the Taiwan Strait. Although significant economic and cultural relations have been established in recent years between the ROC and the PRC, relations have often been strained. The PRC government has refused to renounce the use of military force to regain control over the ROC. Furthermore, the PRC government passed an Anti-Secession Law in March 2005, which has authorized the government to use all necessary measures, including non-peaceful means, against Taiwan's independence movement in the event of such declaration. In February 2006, the then president of the ROC ceased all activities in the country's National Unification Council, a committee established to assist the ROC in its efforts to reunite with the PRC. Such cessation is commonly viewed as having a detrimental effect on the relations between the two sides. Past developments in the relationship between the ROC and the PRC has depressed the share prices of several Taiwanese companies. A recent cessation of dialogue between the ROC and mainland the PRC was followed by an approximate 30% decline of imports from mainland China to the ROC in 2016. An unstable relationship between the ROC and the PRC could materially and adversely affect our financial condition and results of operations, as well as the market price and the liquidity of our securities.

Business relationships between entities in the ROC and entities in the PRC are regulated by the ROC "Act Governing Relations between the People of the Taiwan Area and the Mainland Area" (臺灣地區與大陸地區人民關係條例) and the regulations promulgated thereunder (ROC Act). Among other things, the ROC Act requires the ROC government's prior approval of many business transactions. Any accumulated direct or indirect investment by us into any entity in the PRC in excess of US$1 million, or any technology cooperation agreement between us and any entity in the PRC that involves our intellectual property would be subject to this approval. While we are not currently party to any material transactions or agreements with any entity in the PRC, our future ability to enter into such arrangements may be limited by the ROC Act, particularly if ROC and PRC political relations deteriorate. Although, to our knowledge, we do not currently have any PRC shareholders, any PRC investor's investment into us must be approved by the Investment Commission, MOEA, Executive Yuan of the ROC, provided our businesses fall within one of the industries included on the list maintained by the MOEA that PRC enterprises are allowed to invest in, or such PRC investor must be a qualified domestic institutional investor (QDII) in the PRC for an investment limit of less than 10% of our issued shares. However, PRC investors, other than QDIIs, are currently prohibited from investing in us as certain aspects of our current business scope are not included on the MOEA's list. Any approval by the ROC government will depend on the then- current political environment between the ROC and PRC, and we cannot assure you that any PRC investor will receive such approval from the ROC government. Furthermore, any such PRC purchaser of American Depositary Receipts (ADRs) will need to qualify as a QDII in order to exchange their ADRs for underlying common shares of our company.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to our current product candidates, any future product candidates which we may develop and our BioSeizer and NanoX technologies, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection, confidentiality agreements and proprietary know how, and intend to seek marketing exclusivity for any approved product, in order to protect the intellectual property related to product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries. If this were to occur, early generic competition could be expected against our product candidates. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being invalidated or deemed as not infringing. Also, a third party may challenge our ownership of patents and patent applications assigned to us, or may challenge our exclusive rights to patents and patent applications that we license from third parties. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the patent applications we hold with respect to our other product candidates fail to issue or if their breadth or strength of protection is threatened, it could dissuade companies from collaborating with us to develop them, and threaten our ability to commercialize any resulting products. We cannot offer any assurances about which, if any, applications will issue as patents or whether any issued patents will be found not invalid and not unenforceable or will go unthreatened by third parties. Further, if we encounter delays in regulatory approvals, the period of time during which we could market our product candidates under patent protection could be reduced. Furthermore, patent applications by third parties can result in an interference proceeding in the United States being provoked by a third party or instituted by us to determine who was the first to invent any of the subject matter covered by the claims of our applications or patents.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug development process that involve proprietary know-how, information or technology that is not covered by patents. Although we generally require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of certain countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

If our trademarks and tradenames are not adequately protected, then we may not be able to build a name recognition in our markets and our business may be adversely affected.

We rely on trademarks, service marks, tradenames and brand names to distinguish our products from the products of our competitors, and have registered or applied to register certain trademarks. We cannot assure you that our trademark applications will be approved or that we will seek registered trademark protection for each of our product names in each jurisdiction in which we operate. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the U.S. Patent and Trademark Office (USPTO) and in proceedings before comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources toward advertising and marketing new brands. Further, we cannot assure you that competitors will not infringe our trademarks or that we will have adequate resources to enforce our trademarks.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and *exparte* reexamination and *inter partes* review before the USPTO. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents issue, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that third parties may assert are infringed by our technologies. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any drug substance formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtain a license under the applicable patents, or until such patents are invalidated or expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtain a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may request injunctive or other equitable relief. If granted, such relief could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products or manufacturing processes, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research, manufacture clinical trial supplies or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot guarantee that third-party patents do not exist which might be enforced against our products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our related patent applications at risk of not issuing.

Derivation proceedings are brought by third parties or may be brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our ADSs.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees or annuity payments on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors that control the prosecution and maintenance of our licensed patents fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

Risks Related to Our ADSs

The price of our ADSs may be volatile and may fluctuate due to factors beyond our control.

The trading market for publicly traded emerging biopharmaceutical and drug discovery and development companies has been highly volatile and is likely to remain highly volatile in the future. The market price of our ADSs may fluctuate significantly due to a variety of factors, including:

- positive or negative results from, or delays in, testing and clinical trials by us, collaborators or competitors;
- technological innovations or commercial product introductions by us or competitors;
- changes in government regulations;
- developments concerning proprietary rights, including patents and litigation matters;
- public concern relating to the commercial value or safety of our product candidates;
- financing, collaborations or other corporate transactions;

- publication of research reports or comments by securities or industry analysts;
- general market conditions in the pharmaceutical industry or in the economy as a whole;
- the loss of any of our key scientific or senior management personnel;
- the perceived values of our common shares trading on the TPEx and our ADSs trading on The Nasdaq Global Market relative to one another;
- sales of our ADSs or common shares by us, our senior management and board members or holders of our ADSs or our common shares in the future; or
- other events and factors, many of which are beyond our control.

These and other market and industry factors may cause the market price and demand for our ADSs to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their ADSs and may otherwise negatively affect the liquidity of our ADSs. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of the holders of our ADSs were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our senior management would be diverted from the operation of our business. Any adverse determination in litigation could also subject us to significant liabilities.

Restrictions on the ability to deposit our common shares into our American depositary receipt facility may adversely affect the liquidity of our ADSs.

The ability to deposit our common shares into our American depositary receipt facility for the issuance of ADSs is restricted by ROC law, which may adversely affect the liquidity of our ADSs. Under current ROC law and the Deposit Agreement, no person or entity, including the holders of ADSs and us, may deposit our common shares in our American depositary receipt facility for the issuance of ADRs without specific approval of the FSC unless:

(1) we pay stock dividends on, or make a free distribution of, our common shares;

(2) the ADS holder exercises pre-emptive rights in the event of capital increases for cash; or

(3) investors purchase our common shares, directly or through the depositary, on the TPEx, and deliver our common shares to the custodian for deposit into our American depositary receipt facility, or our existing shareholders deliver our common shares to the custodian for deposit into our American depositary receipt facility.

With respect to (3) above, the depositary may issue ADSs against the deposit of those shares only if the total number of ADSs outstanding following the deposit will not exceed the number of ADSs previously approved by the ROC Financial Supervisory Commission (FSC), plus any ADSs issued pursuant to the events described in items (1) and (2) above. Issuance of additional ADSs under item (3) above will be permitted to the extent that a corresponding number of previous ADSs have been cancelled.

Further, we have agreed to not assist existing shareholders in filing the government approval necessary for exchanging their common shares for ADSs until the end of the 180-day lock-up period described under the caption “Underwriting—No Sales of Similar Securities,” unless we have obtained the prior written consent of Cantor Fitzgerald & Co. As a result this contractual restriction and the restrictions under ROC law described above, the U.S. dollar equivalent price of our common shares on the TPEx may differ from the U.S. dollar price of our ADSs on The Nasdaq Global Market.

The price of our ADSs may be limited by the trading price of our common shares on the TPEx.

Our common shares are currently traded on the TPEx. From November 21, 2018 through April 22, 2019, the closing price of our common shares on the TPEx ranged from NT$89.40 per share to NT$100.00 per share. During the same period, the closing price of our ADSs on The Nasdaq Global Market ranged from $5.02 per ADS to $7.29 per ADS. The TPEx sets certain limitations on the trading volatility of our common shares and there are currently limits on the range of daily price movements on the TPEx. As a result of these limitations, the potential increase in trading price of our ADSs may be

materially limited based on the perceived value of our common shares on the TPEx. Similarly, decreases in the trading price of our common shares on the TPEx due to the perceptions of investors in that market, which may be different from your own, may impact the value of your investment.

We have incurred and will incur increased costs as a result of operating as a public company in the United States, and our senior management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

Our ADSs began trading on The Nasdaq Global Market on November 21, 2018 under the trading symbol "TLC". As a U.S. public company, we have incurred significant legal, accounting and other expenses that we did not incur previously, and we will incur additional expenses after we no longer qualify as an EGC. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Stock Market LLC (Nasdaq) and other applicable securities rules and regulations impose various requirements on non-U.S. reporting public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our senior management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified senior management personnel or members for our board of directors.

However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 (Section 404), we will be required to furnish a report by our senior management on our internal control over financial reporting (starting with our Annual Report on Form 20-F for the year ended December 31, 2019), and an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an EGC we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

As a foreign private issuer, we are permitted to adopt certain home country practices in relation to corporate governance matters that differ significantly from Nasdaq corporate governance listing standards. These practices may afford less protection to shareholders than they would enjoy if we complied fully with corporate governance listing standards.

As a foreign private issuer, we are permitted to take advantage of certain provisions in the Nasdaq listing rules that allow us to follow ROC law for certain governance matters. Certain corporate governance practices in the ROC may differ significantly from corporate governance listing standards. When our ADSs are listed on The Nasdaq Global Market, we intend to continue to follow Taiwan corporate governance practices in lieu of the following corporate governance requirements of Nasdaq: (i) disclosure requirement within four business days of any determination to grant a waiver of the code of business conduct and ethics to directors and officers; (ii) the requirement that a majority of our board consist of independent directors; (iii) the requirement that our audit committee be made up of members of our board of directors and have at least one member that has financial sophistication; (iv) requirement that a compensation committee be comprised solely of independent directors with a written charter addressing the committee's responsibilities and authority; (v) requirement that we have independent director oversight of director nominations and a formal written charter or board resolution addressing the nominations process; (vi) requirement that we have a code of conduct applicable to all directors, officers and employees; (vii) requirement to obtain shareholder approval for certain issuances of securities, including

shareholder approval of stock option plans; and (viii) requirement that our audit committee have review and oversight over all "related party transactions," as defined in Item 7.B of Form 20-F. Taiwan law either does not impose the foregoing requirements or does not impose them to the specificity of Nasdaq's rules. Therefore, our shareholders may be afforded less protection than they otherwise would have under corporate governance listing standards applicable to U.S. domestic issuers.

You may face difficulties in protecting your interests, and your ability to protect your rights through the U.S. federal courts may be limited, because we are incorporated under the Taiwan Company Act, conduct substantially all of our operations outside the United States and most of our executive officers reside outside the United States.

We are incorporated under the Taiwan Company Act, conduct substantially all of our operations outside the United States, and most of our executive officers reside outside the United States. As a result, it may be difficult if not impossible for you to bring an action against us or against these individuals in Taiwan in the event that you believe that your rights have been infringed under the securities laws or otherwise. Even if you are successful in bringing an action of this kind outside Taiwan, the laws of Taiwan may render you unable to effect service of process upon, or to enforce a judgment against our assets or the assets of our directors and officers. A judgment of a court of another jurisdiction may be reciprocally recognized or enforced if the jurisdiction has a treaty with Taiwan or if judgments of the Taiwanese courts have been recognized before in that jurisdiction, subject to the satisfaction of other requirements. As a result of all of the foregoing, our public shareholders and ADS holders may have more difficulty in protecting their interests through actions against our management, directors or major shareholders than would shareholders or ADS holders of a corporation incorporated in a jurisdiction in the United States.

Certain of our existing shareholders, members of our board of directors and senior management maintain the ability to exercise significant control over us. Your interests may conflict with the interests of these existing shareholders.

As of February 28, 2019, our senior management, board of directors and shareholders holding over 5% of our common shares, determined as of February 28, 2019, and their respective affiliates, in the aggregate, beneficially owned 28.9% of our common shares (including common shares represented by ADSs). These shareholders either alone or voting together as a group may be in a position to determine or significantly influence the outcome of decisions taken at any such general meeting. Any shareholder or group of shareholders controlling more than 50% of the outstanding shares present and voting at our general meetings of shareholders in which a quorum is present may control any shareholder resolution requiring a majority. For example, a quorum of two-thirds of our share capital must be present and voting at a meeting of shareholders for certain approvals, including certain decisions relating to our capital structure, the approval of certain significant corporate transactions and amendments to our Articles of Incorporation. If such quorum is met, then any shareholder or group of shareholders controlling more than 50% can control the voting of any such resolution. Among other consequences, this concentration of ownership may have the effect of delaying or preventing a change in control and might therefore negatively affect the market price of our ADSs.

Future sales, or the possibility of future sales, of a substantial number of our ADSs or common shares could adversely affect the price of our ADSs.

Future sales of a substantial number of our ADSs or common shares, or the perception that such sales will occur, could cause a decline in the market price of our ADSs. ADSs issued and sold may be resold in the U.S. public market immediately without restriction. The common shares held by our directors, executive officers, and certain shareholders will be subject to the lock-up agreements described in "Shares and ADSs Eligible for Future Sale" and "Underwriting." If, after the end of such lock-up agreements, these shareholders sell substantial amounts of our securities in the public markets, or the market perceives that such sales may occur, the market price of our ADSs and our ability to raise capital through an issue of equity securities in the future could be adversely affected.

Because we do not anticipate paying any cash dividends on our ADSs or common shares in the foreseeable future, capital appreciation, if any, will be the sole source of potential gains with respect to our ADSs or common shares.

Under current Taiwan law, a company must cover all of its accumulated losses and set aside a statutory reserve before dividends can be paid. Therefore, we must have distributable profits before issuing a dividend. We have not paid dividends in the past on our common shares. We intend to retain earnings, if any, for use in our business and do not anticipate paying any cash dividends in the foreseeable future. As a result, capital appreciation, if any, on our ADSs or common shares will be the sole source of potential gains for the foreseeable future, and holders of our ADSs or common shares will suffer a loss on their investment if they are unable to sell their ADSs or the underlying common shares at or above the purchase price.

Holders of our ADSs may not have the same voting rights as the holders of our common shares and may not receive voting materials in time to be able to exercise their right to vote.

Except as described in this Annual Report, holders of our ADSs will not be able to exercise voting rights attaching to the common shares represented by our ADSs on an individual basis. Holders of our ADSs will appoint the depositary or its nominee as their representative to exercise the voting rights attaching to the common shares in the form of ADSs in accordance with the deposit agreement. Holders of ADSs may not receive voting materials in time to instruct the depositary to vote, and it is possible that they, or persons who hold their ADSs through brokers, dealers or other third parties, will not have the opportunity to exercise a right to vote. In certain cases, the shares represented by your ADSs may be voted contrary to your instructions and you may be deemed to have instructed the depositary to give a discretionary proxy to a person we designate to vote shares represented by your ADSs in such person's discretion. Furthermore, the depositary will not be liable for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, holders of ADSs may not be able to exercise voting rights and may lack recourse if their shares represented by ADSs are not voted as requested. In addition, ADS holders do not have the right to call a shareholders' meeting.

You may not be able to withdraw the underlying common shares of our ADSs.

Pursuant to ROC law, an ADS holder who is a non-ROC person wishing to withdraw and hold deposited common shares from the ADS facility is required to appoint an eligible agent in the ROC for filing tax returns and making tax payments (Tax Guarantor). Such Tax Guarantor will be required to meet the qualifications set by the Taiwan Ministry of Finance and will act as the guarantor of the withdrawing ADS holder's tax payment obligations. In addition, subject to certain limited exceptions, under current ROC law, repatriation of profits by a non-ROC withdrawing ADS holder is subject to the submission of evidence by the withdrawing ADS holder of the appointment of a Tax Guarantor to, and approval thereof by, the ROC tax authority and of tax clearance certificates or evidentiary documents issued by the Tax Guarantor. We cannot provide any assurances that a withdrawing ADS holder will be able to appoint and obtain approval from the tax authority in a timely manner or at all.

Pursuant to ROC law, an ADS holder who is not an ROC person or ROC entity wishing to present ADSs to the depositary for cancellation and withdrawal and holding of the underlying common shares from the depositary receipt facility is required to register as a foreign investor with the Taiwan Stock Exchange (TWSE), if the ADS holder has never been registered as foreign investor with the TWSE previously, for making investments in the ROC securities market prior to withdrawing and holding the underlying common shares from the depositary receipts facility.

Additionally, pursuant to ROC law, such withdrawing ADS holder is required to appoint a local agent in the ROC to, on such ADS holder's behalf, open a securities trading account with prior approval granted by the TWSE with a local securities brokerage firm (with qualification set by the FSC), and a bank account, pay ROC taxes, remit funds, exercise shareholder rights and perform such other functions as the ADS holder may designate upon such withdrawal. In addition, such withdrawing ADS holder is also required to appoint a custodian bank and open a custodian account to hold the securities and cash in safekeeping, make confirmations, settle trades and report all relevant information. Without making such appointment and the opening of such custodian account, the withdrawing ADS holder would be unable to hold or subsequently sell the deposited common shares withdrawn from the ADR facility on the TPEx. The laws of the ROC applicable to the withdrawal of the underlying common shares may change from time to time. We cannot provide any assurances that current law will remain in effect or that future changes in ROC law will not adversely affect the ability of ADS holders to withdraw deposited common shares.

Currently, a party who is a PRC person may not withdraw and hold the underlying common shares unless it is a QDII in the PRC or has obtained the investment approval from the Taiwanese Investment Commission. Whether a PRC person may freely withdraw and hold the underlying common shares will depend on the total PRC ownership limit or whether the business of the issuer of the underlying common shares is subject to the total PRC ownership limit or within the ROC government's list of industries open to PRC investment as then in effect. Our business scope currently includes businesses that are not allowed for a PRC person that is not a QDII. We cannot guarantee whether additional or different restrictions or prohibitions will be imposed in the future on PRC persons (including QDIIs) that intend to invest in certain industries in the ROC, and a PRC person may be unable to withdraw and hold the underlying common shares. Under current ROC law, a PRC person means an individual having residence in the PRC (but not including a special administrative region of the PRC such as Hong Kong or Macau, if excluded by applicable laws of the ROC), any legal person, group, or other institutions of the PRC and any corporation and other entity organized in countries outside of the ROC or PRC that is directly or indirectly controlled by or directly or indirectly has more than 30% of its capital beneficially owned by any PRC person described above.

Holders of our ADSs may not receive distributions on our common shares in the form of ADSs or any value for them if it is illegal or impractical to make them available to holders of ADSs.

The depositary for our ADSs has agreed to pay to purchasers of our ADSs the cash dividends or other distributions it or the custodian receives on our common shares or other deposited securities after deducting its fees and expenses and certain taxes. Purchasers of our ADSs will receive these distributions in proportion to the number of our common shares their ADSs represent. However, in accordance with the limitations set forth in the deposit agreement, it may be unlawful or impractical to make a distribution available to holders of ADSs. We have no obligation to take any other action to permit the distribution of our ADSs, common shares, rights or anything else to holders of our ADSs. This means that purchasers of our ADSs may not receive the distributions we make on our common shares or any value from them if it is unlawful or impractical to make them available to ADS holders. These restrictions may have a negative impact on the market value of our ADSs.

Holders of our ADSs may be subject to limitations on transfer of their ADSs.

ADSs are transferable on the books of the depositary. However, the depositary may close its transfer books at any time or from time to time when it deems expedient in connection with the performance of its duties. In addition, the depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary deems it advisable to do so because of any requirement of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason in accordance with the terms of the deposit agreement.

ADS holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could result in less favorable results to the plaintiff(s) in any such action.

The deposit agreement governing the ADSs representing our common shares provides that holders and beneficial owners of ADSs irrevocably waive the right to a trial by jury in any legal proceeding arising out of or relating to the deposit agreement or the ADSs, including claims under U.S. federal securities laws, against us or the depositary to the fullest extent permitted by applicable law. If this jury trial waiver provision is prohibited by applicable law, an action could nevertheless proceed under the terms of the deposit agreement with a jury trial. Although we are not aware of a specific federal decision that addresses the enforceability of a jury trial waiver in the context of U.S. federal securities laws, it is our understanding that jury trial waivers are generally enforceable. Moreover, insofar as the deposit agreement is governed by the laws of the State of New York, New York laws similarly recognize the validity of jury trial waivers in appropriate circumstances. In determining whether to enforce a jury trial waiver provision, New York courts and federal courts will consider whether the visibility of the jury trial waiver provision within the agreement is sufficiently prominent such that a party has knowingly waived any right to trial by jury.

We believe that this is the case with respect to the deposit agreement and the ADSs. In addition, New York courts will not enforce a jury trial waiver provision in order to bar a viable setoff or counterclaim sounding in fraud or one which is based upon a creditor's negligence in failing to liquidate collateral upon a guarantor's demand, or in the case of an intentional tort claim (as opposed to a contract dispute). No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depositary of compliance with any provision of U.S. federal securities laws and the rules and regulations promulgated thereunder.

If you or any other holder or beneficial owner of ADSs brings a claim against us or the depositary in connection with matters arising under the deposit agreement or the ADSs, including claims under U.S. federal securities laws, you or such other holder or beneficial owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us and/or the depositary. If a lawsuit is brought against us and/or the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different results than a trial by jury would have had, including results that could be less favorable to the plaintiff(s) in any such action, depending on, among other things, the nature of the claims, the judge or justice hearing such claims, and the venue of the hearing.

The depositary for the ADSs is entitled to charge holders fees for various services, including annual service fees.

The depositary for the ADSs is entitled to charge holders fees for various services including for the issuance of ADSs upon deposit of common shares, cancellation of ADSs, distributions of cash dividends or other cash distributions, distributions of ADSs pursuant to share dividends or other free share distributions, distributions of securities other than ADSs and annual service fees. In the case of ADSs issued by the depositary into The Depository Trust Company (DTC), the fees will be charged by the DTC participant to the account of the applicable beneficial owner in accordance with the procedures and practices of the DTC participant as in effect at the time.

The rights of our shareholders differ from the rights typically offered to shareholders of a U.S. corporation.

Our corporate affairs are governed by our articles of incorporation and by the laws governing ROC corporations and companies engaging in drug development, marketing and sales businesses. Certain rights and responsibilities of our shareholders, ADS holders and members of our board of directors under ROC law are different from those that apply to a U.S. corporation. For example, directors of ROC corporations are required to conduct business faithfully and act with the care of good administrators; however, the duty of care required of an ROC corporation's directors may not be the same as the fiduciary duty of a director of a U.S. Delaware corporation. In addition, controlling shareholders of U.S. Delaware corporations owe fiduciary duties to minority shareholders, while controlling shareholders in ROC corporations do not. Further, the rights of our shareholders to bring shareholders' suits against us or our board of directors under ROC law are more limited than those of shareholders of a U.S. Delaware corporation. Under ROC law, only shareholders who collectively hold at least three percent of our shares for at least one year may demand that one of our members of the audit committee institute a lawsuit on our behalf against our directors, and may directly initiate a lawsuit on our behalf if the requested member fails to do so. The court may order the suing shareholders to furnish an appropriate bond. Furthermore, if the suing shareholders do not prevail but cause damage to us, they will be liable for indemnifying us for such damages. As a result, it may be more difficult for our shareholders to protect their rights in connection with actions taken by our directors than would be the case for stockholders of a U.S. Delaware corporation. See the section of this Annual Report titled "Description of Share Capital and Articles of Incorporation" for a description of the principal differences between the provisions of Taiwan law applicable to us and the U.S. Delaware General Corporate Law relating to shareholders' rights and protections. The Taiwan Company Act was amended on August 1, 2018, and took effect on November 1, 2018. Under the amended Taiwan Company Act (the Effective Company Act Amendment), the minimum holding and hold period for a shareholders' suit is reduced to one percent for at least six months. In addition, the court fees payable by such shareholders in a shareholders' suit will be capped NT$600,000, and the court may upon request appoint counsel for the shareholder plaintiffs.

We qualify as a foreign private issuer and, as a result, we are not subject to U.S. proxy rules and are subject to Exchange Act reporting obligations that permit less detailed and frequent reporting than that of a U.S. domestic public company.

We report under the Exchange Act as a non-U.S. company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act; (ii) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K upon the occurrence of specified significant events. In addition, our officers, directors and principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and the rules thereunder. Therefore, our shareholders may not know on a timely basis when our officers, directors and principal shareholders purchase or sell our common shares or ADSs. In addition, foreign private issuers are not required to file their annual report on Form 20-F until 120 days after the end of each fiscal year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers also are exempt from Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

If we lose our status as a foreign private issuer, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various

U.S. Securities and Exchange Commission (SEC) and Nasdaq rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors and more expensive to procure director and officer liability insurance.

We are an EGC and we cannot be certain if the reduced reporting requirements applicable to "emerging growth companies" will make our ADSs less attractive to investors.

We are an EGC as defined in the JOBS Act. For as long as we continue to be an EGC, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not EGCs, including not being required to comply with the auditor attestation requirements of Section 404, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We may take advantage of these exemptions until we are no longer an EGC. We could be an EGC until December 31, 2023, although circumstances could cause us to lose that status earlier, including if the aggregate market value of our ADSs and common shares held by non-affiliates exceeds $700 million as of the end of our second fiscal quarter before that time, in which case we would no longer be an EGC as of the following December 31st (the last day of our fiscal year). We cannot predict if investors will find our ADSs less attractive because we may rely on these exemptions. If some investors find our ADSs less attractive as a result, there may be a less active trading market for our ADSs and the price of our ADSs may be more volatile.

If we fail to maintain an effective system of internal controls over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our ADSs.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inadequate internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our ADSs.

Management will be required to assess the effectiveness of our internal controls annually, starting with our Annual Report on Form 20-F for the year ended December 31, 2019. However, for as long as we are an EGC under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements requiring us to incur the expense of remediation and could also result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

The dual listing of our common shares and our ADSs may adversely affect the liquidity and value of our ADSs.

We cannot predict the effect of this dual listing on the value of our common shares and ADSs. However, the dual listing of our common shares and our ADSs may dilute the liquidity of these securities in one or both markets and may adversely affect the development of an active trading market for the ADSs in the United States. The price of the ADSs could also be adversely affected by trading in our common shares on the TPEx. In addition, currency fluctuations as between the New Taiwan dollar and U.S. dollar may have an adverse impact on the value of our ADSs.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, the price of our ADSs and our trading volume could decline.

The trading market for our ADSs will depend in part on the research and reports that securities or industry analysts publish about us or our business. If no or too few securities or industry analysts commence coverage on us, the trading price for our ADSs would likely be negatively affected. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our ADSs or publish inaccurate or unfavorable research about our business, the price of our ADSs would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our ADSs could decrease, which might cause the price of our ADSs and trading volume to decline.

We may be classified as a passive foreign investment company (PFIC) in any taxable year and U.S. holders of our ADSs could be subject to adverse U.S. federal income tax consequences as a result.

Generally, if for any taxable year, at least 75% of our gross income is passive income, or at least 50% of the value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would be characterized as a passive foreign investment company, for U.S. federal income tax purposes. The determination of whether we are a PFIC depends on the particular facts and circumstances (such as the valuation of our assets, including goodwill and other intangible assets, and the characterization of our income, including whether certain research and development tax credits received from the government of Taiwan will constitute gross income, and if they do, whether they will constitute passive income for purposes of the PFIC income test) and may also be affected by the application of the PFIC rules, which are subject to differing interpretations. Based on our gross income, the average value of our assets, including goodwill and the nature of our active business, we do not expect to be treated as a PFIC for U.S. federal income tax purposes for the taxable year ending December 31, 2017 or December 31, 2018.

If we become a PFIC, U.S. holders of our ADSs may be subject to adverse U.S. federal income tax consequences, such as the ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends for individuals who are U.S. holders, having interest apply to distributions by us and the proceeds of sales of the ADSs, and additional reporting requirements under U.S. federal income tax laws and regulations. Investors should consult their own tax advisors regarding all aspects of the application of the PFIC rules to our ADSs. For more information related to classification as a PFIC, see "Taxation—Material Income Tax Considerations—Passive Foreign Investment Company Consequences."

Comprehensive tax reform bills could adversely affect our business and financial condition.

The U.S. government has enacted comprehensive tax legislation that includes significant changes to the taxation of business entities. These changes include, among others, a permanent reduction to the corporate income tax rate. Notwithstanding the reduction in the corporate income tax rate, the overall impact of this tax reform is uncertain, and our business and financial condition could be adversely affected. We urge our shareholders to consult with their legal and tax advisors with respect to any such legislation and the potential tax consequences of investing in our common stock.

Item 4. Information on the Company

A. History and Development of the Company

Taiwan Liposome Company, Ltd. was incorporated as a company limited by shares under the provisions of the Company Act of the ROC in 1997 by Dr. Keelung Hong and was listed on the Taipei Exchange on December 21, 2012. We are primarily engaged in the development and commercialization of pharmaceutical products based on our proprietary lipid-assembled drug delivery platform technologies. On November 21, 2018, we completed our initial public offering of American Depositary Shares on the Nasdaq Global Market. Our ADSs are traded under the symbol "TLC". Our common shares have been trading on the TPEx under "4152" since December 21, 2012.

Our registered and principal executive offices are located at 11F-1, No. 3 Yuanqu Street, Nangang District, Taipei City, Taiwan 11503, Republic of China, and our general telephone number is +886 2 2655 7377. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at http://www.sec.gov. We also maintain a corporate website at www.tlcbio.com. Information contained in, or that can be accessed through, our website is not a part of, and shall not be incorporated by reference into, this document. We have included our website address in this document solely as an inactive textual reference.

Our agent for service of process in the United States is George Yeh, TLC Biopharmaceuticals, Inc. (a wholly-owned subsidiary of the registrant) located at 432 North Canal Street, #20 South San Francisco, California 94080 (650) 872-8816.

Our actual capital expenditures for the years ended December 31, 2016, 2017 and 2018 amounted to NT$21,427 (US$700), NT$18,133 (US$592) and NT$66,709 (US$2,179), respectively. These capital expenditures primarily consisted of our continued investment in construction of additional facilities to support the development of our products and technologies. We expect our capital expenditures to increase in absolute terms in the near term as we continue to advance our research and development programs and grow our operations. We anticipate our capital expenditures in 2019 to be financed from the proceeds from our existing cash and cash equivalents, including the net proceeds from our initial public offering of American Depositary Shares on the Nasdaq Global Market.

B. Business Overview

We are a clinical-stage specialty pharmaceutical company dedicated to the development and commercialization of novel nanomedicines that combine our proprietary lipid-assembled drug delivery platform with approved APIs. We believe that our extensive experience with liposome science allows us to combine onset speed and benefit duration, and to improve API concentrations at target tissues while decreasing unwanted systemic exposures. Our BioSeizer lipid formulation technology is designed to enable both local sustained release and fast onset of APIs at the site of disease or injury with increased pharmacokinetic (PK) control, made possible by customization of lipid layers. BioSeizer is utilized in our TLC599, TLC399 and TLC590 programs. Our NanoX active drug loading technology is designed to alter the systemic exposure of the drug, enabling the potential for reduced dosing frequency, and enhanced distribution of liposome-encapsulated APIs to the desired site. We believe NanoX is capable of loading over 50 various compounds and is applied to our TLC178 program. We believe our technologies can be used with a broad range of APIs and enable a simplified and scalable manufacturing process. Because our product candidates use already approved APIs, we intend to utilize the streamlined 505(b)(2) regulatory pathway for approval in the United States, which would allow us to rely, in part, on data from investigations that we have not conducted or sponsored and for which we have not obtained a right of reference. We have used our proprietary technology platforms to assemble a diverse product candidate portfolio that targets significant areas of unmet medical need in pain management, ophthalmology and oncology. We anticipate that our four lead product candidates will be in late or pivotal stage clinical trials by the end of 2020.

TLC599

Our primary lead product candidate, TLC599, is an intraarticular, or in-joint, injectable BioSeizer formulation of the API steroid dexamethasone sodium phosphate (DSP), which we believe has the potential to become an attractive treatment for the management of OA pain. We have completed an open-label Phase I/II clinical trial of 40 patients with knee OA. Patients were randomized to be treated with a single dose of TLC599 at a dose level of either 6mg or 12mg DSP, and then followed up for 12 weeks with the primary efficacy endpoint to assess pain. We have also completed a double-blind, placebo-controlled Phase II clinical trial in 75 patients to evaluate the effects of TLC599 at two different dose levels at multiple time points over a 24-week period. TLC599 met the primary endpoint of mean change from baseline using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain subscale through week 12. TLC599 also met key secondary endpoints of reductions in WOMAC pain scores through and at weeks 1, 4, 8, 12, 16, 20 and 24. Pain reductions observed through and at 24 weeks showed both rapid onset of pain relief as well as durable and persistent pain relief.

Preclinical canine and rabbit studies, which included an evaluation of effect on cartilage, found that TLC599 was not associated with any cartilage damage. In addition, we recently conducted a comparative *in vivo* animal study in beagle dogs to evaluate the toxicity and knee joint changes observed with TLC599 and two marketed products - triamcinolone acetonide (TA) and extended release triamcinolone acetonide (ER TA) - against a saline control. This study, described further below, showed a moderate reduction in histologic staining for both TA and ER TA, which was attributed to the loss of cartilage matrix.

TLC599 is designed to be administered using needle sizes ranging from 21 gauge to 30 gauge, allowing for possible expanded administration capabilities, for example into smaller joints such as within the hands and fingers. TLC599 is produced using a scalable manufacturing process that uses sterile filtration at the near end stage, rather than an entirely aseptic process from raw material to final product.

We completed an end of Phase II meeting with the FDA in February 2019 and expect to initiate a single pivotal trial in mid-2019 for the purpose of an NDA submission.

TLC590

Our second product candidate, TLC590, is a non-opioid, BioSeizer formulation of the API ropivacaine and is in development for post-surgical pain management. TLC590 has the potential to offer distinct advantages over other approved extended release products in this indication. In particular, we believe that (i) ropivacaine as the API has the potential to confer less cardiovascular and central nervous system toxicity than bupivacaine, the API in some extended release formulations, and (ii) TLC590's dense multilameller structures are capable of providing high concentration drug loading and continuous release of the API which, when administered into the surgical site, may provide both rapid and extended pain relief. In preclinical studies, TLC590 extended the effective half-life of ropivacaine by about 20-fold and displayed earlier onset and a longer and larger magnitude of anesthetic effect than a marketed extended release bupivacaine.

We filed an IND application for TLC590 with the FDA in April 2018. We have finished the recruitment and dosing of patients following inguinal hernia surgery in a Phase I/II dose-escalation clinical trial in the United States. Topline data from this trial, which we received in March 2019, showed that patients treated with TLC590 demonstrated durable, statistically significant and clinically meaningful improvement over the ropivacaine through 96 hours. 58.3% of patients treated with TLC590 were opioid-free through the entire duration of the study; among those who did use rescue opioids, time to first use was about four times that of the ropivacaine group. Mean total opioid consumption for the TLC590 group was 54% less than the ropivacaine group.

We have begun a Phase II clinical trial of TLC590 in patients following bunionectomy. Topline data from the first part of this trial is expected in mid-2019.

TLC399

Our third product candidate, TLC399, is a multilamellar (multilayered) and multivesicular (membrane enclosed sacs) BioSeizer formulation of DSP for ophthalmology indications. We designed TLC399 to have fast-acting and long-lasting effects when injected into the eye's vitreous humor to treat macular edema associated with RVO.

Macular edema is one of the most prominent treatable causes of decreased visual acuity in patients with RVO. In preclinical models, TLC399 achieved therapeutic drug levels in the eye for at least six months after a single administration. We have observed in an ongoing Phase I clinical trial that four out of five evaluable patients among the nine patients treated with TLC399 have experienced improvements in and/or stabilized vision and decreased retinal central subfield thickness (CST), with one patient in group 1 reaching and maintaining target CST for 12 months. An increase in intraocular pressure was reported as a serious adverse event in two patients in the Phase I clinical trial but was manageable with eye drops. An increase in intraocular pressure is a known risk of other intravitreal steroid injections, including the standard of care therapies for macular edema. We submitted an IND for macular edema secondary to RVO indication on November 22, 2013.

A randomized, double-blind Phase II clinical trial evaluating three different doses of TLC399 in RVO patients is underway, with a temporary recruitment pause for an SMC to make a comprehensive assessment to select an optimal dose group with the best vision response. In August 2018, the SMC recommended the 0.6mg DSP with 50mM phospholipid (PL) in 50μL solution dose to move forward; this dose will be further studied along with a higher dose (70μL) of the same formulation (containing 50mM PL). We expect to resume recruitment after the study protocol amendment is implemented. The preliminary evaluation of our Phase II trial data in TLC399 has not been able to show evidence of efficacy beyond three months. We believe this is due to the use of rescue medications in the majority of patients, even those who did not meet rescue criteria. Efficacy evaluation has also been limited by observations of vitreous haze, which was judged as serious adverse events in two patients in the group treated with the higher concentration formulation. In clinical and animal studies conducted to date, we have observed potential sustained duration of action of three to six months.

Unlike a current dexamethasone treatment, whose drug-eluting implant may take up to six months to dissolve, TLC399 does not use any implants. TLC399 is designed to be administered using a 30-gauge needle, which is smaller in diameter (0.3112mm) than current marketed steroid injections' 22-gauge (0.7176mm), and consequently could reduce the risk of conjunctival hemorrhaging, infections and complications.

We anticipate exploring additional ophthalmic indications for TLC399 alone or in combination with intravitreal anti-vascular endothelial growth factor (anti-VEGF) drugs, such as diabetic macular edema (DME), an indication where other steroid products have previously demonstrated efficacy.

TLC178

Our fourth product candidate, TLC178, which uses our NanoX targeted delivery technology with vinorelbine tartrate as the API, is under development to treat RMS, a form of soft tissue sarcoma (STS) that most frequently occurs in children. Non-resectable RMS tumors and tumors that recur after surgery are generally treated with chemotherapeutic agents such as vincristine, dactinomycin, cyclophosphamide, and vinorelbine. In clinical trials of relapsed or refractory RMS, vinorelbine treatment yielded an approximately 36% overall response rate, with four to seven months duration of response. Dose limiting toxicity of vinorelbine is mainly hematological, and TLC178 is designed to enhance the accumulation of vinorelbine in the tumor while limiting systemic exposure, thus reducing hematological toxicity. We submitted an IND to evaluate TLC178 in clinical trials in advanced solid tumors/lymphoma indication on August 31, 2016. A Phase I/II dose escalation trial of TLC178 in adult patients with advanced malignancies is currently underway. We filed an IND application for TLC178 in pediatric RMS with the FDA in June 2018, and plan to initiate a pediatric Phase I/II clinical trial once we have identified a suitable dose in adult patients, which we expect to report in an analysis in the second half of 2019. We have received a Rare Pediatric Disease Designation for TLC178 in RMS, which will qualify TLC178 in this indication for priority review in the United States and make us eligible to receive a transferable Priority Review Voucher, if approved. Assuming successful completion of our development program, we plan to seek initial approval for TLC178 in RMS and believe that a single-arm, response-oriented registration trial may be sufficient for approval. In parallel with our efforts in RMS, we also plan to initiate clinical trials evaluating TLC178 in other STSs, for which TLC178 has already received from both the FDA and the European Medicines Agency an Orphan Drug Designation (ODD) that can potentially provide marketing exclusivity for seven years in the United States (ten years in the European Union), and in non-small cell lung cancer (NSCLC).

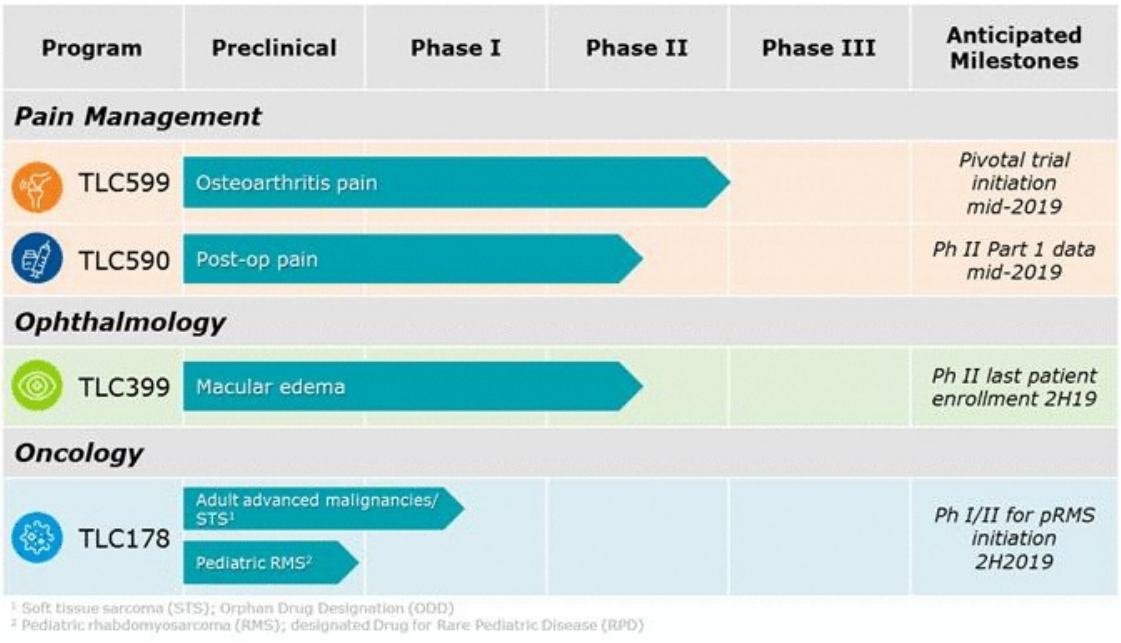
Corporate Information

We were founded in 1997 by Dr. Keelung Hong, who also co-founded Hermes Biosciences Inc. (Hermes) in 1998 and served as its Chief Scientific Officer from 1998 to 2005. Dr. Hong is the co-inventor and patent holder of Hermes' liposomal irinotecan Onivyde. Hermes was acquired by Merrimack Pharmaceuticals, Inc. in 2009 and the Onivyde program was subsequently acquired by Ipsen SA in 2017. Dr. Hong also served as a scientific advisor to Sequus Pharmaceuticals, Inc. (Sequus), which was founded by Dr. Demetrios Papahadjopoulos, a pioneer in liposome development. Sequus was acquired by ALZA Corporation in 1998 after developing its liposomal doxorubicin, Doxil. Dr. Hong has over 35 years of experience in liposome science, accumulating over time at the University of California Berkeley, Stanford University and the Liposome Research Lab at the University of California, San Francisco. During their tenure at our company, Dr. Hong and our Vice President of Research and Development, Dr. Yunlong Tseng, invented our NanoX platform. Our Senior Director of Product and Development, Dr. Sheue Fang Shih, is the inventor of our BioSeizer platform. Our President, George Yeh, leads our seasoned team, Mr. Yeh also served as the Chief Financial Officer at Hermes from 2002 to 2005.

Our team has over 200 years of domestic and global experience in lipids and other life sciences products and drug development expertise. Their accomplishments include gaining the approval of two generic lipid formulation products marketed in Asia. We are headquartered in Taipei, Taiwan, with offices in Hsinchu, Hong Kong, Leiden, Melbourne, Shanghai, South San Francisco and Tokyo.

We are a publicly traded company listed on the TPEx. We have been listed since December 2012 and have been ranked in the top 5% in the Corporate Governance Evaluation among all Taiwan listed companies every year since our listing on TPEx.

Pipeline



Our Strategy

Our strategy is to develop and commercialize highly differentiated liposome-based products for indications associated with high unmet medical needs. Our strategy includes the following key components:

- **Rapidly advance our sustained release product candidates.**
- TLC599 for OA pain. We have completed our randomized, double-blind, placebo-controlled Phase II trial for knee OA pain. We announced topline data from this trial in August 2018, which showed that TLC599 met the primary endpoint of mean change from baseline in WOMAC pain scores at week 12 as well as numerous key secondary endpoints. We recently completed an end of Phase II meeting with the FDA which indicated that a single pivotal trial would be sufficient for a potential NDA submission in the U.S. We intend to launch this Phase III pivotal clinical trial in mid-2019.
- TLC590 for post-surgical pain. We have successfully completed a Phase I/II clinical trial in patients following inguinal hernia surgery. We received topline data from this trial in March 2019, which showed that patients treated with TLC590 demonstrated durable, statistically significant and clinically meaningful improvement over the standard of care through 96 hours. We have begun enrollment of a Phase II clinical trial of TLC590 in patients with bunionectomy, a type of bony tissue surgery, and topline data from the first part of this trial is expected in mid-2019. We plan to initiate our first pivotal trial in bunionectomy in 2020. We also plan to conduct a Phase II clinical trial in patients undergoing abdominal wall surgery in 2020. In addition, we plan to explore TLC590 in other indications such as nerve block.
- TLC399 for retinal diseases. Upon completion of our ongoing randomized, double-blind, dose-finding Phase II clinical trial in RVO (expected in 2020), we plan to conduct a Phase IIb trial to confirm the dose and effect size for a pivotal trial. We are also studying opportunities to develop TLC399 in other indications, including DME.

- **Rapidly advance our targeted delivery product candidates**. We are currently conducting a Phase I/II dose escalation trial of TLC178 in adult patients with advanced malignancies. We filed an IND application for TLC178 in pediatric RMS with the FDA in June 2018 and plan to initiate a pediatric Phase I/II clinical trial once we have identified a suitable dose in adult patients, which we expect to report in an analysis in the second half of 2019. Upon determination of the pediatric maximum tolerated dose (MTD) in Part I, which we expect to complete in the first half of 2020, we plan to initiate Part II, which we believe will be considered a single arm, pivotal trial due to the rarity of pediatric RMS. We also intend to initiate clinical trials in other indications such as NSCLC and STS.
- **Selectively pursue additional indications**. We will continue to focus on opportunities where existing pharmacotherapy poses (i) suboptimal tradeoffs in speed of onset versus duration of effect or (ii) inadequate delivery with undesirable systemic exposure.
- **Continue to leverage our proprietary technology**. We plan to sustain our leadership position in the development of complex liposomal drugs and provide attractive solutions using our proprietary sustained release and/or targeted delivery technologies.
- **Take advantage of opportunities for streamlined regulatory approval**. We intend to focus our research and development on product candidates that are eligible for the streamlined 505(b)(2) regulatory pathway. TLC599, TLC399, TLC590 and TLC178 are all product candidates for which we intend to seek regulatory approval pursuant to the 505(b)(2) regulatory pathway.
- **Expand our pipeline**. We intend to identify additional opportunities for our extensive library of over 50 formulated discovery compounds to be considered for preclinical development, with the aim of submitting at least one new IND application every 18 months.
- **Continue to expand our global market**. We plan to continue to increase our global market opportunities by expanding our presence in other countries, particularly in China, including Hong Kong and Macau.

TLC599

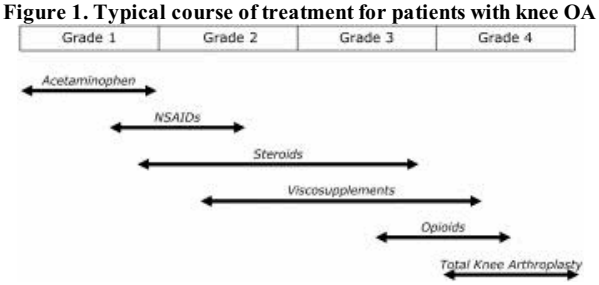
TLC599 is our proprietary BioSeizer formulation of DSP under development for the treatment of OA pain. We are investigating TLC599 as a therapeutic that has the potential to deliver rapid pain relief and to maintain this pain relief for up to six months.

OA Background

OA is a joint disorder involving the degeneration of the articular cartilage. OA leads to inflammation of the soft tissue and bony structures of the joint. This condition grows more severe over time and leads to progressive thinning of articular cartilage. Symptoms include pain, stiffness, swelling and limitation in the function of the joint. Physicians are currently unable to reverse the progression of OA.

The following graph outlines what we believe to be the standard treatment progression for the treatment of OA pain in the knee:

Figure 1. Typical course of treatment for patients with knee OA



A number of therapeutic options exist to treat the pain associated with knee OA. In the early stage, oral pain medications such as acetaminophen are often prescribed, followed by oral or topical non-steroidal anti-inflammatory drugs (NSAIDs). These oral drugs may have side effects such as stomach pain, heartburn, ulcers, bleeding, headaches, dizziness, liver and kidney problems and high blood pressure. When these therapies fail to alleviate the pain, physicians often prescribe intraarticular, or in-joint, injections of hyaluronic acid or steroid into the affected joint. If the disease continues to progress, patients may eventually require joint replacement surgery, such as total knee arthroplasty, which is expensive and may require substantial recovery time.

According to the Arthritis Foundation, there were an estimated 30.8 million OA patients in the United States in 2015, with the number of patients expected to grow as a result of aging, obesity and sports injuries. According to data published in October 2010 by the National Institutes of Health, by 2030 an estimated 20% of Americans over the age of 65 will be at risk of developing OA. According to GlobalData, the OA market in the United States, France, Germany, Italy, Spain, the United Kingdom and Japan is expected to increase from an aggregate of $1.6 billion in 2016 to an aggregate of $3.5 billion by 2026 at a compound annual growth rate of 8.1%.

Limitations of Current Treatments in OA

Approved intraarticular treatments include steroids and hyaluronic acid viscosupplements. While immediate release steroid injections can provide rapid pain relief, the effect generally only lasts for two to four weeks post injection. In addition, clinical guidelines suggest limiting intraarticular steroid injections in any given joint. Currently approved dexamethasone preparations are freely soluble in water and can therefore be taken up rapidly by cells, leading to a quicker onset of effect as compared to other steroids, but suffer from a concomitant reduced duration of action. The American Academy of Orthopedic Surgeons has stated that they cannot recommend using hyaluronic acid for patients with symptomatic knee OA due to a lack of efficacy.

While an extended release steroid formulation for knee OA pain was recently approved by the FDA, this product uses a steroid called TA instead of DSP as the API. TA and ER TA, as described further below, have been associated with chondrotoxicity and related cartilage damage in preclinical and clinical studies. We have not observed this effect in our preclinical studies of TLC599 to date. A randomized, placebo-controlled, double-blind clinical trial of intra-articular triamcinolone versus saline for moderate knee OA in 140 patients was conducted from June 2011 to January 2015 at Tufts Medical Center to determine the effects of 40mg of TA on cartilage loss using annual knee magnetic resonance and on knee pain using the WOMAC index. 119 patients completed the study; those who received 40mg immediate release TA four times per year for two years had significantly greater cartilage loss than those receiving placebo, with no significant differences in pain scores between the two groups. The currently marketed long-acting steroid is not approved for repeat administration. However, in connection with a Phase 3b open-label repeat dose safety trial in patients with knee OA, the manufacturer of this extended release steroid formulation recently announced that an analysis of X-rays taken at baseline and Week 52 showed that repeat administration of this extended release steroid formulation had no deleterious effects on cartilage or joint structure and that there were no observations of chondrotoxicity.

Despite the use of currently available intraarticular treatments, many OA patients experience persistent and worsening pain, which has the potential to lead to opioid abuse. Therefore, joint replacement surgery, such as total knee arthroplasty, is generally the last option for the treatment of OA. Due to the expense of surgery and the limitations of treatments administered to prevent such surgeries, we believe there is a need for a safe alternative treatment that could provide both rapid and sustained relief from OA pain, which would reduce the risk of opioid abuse, and potentially delay the need for joint replacement surgery. Postponing joint replacement surgery, such as total knee arthroplasty, may further decrease the chance of requiring a second “revision” surgery in the patient’s lifetime, which is typically even more complicated and costly than the initial surgery.

Our Solution: TLC599

TLC599 is our proprietary BioSeizer formulation of DSP designed to provide sustained pain management over an extended period of up to six months. We believe TLC599 has the potential to show distinct advantages over current anti-inflammatory products in knee OA because it has the potential to enable patients to receive both immediate and sustained benefit from the local delivery of a highly potent and clinically validated steroid, DSP, that typically has a very short half-life. Based on our clinical studies to date, we have observed a reduction in pain as measured by WOMAC pain scores measured at 24 weeks from baseline. We therefore believe that TLC599 has the potential to achieve one of the longest durations of action for an intra-articular steroid if successfully developed and approved. Furthermore, we believe that the selection of DSP as our API may confer less chondrotoxicity, enabling safer repeat dosing.

We believe that TLC599 has the potential to provide long-lasting pain relief due to our process of encapsulating the steroid through our BioSeizer technology. Specifically, TLC599 traps DSP in multiple layers and pockets of liposome, much like the structure of an onion. As time progresses, the layers of these multilamellar and multivesicular vesicles are designed to slowly peel off, freeing the DSP that was trapped, or seized, and resulting in a consistent release of the API over time.

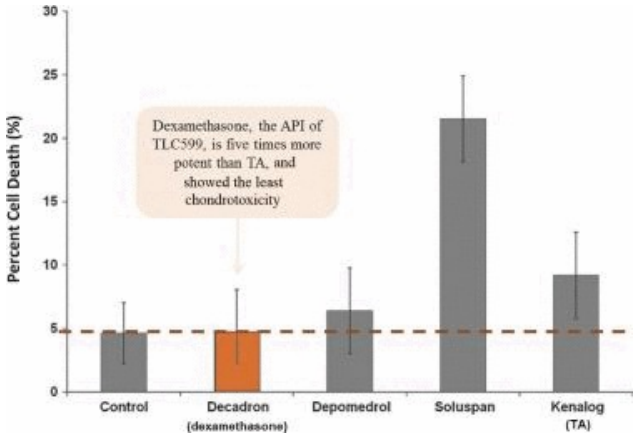
The greater solubility of DSP has limited its routine use in knee OA because of its tendency to dissolve and not stay localized in the knee. Our formulation of DSP in TLC599 exploits the fact that DSP is amphipathic (contains both polar (water-soluble) and nonpolar (not water-soluble) portions in its structure). We believe this amphipathic property is well-suited for liposome-based formulations as it allows DSP to be entrapped into the aqueous portion of the interior volume of the liposome via the polar portion and associated with the vesicle surface of the liposome via the nonpolar portion. This formulation also provides free, non-entrapped drug designed for immediate therapeutic relief while the lipid-entrapped drug is gradually released over a long period of time through hydrolysis and oxidation of the lipids resulting in the lipid bilayer breakdown. Accordingly, TLC599 is designed to convert DSP's key limitation for treating knee OA, its solubility, into an asset, potentially enabling long residence time in the knee with continuous slow release.

DSP has a five-fold increased anti-inflammatory potency compared to TA, allowing more activity to be delivered with a smaller quantity of drug. In *in vivo* and *in vitro* studies, DSP did not cause chondrotoxicity, unlike in third party studies of TA where chondrotoxicity was observed. We believe the selection of DSP as the API for TLC599 will confer less chondrotoxicity.

TLC599 Preclinical Toxicology Data

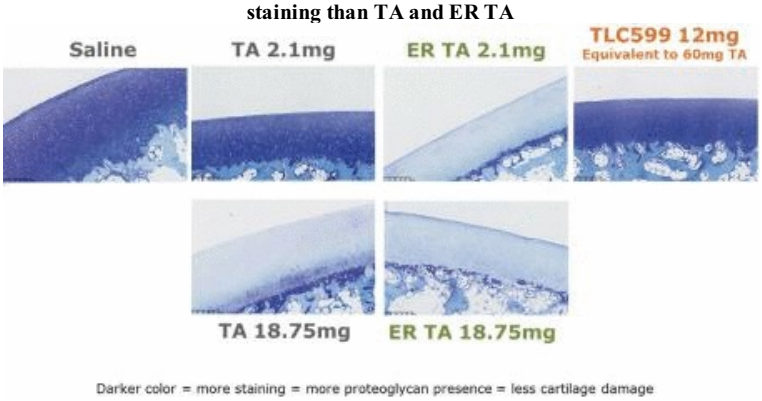
According to published data, in a recent human chondrocyte *in vitro* study of various steroids, Decadron, which is the brand name for DSP, showed the least chondrotoxicity (comparable to negative control). Kenalog, the brand name for TA, which is the API used in the recently approved long-acting steroid for OA knee pain, showed doubled chondrocyte cell death versus control.

Figure 2. Human chondrocyte *in vitro* studies – Dexamethasone showed the least chondrotoxicity



In our recent *in vivo* study, we evaluated the potential toxicity of TLC599 by comparing cartilage damage, proteoglycan loss and the suggested underlying chondrotoxicity of a single-dose intraarticular injection of 12mg of TLC599 with two different doses of two marketed products — TA and ER TA. Beagle dogs were dosed with saline (control), a higher (18.75mg) and lower (2.1mg) dose of TA, a higher (18.75mg) and lower (2.1mg) dose of ER TA, or 12mg of TLC599 (equivalent to 60mg TA) in knee joints. At Day 30, all knee joints (n = 4 per group) were observed microscopically and histology slides with Toluidine blue staining were used to evaluate any loss of cartilage matrix. The less intense the staining is compared to saline control, the more proteoglycan loss and underlying chondrotoxicity. As shown below, at 30 days post treatment, TLC599 showed comparable stain intensity to saline. Higher dose TA and ER TA both showed less staining compared to saline, while lower dose ER TA showed less staining than its equipotent dose TA, as well as saline. In this study, ER TA was therefore observed to result in more proteoglycan loss and underlying chondrotoxicity than the API of TA alone.

Figure 3. Proteoglycan staining of the cartilage in beagle dogs – TLC599 showed more intense staining than TA and ER TA



TLC599 Phase I/II Data

In our open-label Phase I/II clinical trial completed in 2016, 40 subjects in Taiwan with moderate to severe knee OA were enrolled and randomly assigned to one of two groups to receive a single intra-articular dose of TLC599 at a dose levels of either 6mg or 12mg DSP and were then followed up for efficacy and safety evaluation over 12 weeks. Visual Analog (VAS) pain and WOMAC scores were utilized as the efficacy measurement instruments. The VAS pain score is a measurement instrument where a patient selects their pain level on a linear scale from 0 to 10 centimeters (with 10 as the worst pain imaginable). The WOMAC is a set of standardized questionnaires used by health professionals to evaluate the condition of patients with knee OA, including pain (max score=20), stiffness (max score=8), and physical functioning (max score=68) of the joints. Higher WOMAC scores indicate worse pain, stiffness and functional limitations. For ease of interpretation, we have shown the WOMAC scores as the average of responses on a 0-4 Likert scale, with 0 being no pain and 4 being extreme pain.

In this Phase I/II clinical trial we found that single doses of TLC599 containing 6mg DSP or 12mg DSP led to rapid decrease, or improvement, in both the VAS pain and WOMAC scores. This exploratory trial only included TLC599 treatment groups and did not make statistical comparisons to a placebo or active control treatment. After a single injection of TLC599, decreases in VAS and WOMAC were observed at the first follow up visit at one week post-injection and persisted without notable loss of effect through the end of the trial at 12 weeks, as shown in the following figures. At baseline, the mean VAS score assessed by all 40 subjects was 6.41 (± 1.19 standard deviation (SD)). The mean value of WOMAC total score was 1.51 (± 0.78 SD) while the mean subscale scores in pain, stiffness and physical function were 1.48 (± 0.77 SD), 1.35 (± 0.90 SD) and 1.54 (± 0.82 SD), respectively.

Figure 4. TLC599 Phase I/II VAS Scores

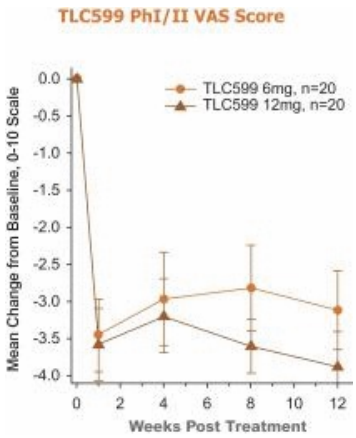
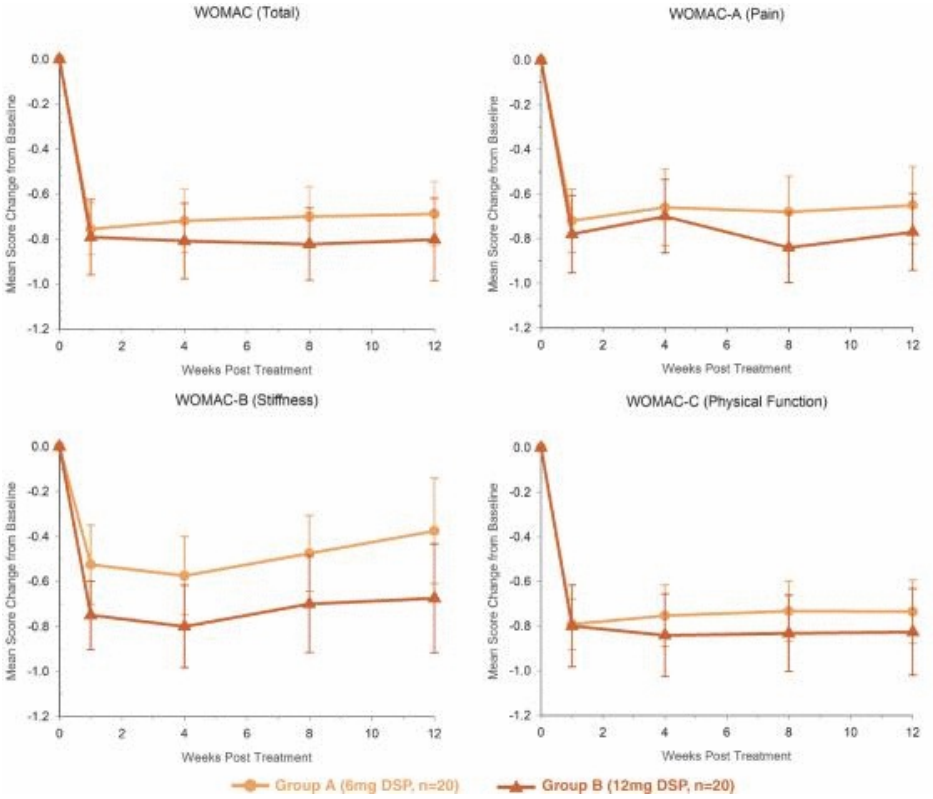


Figure 5. Phase I/II WOMAC scores of TLC599 in knee OA — onset within one week, persisted to week 12



This trial provided preliminary data of pain reduction in WOMAC score from baseline throughout the trial period. The extent of decrease in WOMAC score also exceeded the minimally clinically important difference cutoff according to the Outcome Measures in Rheumatology-Osteoarthritis Research Society International, a new OA pain measurement tool, indicating the improvement in symptoms was clinically meaningful. Responder criteria is defined as 1) having 50% or more improvement in pain or in function with absolute change of 20 or more points, or 2) 20% or more improvement in both pain and function with absolute change of 10 or more points in each evaluation. The majority of the patients displayed clinical response at all time points through 12 weeks for both dose levels.

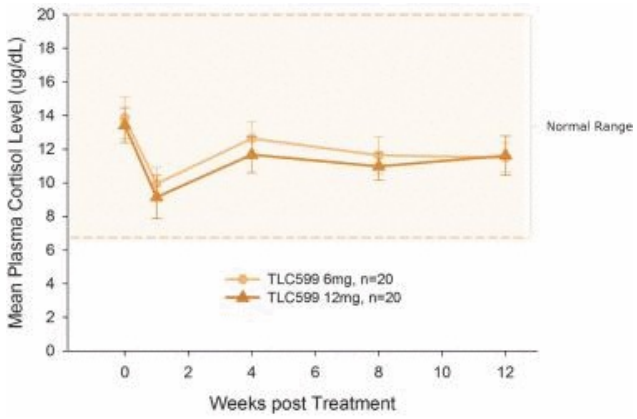
Figure 6. Percentage of clinical responders through 12 weeks

Responder	6mg DSP (n=20)	12mg DSP (n=20)
Week 1	70%	75%
Week 4	70%	65%
Week 8	70%	85%
Week 12	70%	75%

Intra-articular injection of TLC599 in knee OA was well tolerated. No serious adverse events (SAE) or adverse events (AE) leading to withdrawal were reported in this trial. There were only two treatment-related AEs, both of which were mild hyperglycemia (elevated blood sugar).

Cortisol levels were monitored because cortisol can disrupt glucose homeostasis, which would be a potential concern in patients with diabetes as a comorbidity. During this trial, the value of plasma cortisol decreased after TLC599 injection but remained within the normal range and gradually elevated over time for both dose levels, as shown in the following figure:

Figure 7. Plasma cortisol levels in Phase I/II clinical trial of TLC599 remained in the normal range



TLC599 Phase II Data

We completed a double-blind, placebo-controlled Phase II clinical trial in Australia and Taiwan to explore the safety and treatment efficacy of two different dose levels of TLC599 compared to placebo in patients with knee OA in August 2018. In this clinical trial, 75 patients with a mean age of 63.9 years, moderate degeneration knee OA, and VAS scores of 5-9 were randomized into three different trial groups, each receiving a single intraarticular administration of either TLC599 12mg, TLC599 18mg, or a placebo control (saline). Study design and demographics are shown in Figure 8.

Figure 8. TLC599 Phase II clinical trial — study design and demographics

	Placebo (n=25)	TLC599 12 mg (n=26)	TLC599 18 mg (n=24)
Age (years)	64.8 (8.45)	63.9 (9.07)	62.9 (8.80)
≥66 years	11 (44.0%)	10 (38.5%)	9 (37.5%)
Male / Female	28% / 72%	42.3% / 57.7%	29.2% / 70.8%
Race			
Asian	12 (48.0%)	13 (50.0%)	12 (50.0%)
Caucasian	13 (52.0%)	13 (50.0%)	11 (45.8%)
Unilateral/Bilateral Pain	40% / 60%	38.5% / 61.5%	38.7% / 61.3%
K-L Grade 2/3	36% / 64%	50% / 50%	37.5% / 62.5%

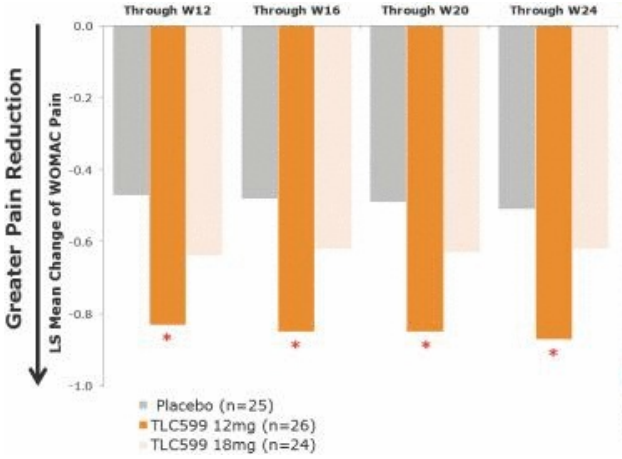
The primary endpoint was to evaluate the change from baseline by WOMAC pain scores through Week 12. Other analyses such as change from baseline in WOMAC pain, WOMAC physical function, and VAS scores through and at various time points up to Week 24, as well as the proportion of clinically durable responders, were included in the secondary endpoints. Safety and efficacy were assessed at Day 3, Week 1, and every four weeks up to 24 weeks.

Using the WOMAC pain outcome measure, TLC599 12mg demonstrated statistically significant reduction in pain compared to placebo from Day 3 through Week 12 (p=0.0027), meeting the primary endpoint. Furthermore, TLC599 12mg demonstrated persistent and statistically significant reduction in pain as measured by WOMAC pain scores compared to placebo from Day 3 through Week 16 (p=0.0024), Week 20 (p=0.0033), and Week 24 (p=0.0037), as shown in Figure 9a, reflecting the sustained reduction in pain for at least 24 weeks. TLC599 12mg also demonstrated statistically significant reduction in pain as measured by WOMAC pain scores compared to placebo at Week 12 (p=0.0050), Week 16 (p=0.0165), Week 20 (p=0.0414), and Week 24 (p=0.0227), as shown in Figure 9b.

Although there were some differences in gender and Kellgren-Lawrence (K-L) grade between groups at baseline, with more males and more subjects with K-L Grade 2 in the TLC599 12mg group than the placebo or 18mg group, we do not believe that these differences affected the results, as we observed the similar trend of greater reductions in pain as measured by WOMAC pain scores in the TLC599 12mg group than in the placebo group regardless of gender and K-L subgroups.

A majority of patients in the TLC599 12mg group had a clinically durable response, maintaining at least 30% pain reduction as measured by WOMAC pain scores at all visits from Week 1 through Week 12 (56% vs 29% in placebo; p=0.0100) and further through Week 24 (52% vs 22% in placebo; p=0.0143), as shown in Figure 9c. The percentage of durable responders over the 24-week period in the TLC599 12mg group was more than twice that of the placebo group. According to the consensus by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT), which provides recommendations for interpreting clinical importance of treatment outcomes in clinical trials of the efficacy and effectiveness of chronic pain treatments, reductions of 30% or more reflect at least moderate clinically important differences.

Figure 9a. TLC599 Phase II clinical trial — TLC599 12mg met primary endpoint of mean change from baseline in WOMAC pain through Week 12, as well as Weeks 16, 20, and 24

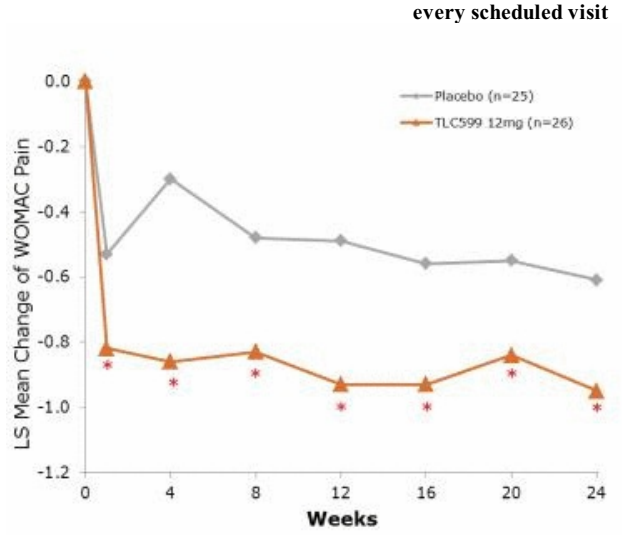


Group	Placebo	TLC 12mg	TLC 18mg
Through W12	-0.47	-0.83* (p=0.0027)	-0.64 (p=0.0971)
Through W16	-0.48	-0.85* (p=0.0024)	-0.62 (p=0.1498)
Through W20	-0.49	-0.85* (p=0.0033)	-0.63 (p=0.1558)
Through W24	-0.51	-0.87* (p=0.0037)	-0.62 (p=0.1985)

* Statistical significance

p-values from MMRM, LS mean change from baseline of WOMAC pain, compared with Placebo

Figure 9b. TLC599 Phase II clinical trial — TLC599 12 mg showed statistically significant reductions in WOMAC pain as compared to placebo at every scheduled visit

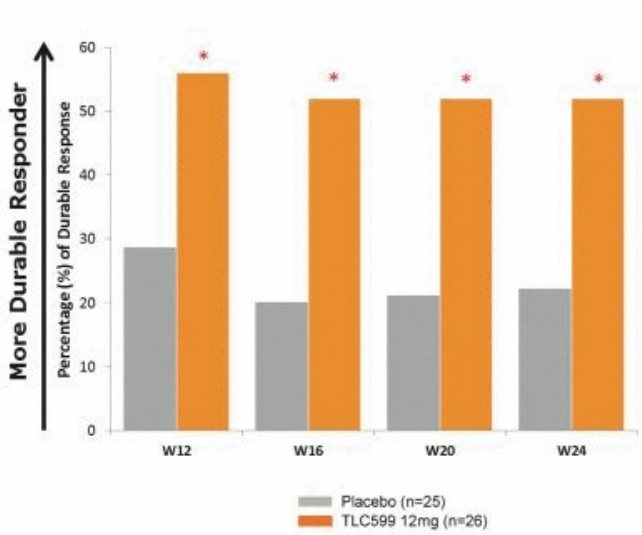


Group	Placebo	TLC 12mg
W12	-0.50	-0.94* (p=0.0050)
W16	-0.57	-0.94* (p=0.0165)
W20	-0.57	-0.85* (p=0.0414)
W24	-0.65	-0.96* (p=0.0227)

* Statistical significance

p-values from MMRM, LS mean change from baseline of WOMAC pain, compared with Placebo

Figure 9c. Phase II clinical trial of TLC599 — over half of patients treated with TLC599 12 mg maintained at least 30% reduction in pain as measured in WOMAC scores throughout the 24-week study



Group	Placebo	TLC 12mg
W12	28.6	56.0* (p=0.0100)
W16	20.0	52.0* (p=0.0062)
W20	21.1	52.0* (p=0.0090)
W24	22.2	52.0* (p=0.0143)

* Statistical significance

Pain score reduction of ≥30% = clinically important difference

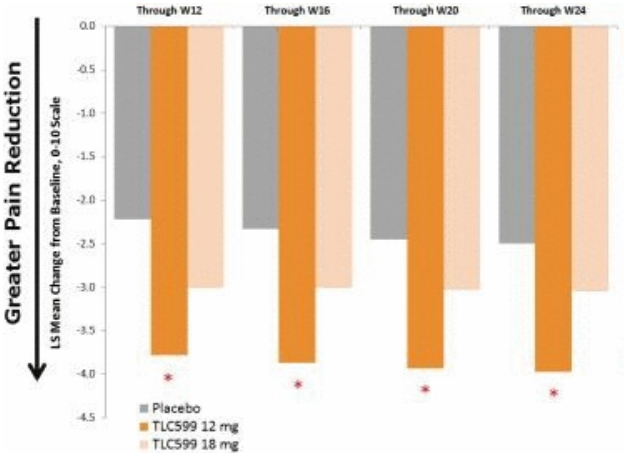
p-values from Logistic regression model of WOMAC pain, compared with Placebo

Similar results were observed using the WOMAC physical function as outcome measure. Patients treated with TLC599 12mg displayed significantly greater improvement in WOMAC physical function than placebo from Day 3 through Weeks 12, 16, 20, and 24, as well as at Week 12, 16, 20, and 24 ($p<0.05$).

Similar results were also observed using the VAS pain scores as outcome measure. TLC599 12mg demonstrated statistically significant reduction in pain based on VAS pain scores compared to placebo from Day 3 through Week 12 (p=0.0018), Week 16 (p=0.0021), Week 20 (p=0.0026), and Week 24 (p=0.0033), as shown in Figure 10a, again reflecting the sustained reduction in pain for at least 24 weeks. TLC599 12mg also demonstrated statistically significant reduction in pain compared to placebo at Week 12 (p=0.0113), Week 16 (p=0.0192), Week 20 (p=0.0349), and Week 24 (p=0.0319), as shown in Figure 10b.

Using the VAS score outcome measure, the percentage of clinically durable responders in the TLC599 12mg group was three times that of the placebo group. Over half of patients in the TLC599 12mg group maintained at least 30% pain reduction at all visits from Week 1 through Week 12 (52% vs 14% in placebo; p=0.0057) and further through Week 24 (52% vs 17% in placebo; p=0.0136), as shown in Figure 10c.

Figure 10a. TLC599 Phase II clinical trial — TLC599 12 mg showed statistically significant improvement in VAS scores through Weeks 12, 16, 20, and 24

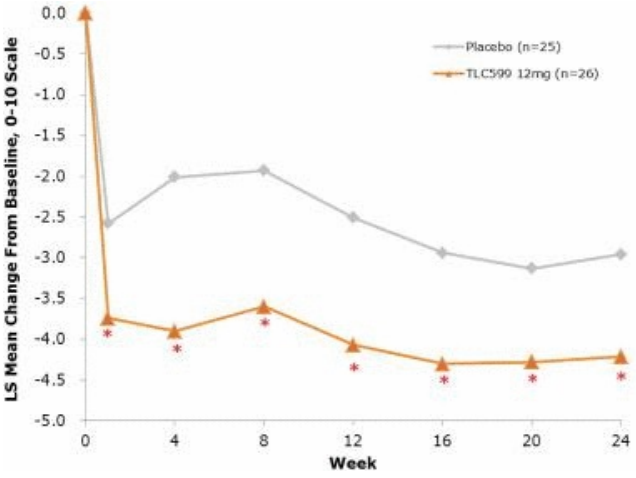


Group	Placebo	TLC 12mg	TLC 18mg
Through W12	-2.22	-3.78* (p=0.0018)	-3.01 (p=0.0697)
Through W16	-2.33	-3.87* (p=0.0021)	-3.01 (p=0.1033)
Through W20	-2.45	-3.93* (p=0.0026)	-3.03 (p=0.1399)
Through W24	-2.50	-3.97* (p=0.0033)	-3.05 (p=0.1555)

* Statistical significance

p-value s from MMRM using LS mean change from baseline of VAS, compared with Placebo

Figure 10b. TLC599 Phase II clinical trial — TLC599 12mg showed statistically significant reduction in VAS pain as compared to placebo at every scheduled visit

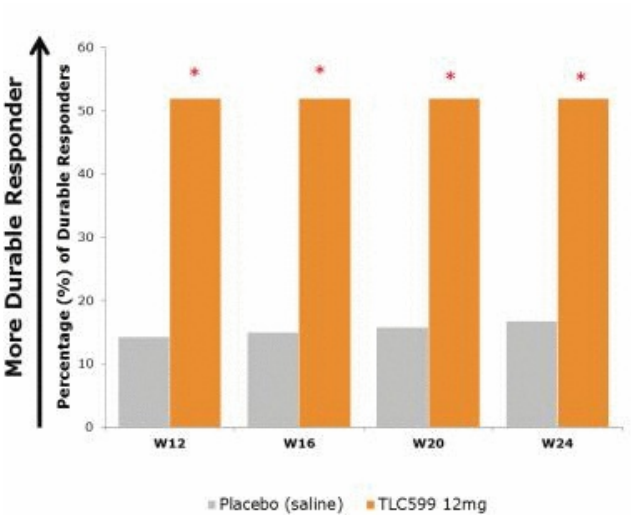


Group	Placebo	TLC 12mg
W12	-2.52	-4.11* (p=0.0113)
W16	-2.91	-4.33* (p=0.0192)
W20	-3.16	-4.33* (p=0.0349)
W24	-2.86	-4.24* (p=0.0319)

* Statistical significance

p-values from MMRM using LS mean change from baseline of VAS, compared with Placebo

Figure 10c. Phase II clinical trial of TLC599 — three times more patients in TLC599 12mg group maintained at least 30% reduction in pain throughout the 24 week study than placebo group



Group	Placebo	TLC 12mg
W12	14.3	52.0* (p=0.0057)
W16	15.0	52.0* (p=0.0075)
W20	15.8	52.0* (p=0.0096)
W24	16.7	52.0* (p=0.0136)

* Statistical significance

Pain score reduction of ≥30% = clinically important difference

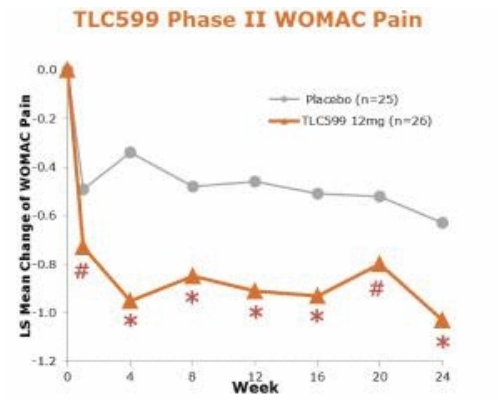
p-values from Logistic regression model of VAS pain, compared with Placebo

Overall, TLC599 12mg showed rapid onset of pain reduction, with a robust magnitude of effect observed as early as the first post-administration assessment at Day 3. A majority of patients in the 12mg group maintained at least 30% pain reduction at every visit through week 24. TLC599 18mg did not lead to as much pain score reduction as the TLC 12mg. Across our clinical trials for TLC599, we studied the effects of three different dose levels: 6mg, 12mg and 18mg, and combined data from these trials suggested that the 12mg dose had the largest improvement in pain, with improvement throughout 24 weeks after one single injection. We believe neither the higher 18mg dose nor the lower 6mg dose of the lipid-formulated TLC599 led to better pain score reductions because a certain amount of released DSP in the joint space needs to be achieved in order to provide sustainable therapeutic effects. In an *in vitro* release study that we conducted to mimic the clinical setting, TLC599 at five different dose levels was injected into artificial synovial fluid and the amount of DSP released was measured at different time points. Our data showed that there was an optimal range of doses of TLC599 that caused DSP to be released at a sustainable level over time. We expect that higher doses of TLC599 cause the release of DSP into the joint environment at a much lower rate, while lower doses of TLC599 cannot produce a sustainable level of DSP over time. We believe that this finding, together with the observation from the Phase II dose-ranging clinical trial, indicates the 12mg dose to be the optimal dose for future development.

Data from the 24-week study showed that the incidence of treatment-emergent adverse events (TEAEs) among the three groups (TLC599 12mg, TLC599 18mg and placebo) were comparable and no drug related serious adverse events were observed. The incidence of injection procedure-related and index knee-related TEAEs were similar between TLC599 18mg and placebo groups and were slightly lower in the TLC599 12mg group.

TLC599 demonstrated sustained reductions in pain through 24 weeks (Figure 11). We believe the development of a product for knee OA that results in a prolonged suppression of pain, along with a quick onset of pain relief, would be welcomed by both patients and physicians.

Figure 11. Reduction in WOMAC pain in Phase II trial of TLC599



Group	W12	W16	W20	W24
TLC599 vs PBO	**-0.45** (p=0.0072)	**-0.43** (p=0.0181)	**-0.28** (p=0.0747)	**-0.40** (p=0.0142)

* p<0.05, vs Placebo, ANCOVA
\# About 40 patients an arm should be sufficient to achieve p<0.05 at week 1 and week 20

TLC599 PK trial

We submitted an IND and received clearance from the FDA in July 2018 to proceed with a Phase II, open-label, pharmacokinetic trial for TLC599 in the United States. The primary objective of this trial is to characterize the PK profiles of TLC599 and immediate release DSP in the knee joint synovial fluid and blood plasma of subjects with mild to moderate knee OA. Safety and tolerability will also be evaluated. We have begun enrollment of patients in this trial and expect to see PK results for a portion of the patients in the third quarter of 2019.

TLC599 Planned Pivotal Trials

We completed an end of Phase II meeting with the FDA in February 2019. Based on our conversations with the FDA, we believe that a single pivotal trial should be sufficient for an NDA submission. We expect to initiate this pivotal trial in the United States in mid-2019, with no need for another pivotal trial one quarter thereafter as previously planned.

For this randomized, controlled pivotal clinical trial, we plan to assess the safety and efficacy of a single intraarticular administration of TLC599 in comparison to placebo and active DSP comparator treatments in patients with knee OA over 24 weeks, as well as assess the benefit of a repeated intraarticular administration at week 24, with a total follow-up period of 52 weeks.

TLC599 – Expanded Indications

If TLC599 is approved for OA knee pain, we anticipate conducting other trials of TLC599 in additional indications, including OA of the hip and frozen shoulder, as well as erosive OA of the hand and finger, especially the base of the thumb in light of the proposed administration of TLC599 through small needle injections.

The FDA has indicated that our proposal to seek approval of TLC599 using the regulatory 505(b)(2) pathway is reasonable. We have received patents from the USPTO for the method of treating arthritis, with terms extending into 2033, and intend to file additional patent applications covering TLC599 based upon additional research and clinical development.

TLC599 – Market Research Study

Prior to the completion of the Phase II clinical trial of TLC599, a market survey was conducted by a third party, ZS Associates, on our behalf to better understand the market potential and potential pricing for TLC599 in the United States. The research was comprised of a quantitative survey of 100 physicians and a set of qualitative interviews with nine physicians. Based on the results of the market survey, we believe that sustained release steroids are positioned to occupy a previously vacant niche in the moderate knee OA pain market.

Based on a hypothetical profile of TLC599 which assumed an efficacy duration of 16 weeks, a one-week timespan to peak pain relief, less toxicity and possibility for repeat dosing, the market research study suggests that TLC599 could achieve usage in up to 26% of the total U.S. moderate knee OA patient population, likely due to the assumed sustained duration of pain reduction. As a result of our topline data from our Phase II study, which showed that TLC599 achieved sustained pain reduction based on the WOMAC and VAS scales through 24 weeks, we believe that there is an opportunity to achieve even higher usage of TLC599.

Based on interviews with five different medical directors of payer organizations, we also believe that TLC599, if approved, could justify benchmarked pricing to that of the approved ER TA. We also believe that an additional price premium would be possible if TLC599 is able to achieve or exceed the hypothetical profile stated above.

TLC590

One additional asset within the BioSeizer technology platform is TLC590, which utilizes the API ropivacaine, a non-opioid anesthetic, and is being developed for post-surgical pain management. We filed an IND application for TLC590 in April 2018. A first-in-human Phase I/II dose-escalation clinical trial in the United States was recently completed, which showed that patients treated with TLC590 demonstrated durable, statistically significant and clinically meaningful improvement over the standard of care while reducing opioid use by 54% through 96 hours.

Post-Surgical Pain Background

According to the World Bank, approximately 96 million surgical procedures were performed in the United States in 2012. Most surgical patients experience post-surgical pain, but less than half of these patients receive adequate pain relief according to a study published in the Journal of Pain by the American Pain Society in February 2016. This ongoing discomfort has been shown to negatively affect patient outcomes. Ongoing pain can increase recovery time and lead to longer hospital stays and readmissions, thereby increasing non-reimbursed hospital costs. The current treatment of post-surgical pain may include wound infiltration with local anesthetics combined with the administration of opioid and NSAID analgesics. Opioids are effective but can also cause many undesirable side effects such as sedation, nausea and vomiting, inhibition of bowel function and dependency or addiction, among others. Respiratory depression is a possible life-threatening complication of opioid use.

A liposomal formulation of bupivacaine indicated for administration at the surgical site to produce post-operative analgesia was commercially launched in the United States in 2012. This drug demonstrated significant reduction in pain intensity in the first two to six hours, with efficacy up to 24 hours post-surgery, but showed minimal to no difference in mean pain intensity compared to placebo between 24 and 72 hours after administration. Local anesthetic systemic toxicity is also a risk of immediate and extended release bupivacaine, as demonstrated in statistical analysis of the FDA Adverse Event Reporting System. Immediate release ropivacaine exhibits reduced cardiotoxicity and central nervous system toxicity compared to bupivacaine. For surgical indications where nerve block is used, ropivacaine may be preferable to bupivacaine, as it may be easier to achieve sensory (pain) blockade with less motor blockade. However, ropivacaine suffers from a relatively short half-life. In addition to the existing unmet need of extended release ropivacaine for prolonged pain control, adequate immediate pain control can be elusive, with some physicians co-administering non-liposomal, or immediate release, bupivacaine in addition to liposomal bupivacaine to augment post-operative pain control.

Our Solution: TLC590

Based on preclinical experiments and results from our Phase I/II clinical trial, we anticipate that a single injection of TLC590 will result in not only immediate effect, but will also yield better pain control than liposomal bupivacaine with at least 72 hours of clinical effectiveness. We believe TLC590 to have competitive advantages over current extended release bupivacaine anesthetics due to our selection of a safer API. Ropivacaine has been shown to exhibit less cardiotoxicity and central nervous system toxicity than bupivacaine. Ropivacaine that is loaded into TLC590's dense multilamellar, or multiple-layered, lipids formulation is released slowly as each layer peels off and dissolves. We also expect that the simplified manufacturing process which requires sterile filtration at the near-end stage will reduce cost of goods sold.

TLC590 Preclinical Findings

In a pharmacokinetic study in rats, TLC590 was found to extend the effective half-life of ropivacaine by about 20-fold. In a preclinical analgesic study of equipotent doses of free ropivacaine (1.9mg), TLC590 (1.9mg) and liposomal bupivacaine (1.33mg), TLC590 displayed statistically significant analgesic effects at 0.5, 5 and 6 hours post-injection when compared to liposomal bupivacaine. TLC590 also showed the earliest onset (t = 0.5 h), similar to free ropivacaine, and produced the longest analgesic action. In a preclinical nerve block study of TLC590 with an equal volume and therefore more potent dose of liposomal bupivacaine, TLC590 exhibited a larger magnitude of anesthetic effect (reduction of 50% paw withdrawal threshold) which persisted to the ninth hour, while the effect of ER bupivacaine had diminished to a level comparable with saline by the eighth hour.

Figure 12a. TLC590 extends the effective half-life of ropivacaine by approximately 20 fold in rat models

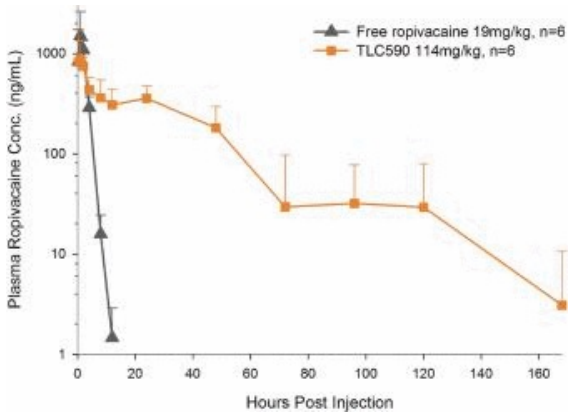


Figure 12b. TLC590 showed statistically significant analgesic effects at 0.5, 5, and 6 hours post-injection

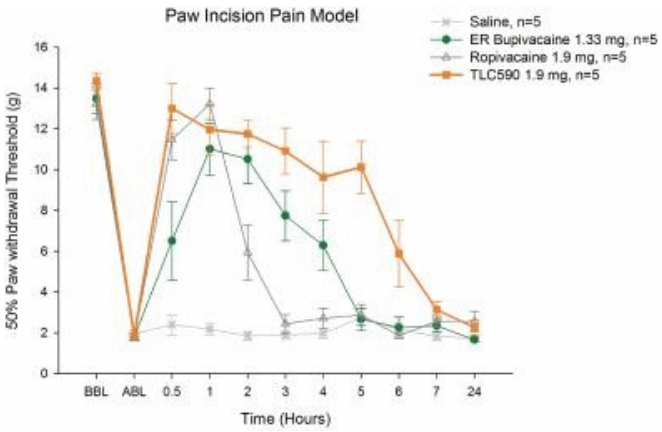
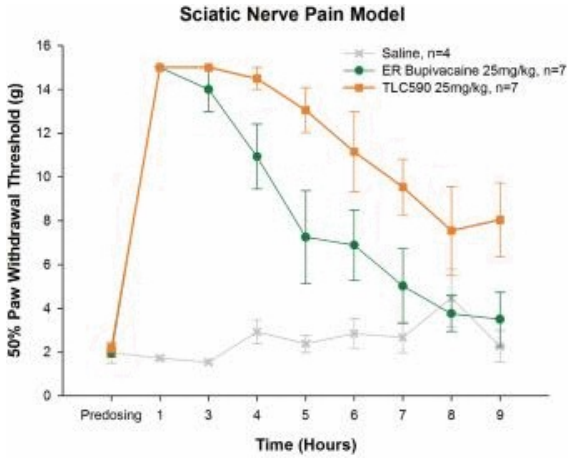


Figure 12c. TLC590 exhibited larger magnitude of anesthetic effect which persisted to the ninth hour

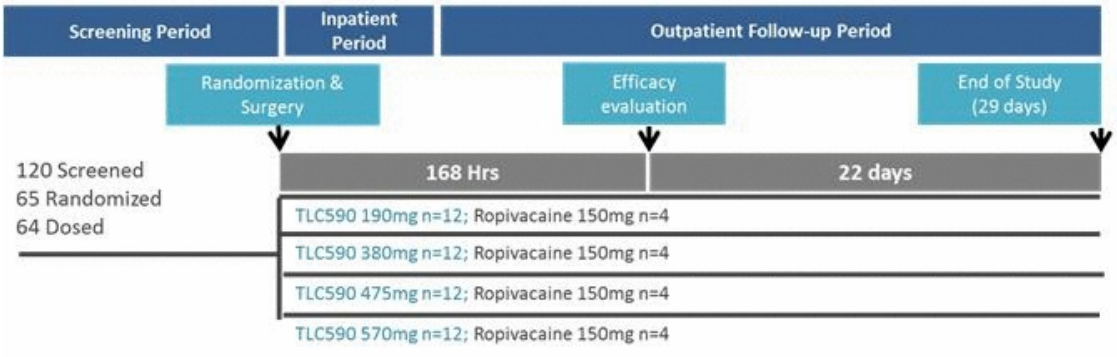


TLC590 Completed Phase I/II Clinical Trial

We filed an IND application with the FDA for TLC590 in April 2018. A first-in-human clinical trial was recently completed to assess the safety, tolerability and pharmacokinetic profile of TLC590. This Phase I/II trial was a randomized, double-blind, comparator-controlled, dose escalation study to evaluate TLC590 compared to free, non-liposomal ropivacaine when given as a single infiltrative local administration in adult patients following inguinal hernia repair surgery.

The trial took place in the United States and enrolled 64 evaluable patients across four cohorts. 16 patients were enrolled in each cohort in a 3:1 ratio, with 12 patients receiving a dose of TLC590 and 4 patients receiving the active comparator drug, ropivacaine. Patients were followed up for 30 days.

Figure 13. TLC590 Phase I/II clinical trial design



The primary endpoint of the trial was safety, and key secondary endpoints included area under the curve (AUC) of numeric pain rating scale at various intervals from 0 to 96 hours, proportion of opioid-free patients, time to first postsurgical opioid use, and total opioid consumption. Top-line data, which we received in March 2019, showed that all four doses of TLC590 resulted in greater reductions in pain intensity than ropivacaine as measured by AUC at every interval. Moreover, the 475mg dose of TLC590 showed the following characteristics:

- There were durable, statistically significant and clinically meaningful reductions in pain intensity with movement compared to ropivacaine, as measured by $AUC_{0\text{-}24h}$ (p=0.0057), $AUC_{0\text{-}48h}$ (p=0.0131), $AUC_{0\text{-}72h}$ (p=0.0117) and $AUC_{0\text{-}96h}$ (p=0.0103); the greater levels of pain reduction was maintained through 168 hours.
- Through the entire duration of the study, 58.3% of patients who received TLC590 475mg did not use any rescue opioids at all.
- Among those who did use rescue opioids, time to first postsurgical opioid use was about four times that of the ropivacaine group (median 13.0 hours vs 3.3 hours).
- Mean total opioid consumption was 54% less through 96 hours post-surgery.

TLC590 exhibited dose-dependent activity based on blood concentration as well as pharmacokinetic markers. TLC590 was well tolerated, even at the highest dose, with a safety profile that is comparable to ropivacaine. Most treatment-related adverse events were mild, with most common symptoms being nausea, headache, vomiting and constipation; higher incidents of these mild adverse events were seen in the ropivacaine group. There were no serious or severe adverse events, no adverse events associated with potential local anesthetic systemic toxicity, and no adverse events leading to patient withdrawal.

We have initiated a Phase II clinical trial evaluating safety and efficacy of TLC590 in patients undergoing bunionectomy. Topline data from the first part of this trial is expected in mid-2019. If the results are positive, we anticipate subsequently conducting our first pivotal trial in the same indication in 2020. We also plan to conduct a Phase II trial in patients undergoing abdominal wall surgery in 2020. In addition, we plan to explore TLC590 in other indications such as nerve block.

TLC399

Following the same design concept of TLC599, TLC399 is our proprietary BioSeizer formulation of DSP intended as an intravitreal, or in-eye, injection for the treatment of macular edema due to RVO. TLC399 in preclinical models has been shown to provide therapeutic levels of DSP in the eye for at least six months after a single administration. In our ongoing Phase I safety trial, we have observed encouraging signs of both reduction of retinal CST and improvements in visual acuity. A larger randomized, double-blind, dose finding Phase II clinical trial is underway. We chose TLC399's first indication as macular edema due to RVO because we believe it provides the most rapid path to both proof of concept for the approach and subsequent approval. We are also evaluating opportunities to develop TLC399 in DME alone or in combination with intravitreal anti-VEGF drugs.

RVO Background

RVO is a sight-threatening disorder resulting from a blockage of one of the veins carrying blood out of the retina. RVO is estimated to affect more than 16 million adults worldwide, according to a 2010 study published in the Journal of Ophthalmology. United States data reported in JAMA Ophthalmology in 2008 indicate a 15-year incidence of 500 new cases of central retinal vein occlusion (CRVO) per 100,000 population and 1,100 branch retinal vein occlusion (BRVO) cases per 100,000 population. In RVO, the blockage of a retinal vein can lead to poor blood circulation, low oxygen and often inflammation. RVO is associated with macular edema, an abnormal thickening of the central area of the retina. Development of macular edema is a common occurrence in multiple retinal disorders besides RVO, such as DME.

There are two primary pharmacologic treatments currently used for the treatment of macular edema due to RVO: intravitreal injections of anti-VEGF drugs and intravitreal steroid injections. The current standard treatment for macular edema associated with RVO involves intravitreal injections of anti-VEGF drugs, such as ranibizumab, aflibercept or bevacizumab. Ranibizumab and aflibercept are approved for monthly treatments in RVO while bevacizumab is used in a similar fashion, but off-label. Anti-VEGF drugs are effective in significantly improving vision in approximately 45% of patients with macular edema associated with RVO, and steroid treatment is often recommended for patients who fail to respond to anti-VEGF treatment. These treatments typically involve injections of TA or dexamethasone.

Limitations of Current Steroid Treatments for Macular Edema Due to RVO

There is currently a marketed steroid injection to treat macular edema due to RVO in the form of dexamethasone intravitreal implant, in which a solid polymer implant is inserted into the vitreous cavity. The duration of effect persists for approximately one to three months after onset; however, it takes up to six months for the implant to dissolve. In clinical trials for this steroid implant, 23% of patients experienced conjunctival hemorrhage. Other adverse reactions from the implant include complication of device insertion (implant misplacement), device dislocation, endophthalmitis, hypotony (very low intraocular pressure) and retinal detachment.

Our Solution: TLC399

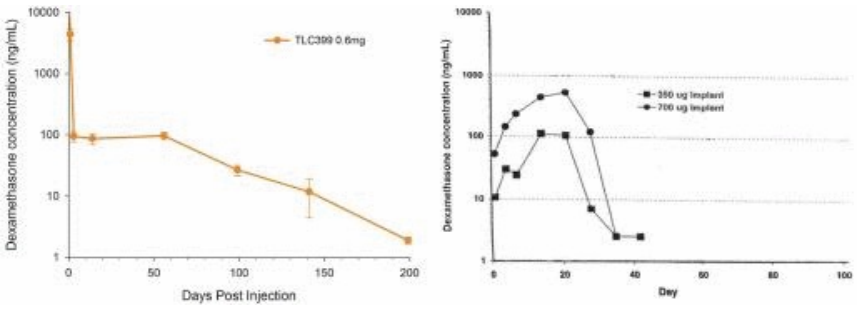
TLC399 is designed to release therapeutic levels of dexamethasone in the eye for periods greater than six months. We believe TLC399 has distinct advantages over other ocular products, with the potential to provide therapeutic benefit for much longer periods. Dexamethasone levels in the eye have been shown to be maintained for greater than six months in preclinical studies using TLC399, while similar studies with the dexamethasone intravitreal implant in animals have only been shown to maintain these levels for approximately 35 days. We believe the interim results from our ongoing open-label Phase I clinical trial demonstrate the potential to provide therapeutic benefits over an extended period, with some RVO patients continuing to show improvement one year after initial treatment.

In addition to potential extended duration of action, TLC399 may provide meaningful advantages in the method of administration. An approved dexamethasone product uses drug-eluting implants injected into the eye using a 22-guage needle, whose diameter of 0.7176mm is 2.3 times larger than the 30-gauge needle (0.3112mm) used with TLC399. We believe this smaller needle can drastically reduce the risk of conjunctival hemorrhaging, as well as infections and complications, due to a smaller insertion wound.

TLC399 Preclinical Findings

In an internal preclinical animal study conducted in 2009 in Taiwan, TLC399 demonstrated the delivery of therapeutically relevant doses of dexamethasone in the eye over a much longer period of time than DSP. DSP that was directly injected into the eye was undetectable within one day of administration. Dexamethasone implants can sustain therapeutic levels of dexamethasone in animals for 35 to 40 days. Dexamethasone levels after administration of TLC399, however, were maintained for at least 200 days in the rabbit model receiving a 100mM PL formulation in our PK study.

Figure 14. TLC399 delivers therapeutically relevant doses of dexamethasone over a period of at least 200 days in preclinical studies in rabbits

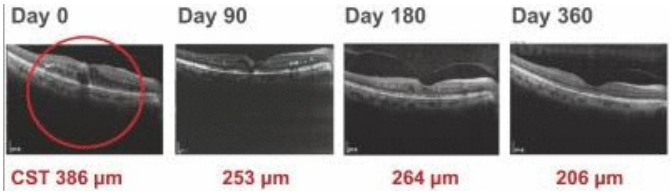


TLC399 Ongoing Clinical Trials

We are conducting a Phase I clinical trial in Taiwan in patients with macular edema due to RVO to characterize the safety of different doses. As of October 21, 2018, a total of nine subjects had been enrolled in this trial, of which three in dose group 1 (0.36 mg DSP with 100 mM PL) and another three in dose group R1 (0.24 mg DSP with 100 mM PL) were evaluable for dose-limiting toxicity.

All three patients in dose group 1 displayed a trend of improvement in CST that lasted for six to 12 months after a single dose of drug administration, and one patient in group 1 achieved target CST levels less than 310 micrometers which were maintained through 12 months. The best corrected visual acuity (BCVA), or the best possible vision a person can achieve with corrective lenses, was impacted by the initial presence of vitreous opacity in all treated patients; this transient visual acuity decrease was improved within two to eight weeks after study drug administration. At month six after treatment, all evaluable subjects in group 1 had improvements in BCVA, ranging from five to 18 letters (one to three lines) on the vision chart. BCVA improvements were maintained through 12 months. All patients who were assigned to dose group R1 also displayed a trend in CST reduction soon after receiving TLC399; however, the complete data for the follow-up period is not yet available. Further patient recruitment will be assigned to dose group R1 to characterize the efficacy and safety profile of this dose group.

Figure 15. Decrease in CST over 12 months after single intra-vitreous TLC399 injection

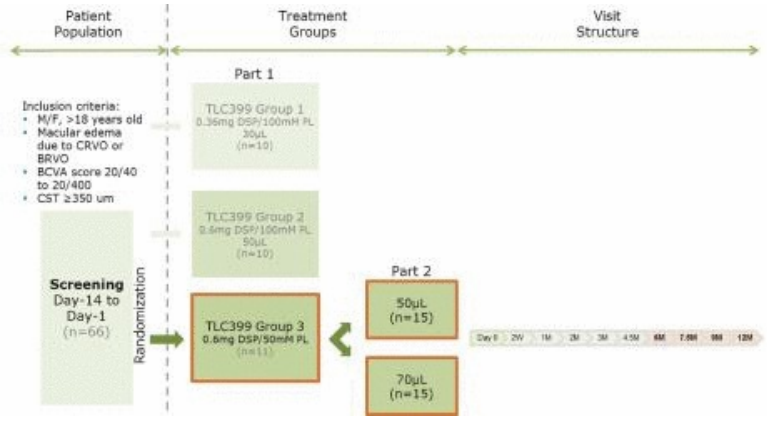


The current treatment-related adverse events reported were of mild to moderate severity, with no unexpected serious adverse reactions or patient withdrawals due to adverse events. One commonly known feature about intra-vitreous steroid injection is the increase of intraocular pressure. Two cases of intraocular pressure elevations during the trial were judged as serious adverse events (SAEs), and both were considered possibly or probably related to TLC399. However, all intraocular pressure elevations were considered manageable with eye drops.

A Phase II clinical trial of TLC399 in patients with macular edema due to RVO was initiated in 2017 and is currently ongoing at 20 sites in the United States. This trial initiated with three groups receiving a single intravitreal dose at one of three different doses of TLC399: 0.36mg DSP with 100mM PL in 30µL solution (Group 1), 0.6mg DSP with 100mM PL in 50µL solution (Group 2), or 0.6mg DSP with 50mM PL in 50µL solution (Group 3). Group 1 and Group 2 were treated with a higher lipid concentration TLC399, and Group 3 was treated with a lower lipid concentration TLC399. The primary

endpoint is defined as the proportion of subjects with BCVA gain of 15 or more letters on the eye chart from baseline in the trial eye at six months, with evaluation of BCVA and CST through 12 months as secondary endpoints. Safety measurements include monitoring for elevated intraocular pressure. At approximately halfway through enrollment (after 31 of 66 planned patients treated), the SMC conducted a pre-planned unblinded analysis of study data as per study protocol; they requested a temporary recruitment pause in order to make a comprehensive assessment to select an optimal dose group with the best vision response. In August 2018, the SMC recommended the group treated with lower lipid concentration TLC399, or Group 3 (0.6mg DSP with 50mM PL in 50µL solution), to move forward; this dose will be further studied along with a higher dose (70µL) of the same formulation (containing 50mM PL). Group 3 had much lower incidence and degree of vitreous haze than the other two groups, and showed improvement of vision and CST. Recruitment will resume after the study protocol amendment is implemented. Last patient enrollment for this trial is expected in November 2019. In this trial, two patients in Group 2 treated with the higher-concentration formulation had significant persistent vitreous haze which the investigator decided to remove via vitrectomy (an out-patient procedure involving removal of the vitreous humor); one of these patients had pre-existing cataracts and suspected vitreous hemorrhage that may have contributed to the persistent haze. These events were assessed as serious and related to study treatment. Following vitrectomy, the haze was resolved in both subjects. This treatment group (Group 2) was not selected to go forward in this study. No other treatment-related SAEs have been observed in this study. Preliminary evaluation of our Phase II trial data has not shown evidence of efficacy beyond three months. We believe this result is attributable to the administration of rescue medication to most patients, even those who did not meet rescue criteria. Patients who receive rescue medication become unevaluable, making it difficult to assess efficacy beyond three months. Moving forward, we have urged trial investigators to confer with the medical monitor to describe the patient's condition including BCVA and CST values over the course of the study to ensure the subject meets rescue criteria prior to administering rescue medication. We believe that the continuation with an optimized formulation, along with more stringent monitoring of the need for rescue medication, should allow more evaluable patients beyond three months.

Figure 16. TLC399 Phase II clinical trial design



Upon completion of our ongoing randomized, double-blind, dosefinding Phase II clinical trial in RVO (expected in 2020), we plan to conduct a Phase IIb trial to confirm the dose and effect size for a pivotal trial.

TLC399 Planned Trial for DME

We plan to have discussions with the FDA to explore the potential of TLC399 as a therapy for other indications. Following these discussions, we plan to initiate a Phase II clinical trial evaluating the treatment of TLC399 alone or in combination with anti-VEGF therapies in patients with DME.

The FDA has indicated that our proposal to seek approval of TLC399 using the regulatory 505(b)(2) pathway is reasonable. We have received patents from the USPTO for the composition of TLC399 and for the method of reducing complications of ocular DSP, with terms extending into 2029 and 2033, and intend to file additional patent applications covering TLC399 based upon additional research and clinical development.

TLC178

TLC178 is our formulation of the anticancer drug vinorelbine utilizing NanoX. We are developing TLC178 for the treatment of RMS, a rare form of STS that most frequently occurs in children. Vinorelbine is a vinca alkaloid chemotherapy agent commonly used off-label to treat RMS and other sarcomas. TLC178 is a formulation of vinorelbine loaded into liposomes using the NanoX encapsulation technology which is designed to alter the systemic exposure of the drug, potentially reducing dosing frequency and enhancing distribution of liposome-encapsulated APIs to the desired site. In April 2017, the FDA granted TLC178 a Rare Pediatric Disease Designation in RMS, which will qualify TLC178 for submission of an NDA in this indication for priority review, which can reduce the standard ten-month FDA review time to six months. In July 2017, the FDA also granted TLC178 an ODD for the treatment of STS. If TLC178 is approved for the treatment of STS, the ODD will provide marketing exclusivity for up to seven years. In January 2019, the EMA also granted ODD for TLC178 for the treatment of STS. If TLC178 is approved for the treatment of STS in the European Union, the ODD by the EMA will provide a 10-year period of marketing exclusivity in the European Union.

We are initially developing TLC178 for relapsed or refractory pediatric RMS. We believe that the increased specificity of TLC178 for tumor versus non tumor tissue through the use of our NanoX technology, which utilizes enhanced permeability and retention (EPR) effects, will enable greater dose intensity, with attendant benefits in antitumor response without impairing the safety profile. In particular, we believe that TLC178 will have significantly lower myelosuppression, a condition in which bone marrow activity is decreased that results in fewer red blood cells, white blood cells and platelets, resulting in a lower rate of severe neutropenia, a decrease in neutrophils, which defend against bacteria and infections. Due to the rarity of this disease and the current unmet need for standardized therapies, we expect to be able to perform one single-arm, response-oriented pivotal trial to demonstrate a clinically meaningful benefit supporting approval.

In parallel with our efforts in RMS, we also plan to initiate clinical trials evaluating TLC178 in other STSs, for which TLC178 has already received an ODD that can potentially provide marketing exclusivity for seven years, and in NSCLC.

RMS Background

RMS is a tumor that develops from skeletal muscle precursors. It often affects children in the first decade of their lives and results in tumors that are located at various sites in the body such as the head, neck, arms, legs, trunk and urinary and reproductive organs. RMS is a rare disease with 350 new cases diagnosed in the United States each year.

Surgical excision of the tumor, when possible, is the primary treatment for RMS. However, for patients with advanced disease, prognosis is poor. Current recommendations include multidrug chemotherapy, often containing vincristine, dactinomycin and cyclophosphamide. Less than 20% of patients with metastatic RMS respond to aggressive multimodality treatment, and up to 30% of RMS patients relapse within three years of diagnosis. Most patients with recurrent RMS will die within one year of relapse (a median survival time of 0.82 years), and, with a five-year survival rate of less than 20%, there are currently no established guidelines for chemotherapy in the relapse setting. Little meaningful improvement in the treatment of this disease has been observed over the last 30 years.

STS Background

There are more than 50 histological subtypes of STS, which are associated with unique clinical, prognostic and therapeutic features. The rarity and heterogeneity of the disease render STS difficult to study and to treat. In the United States, the incidence of diagnosed STS is approximately 12,310 new cases per year, leading to approximately 5,000 deaths annually. The heterogeneity of STS poses a challenge to a standard chemotherapy approach. For most patients with unresectable or metastatic disease, chemotherapy is primarily palliative. Ifosfamide and doxorubicin are routinely used for these patients, with response rates of 50 to 60%. However, it is unclear if the treatment improves overall survival, which remains at approximately 12 to 18 months for these patients. Olaratumab, a platelet-derived growth factor receptor α blocking antibody, has recently been granted accelerated approval by showing improved median overall survival in an open-label, randomized, active-controlled trial with 133 patients. Other treatment options for second-line therapeutic regimens remain very limited and are only recommended for palliative therapy.

NSCLC Background

According to a 2017 American Cancer Society analysis, lung cancer is the leading cancer death in the United States with 155,870 deaths every year. Lung cancer is also the second most common cancer in the United States with 222,500 new cases annually. NSCLC constitutes 80% of all types of lung cancer. Adenocarcinoma and squamous cell carcinoma are major histological subtypes of NSCLC. Most patients are diagnosed with advanced disease and cannot be cured. Immunotherapy, several targeted therapies and platinum-based doublet chemotherapy are first-line treatment options for advanced disease.

Somatic mutations involving epidermal growth factor receptors (EGFR), which are receptor proteins that span the cell membrane, whose constant activation produces uncontrolled cell division (also known as EGFR-sensitizing mutation) is the most common and well established driver mutation in lung adenocarcinoma in Asian populations, with an incidence rate of 47.9%; however, the incidence of EGFR-sensitizing mutation is only 19.2% in Western populations. Other druggable driver mutations, such as anaplastic lymphoma kinase or ROS1 gene arrangements, are not common, with an incidence rate of less than 5%. Immunotherapy, such as programmed cell death protein 1 (PD-1) antibody, is most active in patients with high programmed death-ligand 1 (PD-L1) expressing tumors (tumor proportion score $\geq$ 50%). The prevalence of high PD-L1 expression is approximately 28%.

For those NSCLC patients without driver mutations and with low PD-L1 expression, combination cytotoxic chemotherapies are recommended as first-line treatment according to the 2017 American Society of Clinical Oncology Clinical Practice Guideline. For patients who progressed after first line combination cytotoxic chemotherapy who are not responsive to first-line immunotherapy or contraindicated to second line immunotherapy, there exists a need to identify a better salvage regimen to decrease the risk of cross-resistance and also reduce toxicity.

Our Solution: TLC178

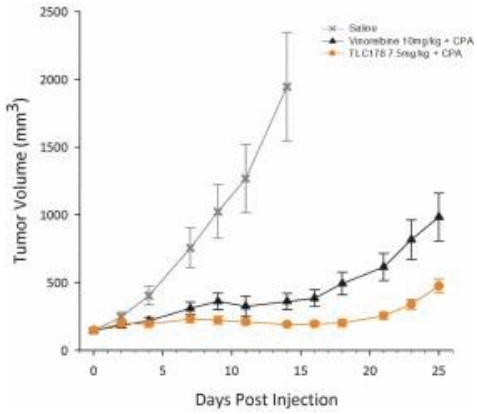
TLC178 is a liposomal intravenous injection formulation of vinorelbine we are evaluating in STS, specifically RMS. A Phase I/II open-label dose escalation clinical trial of TLC178 in patients with advanced malignancies is currently underway.

Vinorelbine is a chemotherapeutic agent that is a member of a class of agents known as microtubule inhibitors that work by preventing cell division. Vinorelbine has been approved by the FDA for use in NSCLC since 2000. The FDA-approved label for vinorelbine states that the safety and effectiveness of vinorelbine in pediatric patients have not been established and showed no meaningful clinical activity in various pediatric cancers; toxicities were similar to those reported in adult patients. The referenced trial was conducted in 46 patients, including 21 with STS, 21 with central nervous system tumors and four with neuroblastoma, with 29 considered evaluable (only seven evaluable patients with STS). The full trial report and data were not submitted for FDA review.

Subsequently, published trials with vinorelbine in pediatric patients conducted by the Children's Oncology Group and other international working groups have shown its potential applications in RMS and other STSs. In several trials targeting relapsed or refractory RMS (11 patients for monotherapy vinorelbine in Kuttesch 2009, 50 patients for combo vinorelbine and cyclophosphamide (VNB+CTX) in Minard-Colin 2012, eight patients for combo VNB+CTX in Casanova 2004), vinorelbine treatment consistently yielded an overall response rate of approximately 36%, with four to seven months duration of response (total of 69 patients in three trials). These trials also demonstrated that vinorelbine was less likely to cause neuropathy than other drugs in the same class such as vincristine. Because of its anticancer activity in this setting and its safety profile, vinorelbine is currently used off-label in RMS and other sarcomas and we believe that based on recent trends in demonstrating potential new indications for previously approved drugs through "Real-World Evidence" the FDA may consider expanding indications for vinorelbine to include the treatment of RMS. Vinorelbine is recommended as an option for RMS by the National Comprehensive Cancer Network (NCCN) guidelines. Vinorelbine is often used in combination with the alkylating agent cyclophosphamide for treatment of sarcomas.

We believe that TLC178 has the capacity to dramatically improve the selective delivery of vinorelbine to tumor versus non-tumor tissue from the results of a number of our preclinical studies. We evaluated TLC178 and standard vinorelbine alone or in combination with cyclophosphamide in a mouse RMS xenograft study. In the study, TLC178 resulted in total drug exposure levels at the tumor site that were 5-fold higher than standard vinorelbine. These higher, sustained levels of active drug resulted in slower tumor growth.

Figure 17. TLC178 can control tumor growth more effectively than free vinorelbine when used in combination with cyclophosphamide (CPA) in a mouse xenograft model of human alveolar RMS

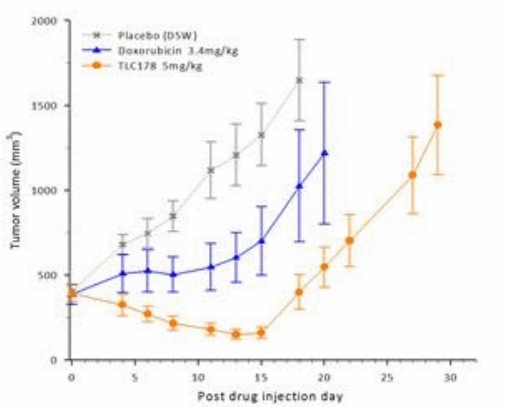


(Note: 10mg/kg in the mouse is approximately equivalent to the therapeutic vinorelbine dose of 30mg/m2 in humans.)

Although vinorelbine demonstrates its potential antitumor activities in pediatrics, it also has significant hematological toxicities. In a third-party conducted trial, which took place from September 1998 to August 2001, of 33 children with advanced sarcomas, grade 3 to 4 neutropenia occurred in 63% of patients. With most liposomal chemotherapeutics (for example, Doxil), the liposomal formulation exhibits less toxicity than the free form. Therefore, we believe TLC178 with preferential distribution to tumor tissue through EPR effect will have reduced systemic toxicity compared to free vinorelbine.

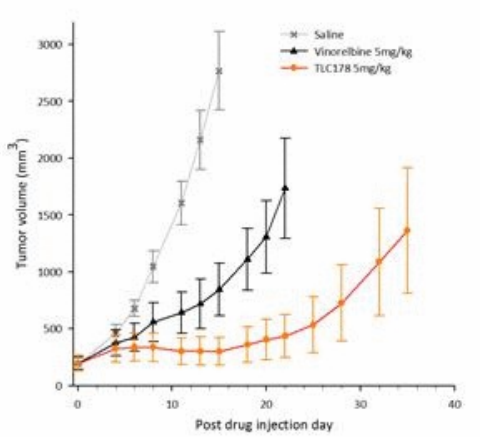
In a preclinical study evaluating the antitumor efficacy of TLC178 versus doxorubicin, the standard of care for patients with STS, in human fibrosarcoma xenograft model, animals treated with TLC178 exhibited a significant tumor reduction compared to placebo and doxorubicin on day 15. Furthermore, TLC178 revealed 14% complete regression and 86% partial regression while no tumor regression was observed in the doxorubicin group.

Figure 18. TLC178 demonstrated superior anti-neoplastic activity and better tolerability than doxorubicin in human fibrosarcoma xenograft model



In a preclinical study comparing the antitumor activity of TLC178 with free vinorelbine in a human alveolar RMS model, TLC178 demonstrated significantly better tumor volume reduction ability than free vinorelbine from day 18 onwards. Moreover, TLC178 exhibited 16.7% complete regression while no tumor regression was observed with free vinorelbine.

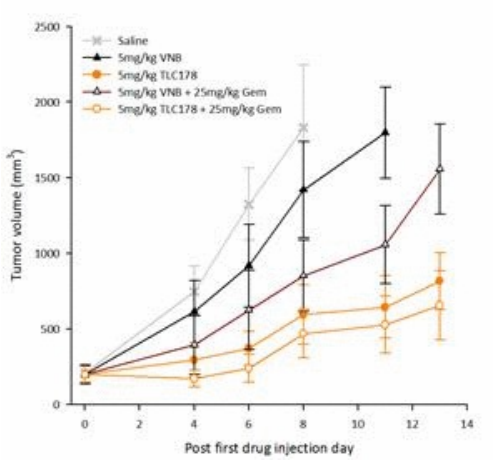
Figure 19. TLC178 demonstrated potent anti-tumor activity in human alveolar RMS xenograft model and exhibited significantly better therapeutic activity than free vinorelbine



Vinorelbine and gemcitabine (GEM) have been reported to be active in STS and NSCLC. For STS, GEM plus vinorelbine (GV) showed a 25% clinical benefit rate with one complete response lasting longer than one year in one single arm trial with 40 patients. GV regimen has also been listed in NCCN guidelines for STS. For NSCLC, GV has been studied as a front-line treatment with a 25% to 36% response rate. The incidence of grade 4 neutropenia observed was 9% to 25%. Compared to previous TAX317 and TAX320 data in second line treatment, the response rate of single agent docetaxel at the dose of 75mg/m^2 was approximately 7% and the rate of grade 4 neutropenia was 54% to 67%. These studies have shown that GEM and vinorelbine can be an active and well-tolerated regimen in advanced NSCLC.

In a preclinical study comparing the antitumor activity of TLC178 alone, TLC178 with GEM (gemcitabine), vinorelbine alone, and vinorelbine with GEM, TLC178 showed significantly better antitumor activity than both vinorelbine alone (day 11) and vinorelbine with GEM (day13). Furthermore, there was very little difference between the antitumor activity of TLC178 alone and TLC178 with GEM.

Figure 20. TLC178 demonstrated potent anti-tumor activity in NSCLC model and exhibited significantly better therapeutic activity than both free vinorelbine and vinorelbine + GEM



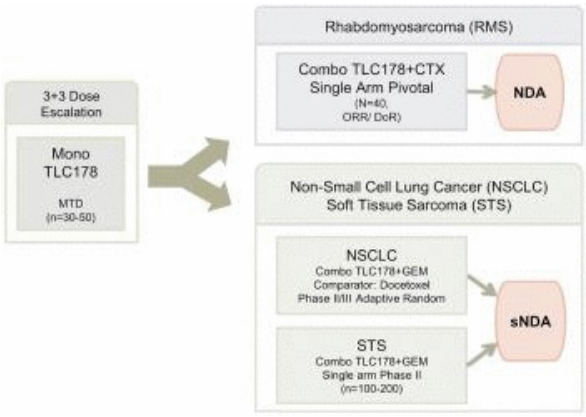
We plan to develop TLC178 alone or in combination with GEM for patients with STS and NSCLC. We will further investigate whether TLC178 in combination with GEM is be able to achieve further efficacy improvement in terms of treatment response rate and duration of response in STS and NSCLC.

Our Plan for TLC178

As of March 8, 2019, we had enrolled 25 patients in our ongoing Phase I/II dose escalation clinical trial evaluating the safety, tolerability and PKs of TLC178 in adults. In the current cohort, there was one case of neutropenia which was determined to be related to treatment. Aside from the one case of neutropenia, no other treatment-related hematological adverse events such as anemia or thrombocytopenia have been observed, although anemia that was determined to be unrelated to the treatment has been observed in three patients. There have been no treatment-related SAEs or adverse events leading to withdrawal. More patients will be enrolled in the current cohort to determine the dose strength of the subsequent cohort. We concluded a pre-IND meeting with the FDA in January 2018 to discuss our plan to initiate a pediatric trial in RMS. We filed an IND application for TLC178 in pediatric RMS with the FDA in June 2018, and plan to initiate a pediatric Phase I/II clinical trial once we have identified a suitable dose in adult patients, which we expect to report in an analysis in the second half of 2019. The pediatric trial will be a Phase I/II clinical trial. Part I, a Phase Ib MTD finding trial for TLC178 plus cyclophosphamide (CTX) combo regimen, will enroll pediatric patients with relapsed or refractory sarcomas. Part II, a single-arm clinical trial, will enroll approximately 40 pediatric patients with relapsed or refractory RMS, with the intent to build substantial evidence of clinical meaningful benefits in objective response rate and duration of response (ORR/DoR). Assuming positive results in this indication, we plan to submit a NDA for RMS along with the Priority Review Voucher request.

For adult indications, we expect to initiate a Phase I MTD finding trial with two to three cohorts for TLC178 plus GEM combo regimen in patients with a group of cancer types, such as NSCLC, esophageal and bladder cancers, which have been shown to be responsive to GV regimens. We plan to conduct a single arm, Phase II clinical trial in 100 to 200 patients to evaluate the efficacy and safety of TLC178 in combination with GEM for second-line therapy of STS. We believe any positive efficacy result in terms of better ORR with more durable response could reasonably predict clinical benefit in patients with relapsed or refractory STS after first-line therapy. For NSCLC, we plan to initiate a randomized, Phase II/III seamlessly adaptive-design clinical trial to evaluate the safety and efficacy of TLC178 in combination with GEM versus docetaxel for patients who have disease progression after platinum-based regimen and/or immunotherapy. The goal of this NSCLC trial would be to provide evidence that a TLC178 plus GEM combination regimen could demonstrate significant superiority to the current standard of care (docetaxel) with a potentially better safety profile.

Figure 21. Clinical development plan for TLC178 in pediatric and adult indications

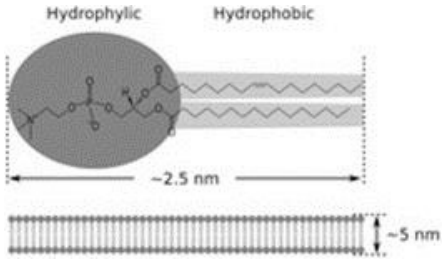


BioSeizer Lipid-based Formulation Platform

Our product candidates are the direct result of our proprietary lipid formulation platform. TLC599, TLC399 and TLC590 all incorporate the BioSeizer technology. BioSeizer is our proprietary, lipid-based drug delivery system which can entrap both small molecule and large molecule APIs and then slowly release them. The release profile of encapsulated compounds or proteins can be adjusted by modulating the compositions of lipid components and altering the manufacturing processes.

Lipid molecules, such as PLs, contain two domains, a hydrophilic, or water-loving, head and a hydrophobic, or water-repelling, tail. In a solution with water, lipid combinations could naturally create bilayers in which the hydrophobic tails are aligned with each other facing away from the aqueous portion of the solution while the hydrophilic heads face the water. Lipid bilayers are key components of cell membranes, nuclear membranes and other membrane structures in the cell.

Figure 22. Depiction of the hydrophilic head and hydrophobic tail of a PL molecule (top) and assembly of these PL into a bilayer structure (bottom)



By carefully modifying lipid combination and the process of bilayer formation, we drive these PLs into vesicles called liposomes as well as into more complex structures. Each of these structures has unique drug release properties and our ability to control the formulation enables us to tailor the PK of each product candidate to specific clinical needs.

Figure 23. Lipid bilayers can form various types of liposomes including small univesicular (SUV), large univesicular (LUV), giant univesicular (GUV), multilamellar, and multivesicular vesicles

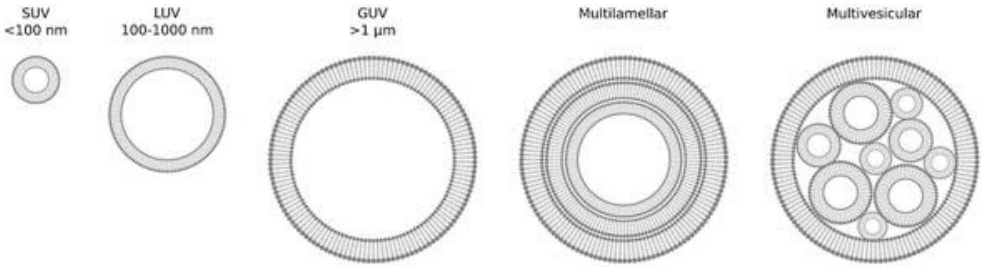
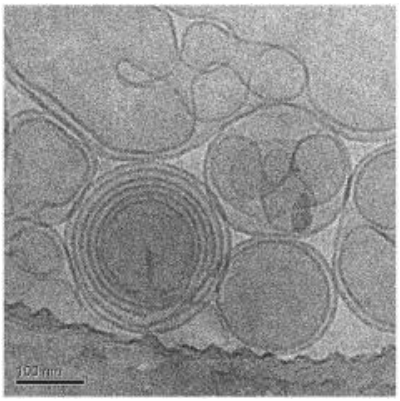


Figure 24. Micrograph of mixed liposome composition of TLC399



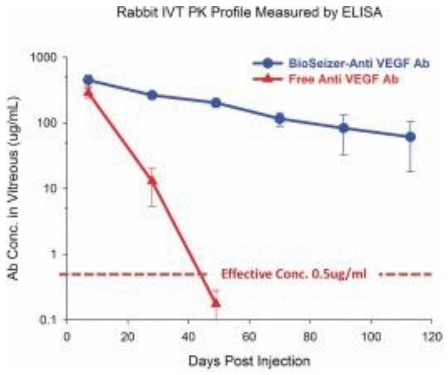
We believe the advantages of BioSeizer compared to other formulation technologies include:

- Ability to deliver biologics (e.g., antibodies) or small molecules
- Ability to design the API's releasing profile.
- Providing immediate availability of free API.
- Prolonging the retention time of APIs at the disease site.
- Reducing the side effects of APIs due to systemic exposure.
- Fully biodegradable components.
- Protection by composition of matter patents.

Unlike other extended release formulations, BioSeizer formulations are not implants or large-size particles. Rather, BioSeizer formulations allow local injections into sensitive tissues such as the eye or inflamed joints using much smaller gauge needles, an advantage that we believe will be welcomed by both patients and clinicians. In contrast to processes used for many other injectable products, our manufacturing process uses sterile filtration at near-end stage, rather than an entirely aseptic process from raw material to final product.

In addition to our existing pipeline programs, we believe BioSeizer can be applied to a broad range small molecule and large molecule drugs. For example, as a part of our plan to further expand into the field of ophthalmology, we intend to formulate an anti-VEGF antibody with BioSeizer for ocular administration. In an *in vivo* study, free anti-VEGF antibody and BioSeizer formulated anti-VEGF antibody were intravitreally injected into rabbit eyes and the concentrations of active anti-VEGF antibody in vitreous humor were monitored over 113 days by enzyme-linked immunosorbent assay (ELISA). Results showed that the concentration of BioSeizer formulated anti-VEGF antibody maintained steady at levels far beyond the effective concentration of 0.5μg/mL, all the way to 113 days, while the free, or unformulated, anti-VEGF antibody concentration went below 0.5μg/mL within 50 days. These data suggest that the duration of anti-VEGF antibodies can be prolonged from one to two months to at least four months when engaged with our proprietary BioSeizer technology.

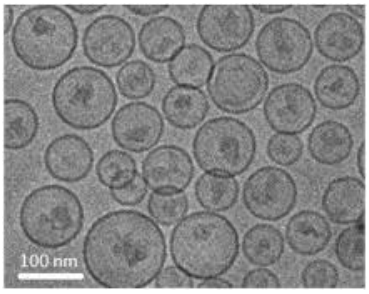
Figure 25. BioSeizer + anti-VEGF demonstrated much longer duration than anti-VEGF alone in rabbits



NanoX Lipid Formulation Platform

The NanoX platform is the cornerstone of the TLC oncology portfolio. NanoX is a proprietary, next generation liposome technology which we believe can overcome the shortcomings of existing remote loading technologies that can only be applied to a certain class of anticancer compounds, anthracyclines (e.g., Doxil/Caelyx). NanoX is a novel drug loading vesicle of small unilamellar (single layered) liposomes of approximately 100nm (±20nm) mean diameter employing a novel combination of counter-ions to create an ionic gradient for active drug loading.

Figure 26. CryoEM image of NanoX technology



We believe the advantages of NanoX compared to existing remote loading technologies include:

- More options for payload selection, including vinca alkaloids and camptothecins
- Greater stability to support longer shelf-life
- Prolonged circulation time by decreased clearance

- Efficient particle size (100±20nm) to deliver more payload to the tumor tissue through EPR effect, which takes advantage of the leakiness of new blood vessels that grow to support tumors
- Potential for altered systemic exposure profiles due to preferential distribution to tumor tissue
- Ability to be applied to both small and large molecules
- No exposure to organic solvents, which might lead to denaturation of the protein API, during the manufacturing process
- A robust, scalable and replicable manufacturing process

We aim to utilize this platform to select APIs that have been widely used in clinical practice with confirmed activity against certain cancers. We believe that NanoX-encapsulated APIs could alter the systemic exposure of the drug, potentially reducing dosing frequency and producing improvement in terms of higher response rate and more durable response due to tissue targeting delivery and prolonged circulation time.

We believe NanoX could also be developed as an antibody-conjugated variant for next-generation tissue/cellular targeting delivery. Furthermore, we believe that the payload-antibody ratio for antibody-conjugated NanoX could reach over 50, an order of magnitude improvement in efficiency over conventional with commonly less than eight. We have performed a series of *in vitro* studies to demonstrate the potential for active targeting delivery to the receptor-bearing cells through a cellular internalization process.

Approved Generic Products

Ampholipad and Lipo-Dox are our two generic products that have been approved for sale in Taiwan and Southeast Asia. We have entered into license agreements with third party distributors to sell our generic products in exchange for royalties.

Ampholipad. Ampholipad, our approved product in Taiwan and Macau, is a liposomal formulation of amphotericin B for systemic fungal infection. Ampholipad is capable of delivering highly effective doses with a more desirable toxicity profile compared to other marketed formulations of amphotericin B products. Ampholipad is manufactured by Yung Shin Pharmaceuticals Ind. Co., Ltd., which is in compliance with GMP guidelines set forth by The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S).

Lipo-Dox. Lipo-Dox is a liposomal encapsulated doxorubicin product which was approved by Taiwan's Department of Health in 1998 for the treatment of breast cancer, ovarian cancer, and AIDS-related Kaposi's sarcoma and multiple myeloma. Lipo-Dox, with its PEGylated liposomes design, reduces the rate at which the active substance is broken down, allowing it to circulate in the blood for a longer period of time. Lipo-Dox also reduces effects on non-cancer tissues and cells, hence has reduced cardiotoxicity compared to free form doxorubicin. Lipo-Dox has been licensed to TTY Biopharm Co., Ltd., a Taiwanese pharmaceutical company which is in compliance with GMP guidelines set forth by PIC/S, for manufacturing and distribution in Taiwan and Southeast Asia.

Manufacturing

We currently utilize contract manufacturing organizations (CMOs) to produce our preclinical and clinical product candidate supplies. We believe our proprietary BioSeizer and NanoX platforms are highly compatible with various chemicals and manufacturing processes, allowing us to incorporate various APIs in these lipid-based formulations. Manufacture of lipid-based formulations is a complex process, and there are a limited number of contract manufacturing sites with lipid-based formulation experience. Particle size is a key attribute to a lipid-based product and is difficult to control. Production batch sizes are currently generally limited for commercial scale-up due to the potential variations in physicochemical properties that may occur during scale-up processes. We believe we have the scientific know-how, however, to deliver reproducible and scalable production, up to 400 liters. We are working with our CMOs to support increasing clinical trial demand and planning for commercialization.

TLC599 and TLC399. Our TLC599 and TLC399 product candidates are manufactured by Yung Shin Pharmaceuticals, Ind. Co., Ltd (YSP), a Taiwan based, cGMP-compliant manufacturer and global supplier for a wide variety of injectable products. YSP is subject to regular inspection by the Taiwan Food and Drug Administration and regular audit by the United States FDA. In May 2018, we entered into a Clinical Manufacturing Agreement with Evonik, which operates a GMP-compliant facility located in the United States, as our supplier of TLC599 drug product for our planned pivotal clinical trial. The facility is also subject to inspection by the United States FDA and the British health authority MHRA.

TLC590. Clinical supply of TLC590 is manufactured by SSP, a Taiwan based, GMP-compliant manufacturer. SSP is subject to regular inspection by the Taiwan Food and Drug Administration and regular audit by the Japan PMDA. We have identified Baxter Oncology GmbH (Baxter) as our supplier of TLC590 for pivotal clinical trials. We signed a proposal with Baxter in August 2018 to supply equipment and are currently negotiating a clinical manufacturing agreement. Baxter is a GMP-compliant manufacturer and global supplier for a wide variety of injectable products. The facility is subject to regular inspection by the United States FDA and Germany BfArM.

TLC178. Our TLC178 product candidate is manufactured by Hospira Australia Pty Ltd (Hospira). Hospira, a subsidiary of Pfizer, is a global, commercial-scale supplier of cGMP-compliant for a wide variety of injectable products. Hospira is subject to regular inspection by the FDA and the Therapeutic Goods Administration.

Competition

The biopharmaceutical industry is intensely competitive and subject to rapid and significant technological change. Our current and potential future competitors include large and specialty pharmaceutical and biotechnology companies, academic research institutions, governmental agencies and public and private research institutions. Several of these companies have robust drug pipelines, readily available capital and established research and development organizations.

We believe the key competitive factors that will determine the success of our product candidates, if approved, are efficacy, durability, safety, ease of administration, price and the availability of reimbursement from government and other third-party payors. In particular, our product candidates rely on improving existing APIs through application of our proprietary lipid formulation technologies. Because these APIs are generic or will be generic before our product candidates are approved, and have established market share and familiarity with patients, physicians and healthcare payors, we will need to demonstrate meaningful superiority in efficacy and/or safety compared to the generic APIs in order to justify premium pricing and gain market share for our product candidates, if approved.

TLC599

We are initially developing TLC599 for OA pain. Current approved intraarticular treatments of OA pain include steroids and hyaluronic acid viscosupplements. Immediate-release steroids are generic, and therefore available at prices that are significantly below the price we would expect to charge for TLC599, if approved. We believe ZILRETTA, an extended-release intraarticular steroid marketed by Flexion Therapeutics, Inc., is our most direct competitor with respect to TLC599. We believe our ability to compete with immediate-release steroids and ZILRETTA will depend primarily on whether TLC599 demonstrates superior duration of pain relief and whether TLC599 proves to be safer, particularly with respect to chondrotoxicity, compared to ZILRETTA.

TLC399

We are initially developing TLC399 for the treatment of macular edema associated with RVO. Current approved treatments for macular edema associated with RVO includes intravitreal injections of anti-VEGF drugs and intravitreal steroid injections. Macular edema due to RVO is also currently treated with steroid injections in the form of dexamethasone intravitreal implants. We believe Ozurdex, marketed by Allergan, Inc., is our most direct competitor with respect to TLC399.

TLC590

We are initially developing TLC590 for the treatment of post-surgical pain management. Numerous post-operative pain treatments exist, including local analgesics, opioids and elastomeric pumps. We believe that EXPAREL, marketed by Pacira Pharmaceuticals, Inc., and Heron Therapeutics, Inc.'s product candidate HTX-011, an extended release formulation of bupivacaine and meloxicam which has completed a Phase III clinical trial, are our most direct competitors with respect to TLC590. In addition, TLC590 will compete against other extended release products currently used for post-surgical pain management.

TLC178

We are initially developing TLC178 for the treatment of relapsed or refractory pediatric RMS. Although there are no FDA approved products for RMS, current treatment options include vinorelbine, doxorubicin, irinotecan, topotecan and trabectedin, which are all conventional chemotherapy drugs.

Many of our potential competitors, alone or with their strategic partners, have substantially greater financial, technical and other resources than we do, such as larger research and development, clinical, marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of competitors. Our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render our product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, proprietary technologies, manufacturing and process discoveries and other know-how, to operate without infringing the proprietary rights of others, and to prevent others from infringing on our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing or in-licensing United States and foreign patents and patent applications related to our proprietary technology, inventions and improvements that we believe are important to the development and implementation of our business. We also rely on trademarks, trade secrets, know-how, continuing technological innovation, and potential in-licensing opportunities to develop and maintain our proprietary position.

We can provide no assurance that our patent applications or those of our licensors will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technologies, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties. Even issued patents may later be found unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. We cannot provide any assurance that any patents will be issued from our pending or any future applications or that any potentially issued patents will our intellectual property.

As of December 31, 2018, we had been granted 54 utility patents worldwide, including 11 Taiwan patents, eight United States patents, six Japan patents, five New Zealand patents, five China patents, four Australia patents, five Korea patents, two Russian patents, two Hong Kong patents, three European patents, two South Africa patent and one Canada patent. We also have 68 patent applications which are under review in the above major markets (including 13 U.S. provisional patent applications) plus India, Brazil and Singapore jurisdictions, as well as three pending PCT patent application, relating to our product candidates. The patent terms for TLC599 and TLC399 extend into 2033 and the patent term for TLC178 extends into 2034. If issued, the patent term for TLC590 and additional patent families of TLC599 would extend into 2039.

We own all of the patents and patent applications relating to our four lead product candidates.

TLC599

Our TLC599 intellectual property portfolio includes five issued patents and 15 patent applications. Our issued patents cover the methods of use of TLC599, were granted in the United States, Australia, New Zealand, China and Taiwan, and are expected to expire in 2033. Our patent applications cover composition as well as methods of use and manufacture of TLC599 and are pending and under review in the United States, South Africa, Singapore, Russia, Korea, Japan, India, Hong Kong, Europe, Canada and Brazil, with expected expiry dates of 2039.

TLC399

Our TLC399 intellectual property portfolio includes 27 issued patents and 13 patent applications. Our issued patents cover the composition of matter of TLC399, were granted in Taiwan, the United States, Canada, South Africa, Russia, New Zealand, Korea, Japan, Hong Kong, China, Europe and Australia, and are expected to expire between 2029 and 2033. Our patent applications cover the composition of matter of TLC399 and are pending and under review in the United States, South Africa, Korea, India, Hong Kong, Europe, China, Canada and Brazil, with expected expiry dates between 2029 and 2033.

TLC590

Our TLC590 intellectual property portfolio includes one PCT application, one Taiwan patent and one U.S. provisional application, which covers the composition of matter of TLC590 and is pending, in the international phase of PCT application and in Taiwan, under review in the United States, with expected expiry dates between 2038 and 2039.

TLC178

Our material TLC178 intellectual property portfolio includes four issued patents and 15 patent applications. Our issued patents cover the composition of matter of TLC178, were granted in Taiwan, Japan, Korea and the United States, and are expected to expire in 2034. Our patent applications cover the composition of matter of TLC178 and are pending and under review in Taiwan, the United States, South Africa, Singapore, Russia, New Zealand, India, Hong Kong, Europe, China, Canada, Brazil and Australia, with expected expiry dates of 2034.

Individual patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued for regularly filed applications in the United States are granted a term of 20 years from the earliest effective non-provisional filing date. In addition, in certain instances, a patent term can be extended to recapture a portion of the USPTO delay in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. However, the actual protection afforded by a patent varies on a product by product basis, from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

The patent terms of novel treatment method claim for TLC599 (US 9,789,062), composition claim for TLC399 (US 8,956,600), (US 9,987,360), (US 10,058,616) and composition claim for TLC178 (US 9,700,511) at least extend into 2033, 2029 and 2034, respectively. For TLC590, TLC399 and TLC599, the patent terms of novel composition claims and improved treatment method claims would extend into 2039, 2033 and 2039 respectively if issued.

In addition to patents, we have filed for trademark registration with the USPTO for “BioSeizer,” “NanoX,” “LipAD,” “Doxolipad,” “Doxisome,” “Nano X,” and “tlc Taiwan Liposome Company.” Furthermore, we rely upon trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our collaborators, employees and consultants and invention assignment agreements with our employees. We also have or intend to implement confidentiality agreements or invention assignment agreements with our collaborators and selected consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, or our product or product candidates or processes, obtain licenses or cease certain activities. Our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our future product candidates may have an adverse impact on us. Since patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months or potentially longer, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference or opposition proceedings brought by third parties or declared by the USPTO. For more information, see "Risk Factors—Risks Related to Our Intellectual Property."

Government Regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, packaging, recordkeeping, tracking, approval, import, export, distribution, advertising and promotion of our products.

U.S. Government Regulation of Drug Products

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (FFDCA) and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- nonclinical laboratory and animal tests that must be conducted in accordance with good laboratory practices;
- submission of an IND, which must become effective before clinical trials may begin;
- approval by an independent institutional review board (IRB) for each clinical site or centrally before each trial may be initiated;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed product candidate for its intended use, performed in accordance with good clinical practices (GCPs);
- submission to the FDA of an NDA and payment of user fees;
- satisfactory completion of an FDA advisory committee review, if applicable;
- pre-approval inspection of manufacturing facilities and selected clinical investigators for their compliance with cGMP and GCPs;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- FDA approval of an NDA to permit commercial marketing for particular indications for use; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy (REMS) and the potential requirement to conduct post-approval studies.

The testing and approval process requires substantial time, effort and financial resources. Preclinical studies include laboratory evaluation of drug substance chemistry, pharmacology, toxicity and drug product formulation, as well as animal studies to assess potential safety and efficacy. Prior to commencing the first clinical trial with a product candidate, we must submit the results of the preclinical tests and preclinical literature, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some preclinical studies may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the conduct of the clinical trial by imposing a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Submission of an IND may not result in FDA authorization to commence a clinical trial.

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development, as well as amendments to previously submitted clinical trials. Further, an independent IRB for each trial site proposing to conduct the clinical trial must review and approve the plan for any clinical trial, its informed consent form and other communications to trial subjects before the clinical trial commences at that site. The IRB must continue to oversee the clinical trial while it is being conducted, including any changes to the trial plans.

Regulatory authorities, an IRB or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk, the clinical trial is not being conducted in accordance with the FDA's or the IRB's requirements, if the drug has been associated with unexpected serious harm to subjects, or based on evolving business objectives or competitive climate. Some studies also include a data safety monitoring board, which receives special access to unblinded data during the clinical trial and may advise us to halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

In general, for purposes of NDA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1—Studies are initially conducted to test the product candidate for safety, dosage tolerance, structure-activity relationships, mechanism of action, absorption, metabolism, distribution and excretion in healthy volunteers or subjects with the target disease or condition. If possible, phase 1 trials may also be used to gain an initial indication of product effectiveness.
- Phase 2—Controlled studies are conducted with groups of subjects with a specified disease or condition to provide enough data to evaluate the preliminary efficacy, optimal dosages and dosing schedule and expanded evidence of safety. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3—These clinical trials are undertaken in larger subject populations to provide statistically significant evidence of clinical efficacy and to further test for safety in an expanded subject population at multiple clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. These trials may be done globally to support global registrations so long as the global sites are also representative of the U.S. population and the conduct of the trial at global sites comports with FDA regulations and guidance, such as compliance with GCPs.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase 4 studies may be made a condition to be satisfied after approval. The results of Phase 4 studies can confirm the effectiveness of a product candidate and can provide important safety information.

Clinical trials must be conducted under the supervision of qualified investigators in accordance with GCP requirements, which includes the requirements that all research subjects provide their informed consent in writing for their participation in any clinical trial, and the review and approval of the trial by an IRB. Investigators must also provide information to the clinical trial sponsors to allow the sponsors to make specified financial disclosures to the FDA. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the trial procedures, the parameters to be used in monitoring safety and the efficacy criteria to be evaluated and a statistical analysis plan. Information about some clinical trials, including a description of the trial and trial results, must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their ClinicalTrials.gov website.

The manufacture of investigational drugs for the conduct of human clinical trials is subject to cGMP requirements. Investigational drugs and active pharmaceutical ingredients imported into the United States are also subject to regulation by the FDA relating to their labeling and distribution. Further, the export of investigational drug products outside of the United States is subject to regulatory requirements of the receiving country as well as U.S. export requirements under the FFDCA. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and the IRB and more frequently if SAEs occur.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Orange Book Listing

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA patents whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book.

Any applicant who files a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA (1) that no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) that such patent has expired; (3) the date on which such patent expires; or (4) that such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a Paragraph IV certification. Generally, the 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the 505(b)(2) NDA applicant challenges a listed patent through a Paragraph IV certification.

If the applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the holder of the NDA for the reference listed drug and the patent owner once the application has been accepted for filing by the FDA. The applicant may also elect to submit a ''section viii'' statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. The NDA holder or patent owner may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification prevents the FDA from approving the application until the earlier of 30 months from the date of the lawsuit, expiration of the patent, settlement of the lawsuit, a decision in the infringement case that is favorable to the applicant or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where a 505(b)(2) NDA applicant files a Paragraph IV certification, the NDA holder or patent owner regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of a 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation.

Exclusivity

The FDA provides periods of non-patent regulatory exclusivity, which provides the holder of an approved NDA limited protection from new competition in the marketplace for the innovation represented by its approved drug for a period of three or five years following the FDA's approval of the NDA. Five years of exclusivity are available to new chemical entities (NCEs). An NCE is a drug that contains no active moiety that has been approved by the FDA in any other NDA. An active moiety is the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt, including a salt with hydrogen or coordination bonds, or other noncovalent, or not involving the sharing of electron pairs between atoms, derivatives, such as a complex (*i.e.*, formed by the chemical interaction of two compounds), chelate (*i.e.*, a chemical compound), or clathrate (*i.e.*, a polymer framework that traps molecules), of the molecule, responsible for the therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review or approve an ANDA or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. An ANDA or 505(b)(2) application, however, may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed.

If a product is not eligible for the NCE exclusivity, it may be eligible for three years of exclusivity. Three-year exclusivity is available to the holder of an NDA, including a 505(b)(2) NDA, if one or more new clinical trials, other than bioavailability or bioequivalence trials, was essential to the approval of the application and was conducted or sponsored by the applicant. This three-year exclusivity period protects against FDA approval of ANDAs and 505(b)(2) NDAs for the particular condition of the new drug's approval or the change to a marketed product, such as a new formulation for a previously approved drug. Five-year and three-year exclusivity will not delay the submission or approval of a 505(b)(1) NDA; however, an applicant submitting a 505(b)(1) NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

In addition, under the Generating Antibiotic Incentives Now (GAIN) Act, which was enacted as part of the Food and Drug Administration Safety and Innovation Act (FDASIA), which was signed into law in July 2012, the FDA may designate a product as a qualified infectious disease product (QIDP). In order to receive this designation, a drug must qualify as an antibiotic or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by either (1) an antibiotic or antifungal resistant pathogen, including novel or emerging infectious pathogens, or (2) a so-called "qualifying pathogen" found on a list of potentially dangerous, drug-resistant organisms to established and maintained by the FDA. A sponsor must request such designation before submitting a marketing application. Upon approving a marketing application for a QIDP-designated product, the FDA will extend by an additional five years any non-patent marketing exclusivity period awarded, such as a three-year exclusivity period awarded for new clinical investigations of previously approved products. This extension is in addition to any pediatric exclusivity extension awarded, and the extension will be awarded only to a drug first approved on or after the date of enactment of the GAIN Act. The GAIN Act prohibits the grant of an exclusivity extension where the application is a supplement to an application for which an extension is in effect or has expired, is a subsequent application for a specified change to an approved product, or is an application for a product that does not meet the definition of QIDP based on the uses for which it is ultimately approved.

Hatch Waxman Amendments and the 505(b)(2) Regulatory Approval Process

Section 505 of the FFDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A regulatory 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A regulatory 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy, but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application. Specifically, the applicant may rely upon the FDA's prior findings of safety and efficacy for an approved product that acts as the reference listed drug for purposes of a 505(b)(2) NDA. The FDA may also require 505(b)(2) applicants to perform additional studies or measurements to support any changes from the reference listed drug. The FDA may then approve the new product candidate for all or some of the labeled indications for which the referenced product has been approved, as well as for any new indication sought by the 505(b)(2) applicant. Lastly, the FDA permits marketing applications through Section 505(j), which establishes an abbreviated approval process for a generic version of approved drug products through the submission of an Abbreviated New Drug Application (ANDA). An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product. ANDAs are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through *in vitro*, *in vivo*, or other testing. The generic version must deliver the same amount of active ingredients into a subject's bloodstream in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug.

Special FDA Expedited Review and Approval Programs

The FDA has various programs, including fast track designation, breakthrough therapy designation, accelerated approval, and priority review, which are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

Under the fast track program, the sponsor of a new drug candidate may request that FDA designate the drug candidate for a specific indication as a fast track drug concurrent with, or after, the filing of the IND for the drug candidate. To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life threatening disease or condition and demonstrates the potential to address an unmet medical need, or that the drug qualifies as a QIDP under the GAIN Act. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast track designation provides additional opportunities for interaction with the FDA's review team and may allow for rolling review of NDA components before the completed application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA. However, FDA's time period goal for reviewing an application does not begin until the last section of the NDA is submitted. The FDA may decide to rescind the fast track designation if it determines that the qualifying criteria no longer apply.

In addition, a sponsor can request breakthrough therapy designation for a drug if it is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are eligible for intensive guidance from FDA on an efficient drug development program, organizational commitment to the development and review of the product including involvement of senior managers, and, like fast track products, are also eligible for rolling review of the NDA. Both fast track and breakthrough therapy products are also eligible for accelerated approval and/or priority review, if relevant criteria are met.

Under the FDA's accelerated approval regulations, the FDA may approve a drug for a serious or life threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. A drug candidate approved on this basis is subject to rigorous post marketing compliance requirements, including the completion of Phase 4 or post approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post approval studies, or confirm a clinical benefit during post marketing studies, will allow FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated approval regulations are subject to prior review by FDA.

Once an NDA is submitted for a product intended to treat a serious condition, the FDA may assign a priority review designation if FDA determines that the product, if approved, would provide a significant improvement in safety or effectiveness. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. Under the current PDUFA agreement, these six and ten month review periods are measured from the 60-day filing date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review from the date of submission. Most products that are eligible for fast track breakthrough therapy designation are also likely to be considered appropriate to receive a priority review.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. In addition, the manufacturer of an investigational drug for a serious or life threatening disease is required to make available, such as by posting on its website, its policy on responding to requests for expanded access. Furthermore, fast track designation, breakthrough therapy designation, accelerated approval and priority review do not change the standards for approval and may not ultimately expedite the development or approval process.

NDA Submission and Review by the FDA

Assuming successful completion of the required clinical and preclinical testing, among other items, the results of product development, including chemistry, manufacture and controls, nonclinical studies and clinical trials are submitted to the FDA, along with proposed labeling, as part of an NDA. The submission of an NDA requires payment of a substantial user fee to the FDA. These user fees must be filed at the time of the first submission of the application, even if the application is being submitted on a rolling basis. Fee waivers or reductions are available in some circumstances. One basis for a waiver of the application user fee is if the applicant employs fewer than 500 employees, including employees of affiliates, the applicant does not have an approved marketing application for a product that has been introduced or delivered for introduction into interstate commerce, and the applicant, including its affiliates, is submitting its first marketing application.

In addition, under the Pediatric Research Equity Act, an NDA or supplement to an NDA for a new active ingredient, indication, dosage form, dosage regimen or route of administration must contain data that are adequate to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults or full or partial waivers from the pediatric data requirements.

The FDA must refer applications for drugs that contain active ingredients, including any ester or salt of the active ingredients, that have not previously been approved by the FDA to an advisory committee or provide in an action letter a summary of the reasons for not referring it to an advisory committee. The FDA may also refer drugs which present difficult questions of safety, purity or potency to an advisory committee. An advisory committee is typically a panel that includes clinicians and other experts who review, evaluate and make a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

The FDA reviews applications to determine, among other things, whether a product is safe and effective for its intended use and whether the manufacturing controls are adequate to assure and preserve the product's identity, strength, quality and purity. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities, including contract manufacturers and subcontracts, are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical trial sites to assure compliance with GCPs.

Once the FDA receives an application, it has 60 days to review the NDA to determine if it is substantially complete to permit a substantive review, before it accepts the application for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. The FDA's NDA review times may differ based on whether the application is a standard review or priority review application. The FDA may give a priority review designation to drugs that are intended to treat serious conditions and provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act (PDUFA), the FDA has set the review goal of 10 months from the 60-day filing date to complete its initial review of a standard NDA for a new molecular entity (NME) and make a decision on the application. For non-NME standard applications, the FDA has set the review goal of 10 months from the submission date to complete its initial review and to make a decision on the application. For priority review applications, the FDA has set the review goal of reviewing NME NDAs within six months of the 60-day filing date and non-NME applications within six months of the submission date. Such deadlines are referred to as the PDUFA date. The PDUFA date is only a goal and the FDA does not always meet its PDUFA dates. The review process and the PDUFA date may also be extended if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding the submission.

Once the FDA's review of the application is complete, the FDA will issue either a Complete Response Letter (CRL) or approval letter. A CRL indicates that the review cycle of the application is complete and the application is not ready for approval. A CRL generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing, or other information or analyses in order for the FDA to reconsider the application. The FDA has the goal of reviewing 90% of application resubmissions in either two or six months of the resubmission date, depending on the kind of resubmission. Even with the submission of additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA may issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

The FDA may delay or refuse approval of an NDA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product, or impose other conditions, including distribution restrictions or other risk management mechanisms. For example, the FDA may require a REMS as a condition of approval or following approval to mitigate any identified or suspected serious risks and ensure safe use of the drug. The FDA may prevent or limit further marketing of a product, or impose additional post-marketing requirements, based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements, FDA notification and FDA review and approval. Further, should new safety information arise, additional testing, product labeling or FDA notification may be required.

If regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed or may include contraindications, warnings or precautions in the product labeling, which has resulted in a Black Box warning. The FDA also may not approve the inclusion of labeling claims necessary for successful marketing. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require Phase 4 post-marketing studies to monitor the effect of approved products, and may limit further marketing of the product based on the results of these post-marketing studies.

Post-approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including manufacturing, periodic reporting, product sampling and distribution, advertising, promotion, drug shortage reporting, compliance with any post-approval requirements imposed as a conditional of approval such as Phase 4 clinical trials, REMS and surveillance, recordkeeping and reporting requirements, including adverse experiences.

After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any approved products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and to list their drug products, and are subject to periodic announced and unannounced inspections by the FDA and these state agencies for compliance with cGMPs and other requirements, which impose procedural and documentation requirements upon us and our third-party manufacturers.

Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented, or FDA notification. FDA regulations also require investigation and correction of any deviations from cGMPs and specifications, and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

Later discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in withdrawal of marketing approval, mandatory revisions to the approved labeling to add new safety information or other limitations, imposition of post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS program, among other consequences.

The FDA closely regulates the marketing and promotion of drugs. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA. Physicians, in their independent professional medical judgement, may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. We, however, are prohibited from marketing or promoting drugs for uses outside of the approved labeling.

In addition, the distribution of prescription pharmaceutical products, including samples, is subject to the Prescription Drug Marketing Act (PDMA), which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. The Drug Supply Chain Security Act also imposes obligations on manufacturers of pharmaceutical products related to product and tracking and tracing.

Failure to comply with any of the FDA's requirements could result in significant adverse enforcement actions. These include a variety of administrative or judicial sanctions, such as refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, imposition of a clinical hold or termination of clinical trials, warning letters, untitled letters, cyber letters, modification of promotional materials or labeling, product recalls, product seizures or detentions, refusal to allow imports or exports, total or partial suspension of production or distribution, debarment, injunctions, fines, consent decrees, corporate integrity agreements, refusals of government contracts and new orders under existing contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement or civil or criminal penalties, including

fines and imprisonment. It is also possible that failure to comply with the FDA's requirements relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws. Any of these sanctions could result in adverse publicity, among other adverse consequences.

Other Healthcare Laws and Regulations

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and use of medical products and drug formulations that are granted marketing approval. Arrangements with third-party payors, existing or potential customers and referral sources, including healthcare providers, are subject to broadly applicable fraud and abuse and other healthcare laws and regulations, and these laws and regulations may constrain the business or financial arrangements and relationships through which manufacturers conduct clinical research, market, sell and distribute the products for which they obtain marketing approval. Such restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or kind, in exchange for, or to induce, either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers and formulary managers, among others, on the other hand. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, PPACA) amended the intent requirement of the federal Anti-Kickback Statute. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to commit a violation. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;
- the federal false claims and civil monetary penalties laws, including the FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent, or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. Government enforcement agencies and private whistleblowers have investigated pharmaceutical companies for or asserted liability under the FCA for a variety of alleged promotional and marketing activities, such as providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees and other benefits to physicians to induce them to prescribe products; engaging in promotion for "off-label" uses; and submitting inflated best price information to the Medicaid Rebate Program. In addition, the PPACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act;
- HIPAA, which prohibits, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services (CMS) information related to payments and other transfers of value to physicians, certain other healthcare providers and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) and their respective implementing regulations, which impose, among other things, specified requirements relating to the security, privacy and transmission of individually identifiable health information held by entities subject to HIPAA, such as health plans, health care clearinghouses and certain healthcare providers, and their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on their behalf. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions; and
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; and state laws governing the privacy and security of health information in certain circumstances, state and local laws that require the registration of pharmaceutical sales and medical representatives; many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that certain business activities can be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws.

Violation of the laws described above or any other governmental laws and regulations may result in significant penalties, including civil, criminal, and administrative penalties, damages, fines, the curtailment or restructuring of operations, the exclusion from participation in federal and state healthcare programs, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, imprisonment, and additional reporting requirements and oversight if a manufacturer becomes subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws. Furthermore, efforts to ensure that business activities and business arrangements comply with applicable healthcare laws and regulations can be costly for manufacturers of branded prescription products.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any products, for which we may obtain regulatory approval, and the procedures utilizing such products. In the United States, sales of any product candidates for which regulatory approval for commercial sale is obtained will depend in part on the availability of coverage and adequate reimbursement from third-party payors for the approved products, and procedures which utilize such products. Third-party payors include government authorities and health programs in the United States such as Medicare and Medicaid, managed care providers, private health insurers and other organizations. These third-party payors are increasingly reducing reimbursements for medical products and services. The process for determining whether a payor will provide coverage for a product, or procedures which utilizes such product, may be separate from the process for setting the reimbursement rate that the payor will pay for the product, or procedures which utilize such product. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of FDA-approved products for a particular indication.

Additionally, the containment of healthcare costs has become a priority of federal and state governments. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of less expensive products and procedures. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results.

A payor's decision to provide coverage for a product, or procedures which utilize such product, does not imply that an adequate reimbursement rate will be approved. Further, coverage and reimbursement for products, and procedure which utilize such products, can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain coverage and reimbursement for any product that might be approved for sale, or any procedure which utilizes such product, it may be necessary to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the products, and procedures which utilize such products, in addition to the costs required to obtain regulatory approvals. If third-party payors do not consider a product, or procedures which utilize such product, to be cost-effective compared to other available therapies, they may not cover the product, or procedures which utilize such product, after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit.

The marketability of any product candidates for which we or our collaborators receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide coverage and adequate reimbursement for the product, or any procedure which utilizes such product. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on medical products and services pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we or our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. European Union Member States may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products, but monitor and control company profits. The downward pressure on health care costs has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations may not allow favorable reimbursement and pricing arrangements.

Health Reform

The United States and some foreign jurisdictions are considering or have enacted a number of reform proposals to change the healthcare system. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state legislative initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products as well as the procedures which utilize such products, especially under government-funded health care programs, and increased governmental control of health care costs.

By way of example, in March 2010, the PPACA was signed into law, which is intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the healthcare industry and impose additional health policy reforms. Among the provisions of the PPACA of importance to our business are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;

- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the PPACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the PPACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018 (BBA), among other things, amended the PPACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In addition, in April 2018, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the PPACA for plans sold through such marketplaces. More recently, in December 2018, CMS published a final rule permitting further collections and payments to and from certain PPACA qualified health plans and health insurance issuers under the PPACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the PPACA will impact the PPACA.

Other legislative changes have been proposed and adopted in the United States since the PPACA was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2012 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to certain providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating

power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The United States Department of Health and Human Services (HHS) has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. On January 31, 2019, the HHS Office of Inspector General, proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. Although a number of these and other proposals will require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Additionally, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservation and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern the use, handling and disposal of various biologic, chemical and radioactive substances used in, and wastes generated by, operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. Equivalent laws have been adopted in other countries that impose similar obligations.

U.S. Foreign Corrupt Practices Act

The FCPA prohibits U.S. corporations and individuals from engaging in certain activities to obtain or retain business or secure any improper advantage, or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any employee or official of a foreign government or public international organization, or political party, political party official, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. The scope of the FCPA also includes employees and official of state-owned or controlled enterprises, which may include healthcare professionals in many countries. Equivalent laws have been adopted in other foreign countries that impose similar obligations.

C. Organizational Structure

The following is a list of our subsidiaries:

Name	Country of Registration	Activity	Ownership Percentage
TLC Biopharmaceuticals, Inc.	United States	Active	100%
TLC Biopharmaceuticals B.V.	Netherlands	Active	100%
TLC Biopharmaceuticals, (H.K.) Limited	Hong Kong	Active	100%
TLC Biopharmaceuticals, (Shanghai) Limited	People's Republic of China	Active	100%*
TLC Biopharmaceuticals Pty Ltd.	Australia	Active	100%
TLC Biopharmaceuticals Japan Co., Ltd.	Japan	Active	100%

*100% owned through TLC Biopharmaceuticals, (H.K.) Limited.

D. Property, Plants and Equipment

Our principal office is located at 11F-1, No. 3 Yuanqu Street, Nangang District, Taipei City 11503, Republic of China and spans three floors with the details of each in the table below. We believe that our current facilities are adequate to meet our near-term needs, and that suitable additional or substitute space will be available as needed on commercially reasonable terms.

Lease Premises	Term	Aggregate Square Footage
Second Floor, No. 3 Yuanqu Street, Nangang District, Taipei	April 1, 2017 to March 31, 2022	21,710 square feet
Seventh Floor, No. 3 Yuanqu Street, Nangang District, Taipei	January 1, 2015 to April 30, 2020	21,347 square feet
Eleventh Floor, No. 3 Yuanqu Street, Nangang District, Taipei	June 1, 2015 to May 31, 2021	3,500 square feet

Item 4A. Unresolved Staff Comments

Not Applicable.

Item 5. Operating and Financial Review and Prospects

The following discussion and analysis of our financial condition and results of operations should be read together with Item 3.A. "Selected Consolidated Financial Data" and our consolidated financial statements and related notes appearing elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those set forth in the Item 3.D. "Risk Factors" section of this Annual Report, our actual results could differ materially from the results described in or implied by these forward-looking statements. Please also see the section titled "Cautionary Statement Regarding Forward-Looking Statements."

A. Operating Results

Overview

We are a clinical-stage specialty pharmaceutical company dedicated to the development and commercialization of novel nanomedicines that combine our proprietary lipid-assembled drug delivery platform with approved APIs. We believe that our extensive experience with liposome science allows us to combine onset speed and benefit duration, and to improve API concentrations at target tissues while decreasing unwanted systemic exposures. Our BioSeizer lipid formulation technology is designed to enable both local sustained release and fast onset of APIs at the site of disease or injury with increased PK control, made possible by customization of lipid layers. BioSeizer is utilized in our TLC599, TLC399 and TLC590 programs.

Our NanoX active drug loading technology is designed to alter the systemic exposure of the drug, enabling the potential for reduced dosing frequency, and enhanced distribution of liposome-encapsulated APIs to the desired site. We believe NanoX is capable of loading over 50 various compounds and is applied to our TLC178 program. Our technologies can be used with a broad range of APIs and enable a simplified and scalable manufacturing process. Because our product candidates use already approved APIs, we intend to utilize the streamlined 505(b)(2) regulatory pathway for approval in the United States, which would allow us to rely, in part, on data from investigations that we have not conducted or sponsored and for which we have not obtained a right of reference.

Since our inception in November 1997 in Taiwan, we have invested most of our resources in developing our product candidates, building our intellectual property portfolio, developing our supply chain, conducting business planning, raising capital and providing general and administrative support for these operations. Our principal executive office and substantially all of our assets are located in Taiwan. Our revenue to date has consisted primarily of (1) royalties from product sales by our third-party licensees of our generic products, which are approved for sale only in Taiwan and Southeast Asia, and (2) revenue received from our collaborators, including upfront payments and milestone payments. We do not currently have any approved products outside of Taiwan and Southeast Asia and have never generated any revenue from sales of our proprietary product candidates. To date, we have funded our operations through public and private placements of equity securities, royalties received from our third party licensees, upfront payments and milestone payments received from our collaborators, funding from governmental bodies and interest income from investments. Through December 31, 2018 we had raised gross proceeds of NT$5.9 billion (US$192.7 million) from private and public offerings of equity securities, received aggregate gross payments of NT$ 456.6 million (US$14.9 million)) from our collaborators, and received NT$ NT$157.7 million (US$5.2 million) in grants and incentives from governmental bodies related to our products and product candidates. Our common shares have been listed on TPEx since December 2012 and our ADSs have been listed on the NASDAQ Global Market since November 2018.

As of December 31, 2018, we had cash and cash equivalents of NT$807.5 million (US$26,380 thousand) and time deposits with maturity over three months of NT$307.2 million (US$10,034 thousand) (shown as "Current financial assets at amortized cost" in our consolidated financial statements). Since inception, we have incurred significant operating losses. Our net losses were NT$824.3 million (US$26,930 thousand), NT$874.0 million (US$28,552 thousand) and NT$901.6 million (US$29,454 thousand) for the years ended December 31, 2016, 2017 and 2018, respectively. For the year ended December 31, 2018, we had a total comprehensive loss of NT$902.8 million (US$29,495 thousand) and an accumulated deficit of NT$910.0 million (US$29,730 thousand). We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance preclinical activities, manufacturing activities and clinical trials of our product candidates. In addition, we have incurred and expect to continue to incur additional costs associated with operating as a public company in the United States. Our expenses will also increase as we:

- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure in anticipation of commercializing any product candidates for which we may obtain marketing approval and intend to commercialize on our own or jointly;
- hire additional clinical, medical and development personnel;
- expand our infrastructure and facilities to accommodate our growing employee base;
- continue to transition our organization from a Taiwan public company to additionally being a public company in the United States; and
- maintain, expand and protect our intellectual property portfolio.

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. If we receive regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution. Until such time, if ever, that we can generate product revenue sufficient to achieve profitability, we expect to finance our cash needs primarily through equity offerings and debt borrowings. Our future funding requirements will depend on and could increase significantly as a result of many factors.

Components of Our Results of Operations

Revenues

Our revenue to date has consisted primarily of (i) royalties from product sales by our third party licensees of our generic products, which are approved for sale only in Taiwan and Southeast Asia, and (ii) revenue received from our collaborators, including upfront payments, and milestone payments.

Sales-based royalty revenue

We have entered into contracts with customers pursuant to which we are entitled to a sales-based royalty in exchange for a license to manufacture and the right to sell our pharmaceutical products. In accordance with such contracts, we agree not to undertake any activities that would significantly affect the intellectual property to which the customer has rights. The purpose of such licenses is to provide a right to use our intellectual property and therefore the revenue is recognized when transferring the license to a customer at a point in time. We recognize revenue at the later of (i) when the performance obligation has been satisfied and (ii) when the subsequent sale occurs.

Authorization collaboration and development revenue

Our authorization collaboration and development transactions generally authorizes intellectual property rights of the drug products to pharmaceutical companies. Though we will continuously provide research and development services on the drug products, pharmaceutical companies could make use of the research and development outcome at any time. Pharmaceutical companies pay a non-refundable up-front payment upon signing of the contracts, and make milestone payments upon each milestone achieved. Based on our assessment, we use our proprietary drug delivery technologies to continue the research and development related services, which are unique such that pharmaceutical companies would have difficulty finding another service provider who offers the same services in terms of continuing research and development on the authorized drug products. The authorization and subsequent research and development services provided by us are bonded and highly interrelated and therefore not distinct and as such are accounted for as one performance obligation to be delivered over time. At the inception of an agreement that includes research and development milestone payments, we evaluate each milestone to determine when and how much of the milestone to be included in the transaction price. We first estimate the amount of the milestone payment that we could receive using the most likely amount approach. We primarily use the most likely amount approach as that approach is generally most predictive for milestone payments with a binary outcome. Then, we consider whether any portion of that estimated amount is subject to the variable consideration constraint (that is, whether it is probable that a significant reversal of cumulative revenue would not occur upon resolution of the uncertainty.) We update the estimate of variable consideration included in the transaction price at each reporting date which includes updating the assessment of the likely amount of consideration and the application of the constraint to reflect current facts and circumstances. The revenue is recognized based on the transaction price, excluding variable considerations considered not achievable, and the stage of completion, which is measured by the proportion of contract costs incurred for research and development services as of the financial reporting date to the estimated total research and development costs for the authorization collaboration and development contracts. As our inputs, including costs of Contract Research Organizations, Contract Manufacture Organizations, and medicines, which have direct relationship with the transfer of control of services to customers, we use the cost incurred method to measure progress towards complete satisfaction of a performance obligation. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

To date, we have not generated any revenue from non-generic product sales, which we believe to be our largest revenue opportunity, and do not expect to generate any such revenue in the near future. We will not be able to generate revenue from the sale of our proprietary product candidates unless and to the extent our development efforts are successful and result in regulatory approval.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the research and development of our product candidates. We expense research and development costs as incurred. These expenses include primarily:

- expenses incurred under agreements with CROs, CMOs, as well as investigative sites and consultants that conduct our clinical trials and preclinical studies and other scientific development services;
- manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical study and clinical trial materials;
- employee-related expenses, including salaries, benefits, travel and share-based compensation for employees engaged in research and development functions;
- costs related to compliance with regulatory requirements;

- facilities costs, depreciation and other expenses, which include rent and utilities; and
- fees for maintaining licenses under our third-party licensing agreements.

We also recognize external development costs upon completion of specific tasks using information provided to us by our service providers. We confirm the costs and make adjustments if necessary.

Our research and development expenses are tracked on a program-by-program basis for our product candidates. Our direct research and development expenses tracked by program consist primarily of external costs, such as fees paid to outside consultants, CROs, and CMOs in connection with our preclinical development, manufacturing and clinical development activities, as well as fees incurred under license agreements. We do not allocate employee costs or facility expenses, including depreciation or other indirect costs, to specific programs because these costs are deployed across multiple programs and, as such, are not separately presented. We use internal resources primarily to oversee research and discovery as well as for managing our preclinical development, process development, manufacturing and clinical development activities. These employees work across multiple programs and, therefore, we do not track their costs by program.

The table below summarizes our research and development expenses incurred by program for the periods presented:

	Year ended December 31,			
	2016	2017	2018	2018
	(in thousands)			
Research and development expense by technology:				
NanoX	NT$ 138,114	NT$ 133,143	NT$ 79,897	US$ 2,610
BioSeizer	127,004	240,603	388,508	12,692
Other	93,235	60,304	30,097	983
Indirect research and development expense:				
Employee benefit expense (including share-based compensation)	267,821	256,029	245,138	8,009
Other indirect research and development expense	110,704	123,173	88,935	2,906
Total research and development expense	NT$ 736,878	NT$ 813,252	NT$ 832,575	US$ 27,200

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect that our research and development expenses will increase substantially over the next several years as we conduct planned clinical trials, increase personnel costs and prepare for regulatory filings related to our product candidates. We also expect to incur additional expenses related to milestone and royalty payments and maintenance fees payable to third parties with whom we have entered into license agreements related to our product candidates.

The successful development and commercialization of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates or when, if ever, material net cash inflows may commence from any of our product candidates. This uncertainty is due to the numerous risks and uncertainties associated with development and commercialization, including the uncertainty of:

- the scope, progress, outcome and costs of our preclinical development activities, clinical trials and other research and development activities;
- establishing an appropriate safety profile with IND-enabling studies;
- successful patient enrollment in, and the initiation and completion of, clinical trials;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- development and timely delivery of commercial-grade drug formulations that can be used in our clinical trials and for commercial supply;

- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- significant and changing government regulation;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others; and
- maintaining a continued acceptable safety profile of our product candidates following any approval.

We may never succeed in achieving regulatory approval for any of our product candidates, including due to unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. Any changes in the outcome of any of these variables with respect to the development of our product candidates in preclinical and clinical development could mean a significant change in the costs and timing associated with the development of these product candidates. For example, if the FDA, EMA, or any other regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other development activities beyond those that we currently expect or if we experience significant delays in enrollment in any of our planned clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of the applicable product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits, travel and share-based compensation expense for personnel in executive, finance and administrative functions. General and administrative expenses also include professional fees for external legal, consulting, accounting and audit services.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates. We also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance, insurance and investor and public relations expenses associated with being a U.S. reporting company.

Other Income (Expense)

As a Taiwanese company that conducts extensive research and development activities, we benefit from various governmental subsidies. These subsidies generally aim to partly reimburse approved expenditures incurred in our research and development efforts. The ROC government has awarded us three subsidies in connection with our clinical development of TLC399 totaling NT$61,295 thousand in the aggregate. Of these awards, NT$41,495 thousand has been received to date. The remaining amounts are scheduled to be paid to us over the next two years based on preapproved project plans, subject to adjustment based on the progress of research and development activities. We also received a financial incentive of AU$593 thousand from the Australian government for our research and development activities in August 2018.

Government Subsidy Income

We recognize government subsidy income in accordance with our progress in TLC399 clinical development pursuant to our agreements with the Institute for Information Industry which are made on behalf of the MOEA. We also recognize government subsidy income from the Australian government for our research and development activities.

The government subsidies are credited to the income statement, under other operating income, when the relevant expenditure has been incurred and there is reasonable assurance that the grant or research and development incentive is receivable.

We have applied for additional subsidies related to our clinical development activities in Taiwan and Australia and we expect to continue applying for and using subsidies to support various research and development programs.

Non-operating Income and Expenses

Interest Income

Interest income consists of interest earned on cash held at banks mainly generated from our time deposit accounts.

Finance Costs

Other finance costs primarily consist of interest expense for bank borrowings and finance lease liabilities.

Other Gains and Losses

Other gains and losses consist primarily of net currency exchange gain.

Comparison of the Years Ended December 31, 2017 and 2018

The following table summarizes our results of operations for the years ended December 31, 2017 and 2018:

	Year ended December 31,				
	2017	2018	2018	Change	Change
			(in thousands)		
Operating revenue	NT$ 49,635	NT$ 62,324	US$ 2,036	NT$ 12,689	US$ 415
Operating expense					
General and administrative expenses	(134,869)	(147,743)	(4,827)	(12,874)	(421)
Research and development expenses	(813,252)	(832,575)	(27,200)	(19,323)	(631)
	(948,121)	(980,318)	(32,027)	(32,197)	(1,052)
Other income and expenses	21,148	26,228	857	5,080	166
Operating loss	(877,338)	(891,766)	(29,134)	(14,428)	(471)
Non-operating income and expenses:					
Interest income	5,060	2,453	80	(2,607)	(85)
Other gains and losses	2,652	(1,508)	(49)	(4,160)	(136)
Finance costs	(3,385)	(9,886)	(323)	(6,501)	(212)
Total non-operating income and expenses	4,327	(8,941)	(292)	(13,268)	(433)
Loss before income tax	(873,011)	(900,707)	(29,426)	(27,696)	(905)
Income tax expense	(951)	(867)	(28)	84	3
Net loss	(873,962)	(901,574)	(29,454)	(27,612)	(902)
Other comprehensive income (loss)					
Remeasurement arising on defined benefit plans	(124)	(527)	(17)	(403)	(13)
Financial statement translation differences of foreign operations	(3,396)	(727)	(24)	2,669	87
Total other comprehensive loss	(3,520)	(1,254)	(41)	2,266	74
Total comprehensive loss	NT$ (877,482)	NT$ (902,828)	US$ (29,495)	NT$ (25,346)	US$ (828)

Revenue

For the years ended December 31, 2017 and 2018, our revenues were NT$49.6 million and NT$62.3 million (US$2.0 million), respectively, primarily consisting of royalty revenues related to sales of our generic products by our third-party licensees. Among the increase of NT$12.7 million (US$0.4 million), NT$10.2 million (US$0.3 million) was the result of the adoption of IFRS 15 in January 2018, which was for the authorization and collaboration and development revenue recognized based on the transaction prices, which is measured by the portion of contract costs incurred for research and development costs.

Operating Income and Expenses

General and Administrative Expenses

For the years ended December 31, 2017 and 2018, our general and administrative expenses were NT$134.9 million and NT$147.7 million (US$4.8 million), respectively. The increase in general and administrative expenses year-over-year of NT$12.8 million (US$0.4 million) was primarily due to an increase in professional service expenses, mainly legal and advisory services in connection with our initial public offering.

Research and Development Expenses

For the years ended December 31, 2017 and 2018, our research and development expenses were NT$813.3 million and NT$832.6 million (US$27.2 million), respectively. The increase in research and development expenses year-over-year of NT$19.3 million (US$0.6 million) was primarily due to increased clinical trial activities and product candidate manufacturing activities in connection with the development of our product candidate pipeline.

Non-Operating Income and Expenses

For the years ended December 31, 2017 and 2018, non-operating income and expenses were income of NT$4.3 million and expenses of NT$8.9 million (US$0.3 million), respectively. The decrease in non-operating income and expenses year-over-year of NT$13.2 million (US$0.4 million) was primarily due to a decrease in interest income as a result of our lower cash and cash equivalents balance resulting from increased spending on clinical trial activities and product manufacturing activities in connection with the development of our product candidate pipeline, and an increase in interest expenses as a result of the Cathay Bank loan entered into in June 2018 and an increase in net currency exchange loss.

Total Other Comprehensive Loss

For the years ended December 31, 2017 and 2018, total other comprehensive losses were NT$3.5 million and NT$1.3 million (US$41 thousand), respectively. The decrease in total other comprehensive losses year-over-year of NT$2.2 million (US$74 thousand) was primarily due to lower foreign currency translation losses as a result of the translation of our assets, liabilities, and results of operations into NT dollars using the relevant foreign currency exchange rates.

Comparison of the Years Ended December 31, 2016 and 2017

The following table summarizes our results of operations for the years ended December 31, 2016 and 2017:

	Year ended December 31,				
	2016	2017	2017	Change	Change
			(in thousands)		
Operating revenue	NT$ 41,674	NT$ 49,635	US$ 1,675	NT$ 7,961	US$ 269
Operating expense					
General and administrative expenses	(141,494)	(134,869)	(4,550)	6,625	224
Research and development expenses	(736,878)	(813,252)	(27,438)	(76,374)	(2,577)
	(878,372)	(948,121)	(31,988)	(69,749)	(2,353)
Other income and expenses	5,575	21,148	713	15,573	525
Operating loss	(831,123)	(877,338)	(29,600)	(46,215)	(1,559)
Non-operating income and expenses:					
Interest income	9,893	5,060	171	(4,833)	(163)
Other gains and losses	417	2,652	90	2,235	75
Finance costs	(2,940)	(3,385)	(114)	(445)	(15)
Total non-operating income and expenses	7,370	4,327	147	(3,043)	(103)
Loss before income tax	(823,753)	(873,011)	(29,453)	(49,258)	(1,662)
Income tax expense	(563)	(951)	(32)	(388)	(13)
Net loss	(824,316)	(873,962)	(29,485)	(49,646)	(1,675)
Other comprehensive income (loss)					
Remeasurement arising on defined benefit plans	(346)	(124)	(4)	222	8
Financial statement translation differences of foreign operations	(857)	(3,396)	(115)	(2,539)	(86)
Total other comprehensive loss	(1,203)	(3,520)	(119)	(2,317)	(78)
Total comprehensive loss	NT$ (825,519)	NT$ (877,482)	US$ (29,604)	NT$ (51,963)	US$ (1,753)

Revenue

For the years ended December 31, 2016 and 2017, our revenues were NT$41.7 million and NT$49.6 million (US$1.7 million), respectively, primarily consisting of royalty revenues related to sales of our generic products by our third-party licensees. The increase in revenue year-over-year of NT$7.9 million (US$0.3 million) was primarily due to an increase in royalties derived from sales of our generic products by our third-party licensees.

Operating Expenses

General and Administrative Expenses

For the years ended December 31, 2016 and 2017, our general and administrative expenses were NT$141.5 million and NT$134.9 million (US$4.6 million), respectively. The decrease in general and administrative expenses year-over-year of NT$6.6 million (US$0.2 million) was primarily due to a decrease in share-based compensation expenses resulting from lower fair value of the granted shares calculated based on our stock price and fewer new grants in 2017.

Research and Development Expenses

For the years ended December 31, 2016 and 2017, our research and development expenses were NT$736.9 million and NT$813.3 million (US$27.4 million), respectively. The increase in research and development expenses year-over-year of NT$76.4 million (US$2.6 million) was primarily due to increased clinical trial activities and product candidate manufacturing activities in connection with the development of our product candidate pipeline.

Non-Operating Income and Expenses

For the years ended December 31, 2016 and 2017, non-operating income and expenses were NT$7.4 million and NT$4.3 million (US$0.1 million), respectively. The decrease in non-operating income and expenses year-over-year of NT$3.1 million (US$0.1 million) was primarily due to a decrease in interest income as a result of our lower cash and cash equivalents balance resulting from increased spending on clinical trial activities and product manufacturing activities in connection with the development of our product candidate pipeline.

Total Other Comprehensive Loss

For the years ended December 31, 2016 and 2017, total other comprehensive losses were NT$1.2 million and NT$3.5 million (US$0.1 million), respectively. The increase in total other comprehensive losses year-over-year of NT$2.3 million (US$0.1 million) was primarily due to foreign currency translation losses as a result of the translation of our assets, liabilities, and results of operations into NT dollars using the relevant foreign currency exchange rates.

B. Liquidity and Capital Resources

Since our inception in 1997, we have invested most of our resources in developing our product candidates, building our intellectual property portfolio, developing our supply chain, conducting business planning, raising capital and providing general and administrative support for these operations. We do not currently have any approved products outside of Taiwan and Southeast Asia and have never generated any revenue from sales of our proprietary product candidates. To date, we have funded our operations through public and private placements of equity securities, royalties received from our third-party licensees, upfront payments and milestone payments received from our collaborators, funding from governmental bodies and interest income from investments. Through December 31, 2018, we had raised gross proceeds of NT$5.9 billion (US$192.7 million) from private and public offerings of equity securities, received aggregate gross payments of NT$ 456.6 million (US$14.9 million) from our collaborators, and received NT$ NT$157.7 million (US$5.2 million) in grants and incentives from governmental bodies related to our products and product candidates.

We entered into a loan and security agreement (First LSA) on June 14, 2018 with Cathay Bank (Cathay). Pursuant to the First LSA, we borrowed an aggregate of $12.0 million. On November 1, 2018, we repaid the $12.0 million outstanding under the First LSA, plus $57 thousand in accrued interest, and the First LSA was terminated.

We entered into a second LSA (Second LSA) on December 27, 2018 with Cathay. Pursuant to the Second LSA, we borrowed an aggregate of $12.0 million. As of December 31, 2018, NT$367.3 million (US$12.0 million) was outstanding under the Second LSA. Amounts borrowed under the facility can be prepaid at any time, without penalty, prior to the June 30, 2020 maturity date, at which time all amounts borrowed will be due and payable. No amounts repaid can be re-borrowed. The terms of the Second LSA require us to begin making 12 equal monthly payments of principal plus accrued interest on July 31, 2019. The Cathay loan currently bears interest at the floating rate of prime. The Cathay loan is secured by a lien covering substantially all of our assets, but excluding our intellectual property (except rights to payment from the sale, licensing or disposition of such intellectual property).

On March 1, 2019, we entered into a commercialization agreement with Hong Kong Sansheng Medical Limited (3SBio) to commercialize two liposomal products utilizing our NanoX technology platform in mainland China, excluding Hong Kong and Macau (Territory). Under the terms of the agreement, we have received an upfront payment in March 2019 and are eligible to receive further development and sales milestones for a total of up to $25 million. In addition, we are also eligible to receive double-digit profit shares from the potential sales of products. We and 3SBio will be jointly responsible for obtaining regulatory approvals for the products in the Territory. We will manufacture the products on our own cost. 3SBio will be responsible for importing, promoting, marketing, selling and distributing the products in the Territory at its own responsibilities and expenses.

Cash Flows

The following table summarizes our cash flows for each of the periods presented:

	Year ended December 31,			
	2016	2017	2018	2018
		(in thousands)		
Net cash used in operating activities	NT$ (607,719)	NT$ (819,139)	NT$ (686,039)	US$ (22,414)
Net cash used in investing activities	(15,678)	(29,491)	(368,764)	(12,046)
Net cash provided by financing activities	38,412	4,484	911,713	29,785
Effect on foreign currency exchange	(742)	(2,941)	(1,139)	(37)
Net decrease in cash and cash equivalents	NT$ (585,727)	NT$ (847,087)	NT$ (144,229)	US$ (4,712)

Net Cash Used in Operating Activities

Operating activities used NT$607.7 million, NT$819.1 million and NT$686.0 million (US$22.4 million) of cash in the years ended December 31, 2016, 2017 and 2018, respectively. The net cash used in operating activities for each year related to increased payments for clinical trial activities and product candidate manufacturing activities in connection with the development of our product candidate pipeline.

Net Cash Used in Investing Activities

Investing activities used NT$15.7 million, NT$29.5 million and NT$368.8 million (US$12.0 million) of cash in the years ended December 31, 2016, 2017 and 2018, respectively. The net cash used in investing activities for each period mainly related to the acquisition of current financial assets at amortized cost and the purchases of property, plant and equipment.

Investing activities used NT$15.7 million of cash in 2016. The net cash used in investing activities for the year related to investing activities for the purchases of property, plant and equipment of NT$21.4 million, offset in part by a decrease in refundable deposits of NT$7.4 million.

Investing activities used NT$29.5 million (US$1.0 million) of cash in 2017. The net cash used in investing activities for the year related to the purchases of property, plant and equipment of NT$18.1 million (US$0.6 million) and intangible assets of NT$7.2 million (US$0.2 million) and an increase in refundable deposits of NT$6.0 million (US$0.2 million).

Investing activities used NT$368.8 million (US$12.0 million) of cash in 2018. The net cash used in investing activities for the year related to the acquisition of current financial assets at amortized cost of NT$307.2 million (US$10.0 million) and the purchases of property, plant and equipment of NT$66.7 million (US$2.2 million) and intangible assets of NT$3.1 million (US$0.1 million), offset in part by a decrease in refundable deposits of NT$8.3 million (US$0.3 million).

Net Cash Provided by Financing Activities

Our net cash flows from financing activities increased from NT$38.4 million, NT$4.5 million to NT$911.7 million (US$29.8 million) for the years ended December 31, 2016, 2017 and 2018, respectively.

During the year ended December 31, 2016, net cash provided by financing activities consisted of net cash proceeds of NT$38.4 million from our sale and issuance of common shares from treasury stock to our employees of NT$37 million.

During the year ended December 31, 2017, net cash provided by financing activities consisted primarily of net cash proceeds of NT$5.0 million (US$0.2 million) from the issuance of restricted stock to our employees.

During the year ended December 31, 2018, net cash provided by financing activities consisted primarily of net cash proceeds of NT$550.9 (US$18.0 million) from the result of our November 2018 underwritten global offering, which included the issuance of ADSs.

Credit Arrangements

We entered into a long-term loan contract with Taiwan Cooperative Bank in September 2015 in the amount of NT$37.8 million with a 1.85% interest rate (fixed interest rate through September 1, 2018, after which it becomes the minimum interest rate). The contract period is from September 2015 to September 2035. Interest is payable monthly for the first three years and payable monthly with an equal amount of principal starting in the fourth year. On December 31, 2018, NT$37.3 million (US$1.2 million) was outstanding under the agreement.

Also in September 2015, we entered into a mid-term loan contract with Taiwan Cooperative Bank in the amount of NT$34.0 million with a floating interest rate initially set at 1.98%. As of December 31, 2016, 2017 and 2018, the applicable interest rates were 1.95%, 1.85% and 1.85%, respectively. The contract period is from September 2015 to September 2022. Interest is payable monthly for the first two years and payable semiannually with 5% of the principal beginning in September 2017. The remaining 50% of the principal is due at maturity. Both the long-term loan contract and the mid-term loan contract provided certain of our land and buildings as collateral. On December 31, 2018, NT$28.9 million (US$0.9 million) was outstanding under the agreement.

On November 2, 2017, we entered into a short-term loan contract with Taiwan Cooperative Bank in the amount of NT$16.0 million (US$0.5 million) with a 1.95% interest rate. The contract period is from December 28, 2018 to December 28, 2019. Interest is payable monthly. On December 31, 2018, NT$16.0 million (US$0.5 million) was outstanding under the agreement.

On December 2, 2016, we entered into a credit agreement with E. Sun Bank for a NT$30.0 million (US$1 million) revolving line of credit with a 2.1% interest rate. The line of credit is available to January 16, 2020 and is fully utilized as of December 31, 2018. Interest is payable monthly. On December 31, 2018, NT$30.0 million (US$1 million) was outstanding under the agreement.

On June 14, 2018, we entered into the First LSA with Cathay for $12.0 million. We repaid the $12.0 million outstanding under the First LSA, including all $57 thousand of accrued interest, on November 1, 2018 and the First LSA was terminated.

We entered into the Second LSA on December 27, 2018 with Cathay. Pursuant to the Second LSA, we borrowed an aggregate of $12.0 million. Amounts borrowed under the facility can be prepaid at any time, without penalty, prior to the June 30, 2020 maturity date, at which time all amounts borrowed will be due and payable. No amounts repaid can be re-borrowed. The terms of the Second LSA require us to begin making 12 equal monthly payments of principal plus accrued interest on July 31, 2019. The Cathay loan currently bears interest at the floating rate of prime. The Cathay loan is secured by a lien covering substantially all of our assets, but excluding our intellectual property (except rights to payment from the sale, licensing or disposition of such intellectual property). Under the Second LSA, Cathay has the right to demand, among other

things, that we repay the outstanding loan early if we violate either of the following two covenants: (i) maintain an adjusted quick ratio (Adjusted Quick Ratio) of at least 2.25 to 1.00 and (ii) maintain an adjusted tangible net worth (Adjusted Tangible Net Worth) no less than US$12 million as of the last day of each quarter on a consolidated basis. Adjusted Quick Ratio means a ratio of cash and cash equivalents plus net trade receivables to the amount of principal payments owing to Cathay under this contract for the next 12 months plus all other current liabilities. Adjusted Tangible Net Worth means the difference between the value of our capital stock, partnership interests, or limited liability company interests, minus intangible assets, plus deferred revenue. We were in compliance with our loan covenants as of December 31, 2018 and March 31, 2019. On April 25, 2019, we entered into an amendment to the Second LSA with Cathay, pursuant to which the applicability of the above-mentioned loan covenants was deferred until September 30, 2019 (and tested as of the last day of each quarter going forward).

Funding Requirements: Plan of Operation

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance preclinical activities, manufacturing activities and clinical trials of our product candidates. In addition, we expect to continue to incur additional costs associated with operating as a public company in the United States. Our expenses will also increase as we:

- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure in anticipation of commercializing any product candidates for which we may obtain marketing approval and intend to commercialize on our own or jointly;
- hire additional clinical, medical and development personnel;
- expand our infrastructure and facilities to accommodate our growing employee base;
- transition our organization from a Taiwan public company to additionally being a public company in the United States; and
- maintain, expand and protect our intellectual property portfolio.

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. If we receive regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including:

- the scope, progress, outcome and costs of our preclinical development activities, clinical trials and other research and development activities;
- the costs, timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- the costs of future activities, including sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- additional revenue, if any, received from royalties on product sales of our generic products, licensing payments and government subsidies, as well as product sales from our proprietary product candidates, should any of our product candidates receive marketing approval;
- the costs and timing of hiring new employees to support our continued growth;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- whether we are required to repay any amounts received under government subsidies or repay our outstanding indebtedness on an accelerated basis; and
- the extent to which we acquire additional products, product candidates or technologies.

Until such time, if ever, that we can generate product revenue sufficient to achieve profitability, we expect to finance our cash needs primarily through equity offerings and debt borrowings. To the extent that we raise additional capital through the sale of equity or convertible debt, your ownership interest will be diluted. If we raise additional funds through other third-party funding, collaboration agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. Additional debt financing, if available, would result in additional debt service obligations and the instruments governing such debt could provide for operating and financing covenants that would restrict our operations. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with IFRS, as issued by the IASB. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 4 to our consolidated financial statements appearing at the end of this Annual Report, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Share-Based Compensation

We recognize compensation expense for equity awards based on the grant date fair value of the award, and expenses are recognized as compensation cost over the vesting period, with a corresponding adjustment to equity. The fair value of the equity instruments granted reflects the impact of market vesting conditions and non-market vesting conditions. Compensation cost is subject to adjustment based on the service conditions that are expected to be satisfied and the estimates of the number of equity instruments that are expected to vest under the non-market vesting conditions at each balance sheet date. Ultimately, the amount of compensation cost recognized is based on the number of equity instruments that eventually vest. The grant date fair value of restricted share awards is calculated based on the grant date fair value of the underlying common shares, and is recognized as compensation cost over the vesting period. Our common shares are currently listed in the ROC public market on TPEx and the fair value of our common shares is determined based on the closing price of our common shares as reported on the date of grant. We set the date when employees signed the agreement as the grant date of restricted share awards. For restricted shares where employees have to pay to acquire those shares, if employees resign during the vesting period, they must return the shares that have not met the vesting conditions to us, and we must refund their payments on the shares. We recognize the payments from the employees who are expected to resign during the vesting period as liabilities at the grant date, and recognize the payments from the employees with respect to shares that are expected to eventually vest in capital surplus.

JOBS Act

The JOBS Act provides that, among other things, an EGC can take advantage of an extended transition period for complying with new or revised accounting standards. As an EGC, we have irrevocably elected not to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards and, as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth public companies.

In addition, we intend to rely on the other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, we are entitled to rely on certain exemptions as an EGC. We are not required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b), (ii) provide all of the compensation disclosure that may be required of non-emerging growth

public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (including critical audit matters), and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation. These exemptions will apply until December 31, 2023 or until we no longer meet the requirements of being an EGC, whichever is earlier.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 3, "Application of new standards, amendments and interpretations," to our consolidated financial statements and related notes appearing elsewhere in this Annual Report.

C. Research and Development, Patents and Licenses, etc.

Full details of our research and development activities and expenditures are given in "Item 4.B. Information on the Company - Business Overview" and "Item 5.A. Operating Results" within this Annual Report.

D. Trend Information

See "Item 5.A. Operating Results" and "Item 5.B. Liquidity and Capital Resources" within this Annual Report.

E. Off Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

F. Tabular Disclosure of Contractual Obligations

The tables below summarize our contractual obligations as of December 31, 2018:

	Payments due by period less than				
	Total	1 year	1–3 years	3–5 years	More than 5 years
	(in thousands of NT$)				
Operating lease commitments	78,102	31,787	46,315	—	—
Capital lease obligations	48,781	24,583	24,198	—	—
Debt obligation	515,543	129,625	331,279	24,210	30,429
Total	642,426	185,995	401,792	24,210	30,429

	Payments due by period less than				
	Total	1 year	1–3 years	3–5 years	More than 5 years
	(in thousands of US$)				
Operating lease commitments	2,551	1,038	1,513	—	—
Capital lease obligations	1,594	803	791	—	—
Debt obligation	16,843	4,235	10,823	791	994
Total	20,988	6,076	13,127	791	994

The commitment amounts in the table above are associated with contracts that are enforceable and legally binding and that specify all significant terms, including fixed or minimum services to be used, fixed, minimum or variable price provisions and the approximate timing of the actions under the contracts. The table does not include obligations under agreements that we can cancel without a significant penalty.

We have received governmental subsidies, portions of which may need to be repaid if subsequent government audits reveal inconsistencies between the approved project plans and our actual research and development expenditures. We do not believe that any material amounts we have received to date pursuant to these subsidies would be required to be repaid and, accordingly, have not included them in the table above.

G. Safe Harbor

This Annual Report on Form 20-F contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act and as defined in the Private Securities Litigation Reform Act of 1995. See the section titled "Cautionary Statement Regarding Forward-Looking Statements" at the beginning of this Annual Report.

Item 6. Directors, Senior Management and Employees

A. Directors and Senior Management

The following table sets forth information regarding our executive officers and directors, including their ages as of April 22, 2019.

Name	Age	Position(s)
Executive Officers:		
Keelung Hong, Ph.D.	76	Chief Executive Officer, Founder and Chairman
George Yeh, M.B.A.	47	President
Nicole Lin, M.B.A.	53	Vice President in Finance and Administration
Yunlong Tseng, Ph.D.	53	Vice President, Research & Development
Wenji Chen, Ph.D., M.B.A	60	Vice President, Corporate Development
Hungwei Chih, Ph.D.	47	Vice President of Manufacturing Development
George Spencer-Green, M.D., M.S.	72	Chief Medical Officer
Non-Executive Directors:		
Hong-Jen Chang, M.D. (representing Taiwan Global Biofund)	63	Director
Shieh-Shung Tom Chen, Ph.D.	68	Director
Anupam Dalal, M.D., M.B.A. (representing Burrill Life Sciences Capital Fund III, L.P.)	47	Director
May Kang, M.B.A.	48	Director
Chan Yu Lee (representing Chang Xiang Investment Company, Ltd.).	47	Director
Moun-Rong Lin, M.B.A.	64	Director
Beatrice Liu, Ph.D.	54	Director

Executive Officers

Keelung Hong, Ph.D. Dr. Hong founded TLC in 1997 and has served as our Chairman of the board of directors since 2002 and Chief Executive Officer since 2005. Prior to serving as CEO, Dr. Hong served as our Science and Technology Adviser from 1997 to 2004. Dr. Hong co-founded Hermes Biosciences, Inc. and served as its Chief Scientific Officer from 1999 to 2005. Before venturing into the world of drug development, Dr. Hong was a Research Scientist for the California Pacific Medical Center Research Institute from 1998 to 2002, prior to which he was a Scientist at the Liposome Research Laboratory at the Cancer Research Institute of the University of California, San Francisco from 1979 to 1998. Dr. Hong has also served as consultant to various biopharmaceutical companies over the years. Dr. Hong received a Ph.D. in Chemistry from the University of California, Berkeley, an M.S. in Chemistry from the University of Texas at El Paso, and a B.S. in Chemistry from Taiwan Cheng Kung University.

George Yeh, M.B.A. Mr. Yeh has served as the President of TLC since 2002. Prior to joining TLC, Mr. Yeh was Vice President of AsiaWired Group, Inc., a venture advisory company, from 1999 to 2002. Before AsiaWired Group, Mr. Yeh was an associate at General Bank, a U.S.-based commercial bank. Mr. Yeh also served as the Chief Financial Officer of Hermes Biosciences, Inc. from 2002 to 2005, where he first started working alongside Dr. Keelung Hong. Mr. Yeh received a Master of Architecture and an M.B.A. from the University of Michigan. He received a B.A. in Architecture from the University of California, Berkeley.

Nicole Lin, M.B.A. Ms. Lin has served as our Vice President in Finance and Administration since 2014. Prior to that, Ms. Lin served as our Director and controller from 2005 to 2013. Before joining us, Ms. Lin served as Accounting Supervisor at MaLab Inc., a computer component distributor, in 2004. Before that, Ms. Lin served as Accounting Manager at NextGen Communications, a high-technology start up, from 2001 to 2004. Ms. Lin obtained finance and banking experience when she served as Commercial Loan Officer within the High Tech/Venture Division of General Bank, a U.S.-based commercial bank, from 1998 to 2001. Ms. Lin served as Security Underwriter at Taiwan Securities Co., Ltd., a securities firm, from 1995 to 1998, and at Rick Chen CPA Firm from 1990 to 1995. Ms. Lin received her M.B.A from the University of California, Riverside and her Bachelors in International Trade from Soochow University in Taipei, Taiwan. She is a U.S. Certified Public Accountant.

Yunlong Tseng, Ph.D. Dr. Tseng has served as our Vice President of Research and Development since January 2014. Prior to holding that position, Dr. Tseng was our Director of Research and Development from 2002 to December 2013. Prior to joining TLC, Dr. Tseng conducted his postdoctoral research at the Department of Oncology at National Taiwan University Hospital. Dr. Tseng received a Ph.D. in Biochemistry from National Taiwan University, College of Medicine, and a B.S. in Chemistry from Tamkang University, Taiwan.

Wenji Chen, Ph.D., M.B.A. Dr. Chen has served as our Vice President of Corporate Development since October 2016. Before joining TLC, Dr. Chen was the Vice President of Industrial Promotion at the Development Center of Biotechnology in Taiwan from January 2016 to August 2016. Prior to that, Dr. Chen was Senior Director of Worldwide Business Development at GlaxoSmithKline China R&D Co., Ltd. in Shanghai, China from 2010 to December 2015. Dr. Chen served as Director of Worldwide Business Development at GlaxoSmithKline LLC in the Research Triangle Park facility in North Carolina from 2006 to 2010 and Business Development Director at Norak Biosciences Inc., a biotechnology firm, from 2002 to 2005. From 1992 to 2002, Dr. Chen was a principle investigator in the Research and Development Division of GlaxoSmithKline in the Research Triangle Park facility in North Carolina. Dr. Chen received a Ph.D. from the University of Texas Southwestern Medical Center, an M.B.A. from the University of North Carolina, Chapel Hill, and a B.S. from National Taiwan University, Taipei, Taiwan.

Hungwei Chih, Ph.D. Dr. Chih has served as our Vice President of Manufacturing Development since July 2018. Prior to joining TLC, Dr. Chih served as the Director of IMP Product Quality at Genentech, Inc., a subsidiary of the Roche Group (Genentech/Roche) in South San Francisco from October 2015 to June 2018. Dr. Chih served various other roles at Genentech/Roche, including Associate Director of Late Stage Pharmaceutical Development from 2013 to October 2015, Senior Manager of Pharma Technical Regulatory from 2011 to 2013, Senior Scientist and Group Leader from 2010 to 2011 and Scientist from 2005 to 2010. Before Genentech/Roche, Dr. Chih was a Scientist at ImmunoGen, Inc. from February 2003 to April 2005 and an Investigator at ArQule, Inc. from October 2001 to February 2003, both in Massachusetts. Dr. Chih received his Ph.D. in Chemistry from the University of Michigan, where he received an Outstanding Graduate Research Award, and his B.S. in Chemistry from the National Sun Yat-Sen University.

George Spencer-Green, M.D., M.S. Dr. Spencer-Green has served as our Chief Medical Officer since January 2019. Prior to joining TLC, Dr. Spencer-Green served as the prior Vice President and clinical head of Pfizer's biosimilars development program from 2012 to 2015, where he led the team that designed and initiated clinical development plans from Phase 1 to Phase 3 for five assets. Prior to Pfizer, Dr. Spencer-Green served as the Senior Medical Director at Vertex Pharmaceuticals, Inc. from 2007 to 2011, where he led the design and execution of clinical development programs in rheumatoid arthritis and cystic fibrosis. Prior to Vertex, Dr. Spencer-Green was the Global Medical Director at Abbott Laboratories from 2002 to 2005, and was the clinical lead for the rheumatoid arthritis registration and long-term extension programs for Humira. Prior to Abbot Laboratories, Dr. Spencer-Green was Franchise Medical Director at Immunex Corporation from 1998 to 2002 for Enbrel, the first targeted biologic treatment approved for the treatment of rheumatoid arthritis. Dr. Spencer-Green served as Associate Professor of Medicine at University of Washington Medical School, Dartmouth Medical School and University of Cincinnati Medical Center. Dr. Spencer-Green received his B.A. from Oberlin College in Oberlin, Ohio, his M.D. from Columbia University College of Physicians and Surgeons in New York, New York, and his M.S. in Clinical Evaluative Science from Dartmouth College in Hanover, New Hampshire.[1]

Non-Executive Directors

Hong-Jen Chang, M.D. (representing Taiwan Global Biofund). Taiwan Global Biofund has served as a member of our board of directors since June 2007. Dr. Chang has served as Taiwan Global Biofund's representative to our board of directors since June 2007. Dr. Chang is the Chief Executive Officer and President of Taiwan Global Biofund, a venture capital fund, as well as the Chairman and Chief Executive Officer of YFY Biotech Management Company, a biotechnology consulting firm. He has held both positions since 2005. Dr. Chang serves as director to several publicly traded companies on the TPEx, including Excelsior Biopharma Inc., Taigen Biopharmaceuticals Holdings Limited, Mycenax Biotech Inc. and Twi Biotechnology, Inc., all of which are biopharmaceutical companies. Dr. Chang served at the Taiwan Department of Health as Deputy Minister from June 2004 to October 2004, as President and Chief Executive Officer of the Bureau of National Health Insurance from 2001 to 2004, and Director General of the Center of Disease Control from 1999 to 2000. Dr. Chang received an M.D. from National Yang-Ming Medical College, an M.S. in Public Health from National Taiwan University, and an M.S. of Health Policy and Management from the Harvard School of Public Health.

Shieh-Shung Tom Chen, Ph.D. Dr. Tom Chen has served as a member of our board of directors since May 2017. He served as vice president at Optimer Biotechnology Inc. from 2005 until he retired in October 2009. Prior to that, Dr. Tom Chen served as the head of the drug development program at the Development Center for Biotechnology in Taiwan from 2002 to 2005. Before that, Dr. Tom Chen held the roles of Senior Microbiologist, Research Fellow, and Senior Investigation in drug discovery and development programs at Merck Research Laboratories between 1981 and 2001. Dr. Tom Chen received a Ph.D. in Medicinal Chemistry from Purdue University, and a B.S. in Chemistry from National Tsing Hua University, Taiwan.

Anupam Dalal, M.D., M.B.A. (representing Burrill Life Sciences Capital Fund III, L.P.). Burrill Life Sciences Capital Fund III, L.P. has served as a member of our board of directors since June 2009. Dr. Dalal has served as Burrill Life Sciences Capital Fund III, L.P.'s representative to our board of directors since September 2017. is currently Chief Investment Officer at Acuta Capital Partners, LLC, an investment management services firm. Prior to joining Acuta Capital Partners, LLC in August 2016, Dr. Dalal was the Managing Director of Kearny Venture Partners, a healthcare investment firm, from 2006 to July 2016. Dr. Dalal founded and was a managing member of KVP Capital GP, LLC, a venture capital firm, from April 2013 to July 2016, and was a principal at Flagship Pioneering, a private equity and venture capital firm, from 2002 to 2006. Dr. Dalal also serves on the board of directors of Aerpio Pharmaceuticals, Inc. (formerly Aerpio Therapeutics, Inc.), a publicly traded biopharmaceutical company. Dr. Dalal received an M.D. from the University of California, San Francisco, an M.B.A. from Harvard Business School, and a B.A. in Economics from the University of California, Berkeley.

May Kang, M.B.A. Ms. Kang has served as a member of our board of directors since 2012. Ms. Kang is currently the Chairman at Fun-I Investment Co., where she has held the position since 2012. Ms. Kang serves as Chief Executive Officer of Lafresh Information Technology Co., and as director of Lafresh Informaiton Technology and IF Technology Company Co. Ms. Kang served as Chief Executive Officer of IF Technology Company Co. from November 2013 to December 2016. Prior to that, Ms. Kang served as the general manager at Waterland Securities Co. Ltd, a brokerage company, from 2006 to 2011. Before that, Ms. Kang served as Vice President at Yuanta SITC (Yuanta Funds), an asset management company, from 2002 to 2006, and as Chief Investment Officer with Yuanta Securities Co. Ltd., a finance service company, from 1993 to 2006. Ms. Kang received an M.B.A. from National Taiwan University, and a B.Com. in International Trade from National Taiwan University.

Chan Yu Lee (representing Chang Xiang Investment Company, Ltd.). Chang Xiang Investment Company, Ltd. has served as a member of our board of directors since June 2014. Mr. Lee has served as Chang Xiang Investment Company, Ltd.'s representative to our board of directors since June 2014. Prior to that, Mr. Lee was self employed in financial investments from April 2012 to May 2014. Mr. Lee received an M.S. in Actuarial Science from the University of Iowa. Mr. Lee has an M.S. in Finance from Seattle University and a B.A. from Tamkang University in Taiwan.

Moun-Rong Lin, M.B.A. Mr. Lin has served as a member of our board of directors since May 2017. Mr. Lin is the Chairman at Nan Hsin Investment Limited Company, an investment firm, where he has held the position since 2001. Prior to that, Mr. Lin served as President of H&Q Taiwan Co., Ltd., an investment firm, from 1995 to 1999, whilst concurrently serving as a managing director of H&Q Asia Pacific, a private equity firm and the parent company of H&Q Taiwan Co., Ltd. From 1987 to 1995, Mr. Lin served in various investment positions from manager to vice president at H&Q Taiwan Co., Ltd. Mr. Lin received an M.B.A from National Chiao Tung University and a B.S. degree from National Taiwan University.

Beatrice Liu, Ph.D. Dr. Liu has served as a member of our board of directors since June 2011. Dr. Liu is currently a partner at BDO Taiwan, an accounting firm, where she has held the position since August 1991. Dr. Liu is also the director at Genovate Biotechnology Co., Ltd., where she has held the position since June 2017. Dr. Liu also serves as the director of the National Federation of Certified Public Accountants Association, ROC and is a member of the American Institute of Certified Public Accounts. Dr. Liu received a Ph.D. in Accounting from Xiamen University, an M.A. in Accounting from the University of Illinois at Urbana-Champaign, and a B.S. in Taxation from National Cheng-Chi University.

Family Relationships

There are no family relationships among any of our executive officers or directors.

B. Compensation.

The following discussion provides the amount of compensation paid, and benefits in-kind granted, by us and our subsidiaries to our directors, executive officers and non-employee directors for services in all capacities to us and our subsidiaries for the year ended December 31, 2018, as well as the amount contributed by us or our subsidiaries into money purchase plans for the year ended December 31, 2018 to provide pension, retirement or similar benefits to, our directors, executive officers and non-employee directors.

For the year ended December 31, 2018, the aggregate compensation accrued or paid to the members of our board of directors and our executive officers for services in all capacities was $49,844,373.

During the year ended December 31, 2018, we had no performance based compensation programs. The amount set aside or accrued by us to provide pension, retirement or similar benefits to members of our board of directors or executive officers amounted to a total of $781,505 in the year ended December 31, 2018.

During the year ended December 31, 2018, we granted options to purchase an aggregate of 222,500 ADSs under our 2018 Employee Stock Option Issuance and Share Subscription Plan (2018 Plan), to our directors and executive officers. All such options had a weighted average exercise price of $100.59 and have an expiration date of five years from the grant date. As of December 31, 2018, members of our board of directors or executive officers held options to purchase an aggregate of 369,500 ADSs. No options were exercised by any members of our board of directors or executive officers during the year ended December 31, 2018.

Executive Officer Compensation

Our executive officers were awarded or earned the following compensation for the year ended December 31, 2018 for serving as our executive officers:

Name and Principal Position	Year	Salary (NT$)	Bonus (NT$)	Stock Award(1) (NT$)	Option Award(2) (NT$)	All Other Compensation (NT$)	Total (NT$)
Keelung Hong *Chief Executive Officer*	2018	8,673,633			3,432,360	171,349(3)	12,277,342
George Yeh *President*	2018	7,454,198			3,432,360	232,456(4)	11,119,014
Yunlong Tseng *Vice President, Research & Development*	2018	3,630,140			2,231,034	108,000(5)	5,969,174
Nicole Lin *Vice President in Finance and Administration*	2018	4,467,080			2,231,034	108,000(5)	6,806,114
Wenji Chen *Vice President, Corporate Development*	2018	4,785,810			1,716,180	108,000(5)	6,609,990
Hungwei Chih *Vice President in Manufacturing*	2018	2,883,129		1,850,000	2,275,910	53,700(5)	7,062,739

(1) Amounts reported represent the aggregate grant date fair value of restricted stock granted to the executive officer during fiscal year ended December 31, 2018 under our 2017 Regulations on the Issuance of New Employee Restricted Stock (2017 RS Regulations) computed in accordance with IFRS 2. The valuation assumptions used in calculating the fair value of the restricted stock is set forth in "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Estimates—Share-based Compensation." This amount does not reflect the actual economic value that may be realized by the executive officer.

(2) Amounts reported represent the aggregate grant date fair value of stock option granted to the executive officer during fiscal year ended December 31, 2018 under our 2018 Plan computed in accordance with IFRS 2. The valuation assumptions used in calculating the fair value of the stock option is set forth in "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Estimates—Share-based Compensation." This amount does not reflect the actual economic value that may be realized by the executive officer.

(3) Includes contributions paid by us to the executive officer's U.S. 401(k) plan.

(4) Includes (a) NT$124,456 paid by us to Mr. Yeh's U.S. 401(k) plan and (b) NT$108,000 contributed by us to Mr. Yeh's pension account.

(5) Includes contributions by us to the executive officer's pension account.

Equity Awards

During the fiscal year ending December 31, 2018, our board of directors issued the following shares of restricted stock to our executive officers pursuant to our 2017 RS Regulations:

Name	Issuance Date	Number of Shares of Restricted Stock	Purchase Price Per Share (NT$)	Vesting Conditions
Hungwei Chih, Ph.D.	July 2, 2018	20,000	10.00	(1)

(1) 20% of the restricted stock vests on the first anniversary of the issuance date, 30% of the restricted stock vests on the second anniversary of the issuance date and 50% of the restricted stock vests on the third anniversary of the issuance date, subject to continued service through each vesting date without violation of the rules set forth in the individual's employment agreement.

Employment Agreements with Executive Officers

Each of the executive officers is subject to an employment agreement providing for a base salary and for two bonuses: a bonus generally equal to one month's salary paid before the lunar New Year, and a holiday bonus generally equal to half a month's salary paid on the eves of the Mid-Autumn Festival in September and Dragon Boat Festival in June.

Additionally, we entered into service agreements with each of Keelung Hong, Ph.D., our chief executive officer, and George Yeh, M.B.A., our president, in May 2009. The service agreements were amended in January 2014. Each service agreement provides for an annual base salary, as well as a stock option grant and severance pay in specified situations, and provides that the executive is entitled to participate in benefit programs made available to our employees. In the event the executive is terminated by us without "cause," or the executive resigns for "good reason," as each term is defined in the applicable service agreement, the executive will receive a lump sum payment equal to six months' base salary and full acceleration of any unvested shares. Each executive's right to receive severance upon a termination without "cause," is conditioned upon his execution of an effective release of claims substantially in the form provided by us. In the event of a change of control of our company, the executive will receive acceleration of 50% of his unvested shares. In the event the executive is terminated by us without "cause" within 12 months following a change in control of our company, the executive will receive a lump sum payment equal to six months' base salary and full acceleration of any unvested shares. Pursuant to the service agreements, each executive agreed to take such actions as reasonably necessary to permit us to obtain a key person insurance policy insuring such executive and naming us as the beneficiary, if we chose to obtain such insurance. Each executive can voluntarily terminate his employment with us by giving us two months' prior written notice.

Incentive Compensation

We do not maintain any incentive cash or bonus programs.

Restricted Stock Grants

We have made grants of restricted stock to certain of our employees pursuant to our 2014 Regulations on the Issuance of New Employee Restricted Stock (the 2014 RS Regulations), and the 2017 RS Regulations, which provide for issuance of 350,000 common shares and 550,000 shares, respectively. The grants require payment of a purchase price of NT$10, the par value of our common shares, by the employee. The restricted stock granted under the 2014 RS Regulations vest at the rate of 30% on the first anniversary of the date of grant, 30% on the second anniversary of the date of grant and 40% on the third anniversary of the date of grant, in each case assuming continued service, achievement of performance targets and the performance of applicable duties, and, if unvested, may be purchased back at the issue price, NT$10 per share, on the third anniversary of the date of grant. The restricted stock granted under the 2017 RS Regulations vest at the rate of 20% on the first anniversary of the date of grant, 30% on the second anniversary of the date of grant and 50% on the third anniversary of the date of grant, in each case assuming continued service without violation of the rules set forth in the grantee's employment agreement. The unvested restricted stock under the 2014 RS Regulations and 2017 RS Regulations are generally repurchased by us at the original issue price and canceled upon the individual's termination of service or leave of absence, although in certain circumstances high-performing employees may receive different treatment, if so determined by the board of directors. Restricted stock is transferable only by inheritance while unvested, and carries the right to receive dividends and other shareholder rights.

Option Grants

We have made grants of options to our employees pursuant to our 2013 First Employee Stock Option Issuance and Share Subscription Plan (2013 Plan), 2014 Employee Stock Option Issuance and Share Subscription Plan (2014 Plan), 2015 Employee Stock Option Issuance and Share Subscription Plan (2015 Plan) and 2018 Plan (collectively, the Option Arrangements). Each of the Option Arrangements provides that options may be granted for a period of one year following its adoption, and provides for a pool for grants of 1,760,000 common shares, 1,800,000 common shares, 1,800,000 common shares and 1,800,000 common shares, respectively. Options granted pursuant to the Option Arrangements vest at the rate of 50% on the second anniversary of grant, with the remainder vesting in equal monthly installments over the remaining two years. Vested options may be exercised during their term and for varying periods following termination of service, depending on the reason for termination. Options will be adjusted to account for any changes in capitalization or certain other corporate events and are not transferable (but may be exercised by the individual's heirs in the case of death, to the extent vested at the time of death).

Retirement Plans

Since July 1, 2005, we have maintained a defined contribution pension plan under the ROC Labor Pension Act covering all regular employees with ROC nationality. Pursuant to this plan, we contribute monthly an amount equal to 6% of the employees' monthly salaries and wages to the employees' individual pension accounts at the ROC Bureau of Labor Insurance. The benefits accrued are paid monthly or in a lump sum upon termination of employment. Certain of our subsidiaries maintain similar defined contribution plans in accordance with local regulations and make annual contributions with respect to such plans.

We maintain a defined benefit pension plan in accordance with the Labor Standards Law covering all regular employees' service years prior to the enforcement of the ROC Labor Pension Act on July 1, 2005 and service years thereafter of employees who chose to continue to be subject to the pension mechanism under this law. Under the defined benefit pension plan, two units are accrued for each year of service for the first 15 years and one unit for each additional year thereafter, subject to a maximum of 45 units. Pension benefits are based on the number of units accrued and the average monthly salaries and wages of the last six months prior to retirement. We contribute monthly an amount equal to 2% of the employees' monthly salaries and wages to the retirement fund and additional annual contributions are made if deemed necessary under applicable law.

We maintain a safe harbor 401(k) plan that provides eligible U.S. employees with an opportunity to save for retirement on a tax advantaged basis. We make matching contributions of up to 4% of the employee's contribution, subject to certain limits of the U.S. Internal Revenue Code of 1986, as amended (Code). Eligible employees are able to defer eligible compensation up to certain Code limits, which are updated annually. We have the ability to make matching and discretionary contributions to the 401(k) plan. The 401(k) plan is intended to be qualified under Section 401(a) of the Code, with the related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan are deductible by us when made, and contributions and earnings on those amounts are not generally taxable to the employees until withdrawn or distributed from the 401(k) plan.

Other Employee Programs—Employee Stock Trust Plan

All employees are eligible to participate on a voluntary basis in our Employee Stock Trust Plan. Employees can contribute up to NT$10,000 per month, and we will match that contribution on a dollar-for-dollar basis. These amounts are then used to purchase our common shares on a monthly basis on the open market. Employees generally vest into the portion of their accounts attributable to our match at the rate of 30% after one year, an additional 30% after two years, and an additional 40% after three years.

Director Compensation

We provide only cash compensation to our non-executive directors for the time and effort necessary to serve as a member of our board of directors. Historically we have paid each director an annual cash retainer of NT$120,000 for serving on our board. We have also paid, and will continue to pay, each director an additional NT$10,000 for each meeting he or she attends, whether in person or by video conference. Our directors do not receive additional cash retainers for serving on the compensation committee or for serving as the chairperson of our board of directors our any committee of the board. The compensation of the non-executive directors is determined by our board as a whole based on a recommendation of the compensation committee, and based on a review of current practices in other companies.

2018 Director Compensation Table

The following table sets forth information regarding the compensation earned by our non-executive directors for service on our board of directors during the year ended December 31, 2018. Dr. Hong also served on our board of directors but did not receive any additional compensation for his service as a director and therefore is not included in the table below.

Name	Fees Earned in Cash (NT$)	All Other Compensation (NT$)	Total (NT$)
Hong-Jen Chang, M.D. (representing Taiwan Global Biofund)	180,000	—	180,000
Shieh-Shung Tom Chen, Ph.D.	210,000	—	210,000
Anupam Dalal, M.D., M.B.A. (representing Burrill Life Sciences Capital Fund III, L.P.)	190,000	—	190,000
May Kang, M.B.A.	190,000	—	190,000
Chan Yu Lee (representing Chang Xiang Investment Company, Ltd.).	210,000	—	210,000
Moun-Rong Lin, M.B.A.	210,000	—	210,000
Beatrice Liu, Ph.D.	210,000	—	210,000

We have not granted any options or issued any shares of restricted stock to our non-executive directors.

Statutory Auditor Compensation

Prior to forming an audit committee in June 2018, we had statutory auditors in lieu of an audit committee, per the laws of the ROC. The statutory auditors of an ROC company play a statutorily-defined role which has no equivalent in companies incorporated under Anglo-American law. The role of statutory auditors was generally to protect the company and shareholders against any potential abuses by the company's board of directors and management. We provided only cash compensation to our statutory auditors for the time and effort necessary to serve as statutory auditors. Historically, we have paid each statutory auditor NT$120,000 annually.

The following table sets forth information regarding the compensation earned by our statutory auditors for their service as statutory auditors during the year ended December 31, 2018.

Name	Fees Earned in Cash (NT$)	All Other Compensation (NT$)	Total (NT$)
Matthew Chan(1)	108,333	—	108,333
Eric Chu(1)	98,333	—	98,333
Ching-Fen Huang(1)	108,333	—	108,333

(1) Served as a statutory auditor until June 26, 2018.

We have not granted any options or issued any shares of restricted stock to our statutory auditors.

Grants of Stock Options and Restricted Stock to Executive Officers

The following table summarizes, as of the date of this Annual Report, outstanding stock options to purchase common shares granted to our executive officers under our Option Arrangements. We have not granted any stock options to our non-executive directors or statutory auditors. The executive officers did not pay an amount to receive the grant of stock options.

Name	Grant Date	Number of Shares Underlying Outstanding Stock Option	Exercise Price per Share (NT$)	Stock Option Expiration Date
Keelung Hong, Ph.D.	June 29, 2018	100,000	$ 100.50	June 29, 2023
	February 25, 2016	30,000	$ 159.00	February 25, 2021
	February 26, 2015	42,000	$ 246.50	February 26, 2020
George Yeh, M.B.A.	June 29, 2018	100,000	$ 100.50	June 29, 2023
	February 25, 2016	30,000	$ 159.00	February 25, 2021
	February 26, 2015	42,000	$ 246.50	February 26, 2020
Nicole Lin, M.B.A.	June 29, 2018	65,000	$ 100.50	June 29, 2023
	February 25, 2016	20,000	$ 159.00	February 25, 2021
	February 26, 2015	30,000	$ 246.50	February 26, 2020
Yunlong Tseng, Ph.D.	June 29, 2018	65,000	$ 100.50	June 29, 2023
	February 25, 2016	20,000	$ 159.00	February 25, 2021
	February 26, 2015	30,000	$ 246.50	February 26, 2020
Wenji Chen, Ph.D., M.B.A.	June 29, 2018	50,000	$ 100.50	June 29, 2023
	November 3, 2016	50,000	$ 122.00	November 3, 2021
Hungwei Chih, Ph.D.	July 2, 2018	65,000	$ 102.50	July 2, 2023

The following table summarizes, as of the date of this Annual Report, outstanding restricted stock purchased by our executive officers under our 2017 RS Regulations and 2014 RS Regulations. We have not issued any shares of restricted stock to our directors or statutory auditors.

Name	Issuance Date	Number of Shares of Restricted Stock	Purchase Price Per Share (NT$)	Vesting Conditions
Keelung Hong, Ph.D.	November 16, 2017	32,000	10.00	(1)
	August 21, 2014	35,000	10.00	(2)
George Yeh, M.B.A.	November 16, 2017	32,000	10.00	(1)
	August 21, 2014	32,000	10.00	(2)
Nicole Lin, M.B.A.	November 16, 2017	24,000	10.00	(1)
	August 21, 2014	20,000	10.00	(2)
Yunlong Tseng, Ph.D.	November 16, 2017	24,000	10.00	(1)
	August 21, 2014	20,000	10.00	(2)
Wenji Chen, Ph.D., M.B.A.	November 16, 2017	24,000	10.00	(1)
Hungwei Chih, Ph.D.	July 2, 2018	20,000	10.00	(2)

(1) 20% of the restricted stock vests on the first anniversary of the issuance date, 30% of the restricted stock vests on the second anniversary of the issuance date and 50% of the restricted stock vests on the third anniversary of the issuance date, subject to continued service through each vesting date without violation of the rules set forth in the individual's employment agreement.

(2) 30% of the restricted stock vests on the first anniversary of the issuance date, 30% of the restricted stock vests on the second anniversary of the issuance date and 40% of the restricted stock vests on the third anniversary of the issuance date, subject to continued service, achievement of performance targets and the performance of applicable duties through each vesting date.

Other Programs

Pursuant to our Articles of Incorporation, we must distribute a certain percentage of earnings we have at the end of each fiscal year to our employees and directors after first reserving the amount to make up any prior accumulated losses. Specifically, up to 2% of our distributable earnings must be distributed as compensation to directors and between 2% and 8% of distributable earnings must be distributed to employees as employee bonuses. Additionally, if any of our subsidiaries meets certain requirements, its employees are also entitled to receive a portion of the employee bonuses. As of December 31, 2018, we had an accumulated deficit and did not accrue employees bonuses or directors compensation. We do not expect to be profitable in the near term, and may never be profitable, and, accordingly, do not anticipate paying such compensation or bonuses in the foreseeable future.

C. Board Practices

Composition of Our Board of Directors

Our board of directors is currently comprised of eight members.

According to our Articles of Incorporation, in order to meet requirements under the Taiwan Securities and Exchange Act (Taiwan Act), at least two of our eight members, and in no event less than one fifth of the total members, shall be "independent directors" as defined under the Taiwan Act. Pursuant to these statutory requirements of the Taiwan Act, during the two years before being elected and during the term of office, none of our independent directors may have been or be any of the following (collectively, the Restricted Persons):

1. An employee of ours or any of our affiliates;
2. A statutory auditor of ours or any of our affiliates;
3. A director of our affiliates, unless he or she was an independent director of our subsidiary;
4. A natural-person shareholder who holds in the aggregate, together with his or her spouse, minor children, and his or her nominees, one percent or more of our shares outstanding or ranks among the top ten in our shareholdings;
5. A spouse, relative within the second degree of kinship, or lineal relative within the third degree of kinship, of any of the persons in the preceding four items;
6. A director, statutory auditor, or employee of a corporate shareholder that directly holds five percent or more of our total number of shares outstanding or of a corporate shareholder that ranks among the top five in our shareholdings;
7. A director, statutory auditor, officer, or shareholder holding five percent or more of the shares of a company or institution that meets certain statutorily specified criteria and has a financial or business relationship with us; or
8. A professional individual who, or an owner, partner, director, statutory auditor, or officer of a sole proprietorship, partnership, company, or institution that, provides commercial, legal, financial, accounting services or consultation to us or to any of our affiliates, or a spouse thereof; provided, this restriction does not apply to a member of the compensation committee, public tender offer review committee, or special committee for merger/consolidation and acquisition, who exercises powers pursuant to the Taiwan Act or to the Taiwan Business Mergers and Acquisitions Act or related laws or regulations.

The "during the two years before being elected" requirement does not apply where an independent director of ours has served as an independent director of ours or any of our affiliates, or of a specified company or institution that has a financial or business relationship with us, as stated in items 3 or 7 above, but is currently no longer in that position.

We meet the director independence requirements under ROC law. We intend to rely on the Nasdaq exemption from the requirement that a majority of our board consist of independent directors.

In accordance with our Articles of Incorporation, our directors serve for a term of three years and, at the expiration of such term, are eligible for reelection by our shareholders. If a new director is not elected after the expiration of the tenure of an existing director, the tenure of such out-going director shall be extended until a new director has been elected. See "Description of Share Capital and Articles of Incorporation—Articles of Incorporation—Board of Directors."

Committees

Our board of directors has two standing committees: a Compensation Committee and an Audit Committee.

Compensation Committee

The compensation committee, which consists of Dr. Liu, Ms. Kang, and Dr. Tom Chen, assists the board of directors in determining director and executive officer compensation. Ms. Kang serves as chairman of the compensation committee.

Under the Taiwan Act, our compensation committee shall be comprised of at least three members, and at least one of them shall be an "independent director," as defined under the Taiwan Act. In addition, during the two years before being appointed to his or her term of office, none of our compensation committee members may have been or be a Restricted Person. This "during the two years before being appointed" requirement does not apply where a compensation committee member has served as an independent director of ours or any of our affiliates, or of a specified company or institution that has a financial or business relationship with us, as stated in items 3 or 7 of the definition of Restricted Person above, but is currently no longer in that position.

All of the current members of the compensation committee are our independent directors as required by the Taiwan Act.

Our compensation committee's responsibilities include:

- prescribing and periodically reviewing the performance and compensation policy, system, standards, and structure for directors and managerial officers; and
- periodically evaluating and prescribing the compensation of directors and managerial officers.

When performing these responsibilities, the compensation committee shall follow the following principles:

- with respect to the performance assessment and compensation of our directors and managerial personnel, including executive officers, it shall refer to the typical pay levels adopted by peer companies and take into consideration the reasonableness of the correlation between compensation and individual performance, as well as our business performance, and future risk exposure;
- it shall not provide an incentive for the directors or executive officers to engage in activities in pursuit of compensation with a risk level exceeding that which we would tolerate; and
- it shall take into consideration the characteristics of the industry and the nature of our business when determining the ratio of bonus payout, based on the short-term performance of our directors and senior management, including executive officers, and the time for payment of the variable part of compensation.

The compensation committee shall submit its recommendations regarding the above for deliberation to the board of directors. When deliberating the recommendations of the compensation committee, the board of directors shall give comprehensive consideration to matters including amounts of compensation, payment methods, and the potential future risks facing our company. If the board of directors would like to decline to adopt, or would like to modify, a recommendation of the compensation committee, the consent of a majority of the directors in attendance at a meeting attended by two-thirds or more of the entire board is required, and the board of directors in its resolution shall provide its comprehensive consideration and shall specifically explain whether the compensation passed by it exceeds in any way the compensation recommended by the compensation committee.

Audit Committee

The audit committee, which consists of Dr. Liu, Ms. Kang and Dr. Tom Chen, assists the board of directors in overseeing our accounting and financial reporting processes and the audits of our financial statements. Dr. Liu serves as chairman of the audit committee. The audit committee consists exclusively of independent members of our board. Our board of directors has determined that Dr. Liu qualifies as an "audit committee financial expert" as defined by applicable SEC rules and has the requisite financial sophistication as defined under the Nasdaq rules and regulations. Our board has determined that all of the members of the audit committee satisfy the "independence" requirements that are applicable to foreign private issuers set forth in Rule 10A-3 under the Exchange Act.

The audit committee's responsibilities include:

- the adoption of or amendments to the internal control system;
- assessment of the effectiveness of the internal control system;
- the adoption or amendment, of the procedures for handling material financial or operational activities, such as acquisition or disposal of assets, derivatives trading, lending of funds to others and endorsements or guarantees for others;
- matters in which a director is an interested party;
- asset transactions or derivatives trading of a material nature;
- loans of funds, endorsements or provision of guarantees of a material nature;
- the offering, issuance or private placement of equity-type securities;
- the hiring or dismissal of a certified public accountant or their compensation;
- the appointment or discharge of a financial, accounting or internal audit officer;
- annual and semi-annual financial reports;
- whistleblower procedures; and
- other material matters as may be required by us or by the competent authority.

The audit committee meets as often as one or more members of the audit committee deem necessary, but in any event will meet at least once every quarter according to the Taiwan Act.

The audit committee is governed by a charter that complies with Nasdaq and Rule 10A-3 rules that are applicable to foreign private issuers following home country rules.

D. Employees

As of December 31, 2018, we had 161 full-time employees, of which 150 employees are located in Taiwan.

None of our employees are subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relationship with our employees to be good. At each date shown, we had the following number of employees, broken out by department and geography.

	As of December 31,		
	2018	2017	2016
Function:			
Research and development	128	132	136
General and administrative	33	36	34
Total	161	168	170

E. Share Ownership

For information regarding the share ownership of our directors and executive officers, see "Item 6.B-Compensation" and "Item 7.A-Major Shareholders."

Item 7. Major Shareholders and Related Party Transactions

A. Major Shareholders

The following table sets forth information with respect to the beneficial ownership of our common shares as of February 28, 2019 for:

- each beneficial owner of 5% or more of our outstanding common shares determined as of February 28, 2019, which was the most recent record date of our common shares under applicable procedures in Taiwan (upon which basis we are able to ascertain whether or not a holder otherwise not affiliated with us may be above the 5% threshold);
- each of our executive officers and directors; and
- all of our executive officers and directors as a group.

Beneficial ownership is determined in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities and include common shares issuable upon the exercise of options that are immediately exercisable or exercisable within 60 days of February 28, 2019. Percentage ownership calculations are based on 64,045,134 common shares outstanding as of February 28, 2019.

As of February 28, 2019, to the best of our knowledge, approximately 16,176,543 ordinary shares (including ordinary shares in the form of ADSs), or 25.26% of our outstanding ordinary shares as of such date, were held by 15 shareholders of record in the United States. The actual number of holders is greater than these numbers of record holders and includes beneficial owners whose ordinary shares or ADSs are held in street name by brokers and other nominees. This number of holders of record also does not include holders whose shares may be held in trust by other entities.

Except as otherwise indicated, all of the shares reflected in the table are common shares and all persons listed below have sole voting and investment power with respect to the shares beneficially owned by them, subject to applicable community property laws. The information is not necessarily indicative of beneficial ownership for any other purpose. The table below excludes shares that were issued to our executive officers as a company contribution pursuant to our Employee Stock Trust Plan in April 2019.

None of our major shareholders have different voting rights with respect to their common shares. We have set forth below information known to us regarding any significant change in the percentage ownership of our common shares by any major shareholders during the past three years.

Except as otherwise indicated in the table below, addresses of the executive officers, directors, and named beneficial owners are in care of Taiwan Liposome Company, Ltd. 11F, No. 3 Yuanqu Street, Nangang District, Taipei City 11503, Taiwan, Republic of China and our telephone number is +886 2 2655 7377.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
Executive Officers and Directors:		
Keelung Hong, Ph.D.(1)	1,396,633	2.2%
George Yeh, M.B.A.(2)	1,155,537	1.8%
Nicole Lin, M.B.A.(3)	108,354	*
Yunlong Tseng, Ph.D.(4)	209,527	*
Wenji Chen, Ph.D., M.B.A(5)	35,010	*
HungWei Chih, Ph.D.(6)	2,000	*
Taiwan Global Biofund (represented by Hong-Jen Chang, M.D.)(7)	2,487,372	3.9%
Shieh-Shung Tom Chen, Ph.D.(8)	453,731	*
Burrill Life Sciences Capital Fund III, L.P. (represented by Anupam Dalal, M.D., M.B.A.)(9)	5,187,921	8.1%
May Kang, M.B.A.	—	*
Chang Xiang Investment Company, Ltd (represented by Chan Yu Lee)(10)	598,283	*
Moun-Rong Lin, M.B.A.(11)	934,507	1.5%
Beatrice Liu, Ph.D.	—	*
George Spencer-Green, M.D., M.S.	—	*
All current executive officers and directors as a group (14 persons)	12,580,504	19.6%
5% Or Greater Shareholders		
Entities affiliated with Karst Peak(12)	6,255,572	9.8%

* Represents beneficial ownership of less than one percent.

(1) Consists of (A) 1,330,883 common shares and (B) 65,750 common shares issuable upon the exercise of stock options granted to Dr. Hong that are exercisable within 60 days of February 28, 2019.

(2) Consists of (A) 888,150 common shares, of which 350,000 common shares are pledged as security for a personal loan as of February 28, 2019, (B) 1,637 common shares held in our Employee Stock Trust Plan, (C) 200,000 shares held by Mr. Yeh's son and (D) 65,750 common shares issuable upon the exercise of stock options granted to Mr. Yeh that are exercisable within 60 days of February 28, 2019.

(3) Consists of (A) 62,516 common shares and (B) 45,838 common shares issuable upon the exercise of stock options granted to Ms. Lin that are exercisable within 60 days of February 28, 2019.

(4) Consists of (A) 117,851 common shares, (B) 57,467 shares held by Dr. Tseng's spouse and (C) 45,838 common shares issuable upon the exercise of stock options granted to Dr. Tseng that are exercisable within 60 days of February 28, 2019.

(5) Consists of (A) 4,800 common shares and (B) 30,210 common shares issuable upon the exercise of stock options granted to Mr. Chen that are exercisable within 60 days of February 28, 2019.

(6) Consists solely of 2,000 common shares.

(7) Consists of solely 2,487,372 common shares held by Taiwan Global Biofund (TGB). Hong-Jen Chang, representative of TGB, disclaims beneficial ownership of all shares held by TGB, except to the extent of his actual pecuniary interest therein. The address for TGB is 4F, 51 Chong Ching South Rd, Sec. 2., Taipei, Taiwan, Republic of China. The percentage ownership of TGB decreased from 5.95% in April 2016 (date joined as a director) to 3.9% in February 2019.

(8) Consists of solely 453,371 common shares.

(9) Consists of solely 5,187,921 common shares held by Burrill Life Sciences Capital Fund III, L.P. (Burrill). Kearny Venture Associates II, LLC (KVA II) is the General Partner of Burrill. Caley Castelein, Andrew Jensen and Anupam Dalal, representative of our director Burrill are the managing members of KVA II and share both voting power and disposal power over the shares. Dr. Dalal disclaims beneficial ownership of all shares held by Burrill, except to the extent of his actual pecuniary interest therein. The address for Burrill is 1 Embarcadero, Suite 3700, San Francisco, CA 94111. The percentage ownership of Burrill decreased from 10.59% in February 2016 to 8.1% in February 2019.

(10) Consists of (A) 593,283 common shares held by Chang Xiang Investment Company, Ltd. and (B) 5,000 common shares held by Chan Yu Lee (representative of Chang Xiang Investment Company, Ltd.).

(11) Consists of solely 934,507 common shares.

(12) Consists of (i) 2,524,000 common shares and 353,910 ADSs held by Karst Peak Asia Master Fund, 1,632,000 common shares and 215,055 ADSs held by Karst Peak Vermilion Partners Master Fund and 961,642 common shares held by Karst Peak Select Master Fund. Karst Peak Capital Limited (KPCL) is the investment manager of these entities. Adam Leitzes is the Chief Investment Officer, director and sole owner of KPCL and may be deemed to have both voting power and disposal power over the shares. The address for KPCL is Kinwick Centre, Suite 1705, 32 Hollywood Road, Central, Hong Kong. This information is based on its most recently filed Schedule 13G.

B. Related Party Transactions.

Since January 1, 2018, we have engaged in the following transactions with our directors, executive officers, statutory auditors or holders of more than 5% of our outstanding share capital and their affiliates, which we refer to as our related parties.

Arrangements with Our Executive Officers, Directors and Statutory Auditors

We have entered into employment agreements with our executive officers.

Pursuant to our Articles of Incorporation, we must distribute a certain percentage of earnings we have at the end of each fiscal year to our employees and directors after first reserving the amount to make up any prior accumulated losses. For a discussion of this requirement see the section of this Annual Report titled “Management—Compensation of Executive Officers, Directors and Statutory Auditors—Other Programs.”

Related Person Transaction Policy

We have adopted procedures for the acquisition or disposal of assets (Procedures), which requires that certain related party transactions involving the acquisition or disposal of assets be approved by our board of directors and audit committee. We intend to afford ourselves of the Nasdaq foreign private issuer exemption from the requirement that our audit committee have review and oversight over all “related party transactions,” as defined in Item 7.B of Form 20-F. The definition of “related party transactions” per our Procedures and ROC law is not as broad as the definition in Item 7.B of Form 20-F.

Indemnification Agreements

We have entered or intend to enter, and intend to continue to enter into, separate indemnification agreements with our directors and executive officers. These indemnification agreements provide our directors and executive officers with contractual rights to indemnification and, in some cases, expense advancement in any action or proceeding arising out of their services as one of our directors or executive officers or as a director or executive officer of any other company or enterprise to which the person provides services at our request.

C. Interests of Experts and Counsel

Not applicable.

Item 8. Financial Information

A. Consolidated Statements and Other Financial Information.

Our consolidated financial statements are appended at the end of this Annual Report, starting at page F-1, and are incorporated herein by reference.

Dividend Policy

We have never declared or paid cash dividends to our shareholders and we do not intend to pay cash dividends in the foreseeable future. To the extent we pay any dividends in the future, at least 10% of such dividends will be cash dividends. We currently intend to reinvest any earnings in developing and expanding our business. One of our debt agreements with Taiwan Cooperative Bank and our loan and security agreement with Cathay Bank restricts our ability to pay cash dividends or other distributions on our common shares if certain conditions are met. We may enter into credit agreements or other borrowing arrangements in the future that will restrict our ability to declare or pay cash dividends on our common shares. Any future determination relating to our dividend policy will be at the discretion of our board of directors in compliance with applicable legal requirements and will depend on a number of factors, including future earnings, our financial condition, operating results, contractual restrictions, capital requirements, business prospects, our strategic goals and plans to expand our business, applicable law and other factors that our board of directors may deem relevant.

Legal Proceedings

From time to time, we may be involved in legal proceedings or be subject to claims arising out of our operations. We are not currently a party to any legal proceedings that in the opinion of our management, would have a material adverse effect on our business.

B. Significant Changes.

Not applicable

Item 9. The Offer and Listing.

A. Offer and Listing Details

Our ADSs began trading on the Nasdaq Global Market under the symbol "TLC" on November 21, 2018. Prior to that date, there was no public trading market for our ADSs. Our common shares have been trading on the TPEx under "4152" since December 21, 2012. Prior to that date, there was no public trading market for our common shares.

B. Plan of Distribution

Not applicable.

C. Markets.

Our ADSs began trading on the Nasdaq Global Market under the symbol "TLC" on November 21, 2018. Our common shares have been trading on the TPEx under "4152" since December 21, 2012.

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

Item 10. Additional Information.

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

The information set forth in our prospectus dated November 26, 2018, filed with the SEC pursuant to Rule 424(b), under the headings "Description of Share Capital and Articles of Incorporation" and "Service of Process and Enforcement of Liabilities" is incorporated herein by reference.

C. Material Contracts

Except as otherwise disclosed in this Annual Report (including the exhibits thereto), we are not currently, and have not been in the last two years, party to any material contract, other than contracts entered into in the ordinary course of our business.

Underwriting Agreement

We entered into an underwriting agreement among Cantor Fitzgerald & Co., as representatives of the underwriters, on November 20, 2018, with respect to the ADSs sold in our IPO. We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the U.S. Securities Act of 1933, as amended, and to contribute to payments the underwriters may be required to make in respect of such liabilities.

D. Exchange Controls

The ROC Foreign Exchange Regulation Act, the Regulations Governing the Declaration of Foreign Exchange Receipts and Disbursements or Transactions, and regulations promulgated thereunder provide for restrictions on the foreign exchange transactions in Taiwan. Under current regulations, trade-related or service-related foreign exchange transactions may be executed without any prior foreign exchange approval. Aside from the trade-related and service related foreign exchange transactions, ROC companies and individual residents of the ROC reaching the age of 20 years old may, without a prior foreign exchange approval, remit foreign currency up to US$50 million (or its equivalent) and US$5 million (or its equivalent) to and from the ROC, respectively, in each calendar year.

The above annual limit does not apply to the sale of the ADSs, nor does the limit apply to the outward remittance from the ROC of the dividends or proceeds of the sale of the underlying common shares withdrawn from the ADSs as long as the withdrawal and holding of the common shares are completed pursuant to the ROC regulations.

Any remittance over NT$100,000 requires submission of a declaration form, and additionally any remittance of US$1 million by a ROC company or of US$500,000 by a ROC resident individual and any remittance relating to securities investment require submission of supporting documents.

E. Taxation

The following summary contains a description of material ROC and U.S. federal income tax consequences of the acquisition, ownership and disposition of our common shares or ADSs. This summary should not be considered a comprehensive description of all the tax considerations that may be relevant to beneficial owners of ADSs.

Material U.S. Federal Income Tax Considerations for U.S. Holders

The following discussion describes the material U.S. federal income tax consequences relating to the ownership and disposition of our common shares or ADSs by U.S. Holders (as defined below). This discussion applies to U.S. Holders that purchase our common shares or ADSs pursuant to this offering and hold such common shares or ADSs as capital assets. This discussion is based on the Code, U.S. Treasury regulations promulgated thereunder and administrative and judicial interpretations thereof, all as in effect on the date hereof and all of which are subject to change, possibly with retroactive effect. This discussion does not address all of the U.S. federal income tax consequences that may be relevant to specific U.S. Holders in light of their particular circumstances or to U.S. Holders subject to special treatment under U.S. federal income tax law (such as certain financial institutions, insurance companies, dealers or traders in securities or other persons that generally mark their securities to market for U.S. federal income tax purposes, tax-exempt entities or governmental organizations, retirement plans, regulated investment companies, real estate investment trusts, grantor trusts, brokers, dealers or traders in securities, commodities, currencies or notional principal contracts, certain former citizens or long-term residents of the United States, persons who hold our common shares or ADSs as part of a "straddle," "hedge," "conversion

transaction," "synthetic security" or integrated investment, persons that have a "functional currency" other than the U.S. dollar, persons that own directly, indirectly or through attribution 10% or more of the voting power of our common shares, corporations that accumulate earnings to avoid U.S. federal income tax, partnerships and other pass-through entities, and investors in such pass-through entities). This discussion does not address any U.S. state or local or non-U.S. tax consequences or any U.S. federal estate, gift or alternative minimum tax consequences.

As used in this discussion, the term "U.S. Holder" means a beneficial owner of our common shares or ADSs that is, for U.S. federal income tax purposes, (1) an individual who is a citizen or resident of the United States, (2) a corporation (or entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state thereof, or the District of Columbia, (3) an estate the income of which is subject to U.S. federal income tax regardless of its source or (4) a trust (x) with respect to which a court within the United States is able to exercise primary supervision over its administration and one or more United States persons have the authority to control all of its substantial decisions or (y) that has elected under applicable U.S. Treasury regulations to be treated as a domestic trust for U.S. federal income tax purposes.

If an entity treated as a partnership for U.S. federal income tax purposes holds our common shares or ADSs, the U.S. federal income tax consequences relating to an investment in such common shares or ADSs will depend in part upon the status and activities of such entity and the particular partner. Any such entity should consult its own tax advisor regarding the U.S. federal income tax consequences applicable to it and its partners of the purchase, ownership and disposition of our common shares or ADSs.

Persons considering an investment in our common shares or ADSs should consult their own tax advisors as to the particular tax consequences applicable to them relating to the purchase, ownership and disposition of our common shares or ADSs, including the applicability of U.S. federal, state and local tax laws and non-U.S. tax laws.

The discussion below assumes that the representations contained in the deposit agreement are true and that the obligations in the deposit agreement and any related agreement will be complied with in accordance with their terms. Generally, a holder of an ADS should be treated for U.S. federal income tax purposes as holding the common shares represented by the ADS. Accordingly, no gain or loss will be recognized upon an exchange of ADSs for common shares. The U.S. Treasury has expressed concerns that intermediaries in the chain of ownership between the holder of an ADS and the issuer of the security underlying the ADS may be taking actions that are inconsistent with the beneficial ownership of the underlying security. Accordingly, the creditability of foreign taxes, if any, as described below, could be affected by actions taken by intermediaries in the chain of ownership between the holders of ADSs and our company if as a result of such actions the holders of ADSs are not properly treated as beneficial owners of the underlying common shares. These actions would also be inconsistent with the claiming of the reduced rate of tax, described below, applicable to dividends received by certain non-corporate holders.

Passive Foreign Investment Company Consequences

In general, a corporation organized outside the United States will be treated as a PFIC for any taxable year in which either (1) at least 75% of its gross income is "passive income" (PFIC income test), or (2) on average at least 50% of its assets, determined on a quarterly basis, are assets that produce passive income or are held for the production of passive income (PFIC asset test). Passive income for this purpose generally includes, among other things, dividends, interest, royalties, rents, and gains from the sale or exchange of property that give rise to passive income. Assets that produce or are held for the production of passive income generally include cash, even if held as working capital or raised in a public offering, marketable securities, and other assets that may produce passive income. Generally, in determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account.

Although PFIC status is determined on an annual basis and generally cannot be determined until the end of the taxable year, based on the nature of our current and expected income and the current and expected value and composition of our assets, we believe we were not a PFIC for our 2017 or 2018 tax years. In part, because we may hold a substantial amount of cash and cash equivalents following this offering, and because the calculation of the value of our assets after this offering may be based in part on the value of our common shares or ADSs, which may fluctuate considerably, there can be no assurance that we will not be a PFIC in future taxable years including our current taxable year. Even if we determine that we are not a PFIC for a taxable year, there can be no assurance that the Internal Revenue Service (IRS) will agree with our conclusion and that the IRS would not assert a contrary position. Because of the uncertainties involved in establishing our PFIC status, our U.S. counsel expresses no opinion regarding our PFIC status.

If we are a PFIC in any taxable year during which a U.S. Holder owns our common shares or ADSs, the U.S. Holder could be liable for additional taxes and interest charges under the "PFIC excess distribution regime" upon (1) a distribution paid during a taxable year that is greater than 125% of the average annual distributions paid in the three preceding taxable years, or, if shorter, the U.S. Holder's holding period for our common shares or ADSs, and (2) any gain recognized on a sale, exchange or other disposition, including a pledge, of our common shares or ADSs, whether or not we continue to be a PFIC. Under the PFIC excess distribution regime, the tax on such distribution or gain would be determined by allocating the distribution or gain ratably over the U.S. Holder's holding period for our common shares or ADSs. The amount allocated to the current taxable year (*i.e.*, the year in which the distribution occurs or the gain is recognized) and any year prior to the first taxable year in which we are a PFIC will be taxed as ordinary income earned in the current taxable year. The amount allocated to other taxable years will be taxed at the highest marginal rates in effect for individuals or corporations, as applicable, to ordinary income for each such taxable year, and an interest charge, generally applicable to underpayments of tax, will be added to the tax.

If we are a PFIC for any year during which a U.S. Holder holds our common shares or ADSs, we must generally continue to be treated as a PFIC by that holder for all succeeding years during which the U.S. Holder holds such common shares or ADSs, unless we cease to meet the requirements for PFIC status and the U.S. Holder makes a "deemed sale" election with respect to our common shares or ADSs. If the election is made, the U.S. Holder will be deemed to sell our common shares or ADSs it holds at their fair market value on the last day of the last taxable year in which we qualified as a PFIC, and any gain recognized from such deemed sale would be taxed under the PFIC excess distribution regime. After the deemed sale election, the U.S. Holder's common shares or ADSs would not be treated as shares of a PFIC unless we subsequently become a PFIC.

If we are a PFIC for any taxable year during which a U.S. Holder holds our common shares or ADSs and one of our non-United States subsidiaries is also a PFIC (*i.e.,* a lower-tier PFIC), such U.S. Holder would be treated as owning a proportionate amount (by value) of the shares of the lower-tier PFIC and would be taxed under the PFIC excess distribution regime on distributions by the lower-tier PFIC and on gain from the disposition of shares of the lower-tier PFIC even though such U.S. Holder would not receive the proceeds of those distributions or dispositions. Any of our non-United States subsidiaries that have elected to be disregarded as entities separate from us or as partnerships for U.S. federal income tax purposes would not be corporations under U.S. federal income tax law and accordingly, cannot be classified as lower-tier PFICs. However, non-United States subsidiaries that have not made the election may be classified as a lower-tier PFIC if we are a PFIC during your holding period and the subsidiary meets the PFIC income test or PFIC asset test. Each U.S. Holder is advised to consult its tax advisors regarding the application of the PFIC rules to any of our non-United States subsidiaries.

If we are a PFIC, a U.S. Holder will not be subject to tax under the PFIC excess distribution regime on distributions or gain recognized on our common shares or ADSs if a valid "mark-to-market" election is made by the U.S. Holder for our common shares or ADSs. An electing U.S. Holder generally would take into account as ordinary income each year, the excess of the fair market value of our common shares or ADSs held at the end of such taxable year over the adjusted tax basis of such common shares or ADSs. The U.S. Holder would also take into account, as an ordinary loss each year, the excess of the adjusted tax basis of such common shares or ADSs over their fair market value at the end of the taxable year, but only to the extent of the excess of amounts previously included in income over ordinary losses deducted as a result of the mark-to-market election. The U.S. Holder's tax basis in our common shares or ADSs would be adjusted to reflect any income or loss recognized as a result of the mark-to-market election. Any gain from a sale, exchange or other disposition of our common shares or ADSs in any taxable year in which we are a PFIC would be treated as ordinary income and any loss from such sale, exchange or other disposition would be treated first as ordinary loss (to the extent of any net mark-to-market gains previously included in income) and thereafter as capital loss. If, after having been a PFIC for a taxable year, we cease to be classified as a PFIC because we no longer meet the PFIC income or PFIC asset test, the U.S. Holder would not be required to take into account any latent gain or loss in the manner described above and any gain or loss recognized on the sale or exchange of the common shares or ADSs would be classified as a capital gain or loss.

A mark-to-market election is available to a U.S. Holder only for "marketable stock." Generally, stock will be considered marketable stock if it is "regularly traded" on a "qualified exchange" within the meaning of applicable U.S. Treasury regulations. A class of stock is regularly traded during any calendar year during which such class of stock is traded, other than in *de minimis* quantities, on at least 15 days during each calendar quarter.

Our ADSs will be marketable stock as long as they remain listed on The Nasdaq Global Market and are regularly traded. A mark-to-market election will not apply to the common shares or ADSs for any taxable year during which we are not a PFIC, but will remain in effect with respect to any subsequent taxable year in which we become a PFIC. Such election will not apply to any of our non-U.S. subsidiaries. Accordingly, a U.S. Holder may continue to be subject to tax under the PFIC excess distribution regime with respect to any lower-tier PFICs notwithstanding the U.S. Holder's mark-to-market election for the common shares or ADSs.

The tax consequences that would apply if we are a PFIC would also be different from those described above if a U.S. Holder were able to make a valid qualified electing fund (QEF) election. As we do not expect to provide U.S. Holders with the information necessary for a U.S. Holder to make a QEF election, prospective investors should assume that a QEF election will not be available.

The U.S. federal income tax rules relating to PFICs are very complex. Prospective U.S. investors are strongly urged to consult their own tax advisors with respect to the impact of PFIC status on the purchase, ownership and disposition of our common shares or ADSs, the consequences to them of an investment in a PFIC, any elections available with respect to the common shares or ADSs and the IRS information reporting obligations with respect to the purchase, ownership and disposition of common shares or ADSs of a PFIC.

Distributions

Subject to the discussion above under "—Passive Foreign Investment Company Consequences," a U.S. Holder that receives a distribution with respect to our common shares or ADSs generally will be required to include the gross amount of such distribution in gross income as a dividend when actually or constructively received by the U.S. Holder (or in the case of ADSs, the Depositary) to the extent of the U.S. Holder's pro rata share of our current and/or accumulated earnings and profits (as determined under U.S. federal income tax principles). To the extent a distribution received by a U.S. Holder is not a dividend because it exceeds the U.S. Holder's pro rata share of our current and accumulated earnings and profits, it will be treated first as a tax-free return of capital and reduce (but not below zero) the adjusted tax basis of the U.S. Holder's common shares or ADSs. To the extent the distribution exceeds the adjusted tax basis of the U.S. Holder's common shares or ADSs, the remainder will be taxed as capital gain. Because we may not account for our earnings and profits in accordance with U.S. federal income tax principles, U.S. Holders should expect all distributions to be reported to them as dividends.

The amount of a dividend will include any amounts withheld by the Company in respect of ROC taxes. Distributions on our common shares or ADSs that are treated as dividends generally will constitute income from sources outside the United States for foreign tax credit purposes and generally will constitute passive category income. Such dividends will not be eligible for the "dividends received'' deduction generally allowed to corporate shareholders with respect to dividends received from U.S. corporations. Dividends paid by a "qualified foreign corporation'' are eligible for taxation at a reduced capital gains rate rather than the marginal tax rates generally applicable to ordinary income provided that a holding period requirement (more than 60 days of ownership, without protection from the risk of loss, during the 121-day period beginning 60 days before the ex-dividend date) and certain other requirements are met. Each U.S. Holder is advised to consult its tax advisors regarding the availability of the reduced tax rate on dividends to its particular circumstances. However, if we are a PFIC for the taxable year in which the dividend is paid or the preceding taxable year (see discussion above under "—Passive Foreign Investment Company Consequences''), we will not be treated as a qualified foreign corporation, and therefore the reduced capital gains tax rate described above will not apply.

The amount of any dividend income paid in New Taiwan dollars will be the U.S. dollar amount calculated by reference to the exchange rate in effect on the date of receipt, regardless of whether the payment is in fact converted into U.S. dollars. If the dividend is converted into U.S. dollars on the date of receipt, a U.S. Holder should not be required to recognize foreign currency gain or loss in respect of the dividend income. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt.

A non-United States corporation (other than a corporation that is classified as a PFIC for the taxable year in which the dividend is paid or the preceding taxable year) generally will be considered to be a qualified foreign corporation with respect to any dividend it pays on common shares or ADSs that are readily tradable on an established securities market in the United States.

Sale, Exchange or Other Disposition of Our Common Shares or ADSs

Subject to the discussion above under "—Passive Foreign Investment Company Consequences,'' a U.S. Holder generally will recognize capital gain or loss for U.S. federal income tax purposes upon the sale, exchange or other disposition of our common shares or ADSs in an amount equal to the difference, if any, between the amount realized (*i.e.,* the amount of cash plus the fair market value of any property received) on the sale, exchange or other disposition and such U.S. Holder's adjusted tax basis in the common shares or ADSs. Such capital gain or loss generally will be long-term capital gain taxable at a reduced rate for non-corporate U.S. Holders or long-term capital loss if, on the date of sale, exchange or other disposition, the common shares or ADSs were held by the U.S. Holder for more than one year. Any capital gain of a non-corporate U.S. Holder that is not long-term capital gain is taxed at ordinary income rates. The deductibility of capital losses is subject to limitations. Any gain or loss recognized from the sale or other disposition of our common shares or ADSs will generally be gain or loss from sources within the United States for U.S. foreign tax credit purposes.

Medicare Tax

Certain U.S. Holders that are individuals, estates or trusts and whose income exceeds certain thresholds generally are subject to a 3.8% tax on all or a portion of their net investment income, which may include their gross dividend income and net gains from the disposition of our common shares or ADSs. If you are a United States person that is an individual, estate or trust, you are encouraged to consult your tax advisors regarding the applicability of this Medicare tax to your income and gains in respect of your investment in our common shares or ADSs.

Information Reporting and Backup Withholding

U.S. Holders may be required to file certain U.S. information reporting returns with the IRS with respect to an investment in our common shares or ADSs, including, among others, IRS Form 8938 (Statement of Specified Foreign Financial Assets). As described above under "Passive Foreign Investment Company Consequences", each U.S. Holder who is a shareholder of a PFIC must file an annual report containing certain information. U.S. Holders paying more than $100,000 for our common shares or ADSs may be required to file IRS Form 926 (Return by a U.S. Transferor of Property to a Foreign Corporation) reporting this payment. Substantial penalties may be imposed upon a U.S. Holder that fails to comply with the required information reporting.

Dividends on and proceeds from the sale or other disposition of our common shares or ADSs may be reported to the IRS unless the U.S. Holder establishes a basis for exemption. Backup withholding may apply to amounts subject to reporting if the holder (1) fails to provide an accurate U.S. taxpayer identification number or otherwise establish a basis for exemption, or (2) is described in certain other categories of persons. However, U.S. Holders that are corporations generally are excluded from these information reporting and backup withholding tax rules.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules generally will be allowed as a refund or a credit against a U.S. Holder's U.S. federal income tax liability if the required information is furnished by the U.S. Holder on a timely basis to the IRS.

U.S. Holders should consult their own tax advisors regarding the backup withholding tax and information reporting rules.

EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT OF AN INVESTMENT IN OUR COMMON SHARES OR ADSs IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES.

ROC Taxation

The following is a summary under present law of the principal ROC tax consequences of the ownership and disposition of ADSs and shares to a Non-Resident Individual or a Non-Resident Entity that owns ADS or shares (each a Non-ROC Holder). As used in this section, a "Non-Resident individual" is a foreign national individual who is not physically present in the ROC for 183 days or more during any calendar year; and a "Non-Resident Entity" is a corporation or a non-corporate body that is organized under the laws of a jurisdiction other than the ROC and has no fixed place of business or other permanent establishment or business agent in the ROC. Prospective purchasers of the ADSs should consult their tax advisors concerning the ROC tax consequences of owning the ADSs or shares and the laws of any other relevant taxing jurisdiction to which they are subject.

Dividends

Dividends (whether in cash or shares) declared by us out of retained earnings and distributed to a Non-ROC Holder in respect of shares are subject to ROC income tax collected by way of withholding at the time of distribution, currently at the rate of 21.0% (unless a preferable tax rate is provided under a tax treaty between the ROC and the jurisdiction where the Non-ROC Holder is a resident), on the amount of the distribution (in the case of cash dividends) or on the par value of the distributed shares (in the case of share dividends). The United States currently does not have an income tax treaty with the ROC. We are subject to a 10.0% retained earnings tax on our after-tax earnings generated before and inclusive of 2017, that are not distributed in the following year of income generation. The retained earnings tax so paid reduces the retained earnings available for future dividends. When we declare dividends out of those retained earnings being subject to 10% retained earnings tax in previous years, a maximum amount of up to 5.0% of the declared dividends will be credited against the 21.0% withholding tax imposed on Non-ROC Holders of ADSs or shares.

The retained earnings tax will be reduced to 5.0% for earnings generated in 2018 and going forward, but such tax will no longer be creditable against the dividend withholding tax for dividends expatriated in 2019 and the years thereafter.

Dividends paid by us out of our capital reserves are not subject to ROC withholding tax, except under limited circumstances.

Sale

There is no ROC tax on (i) the purchase of the ADSs, (ii) the sale of the ADSs or (iii) conversion of the ADSs into their underlying shares. However, securities transaction tax will be withheld at the rate of 0.3% of the transaction price upon a sale of the underlying shares in the ROC.

Under current ROC law, capital gains on transactions in securities issued by ROC companies and held by a Non-ROC Holder are exempt from income tax. This exemption applies to capital gains derived from the sale of the said shares.

Pre-emptive Rights

Distributions of statutory subscription rights for the shares in compliance with the Taiwan Company Act are not subject to ROC tax. Proceed derived from sale of statutory subscription rights evidenced by securities by a Non-ROC Holder are currently exempted from income tax but are subject to securities transactions tax, currently at the rate of 0.3% of the gross sales amount. Proceeds derived from sales of statutory subscription rights which are not evidenced by securities are subject to capital gains tax at the rate of 20% of the income. Subject to compliance with ROC law, we have the sole discretion to determine whether statutory subscription rights shall be evidenced by the issuances of securities.

Tax Treaties

At present, the ROC does not have a double taxation treaty with the United States, but it does have double taxation treaties with Indonesia, Singapore, South Africa, Australia, Vietnam, New Zealand, Malaysia, Swaziland, Macedonia, Gambia, the Netherlands, the United Kingdom, Senegal, Sweden, Belgium, Denmark, Israel, Paraguay, Hungary, France, India, Slovakia, Switzerland, Germany, Thailand, Kiribati, Luxembourg, Austria, Italy, Japan, Canada, and Poland, which generally have reduced the rate of withholding tax on dividends and interest paid by ROC companies to residents of these countries. It is unclear whether a Non-ROC Holder of ADSs will be considered as share owners for the purposes of such treaties. Accordingly, residents of these countries should consult their tax advisors concerning their eligibility for benefits under the relevant treaty.

Estate Taxation and Gift Taxation

Subject to allowable exclusions, deductions and exemptions, ROC estate tax is payable on any property within the ROC of a deceased foreign national individual, and ROC gift tax is payable on any property within the ROC donated by a foreign national individual. Estate tax is currently imposed at progressive rates ranging from 10% of the first NT$50,000,000 to 20.0% of amount in excess of NT$100,000,000. Gift tax is also imposed at progressive rates ranging from 10.0% of the first NT$25,000,000 donated to 20.0% of amount donated in excess of NT$50,000,000. Under ROC estate and gift tax law, the shares will be deemed to be located in the ROC without regard to the location of the owner. As our principal business place is located in the ROC, both ADSs and the shares are regarded as ROC properties and thus subject to taxation in ROC for the estate and gift tax purposes.

Tax Guarantor

If a holder of non-ROC nationality converts the ADSs held by the holder into the underlying shares, such holder is required under current ROC law and regulations to appoint a tax agent in the ROC. Such agent must meet certain qualifications set by the ROC FSC and, upon appointment, become a guarantor of such holder's ROC tax obligations. Evidence of the appointment of such agent and the approval for such appointment by the ROC tax authorities would be required as conditions to such holder's repatriation of the profit derived from the sale of shares. There can be no assurance that a foreign holder will be able to appoint and obtain approval for the required agent in a timely manner.

Subject to certain exceptions, under current ROC law, upon the repatriation of profits of shares sold within the ROC, the tax agent so appointed is required to submit evidence of the appointment of the tax agent to, and approval thereof by, the tax authority, or to submit tax clearance certificates issued by the tax authority. Notwithstanding the above requirements for the appointment of a tax agent or submission of tax clearance certificates as provided in the ROC regulations, the Central Bank of the Republic of China has not required submission of such evidence or tax clearance certificates as condition to repatriation of sale proceeds of shares from sales that take place within the ROC. However, there can be no assurance that the Central Bank of the Republic of China will not require submission of such evidence or tax clearance certificates in the future.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to the information reporting requirements of the Exchange Act applicable to foreign private issuers and file reports under those requirements with the SEC. Those reports may be inspected without charge at the locations described below. As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as United States companies whose securities are registered under the Exchange Act.

We maintain a corporate website at www.tlcbio.com. Information contained in, or that can be accessed through, our website is not a part of, and shall not be incorporated by reference into, this Annual Report. We have included our website address in this Annual Report on Form 20-F solely as an inactive textual reference.

The SEC also maintains a website (www.sec.gov) that contains reports, proxy and information statements and other information regarding registrants, such as us, that file electronically with the SEC.

With respect to references made in this Annual Report to any contract or other document of our company, such references are not necessarily complete and you should refer to the exhibits attached or incorporated by reference to this Annual Report for copies of the actual contract or document.

I. Subsidiary Information.

Not applicable.

Item 11. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks in the ordinary course of our business, which are principally limited to interest rate fluctuations and foreign currency exchange rate fluctuations. We maintain significant amounts of cash and cash equivalents that are in excess of federally insured limits in various currencies, placed with one or more financial institutions for varying periods according to expected liquidity requirements.

Interest Rate Risk

As of December 31, 2018, we had cash and cash equivalents of NT$807.5 million (US$26,380 thousand) and time deposits with maturity over three months of NT$307.2 million (US$10,034 thousand) (shown as "Current financial assets at amortized cost" in our consolidated financial statements). Our exposure to interest rate sensitivity is impacted by changes in the underlying Taiwanese and U.S. bank interest rates. Our surplus cash and cash equivalents have been invested in interest-bearing savings and time deposit accounts from time to time. We have not entered into investments for trading or speculative purposes. Due to the conservative nature of our investment portfolio, which is predicated on capital preservation of investments with short-term maturities, we do not believe an immediate one percentage point change in interest rates would have a material effect on the fair market value of our portfolio, and therefore we do not expect our operating results or cash flows to be significantly affected by changes in market interest rates.

Our major market risk exposure is changing interest rates. Our exposure to market risk for changes in interest rates relates primarily to our long-term debt obligations. We primarily enter into debt obligations to support general corporate purposes including capital expenditures and working capital needs. We have not entered into any interest rate swaps, caps or any contracts hedge to modify our exposure to interest rate movements.

As of December 31, 2018, we also had long-term borrowings of NT$368,010 (US$12,023). We primarily enter into debt obligations to support general corporate purposes including capital expenditures and working capital needs. We have not entered into any interest rate swaps, caps or any contracts hedge to modify our exposure to interest rate movements. At December 31, 2018, if interest rates had been 0.2% higher/lower with all other conditions held constant, net loss for the year ended December 31, 2018 would have been NT$653 thousand (US$21 thousand).

Foreign Currency Exchange Risk

We maintain our consolidated financial statements in New Taiwan Dollars, the functional currency of the ROC. Monetary assets and liabilities denominated in currencies other than the functional currency are translated into the functional currency at rates of exchange prevailing at the balance sheet dates. Non-monetary assets and liabilities denominated in foreign currencies are translated into the functional currency at the exchange rates prevailing at the date of the transaction. Exchange gains or losses arising from foreign currency transactions are included in the determination of net income (loss) for the respective periods.

As of December 31, 2018, we had bank deposits denominated in U.S. dollars of US$29.3 million. As of December 31, 2018, we also had other payables denominated in U.S. dollars and Australian dollars of US$17.9 million and of AU$2.5 million, respectively. We use the policy of natural hedging to reduce our foreign exchange exposure arising out of changes in the rates of exchange among the U.S. dollar and Australian dollars. Based on a sensitivity analysis performed on our financial position as of December 31, 2018, a hypothetical, unfavorable 1% movement in the levels of foreign currency exchange rates relative to the NT dollar, after taking into account offsetting positions, would have increased our net unrealized losses by NT$3,149 thousand (US$103 thousand).

We do not currently engage in currency hedging activities in order to reduce our currency exposure, but we may begin to do so in the future. Instruments that may be used to hedge future risks may include foreign currency forward and swap contracts. These instruments may be used to selectively manage risks, but there can be no assurance that we will be fully protected against material foreign currency fluctuations. Currently, international purchases account for a lower relative percentage of our total purchases so we are less susceptible to impact of exchange rate risk than we would otherwise be if we were dependent on international purchases. Moreover, we have an operating strategy and risk control procedure in place which are designed to allow us to respond to change in the exchange rate quickly and adjust our foreign exchange strategy to minimize exchange risk. See Note 12(2)C to our consolidated financial statements for further disclosure.

Item 12. Description of Securities Other than Equity Securities.

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

JPMorgan Chase Bank, N.A., ("JPMorgan"), as depositary bank, registers and delivers our American Depositary Shares, also referred to as ADSs. Each ADS represents two common shares (or a right to receive two common shares) deposited with JPMorgan, Taipei Branch, or any successor, as custodian for the depositary. Each ADS will also represent any other securities, cash or other property which may be held by the depositary in respect of the depositary facility. The depositary's corporate office at which the ADSs are administered is located at 383 Madison Avenue, Floor 11, New York, NY 10179. A deposit agreement among us, the depositary and the ADS holders sets out ADS holder rights as well as the rights and obligations of the depositary. A form of the deposit agreement is incorporated by reference as an exhibit to this Annual Report.

Fees and Charges

The depositary may charge each person to whom ADSs are issued, including, without limitation, issuances against deposits of common shares, issuances in respect of share distributions, rights and other distributions, issuances pursuant to a stock dividend or stock split declared by us or issuances pursuant to a merger, exchange of securities or any other transaction or event affecting the ADSs or deposited securities, and each person surrendering ADSs for withdrawal of deposited securities or whose ADRs are cancelled or reduced for any other reason, US$5.00 for each 100 ADSs (or any portion thereof) issued, delivered, reduced, cancelled or surrendered, as the case may be. The depositary may sell (by public or private sale) sufficient securities and property received in respect of a share distribution, rights and/or other distributions prior to such deposit to pay such charge.

The following additional charges shall be incurred by the ADR holders, by any party depositing or withdrawing shares or by any party surrendering ADSs and/or to whom ADSs are issued (including, without limitation, issuances pursuant to a stock dividend or stock split declared by us or an exchange of stock regarding the ADSs or the deposited securities or a distribution of ADSs), whichever is applicable:

- a fee of up to US$0.05 per ADS for any cash distribution made pursuant to the deposit agreement;
- an aggregate fee of US$0.05 per ADS per calendar year (or portion thereof) for services performed by the depositary in administering the ADRs (which fee may be charged on a periodic basis during each calendar year and shall be assessed against holders of ADRs as of the record date or record dates set by the depositary during each calendar year and shall be payable in the manner described in the next succeeding provision);
- a fee for the reimbursement of such fees, charges and expenses as are incurred by the depositary and/or any of its agents (including, without limitation, the custodian and expenses incurred on behalf of ADR holders in connection with compliance with foreign exchange control regulations or any law or regulation relating to foreign investment) in connection with the servicing of the common shares or other deposited securities, the sale of securities (including, without limitation, deposited securities), the delivery of deposited securities or otherwise in connection with the depositary's or its custodian's compliance with applicable law, rule or regulation (which fees and charges shall be assessed on a proportionate basis against ADR holders as of the record date or dates set by the depositary and shall be payable at the sole discretion of the depositary by billing such ADR holders or by deducting such charge from one or more cash dividends or other cash distributions);

- a fee for the distribution of securities (or the sale of securities in connection with a distribution), such fee being in an amount equal to the US$0.05 per ADS issuance fee for the execution and delivery of ADSs which would have been charged as a result of the deposit of such securities (treating all such securities as if they were common shares) but which securities or the net cash proceeds from the sale thereof are instead distributed by the depositary to those ADR holders entitled thereto;
- stock transfer or other taxes and other governmental charges;
- SWIFT, cable, telex and facsimile transmission and delivery charges incurred at your request in connection with the deposit or delivery of shares, ADRs or deposited securities;
- transfer or registration fees for the registration or transfer of deposited securities on any applicable register in connection with the deposit or withdrawal of deposited securities;
- expenses of the depositary in connection with the sale of shares to pay ROC withholdings taxes on stock dividends pursuant to the deposit agreement (which are paid out of such foreign currency);
- in connection with the conversion of foreign currency into U.S. dollars, JPMorgan shall deduct out of such foreign currency the fees, expenses and other charges charged by it and/or its agent (which may be a division, branch or affiliate) so appointed in connection with such conversion; and
- fees of any division, branch or affiliate of JPMorgan utilized to direct, manage and/or execute any public and/or private sale of securities under the deposit agreement.

As an ADR holder, you will also be responsible to pay any required charges to the Taiwan tax authority, which are subject to change. As of the date hereof, the charges may include:

Service	Fee
Issuance of ADSs upon a deposit of common shares	0.3% of the aggregate price of ADS issued
Withdrawal of common shares upon cancellation of ADSs	0.3% of the aggregate price of ADS canceled
Sale of common shares on the Taiwan Exchange	0.3% of the aggregate price of common shares sold

JPMorgan and/or its agent may act as principal for any conversion of foreign currency.

We will pay all other charges and expenses of the depositary and any agent of the depositary (except the custodian) pursuant to agreements from time to time between us and the depositary. The charges described above may be amended from time to time by agreement between us and the depositary. The right of the depositary to receive payment of fees, charges and expenses as provided above shall survive the termination of the deposit agreement.

The depositary anticipates reimbursing us for certain expenses incurred by us that are related to the establishment and maintenance of the ADR program upon such terms and conditions as we and the depositary may agree from time to time. The depositary may make available to us a set amount or a portion of the depositary fees charged in respect of the ADR program or otherwise upon such terms and conditions as we and the depositary may agree from time to time. The depositary collects its fees for issuance and cancellation of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions, or by directly billing investors, or by charging the book-entry system accounts of participants acting for them. The depositary will generally set off the amounts owing from distributions made to holders of ADSs. If, however, no distribution exists and payment owing is not timely received by the depositary, the depositary may refuse to provide any further services to holders that have not paid those fees and expenses owing until such fees and expenses have been paid. At the discretion of the depositary, all fees and charges owing under the deposit agreement are due in advance and/or when declared owing by the depositary.

Payment of Taxes

If any taxes or other governmental charges (including any penalties and/or interest) shall become payable by or on behalf of the custodian or the depositary with respect to any ADR, any deposited securities represented by the ADSs evidenced thereby or any distribution thereon, such tax or other governmental charge shall be paid by the ADR holders to the depositary and by holding or having held an ADR the holder thereof and all prior holders thereof, jointly and severally, agree to indemnify, defend and save harmless each of the depositary and its agents in respect thereof. If an ADR holder owes any tax or other governmental charge, the depositary may (i) deduct the amount thereof from any distributions, or (ii) sell deposited securities (by public or private sale) and deduct the amount owing from the net proceeds of such sale. In either case the ADR holder remains liable for any shortfall. If any tax or governmental charge is unpaid, the depositary may also refuse to effect any registration, registration of transfer, split-up or combination of ADRs or withdrawal of deposited securities until such payment is made. If any tax or governmental charge is required to be withheld on any cash distribution, the depositary may deduct the amount required to be withheld from any cash distribution or, in the case of a non-cash distribution, sell the distributed property or securities (by public or private sale) in such amounts and in such manner as the depositary deems necessary and practicable to pay such taxes and shall distribute any remaining net proceeds or the balance of any such property after deduction of such taxes to the ADR holders entitled thereto.

Notwithstanding the above, we will pay all stamp duties and other similar duties or taxes payable in the ROC, the United States of America and any other jurisdiction, on or in connection with the constitution and issue of the ADSs and the execution or other event concerning the deposit agreement. If any legal proceedings are taken to enforce our obligations under the deposit agreement or the ADSs and for the purpose of such proceedings any of them are required to be taken into or enforced in any jurisdiction and stamp duties or other similar duties or taxes become payable in connection with such proceedings in such jurisdiction, the ADR holders will pay (or reimburse the person making a valid payment of) all such stamp duties and other similar duties and taxes, including any penalties and interest, unless otherwise ordered by a court of competent jurisdiction in such proceedings. The depositary may sell any deposited securities and cancel ADSs with respect thereof in order to pay any such stamp duties or other similar duties or taxes owed under the deposit agreement by ADR holders without the depositary being required to request payment thereof from the ADR holders.

By holding an ADR or an interest therein, you will be agreeing to indemnify us, the depositary, its custodian and any of our or their respective officers, directors, employees, agents and affiliates against, and hold each of them harmless from, any claims by any governmental authority with respect to taxes, additions to tax, penalties or interest arising out of any refund of taxes, reduced rate of withholding at source or other tax benefit obtained, and such obligations shall survive the transfer or surrender of ADSs or the termination of the deposit agreement.

Reclassifications, Recapitalizations and Mergers

If we take certain actions that affect the deposited securities, including (i) any change in par value, split-up, consolidation, cancellation or other reclassification of deposited securities or (ii) any distributions of common shares or other property not made to holders of ADRs or (iii) any recapitalization, reorganization, merger, consolidation, liquidation, receivership, bankruptcy or sale of all or substantially all of our assets, then the depositary may choose to, and shall if reasonably requested by us:

(1) amend the form of ADR;

(2) distribute additional or amended ADRs;

(3) distribute cash, securities or other property it has received in connection with such actions;

(4) sell by public or private sale any securities or property received; or

(5) none of the above.

If the depositary does not choose any of the above options, any of the cash, securities or other property it receives will constitute part of the deposited securities and each ADS will then represent a proportionate interest in such property.

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies.

Not applicable.

Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds.

Not applicable.

Item 15. Controls and Procedures.

A. Disclosure Controls and Procedures.

Our management, with the participation of our Chief Executive Officer and Vice President of Finance and Administration, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of December 31, 2018. Based on such evaluation, our Chief Executive Officer and Vice President of Finance and Administration have concluded that, as of December 31, 2018, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our Chief Executive Officer and Vice President of Finance and Administration, as appropriate to allow timely decisions regarding required disclosure.

B. Management's Annual Report on Internal Control Over Financial Reporting.

This annual report does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

C. Attestation Report of the Registered Public Accounting Firm.

This annual report does not include an attestation report of the company's independent registered public accounting firm. Our independent registered public accounting firm will not be required to opine on the effectiveness of our internal control over financial reporting until we are no longer an emerging growth company.

D. Changes in Internal Control Over Financial Reporting.

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the period covered by this Annual Report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 16. [Reserved]

Item 16A. Audit Committee Financial Expert

Our Audit Committee is comprised of three of our non-executive directors, Dr. Liu, Ms. Kang and Dr. Tom Chen. The audit committee consists exclusively "independent directors" as such term is defined in Rule 10A-3 under the Exchange Act and under the listing standards of the Nasdaq Stock Market. Dr. Liu serves as chair of this committee. Our Board has determined that Dr. Liu is an "audit committee financial expert" as defined in Item 16A of Form 20-F.

Item 16B. Code of Ethics

We have adopted a Code of Ethics for directors and officers, which covers a broad range of matters including the handling of conflicts of interest, compliance issues and other corporate policies. We have also adopted a Code of Conduct for our employees which covers the same topics. Our Code of Ethics is available on our website at http://www.tlcbio.com.

Item 16C. Principal Accountant Fees and Services

PricewaterhouseCoopers, Taiwan has served as our independent registered public accountant since 2002 and has audited our consolidated financial statements for the years ended December 31, 2018, 2017 and 2016, which appear elsewhere in this Annual Report.

The following table shows the aggregate fees for services rendered by PricewaterhouseCoopers, Taiwan to us and our subsidiaries, in the fiscal years ended December 31, 2018 and 2017.

	Year Ended December 31,					
	2017		2018			
	(in thousands)					
Fee Category						
Audit fees	NT$	3,290	NT$	22,700	US$	742
Audit-related fees		—		4,591		150
Tax fees		1,151		670		22
All other fees		579		167		5
Total	$	5,020	$	28,128	$	919

Audit Fees. Audit fees consisted of fees for the audit of our annual financial statements included in our annual filings with the SEC and other professional services provided in connection with the statutory and regulatory filings or engagements. Audit fees also include fees for assurance reporting on our current and historical financial information included in our SEC registration statements in connection with our initial public offering on the Nasdaq Global Market and also fees for the interim review period also included in our SEC registration statements in connection with our initial public offering on the Nasdaq Global Market.

Audit-related fees. Audit-related fees included fees for comfort letter on our current and historical financial information included in our SEC registration statements in connection with our initial public offering on the Nasdaq Global Market.

Tax fees. Tax fees consisted of fees relating to tax compliance services and advice relating to the company's assessment of its passive foreign investment status.

All Other Fees. This category includes aggregate fees for respective years for services other than the services included in the above.

Audit Committee Pre-Approval Policies and Procedures

Our audit committee reviews and pre-approves the scope and the cost of audit services related to us and permissible non-audit services performed by the independent auditors, other than those for *de minimis* services which are approved by the audit committee prior to the completion of the audit. All of the services related to our company provided by PricewaterhouseCoopers, Taiwan during the last fiscal year have been approved by the audit committee.

Item 16D. Exemptions from the Listing Standards for Audit Committees

Not applicable.

Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Not applicable.

Item 16F. Change in Registrant's Certifying Accountant

Not Applicable.

Item 16G. Corporate Governance

We are a "foreign private issuer," as defined by the SEC. As a result, in accordance with the rules and regulations of The Nasdaq Stock Market LLC (Nasdaq), we will comply with home country governance requirements and certain exemptions thereunder rather than complying with Nasdaq corporate governance standards. While we voluntarily follow most Nasdaq corporate governance rules, we may choose to take advantage of the following exemptions afforded to foreign private issuers:

- Exemption from the Nasdaq rules applicable to domestic issuers requiring disclosure within four business days of any determination to grant a waiver of the code of business conduct and ethics to directors and officers. Although we will require board approval of any such waiver, we may choose not to disclose the waiver in the manner set forth in the Nasdaq rules, as permitted by the foreign private issuer exemption.
- Exemption from the requirement that a majority of our board consist of independent directors.
- Exemption from the requirement that our board have a compensation committee that is comprised entirely of independent directors with a written charter addressing the committee's responsibilities and authority.
- Exemption from the requirement to have independent director oversight of director nominations and a formal written charter or board resolution addressing the nominations process.
- Exemption from the requirement that we have a code of conduct applicable to all directors, officers and employees (but not from any requirement that we have a code of conduct in compliance with Section 406 of the Sarbanes-Oxley Act of 2002).
- Exemption from the requirement to obtain shareholder approval for certain issuances of securities, including shareholder approval of stock option plans.
- Exemption from the requirement that our audit committee have review and oversight over all "related party transactions," as defined in Item 7.B of Form 20-F.
- Exemption from the requirement that we hold regularly scheduled meetings at which only independent directors are present.

We intend to follow our home country, Taiwan, practices in lieu of the foregoing requirements. Although we may rely on home country corporate governance practices in lieu of certain of the rules in the Nasdaq Rule 5600 Series and Rule 5250(d), we must comply with Nasdaq's Notification of Noncompliance requirement (Rule 5625), the Voting Rights requirement (Rule 5640) and have an audit committee that satisfies Rule 5605(c)(3), consisting of committee members that meet the independence requirements of Rule 5605(c)(2)(A)(ii). Although we currently comply with the Nasdaq corporate governance rules applicable other than as noted above, we may in the future decide to use the foreign private issuer exemption with respect to some or all the other Nasdaq corporate governance rules.

In addition, as a foreign private issuer, we expect to take advantage of the following exemptions from SEC reporting obligations:

- Exemption from filing quarterly reports on Form 10-Q or provide current reports on Form 8-K disclosing significant events within four days of their occurrence.
- Exemption from Section 16 rules regarding sales of common shares by insiders, which will provide less data in this regard than shareholders of U.S. companies that are subject to the Exchange Act.

Accordingly, our shareholders will not have the same protections afforded to shareholders of companies that are subject to all of the corporate governance requirements of Nasdaq and the domestic reporting requirements of the SEC. We may utilize these exemptions for as long as we continue to qualify as a foreign private issuer.

Item 16H. Mine Safety Disclosure

Not applicable.

Item 17. Financial Statements.

See pages F-1 through F-62 of this Annual Report on Form 20-F.

Item 18. Financial Statements.

The financial statements are filed as part of this Annual Report beginning on page F-1.

Item 19. Exhibits.

List all exhibits filed as part of the registration statement or annual report, including exhibits incorporated by reference.

EXHIBIT INDEX

Exhibit	Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibit	File Date
1.1	Articles of Incorporation of Taiwan Liposome Company, Ltd. (English translation).	F-1/A	333-223090	3.1	9/17/2018
2.1	Form of Deposit Agreement (incorporated by reference to Exhibit (a) to the Registrant's Amendment No. 2 to the Registration Statement on Form F-6 filed with the Securities and Exchange Commission on November 9, 2018).	F-1/A	333-223090	2.1	11/14/2018
2.2	Form of American Depositary Receipt (included in Exhibit 2.1)	F-1/A	333-223090	2.2	11/14/2018
4.1†	2013 Employee Stock Option Issuance and Share Subscription Plan of Taiwan Liposome Company, Ltd. (English translation).	F-1	333-223090	10.1	2/16/2018
4.2†	2014 Employee Stock Option Issuance and Share Subscription Plan of Taiwan Liposome Company, Ltd. (English translation).	F-1	333-223090	10.2	2/16/2018
4.3†	2015 Employee Stock Option Issuance and Share Subscription Plan of Taiwan Liposome Company, Ltd. (English translation).	F-1	333-223090	10.3	2/16/2018
4.4†	2014 Regulations on the Issuance of New Employee Restricted Stock (English translation).	F-1	333-223090	10.4	2/16/2018
4.5†	2017 Regulations on the Issuance of New Employee Restricted Stock (English translation).	F-1	333-223090	10.5	2/16/2018
4.6	Lease Agreement by and between Taiwan Liposome Company, Ltd. and Mercuries Life Insurance Company Ltd., dated March 29, 2017 (English translation).	F-1	333-223090	10.6	2/16/2018
4.7	Lease Agreement by and between Taiwan Liposome Company, Ltd. and Yi Kuan Technology Company Ltd., dated May 5, 2015 (English translation).	F-1	333-223090	10.7	2/16/2018
4.8	Lease Agreement by and between Taiwan Liposome Company, Ltd. and China Life Insurance Co., Ltd., dated December 9, 2014 (English translation).	F-1	333-223090	10.8	2/16/2018

Exhibit	Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibit	File Date
4.9	Loan and Security Agreement, by and among Taiwan Liposome Company, Ltd., TLC Biopharmaceuticals, Inc. and Cathay Bank, dated December 27, 2018.	6-K	001-38746	10.1	1/03/2019
4.10*	First Amendment to Loan and Security Agreement, by and among Taiwan Liposome Company, Ltd., TLC Biopharmaceuticals, Inc. and Cathay Bank, dated April 25, 2019.				
4.11†	2018 Employee Stock Option Issuance and Share Subscription Plan of Taiwan Liposome Company, Ltd. (English translation).	F-1/A	333-223090	10.9	9/17/2018
4.12†	Form of indemnity agreement by and between Taiwan Liposome Company, Ltd. and its directors and officers.	F-1/A	333-223090	10.11	9/17/2018
8.1	Subsidiaries of the registrant.	F-1	333-223090	21.1	2/16/2018
12.1*	Certification by the Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
12.2*	Certification by the Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
13.1**	Certification by the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
15.1*	Consent of PricewaterhouseCoopers, Taiwan, an independent registered public accounting firm.				
101.INS*	XBRL Instance Document				
101.SCH*	XBRL Taxonomy Extension Schema Document				
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document				

* Filed herewith.
** Furnished herewith.
† Indicates a management contract or any compensatory plan, contract or arrangement.

SIGNATURES

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

TAIWAN LIPOSOME COMPANY, LTD.

Date: April 30, 2019

By: /s/ Keelung Hong, Ph.D.
Keelung Hong, Ph.D.
Chief Executive Officer and Chairman

INDEX TO THE FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Taiwan Liposome Company, Ltd.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Taiwan Liposome Company, Ltd. and its subsidiaries (the "Company") as of December 31, 2018, and 2017, and the related consolidated statements of comprehensive income, of changes in equity and of cash flows for each of the three years in the period ended December 31, 2018, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Emphasis of Matter

As discussed in Note 1 to the consolidated financial statements, the Company will require additional financing to fund future operations. Management's plans in regard to this matter are also described in Note 1.

/s/ PricewaterhouseCoopers, Taiwan
Taipei, Taiwan
Republic of China
April 30, 2019

We have served as the Company's auditor since 2002.

TAIWAN LIPOSOME COMPANY, LTD. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

Assets	Notes	December 31, 2017 NT$000	December 31, 2018 NT$000	December 31, 2018 US$000 (Note 4(24))
Current Assets				
Cash and cash equivalents	6(1)	$ 951,713	$ 807,484	$ 26,380
Current financial assets at amortized cost	6(2)	—	307,150	10,034
Current contract assets	6(18)	—	2,283	75
Accounts receivable, net	6(3)	8,622	9,343	305
Other receivables	6(19)	19,726	5,811	190
Current income tax assets		414	113	4
Prepayments	6(4)	71,400	56,511	1,846
		1,051,875	1,188,695	38,834
Non-current Assets				
Property, plant and equipment	6(5) and 8	153,835	158,245	5,170
Intangible assets	6(6)	8,637	4,030	131
Deferred income tax assets	6(24)	81	79	2
Other non-current assets	6(7)	48,111	66,872	2,185
		210,664	229,226	7,488
Total Assets		$ 1,262,539	$ 1,417,921	$ 46,322

Liabilities and Equity	Notes	December 31, 2017 NT$000	December 31, 2018 NT$000	December 31, 2018 US$000 (Note 4(24))
Current Liabilities				
Short-term borrowings	6(8)	$ 46,000	$ 46,000	$ 1,503
Other payables	6(9)(26)	93,541	206,268	6,739
Other current liabilities	6(10)(11)	53,513	92,020	3,006
		193,054	344,288	11,248
Non-current Liabilities				
Long-term borrowings	6(10)	66,177	368,010	12,023
Provisions for liabilities – non-current	6(14)	6,922	6,922	226
Other non-current liabilities	6(11)(12)	9,102	29,505	963
		82,201	404,437	13,212
Total Liabilities		275,255	748,725	24,460
Equity				
Common shares	6(15)	561,990	640,451	20,923
Capital surplus	6(16)	1,322,625	952,364	31,113
Accumulated deficit	6(17)	(874,086)	(910,042)	(29,730)
Other equity interest		(23,245)	(13,577)	(444)
Total Equity		987,284	669,196	21,862
Events after the reporting period	11			
Total Liabilities and Equity		$ 1,262,539	$ 1,417,921	$ 46,322

The accompanying notes are an integral part of these consolidated financial statements.

TAIWAN LIPOSOME COMPANY, LTD. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
FOR THE YEARS ENDED DECEMBER 31, 2016, 2017 AND 2018

Items	Notes	2016 NT$000	2017 NT$000	2018 NT$000	2018 US$000 (Note 4(24))
Operating revenue	(18) and 6 12(5)	$ 41,674	$ 49,635	$ 62,324	$ 2,036
Operating expenses	(12)(13)(22) 6(23)				
General and administrative expenses		(141,494)	(134,869)	(147,743)	(4,827)
Research and development expenses		(736,878)	(813,252)	(832,575)	(27,200)
		(878,372)	(948,121)	(980,318)	(32,027)
Other income and expenses	6(19)	5,575	21,148	26,228	857
Operating loss		(831,123)	(877,338)	(891,766)	(29,134)
Non-operating income and expenses					
Interest income		9,893	5,060	2,453	80
Other gains and losses	6(20)	417	2,652	(1,508)	(49)
Finance costs	6(21)	(2,940)	(3,385)	(9,886)	(323)
		7,370	4,327	(8,941)	(292)
Loss before income tax		(823,753)	(873,011)	(900,707)	(29,426)
Income tax expense	6(24)	(563)	(951)	(867)	(28)
Net loss		$ (824,316)	$ (873,962)	$ (901,574)	$ (29,454)
Other comprehensive income (loss)					
Items that will not be reclassified to profit or loss					
Remeasurement arising on defined benefit plans	6(12)	$ (346)	$ (124)	$ (527)	$ (17)
Items that may be subsequently reclassified to profit or loss					
Financial statement translation differences of foreign operations		(857)	(3,396)	(727)	(24)
Total other comprehensive loss, net		$ (1,203)	$ (3,520)	$ (1,254)	$ (41)
Total comprehensive loss		$ (825,519)	$ (877,482)	$ (902,828)	$ (29,495)
Loss attributable to:					
Owners of the parent		$ (824,316)	$ (873,962)	$ (901,574)	$ (29,454)
Total comprehensive loss attributable to:					
Owners of the parent		$ (825,519)	$ (877,482)	$ (902,828)	$ (29,495)
Loss per share of common share	6(25)				
Basic loss per share (in dollars)		$ (14.89)	$ (15.75)	$ (14.37)	$ (0.47)
Diluted loss per share (in dollars)		$ (14.89)	$ (15.75)	$ (14.37)	$ (0.47)

The accompanying notes are an integral part of these consolidated financial statements.

TAIWAN LIPOSOME COMPANY, LTD. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2016, 2017 AND 2018

		Equity attributable to owners of the parent									
			Capital surplus					Other equity interest			
	Notes	Common shares	Additional paid-in capital	Treasury stocks	Share options	Restricted stocks	Accumulated deficit	Exchange difference on translation of foreign financial statements	Unearned compensation	Treasury Stock	Total equity
		NT$000	NT$000	NT$000	NT$000	NT$000	NT$000	NT$000	NT$000	NT$000	NT$000
2016											
Balance at January 1, 2016		$ 556,203	$ 2,465,421	$ —	$ 156,053	$ 31,495	($ 673,652)	$ 2,541	($ 15,788)	($ 36,893)	$ 2,485,470
Net loss		—	—	—	—	—	(824,316)	—	—	—	(824,316)
Other comprehensive loss		—	—	—	—	—	(346)	(857)	—	—	(1,203)
Total comprehensive loss		—	—	—	—	—	(824,662)	(857)	—	—	(825,519)
Share-based payments	6(13)	—	—	—	94,479	—	—	—	6,094	—	100,573
Exercise of employee stock options	6(13)(15)	1,449	34,820	—	(30,169)	—	—	—	—	—	6,100
Cancellation of restricted stocks		(346)	—	—	—	346	—	—	—	—	—
Restricted stocks vested	6(13)	—	9,279	—	—	(9,279)	—	—	—	—	—
Treasury stocks transferred to employees		—	—	7,009	(6,984)	—	—	—	—	36,893	36,918
Capital surplus used to cover accumulated deficit	6(17)	—	(673,562)	—	—	—	673,562	—	—	—	—
Balance at December 31, 2016		$ 557,306	$ 1,835,958	$ 7,009	$ 213,379	$ 22,562	($ 824,662)	$ 1,684	($ 9,694)	$ —	$ 1,803,542
2017											
Balance at January 1, 2017		$ 557,306	$ 1,835,958	$ 7,009	$ 213,379	$ 22,562	($ 824,662)	$ 1,684	($ 9,694)	$ —	$ 1,803,542
Net loss		—	—	—	—	—	(873,962)	—	—	—	(873,962)
Other comprehensive loss		—	—	—	—	—	(124)	(3,396)	—	—	(3,520)
Total comprehensive loss		—	—	—	—	—	(874,086)	(3,396)	—	—	(877,482)
Issuance of restricted stocks to employees	6(13)(15)	5,000	—	—	—	22,489	—	—	(23,114)	—	4,375
Share-based payments	6(13)	—	—	—	52,835	—	—	—	4,314	—	57,149
Share options forfeited		—	37,000	—	(37,000)	—	—	—	—	—	—
Cancellation of restricted stocks	6(13)(15)	(316)	—	—	—	16	—	—	—	—	(300)
Restricted stocks vested	6(13)	—	10,312	—	—	(17,273)	—	—	6,961	—	—
Capital surplus used to cover accumulated deficit	6(17)	—	(824,662)	—	—	—	824,662	—	—	—	—
Balance at December 31, 2017		$ 561,990	$ 1,058,608	$ 7,009	$ 229,214	$ 27,794	($ 874,086)	($ 1,712)	($ 21,533)	—	$ 987,284
2018											
Balance at January 1, 2018		$ 561,990	$ 1,058,608	$ 7,009	$ 229,214	$ 27,794	($ 874,086)	($ 1,712)	($ 21,533)		$ 987,284
Effects of retrospective application of new standards	3	—	—	—	—	—	(7,941)	—	—		(7,941)
Balance at January 1, 2018 after adjustments		561,990	1,058,608	7,009	229,214	27,794	(882,027)	(1,712)	(21,533)		979,343
Net loss		—	—	—	—	—	(901,574)	—	—		(901,574)
Other comprehensive loss		—	—	—	—	—	(527)	(727)	—		(1,254)
Total comprehensive loss		—	—	—	—	—	(902,101)	(727)	—		(902,828)
Issuance of new share capital, net of issuance costs of $100,499 thousand	6(15)	78,311	472,546	—	—	—	—	—	—		550,857
Issuance of restricted stocks to employees	6(13)(15)	500	—	—	—	3,539	—	—	(3,421)		438
Share-based payments	6(13)	—	—	—	27,570	—	—	—	13,816		41,386
Share options forfeited		—	69,935	—	(69,935)	—	—	—	—		—
Cancellation of restricted stocks	6(13)(15)	(350)	—	—	—	350	—	—	—		—
Restricted stocks vested	6(13)	—	5,813	—	—	(5,813)	—	—	—		—
Capital surplus used to cover accumulated deficit	6(17)	—	(874,086)	—	—	—	874,086	—	—		—
Balance at December 31, 2018		$ 640,451	$ 732,816	$ 7,009	$ 186,849	$ 25,690	($ 910,042)	($ 2,439)	($ 11,138)		$ 669,196
Balance at December 31, 2018 (in US$000)	4(24)	$ 20,923	$ 23,941	$ 229	$ 6,104	$ 839	($ 29,730)	($ 80)	($ 364)		$ 21,862

The accompanying notes are an integral part of these consolidated financial statements.

TAIWAN LIPOSOME COMPANY, LTD. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2016, 2017, AND 2018

	Notes	2016	2017	2018	
		NT$000	NT$000	NT$000	US$000 (Note 4(24))
CASH FLOWS FROM OPERATING ACTIVITIES					
Loss before tax		($ 823,753)	($ 873,011)	($ 900,707)	($ 29,426)
Adjustments					
Adjustments to reconcile profit (loss) before income tax to net cash flows					
Provision for doubtful accounts	12(4)	9,067	9,065	—	—
Share-based payments	6(13)	100,573	57,149	41,386	1,352
Deferred revenue		(1,103)	—	—	—
Depreciation	6(5)(22)	63,571	41,926	39,315	1,284
Amortization	6(6)(22)	11,668	10,570	8,144	266
Interest expense	6(21)	2,940	3,385	9,886	323
Interest income		(9,893)	(5,060)	(2,453)	(80)
Gain on disposal of property, plant and equipment	6(20)	—	(20)	(1,478)	(48)
Prepayments for equipment being transferred to other expense	6(26)	—	—	780	25
Changes in operating assets and liabilities					
Changes in operating assets					
Accounts receivable, net		(523)	(701)	(721)	(24)
Current contract assets		—	—	(2,283)	(75)
Other receivables		1	(19,546)	14,158	463
Prepayments		(5,886)	(24,501)	17,475	571
Changes in operating liabilities					
Notes payable		(544)	(206)	—	—
Current contract liabilities		—	—	(7,941)	(259)
Other payables		42,933	(25,035)	106,776	3,488
Other current liabilities		(75)	248	(366)	(12)
Provisions for liabilities- non-current		—	(74)	—	—
Other non-current liabilities		(3,293)	47	(124)	(4)
Cash outflow from operations		(614,317)	(825,764)	(678,153)	(22,156)
Interest received		10,163	5,165	2,210	72
Interest paid		(2,945)	(3,361)	(9,924)	(324)
Income tax paid		(620)	(230)	(488)	(16)
Tax refunds received		—	5,051	316	10
Net cash flows used in operating activities		(607,719)	(819,139)	(686,039)	(22,414)

(Continued)

TAIWAN LIPOSOME COMPANY, LTD. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2016, 2017 AND 2018

	Notes	2016	2017	2018	
		NT$000	NT$000	NT$000	US$000 (Note 4(9))
CASH FLOWS FROM INVESTING ACTIVITIES					
Acquisition of current financial assets at amortized cost		$ —	$ —	($ 307,150)	($ 10,034)
Decrease in other financial assets		4,761	1,817	—	—
Increase in other financial assets		(1,817)	—	—	—
Acquisition of property, plant and equipment	6(26)	(21,427)	(18,133)	(66,709)	(2,179)
Proceeds from disposal of property, plant and equipment	6(26)	—	24	—	—
Acquisition of intangible assets		(4,644)	(7,201)	(3,163)	(103)
(Increase) decrease in refundable deposits		7,449	(5,998)	8,258	270
Net cash flows used in investing activities		(15,678)	(29,491)	(368,764)	(12,046)
CASH FLOWS FROM FINANCING ACTIVITIES					
Proceeds from short-term borrowings		$ 46,000	$ 46,000	$ 46,000	$ 1,503
Payments of short-term borrowings		(46,000)	(46,000)	(46,000)	(1,503)
Proceeds from long-term borrowings		—	—	731,580	23,900
Payments of long-term borrowings		(2,760)	(1,700)	(366,874)	(11,986)
Proceeds from finance lease liabilities		21,500	48,000	40,000	1,307
Payment of finance lease liabilities		(23,000)	(46,500)	(44,000)	(1,437)
Employee stock option exercised		6,100	—	—	—
Issuance of restricted stocks to employees		—	5,000	500	16
Cancellation of restricted stocks		(346)	(316)	(350)	(11)
Treasury stock transferred to employees		36,918	—	—	—
Proceeds from issuance of new share capital, net of issuance costs of $100,499 thousand	6(15)	—	—	550,857	17,996
Net cash flows from financing activities		38,412	4,484	911,713	29,785
Effect from foreign currency exchange		(742)	(2,941)	(1,139)	(37)
Net decrease in cash and cash equivalents		(585,727)	(847,087)	(144,229)	(4,712)
Cash and cash equivalents at beginning of year		2,384,527	1,798,800	951,713	31,092
Cash and cash equivalents at end of year		$ 1,798,800	$ 951,713	$ 807,484	$ 26,380

The accompanying notes are an integral part of these consolidated financial statements.

TAIWAN LIPOSOME COMPANY, LTD. AND SUBSIDIARIES
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2016, 2017 AND 2018
(EXPRESSED IN THOUSANDS OF NEW TAIWAN DOLLARS,
EXCEPT AS OTHERWISE INDICATED)

1. HISTORY AND ORGANIZATION

Taiwan Liposome Company, Ltd. (the "Company") was incorporated as a company limited by shares under the provisions of the Company Act of the Republic of China (R.O.C.) and was listed on the Taipei Exchange on December 21, 2012. In November 2018, the Company's American Depositary Shares ("ADSs") was listed on the Nasdaq Global Market. The Company and its subsidiaries (collectively referred herein as the "Group") are mainly engaged in the development and commercialization of pharmaceutical products based on its proprietary lipid-assembled drug delivery platform technologies.

The Company's financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The Company has financed its operations to date primarily through the issuance of common shares. The Company has incurred net losses of NT$901.574 million (US$29,454 thousand) for the year ended December 31, 2018. As of December 31, 2018, the Company had an accumulated deficit of NT$910.042 million (US$29,730 thousand) after taking into account of capital surplus to cover accumulated deficit amounted to NT$874.086 million (US$28,556 thousand). The Company has reported a net loss in all fiscal periods since inception and expects to incur substantial and increased expenses to expand its development activities and advance its clinical programs. The Company expects to continue to generate operating losses in the foreseeable future.

As of December 31, 2018, the Company had cash and cash equivalents of NT$807.484 million (US$26,380 thousand) and a time deposit with maturity over three months of NT$307.150 million (US$10,034 thousand) (shown as "Current financial assets at amortized cost"). The above time deposits include the funding from a loan and security agreement of NT$368.580 million (US$12,000 thousand) that has a maturity date in June 2020. As disclosed in Note 6(10), the Group is required to maintain certain financial covenants quarterly and annually agreed by both parties, and the bank can inspect at any time when necessary.

As the Company is in the research and development phase, the Company may seek future funding based on the need of capital. The Company is able to exercise discretion and flexibility to deploy its capital resources in the progress of the research and development according to the schedule of fund raising. Based on the Company's business plans, management believes that its cash and cash equivalents are sufficient to fund its operating expenses and capital expenditure requirements and meet its obligations for at least the next twelve months from the issuance date of these consolidated financial statements. However, the future viability of the Company beyond that date is dependent on its ability to raise additional capital to finance its operations. Until such time, if ever, that the Company can generate product revenue sufficient to achieve profitability, the Company expects to finance its cash needs primarily through equity offerings and debt borrowings. If the Company is unable to obtain sufficient funds on acceptable terms when needed, the Company could be required to delay, limit, reduce or terminate certain of its research and development programs, which could have adverse effects on the Company's business prospects. The Company's business plans, consider, among others, the cost management, the issuance of its common shares and renewal of its banking facilities with the financial institutions. Although management continues to pursue these plans, there can be no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations.

2. THE DATE OF AUTHORIZATION FOR ISSUANCE OF THE CONSOLIDATED FINANCIAL STATEMENTS AND PROCEDURES FOR AUTHORIZATION

These consolidated financial statements were authorized for issuance by the Audit Committee on April 30, 2019.

3. APPLICATION OF NEW STANDARDS, AMENDMENTS AND INTERPRETATIONS

(1) New and amended standards adopted by the Group

A number of new or amended standards became applicable for the current reporting period and the Group had to change its accounting policies as a result of adopting the following standards:

- IFRS 2, "Share-based Payment"
- IFRS 9, "Financial Instruments"
- IFRS 15, "Revenue from Contracts with Customers"
- IFRIC 22, "Foreign Currency Transactions and Advance Consideration"
- Amendments resulting from Annual Improvements 2014–2016 Cycle

The adoption and impact of these standards from January 1, 2018 are described as below and the new accounting policies are disclosed in Note 4. The other standards did not have material impact on the Group's accounting policies.

Adoption and impact of IFRS 15 – Revenue from Contract with Customers and amendments

(a) In accordance with the transition provisions in IFRS 15, the group has adopted the modified retrospective approach for transition and applied IFRS 15 only to contracts that are not completed at the date of initial application.

(b) The cumulative effects of applying the new standards as of January 1, 2018 are summarized below:

	Book value under previous revenue standard	Adjustment for initial application of IFRS	Adjusted amount after IFRS 15 adoption
	NT$000	NT$000	NT$000
Affected items			
January 1, 2018			
Contract liabilities	$ —	$ 7,941	$ 7,941
Total affected liabilities	—	7,941	7,941
Accumulated deficit	(874,086)	(7,941)	(882,027)
Total affected equity	(874,086)	(7,941)	(882,027)
Total affected liabilities and equity	($ 874,086)	$ —	($ 874,086)

	Book value under previous revenue standard	Adjustment for initial application of IFRS	Adjusted amount after IFRS 15 adoption
	US$000	US$000	US$000
Affected items			
January 1, 2018			
Contract liabilities	$ —	$ 259	$ 259
Total affected liabilities	—	259	259
Accumulated deficit	(28,556)	(259)	(28,815)
Total affected equity	(28,556)	(259)	(28,815)
Total affected liabilities and equity	($ 28,556)	$ —	($ 28,556)

The Group's authorization collaboration and development transactions generally authorizes intellectual property rights of the drug products to pharmaceutical companies. Though the Group will continuously provide research and development services on the drug products, pharmaceutical companies could make use of the research and development outcome at any time. Pharmaceutical companies pay a non-refundable up-front payment upon the signing of the contracts, and make milestone payments upon each milestone achieved. Pharmaceutical companies would have difficulty finding another service provider who offers the same services in terms of continuing research and development on the authorized drug products. Under the previous accounting policy, the Group recognized milestone payment revenue upon each milestone achieved, without distinguishing between authorization and continuing research and development services. After adopting IFRS 15, due to the authorization and follow-up milestones of research and development not meeting the criteria of distinction, the Group concluded that it will account for all the authorization and continuing research and development services as a single performance obligation and recognizes the transaction price according to the progress of performance obligations satisfied.

(c) Please refer to Note 12(5) for other disclosures in relation to the first adoption of IFRS 15.

(2) New standards and interpretations not yet adopted

Amendments to IFRSs which have been published but are not mandatory for the financial period ended December 31, 2018 are listed below:

IFRS 16 "Leases" is effective from January 1, 2019, with early application permitted. The new standard requires operating leases to be accounted for through the recognition of a "right of use asset" and a corresponding lease liability. Interest-bearing borrowings and non-current assets will increase on implementation of this standard. Operating lease costs will no longer be classified within the income statement based on amounts paid, but via a "right of use asset" depreciation charge recognized within operating profit and a lease interest expense within finance costs, subject to the exemptions on amount and duration. As at the reporting date, the Group has non-cancellable operating lease commitments of NT$78,102 thousand (US$2,551 thousand), see Note 9(2). As of January 1, 2019, the Group expects to increase both "right-of-use asset" and "lease liability" by approximately NT$73,021 thousand (US$2,386 thousand) and no significant impact to retained earnings.

Operating cash flows will increase and financing cash flows decrease by approximately NT$32,099 thousand (US$1,049 thousand) as repayment of the principal portion of the non-finance lease liabilities will be classified as cash flows from financing activities, where previously it was classified as operating cash outflows.

In addition, the following new and amended standards have been issued but not effective, which are not expected to have a significant impact on the Group's financial condition and financial performance based on the Group's assessment.

New Standards, Interpretations and Amendments	Effective Date by International Accounting Standards Board ("IASB")
Amendments to IFRS 9, 'Prepayment Features with Negative Compensation and Modifications of Financial Liabilities'	January 1, 2019
Amendments to IFRS 10 and IAS 28, 'Sale or contribution of assets between an investor and its associate or joint venture'	To be determined by IASB
IFRS 17, 'Insurance Contracts'	January 1, 2021
Amendments to IAS 19, 'Plan Amendment, Curtailment or Settlement'	January 1, 2019
Amendments to IAS 28, 'Long-term Interests in Associates and Joint Ventures'	January 1, 2019
IFRIC 23, 'Uncertainty over Income Tax Treatments'	January 1, 2019
Annual improvements 2015–2017 cycle	January 1, 2019
Amendments to IFRS 3, 'Definition of a business'	January 1, 2020
Amendment to IAS 1 and IAS 8, 'Disclosure Initiative-Definition of Material'	January 1, 2020

4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The principal accounting policies applied in the preparation of these consolidated financial statements are set out below. These policies have been consistently applied to all the periods presented, unless otherwise stated.

(1) Basis of preparation

A. Compliance with IFRS

These consolidated financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRSs"), which collective term includes all applicable individual IFRSs, International Accounting Standards ("IASs") issued by the International Accounting Standards Board ("IASB") and Interpretations issued by the International Financial Reporting Interpretations Committee ("IFRIC") of the IASB.

B. Historical cost convention

Except for defined benefit liabilities recognized based on the net amount of pension fund assets less present value of defined benefit obligation, these consolidated financial statements have been prepared under the historical cost convention.

The preparation requires the use of certain critical accounting estimates and also requires management to exercise its judgement in the process of applying the accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements are disclosed in Note 5.

C. In adopting IFRS 9 and IFRS 15 effective January 1, 2018, the Group elected to apply the modified retrospective approach whereby the cumulative impact of the adoption was recognized as retained earnings or other equity as of January 1, 2018 and the financial statements for each of the two years in the period ended December 31, 2017 were not restated. The financial statements for the years ended December 31, 2016 and 2017 were prepared in compliance with International Accounting Standard 39 ('IAS 39'), International Accounting Standard 11 ('IAS 11'), International Accounting Standard 18 ('IAS 18') and related financial reporting interpretations. Please refer to Notes 12(4) and (5) for details of significant accounting policies.

(2) Basis of consolidation

A. Basis for preparation of consolidated financial statements:

(a) All subsidiaries are included in the Group's consolidated financial statements. Subsidiaries are all entities (including structured entities) controlled by the Group. The Group controls an entity when the Group is exposed, or has rights, to variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. Consolidation of subsidiaries begins from the date the Group obtains control of the subsidiaries and ceases when the Group loses control of the subsidiaries.

(b) Inter-company transactions, balances and unrealized gains or losses on transactions between companies within the Group are eliminated. Accounting policies of subsidiaries have been adjusted where necessary to ensure consistency with the policies adopted by the Group.

B. Subsidiaries included in the consolidated financial statements:

Name of Investor	Name of Subsidiary	Main Business Activities	Ownership (%) December 31, 2017	Ownership (%) December 31, 2018
Taiwan Liposome Company, Ltd.	TLC Biopharmaceuticals, Inc.	Research on new anti-cancer drugs and biotechnology services	100	100
Taiwan Liposome Company, Ltd.	TLC Biopharmaceuticals B.V.	Technical authorization and product development	100	100
Taiwan Liposome Company, Ltd.	TLC Biopharmaceuticals, (H.K.) Limited	Biotechnology services and reinvestment	100	100
Taiwan Liposome Company, Ltd.	TLC Biopharmaceuticals Pty Ltd.	Technical authorization and product development	100	100
Taiwan Liposome Company, Ltd.	TLC Biopharmaceuticals, Japan Co., Ltd.	Technical authorization and product development	100	100
TLC Biopharmaceuticals, (H.K.) Limited	TLC Biopharmaceuticals, (Shanghai) Limited	Consulting and technical service of medication	100	100

C. Subsidiaries not included in the consolidated financial statements: None.

D. Adjustments for subsidiaries with different balance sheet dates: None.

E. Significant restrictions: None.

F. Subsidiaries that have non-controlling interests that are material to the Group: None.

(3) Foreign currency translation

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates (the "functional currency"). The consolidated financial statements are presented in New Taiwan dollars, which is the Company's functional and the Group's presentation currency.

A. Foreign currency transactions and balances

(a) Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions or valuation where items are remeasured. Foreign exchange gains and losses resulting from the settlement of such transactions are recognized in profit or loss in the period in which they arise.

(b) Monetary assets and liabilities denominated in foreign currencies at the period end are re-translated at the exchange rates prevailing at the balance sheet date. Exchange differences arising upon re-translation at the balance sheet date are recognized in profit or loss.

(c) All other foreign exchange gains and losses are presented in the statement of comprehensive income within other gains and losses.

B. Translation of foreign operations

The operating results and financial position of all the group entities that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

(a) Assets and liabilities for each balance sheet presented are translated at the closing exchange rate at the date of that balance sheet;

(b) Income and expenses for each statement of comprehensive income are translated at average exchange rates of that period; and

(c) All resulting exchange differences are recognized in other comprehensive income.

(4) Classification of current and non-current items

A. Assets that meet one of the following criteria are classified as current assets:

(a) Assets arising from operating activities that are expected to be realized, or are intended to be sold or consumed within the normal operating cycle;

(b) Assets held mainly for trading purposes;

(c) Assets that are expected to be realized within twelve months from the balance sheet date;

(d) Cash and cash equivalents, excluding restricted cash and cash equivalents and those that are to be exchanged or used to pay off liabilities more than twelve months after the balance sheet date.

B. Liabilities that meet one of the following criteria are classified as current liabilities:

(a) Liabilities that are expected to be paid off within the normal operating cycle;

(b) Liabilities arising mainly from trading activities;

(c) Liabilities that are to be paid off within twelve months from the balance sheet date;

(d) Liabilities for which the repayment date cannot be extended unconditionally to more than twelve months after the balance sheet date. Terms of a liability that could, at the option of the counterparty, result in its settlement by the issue of equity instruments do not affect its classification.

Assets and liabilities that are not classified as current are non-current assets and liabilities, respectively.

(5) Cash equivalents

Cash equivalents refer to short-term, highly liquid investments that are readily convertible to known amounts of cash, and are subject to an insignificant risk of changes in value, and have a short maturity of generally within three months when acquired.. Time deposits that meet the definition above and are held for the purpose of meeting short-term cash commitments in operations are classified as cash equivalents.

(6) Accounts receivable

A. In accordance with contracts, accounts receivable entitle the Group a legal right to receive consideration in exchange for transferred goods or rendered services.

B. The short-term accounts receivable not bearing interest are measured at initial invoice amount as the effect of discounting is immaterial.

(7) Impairment of financial assets

For financial assets at amortized cost including accounts receivable or contract assets that have a significant financing component, at each reporting date, the Group recognizes the impairment provision for 12 months expected credit losses if there has not been a significant increase in credit risk since initial recognition or recognizes the impairment provision for the lifetime expected credit losses ("ECLs") if such credit risk has increased since initial recognition after taking into consideration all reasonable and verifiable information that includes forecasts. On the other hand, for accounts receivable or contract assets that do not contain a significant financing component, the Group recognizes the impairment provision for lifetime ECLs.

(8) Derecognition of financial assets

The Group derecognizes a financial asset when one of the following conditions is met:

A. The contractual rights to receive the cash flows from the financial asset expire.

B. The contractual rights to receive cash flows of the financial asset have been transferred and the Group has transferred substantially all risks and rewards of ownership of the financial asset.

C. The contractual rights to receive cash flows of the financial asset have been transferred and the Group has not retained control of the financial asset.

(9) Property, plant and equipment

A. Property, plant and equipment are initially recorded at cost. Borrowing costs incurred during the construction period are capitalized.

B. Subsequent costs are included in the asset's carrying amount or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Group and the cost of the item can be reliably measured. The carrying amount of the replaced component is derecognized. All other repairs and maintenance are charged to profit or loss as incurred.

C. Land is not depreciated. The cost model is applied to other property, plant and equipment which is depreciated on a straight-line basis. Each component of an item of property, plant, and equipment with a cost that is significant in relation to the total cost of the item is depreciated separately.

D. The assets' residual values, useful lives and depreciation methods are reviewed, and adjusted if appropriate, at each financial year-end or earlier if events and circumstances warrant. If expectations for the assets' residual values and useful lives differ from previous estimates or the patterns of consumption of the assets' future economic benefits embodied in the assets have changed significantly, any change is accounted for as a change in estimate under IAS 8, 'Accounting Policies, Changes in Accounting Estimates and Errors', from the date of the change. The estimated useful lives of property, plant and equipment are as follows:

Buildings	44 years
Testing equipment	3 years ~ 8 years
Office equipment	3 years ~ 5 years
Leasehold assets	5 years ~ 10 years
Leasehold improvements	1 years ~ 5 years

(10) Leased assets/ lessee

A. Based on the terms of a lease contract, a lease is classified as a finance lease if the Group assumes substantially all the risks and rewards incidental to ownership of the leased asset.

(a) A finance lease is recognized as an asset and a liability at the lease's commencement at the lower of the fair value of the leased asset or the present value of the minimum lease payments.

(b) The minimum lease payments are apportioned between the finance charges and the reduction of the outstanding liability. The finance charges are allocated to each period over the lease term so as to produce a constant periodic rate of interest on the remaining balance of the liability.

(c) Property, plant and equipment held under finance leases are depreciated over their estimated useful lives. If there is no reasonable certainty that the Group will obtain ownership at the end of the lease, the asset shall be depreciated over the shorter of the lease term and its useful life.

B. Payments made under an operating lease (net of any incentives received from the lessor) are recognized in profit or loss on a straight-line basis over the lease term.

(11) Intangible assets

A. Professional technology, mainly patents and technology knowledge, which the Group acquired from third parties, is stated at cost and amortized on a straight-line basis over 10 years.

B. Computer software is stated at cost and amortized on a straight-line basis over its contract terms of 1 to 4 years.

(12) Impairment of non-financial assets

The Group assesses at each balance sheet date the recoverable amounts of those assets where there is an indication of impairment. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell or value in use. When the circumstances or reasons for recognizing impairment loss for an asset in prior years no longer exist or diminish, the impairment loss is reversed. The increased carrying amount due to reversal should not be more than what the depreciated or amortized historical cost would have been if the impairment had not been recognized.

(13) Borrowings

Borrowings are recognized initially at fair value, net of transaction costs incurred. Borrowings are subsequently stated at amortized cost; any difference between the proceeds (net of transaction costs) and the redemption value is recognized in profit or loss over the period of the borrowings using the effective interest method.

(14) Derecognition of financial liabilities

A financial liability (or a part of a financial liability) is derecognized when the obligation specified in the contract is either discharged or cancelled or expires.

(15) Provisions

Decommissioning provisions are recognized when the Group has a present legal or constructive obligation as a result of past events, and it is probable that an outflow of economic resources will be required to settle the obligation and the amount of the obligation can be reliably estimated. Provisions are measured at the present value of the expenditures expected to be required to settle the obligation on the balance sheet date, which is discounted using a pre-tax discount rate that reflects the current market assessments of the time value of money and the risks specific to the obligation. When discounting is used, the increase in the provision due to passage of time is recognized as interest expense. Provisions are not recognized for future operating losses.

(16) Employee benefits

A. Short-term employee benefits

Short-term employee benefits are measured at the undiscounted amount of the benefits expected to be paid in respect of service rendered by employees in a period and should be recognized as expenses in that period when the employees render service.

B. Pensions

(a) Defined contribution plans

For defined contribution plans, the contributions are recognized as pension expensen on an accrual basis. Prepaid contributions are recognized as an asset to the extent of a cash refund or a reduction in the future payments.

(b) Defined benefit plans

i. Net obligation under a defined benefit plan is defined as the present value of an amount of pension benefits that employees will receive on retirement for their services with the Group in current period or prior periods. The liability recognized is the present value of the defined benefit obligation at the balance sheet date less the fair value of plan assets. The defined benefit net obligation is calculated annually by independent actuaries using the projected unit credit method. The rate used to discount is determined by using interest rates of government bonds (at the balance sheet date) of a currency and term consistent with those of the employment benefit obligations.

ii. Remeasurements arising on defined benefit plans are recognized in other comprehensive income in the period in which they arise and are recorded as retained earnings.

(17) Employee share-based payment

A. (a) For the equity-settled share-based payment arrangements, the employee services received are measured at the fair value of the equity instruments granted at the grant date, and are recognized as compensation cost over the vesting period, with a corresponding adjustment to equity. The fair value of the equity instruments granted shall reflect the impact of market vesting conditions. Compensation cost is subject to adjustment based on the service conditions that are expected to be satisfied and the estimates of the number of equity instruments that are expected to vest at each balance sheet date. Ultimately, the amount of compensation cost recognized is based on the number of equity instruments that eventually vest.

(b) Whenever share options expire, the previous compensation costs recognized in “Capital surplus – Share options” are reclassified as “Capital surplus – Additional paid-in capital”.

B. Restricted stocks:

(a) Restricted stocks issued to employees are measured at the fair value of the equity instruments granted at the grant date subtracting the subscription price of NT$10 (in dollars), and are recognized as compensation cost over the vesting period. The Group has set the date when employees signed the agreement as the grant date of restricted stocks.

(b) For restricted stocks where those stocks do not restrict distribution of dividends to employees and employees are not required to return the dividends received if they resign during the vesting period, the Group recognizes the fair value of the dividends received by the employees who are expected to resign during the vesting period as compensation cost at the date of dividend declaration.

(c) For restricted stocks where employees have to pay to acquire those stocks, if employees resign during the vesting period, they must return the stocks to the Group and the Group must refund their payments on the stocks based on the original subscription price, the Group recognizes the payments from the employees who are expected to resign during the vesting period as liabilities at the grant date, and recognizes the payments from the employees who are expected to be eventually vested with the stocks in “Capital surplus – Restricted stocks”.

(18) Income tax

A. The tax expense for the period comprises current and deferred tax. Tax is recognized in profit or loss, except to the extent that it relates to items recognized in other comprehensive income or items recognized directly in equity, in which cases the tax is recognized in other comprehensive income or equity, respectively.

B. The current income tax expense is calculated on the basis of the tax laws enacted or substantively enacted at the balance sheet date in the countries where the Company and its subsidiaries operate and generate taxable income. Management periodically evaluates positions taken in tax returns with respect to situations in accordance with applicable tax regulations. It establishes provisions where appropriate based on the amounts expected to be paid to the tax authorities.

C. Deferred tax is recognized, using the balance sheet liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated balance sheet. However, the deferred tax is not accounted for if it arises from initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit or loss. Deferred tax is provided on temporary differences arising on investments in subsidiaries, except where the timing of the reversal of the temporary difference is controlled by the Group and it is probable that the temporary difference will not reverse in the foreseeable future. Deferred tax is determined using tax rates (and laws) that have been enacted or substantially enacted by the balance sheet date and are expected to apply when the related deferred tax asset is realized or the deferred tax liability is settled.

D. Deferred tax assets are recognized only to the extent that it is probable that future taxable profit will be available against which the temporary differences can be utilized. At each balance sheet date, unrecognized and recognized deferred tax assets are reassessed.

E. Current income tax assets and liabilities are offset and the net amount reported in the balance sheet when there is a legally enforceable right to offset the recognized amounts and there is an intention to settle on a net basis or realize the asset and settle the liability simultaneously. Deferred tax assets and liabilities are offset on the balance sheet when the entity has the legally enforceable right to offset current tax assets against current tax liabilities and they are levied by the same taxation authority on either the same entity or different entities that intend to settle on a net basis or realize the asset and settle the liability simultaneously.

F. A deferred tax asset shall be recognized for the carryforward of unused tax credits resulting from research and development expenditures and employees' training costs to the extent that it is possible that future taxable profit will be available against which the unused tax credits can be utilized.

(19) Common shares

A. Common shares are classified as equity. Incremental costs directly attributable to the issue of new shares or stock options are shown in equity as a deduction, net of tax, from the proceeds.

B. Where the Company repurchases the Company's equity share capital that has been issued, the consideration paid, including any directly attributable incremental costs (net of income taxes) is deducted from equity attributable to the Company's equity holders. Where such shares are subsequently reissued, the difference between their book value and any consideration received, net of any directly attributable incremental transaction costs and the related income tax effects, is included in equity attributable to the Company's equity holders.

(20) Revenue recognition

The Group's revenue is comprised of up-front payments and milestone payments under authorization collaboration and development contracts, and sales-based royalty payment under royalty contracts.

A. The Group's authorization collaboration and development transactions generally authorizes intellectual property rights of the drug products to pharmaceutical companies. Though the Group will continuously provide research and development services on the drug products, pharmaceutical companies could make use of the research and development outcome at any time. Pharmaceutical companies pay a non-refundable up-front payment upon signing of the contracts, and make milestone payments upon each milestone achieved. Based on the Group's assessment, the Group uses its proprietary drug delivery technologies to continue the research and development related services, which are unique such that pharmaceutical companies would have difficulty finding another service provider who offers the same services in terms of continuing research and development on the authorized drug products. The authorization and subsequent research and development services provided by the Group are bonded and highly interrelated and therefore not distinct and as such are accounted for as one performance obligation to be delivered over time. At the

inception of an agreement that includes research and development milestone payments, the Group evaluates each milestone to determine when and how much of the milestone to be included in the transaction price. The Group first estimates the amount of the milestone payment that the Group could receive using the most likely amount approach. The Group primarily uses the most likely amount approach as that approach is generally most predictive for milestone payments with a binary outcome. Then, the Group considers whether any portion of that estimated amount is subject to the variable consideration constraint (that is, whether it is probable that a significant reversal of cumulative revenue would not occur upon resolution of the uncertainty.) The Group updates the estimate of variable consideration included in the transaction price at each reporting date which includes updating the assessment of the likely amount of consideration and the application of the constraint to reflect current facts and circumstances. The revenue is recognized based on the transaction price, excluding variable considerations considered not achievable, and the stage of completion, which is measured by the proportion of contract costs incurred for research and development services as of the financial reporting date to the estimated total research and development costs for the authorization collaboration and development contracts. As the Group's inputs, including costs of Contract Research Organizations, Contract Manufacture Organizations, and medicines, which have direct relationship with the transfer of control of services to customers, the Group uses the cost incurred method to measure progress towards complete satisfaction of a performance obligation. The Group evaluates the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. The customer pays at the time specified in the payment schedule. If the services rendered exceed the payment, a contract asset is recognized. If the payments exceed the services rendered, a contract liability is recognized. A contract liability is recognized as revenue through the performance obligation is satisfied over time.

B. The Group also entered into contracts with customers, where the Group is entitled to a sales-based royalty in exchange for a license of manufacturing and the right to sell pharmaceutical products. In accordance with the contracts, the Group will not undertake any activities that will significantly affect the intellectual property to which the customer has rights. The nature of the Group's promise in granting a license is a promise to provide a right to use the Group's intellectual property and therefore the revenue is recognized when transferring the license to a customer at a point in time. The Group recognizes revenue at the later of when the performance obligation has been satisfied and the subsequent sale occurs.

C. Given that the period between the transfer of promised services to customers and payment by customers exceed one year for authorization collaboration and development contracts, the transaction price is adjusted using the discount rate that would be reflected in a separate financing transaction between the Group and its customers at contract inception. The discount rate would reflect the credit characteristics of the Group receiving funding from financial institution.

(21) Research and development costs

Research and development costs that do not meet the criteria of internally generated intangible assets of IAS 38 "Intangible Assets" are expensed in the period in which it is incurred.

(22) Government grants

Government grants are recognized at their fair value only when there is reasonable assurance that the Group will comply with any conditions attached to the grants and the grants will be received. Government grants are recognized in profit or loss on a systematic basis over the periods in which the Group recognizes expenses for the related costs for which the grants are intended to compensate.

(23) Operating segments

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker. The Group's chief operating decision-maker is responsible for allocating resources and assessing performance of the operating segments.

(24) Convenience translation into U.S. dollar amounts

The Group maintains its accounts and expresses its consolidated financial statements in New Taiwan dollars. For convenience purposes, U.S. dollar amounts presented in the accompanying consolidated financial statements have been translated from New Taiwan dollars to U.S. dollars at the noon buying rate in the City of New York for cable transfers as certified for customs purposes by the Federal Reserve Bank of New York as of December 31, 2018, which was NT$30.61 to US$1.00. These convenience translations should not be construed as representations that the New Taiwan dollar amounts have been, or could in the future be, converted into U.S. dollars at this or any other rate of exchange.

5. CRITICAL ACCOUNTING ESTIMATES AND KEY SOURCES OF ASSUMPTION UNCERTAINTY

The preparation of these consolidated financial statements requires management to make critical judgements in applying the Group's accounting policies and make critical assumptions and estimates concerning future events. Assumptions and estimates may differ from the actual results and are continually evaluated and adjusted based on historical experience and other factors. Such assumptions and estimates have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year; and the related information is addressed below:

(1) Critical judgements in applying the Group's accounting policies:

The Group provides authorization collaboration and development services to its customers, which generally includes authorization of intellectual property rights of drug products to pharmaceutical companies together with continuing research and development services, which pharmaceutical companies can access and make use of the research outcome at any time. In determining the performance obligations under authorization collaboration and development contracts, the Group takes into account the guidance IFRS 15 par. 29:

Factors that indicate that an entity's promise to transfer a good or service to a customer is separately identifiable (in accordance with paragraph 27(b)) include, but are not limited to, the following:

a.The entity does not provide a significant service of integrating the good or service with other goods or services promised in the contract into a bundle of goods or services that represent the combined output for which the customer has contracted. In other words, the entity is not using the good or service as an input to produce or deliver the combined output specified by the customer.

b.The good or service does not significantly modify or customize another good or service promised in the contract.

c.The good or service is not highly dependent on, or highly interrelated with, other goods or services promised in the contract. For example, the fact that a customer could decide to not purchase the good or service without significantly affecting the other promised goods or services in the contract might indicate that the good or service is not highly dependent on, or highly interrelated with, those other promised goods or services.

Based on the Group's assessment, the Group uses its proprietary drug delivery technologies to continue the research and development related services, which are unique, and based on the intellectual property rights authorized and therefore, pharmaceutical companies would have difficulty finding alternative service provider in offering the same services. In addition, the authorization and subsequent research and development services provided by the Group are bonded and highly interrelated and therefore not distinct and are identified as one performance obligation to be delivered over time.

(2) Critical accounting estimates and assumptions:

Revenue recognition

The Group accounts for all the authorization and subsequent research and development services as one performance obligation and recognizes revenue based on the transaction price and the stage of completion, which is measured by the proportion of contract costs incurred for research and development services as of the financial reporting date to the estimated total research and development costs for the authorization collaboration and development contracts. The estimated total research and development costs would be affected by the progress of research and development, development of pharmaceutical products, collaboration with pharmaceutical companies, clinical trials, etc. The Group reassesses the reasonableness of estimates periodically

6. DETAILS OF SIGNIFICANT ACCOUNTS

(1) Cash and cash equivalents

	December 31,		
	2017	2018	
	NT$000	NT$000	US$000
Cash on hand	$ 81	$ 56	$ 2
Checking and demand deposits	547,232	807,428	26,378
Time deposits	404,400	—	—
	$ 951,713	$ 807,484	$ 26,380

The Group transacts with a variety of financial institutions with good credit quality to disperse credit risk, so it expects that the probability of counterparty default is remote.

(2) Financial assets at amortized cost

Items	December 31,		
	2017	2018	
Current items:	NT$000	NT$000	US$000
Time deposit with maturity over three months	$ —	$ 307,150	$ 10,034

Amounts recognized in profit or loss in relation to financial assets at amortized cost are listed below:

Items	December 31,		
	2017	2018	
	NT$000	NT$000	US$000
Interest income	$ —	$ 380	$ 12

(3) Accounts receivable

	December 31,		
	2017	2018	
	NT$000	NT$000	US$000
Accounts receivable	$ 26,754	$ 27,475	$ 898
Less: Allowance for doubtful accounts	(18,132)	(18,132)	(593)
	$ 8,622	$ 9,343	$ 305

A. The Group does not hold any collateral as security

B. The ageing analysis of accounts receivable is as follows:

	December 31,		
	2017	2018	
	NT$000	NT$000	US$000
Not past due	$ 8,622	$ 9,343	$ 305
Up to 30 days	—	—	—
31 to 90 days	—	—	—
91 to 180 days	—	—	—
Over 181 days	18,132	18,132	593
	$ 26,754	$ 27,475	$ 898

The above ageing analysis was based on past due date.

C. Information relating to credit risk of accounts receivable is provided in Note 12(2):

(4) Prepayments

	December 31,		
	2017	2018	
	NT$000	NT$000	US$000
Net input VAT	$ 36,103	$ 40,614	$ 1,326
Prepaid repair expense	7,042	1,580	52
Prepaid insurance expense	1,068	1,568	51
Prepaid handling charges	1,352	1,294	42
Prepaid rent	301	487	16
Prepaid expense for medical research	1,850	3	1
Prepaid service charges	15,742	—	—
Others	7,942	10,965	358
	$ 71,400	$ 56,511	$ 1,846

(5) Property, plant and equipment

A. The details of property, plant and equipment are as follows:

	Land	Buildings	Testing equipment	Office equipment	Leasehold assets	Leasehold improvements	Total
	NT$000	NT$000	NT$000	NT$000	NT$000	NT$000	NT$000
At January 1, 2017							
Cost	$ 14,962	$ 29,532	$ 66,266	$ 16,235	$ 100,070	$ 72,504	$ 299,569
Accumulated depreciation	—	(4,703)	(34,843)	(9,458)	(30,239)	(41,383)	(120,626)
	$ 14,962	$ 24,829	$ 31,423	$ 6,777	$ 69,831	$ 31,121	$ 178,943
2017							
Opening net book amount	$ 14,962	$ 24,829	$ 31,423	$ 6,777	$ 69,831	$ 31,121	$ 178,943
Additions	—	—	12,069	2,840	—	1,072	15,981
Disposals	—	—	—	(4)	—	—	(4)
Reclassifications	—	—	(25,390)	—	25,642	(252)	—
Transfer (Note)	—	—	1,256	—	—	—	1,256
Depreciation charges	—	(657)	(4,045)	(3,581)	(20,983)	(12,660)	(41,926)
Net exchange differences	—	—	(376)	20	(1)	(58)	(415)
	$ 14,962	$ 24,172	$ 14,937	$ 6,052	$ 74,489	$ 19,223	$ 153,835
At December 31, 2017							
Cost	$ 14,962	$ 29,532	$ 40,708	$ 18,329	$ 98,170	$ 73,014	$ 274,715
Accumulated depreciation	—	(5,360)	(25,771)	(12,277)	(23,681)	(53,791)	(120,880)
	$ 14,962	$ 24,172	$ 14,937	$ 6,052	$ 74,489	$ 19,223	$ 153,835

	Land	Buildings	Testing equipment	Office equipment	Leasehold assets	Leasehold improvements	Total
	NT$000	NT$000	NT$000	NT$000	NT$000	NT$000	NT$000
At January 1, 2018							
Cost	$ 14,962	$ 29,532	$ 40,708	$ 18,329	$ 98,170	$ 73,014	$ 274,715
Accumulated depreciation	—	(5,360)	(25,771)	(12,277)	(23,681)	(53,791)	(120,880)
	$ 14,962	$ 24,172	$ 14,937	$ 6,052	$ 74,489	$ 19,223	$ 153,835
2018							
Opening net book amount	$ 14,962	$ 24,172	$ 14,937	$ 6,052	$ 74,489	$ 19,223	$ 153,835
Additions	—	—	34,802	1,318	—	5,950	42,070
Disposals	—	—	(9)	—	—	—	(9)
Reclassifications	—	—	9,114	1,847	(7,679)	(1,847)	1,435
Transfer (Note)	—	—	143	—	—	—	143
Depreciation charges	—	(656)	(6,143)	(3,157)	(19,840)	(9,519)	(39,315)
Net exchange differences	—	—	87	(4)	—	3	86
	$ 14,962	$ 23,516	$ 52,931	$ 6,056	$ 46,970	$ 13,810	$ 158,245
At December 31, 2018							
Cost	$ 14,962	$ 29,532	$ 82,584	$ 19,878	$ 50,013	$ 77,208	$ 274,177
Accumulated depreciation	—	(6,016)	(29,653)	(13,822)	(3,043)	(63,398)	(115,932)
	$ 14,962	$ 23,516	$ 52,931	$ 6,056	$ 46,970	$ 13,810	$ 158,245
At December 31, 2018 **(US$000)**							
Cost	$ 489	$ 965	$ 2,698	$ 649	$ 1,634	$ 2,522	$ 8,957
Accumulated depreciation	—	(197)	(969)	(451)	(99)	(2,071)	(3,787)
	$ 489	$ 768	$ 1,729	$ 198	$ 1,535	$ 451	$ 5,170

Note: Transferred from prepayments for equipment (shown as “Other non-current assets”).

B. Information about the investing activities that were partially paid by cash is provided in Note 6(26).

C. Information about the leasehold assets is provided in Note 6(11).

D. Information about the property, plant and equipment that were pledged to others as collateral is provided in Note 8.

(6) Intangible assets

A.The details of intangible assets are as follows:

	Professional technology	Computer software	Total
	NT$000	NT$000	NT$000
At January 1, 2017			
Cost	$ 49,239	$ 17,589	$ 66,828
Accumulated amortization	(41,299)	(12,216)	(53,515)
	$ 7,940	$ 5,373	$ 13,313
2017			
Opening net book amount	$ 7,940	$ 5,373	$ 13,313
Additions	—	5,706	5,706
Transfers (Note)	—	227	227
Amortization charges	(5,102)	(5,468)	(10,570)
Net exchange differences	(39)	—	(39)
Closing net book amount	$ 2,799	$ 5,838	$ 8,637
At December 31, 2017			
Cost	$ 49,114	$ 23,522	$ 72,636
Accumulated amortization	(46,315)	(17,684)	(63,999)
	$ 2,799	$ 5,838	$ 8,637

	Professional technology	Computer software	Total
	NT$000	NT$000	NT$000
At January 1, 2018			
Cost	$ 49,114	$ 23,522	$ 72,636
Accumulated amortization	(46,315)	(17,684)	(63,999)
	$ 2,799	$ 5,838	$ 8,637
2018			
Opening net book amount	$ 2,799	$ 5,838	$ 8,637
Additions	—	3,537	3,537
Amortization charges	(2,799)	(5,345)	(8,144)
	$ —	$ 4,030	$ 4,030
At December 31, 2018			
Cost	$ 49,290	$ 27,058	$ 76,438
Accumulated amortization	(49,290)	(23,028)	(72,318)
	$ —	$ 4,030	$ 4,030
At December 31, 2018 **(US$000)**			
Cost	$ 1,610	$ 884	$ 2,494
Accumulated amortization	(1,610)	(753)	(2,363)
	$ —	$ 131	$ 131

(Note): Transferred from prepayments for equipment (shown as “Other non-current assets”).

B.Information about the investing activities that were partially paid by cash is provided in Note 6(26).

C.The details of the amortization charges of intangible assets (recorded in "Operating expenses") are as follows:

	Years ended December 31,		
	2017	2018	
	NT$000	NT$000	US$000
General and administrative expenses	$ 3,001	$ 2,983	$ 97
Research and development expenses	7,569	5,161	169
	$ 10,570	$ 8,144	$ 266

(7) Other non-current assets

	December 31,		
	2017	2018	
	NT$000	NT$000	US$000
Refundable deposits	$ 27,188	$ 18,930	$ 619
Prepaid expense for medical research-non-current	20,000	20,000	653
Prepayments for equipment	923	27,942	913
	$ 48,111	$ 66,872	$ 2,185

(8) Short-term borrowings

Type of borrowings	December 31,		
	2017	2018	
	NT$000	NT$000	US$000
Bank unsecured borrowings	$ 46,000	$ 46,000	$ 1,503
Interest rate	1.95%~2.10%	1.95% ~2.10%	1.95% ~2.10%
Credit line	$ —	$ —	$ —

Interest expense recognized in profit or loss amounted to NT$942 thousand and NT$942 thousand (US$31 thousand) for the years ended December 31, 2017 and 2018, respectively.

(9) Other payables

	December 31,		
	2017	2018	
	NT$000	NT$000	US$000
Research expenses	$ 33,742	$ 97,930	$ 3,199
Service expenses	9,825	48,137	1,573
Salaries and bonuses	30,539	31,049	1,014
Payables on machinery, equipment and intangible assets	—	3,677	120
Medical research expenses	4,697	2,707	89
Labor and health insurance	2,218	2,191	72
Repair expenses	6,668	676	22
Other accrued expenses	5,852	19,901	650
	$ 93,541	$ 206,268	$ 6,739

(10) Long-term borrowings

Type of loans	Borrowing period and repayment term	Interest rate	Collateral	December 31, 2017
				NT$000
Taiwan Cooperative Bank - secured borrowings	Note 1	1.85%	Note 5	$ 37,750
Taiwan Cooperative Bank - secured borrowings	Note 2	1.85%	Note 5	32,300
				70,050
Less: Current portion (Shown as "Other current liabilities")				(3,873)
				$ 66,177

Type of loans	Borrowing period and repayment term	Interest rate	Collateral	December 31, 2018	
				NT$000	US$000
Taiwan Cooperative Bank - secured borrowings	Note 1	1.85%	Note 5	$ 37,277	$ 1,218
Taiwan Cooperative Bank - secured borrowings	Note 2	1.85%	Note 5	28,900	944
Cathay Bank - secured borrowings	Note 3 and 4	5.25%	Note 5	368,580	12,041
				434,757	14,203
Less: Current portion (Shown as "Other current liabilities")				(66,747)	(2,180)
				$ 368,010	$ 12,023

Note 1: The Company entered into a long-term loan contract with Taiwan Cooperative Bank on September 1, 2015 in the amount of NT$37,750 thousand (US$1,233 thousand). The contract period is from September 2015 to September 2035. The interest is payable monthly for the first 3 years and payable monthly along with the same amount of principal starting from the fourth year.

Note 2: The Company entered into a mid-term loan contract with Taiwan Cooperative Bank on September 4, 2015 in the amount of NT$34,000 thousand (US$1,111 thousand). The contract period is from September 2015 to September 2022. The interest is payable monthly for the first 2 years and payable semi-annually along with 5% (NT$1,700 thousand (US$56 thousand)) of the principal starting from September 2017. The remaining 50% of principal (NT$17,000 thousand (US$555 thousand)) is required to be repaid in September 2022.

Note 3: The Company and its subsidiary, TLC Biopharmaceuticals, Inc. ("TLC US") entered into a loan and security agreement with Cathay Bank on June 14, 2018 in the amount of US$12 million. The contract period was from June 2018 to December 2020. The interest is payable monthly for the first six months and payable monthly along with the same amount of principal starting from January 2019. The Company repaid the loan in full amount in November 2018 and the agreement was terminated.

Note 4: The Company and its subsidiary, TLC US entered into a loan and security agreement with Cathay Bank on December 27, 2018 in the amount of US$12 million. The contract period is from December 2018 to June 2020. The interest is payable monthly for the first six months and payable monthly along with the same amount of principal starting from July 2019.

Note 5: Information about the collateral provided for the loans is provided in Note 8.

A. According to the above two bank loan contracts with Taiwan Cooperative Bank, the Company is restricted from paying cash dividends or other distributions on the common shares and Taiwan Cooperative Bank retains the right in requesting the Company to raise paid-in capital or to improve financial structure if certain conditions are met.

B. According to the above loan and security agreement with Cathay Bank, if the Company or TLC US violate any of the following covenants, Cathay Bank has the right to demand, among other things, that the Company and TLC US repay the outstanding loan early:

(i)The Group must maintain an adjusted quick ratio ("Adjusted Quick Ratio") of at least a minimum of 2.25 to 1.00 and (ii) the Group must maintain an adjusted tangible net worth ("Adjusted Tangible Net Worth") of no less than US$12 million as per its quarterly and yearly consolidated financial statements.

"Adjusted Quick Ratio" means a ratio of cash and cash equivalents plus net trade receivables to the amount of principal payments owing to Cathay Bank under this contract for the next 12 months plus all other current liabilities. "Adjusted Tangible Net Worth" means the differences between the value of the capital stock, partnership interests, or limited liability company interests of the company and TLC US (and their respective subsidiaries), minus intangible assets, plus deferred revenue.

The Company was in compliance with all of the loan covenants as of December 31, 2018. Accordingly, the entire debt balance for this loan has been classified as non-current liability at December 31, 2018.

On April 25, 2019, the Company entered into an amendment to the loan and security agreement with Cathay Bank, pursuant to which the applicability of the above-mentioned loan covenants was deferred until September 30, 2019 (and tested as of the last day of each quarter going forward).

The loan and security agreement with Cathay Bank also prohibits the Company from paying cash dividends or making distributions on account of the Company's capital stock without the consent of Cathay Bank, subject to certain exceptions.

C. As of December 31, 2017 and 2018, the undrawn loan facilities amounted to NT$2,750 thousand and NT$6,632 thousand (US$216 thousand), respectively. The information about the Group's liquidity risk is provided in Note 12(2)C(c).

(11) Finance lease liabilities

The Group leases testing equipment under finance leases. Future minimum lease payments and their present values as of December 31, 2017 and 2018 are as follows:

	December 31, 2017		
	Total finance lease liabilities	Future finance charges	Present value of finance lease liabilities
	NT$000	NT$000	NT$000
Current			
Not later than one year (Note)	$ 48,466	($ 466)	$ 48,000
Non-current			
Later than one year but not later than two years (Note)	4,008	(8)	4,000
	$ 52,474	($ 474)	$ 52,000

	December 31, 2018		
	Total finance lease liabilities	Future finance charges	Present value of finance lease liabilities
	NT$000	NT$000	NT$000
Current			
Not later than one year (Note)	$ 24,583	($ 583)	$ 24,000
Non-current			
Later than one year but not later than two years (Note)	24,198	(198)	24,000
	$ 48,781	($ 781)	$ 48,000

	December 31, 2018		
	Total finance lease liabilities	Future finance charges	Present value of finance lease liabilities
	US$000	US$000	US$000
Current			
Not later than one year (Note)	$ 803	($ 19)	$ 784
Non-current			
Later than one year but not later than two years (Note)	791	(7)	784
	$ 1,594	($ 26)	$ 1,568

Note: Shown as “Other current liabilities” and “Other non-current liabilities”, respectively.

(12) Pensions

A. Defined benefit plan

(a) The Company has a defined benefit pension plan in accordance with the Labor Standards Act, covering all regular employees’ service years prior to the enforcement of the Labor Pension Act on July 1, 2005 and service years thereafter of employees who chose to continue to be subject to the pension mechanism under the Labor Standards Act. Under the defined benefit pension plan, two units are accrued for each year of service for the first 15 years and one unit for each additional year thereafter, subject to a maximum of 45 units. Pension benefits are based on the number of units accrued and the average monthly salaries and wages of the last 6 months prior to retirement. The Company contributes monthly an amount equal to 2% of the employees’ monthly salaries and wages to the retirement fund deposited with Bank of Taiwan, the trustee, under the name of the independent retirement fund committee. Also, the Company would assess the balance in the aforementioned labor pension reserve account by December 31, every year. If the account balance is insufficient to pay the pension calculated by the aforementioned methods to the employees expected to qualify for retirement in the following year, the Company will make contributions to cover for the deficit by the following March.

(b) The amounts recognized in the balance sheet are as follows:

	December 31,		
	2017	2018	
	NT$000	NT$000	US$000
Present value of defined benefit obligations	$ 6,421	$ 7,064	$ 231
Fair value of plan assets	(1,319)	(1,560)	(51)
Net defined benefit liability	$ 5,102	$ 5,504	$ 180

(c) Movements in net defined benefit liabilities are as follows:

Year ended December 31, 2017	Present value of defined benefit obligations	Fair value of plan assets	Net defined benefit liability
	NT$000	NT$000	NT$000
Balance at January 1	$ 6,141	($ 1,086)	$ 5,055
Current service cost	59	—	59
Interest expense / income	105	(18)	87
	6,305	(1,104)	5,201
Remeasurements:			
Change in financial assumptions	312	—	312
Experience adjustments	(196)	8	(188)
	116	8	124
Pension fund contribution	—	(223)	(223)
Balance at December 31	$ 6,421	($ 1,319)	$ 5,102

Year ended December 31, 2018	Present value of defined benefit obligations	Fair value of plan assets	Net defined benefit liability
	NT$000	NT$000	NT$000
Balance at January 1	$ 6,421	($ 1,319)	$ 5,102
Interest expense / income	83	(17)	66
	6,504	(1,336)	5,168
Remeasurements:			
Change in financial assumptions	162	—	162
Experience adjustments	398	(33)	365
	560	(33)	527
Pension fund contribution	—	(191)	(191)
Balance at December 31	$ 7,064	($ 1,560)	$ 5,504
Balance at December 31 **(US$000)**	$ 231	($ 51)	$ 180

(d) The Bank of Taiwan was commissioned to manage the Fund of the Company's defined benefit pension plan in accordance with the Fund's annual investment and utilization plan and the "Regulations for Revenues, Expenditures, Safeguard and Utilization of the Labor Retirement Fund" (Article 6: The scope of utilization for the Fund includes deposit in domestic or foreign financial institutions, investment in domestic or foreign listed, over-the-counter, or private placement equity securities, and investment in domestic or foreign real estate securitization products, etc.). With regard to the utilization of the Fund, its minimum earnings in the annual distributions on the final financial statements shall be no less than the earnings attainable from the amounts accrued from two-year time deposits with the interest rates offered by local banks. If the earnings is less than aforementioned rates, government shall make payment for the deficit after being authorized by the Regulator. The Company has no right to participate in managing and operating that fund and hence the Company is unable to disclose the classification of plan asset fair value in accordance with IAS 19 paragraph 142. The composition of fair value of plan assets as of December 31, 2017 and 2018 is given in the Annual Labor Retirement Fund Utilization Report announced by the government.

(e) The principal actuarial assumptions used were as follows:

	Years ended December 31,	
	2017	2018
Discount rate	1.30%	1.10%
Future salary increases	2.00%	2.00%

Assumptions regarding future mortality experience are set based on actuarial valuation in accordance with the 5th version of Taiwan Standard Ordinary Experience Mortality Tables. The present value of defined benefit obligation is affected whenever there is change in main actuarial assumption. The sensitivity analysis is as follows:

	Discount rate		Future salary increases	
	Increase 0.25%	Decrease 0.25%	Increase 0.25%	Decrease 0.25%
	NT$000	NT$000	NT$000	NT$000
December 31, 2017				
Effect on present value of defined benefit obligations	($ 197)	$ 205	$ 186	($ 181)

	Discount rate		Future salary increases	
	Increase 0.25%	Decrease 0.25%	Increase 0.25%	Decrease 0.25%
	NT$000	NT$000	NT$000	NT$000
December 31, 2018				
Effect on present value of defined benefit obligations	($ 201)	$ 209	$ 189	($ 183)
December 31, 2018 (US$000)				
Effect on present value of defined benefit obligation	($ 7)	$ 7	$ 6	($ 6)

The sensitivity analysis above was arrived at based on the assumption that other conditions remain unchanged. In practice, more than one assumption may change all at once. The method of analyzing sensitivity and the method of calculating net pension liability in the balance sheet are the same..

(f) Expected contributions to the defined benefit pension plans of the Company for the year ending December 31, 2019 is NT$194 thousand (US$6 thousand).

(g) As of December 31, 2018, the weighted average duration of the retirement plan is 15 years. The analysis of timing of the future pension payment is as follows:

	NT$000	US$000
Within 1 year	$ —	$ —
1-2 year(s)	—	—
2-5 years	462	15
6-10 years	2,753	90
	$ 3,215	$ 105

B. Defined contribution plans

Effective July 1, 2005, the Company has established a defined contribution pension plan (the "New Plan") under the Labor Pension Act (the "Act"), covering all regular employees with R.O.C. nationality. Under the New Plan, the Company contributes monthly an amount based on 6% of the employees' monthly salaries and wages to the employees' individual pension accounts at the Bureau of Labor Insurance. The benefits accrued are paid monthly or in lump sum upon termination of employment. The pension costs under the defined contribution pension plan of the Company for the years ended December 31, 2017 and 2018 are NT$8,676 thousand and NT$8,843thousand (US$289 thousand), respectively.

C. The subsidiaries have defined contribution plans in accordance with the local regulations, and contributions are based on a certain percentage of employees' salaries and wages. Other than the yearly contributions, the subsidiaries have no further obligations. The pension costs of the subsidiaries for the years ended December 31, 2017 and 2018 were NT$1,423 thousand and NT$1,487 (US$49 thousand), respectively.

(13) Share-based payment

A. For the years ended December 31, 2016, 2017, and 2018 the Company's equity-settled share-based payment arrangements are as follows:

Type of arrangement	Grant date	Quantity granted (in thousands)	Contract period	Vesting conditions
Employee stock options	2012.05.08	62.8	5 years	Gradually vested after 2 year service (Note 1)
Employee stock options	2013.11.14	883.0	5 years	Gradually vested after 2 year service (Note 1)
Employee stock options	2014.03.20	153.0	5 years	Gradually vested after 2 year service (Note 1)
Employee stock options	2014.08.15	82.3	5 years	Gradually vested after 2 year service (Note 1)
Employee stock options	2015.02.26	1,102.0	5 years	Gradually vested after 2 year service (Note 1)
Employee stock options	2015.04.30	16.0	5 years	Gradually vested after 2 year service (Note 1)
Employee stock options	2015.05.04	35.0	5 years	Gradually vested after 2 year service (Note 1)
Employee stock options	2015.07.30	50.0	5 years	Gradually vested after 2 year service (Note 1)
Employee stock options	2015.10.29	180.0	5 years	Gradually vested after 2 year service (Note 1)
Employee stock options	2016.02.25	1,391.0	5 years	Gradually vested after 2 year service (Note 1)
Employee stock options	2016.08.11	140.0	5 years	Gradually vested after 2 year service (Note 1)
Employee stock options	2016.11.03	73.0	5 years	Gradually vested after 2 year service (Note 1)
Employee stock options	2018.06.29	1,320.0	5 years	Gradually vested after 2 year service (Note 1)
Employee stock options	2018.07.02	65.0	5 years	Gradually vested after 2 year service (Note 1)
Restricted stocks to employees(Note 2)	2014.08.15	307.0	3 years	Service and performance (Note 3)
Restricted stocks to employees(Note 2)	2014.11.14	43.0	3 years	Service and performance (Note 3)
Restricted stocks to employees(Note 2)	2017.11.16	500.0	3 years	(Note 4)
Restricted stocks to employees(Note 2)	2018.07.02	50.0	3 years	(Note 4)

Note 1: Employees with 2 year service are entitled to 50%; after the 2 year service, the ratio will increase by 1/48 every month for the following 24 months; and employees with 4 year service are entitled to 100%.

Note 2: The restricted stocks issued by the Company cannot be transferred within the vesting period, but voting rights and dividend rights are not restricted on these stocks. Employees are required to return the stocks but not required to return the dividends received if they resign during the vesting period.

Note 3: For the employees who are currently working in the Company and whose services have reached 1 year, 2 years and 3 years while achieving targeted performance, which are mainly based on the progress of research and development projects, and they have made certain contribution. The applicable accumulated maximum vested share ratio is 30%, 60% and 100%, respectively.

Note 4: For the employees who are currently working in the Company and whose services have reached 1 year, 2 years and 3 years without violating the terms of employment agreement entered between the Company and employees, they are entitled to 20%, 30% and 50%, respectively.

B. Details of the share-based payment arrangements are as follows:

(a) Employee stock options

	2016	
Stock options	No. of units (in thousands)	Weighted-average exercise price (in NT dollars)
Options outstanding at beginning of the year	3,148	$ 267
Options granted	1,800	155
Options exercised	(145)	42
Options forfeited	(635)	237
Options outstanding at end of the year	4,168	231
Options exercisable at end of the year	901	338
Options permitted but not yet granted at end of the year	—	

	2017	
Stock options	No. of units (in thousands)	Weighted-average exercise price (in NT dollars)
Options outstanding at beginning of the year	4,168	$ 231
Options forfeited	(655)	189
Options outstanding at end of the year	3,513	239
Options exercisable at end of the year	1,844	301
Options permitted but not yet granted at end of the year	—	

	2018		
Stock options	No. of units (in thousands)	Weighted-average exercise price (in NT dollars)	Weighted-average exercise price (in US dollars)
Options outstanding at beginning of the year	3,513	$ 239	$ 8
Options granted	1,385	101	3
Options expired	(831)	379	12
Options forfeited	(338)	196	6
Options outstanding at end of the year	3,729	152	5
Options exercisable at end of the year	1,957	188	6
Options permitted but not yet granted at end of the year	415		

(b) Restricted stocks to employees

	2016	2017	2018
	Shares (in thousands)	Shares (in thousands)	Shares (in thousands)
At January 1	204	111	500
Granted for the year (Note 1)	—	500	50
Expired for the year (Note 2)	(26)	(31)	(35)
Vested/restrictions removed for the year	(67)	(80)	(93)
At December 31	111	500	422

Note 1: For the restricted stocks granted with the compensation cost accounted for using the fair value method, the fair values on the grant date are calculated based on the closing price on the grant date subtracting the subscription price of NT$10 (in dollars).

Note 2: Please refer to Note 6(15)D.

C. The weighted-average stock price of stock options at exercise dates for the year ended December 31, 2016 was NT$134.73 (in dollars). No stock options were exercised for the year ended December 31, 2017 and 2018.

D. The expiry date and exercise price of stock options outstanding at the balance sheet dates are as follows:

		December 31, 2017			
		Options outstanding at end of year		Options exercisable at end of year	
Exercise price (in dollars)	Quantity (in thousands)	Remaining contractual life (years)	Exercise price (in dollars)	Quantity (in thousands)	Exercise price (in dollars)
NT$			NT$		NT$
$ 379	831	0.87	$ 379	831	$ 379
272	150	1.22	272	142	272
206	60	1.62	206	51	206
246.5	955	2.16	246.5	688	246.5
225	16	2.33	225	11	225
225	35	2.34	225	23	225
148	38	2.58	148	23	148
141	138	2.83	141	75	141
159	1,148	3.15	159	—	—
128.5	69	3.61	128.5	—	—
122	73	3.84	122	—	—
	3,513			1,844	

December 31, 2018					
Options outstanding at end of year			Options exercisable at end of year		
Exercise price (in dollars)	Quantity (in thousands)	Remaining contractual life (years)	Exercise price (in dollars)	Quantity (in thousands)	Exercise price (in dollars)
NT$			NT$		NT$
$ 249.7	119	0.22	$ 249.7	119	$ 249.7
191.7	52	0.62	191.7	52	191.7
227.3	820	1.16	227.3	787	227.3
208.4	15	1.33	208.4	14	208.4
208.4	35	1.34	208.4	31	208.4
140.8	38	1.58	140.8	33	140.8
134.7	138	1.83	134.7	109	134.7
150.5	1,063	2.15	150.5	758	150.5
123.7	28	2.61	123.7	16	123.7
118.0	61	2.84	118.0	38	118.0
99.2	1,295	4.49	99.2	—	—
101.2	65	4.50	101.2	—	—
	3,729			1,957	

December 31, 2018					
Options outstanding at end of year			Options exercisable at end of year		
Exercise price (in dollars)	Quantity (in thousands)	Remaining contractual life (years)	Exercise price (in dollars)	Quantity (in thousands)	Exercise price (in dollars)
US$			US$		US$
$ 8.16	119	0.22	$ 8.16	119	8.16
6.26	52	0.62	6.26	52	6.26
7.43	820	1.16	7.43	787	7.43
6.81	15	1.33	6.81	14	6.81
6.81	35	1.34	6.81	31	6.81
4.60	38	1.58	4.60	33	4.60
4.40	138	1.83	4.40	109	4.40
4.92	1,063	2.15	4.92	758	4.92
4.04	28	2.61	4.04	16	4.04
3.85	61	2.84	3.85	38	3.85
3.24	1,295	4.49	3.24	—	—
3.31	65	4.50	3.31	—	
	3,729			1,957	

E. The fair value of stock options granted on grant date is measured using the Black-Scholes option-pricing model. Relevant information is as follows:

Employee stock options

Grant date	June 29, 2018	July 2, 2018
Dividend yield	—	—
Expected volatility	43.59%~44.04%	43.60%~44.03
Risk-free interest rate	0.65%~0.69%	0.65%~0.70%
Expected life (years)	3.5~4.5	3.5~4.5
Per share exercise price (in NT dollars)	$ 100.5 (US$3.28 dollars)	$ 102.5 (US$3.35 dollars)
Weighted average stock options fair value (in NT dollars)	$ 33~37 (US$1.1~1.2 dollars)	$ 33~38 (US$1.1~1.2 dollars)

F. Expenses incurred on share-based payment transactions are shown below:

	Years ended December 31,			
	2016	2017	2018	
	NT$000	NT$000	NT$000	US$000
Equity-settled	$ 100,573	$ 57,149	$ 41,386	$ 1,352

(14) Provisions (decommissioning liabilities)

	2018
	NT$000
At January 1	$ 6,922
Used during the year	—
At December 31	$ 6,922
At December 31 (US$000)	$ 226

Analysis of total provisions is shown below:

	December 31, 2017	December 31, 2018	
	NT$000	NT$000	US$000
Non-current	$ 6,922	$ 6,922	$ 226

In accordance with the requirements specified in the agreements, the Group bears the obligation for the costs of dismantling, removing the asset and restoring the site of its rented office in the future. A provision is recognized for the present value of costs to be incurred for dismantling, removing the asset and restoring the site. It is expected that the provision will be used in 1~4 years.

(15) Common stock

A. As of December 31, 2018, the Company's authorized capital was NT$2,000,000 thousand (US$65,338 thousand), and the paid-in capital was NT$640,451 thousand (US$20,923 thousand) with a par value of NT$10 (in dollars) (US$0.3 (in dollars)) per share. All proceeds from shares issued have been collected.

Movements in the number of the Company's common shares outstanding are as follows (Unit: thousand shares):

	2016	2017	2018
At January 1	55,620	55,730	56,199
Cash capital increase – issuance of American Depositary Shares	—	—	7,831
Issuance of employee restricted stocks	—	500	50
Employee stock options exercised	145	—	—
Cancellation of employee restricted stocks	(35)	(31)	(35)
At December 31	55,730	56,199	64,045

B. To increase the Company's working capital, the stockholders at their extraordinary stockholders' meeting on March 10, 2011 adopted a resolution to raise additional cash through private placement with the effective date set on March 25, 2011. The maximum number of shares to be issued through the private placement was 4,711 thousand shares at a subscription price of NT$42.45 (in dollars) per share. The amount of capital raised through the private placement was NT$200,000 thousand which had been registered. Pursuant to the Securities and Exchange Act of the ROC, the common shares raised through the private placement are subject to certain transfer restrictions and cannot be listed on the stock exchange until three years after they have been issued and have applied for retroactive handling of public issuance procedures. Other than these restrictions, the rights and obligations of the common shares raised through the private placement are the same as other issued common shares.

C. In February, 2018, the Company filed the registration statement on Form F-1, with the U.S. Securities and Exchange Commission ("SEC") for the initial public offering in the United States of its American Depositary Shares ("ADS") representing common shares. The registration statement for listing its ADSs in the Nasdaq Global Market was declared effective by the SEC in November 2018, and the Company' s ADSs began trading on the Nasdaq Global Market under the symbol "TLC".

The Company sold an aggregate of 3,915,550 ADSs in this offering, each ADS represents representing two of the Company's common shares, which in the aggregate represents 7,831,100 common shares. The offering price per ADS was US$5.80 (in dollars), equivalent to a price per common share of NT$89.32 (in dollars).

The terms of ADS are as follows:

(a) Voting rights

ADSs holders may, pursuant to the Depositary Agreement and the relevant laws and regulations of the R.O.C., exercise the voting rights pertaining to the underlying common shares represented by the ADSs.

(b) Dividends, stock warrants and other rights

ADSs holders and common shareholders are all entitled to receive dividends. The Depositary may issue new ADSs in proportion to ADSs holding ratios or raise the number of shares of common share represented by each unit of ADSs or sell stock dividends on behalf of ADSs holders and distribute proceeds to them in proportion to their ADSs holding ratios.

D. Employee restricted stocks

(a) The Board of Directors during its meeting on June 18, 2014 adopted a resolution to issue employee restricted stocks (see Note 6(13)) with the effective date set on August 21, 2014 and November 20, 2014, respectively. The subscription price was NT$10 (in dollars) per share. The employee restricted stocks issued are subject to certain restrictions on selling, pledging as collateral, transfer, donation or other methods to dispose before their vesting conditions are met. Other than these restrictions, the rights and obligations of these shares issued are the same as other issued common shares.

(b) As 9,000 shares of employee restricted stocks distributed to certain employees in November 2015 did not meet the vesting conditions in accordance with the terms of restricted stocks, the Board of Directors has resolved on February 25, 2016 to buy back the restricted stocks to retire for capital reduction. The registration was completed on April 22, 2016.

(c) As 14,000 shares of employee restricted stocks distributed to certain employees in April 2016 did not meet the vesting conditions in accordance with the terms of restricted stocks, the Board of Directors has resolved on May 5, 2016 to buy back the restricted stocks to retire for capital reduction. The registration was completed on July 18, 2016.

(d) As 12,000 shares of employee restricted stocks distributed to certain employees in July and August 2016 did not meet the vesting conditions in accordance with the terms of restricted stocks, the Board of Directors has resolved on August 11, 2016 to buy back the restricted stock to retire for capital reduction. The registration was completed on October 11, 2016.

(e) As 2,000 shares of employee restricted stocks granted to certain employees in March 2017 did not meet the vesting conditions in accordance with the terms of restricted stocks, the Board of Directors has resolved on May 11, 2017 to buy back the restricted stocks to retire for capital reduction. The registration was completed on June 23, 2017.

(f) As 15,000 shares of employee restricted stocks granted to certain employees in July and August 2017 did not meet the vesting conditions in accordance with the terms of restricted stocks, the Board of Directors has resolved on August 10, 2017 to buy back the restricted stocks to retire for capital reduction. The registration was completed on September 7, 2017.

(g) As 14,000 shares of employee restricted stocks granted to certain employees in September and November 2017 did not meet the vesting conditions in accordance with the terms of restricted stocks, the Board of Directors has resolved on November 1, 2017 to buy back the restricted stocks to retire for capital reduction. The registration was completed on December 8, 2017.

(h) As 25,000 shares of employee restricted stocks granted to certain employees in June and July 2018 did not meet the vesting conditions in accordance with the terms of restricted stocks, the Board of Directors has resolved on August 1, 2018 to buy back the restricted stocks to retire for capital reduction. The registration was completed on August 29, 2018.

(i) As 10,000 shares of employee restricted stocks granted to certain employees in November 2018 did not meet the vesting conditions in accordance with the terms of restricted stocks, the Board of Directors has resolved on October 31, 2018 to buy back the restricted stocks to retire for capital reduction. The registration was completed on January 3, 2019.

(j) The stockholders at their annually stockholders' meeting on May 31, 2017 adopted a resolution to issue employee restricted stocks (see Note 6(13)) with the effective date set on November 16, 2017 and July 2, 2018. The subscription price is NT$10 (in dollars) (US$0.3 (in dollars)) per share. The employee restricted stocks issued are subject to certain restrictions on selling, pledging as collateral, transfer, donation or other methods to dispose before their vesting conditions are met. Other than these restrictions, the rights and obligations of these shares issued are the same as other issued common shares.

E. Treasury stocks

(a) Reason for share repurchase and movements in the number of the Company's treasury stock are as follows:

	2016			
Reason for repurchase	**January 1**	**Additions**	**Disposal**	**December 31**
To be reissued to employees				
—Number of shares (in thousands)	276	—	(276)	—
—Carrying amount (NT$000)	$ 36,893	$ —	$ (36,893)	$ —

For the year ended December 31, 2017 and 2018: None.

(b) Pursuant to the R.O.C. Securities and Exchange Act, the number of shares repurchased as treasury stocks should not exceed 10% of the number of the Company's issued and outstanding shares and the amount repurchased should not exceed the sum of retained earnings, paid-in capital in excess of par value and realized capital surplus.

(c) Pursuant to the R.O.C. Securities and Exchange Act, treasury stocks should not be pledged as collateral and is not entitled to dividends before it is reissued.

(d) Pursuant to the R.O.C. Securities and Exchange Act, treasury stocks should be reissued to the employees within three years from the repurchase date and shares not reissued within the three-year period are to be retired.

(16) Capital surplus

Pursuant to the R.O.C. Company Act, capital reserve arising from paid-in capital in excess of par value on issuance of common stocks and donations can be used to cover accumulated deficit or to issue new stocks or cash to shareholders in proportion to their share ownership, provided that the Company has no accumulated deficit. Further, the R.O.C. Securities and Exchange Act requires that the amount of capital reserve to be capitalized mentioned above should not exceed 10% of the paid-in capital each year. Capital surplus should not be used to cover accumulated deficit unless the legal reserve is insufficient.

(17) Retained earnings / accumulated deficit

A. Under the Company's Articles of Incorporation, the current earnings, if any, shall be distributed in the following order:

(a) Payment of taxes and duties.

(b) Cover prior years' accumulated deficit, if any.

(c) After deducting items a and b, set aside 10% of the remaining amount as legal reserve.

(d) Appropriate or reverse special reserve in accordance with the relevant laws and regulations, if necessary;

(e) After deducting items a to d, the remainder, if any, to be retained or to be appropriated shall be resolved by the shareholders at the shareholders' meeting.

B. The Company's dividend policy is summarized below:

As the Company operates in a volatile business environment and is in the growth stage, the residual dividend policy is adopted taking into consideration the Company's financial structure, operating results and future expansion plans. According to the dividend policy adopted by the Board of Directors, cash dividends shall account for at least 10% of the total dividends distributed.

C. Under the R.O.C. Company Act, when the accumulated deficit exceeds 50% of the capital, the directors should convene a meeting of the shareholders and report the situation.

D. The shareholders during their meetings on June 21, 2016, May 31, 2017 and June 26, 2018 adopted a resolution to use capital surplus amounting to NT$673,652 thousand, NT$824,662 thousand and NT$874,086 thousand (US$28,555 thousand) to cover accumulated deficit, respectively.

E. As of December 31, 2017 and 2018, the Company had an accumulated deficit. Therefore, the earnings distribution information disclosure is not applicable.

F. For the information relating to employees' compensation and directors' and supervisors' remuneration, please refer to Note 6(23).

(18) Operating revenue

	Years ended December 31, 2018	
	NT$000	US$000
Revenue from contracts with customers	$ 62,324	$ 2,036

A. Disaggregation of revenue from contracts with customers

The Group derives revenue from the transfer of goods and services over time and at a point in time in the following types:

Year ended December 31, 2018	Royalty Revenue	Authorization collaboration and development revenue	Total
	NT$000	NT$000	NT$000
Timing of revenue recognition			
At a point in time	$ 52,100	$ —	$ 52,100
over time	—	10,224	10,224
Total	$ 52,100	$ 10,224	$ 62,324
Total **(US$000)**	$ 1,702	334	$ 2,036

B. Contract assets and liabilities

The Group has recognized the following revenue-related contract liabilities and assets:

	December 31		
	2017 (Note)	2018	
	NT$000	NT$000	US$000
Contract liabilities – authorization collaboration and development revenue	$ 7,941		
Contract assets- authorization collaboration and development revenue		$ 2,283	$ 75

Note: Please refer to Note 3(1)(b) for the reclassified amount.

(a) Revenue recognized that was included in the contract liability balance at the beginning of the year:

	December 31, 2018	
	NT$000	US$000
Revenue recognized that was included in the contract liability balance at the beginning of the year		
Authorization collaboration and development contracts	$ 7,941	$ 259

(b) Unfulfilled long-term authorization collaboration and development contracts

Aggregate amount of the transaction price allocated to long-term authorization collaboration and development contracts that are partially unsatisfied as of December 31, 2018 amounted to NT$37,716 thousand (US$1,232 thousand). Considering the progress of research and development, management expects that the transaction price allocated to the unsatisfied contracts amounting to NT$37,716 thousand (US$1,232 thousand) as of December 31, 2018 will be recognized as revenue in the next three years, which is subject to the management's plan in terms of completion of clinical and bioequivalence study.

C. Related disclosures in relation to operating revenue for the year ended December 31, 2017 are provided in Note 12(5)B.

D. Authorization collaboration and development revenue is the revenue arising from authorization collaboration and development of generic drugs. The details are as follows:

In December 2013, the Company entered into a license and collaboration agreement with Sandoz AG. ("Sandoz") for the development and commercialization of products in Europe and in the USA. Under the terms of the agreement, the Company received an upfront, non-refundable payment of US$0.1 million in January 2014, and aggregated milestone payments of US$2.275 million related to the Europe submission in March and April 2014, and January 2015, respectively.

Once the new drug is launched in the market, a royalty fee will be received by the Company, which is equal to an agreed upon percentage of net sales. The Company is also eligible to receive performance-based milestone payment upon entering the local market in Europe and in the USA, and upon achieving a certain net sales volume and market position within five years.

E. The details of royalty revenue are as follows:

(a) The Company granted TTY Biopharm Company Limited ("TTY") the exclusive right in Taiwan to produce and promote LIPO-DOX, a medicinal product developed by the Company. Under the agreement, royalty payments are based on 12% of the net product sales.

(b) The Company authorizes Yung Shin Pharm. Ind. Co., Ltd. ("YSP") the exclusive right in Taiwan to produce and promote generic drugs. Under the agreement, the Company will receive a royalty payment based on a certain percentage of the net sales.

(19) Other income and expenses

	Years ended December 31,			
	2016	2017	2018	
	NT$000	NT$000	NT$000	US$000
Government subsidy income (Note 1 and 2)	$ 1,810	$ 14,206	$ 21,100	$ 689
Others	3,765	6,942	5,128	168
	$ 5,575	$ 21,148	$ 26,228	$ 857

Note 1: The Company has entered into contracts of "A phase IIa trial of lipid-based investigational drug TLC399 in the subjects with macular edema due to retinal vein occlusion in the United States" and "A phase I/II trial of lipid-based, sustained release investigational drug TLC399 (ProDex®) for treating macular edema due to retinal vein occlusion" with the Institute for Information Industry in 2017 and 2014, respectively. The Company has accrued government subsidy income in accordance with the progress of the plans. The aforesaid subsidy plans has recognized income of NT$1,810 thousand, NT$14,206 thousand and NT$7,615 thousand (US$249 thousand) for the years ended December 31, 2016, 2017 and 2018, respectively. As of December 31, 2018, the Company has not received the government subsidy of NT$2,661 thousand (US$87 thousand) (shown as "Other receivables").

Note 2: The Company's subsidiary, TLC Biopharmaceuticals Pty Ltd. received the financial incentives from Australian government in August 2018 of NT$13,485 thousand (US$441 thousand) for its research and development activities.

(20) Other gains and losses

	Years ended December 31,			
	2016	2017	2018	
	NT$000	NT$000	NT$000	US$000
Net currency exchange gain (loss)	$ 417	$ 2,632	$ (2,986)	$ (97)
Gain on disposal of property, plant and equipment	—	20	1,478	48
	$ 417	$ 2,652	$ (1,508)	$ (49)

(21) Finance costs

	Years ended December 31,			
	2016	2017	2018	
	NT$000	NT$000	NT$000	US$000
Bank borrowings	$ 2,376	$ 2,255	$ 9,379	$ 306
Financial lease liabilities	564	1,130	507	17
	$ 2,940	$ 3,385	$ 9,886	$ 323

(22) Expenses by nature (Shown as operating expenses)

	Years ended December 31,			
	2016	2017	2018	
	NT$000	NT$000	NT$000	US$000
Employee benefit expenses	$ 346,111	$ 323,991	$ 314,655	$ 10,280
Depreciation charges	$ 63,571	$ 41,926	$ 39,315	$ 1,284
Amortization charges	$ 11,668	$ 10,570	$ 8,144	$ 266

(23) Employee benefit expenses

	Years ended December 31,			
	2016	2017	2018	
	NT$000	NT$000	NT$000	US$000
Wages and salaries	$ 207,591	$ 225,633	$ 234,735	$ 7,669
Share-based payment compensation costs	100,573	57,149	41,386	1,352
Labor and health insurance fees	17,194	19,117	19,026	621
Pension costs	9,369	10,245	10,396	340
Other personnel expenses	11,384	11,847	9,112	298
	$ 346,111	$ 323,991	$ 314,655	$ 10,280

According to the Articles of Incorporation of the Company, a ratio of distributable profit of the current year, after covering accumulated deficit, shall be distributed as employees' compensation and directors' and supervisors' remuneration. The ratio shall be 2%~8% for employees' compensation and shall not be higher than 2% for directors' remuneration. As of December 31, 2016, 2017, and 2018, the Company had accumulated deficits and did not accrue employees' compensation and directors' and supervisors' remuneration.

(24) Income tax

A. Components of income tax expense:

	Years ended December 31,			
	2016	2017	2018	
	NT$000	NT$000	NT$000	US$000
Current income tax:				
Current income tax on profits for the year	$ 535	$ 735	$ 538	$ 17
Prior year income tax underestimation	117	133	329	11
Total current income tax	652	868	867	28
Deferred income tax:				
Origination and reversal of temporary differences	(89)	83	—	—
	$ 563	$ 951	$ 867	$ 28

B. Reconciliation between income tax expense and accounting profit:

	Years ended December 31,			
	2016	2017	2018	
	NT$000	NT$000	NT$000	US$000
Tax calculated based on profit (loss) before tax and statutory tax rate (Note)	($ 140,038)	($ 148,412)	($ 180,141)	($ 5,885)
Effect of different tax rates in countries in which the group operates	439	573	300	10
Tax effect of amounts which are not (taxable) deductible in calculating taxable income	(89)	83	—	—
Taxable loss not recognized as deferred tax assets	140,134	148,574	180,379	5,892
Prior year income tax underestimation	117	133	329	11
Income tax expense	$ 563	$ 951	$ 867	$ 28

Note: The basis for computing the applicable tax rate is the rate applicable of 17% and 17% in the parent company's country in 2016 and 2017, and 20% in 2018, respectively.

C. Amounts of deferred income tax assets or liabilities as a result of temporary differences are as follows:

	2016				
Reason for reacquisition	January 1	Recognized in profit or loss	Recognized in other comprehensive income	Recognized in equity	December 31
	NT$000	NT$000	NT$000	NT$000	NT$000
Temporary differences:					
—Deferred income tax assets:					
Unrealized expenses	$ 75	$ 89	$ —	$ —	$ 164

	2017				
Reason for reacquisition	January 1	Recognized in profit or loss	Recognized in other comprehensive income	Recognized in equity	December 31
	NT$000	NT$000	NT$000	NT$000	NT$000
Temporary differences:					
—Deferred income tax assets:					
Unrealized expenses	$ 164	($ 83)	$ —	$ —	$ 81

	2018					
Reason for reacquisition	January 1	Recognized in profit or loss	Recognized in other comprehensive income	Recognized in equity	December 31	December 31
	NT$000	NT$000	NT$000	NT$000	NT$000	US$000
Temporary differences:						
—Deferred income tax assets:						
Unrealized expenses	$ 81	$ —	($ 2)	$ —	$ 79	$ 3

D. Details of investment tax credits and unrecognized deferred tax assets are as follows:

	December 31, 2017		
	Unused credits	Unrecognized deferred income tax assets	Final year tax credits are due
	NT$000	NT$000	
Qualifying items			
Research and development expenditure	$ 307,403	$ 307,403	Note
Employees' development and training	72	72	Note

	December 31, 2018		
	Unused credits	Unrecognized deferred income tax assets	Final year tax credits are due
	NT$000	NT$000	
Qualifying items			
Research and development expenditure	$ 358,394	$ 358,394	Note
Employees' development and training	72	72	Note

	December 31, 2018		
	Unused tax credits	Unrecognized deferred income tax assets	Final year tax credits are due
	US$000	US$000	
Qualifying items			
Research and development expenditure	$ 11,708	$ 11,708	Note
Employees' development and training	2	2	Note

Note: In accordance with the Ministry of Economic Affairs (MOEA) Jing-Shou-Gong-Zi Letter No. 10020409420 dated June 10, 2011 and Letter No. 10320407210 dated April 3, 2014, the Company was approved as a biotech pharmaceuticals company. Accordingly, the Company and its shareholders are eligible for investment tax credits under the Statute for Development of Biotech New Pharmaceuticals Industry. Relevant investment tax credits can be used to offset against the Company's income tax within five years from the year in which the Company starts to have income tax payable.

E. Expiration dates of unused loss carryforward and amounts of unrecognized deductible amounts of the Company are as follows:

	December 31, 2017			
Year incurred	Amount filed / assessed	Unused amount	Unrecognized amount (Note)	Expiry year
	NT$000	NT$000	NT$000	
2008	$ 200,442	$ 200,442	$ 200,442	2018
2009	136,642	136,642	136,642	2019
2010	196,215	196,215	196,215	2020
2011	212,903	212,903	212,903	2021
2012	187,946	187,946	187,946	2022
2013	407,816	407,816	407,816	2023
2014	632,283	632,283	632,283	2024
2015	649,799	649,799	649,799	2025
2016	792,388	792,388	792,388	2026
2017	869,479	869,479	869,479	2027
	$ 4,285,913	$ 4,285,913	$ 4,285,913	

Note: Unrecognized amount represents unused tax losses for which no deferred income tax asset has been recognized.

	December 31, 2018			
Year incurred	Amount filed / assessed	Unused amount	Unrecognized amount (Note)	Expiry year
	NT$000	NT$000	NT$000	
2009	$ 136,642	$ 136,642	$ 136,642	2019
2010	196,215	196,215	196,215	2020
2011	212,903	212,903	212,903	2021
2012	187,946	187,946	187,946	2022
2013	407,816	407,816	407,816	2023
2014	632,283	632,283	632,283	2024
2015	649,799	649,799	649,799	2025
2016	792,388	792,388	792,388	2026
2017	832,622	832,622	832,622	2027
2018	918,113	918,113	918,113	2028
	$ 4,966,727	$ 4,966,727	$ 4,966,727	

Note: Unrecognized amount represents unused tax losses for which no deferred income tax asset has been recognized.

Year incurred	December 31, 2018			
	Amount filed / assessed	Unused amount	Unrecognized amount (Note)	Expiry year
	US$000	US$000	US$000	
2009	$ 4,464	$ 4,464	$ 4,464	2019
2010	6,410	6,410	6,410	2020
2011	6,955	6,955	6,955	2021
2012	6,140	6,140	6,140	2022
2013	13,323	13,323	13,323	2023
2014	20,656	20,656	20,656	2024
2015	21,228	21,228	21,228	2025
2016	25,887	25,887	25,887	2026
2017	27,201	27,201	27,201	2027
2018	29,994	29,994	29,994	2028
	$ 162,258	$ 162,258	$ 162,258	

Note: Unrecognized amount represents unused tax losses for which no deferred income tax asset has been recognized.

F. The U.S. subsidiary, TLC Biopharmaceuticals, Inc., has not recognized unused tax losses as deferred income tax assets. As of December 31, 2017 and 2018, the amounts of unused tax losses not recognized as deferred income tax assets are NT$48,732 thousand and NT$1,968 thousand (US$64 thousand), respectively.

G. The amounts of deductible temporary differences that were not recognized as deferred income tax assets are as follows:

	December 31,		
	2017	2018	
	NT$000	NT$000	US$000
Deductible temporary differences	$ 104,865	$ 85,337	$ 2,788

H. The Company's income tax returns through 2016 have been assessed and approved by the Tax Authority.

(25) Loss per share

	Year ended December 31, 2016		
	Amount after tax	Weighted average number of common shares outstanding (in thousands of shares)	Loss per share (in dollars)
	NT$000		NT$
Basic loss per share			
Loss attributable to common shareholders of the Company	($ 824,316)	55,361	($ 14.89)
Dilutive effect of common shares equivalents:			
Employees' stock options	—	(Note)	
Restricted stocks	—	(Note)	
Diluted loss per share			
Loss attributable to common shareholders of the Company plus assumed conversion of all dilutive potential common shares	($ 824,316)	55,361	($ 14.89)

	Year ended December 31, 2017		
	Amount after tax	Weighted average number of common shares outstanding (in thousands of shares)	Loss per share (in dollars)
	NT$000		NT$
Basic loss per share			
Loss attributable to common shareholders of the Company	($ 873,962)	55,489	($ 15.75)
Dilutive effect of common shares equivalents:			
Employees' stock options	—	(Note)	
Restricted stocks	—	(Note)	
Diluted loss per share			
Loss attributable to common shareholders of the Company plus assumed conversion of all dilutive potential common shares	($ 873,962)	55,489	($ 15.75)

	Year ended December 31, 2018		
	Amount after tax	Weighted average number of common shares outstanding (in thousands of shares)	Loss per share (in dollars)
	NT$000		NT$
Basic loss per share			
Loss attributable to common shareholders of the Company	($ 901,574)	62,719	($ 14.37)
Dilutive effect of common shares equivalents:			
Employees' stock options	—	(Note)	
Restricted stocks	—	(Note)	
Diluted loss per share			
Loss attributable to common shareholders of the Company plus assumed conversion of all dilutive potential common shares	($ 901,574)	62,719	($ 14.37)

	Year ended December 31, 2018		
	Amount after tax	Weighted average number of common shares outstanding (in thousands of shares)	Loss per share (in dollars)
	US$000		US$
Basic loss per share			
Loss attributable to common shareholders of the Company	($ 29,454)	62,719	($ 0.47)
Dilutive effect of common shares equivalents:			
Employees' stock options	—	(Note)	
Restricted stocks	—	(Note)	
Diluted loss per share			
Loss attributable to common shareholders of the Company plus assumed conversion of all dilutive potential common shares	($ 29,454)	62,719	($ 0.47)

Note: Employee stock options and employee restricted stocks have no dilutive effect for any period due to the fact that the Company was in loss position for all periods presented.

(26) Cash flow information

Investing activities with partial cash payments

	Years ended December 31,			
	2016	2017	2018	
	NT$000	NT$000	NT$000	US$000
Acquisition of property, plant and equipment (including transfers)	$ 20,497	$ 17,237	$ 42,213	$ 1,379
Add: Opening balance of payables on machinery, equipment, and intangible assets	3,826	1,229	—	—
Ending balance of prepayments for equipment	1,483	923	27,942	913
Opening balance of prepayments for equipment being transferred to other expenses	—	—	780	25
Opening balance of prepayments for equipment being transferred to intangible assets	71	227	—	—
Less: Ending balance of payables on machinery, equipment, and intangible assets	(1,229)	—	(3,303)	(108)
Opening balance of prepayments for equipment	(71)	(1,483)	(923)	(30)
Provisions	(3,150)	—	—	—
Cash paid	$ 21,427	$ 18,133	$ 66,709	$ 2,179

	Years ended December 31,			
	2016	2017	2018	
	NT$000	NT$000	NT$000	US$000
Acquisition of intangible assets (including transfers)	$ 6,126	$ 5,933	$ 3,537	$ 115
Add: Opening balance of payable on machinery, equipment, and intangible assets	84	1,495	—	—
Less: Ending balance of payables on machinery, equipment, and intangible assets	(1,495)	—	(374)	(12)
Opening balance of prepayments for equipment	(71)	(227)	—	—
Cash paid	$ 4,644	$ 7,201	$ 3,163	$ 103

(27) Changes in liabilities from financing activities

	2017			
	Short-term borrowings	Long-term borrowings (including current portion)	Financial lease liabilities (including current portion)	Liabilities from financing activities
	NT$000	NT$000	NT$000	NT$000
At January 1	$ 46,000	$ 71,750	$ 50,500	$ 168,250
Changes in cash flow from financing activities	—	(1,700)	1,500	(200)
At December 31	$ 46,000	$ 70,050	$ 52,000	$ 168,050

	2018			
	Short-term borrowings	Long-term borrowings (including current portion)	Financial lease liabilities (including current portion)	Liabilities from financing activities
	NT$000	NT$000	NT$000	NT$000
At January 1	$ 46,000	$ 70,050	$ 52,000	$ 168,050
Changes in cash flow from financing activities	—	364,107	(4,000)	360,107
Net exchange differences	—	600	—	600
At December 31	$ 46,000	$ 434,757	$ 48,000	$ 528,757
At December 31 (US$000)	$ 1,503	$ 14,203	$ 1,568	$ 17,274

7. RELATED PARTY TRANSACTIONS

(1) Names of related parties and relationship

Names of related parties	Relationship with the Group
Keelung Hong	The Group's Chairman
George Yeh	The Group's General Manager

(2) Significant transactions and balances with related parties

A. The Company's Chairman provided guarantees for the Company's long-term and short-term borrowings with Taiwan Cooperative Bank.

B. The Company's Chairman and General Manager provided guarantees for the Company's short-term borrowings with E.SUN Commercial Bank.

C. The Company's Chairman provided guarantees to Taiwan Cooperative Bank for the Company's government grant in relation to the research and development program from the Institute of Information Industry.

As of December 31, 2017 and 2018, details of loans are described in Notes 6(8) and 6(10).

(3) Key management personnel compensation

	Years ended December 31,			
	2016	2017	2018	
	NT$000	NT$000	NT$000	US$000
Salaries and other short-term employee benefits	$ 26,810	$ 33,072	$ 38,227	$ 1,249
Post-employment benefits	350	432	486	16
Share-based payments	11,823	8,120	9,366	306
	$ 38,983	$ 41,624	$ 48,079	$ 1,571

8. PLEDGED ASSETS

(1)

	December 31,			
Assets pledged	2017	2018		Pledge purpose
	NT$000	NT$000	US$000	
Shown as "Property, plant and equipment"				
Land	$ 14,962	$ 14,962	$ 489	Note
Buildings	24,172	23,516	768	Note
	$ 39,134	$ 38,478	$ 1,257	

Note: Provided as collateral for borrowings.

(2) Pursuant to the loan and security agreement entered between Cathay Bank and the Company and its subsidiary, TLC US, on December 27, 2018, except for the Intellectual Property, including trademarks, patents, copyrights, servicemarks, technology, trade secrets, and etc., defined in the loan agreement, all other personal property, including tangible and intangible assets, of the Company and its subsidiary, TLC US are pledged as collateral for borrowings. Cathay Bank constitutes a first priority security interest in the personal property of the Company and TLC US located in the United States and does not constitute a first priority security interest in the personal property of the Company located outside of the United States.

9. SIGNIFICANT CONTINGENT LIABILITIES AND UNRECOGNIZED CONTRACT COMMITMENTS

(1) Contingencies

Under certain special generic product agreements, the Company is required to have a certain market supply capacity before the launch of the products in the market. Otherwise, the Company is obligated to pay a certain amount as compensation.

(2) Commitments

In addition to the commitment mentioned in Note 6(10)A and B, the Group's significant commitments are as follows:

A. Capital expenditures contracted for at the balance sheet date but not yet incurred and are cancelable without cause are as follows:

	December 31,		
	2017	2018	
	NT$000	NT$000	US$000
Property, plant and equipment	$ 1,781	$ 11,037	$ 361

B. Operating lease commitments

The Group leases offices with lease terms between 1 and 5 years, and the majority of lease agreements are renewable at the end of the lease terms at market rate. The future aggregate minimum lease payments are as follows:

	December 31,		
	2017	2018	
	NT$000	NT$000	US$000
Not later than one year	$ 32,999	$ 31,787	$ 1,038
Later than one year but not later than five years	75,450	46,315	1,513
	$ 108,449	$ 78,102	$ 2,551

C. The Company has outstanding commitments on purchase agreements for the research and manufacturing of medicines which are cancelable without cause as follows:

	December 31,		
	2017	2018	
	NT$000	NT$000	US$000
	$ 31,577	$ 120,707	$ 3,943

D. The Company has outstanding commitments on research and development which are cancelable without cause as follows:

	December 31,		
	2017	2018	
	NT$000	NT$000	US$000
	$ 478,977	$ 603,178	$ 19,705

E. The Company has signed a licensing agreement for technology transition with TWI Pharmaceuticals, Inc. with maximum royalty charges of US$5,000 thousand according to the R&D achievement. Once the new drug is launched in the market, the Company will pay a royalty fee based on a certain percentage of the net product sales.

F. The Company's subsidiary entered into a synthesis technology of novel camptothecin derivative transfer agreement with Sutter West Bay Hospitals (SWBH, formerly, California Pacific Medical Center). Under the agreement, SWBH charges the Company's subsidiary a patent usage fee of US$10 thousand per annum, royalty fees up to US$300 thousand according to the R&D achievement and royalty fees to a certain percentage of relevant product sales volume. Through December 31, 2018, the Company's subsidiary has paid US$100 thousand.

10. SIGNIFICANT DISASTER LOSS

None.

11. EVENTS AFTER THE REPORTING PERIOD

A. On March 1, 2019, the Company entered into a commercialization agreement with Hong Kong Sansheng Medical Limited ("3SBio") to commercialize two liposomal products utilizing the Company's NanoX technology platform in mainland China, excluding Hong Kong and Macau (the "Territory"). Under the terms of the agreement, the Company has received an upfront payment in March 2019 and is eligible to receive further development and sales milestones for a total of up to US$25 million. In addition, the Company is also eligible to receive double-digit profit shares from the potential sales of products. The Company and 3SBio will be jointly responsible for obtaining the regulatory approvals for the products in the Territory. The Company will manufacture the products on its own cost. 3SBio will be responsible to import, promote, market, sell and distribute the products in the Territory at its own responsibilities and expenses.

B. On April 25, 2019, the Company entered into an amendment to the loan and security agreement with Cathay Bank. Please refer to Note 6(10) for details.

12. OTHERS

(1) Capital risk management

The Group's objectives when managing capital are to safeguard the Group's ability to continue as a going concern in order to provide returns for shareholders and to maintain an optimal capital structure to reduce the cost of capital. In order to improve the Group's capital structure, the Group may issue new shares or sell assets to reduce debt ratio. The Group monitors capital on the basis of the gearing ratio. This ratio is calculated as total debt divided by total capital.

As of December 31, 2017 and 2018, the Group's gearing ratios are as follows:

	December 31,		
	2017	2018	
	NT$000	NT$000	US$000
Total debt	$ 275,255	$ 748,725	$ 24,460
Total capital	$ 561,990	$ 640,451	$ 20,923
Debt ratio	48.98%	116.91%	116.91%

(2) Financial instruments

A. Financial instruments by category

	December 31,		
	2017	2018	
	NT$000	NT$000	US$000
Financial assets			
Financial assets at amortized cost/ loans and receivables			
Cash and cash equivalents	$ 951,713	$ 807,484	$ 26,380
Current financial assets at amortized cost	—	307,150	10,034
Accounts receivables, net	8,622	9,343	305
Other receivables	19,726	5,811	190
Refundable deposits	27,188	18,930	618
	$ 1,007,249	$ 1,148,718	$ 37,527
Financial liabilities			
Financial liabilities at amortized cost			
Short-term borrowings	$ 46,000	$ 46,000	$ 1,503
Other payables	93,541	206,268	6,739
Financial lease liabilities (including current portion)	52,000	48,000	1,568
Long-term borrowings (including current portion)	70,050	434,757	14,203
	$ 261,591	$ 735,025	$ 24,013

B. Financial risk management policies

(a) The Group's activities expose it to a variety of financial risks: market risk, credit risk, liquidity risk and cash flow interest rate risk. The Group adopts overall risk management program and control system to identify all financial risks and seeks to control and balance potential adverse effects from those aforesaid financial risks.

(b) The goal of market risk management is to appropriately consider the impacts of economic environment, competition and market value risk, in order to achieve the best risk position, to maintain appropriate liquidity position and to centrally manage all market risks.

(c) To meet its risk management objectives, the Group's procedures of hedge focus on market risk and cash flow interest rate risk.

C. Significant financial risks and degree of financial risks

(a) Market risk

i. Foreign exchange risk

(i) The Group's businesses involve some non-functional currency operations (the Company's functional currency: NTD; the subsidiaries' functional currencies: USD, EUR, HKD, RMB, AUD and JPY). The information on assets and liabilities denominated in foreign currencies whose values would be materially affected by the exchange rate fluctuations is as follows:

	December 31, 2017			
(Foreign currency: functional currency)	Foreign currency amount		Exchange Rate	Book value
	$000			NT$000
Financial assets Monetary items				
USD : NTD	US$	575	29.76	$ 17,112
Non-monetary items				
USD : NTD	US$	1,437	29.76	42,762
AUD : NTD	AUD$	1,084	23.71	25,135
Financial liabilities Monetary items				
USD : NTD	US$	741	29.76	22,052
AUD : NTD	AUD$	1,466	23.71	34,752

	December 31, 2018				
(Foreign currency: functional currency)	Foreign currency amount		Exchange Rate	Book value	Book value
	$000			NT$000	US$000
Financial assets Monetary items					
USD : NTD	US$	29,333	30.715	$ 919,392	$ 30,036
Non-monetary items					
USD : NTD	US$	1,529	30.715	46,963	1,534
AUD : NTD	AUD$	1,754	21.665	38,000	1,241
Financial liabilities Monetary items					
USD : NTD	US$	17,886	30.715	549,368	17,947
AUD : NTD	AUD$	2,544	21.665	55,116	1,801

(ii) Analysis of foreign currency market risk arising from significant foreign exchange variation:

	Year ended December 31, 2017		
	Sensitivity analysis		
(Foreign currency: functional currency)	Extent of variation	Effect on profit or loss	Effect on other comprehensive income
		NT$000	NT$000
Financial assets Monetary items			
USD : NTD	1%	$ 171	$ —
Non-monetary items			
USD : NTD	1%	—	428
AUD:NTD	1%	—	251
Financial liabilities Monetary items			
USD : NTD	1%	221	—
AUD:NTD	1%	348	—

(Foreign currency: functional currency)	Year ended December 31, 2018				
	Sensitivity analysis				
	Extent of variation	Effect on profit or loss	Effect on profit or loss	Effect on other comprehensive income	Effect on other comprehensive income
		NT$000	US$000	NT$000	US$000
Financial assets Monetary items					
USD : NTD	1%	$ 9,194	$ 300	$ —	$ —
Non-monetary items					
USD : NTD	1%	—	—	470	15
AUD : NTD	1%	—	—	380	12
Financial liabilities Monetary items					
USD : NTD	1%	5,494	179	—	—
AUD : NTD	1%	551	18	—	—

(iii) The unrealized exchange gain (loss) arising from significant foreign exchange variation on the monetary items held by the Group for the years ended December 31, 2016, 2017, and 2018 are (NT$461) thousand, NT$329 thousand and NT$24 thousand (US$1 thousand), respectively.

ii. Cash flow and fair value Interest rate risk

The Group's interest rate risk arises from short-term and long-term borrowings. Borrowings issued at floating interest rates expose the Group to cash flow interest rate risk. During the years ended December 31, 2016, 2017 and 2018, the Group's borrowings at floating interest rate were denominated in the NT dollars.

At December 31, 2017 and 2018, if interest rates had been 0.2% higher/lower with all other conditions held constant, net loss for the years ended December 31, 2017 and 2018 would have been NT$232 thousand and NT$653 thousand (US$21 thousand) higher/lower, respectively. The main factor is that the floating-rate borrowings resulted in changes in interest expense.

(b) Credit risk

i. Credit risk refers to the risk of financial loss to the Group arising from cash and deposits with banks and financial institutions, as well as default by the customers on the contract obligations. The main factor is that counterparties could not repay in full the accounts receivable based on the agreed terms

ii. The Group manages their credit risk taking into consideration the entire Group's concern. For banks and financial institutions, only financial institutions with a good credit rating are accepted. According to the Group's credit policy, each entity in the Group is responsible for managing and analyzing the credit risk for each of their new customers before entering into license contracts. Internal risk control assesses the credit quality of the customers, taking into account their financial positions, past experience and other factors.

iii. The default occurs when the contract payments are past due based on the agreed terms.

iv. The Group classifies customers' accounts receivable in accordance with credit rating of customers. The Group applies the simplified approach to estimate expected credit loss under the provision matrix basis.

v. The Group wrote off the financial assets, which cannot be reasonably expected to be recovered, after initiating recourse procedures. However, the Group will continue executing the recourse procedures to secure their rights.

vi. The Group assesses the expected credit losses based on the payment terms stipulated in the contracts with the customers. To measure the expected credit losses, trade receivables have been grouped based on shared credit risk characteristics and the days past due. The historical loss rates are adjusted to reflect current and forward-looking information on factors affecting the ability of the customers to settle the receivables. Except for loss allowance of NT$18,132 thousand (US$592 5housand) established based on the delay payment of the balances due from one customer, the Group has not identified impairments on the trade receivables. The Group has therefore concluded that the expected loss rates for the trade receivables and contract assets is very low, and the loss allowance for the trade receivables and contract assets recognized is immaterial as of December 31, 2018.

Movements in relation to the group applying the simplified approach to provide loss allowance for accounts receivable and contract assets are as follows:

	2018			
	Accounts receivable		Contact assets	
	NT$000	US$000	NT$000	US$000
At January 1_IAS 39	$ 18,132	$ 592	$ —	$ —
Adjustments under new standards	—	—	—	—
At January 1_IFRS 9	18,132	592	—	—
Provision for impairment	—	—	—	—
At December 31	$ 18,132	$ 592	$ —	$ —

i. Credit risk information for the years ended December 31, 2016 and 2017 is provided in Note 12(4).

(c) Liquidity risk

i. Cash flow forecasting is performed in the operating entities of the Group and aggregated by Group treasury. Group treasury monitors rolling forecasts of the Group's liquidity requirements to ensure it has sufficient cash to meet operational needs.

ii. The table below analyzes the Group's non-derivative financial liabilities based on the remaining period at the balance sheet date to the contractual maturity date. The amounts disclosed in the table are the contractual undiscounted cash flows.

	December 31, 2017				
	Within 1 year	Between 1 and 2 years	Between 2 and 3 years	Between 3 and 5 years	Over 5 years
	NT$000	NT$000	NT$000	NT$000	NT$000
Short-term borrowings	$ 46,062	$ —	$ —	$ —	$ —
Other payables	93,541	—	—	—	—
Finance lease liabilities (including current portion)	48,466	4,008	—	—	—
Long-term borrowings (including current portion)	5,137	6,493	6,430	27,901	33,019

	December 31, 2018				
	Within 1 year	Between 1 and 2 years	Between 2 and 3 years	Between 3 and 5 years	Over 5 years
	NT$000	NT$000	NT$000	NT$000	NT$000
Short-term borrowings	$ 46,761	$ —	$ —	$ —	$ —
Other payables	206,268	—	—	—	—
Finance lease liabilities (including current portion)	24,583	24,198	—	—	—
Long-term borrowings (including current portion)	82,864	322,928	8,351	24,210	30,429

	December 31, 2018				
	Within 1 year	Between 1 and 2 years	Between 2 and 3 years	Between 3 and 5 years	Over 5 years
	US$000	US$000	US$000	US$000	US$000
Short-term borrowings	$ 1,528	$ —	$ —	$ —	$ —
Other payables	6,739	—	—	—	—
Finance lease liabilities (including current portion)	803	791	—	—	—
Long-term borrowings (including current portion)	2,707	10,550	273	791	994

(3) Fair value estimation

A. The Group had no financial instruments measured at fair value, by valuation method, as of December 31, 2017 and 2018.

B. The management considers that the carrying amounts of financial assets and liabilities not measured at fair value are approximate to their fair values, including cash and cash equivalents, financial assets at amortized cost, receivables, refundable deposits, short-term borrowings, long-term borrowings (including current portion), payables, and finance lease liabilities (including current portion).

(4) Effects on initial application of IFRS 9 and information in relation to the application of IAS 39 for the years ended December 31, 2016 and 2017

A. The significant accounting policies of accounts receivable, other receivables, and impairment of financial assets adopted in the years ended December 31, 2016 and 2017 are as follows:

(a) Accounts receivable and other receivables

Accounts receivable are claims resulting from the sale of goods or services. Other receivables are those arising from transactions other than the sale of goods or services. Accounts receivable and other receivables are recognized initially at fair value and subsequently measured at amortized cost using the effective interest method, less provision for impairment. However, short-term accounts receivable without bearing interest are subsequently measured at initial invoice amount as the effect of discounting is immaterial.

(b) Impairment of financial assets

i. The Group assesses at each balance sheet date whether there is objective evidence that a financial asset or a group of financial assets is impaired as a result of one or more events that occurred after the initial recognition of the asset (a 'loss event') and that loss event (or events) has an impact on the estimated future cash flows of the financial asset or group of financial assets that can be reliably estimated.

ii. The criteria that the Group uses to determine whether there is objective evidence of an impairment loss is as follows:

(a) Significant financial difficulty of the issuer or debtor;

(b) A breach of contract, such as a default or delinquency in interest or principal payments;

(c) The Group, for economic or legal reasons relating to the borrower's financial difficulty, granted the borrower a concession that a lender would not otherwise consider;

(d) It becomes probable that the borrower will enter bankruptcy or other financial reorganization;

(e) Information about significant changes with an adverse effect that have taken place in the technology, market, economic or legal environment in which the issuer operates, and indicates that the cost of the investment in the equity instrument may not be recovered.

iii. When the Group assesses that there has been objective evidence of impairment and an impairment loss has occurred on financial assets measured at amortized cost, the amount of the impairment loss is measured as the difference between the asset's carrying amount and the present value of estimated future cash flows discounted using the financial asset's original effective interest rate, and is recognized in profit or loss. If, in

a subsequent period, the amount of the impairment loss decreases and the decrease can be related objectively to an event occurring after the impairment loss was recognized, the previously recognized impairment loss is reversed through profit or loss to the extent that the carrying amount of the asset does not exceed its amortized cost that would have been at the date of reversal had the impairment loss not been recognized previously. Impairment loss is recognized and reversed by adjusting the carrying amount of the asset through the use of an impairment allowance account.

B. The reconciliation of allowance for impairment and provision from December 31, 2017, as these are impaired under IAS 39, to January 1, 2018, as these are expected to be impaired under IFRS 9, are as follows:

	Accounts receivable	
	NT$000	US$000
IAS 39	$ 18,132	$ 592
Impairment loss adjustment	—	—
IFRS 9	$ 18,132	$ 592

C. Credit risk information for the years ended December 31, 2016 and 2017 are as follows:

(a) Credit risk refers to the risk of financial loss to the Group arising from default by the customers on the contract obligations. According to the Group's credit policy, each entity in the Group is responsible for managing and analysing the credit risk for each of their new customers before signing the license agreement. Internal risk control assesses the credit quality of the customers, taking into account their financial position, past experience and other factors. Credit risk arises from cash and deposits with banks and financial institutions, as well as credit exposures to corporate pharmaceutical companies, including outstanding receivables. For banks and financial institutions, only financial institutions with a good credit rating are accepted.

(b) For the years ended December 31, 2016 and 2017, no credit limits were exceeded during the reporting periods, and management does not expect any significant losses from non-performance by these counterparties.

(c) The Group's accounts receivable that were neither past due nor impaired were fully performing in line with the credit standards prescribed based on counterparties' industrial characteristics, scale of business and profitability. As of December 31, 2017, the Group's accounts receivable that were neither past due nor impaired amounted to NT$8,622 thousand. The Group deals with counterparties with good credit reputation and has policies in place to ensure that customers have an appropriate credit history when signing the contracts.

(d) The ageing analysis of financial assets that were past due but not impaired is as follows:

	December 31, 2017
	NT$000
Up to 30 days	$ —
31 to 90 days	—
91 to 180 days	—
Over 181 days	—
	$ —

The above ageing analysis were based on past due date.

D. Movement analysis of accounts receivable that were impaired is as follows:

(a) As of December 31, 2017, the Group's accounts receivable that were individually determined to be impaired amounted to NT$18,132 thousand.

(b) Movements on the Group's provision for impairment of accounts receivable for the year ended December 31, 2017 are as follows:

	2017		
	Individually assessed for impairment	Collectively assessed for impairment	Total
	NT$000	NT$000	NT$000
At January 1	$ 9,067	$ —	$ 9,067
Provision for impairment	9,065	—	9,065
At December 31	$ 18,132	$ —	$ 18,132

(5) Effects of initial application of IFRS 15 and information in relation to the application of IAS 18 for the years ended December 31, 2016 and 2017

A. The significant accounting policies of revenue recognition for the years ended December 31, 2016 and 2017 are as follows:

(a) Out-licensing development collaboration revenue includes up-front fees and milestone payments. Upfront fees are recognized in a reasonable and systematic approach over the development period, and is not recognized in full, if the authorization contract of the Group does not meet all of the following criteria:

i. The amount of royalty is fixed or non-refundable.

ii. The contract is irrevocable.

iii. Relevant rights may be at the authorized party's own disposition.

iv. The party granting authority has no further obligations after passing on the rights to the authorized party.

Milestone payments are contractual payments due to the Group upon the achievement of certain additional events. The entire milestone payment due is recognized as revenue, in full, at the time the milestone set forth in the respective agreements has been achieved and the amount is reasonably assured of collection.

(b) Royalty revenues are recognized based on the substance of contracts when the earning process is substantially completed and are realized or realizable, which is in the same period that the licensee makes a qualifying sale of licensed products.

B. The revenue recognized by using previous accounting policies for the years ended December 31, 2016 and 2017 are as follows:

	2016	2017
	NT$000	NT$000
Royalty revenue	$ 40,571	$ 49,635
Co-development revenue	1,103	—
	$ 41,674	$ 49,635

C. The effects and description of current balance sheets and comprehensive income statements items if the Company continued adopting previous accounting policies as of and for the year ended December 31, 2018 are as follows:

Items	Description	As of and for the year ended December 31, 2018		
		Balance by using IFRS 15	Balance by using previous accounting policies	Effects from changes in accounting policies
		NT$000	NT$000	NT$000
Contract assets	Note	$ 2,283	$ —	$ 2,283
Operating revenue	Note	$ 10,224	$ —	$ 10,224
Accumulated deficit	Note	$ 7,941	$ —	$ 7,941

Items	Description	As of and for the year ended December 31, 2018		
		Balance by using IFRS 15	Balance by using previous accounting policies	Effects from changes in accounting policies
		US$000	US$000	US$000
Contract assets	Note	$ 75	$ —	$ 75
Operating revenue	Note	$ 334	$ —	$ 334
Accumulated deficit	Note	$ 259	$ —	$ 259

Note: The Group accounts for all the authorization and subsequent research and development services provided by the Group as one performance obligation, and recognizes revenue based on the transaction price, and the stage of completion, which is measured by the proportion of contract costs incurred for research and development services performed as of the financial reporting date to the estimated total research and development costs for the authorization collaboration and development contracts.

13. SEGMENT INFORMATION

(1) General information

The Group's major business is research and development for new medicine and operates only in one single industry. The Chief Operating Decision-Maker, who allocates resources and assesses performance of the Group as a whole, has identified that the Group has only one reportable operating segment.

(2) Information about segment profit or loss, assets and liabilities

The Group has only one reportable operating segment, and therefore, the reportable segment information is the same as the financial statements.

(3) Reconciliation for segment income (loss)

The segment income (loss) reported to the chief operating decision-maker is measured in a manner consistent with that in the statement of comprehensive income. There is no reconciliation because the report provided to the chief operating decision-maker for business decisions has no difference to the segment income (loss) information.

(4) Information on product and service

Please refer to Note 6(18) for the related information.

(5) Geographical information

Geographical information for the years ended December 31, 2016, 2017, and 2018 is as follows:

	Year ended December 31, 2016		Year ended December 31, 2017	
	Revenue	Non-current assets (Note)	Revenue	Non-current assets (Note)
	NT$000	NT$000	NT$000	NT$000
Taiwan	$ 40,571	$ 199,916	$ 49,635	$ 176,727
Europe	1,003	—	—	—
China	—	35	—	23
Others	100	13,788	—	6,645
	$ 41,674	$ 213,739	$ 49,635	$ 183,395

	Year ended December 31, 2018		Year ended December 31, 2018	
	Revenue	Non-current assets (Note)	Revenue	Non-current assets (Note)
	NT$000	NT$000	US$000	US$000
Taiwan	$ 52,100	$ 202,724	$ 1,702	$ 6,623
Europe	10,224	—	334	—
China	—	11	—	—
Others	—	7,482	—	245
	$ 62,324	$ 210,217	$ 2,036	$ 6,868

Note: Deferred tax assets and refundable deposits are excluded from non-current assets.

(6) Major customer information

Details of sales to individual customers exceeding 10% of the Group's revenue for the years ended December 31, 2016, 2017 and 2018 are as follows:

	Year ended December 31,			
	2016		2017	
Customer	Revenue		Revenue	
	NT$000		NT$000	
A	$	34,357	$	40,385
B		6,214		9,250
F		1,003		—

	Year ended December 31,			
	2018		2018	
Customer	Revenue		Revenue	
	NT$000		US$000	
A	$	40,765	$	1,332
B		11,335		370
F		10,224		334

Exhibit 4.10

FIRST AMENDMENT
TO
LOAN AND SECURITY AGREEMENT

THIS **FIRST AMENDMENT** to Loan and Security Agreement (this "Amendment") is entered into as of April 25, 2019, by and between CATHAY BANK ("Bank") and TAIWAN LIPOSOME COMPANY, LTD., a Taiwan registered company ("Parent"), and TLC BIOPHARMACEUTICALS, INC., a Delaware corporation ("TLC," and together with Parent, each a "Borrower" and collectively, "Borrowers").

Recitals

A. Bank and Borrowers have entered into that certain Loan and Security Agreement dated as of December 27, 2018 (as the same may from time to time be further amended, modified, supplemented or restated, the "Loan Agreement").

B. Bank has extended credit to Borrowers for the purposes permitted in the Loan Agreement.

C. Borrowers have requested that Bank amend the Loan Agreement to modify certain covenants, as more fully set forth herein.

D. Bank has agreed to so amend certain provisions of the Loan Agreement, but only to the extent, in accordance with the terms, subject to the conditions and in reliance upon the representations and warranties set forth below.

Agreement

Now, Therefore, in consideration of the foregoing recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

1. Definitions. Capitalized terms used but not defined in this Amendment shall have the meanings given to them in the Loan Agreement.

2. Amendments to Loan Agreement.

2.1 Section 6.7 (Financial Covenants). Section 6.7 is amended in its entirety and replaced with the following:

6.7 Financial Covenants. Commencing September 30, 2019, maintain as of the last day of each quarter on a consolidated basis, each of the financial covenants set forth below, such covenants also to be reported and tested as of the last day of each quarter beginning September 30, 2019:

2.2 Compliance Certificate. Exhibit D (Compliance Certificate) attached to the Loan Agreement is hereby replaced with Exhibit A attached hereto.

3. Limitation of Amendment.

3.1 The amendments set forth in **Section 2**, above, are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right or remedy which Bank may now have or may have in the future under or in connection with any Loan Document.

3.2 This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents, except as herein amended, are hereby ratified and confirmed and shall remain in full force and effect.

4. Representations and Warranties. To induce Bank to enter into this Amendment, Borrowers hereby represent and warrant to Bank as follows:

4.1 Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date), and (b) no Event of Default has occurred and is continuing;

4.2 Borrowers have the power and authority to execute and deliver this Amendment and to perform their obligations under the Loan Agreement, as amended by this Amendment;

4.3 The Operating Documents of TLC and Parent delivered to Bank on the Closing Date remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;

4.4 The execution and delivery by Borrowers of this Amendment and the performance by Borrowers of their obligations under the Loan Agreement, as amended by this Amendment, have been duly authorized;

4.5 The execution and delivery by Borrowers of this Amendment and the performance by Borrowers of their obligations under the Loan Agreement, as amended by this Amendment, do not and will not contravene (a) any law or regulation binding on or affecting Borrowers, (b) any contractual restriction with a Person binding on Borrowers, (c) any order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrowers, or (d) the Operating Documents of Borrowers;

4.6 The execution and delivery by Borrowers of this Amendment and the performance by Borrowers of their obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on either Borrower, except as already has been obtained or made; and

4.7 This Amendment has been duly executed and delivered by Borrowers and is the binding obligation of each Borrower, enforceable against each Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

5. Integration. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents.

6. Loan Document. This Amendment shall constitute a Loan Document under the Loan Agreement.

7. Governing Law. This Amendment and the rights and obligations of the parties hereto shall be governed by and construed in accordance with the laws of the State of California.

8. Counterparts. This Amendment may be executed in any number of counterparts and all of such counterparts taken together shall constitute one and the same instrument. Delivery of an executed counterpart of a signature page to this Amendment by facsimile or in electronic (i.e., "pdf" or "tif" format) shall be effective as delivery of a manually executed counterpart of this Amendment.

9. Effectiveness. This Amendment shall be deemed effective upon (a) the due execution and delivery to Bank of this Amendment by the Borrowers, and (b) Borrowers' payment of Bank Expenses due and owing in connection with this Amendment.

[Signature page follows.]

In Witness Whereof, the parties hereto have caused this Amendment to be duly executed and delivered as of the date first written above.

BORROWERS

TAIWAN LIPOSOME COMPANY, LTD.

By: /s/ Keelung Hong
Name: Keelung Hong
Title: Chairman

TLC BIOPHARMACEUTICALS, INC.

By: /s/ Keelung Hong
Name: Keelung Hong
Title: Chief Executive Officer

BANK

CATHAY BANK

By: /s/ Yu-Fu Lin
Name: Yu-Fu Lin
Title: Relationship Manager & First Vice President

[Signature page to First Amendment]

Exhibit A to First Amendment

EXHIBIT D

COMPLIANCE CERTIFICATE

To: Cathay Bank
Email: _____

FROM: Taiwan Liposome Company, Ltd. and TLC Biopharmaceuticals, Inc. (collectively, "Borrower")

The undersigned authorized Officer of a Borrower certifies that in accordance with the terms and conditions of the Loan and Security Agreement between Borrower and Bank (as amended, restated, or otherwise modified from time to time, the "**Agreement**"), (i) Borrower is in compliance for the period ending _____ with all provisions of the Agreement, except as noted below and (ii) all representations and warranties of Borrower stated in the Agreement are true and correct in all material respects as of the date hereof. The Officer further certifies that these are prepared in accordance with IFRS or TIFRS, as applicable, and are consistently applied from one period to the next except as explained in an accompanying letter or footnotes.

Please indicate compliance status by circling Yes/No under "Complies" or "Applicable" column.

REPORTING COVENANTS	**REQUIRED**		**COMPLIES**
Company Prepared Quarterly F/S	Quarterly, within 45 days	YES	NO
Compliance Certificate	Quarterly, within 45 days	YES	NO
CPA Audited, Unqualified F/S	Annually, within 120 days of FYE	YES	NO

FINANCIAL COVENANTS	**REQUIRED**	**ACTUAL**		**COMPLIES**
Beginning September 30, 2019, and each quarter thereafter:				
Minimum Adjusted Quick Ratio	2.25:1:00	_____:1.00	YES	NO
Minimum Adjusted Tangible Net Worth	$12,000,000	$_____	YES	NO

Please Enter Below Comments Regarding Violations:

Very truly yours,

_____
Authorized Signer

Name: _____

Title: _____

201967361 v1

Exhibit 12.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Keelung Hong, certify that:

1. I have reviewed this annual report on Form 20-F of Taiwan Liposome Company Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: April 30, 2019

By: /s/ Keelung Hong, Ph.D.

Keelung Hong, Ph.D.
Chief Executive Officer and Chairman
(Principal Executive Officer)

Exhibit 12.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Nicole Lin, certify that:

1. I have reviewed this annual report on Form 20-F of Taiwan Liposome Company Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: April 30, 2019

By: /s/ Nicole Lin, M.B.A.

Nicole Lin, M.B.A.
Vice President of Finance and Administration
(Principal Financial Officer and
Principal Accounting Officer)

Exhibit 13.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Taiwan Liposome Company Ltd. (the "Company") does hereby certify, to his or her knowledge, that:

1. The Company's Annual Report on Form 20-F for the year ended December 31, 2018, to which this Certification is attached as Exhibit 13.1 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 30, 2019

By: /s/ Keelung Hong, Ph.D.
Keelung Hong Ph.D.
Chief Executive Officer and Chairman
(Principal Executive Officer)

By: /s/ Nicole Lin, M.B.A.
Nicole Lin, M.B.A.
Vice President of Finance and Administration
(Principal Financial Officer and
Principal Accounting Officer)

Exhibit 15.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-228558) of Taiwan Liposome Company, Ltd. of our report dated April 30, 2019 relating to the financial statements, which appears in this Form 20-F.

/s/ PricewaterhouseCoopers, Taiwan
Taipei, Taiwan

Republic of China
April 30, 2019