

# SCICLONE PHARMACEUTICALS INC

## FORM 10-Q (Quarterly Report)

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

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**FORM 10-Q**

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(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2017

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 0-19825

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**SCICLONE PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

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Delaware  
(State or other jurisdiction of  
incorporation or organization)

94-3116852  
(I.R.S. employer  
Identification no.)

950 Tower Lane, Suite 900, Foster City, California  
(Address of principal executive offices)

94404  
(Zip code)

(650) 358-3456

(Registrant's telephone number, including area code)

Not Applicable

(Former name, former address and former fiscal year, if changed since last report)

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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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller Reporting Company

Emerging Growth Company

If an emerging growth company, 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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of August 3, 2017, 52,191,854 shares of the registrant's Common Stock, \$0.001 par value, were issued and outstanding.

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SCICLONE PHARMACEUTICALS , INC.

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CONDENSED CONSOLIDATED BALANCE SHEETS  
(In thousands, except share and per share amounts)**

	<u>June 30, 2017</u>	<u>December 31, 2016</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 157,328	\$ 134,395
Accounts receivable, net of allowances of \$0 and \$0 as of June 30, 2017 and December 31, 2016, respectively	48,002	41,510
Inventories	22,039	16,587
Prepaid expenses and other current assets	3,639	3,241
Total current assets	<u>231,008</u>	<u>195,733</u>
Property and equipment, net	2,002	2,002
Investment in third party (Note 4)	724	794
Goodwill	31,592	30,838
Other assets	12,285	12,531
Total assets	<u>\$ 277,611</u>	<u>\$ 241,898</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 7,066	\$ 3,645
Accrued and other current liabilities	20,561	22,796
Total current liabilities	<u>27,627</u>	<u>26,441</u>
Other long-term liabilities	117	92
Commitments and Contingencies (Note 10)		
Stockholders' equity:		
Preferred stock; \$0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock; \$0.001 par value; 100,000,000 shares authorized; 52,191,854 and 51,236,952 shares issued and outstanding as of June 30, 2017 and December 31, 2016, respectively	52	51
Additional paid-in capital	311,837	304,599
Accumulated other comprehensive loss	(902)	(1,520)
Accumulated deficit	<u>(61,120)</u>	<u>(87,765)</u>
Total stockholders' equity	<u>249,867</u>	<u>215,365</u>
Total liabilities and stockholders' equity	<u>\$ 277,611</u>	<u>\$ 241,898</u>

See accompanying notes to unaudited condensed consolidated financial statements.

**SCICLONE PHARMACEUTICALS, INC.**  
**CONDE NSED CONSOLIDATED STATEMENTS OF INCOME**  
**(In thousands, except per share amounts)**

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2017	2016	2017	2016
<b>Revenues:</b>				
Product sales, net	\$ 43,369	\$ 37,869	\$ 85,006	\$ 73,189
Promotion services	1,151	1,122	2,406	2,301
<b>Total net revenues</b>	<b>44,520</b>	<b>38,991</b>	<b>87,412</b>	<b>75,490</b>
<b>Operating expenses:</b>				
Cost of product sales	5,654	5,712	11,819	11,525
Sales and marketing	15,435	14,432	28,200	26,784
Research and development	2,828	4,765	5,323	6,232
General and administrative	8,286	8,129	15,516	15,572
<b>Total operating expenses</b>	<b>32,203</b>	<b>33,038</b>	<b>60,858</b>	<b>60,113</b>
<b>Income from operations</b>	<b>12,317</b>	<b>5,953</b>	<b>26,554</b>	<b>15,377</b>
<b>Non-operating income (expense):</b>				
Interest and investment income	297	263	593	522
Other income (expense), net	167	(249)	1,242	(121)
<b>Income before provision (benefit) for income tax</b>	<b>12,781</b>	<b>5,967</b>	<b>28,389</b>	<b>15,778</b>
Provision (benefit ) for income tax	589	(371)	1,601	1,576
<b>Net income</b>	<b>\$ 12,192</b>	<b>\$ 6,338</b>	<b>\$ 26,788</b>	<b>\$ 14,202</b>
<b>Basic net income per share</b>	<b>\$ 0.24</b>	<b>\$ 0.13</b>	<b>\$ 0.52</b>	<b>\$ 0.29</b>
<b>Diluted net income per share</b>	<b>\$ 0.23</b>	<b>\$ 0.12</b>	<b>\$ 0.50</b>	<b>\$ 0.27</b>
<b>Weighted average shares used in computing net income per share:</b>				
<b>Basic shares outstanding</b>	<b>51,820</b>	<b>49,897</b>	<b>51,630</b>	<b>49,743</b>
<b>Diluted shares outstanding</b>	<b>53,252</b>	<b>52,819</b>	<b>53,155</b>	<b>52,405</b>

See accompanying notes to unaudited condensed consolidated financial statements.

**SCICLONE PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME**  
**(In thousands)**

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2017	2016	2017	2016
<b>Net income</b>	\$ 12,192	\$ 6,338	\$ 26,788	\$ 14,202
<b>Other comprehensive income (loss), net of income tax:</b>				
Foreign currency translation	466	(787)	688	(590)
Unrealized loss on available-for-sale investment in common stock of third party	(229)	—	(70)	—
Total other comprehensive income	237	(787)	618	(590)
<b>Total comprehensive income</b>	<u>\$ 12,429</u>	<u>\$ 5,551</u>	<u>\$ 27,406</u>	<u>\$ 13,612</u>

See accompanying notes to unaudited condensed consolidated financial statements.

**SCICLONE PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(In thousands)**

	Six Months Ended	
	June 30.	
	2017	2016
<b>Operating activities:</b>		
Net income	\$ 26,788	\$ 14,202
Adjustments to reconcile net income to net cash provided by operating activities:		
Non-cash expense related to stock-based compensation	3,853	2,469
Provision for expiring inventory	—	34
Depreciation and amortization	514	493
Loss on disposal of fixed assets	7	1
Deferred income taxes	—	127
Unrealized foreign exchange gain	(289)	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(6,170)	3,911
Inventories	(126)	527
Prepaid expenses and other assets	(809)	348
Accounts payable	(931)	(2,529)
Accrued and other current liabilities	(2,522)	(346)
Deferred revenue	—	(140)
Other long-term liabilities	24	28
Net cash provided by operating activities	20,339	19,125
<b>Investing activities:</b>		
Purchases of property and equipment	(674)	(54)
Net cash used in investing activities	(674)	(54)
<b>Financing activities:</b>		
(Payments of cost) proceeds from issuances of common stock, net	3,183	(2,888)
Net cash provided by (used in) financing activities	3,183	(2,888)
Effect of exchange rate changes on cash and cash equivalents	85	23
Net increase in cash and cash equivalents	22,933	16,206
Cash and cash equivalents, beginning of period	134,395	101,403
Cash and cash equivalents, end of period	\$ 157,328	\$ 117,609
<b>Supplemental disclosure of non-cash operating activities:</b>		
Release of restricted cash in escrow for SEC settlement	\$ —	\$ 12,826

See accompanying notes to unaudited condensed consolidated financial statements.

**SCICLONE PHARMACEUTICALS, INC.**

Notes to Unaudited Condensed Consolidated Financial Statements

**Note 1 — Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements of SciClone Pharmaceuticals, Inc. (“SciClone” or the “Company”) have been prepared in conformity with U.S. generally accepted accounting principles (“GAAP”) consistent with those applied in, and should be read in conjunction with, the audited consolidated financial statements and the notes thereto for the year ended December 31, 2016 included in the Company’s Form 10-K as filed with the Securities and Exchange Commission (“SEC”). The Company prepared the unaudited condensed consolidated financial statements following the requirements of the SEC for interim reporting. As permitted under those rules, certain footnotes or other information that are normally required by GAAP can be condensed or omitted.

The unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated.

The interim financial information reflects all adjustments, consisting only of normal recurring adjustments, which are, in the opinion of management, necessary for a fair statement of the results for the interim periods presented and are not necessarily indicative of results for subsequent interim periods or for the full year. The unaudited condensed consolidated balance sheet data as of December 31, 2016 is derived from the audited consolidated financial statements at that date but does not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements.

**Use of Estimates**

The preparation of financial statements in conformity with GAAP requires management to make informed estimates and assumptions that affect the amounts reported in the unaudited condensed consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates.

**Customer Concentration**

In China, pharmaceutical products are imported and distributed through a tiered method of distribution. For the Company’s proprietary product ZADAXIN, the Company manufactures its product using its U.S. and European contract manufacturers, and it generates its product sales revenue through sales of ZADAXIN products to Sinopharm Holding Lingyun Biopharmaceutical (Shanghai) Co. Limited (“Sinopharm”). Sinopharm acts as an importer, and also as the top “tier” of the distribution system (“Tier 1”) in China. The Company’s ZADAXIN sales occur when the importer purchases product from the Company, without any right of return except for replacement of product in the events of damaged product or quality control issues. As the Company bears risk of loss until delivery has occurred, revenue is not recognized until the shipment reaches its destination. After the Company’s sale of ZADAXIN to the importer, Sinopharm clears products through China import customs, sells directly to large hospitals and holds additional product it has purchased in inventory for sale to the next tier in the distribution system. The second-tier (“Tier 2”) distributors are responsible for the further sale and distribution of the products they purchase from the importer, either through sales of product directly to the retail level (hospitals and pharmacies), or to third-tier (“Tier 3”) local or regional distributors who, in turn, sell products to hospitals and pharmacies. The Company’s other product sales revenues result from the sale of the Company’s in-licensed products to importing agents and distributors.

Promotion services revenues result from fees received for exclusively promoting products for certain pharmaceutical partners. These importing agents, distributors and partners are the Company’s customers.

Sinopharm contributed 93 % of the Company’s total net revenue for both the three month periods ended June 30, 2017 and 2016, respectively, which revenues related to the Company’s China segment. Sinopharm contributed 92% of the Company’s total net revenue for both the six month periods ended June 30, 2017 and 2016, respectively, which revenues related to the Company’s China segment. There were no other customers that exceeded 10% of the Company’s total net revenue in the periods presented.



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Product sales of \$ 4 1.6 million or 93 % and \$ 3 6.5 million or 9 4 % , for the t hree months ended June 30 , 2017 and 2016 , respectively, related to consolidated sales of ZADAXIN. Of the \$41.6 million in ZADAXIN revenues in the second quarter of 2017 , \$ 3.3 million was attributed to revenues fr om sales generated in the first quarter of 2017 but r ecognized in the second quarter of 2017 for first quarter sales that were above the reference (baseline) tender price under a provision in the agreement with the Company's China distributor to share, in part, in the burden of price reductions and the benefit of higher pricing in provinces with higher tender prices . In the second quarter of 2017, revenue was reduced by \$0.8 million for sales in the second quarter that we estimate will be sold at prices below the reference tender price under a provision in the agreement with the Company's China distributor . Product sales of \$ 81.1 million or 92% and \$70.1 million or 93 % , for the six months ended June 30, 2017 and 2016, respectively, related to consolidate d sales of ZADAXIN. Of the \$81.1 m illion in ZADAXIN revenues for the first half of 2017 , \$4.2 million was attributed to revenues from sales generated in the fourth quarter of 2016 and \$3.3 million was attributed to revenues from sales generated in the first quarter that were both above the reference (baseline) tender price under a provision in the agreement with the Company's China distributor to share, in part, in the burden of price reductions and the benefit of higher pricing in provinces with higher tender prices and which had no corresponding revenues in the same 2016 period . In the six months ended June 30, 2017, revenue was also reduced by \$0.8 million for sales in the second quarter that we estimate will be sold at prices below the reference tender price under a provision in the agreement with the Company's China distributor. As of June 30 , 2017 , approximately \$ 44.7 million, or 93 % , of the Company's accounts receivable was attributable to one customer, Sinopharm, in China. The Company generally does not require collateral from its customers. The Company maintains reserves for potential credit losses and such actual losses may vary significantly from its estimates.

Per the Company's previous contractual arrangement with Sinopharm through December 31, 2015, and a renewed contractual arrangement with Sinopharm (the Company's sole distributor for ZADAXIN in China) which took effect January 1, 2016, the Company's sales of ZADAXIN to Sinopharm w ere denominated in U . S . dollars through June 30, 2016 . However, the e stablished importer price was adjusted quarterly based upon exchange rate fluctuations between the U . S . dollar and Chinese Yuan Renminbi ("RMB") . Effective July 1, 2016, the Company's sales of ZADAXIN to Sinopharm were and have continue d to be denominated in RMB. A significant portion of the Company's other revenues and expenses are also denominated in RMB and a significant portion of the Company's assets and liabilities are denominated in RMB and all are exposed to foreign exchange risk. In the recent year , the RMB has experienced d evaluation. Such devaluation negatively affect s the U . S . dollar value of revenues while it positively affects the U.S. dollar value of China operating expenses . RMB is not freely convertible into foreign currencies. In China, foreign exchange transactions are required by law to be transacted only by authorized financial institutions at the exchange rates quoted by the People's Bank of China. Remittances in currencies other than RMB by the Company in China require certain supporting documentation in order to process the remittance.

### Accounts Receivable

**Receivable Reserve.** The Company records a receivable reserve based on a specific review of its overdue invoices. The Company's estimate for a reserve is determined after considering its existing contractual payment terms, payment patterns of its customers and individual customer circumstances, the age of any outstanding receivables and its current customer relationships. Accounts receivable are written off at the point when they are considered uncollectible.

As of June 30 , 2017 and December 31, 2016 , the Company determined no bad debt reserve was necessary.

### Revenue Recognition

The Company recognizes revenue when persuasive evidence of an arrangement exists, services have been rendered or delivery has occurred, the price to the buyer is fixed or determinable and collectability is reasonably assured.

**Product Revenue.** The Company recognizes product revenue from selling manufactured ZADAXIN product at the time of delivery. Sales of ZADAXIN to Sinopharm are recognized upon arrival of a shipment to its destination, which marks the point when title and risk of loss to product are transferred. The Company also earns product revenue from purchasing medical products from pharmaceutical companies and selling them directly to importers or distributors. The Company recognizes revenue related to these products based on the "sell-in" method, when the medical products have been delivered to the importers or distributors. Payments by the importing agents and distributors are not contingent upon sale to the end user by the importing agents or distributors.

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Effective January 1, 2016, the Company's new contractual arrangement with its China importer and distributor for ZADAXIN, Sinopharm, is resulting in the later recognition (relative to practices prevailing under the old contractual arrangement through December 31, 2015) of a portion of the Company's revenue due from Sinopharm related to situations where the provincial tender price is greater relative to a reference (baseline) tender price. The tender price is the ultimate retail end price approved by provincial authorities. There is a price adjustment mechanism in the new contractual arrangement whereby Sinopharm is invoiced at a lower base price relative to that prevailing in the previous agreement. The lower base price (reduced by estimated price compensation payable to Sinopharm for situations where the provincial tender price is lower than the reference (baseline) tender price) is recorded as revenue at the time the sale is completed upon arrival at destination. Recently, Guangdong and Fujian provinces have each announced maximum prices for ZADAXIN that are approximately six and four percent lower, respectively, than the reference (baseline) tender price. We expect these provincial decisions to affect the pricing of ZADAXIN in these provinces with respect to sales made pursuant to contracts dated on and after March 2017 for Guangdong and Fujian, and to affect pricing in other provinces, but the exact timing and consequences to our pricing, especially in other provinces, is uncertain. Sinopharm is invoiced for the portion of the price that results from situations where the provincial tender price is greater than the reference (baseline) tender price at a later time, and that portion of the price is recognized as revenue after the amount has been agreed to with them. It is expected that the price increment due to the Company related to sales in a quarter under the price adjustment mechanism for provinces with tender prices above the reference (baseline) tender price will continue to be recognized on a rolling one-to-two quarter delayed basis relative to the originating sales quarter.

**Promotion Services Revenue.** The Company recognizes promotion services revenue after designated medical products are delivered to the distributors as specified in a promotion services contract, which marks the period when marketing and promotion services have been rendered and the revenue recognition criteria are met.

**Revenue Reserve.** The Company generally maintains a revenue reserve for product returns based on estimates of the amount of product to be returned by its customers that are based on historical patterns, analysis of market demand and/or a percentage of sales based on industry trends, and management's evaluation of specific factors that may increase the risk of product returns. Importing agents or distributors do not have contractual rights of return except under limited terms regarding product quality. However, the Company is expected to replace products that have expired or are deemed to be damaged or defective when delivered upon arrival at destination. The calculation of the revenue reserve requires estimates and involves a high degree of subjectivity and judgment. As a result of the uncertainties involved in estimating the revenue reserve, there is a possibility that materially different amounts could be reported under different conditions or using different assumptions.

As of June 30, 2017 and December 31, 2016, the Company's revenue reserves were \$ 0.3 million and \$0.3 million, respectively.

The Company evaluates the need for a returns reserve quarterly and adjusts it when events indicate that a change in estimate is appropriate. Changes in estimates could materially affect the Company's results of operations or financial position. It is possible that the Company may need to adjust its estimates in future periods.

### Inventories

Inventories consist of raw materials, work in progress and finished products. Inventories are valued at the lower of cost or net realizable value, with cost determined on a first-in, first-out basis, and include amounts related to materials, labor and overhead. The Company periodically reviews the inventory in order to identify excess and obsolete items. If obsolete or excess items are observed and there are no alternate uses for the inventory, the Company will record a write-down to net realizable value in the period that the impairment was first indicated. For the three month periods ended June 30, 2017 and 2016, the Company did not record any write-downs related to inventory.

### Loans Receivable

Loans receivable are due from a single third party (see Note 5). Loans are initially recorded, and continue to be carried, at unpaid principal balances under "other assets" on the unaudited condensed consolidated balance sheets. Carried balances are subsequently adjusted for payments of principal or adjustments to the allowance for loan losses to account for any impairment. Interest income is recognized over the term of the loans and is calculated using the simple-interest method, as the loans do not have associated premium or discount. If the loans were to experience impairment, interest income would not be recognized unless the likelihood of further loss was remote.

Although the measurement basis is unpaid principal (as adjusted for subsequent payments or impairment), not fair value, the loans receivable would qualify as Level 3 measurements under the fair value hierarchy (Note 2) due to the presence of significant unobservable inputs related to the counterparty, which is a private entity.

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Management considers impairment to exist when, based on current information or factors (such as payment history, value of collateral, and assessment of the counterparty's current creditworthiness), it is probable that principal and interest payments will not be collected according to the contractual agreements. Management considers a loan payment delinquent when not received by the due date. As of June 30, 2017 and December 31, 2016, management concluded the loans receivable were not impaired, and there was no allowance for loan losses.

### Net Income Per Share

Basic net income per share has been computed by dividing net income by the weighted-average number of shares of common stock outstanding for the period. Diluted net income per share is computed by dividing net income by the weighted-average number of common equivalent shares outstanding for the period. Diluted net income per share includes any dilutive impact from outstanding stock options, stock awards and the employee stock purchase plan using the treasury stock method.

The following is a reconciliation of the numerator and denominators of the basic and diluted net income per share computations (*in thousands, except per share amounts*):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
<b>Numerator:</b>				
Net income	\$ 12,192	\$ 6,338	\$ 26,788	\$ 14,202
<b>Denominator:</b>				
Weighted-average shares outstanding used to compute net income per share	51,820	49,897	51,630	49,743
Effect of dilutive securities	1,432	2,922	1,525	2,662
Weighted-average shares outstanding used to compute diluted net income per share	53,252	52,819	53,155	52,405
Basic net income per share	\$ 0.24	\$ 0.13	\$ 0.52	\$ 0.29
Diluted net income per share	\$ 0.23	\$ 0.12	\$ 0.50	\$ 0.27

For the three months ended June 30, 2017 and 2016, outstanding stock options and awards for 3,411,268 and 1,202,70 shares, respectively, were excluded from the calculation of diluted net income per share because the effect from the assumed exercise or issuance of these options and awards calculated under the treasury stock method would have been anti-dilutive. In addition, for the three months ended June 30, 2017 and 2016, outstanding stock options and awards for 375,000 and 312,500 shares, respectively, subject to performance conditions were excluded from the calculation of diluted net income per share because the performance criteria had not been met and were not considered probable of being met.

For the six months ended June 30, 2017 and 2016, outstanding stock options and awards for 3,023,879 and 1,974,551 shares, respectively, were excluded from the calculation of diluted net income per share because the effect from the assumed exercise or issuance of these options and awards calculated under the treasury stock method would have been anti-dilutive. In addition, for the six months ended June 30, 2017 and 2016, outstanding stock options and awards for 375,000 and 312,500 shares, respectively, subject to performance conditions were excluded from the calculation of diluted net income per share because the performance criteria had not been met and were not considered probable of being met.

### Error Corrections

The Company provided \$1.2 million of additional income tax expense, and recorded a corresponding accrual in accrued and other current liabilities, during the three months ended March 31, 2016 to correct an error. The error correction reflected the recognition of a previously unrecognized liability for an uncertain tax position related to the potential non-deductibility, under PRC tax regulations, of certain marketing costs related to the Company's China operations. The adjustment related to tax years 2013 to 2015 and reflected the estimated tax exposure for each year as well as accrued interest thereon; such tax and interest amounts were \$0.3 million, \$0.5 million, and \$0.4 million for the full years 2013, 2014, and 2015, respectively. The Company's management evaluated the effects of the error on each prior annual and interim period, as well as the total error accumulated at the end of each respective prior period, and concluded under both approaches that the effects of the error were not material to previously issued annual or interim financial statements. The Company's management also evaluated the total amount of the error correction in relation to actual results for full year 2016 and concluded the impact was not material to the 2016 financial statements. The total adjustment was recorded out-of-period in the first quarter of 2016.

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### *New Accounting Standards Updates*

#### *Standards Recently Effective*

In November 2015, the FASB issued ASU 2015-17, "*Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes*". This ASU amends existing guidance to require that deferred income tax liabilities and assets be classified as noncurrent in a classified balance sheet, and eliminates the prior guidance which required an entity to separate deferred tax liabilities and assets into a current amount and a noncurrent amount in a classified balance sheet. The amendments in this ASU are effective for annual reporting periods beginning after December 15, 2016, and interim periods within those annual periods. The new guidance may be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. The Company adopted the new guidance with effect from January 1, 2017 and is applying the new guidance retrospectively. The impact of adopting this guidance is not material to the consolidated financial statements given the Company's limited deferred tax amounts.

In March 2016, the FASB issued ASU 2016-09, "*Compensation — Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*," which outlines new provisions intended to simplify various aspects related to accounting for share-based payments and their presentation in the financial statements. The Company adopted this ASU as stipulated with effect from January 1, 2017. Of the various provisions included in the ASU, the only provision that at present is material to the Company's financial statements is the provision providing alternatives to account for forfeitures of share-based awards using either estimated forfeitures (periodically adjusted for differences from actuals) or simply using actual forfeitures. The Company has changed its accounting policy upon the adoption of this updated standard to account for forfeitures on an actual basis. This change resulted in a cumulative-effect adjustment related to prior periods (Note 9) which was not material and is not expected to be material to the consolidated financial statements in future periods given the Company's past and present experience with its grants of share-based awards and related pre-vesting forfeitures.

#### *Standards Effective in Future Periods*

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, "*Revenue from Contracts with Customers (Topic 606)*", which contains new accounting literature relating to how and when a company recognizes revenue. Under ASU 2014-09, a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods and services. ASU 2014-09 is effective for the Company's fiscal year beginning January 1, 2018, which reflects a one year deferral approved by the FASB in July 2015, and will be adopted by the Company from January 1, 2018. The Company is currently undertaking an evaluation of its revenue contracts to determine what impact, if any, the adoption of ASU 2014-09 will have on its financial statements and related disclosures. The Company anticipates the impact of ASU 2014-09 will likely be limited to the timing of recognition of its variable consideration. This variable consideration arises from situations where the Company's exclusive distributor in China is invoiced at a later time subsequent to the original sale for the portion of the price that results from situations where the provincial tender price is greater than the reference (baseline) tender price. Such amount is currently recognized as revenue after the amount has been agreed to with the distributor in a later quarter relative to the originating sales quarter. The timing of the recognition of such amounts is expected to be earlier (estimated at the time of the originating product sale) under the new guidance. The Company plans to finalize its assessment in the third quarter of 2017. The standard permits the use of either the full retrospective or modified retrospective transition method. The Company has determined it will employ the full retrospective transition method.

In January 2016, the FASB issued ASU 2016-01, "*Financial Instruments (Topic 825): Recognition and Measurement of Financial Assets and Liabilities*". The amended guidance (i) requires equity investments (except those accounted for under the equity method of accounting or those that result in consolidation of the investee) to be measured at fair value with changes in fair value recognized in net income; (ii) eliminates the requirement to disclose the method(s) and significant assumptions used to estimate the fair value that is currently required to be disclosed for financial instruments measured at fair value; (iii) requires an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments and (iv) requires separate presentation of financial assets and financial liabilities by measurement category and form of financial asset (that is, securities or loans and receivables) on the balance sheet or the accompanying notes to the financial statements. ASU 2016-01 is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, or calendar 2018 for the Company. The amended guidance should be applied by means of a cumulative-effect adjustment to the balance sheet as of the beginning of the fiscal year of adoption. The Company has evaluated the impact of adoption of this guidance on its consolidated financial statements and has concluded that the impact will be limited to a cumulative-effect adjustment for its investment in the common stock of a third-party which is currently classified as an available-for-sale equity investment, as well as prospective recognition of changes in the fair value of such investment, to the extent the Company continues to own the investment, as a component of net income.

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In February 2016, the FASB issued ASU 2016-02, “*Leases (Topic 842)*”. Under the new guidance, lessees will be required to recognize a lease liability and a lease asset for all leases, including operating leases, with a term greater than 12 months on the balance sheet. The update also expands the required quantitative and qualitative disclosures surrounding leases. This update is effective for the Company from calendar 2019 and from the first interim period of calendar 2019, with earlier application permitted. The Company is evaluating the impact of the adoption of this update on its consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU 2016-13, “*Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*.” This ASU requires a financial asset (or group of financial assets) measured at amortized cost basis to be presented at the net amount expected to be collected. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial asset(s) to present the net carrying value at the amount expected to be collected on the financial asset. The standard is effective for the Company from calendar 2020, with early adoption permitted for calendar 2019. The Company has yet to commence an evaluation of the impact of the adoption of this standard on its consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, “*Classification of Certain Cash Receipts and Cash Payments (Topic 230)*.” Current GAAP is unclear or does not include specific guidance on how to classify certain transactions in the statement of cash flows. This ASU is intended to reduce diversity in practice in how eight particular transactions are classified in the statement of cash flows. ASU No. 2016-15 is effective for interim and annual reporting periods beginning after December 15, 2017. Early adoption is permitted, provided that all of the amendments are adopted in the same period. Entities will be required to apply the guidance retrospectively. If it is impracticable to apply the guidance retrospectively for an issue, the amendments related to that issue would be applied prospectively. ASU 2016-15 is not expected to have a material impact on the Company's consolidated financial statements.

In January 2017, the FASB issued ASU 2017-04, “*Intangibles - Goodwill and Other (Topic 350): Simplifying the Accounting for Goodwill Impairment*” (Topic 350), which removes the requirement to perform a “Step 2” hypothetical purchase price allocation to measure goodwill impairment if “Step 1” of the traditional two-step goodwill impairment model is failed. A goodwill impairment will now be the amount by which a reporting unit's carrying value exceeds its fair value (the determination from “Step 1”), not to exceed the carrying amount of goodwill. ASU 2017-04 is effective for the Company for annual and interim periods beginning January 1, 2020, with early adoption permitted, and is to be applied prospectively. ASU 2017-04 will impact the Company's goodwill balance to the extent such goodwill balance exists at the adoption date and to the extent that the fair value of the Company's China reporting unit is less than its carrying value.

### Note 2 — Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Fair value measurements are based on a three-tier hierarchy that prioritizes the inputs used to measure fair value. The three levels of input are:

Level 1 - Quoted prices in active markets for identical assets or liabilities.

Level 2 - Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The following tables represent the Company's fair value hierarchy for its financial assets (cash equivalents and common stock investment) measured at fair value on a recurring basis (*in thousands*):

Description	Fair Value Measurements as of June 30, 2017 Using			Balance as of June 30, 2017
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Money market funds	\$ 19,739	\$ —	\$ —	\$ 19,739
Common stock investment in third party (Note 4)	\$ —	\$ 724	\$ —	\$ 724
Total	\$ 19,739	\$ 724	\$ —	\$ 20,463

Fair Value Measurements as of December 31, 2016 Using

Description	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of December 31, 2016
Money market funds	\$ 19,701	\$ —	\$ —	\$ 19,701
Common stock investment in third party (Note 4)	\$ —	\$ 794	\$ —	\$ 794
Total	\$ 19,701	\$ 794	\$ —	\$ 20,495

**Note 3 — Inventories**

Inventories consisted of the following (in thousands) :

	June 30, 2017	December 31, 2016
Raw materials	\$ 7,116	\$ 5,304
Work in progress	444	498
Finished goods	14,479	10,785
	\$ 22,039	\$ 16,587

As of June 30, 2017 and December 31, 2016, the Company had \$ 4.0 million and \$ 3.3 million, respectively, in inventory held at distributors related to non-ZADAXIN products. Raw materials increased \$1.8 million from the purchase of an active pharmaceutical ingredient (API) for increased production of safety stocks in anticipation of the renewal of the Import Drug License (“IDL”) for ZADAXIN in the fourth quarter of 2017. Work in progress decreased by \$53,000 due to timing of production. Finished goods increased by \$3.7 million, primarily due to forecasted increases in ZADAXIN sales volumes for the third quarter as well as buildup of safety stock of finished ZADAXIN product in anticipation of the ZADAXIN IDL renewal.

**Note 4 — Investment in Third Party**

On September 9, 2016, the Company and Soligenix, Inc., a publicly-traded entity, entered into an exclusive license agreement (the “License Agreement”), including a common stock purchase agreement, pursuant to which Soligenix granted rights to the Company to develop, promote, market, distribute and sell an oral mucositis-targeted drug candidate (“SGX942”) in the People’s Republic of China, Hong Kong, Macau, Taiwan, South Korea, and Vietnam (the “Territory”). Under the terms of the License Agreement, the Company will be responsible for all aspects of development, product registration, and commercialization in the Territory, having access to data generated by Soligenix. In exchange for exclusive rights, beyond an upfront payment, the Company will pay to Soligenix royalties on net sales, and Soligenix will supply commercial drug product to the Company on a cost-plus basis, while maintaining worldwide manufacturing rights. This exclusive agreement builds on an existing collaboration between the two companies established in 2013, in which the Company provided its complete oral mucositis clinical and regulatory data library to Soligenix in exchange for certain, previously undisclosed, commercialization rights to the oral mucositis drug candidate in the Greater China market. As the Company obtained rights for Greater China (mainland China, Hong Kong, and Macau) in the earlier 2013 exchange, the September 2016 agreement in substance represented the acquisition of additional rights for Taiwan, South Korea, and Vietnam.

As part of the License Agreement, the Company entered into a common stock purchase agreement with Soligenix pursuant to which the Company bought 3,529,412 shares of Soligenix common stock. These common shares are unregistered but the Company has demand registration rights and can compel a registration of the securities in a reasonably short time in the event the Company plans to sell the shares. The total cash consideration of \$3,000,000 paid to Soligenix at the time of the transaction reflected the purchase price of the common stock and the consideration for expanded territorial rights in South Korea, Taiwan, and Vietnam.

As of the transaction date, the common stock was recorded at an initial fair value of \$2.7 million representing publicly quoted closing share prices from the OTCQB, the over-the-counter market on which Soligenix’s securities were listed at the time. The residual cash consideration of \$0.3 million related to the expanded territorial rights was recorded as research and development expense in the third quarter of fiscal 2016.



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The Company is holding the Soligenix shares in the context of a business relationship, and as such has classified them as available-for-sale. The common stock investment is adjusted to fair value at each reporting date with unrealized gains (losses) reported as a component of other comprehensive income (loss).

In October 2016, in connection with an up-listing of its stock from the OTCQB market to the NASDAQ Common Market, Soligenix declared a 1 for 10 reverse stock split, converting the Company's ownership in Soligenix from 3,529,412 shares to 352,942 shares. As of June 30, 2017, the fair value of the Soligenix common stock investment was \$ 0.7 million and the unrealized holding loss on the investment was \$ 2.0 million, which was recorded as a component of other comprehensive loss (net of tax, which is zero as the entity holding the security is in a zero-tax jurisdiction). The Company considered whether the decline in fair value was an other than temporary impairment (OTTI), and determined that the decline in fair value was temporary after considering the volatility of the common stock, external research reports and market expectations, and other investee-specific facts and circumstances. In particular, the investee's share price increased in the first quarter of 2017 by \$159,000, and decreased by \$229,000 in the second quarter, with a cumulative net decrease of \$70,000 in the first six months of 2017.

### **Note 5 — Loans Receivable**

As part of the Company's May 2013 license and supply agreement with Zensun (Shanghai) Science & Technology Co. Ltd (together with any successors or assigns, "Zensun"), the Company previously agreed to loan up to \$12 million to Zensun. The entry into the license and supply agreement in the second quarter of 2013, pursuant to which the Company licensed the exclusive rights to promote, market, distribute, and sell Neucardin™, a chronic heart failure product under development by Zensun (such rights licensed for the People's Republic of China, Hong Kong and Macao) is more fully described in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 (the "2016 Form 10-K"), Note 13.

Pursuant to its agreement to loan funds, the Company loaned \$12 million to Zensun. The extension of credit and funding to Zensun was accomplished through two of the Company's subsidiaries, SPIL China and SciClone Pharmaceuticals (China) Ltd. ("SciClone China").

With respect to lender SciClone China, Zensun can make RMB-denominated borrowings for up to RMB 1,550,000 using an entrustment mechanism with a bank as an intermediary. In the third quarter of 2014, SciClone China entered into an entrusted loan agreement for RMB 1,550,000 (approximately US\$ 229,000 as of June 30, 2017) with Zensun, using a major Chinese bank as the lending agent. SciClone China is the principal and ultimately bears the credit risk, not the bank. The loan bears interest at a fixed rate of 7.5% per annum and Zensun is subject to obligations of the borrower as specified in the loan agreements. The loan term is sixty-six months. All outstanding principal and interest balances must be repaid by the maturity date, with prepayments permitted without penalty upon prior notice.

With respect to lender SPIL China, Zensun could request U.S. dollar denominated borrowings up to \$11.75 million. As of June 30, 2017, borrowings totaling \$11.75 million had been requested by Zensun and paid by SPIL China with \$4.5 million lent in the second half of 2014 and \$7.25 million lent in the second quarter of 2015. These borrowings bear interest at a fixed rate of 7.5% per annum payable annually in arrears at each interest payment date as defined in the overall loan agreement. These borrowings were originally scheduled to mature on September 26, 2017, with an option (granted at loan origination) electable by Zensun to extend for two additional years provided certain conditions are met. As of June 30, 2017, the borrower had notified the Company of its intent to exercise its option to extend the borrowings for two additional years, or to September 26, 2019. All outstanding balances must be repaid by the maturity date, with prepayments permitted without penalty upon prior notice.

The proceeds of the two separate but related loans are to be used for working capital and general corporate purposes by Zensun. To secure the loans, Zensun pledged its entire equity interest in its subsidiary, Shanghai Dongxin Biochemical Technology Co. Ltd. (whose assets include real property) to SPIL China.

Management, on the basis of (i) a creditworthiness evaluation using recent Zensun financial information, (ii) consideration of evidence of the market value of the pledged security indicating such market value exceeded the outstanding loan principal, and (iii) consideration of Zensun's compliance with the terms of the loans and timely payments of interest, concluded that there were no indications of loan impairment as of June 30, 2017 or December 31, 2016. Accordingly, no allowance for losses was recorded.

The two loans are included in "other assets" on the Company's unaudited condensed consolidated balance sheets as of June 30, 2017 and December 31, 2016. Interest income on the loans amounted to \$ 0.2 million and \$0.2 million for the three months ended June 30, 2017 and 2016, respectively, and is included in interest and investment income in the unaudited condensed consolidated statements of income. Interest income on the loans amounted to \$ 0.5 million and \$0.5 million for the six months ended June 30, 2017 and 2016, respectively, and is included in interest and investment income in the unaudited condensed consolidated statements of income.

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The following table represents the changes in goodwill for the six months ended June 30, 2017 ( *in thousands* ):

Balance as of December 31, 2016	\$	30,838
Translation adjustments		754
Balance as of June 30, 2017	\$	<u>31,592</u>

**Note 7 — Accrued and Other Current Liabilities**

Accrued and other current liabilities consisted of the following ( *in thousands* ):

	June 30, 2017	December 31, 2016
Accrued sales and marketing expenses	\$ 6,932	\$ 8,623
Accrued taxes, tax reserves and interest	6,157	5,335
Accrued compensation and benefits	3,044	5,140
Accrued professional fees	1,442	1,298
Accrued manufacturing costs	1,712	715
Other	1,275	1,685
	\$ 20,561	\$ 22,796

**Note 8 — Accumulated Other Comprehensive Income ( Loss )**

Changes in the composition of accumulated other comprehensive income (loss) for the three and six months ended June 30, 2017 and 2016 are as follows ( *in thousands* ):

Balances as of April 1, 2017	\$	(1,139)
Other comprehensive loss — unrealized loss on available-for-sale investment in common stock of third party		(229)
Other comprehensive income — foreign currency translation		466
Balances as of June 30, 2017	\$	<u>(902)</u>
Balances as of April 1, 2016	\$	2,267
Other comprehensive loss — foreign currency translation		(787)
Balances as of June 30, 2016	\$	<u>1,480</u>
Balances as of January 1, 2017	\$	(1,520)
Other comprehensive loss — unrealized loss on available-for-sale investment in common stock of third party		(70)
Other comprehensive income — foreign currency translation		688
Balances as of June 30, 2017	\$	<u>(902)</u>
Balances as of January 1, 2016	\$	2,070
Other comprehensive loss — foreign currency translation		(590)
Balances as of June 30, 2016	\$	<u>1,480</u>



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### Note 9 — Stockholders' Equity

#### **Stock-based Compensation**

The Company adopted ASU 2016-09, "Compensation — Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting," which outlines new provisions intended to simplify various aspects related to accounting for share-based payments and their presentation in the financial statements beginning January 1, 2017. Under the amended guidance, the Company has elected to account for forfeitures as they occur, instead of continuing to estimate forfeitures, as previously required. The new forfeiture guidance was adopted using a modified retrospective approach, resulting in the Company recording a \$133,000 cumulative effect charge to accumulated deficit for the difference between the amount of compensation cost previously recorded and the amount that would have been recorded without assuming forfeitures.

The following table summarizes the stock-based compensation expenses included in the unaudited condensed consolidated statements of income (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Sales and marketing	\$ 326	\$ 233	\$ 602	\$ 442
Research and development	149	56	249	108
General and administrative	1,707	887	3,002	1,919
	<u>\$ 2,182</u>	<u>\$ 1,176</u>	<u>\$ 3,853</u>	<u>\$ 2,469</u>

#### **Stock Options**

During the six months ended June 30, 2017, the Company granted options to purchase a total of 1,365,500 shares of common stock with a weighted-average grant-date fair value of \$4.27 per share option granted, and options to purchase 809,341 shares of common stock were exercised; resulting in total cash proceeds of \$3.4 million. As of June 30, 2017, there was approximately \$10.7 million of unrecognized compensation expense related to non-vested stock options, which is expected to be recognized over a weighted-average remaining period of approximately 2.7 years.

#### **Restricted Stock Units (RSUs) and Restricted Performance Stock Units (PSUs)**

During the six months ended June 30, 2017, 77,000 RSUs and 150,000 PSUs were granted at a grant date fair value per share of \$9.65, and 165,000 RSUs vested. The PSUs will vest and be released on meeting performance goals within an established time frame. If the performance goals are not met within the established time frame, the PSUs will expire. The Company recognizes expense related to the PSUs over the period of time the Company determines that it is probable that the performance goals will be achieved. If it is subsequently determined that the performance goals are not probable of achievement, the expense related to the PSUs is reversed. As of June 30, 2017, there was approximately \$2.9 million of unrecognized compensation cost related to non-vested RSUs, which is expected to be recognized over a weighted-average remaining period of approximately 1.4 years.

### Note 10 — Commitments and Contingencies

Under agreements with certain of the Company's pharmaceutical partners, the Company is committed to certain annual minimum product purchases where the contract is subject to termination if the annual minimum order is not met. As of June 30, 2017, the Company did not have any material unmet purchase obligations.

#### **Legal Matters**

NovaMed Shanghai, one of the Company's China subsidiaries, was a party to a Distribution and Supply Agreement with MEDA Pharma GmbH & Co. KG ("MEDA"). Following the Company's acquisition of NovaMed Shanghai, MEDA claimed it had a right to terminate the agreement under a change of control provision. NovaMed Shanghai does not believe that MEDA had a right of termination under the agreement. As of February 24, 2017, NovaMed Shanghai entered into a settlement agreement with MEDA to resolve all outstanding claims of each party under the Distribution and Supply Agreement, including as related to the China International Economic and Trade Arbitration Commission ("CIETAC") arbitration in which NovaMed Shanghai had been claiming remuneration of services and certain reimbursement amounts. Per the terms of the settlement agreement, MEDA paid NovaMed Shanghai \$83,333 on March 7, 2017, NovaMed Shanghai withdrew its "Request for Second Arbitration" with CIETAC, and the CIETAC arbitral tribunal dismissed the arbitration case.

**Note 11 — Income Taxes**

The provision for income taxes for the three months ended June 30, 2017, was approximately \$0.6 million compared with \$0.4 million of income tax benefits for the three months ended June 30, 2016. In the three months ended June 30, 2017, we booked \$1.1 million of additional tax expense representing expected deferred tax liabilities which arose as a consequence of a change in our position regarding reinvestment of certain offshore undistributed earnings of our foreign subsidiaries, which is further described in Note 11 – Income Taxes. Without this \$1.1 million of additional tax expense, we would have approximately \$0.5 million income tax benefit for the three months ended June 30, 2017 compared to \$0.4 million income tax benefit for the three months ended June 30, 2016. The benefit for income taxes relate to a reduction in the Company’s liabilities for uncertain tax positions in China due to certain tax years becoming closed to assessment due to the statute of limitations.

The provision for income taxes for the six months ended June 30, 2017, was approximately \$1.6 million compared with \$1.6 million for the six months ended June 30, 2016. In the six months ended June 30, 2017 we booked \$1.1 million of additional tax expense representing expected deferred tax liabilities which arose as a consequence of a change in our position regarding reinvestment of certain offshore undistributed earnings of our foreign subsidiaries, which is further described in Note 11 – Income Taxes. In the six months ended June 30, 2016 we booked \$1.2 million of additional income tax expense, and recorded a corresponding accrual in accrued and other current liabilities, to correct an error. The error correction reflected the recognition of a previously unrecognized liability for an uncertain tax position related to the potential non-deductibility, under PRC tax regulations, of certain marketing costs related to the Company’s China operations, which is described in further detail in Note 1, “Error Corrections.” The Company’s tax statutory tax rate in China was 25% in 2017 and 2016.

The Company had previously concluded, up to the second quarter of 2017, that its offshore undistributed accumulated earnings as of December 31, 2016 of \$249 million were indefinitely reinvested and had therefore provided no taxes thereon. The Company had also previously concluded, in conjunction with this assertion, that a portion of its earnings expected to be generated by foreign subsidiaries in 2017 would be repatriated to the parent company in order to address the parent company’s liquidity needs.

The Company entered into a definitive merger agreement (subject to stockholder approval and other customary closing conditions) in the second quarter of 2017 with a consortium of buyers intending to acquire the Company in a “going private” transaction (announced via a Form 8-K filed with the SEC on June 8, 2017). The terms of the definitive merger agreement, among other provisions regarding the funding of the acquisition, provide that the Company may distribute funds from its foreign subsidiaries (Cayman Islands entities) to the United States parent company in order to commit a portion of the merger funds necessary to effect the “going private” transaction and repurchase common shares. As a result of this contractual provision, the Company concluded in Q2 that the likelihood of distribution of offshore undistributed earnings cast doubt upon the ability to indefinitely reinvest of offshore undistributed earnings. Accordingly, following consideration of amounts specified in the merger agreement and related agreements, it was concluded that \$123 million of the unremitted earnings are no longer indefinitely reinvested as a result of expected distribution before the close of the announced merger in late 2017. The Company determined, after further analysis, that its parent company’s available tax net operating loss carryforwards, which had been fully reserved via valuation allowances, are available to eliminate tax liability associated with substantially all of the Federal taxable dividend income of \$123 million that would arise from a planned remittance. After determination of the amount, the Company recorded additional net tax expense of approximately \$1.1 million as a discrete tax charge in the second quarter of 2017 for the full estimated US tax cost associated with the expected remittance of such earnings. The net expense represents the Federal deferred tax liability associated with the planned remittance, substantially offset by the reversal of the associated valuation allowance on the tax net operating loss carryforwards expected to be utilized. No withholding taxes are anticipated for the planned remittance due to the jurisdictions in which the cash expected to be remitted is held.

The Company evaluated its remaining offshore undistributed earnings of \$126 million (after excluding the anticipated \$123 million dividend distribution) and after further consideration of business needs in its foreign subsidiaries and the lack of further needs by its parent company concluded it has the intent and ability to indefinitely reinvest the remainder. Accordingly, no deferred taxes have been provided for the remaining unremitted earnings; determination of the amount of such taxes on the remainder is not practicable given substantial complexity stemming from the various jurisdictions involved, tax attributes to be considered, time periods involved, and withholding taxes that may need to be considered.

**Note 12 — Segment Information and Geographic Data**

The Company reports segment information based on the internal reporting used by management for evaluating segment performance based on management’s estimates of the appropriate allocation of resources to segments.

The Company operates and manages its business primarily on a geographic basis. Accordingly, the Company determined its operating segments and reporting units, which are generally based on the nature and location of its customers, to be 1) China, and 2) Rest of the World, including the U.S. and Hong Kong.

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The Company evaluates the performance of its operating segments based on revenues and operating income (loss). Revenues for geographic segments are generally based on the location of customers. Operating income (loss) for each segment includes revenues, related cost of sales and operating expenses directly attributable to the segment. Operating income (loss) for each segment excludes non-operating income and expense.

Summary information by operating segment for the three and six month periods ended June 30 , 2017 and 201 6 is as follows ( *in thousands* ):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
<b>Revenue:</b>				
China	\$ 42,561	\$ 37,257	\$ 82,489	\$ 72,127
Rest of the World (including the US and Hong Kong)	1,959	1,734	4,923	3,363
Total net revenues	\$ 44,520	\$ 38,991	\$ 87,412	\$ 75,490
<b>Income (loss) from operations:</b>				
China	\$ 17,581	\$ 13,314	\$ 35,083	\$ 26,654
Rest of the World (including the US and Hong Kong)	(5,264)	(7,361)	(8,529)	(11,277)
Total income from operations	\$ 12,317	\$ 5,953	\$ 26,554	\$ 15,377
<b>Non-operating income (loss), net:</b>				
China	\$ 446	\$ 18	\$ 1,799	\$ 394
Rest of the World (including the US and Hong Kong)	18	(4)	36	7
Total non-operating income, net	\$ 464	\$ 14	\$ 1,835	\$ 401
<b>Income (loss) before provision for income tax:</b>				
China	\$ 18,027	\$ 13,332	\$ 36,882	\$ 27,048
Rest of the World (including the US and Hong Kong)	(5,246)	(7,365)	(8,493)	(11,270)
Total income before provision for income tax	\$ 12,781	\$ 5,967	\$ 28,389	\$ 15,778

Long-lived assets by operating segment as of June 30 , 2017 and December 31, 2016 are as follows ( *in thousands* ):

	June 30, 2017	December 31, 2016
China	\$ 45,096	\$ 44,603
Rest of the World (including the US and Hong Kong)	1,507	1,562
	\$ 46,603	\$ 46,165

## Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations

### Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q 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. These forward-looking statements are based on our current expectations, estimates and projections about our business, industry, management’s beliefs and certain assumptions made by us. Words such as "may," "will," "would," "could," "should," "might," "believes," "estimates," "projects," "potential," "expects," "plans," "anticipates," "intends," "continues," "forecast," "designed," "goal," "approximately" or the negative of those words or similar expressions are intended to identify forward-looking statements, including those statements we make regarding our future financial results. These statements are subject to risks and uncertainties that are difficult to predict and actual outcomes may differ materially.

These include risks and uncertainties relating to:

- our substantial dependence on sales of ZADAXIN in China and renewal of our Import Drug License with respect to ZADAXIN;
- government regulatory action affecting our Company or our drug products or our competitors' drug products in China, the U.S. and other foreign countries, including the effect of government initiatives in China, particularly the Chinese government’s increasing regulation of the pharmaceutical industry through anti-corruption activities;
- Chinese government regulatory actions intended to reduce pharmaceutical prices such as the reduction in some provinces of the governmentally permitted maximum listed price for our products and increased oversight of the health care market and pharmaceutical industry;
- prospects for ZADAXIN and our plans for its enhancement and commercialization as well as our expectations regarding other products;
- future size of the oncology, cardiovascular, hepatitis B virus (“HBV”) and hepatitis C virus (“HCV”) and other markets, particularly in China ;
- anticipated product sales of current or anticipated products;
- the sufficiency of our resources to complete clinical trials and other new product development initiatives; government regulatory actions that may affect product reimbursement, product pricing or otherwise affect the scope of our sales and marketing, and the timing and outcome of clinical trials;
- the dependence of our current and future revenue and prospects on third-party license, promotion or distribution agreements, including the need to renew such agreements, enter into similar agreements, or end arrangements that SciClone does not believe are beneficial;
- the effects of the resolved U.S. Securities and Exchange Commission (“SEC”) and U.S. Department of Justice (“DOJ”) investigations and our ability to continue to comply with applicable laws and regulations, and carry out the continued reporting responsibilities agreed to with the SEC;
- announcement and completion of corporate acquisition, merger, licensing or marketing arrangements, or sales of assets ;
- our ability to implement and maintain controls over our financial reporting;
- operating an international business, particularly in China including pricing regulations, slow payment cycles and currency exchange fluctuations;
- uncertainty in the prospects for unapproved products, including uncertainties as to pricing and competition and risks relating to the clinical trial process and related regulatory approval process and the process of initiating trials at, and enrolling patients at, clinical sites;
- research and development and other expense levels;
- the ability of our suppliers to continue financially viable production of our products;
- the allocation of financial resources to certain trials and programs, and the outcome and expenses related to litigation; and
- other factors discussed in this Report in Part I, Item 2 “Management Discussion and Analysis of Financial Condition and Results of Operations” and Part II, Item 1A “Risk Factors”.

These statements are not guarantees of future performance and are subject to certain risks, uncertainties and assumptions that are difficult to predict. Therefore, our actual results could differ materially and adversely from those expressed in any forward-looking statements as a result of various factors including, but not limited to, those described under the caption “Risk Factors” in this Quarterly Report on Form 10-Q and under the same caption in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016. We undertake no obligation to revise or update publicly any forward-looking statements for any reason.

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### Overview

SciClone Pharmaceuticals, Inc. (NASDAQ: SCLN) is a United States (“U.S.”)-headquartered, China-focused, specialty pharmaceutical company with a substantial commercial business and a product portfolio of therapies for oncology, infectious diseases and cardiovascular disorders. We are focused on continuing to grow our revenue and profitability. Our business and corporate strategy is focused primarily on the People’s Republic of China (“China” or “PRC”) where we have built a solid reputation and established a strong brand through many years of experience marketing our lead product, ZADAXIN<sup>®</sup> (thymalfasin). In addition, we have an established business model with large pharmaceutical partners to promote and sell products. We believe our sales and marketing strengths position us to benefit from the long-term expansion of the pharmaceutical market in China. We seek to expand our presence in China and increase revenues by growing sales and profits of our current product portfolio, launching new products from our development pipeline, adding new, profitable product services agreements and leveraging our strong cash position to in-license additional products.

On June 7, 2017, we entered into an Agreement and Plan of Merger (the “Merger Agreement”) with Silver Biotech Investment Limited, a company organized under the laws of the Cayman Islands (“Holdco”), and Silver Delaware Investment Limited, a Delaware corporation and a wholly-owned subsidiary of Holdco (“Merger Sub”), under which Merger Sub will be merged with and into the Company (the “Merger”), with the Company continuing after the Merger as the surviving corporation and subsidiary of Holdco. Holdco and Merger Sub were formed by a consortium affiliated with GL Capital Management GP Limited, Bank of China Group Investment Limited, CDH Investments, Ascendent Capital Partners and Boying.

At the effective time of the Merger (the “Effective Time”), each share of the Company’s common stock, par value \$0.001 per share (the “Common Stock”), issued and outstanding immediately prior to the Effective Time (other than (i) shares of the Common Stock that are held by the Company, Holdco or Merger Sub or any direct or indirect wholly-owned subsidiary of either the Company or Holdco, including the shares held by GL Capital, and (ii) certain shares of the Common Stock with respect to which the holder thereof shall have properly complied with the provisions of Section 262 of the General Corporation Law of the State of Delaware as to appraisal rights) shall be converted into the right to receive \$11.18 in cash, without interest.

The transaction, which was unanimously approved by SciClone’s Board, is expected to close this calendar year, subject to approval by SciClone stockholders and other customary closing conditions.

Additional information about the Merger Agreement and the related transactions can be found in the Company’s Current Report on Form 8-K filed with the Securities and Exchange Commission on June 8, 2017.

We operate in two segments which are generally based on the nature and location of our customers: 1) China and 2) the Rest of the World, which includes our U.S. and Hong Kong operations.

We have two categories of revenues: “product sales revenues” and “promotion services revenues.” Our product sales revenues result from our proprietary and in-licensed products, including our lead product, ZADAXIN; DC Bead<sup>®</sup>, a product for the embolization of malignant hypervascularized tumors, and oncology products from Pfizer International Trading (Shanghai) Ltd. (“Pfizer”). ZADAXIN has the highest margins in our portfolio as it is a premium product sold exclusively by SciClone. Our “promotion services revenues” result from fees we receive for exclusively promoting oncology and cancer supportive care products in China for Baxter International, Inc. (“Baxter”). We recognize promotion services revenues as a percentage of our collaborator’s product sales revenue for these exclusively promoted products.

ZADAXIN is approved in over 30 countries and may be used for the treatment of HBV, HCV, and certain cancers, and as an immune system enhancer according to the local regulatory approvals we have in these countries. In China, thymalfasin is included in the treatment guidelines issued by the Ministry of Health (“MOH”) for liver cancer, as well as guidelines for treatment of chronic HBV (issued by both the Chinese Medical Association and the Asian-Pacific Association for the Study of the Liver) and invasive fungal infections of critically ill patients (issued by the Chinese Medical Association). Our sales force is focused on increasing sales to the country’s largest hospitals (class 3A with over 500 beds) as well as mid-size hospitals (class 2A). These hospitals serve Tier 1 and Tier 2 cities located mostly in the eastern part of China, which are the largest and generally have the most affluent populations. We are widening our market strategies by piloting e-commerce approaches to reach customers. We are also seeking to expand the indications for which ZADAXIN could be used, including sepsis, and in September 26, 2016, we announced the first patient has been treated in a clinical trial for sepsis using ZADAXIN in China.

We initiated sales and recorded our first product revenue from DC Bead in the third quarter of fiscal 2015. The China Food and Drug Administration had approved the registration of DC Bead for the embolization of malignant hypervascularized tumors in August 2014. DC Bead may be used to treat liver cancer, a large and growing indication in China.

We are also pursuing the registration of Loramyc<sup>®</sup>, a mucoadhesive tablet formulation of miconazole laurid to treat oropharyngeal candidiasis.

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Our agreement with Baxter is for a 5-year term, through December 2017, and our agreement with Pfizer is for a 5-year term, through June 2019. We continue to seek in-licensing arrangements for well-differentiated products at various stages of development that, if not yet approved, have a defined regulatory approval pathway in China, to increase our revenues and profitability. We have in-license agreements for the following products:

### **Our In-Licensed Drug Candidates in Clinical Development Include the Following:**

**PT-112:** On September 26, 2016, we announced the first patient has been treated in the Phase 1 proof-of-concept trial of PT-112, a multi-targeted platinum-pyrophosphate anticancer agent being developed for patients with advanced solid tumors, in Taiwan. PT-112 is a key early-stage asset supporting our strategy to expand our oncology portfolio and drive long-term growth. We obtained, in 2015, exclusive development and commercialization rights from Phosplatin Therapeutics to PT-112 for Greater China (mainland China, Hong Kong, and Macau), and Vietnam, along with the exclusive option to expand the territory to include South Korea, and Taiwan.

**SGX942:** On September 12, 2016, we and Soligenix, Inc. announced that we entered into an exclusive license agreement granting rights to SciClone to develop, promote, market, distribute and sell SGX942 (dusquetide), a novel, first-in-class therapy being developed for the treatment of oral mucositis in patients with head and neck cancer. The licensing agreement includes the PRC, Hong Kong, Macau, Taiwan, South Korea, and Vietnam (the "Territory"). This exclusive agreement builds on an existing collaboration, in which we provided our complete oral mucositis clinical and regulatory data library to Soligenix in exchange for certain, previously undisclosed, commercialization rights to SGX942 in the Greater China market (the "2013 exchange"). The Phase 2 results reported by Soligenix, Inc. showed a significant reduction in the duration of severe oral mucositis in patients receiving chemoradiation therapy for treatment of their head and neck cancer.

Under the terms of the agreement, we transferred cash consideration of \$3 million to Soligenix for 3,529,412 shares of Soligenix common stock and expanded rights for SGX942 in Taiwan, South Korea, and Vietnam, as we had previously obtained rights for Greater China in the 2013 exchange. In October 2016, Soligenix announced a 1 for 10 reverse stock split resulting in the Company's ownership of 352,942 shares. In addition, we will be responsible for all aspects of development, product registration and commercialization in the Territory, having access to data generated by Soligenix. In the future, we will pay to Soligenix royalties on net sales, and Soligenix will supply commercial drug product to us on a cost-plus basis, while maintaining worldwide manufacturing rights.

**VIBATIV<sup>®</sup>-(telavancin):** In May 2015, Theravance Biopharma, Inc. ("Theravance Biopharma") granted SciClone exclusive development and commercialization rights to VIBATIV (telavancin) in China, Hong Kong, Macao, Taiwan, and Vietnam, in exchange for upfront and regulatory milestone payments totaling \$6 million. SciClone will be responsible for all aspects of development and commercialization in the partnered regions, including pre- and post-launch activities and product registration. SciClone will initially develop VIBATIV for hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia, and additional indications may include complicated skin and skin structure infections and potentially bacteremia. Theravance Biopharma will sell to SciClone all clinical and commercial product required to develop and commercialize VIBATIV in China and our other licensed territories. We anticipate commencing a bridging trial for VIBATIV.

**Angiomax<sup>®</sup>-(bivalirudin) and Cleviprex<sup>®</sup>-(clevidipine):** In December 2014, we entered into a strategic partnership with The Medicines Company. The partnership includes an agreement granting us a license and the exclusive rights in China to promote two cardiovascular products including 1) Angiomax (bivalirudin) for Injection, an anticoagulant indicated in patients undergoing percutaneous coronary intervention (PCI) with provisional use of glycoprotein IIb/IIIa inhibitor (GPI) and in patients with, or at risk of, heparin-induced thrombocytopenia and thrombosis syndrome undergoing PCI and 2) Cleviprex (clevidipine) Injectable Emulsion, a third-generation dihydropyridine calcium channel blocker indicated for the reduction of blood pressure when oral therapy is not feasible or desirable.

For Angiomax, a Phase 3 registration trial was completed in China. We also completed, for Angiomax, a Clinical Trial Application ("CTA") approval and a Clinical Trial Waiver with the China Food and Drug Administration ("CFDA") in December 2016, and are in the process of preparing a New Drug Application ("NDA") with respect to Angiomax.

For Cleviprex, a CTA for China was filed in 2013. We received CTA approval from the CFDA in early 2016 and had been preparing a clinical study with respect to Cleviprex. Chiesi USA, Inc. and its parent company, Chiesi Farmaceutici S.p.A. ("Chiesi"), acquired the rights to Cleviprex in June 2016 from the Medicines Company. SciClone has decided not to continue proceeding with the preparation of a clinical study with respect to Cleviprex and is evaluating options with respect to the program, including exploring potential opportunities to out-license SciClone's rights with respect to Cleviprex.



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Under the terms of the agreements for Angiomax and Cleviprex, which also apply to Chiesi for Cleviprex, we have the rights to, and will be responsible for all aspects of commercialization, including pre-and post-launch activities, for both products (Cleviprex and Angiomax) in the China market (excluding Hong Kong and Macao). We had also agreed to initially participate in the China registration process for both products. Financial terms of the agreements for the two products, in addition to net sales royalties payable to The Medicines Company and/or Chiesi, include the following additional payments to The Medicines Company and/or Chiesi: an upfront payment made in the fourth quarter of 2014; a project support services fee; and regulatory/commercial success milestone payments of up to an aggregate of \$50.5 million.

**Neucardin™**: In May 2013, we entered into a framework agreement with Zensun for the exclusive promotion, marketing, distribution and sale of Neucardin in China, Hong Kong and Macao. Neucardin is a novel, first-in-class therapeutic for the treatment of patients with intermediate to advanced heart failure, for which an NDA was submitted to and accepted for review by the CFDA in 2012. In December 2013, the CFDA informed Zensun that its Phase 2 data is insufficient, and has asked Zensun to submit a new NDA once the ongoing Phase 3 study reached its endpoints. As part of our agreement with Zensun, we agreed to loan up to \$12 million to Zensun, of which \$12 million had been loaned as of December 31, 2016 (refer to Note 5 to the condensed consolidated financial statements appearing under Part I, Item 1 for further information regarding the Zensun loans).

**ABTL-0812**: Our license agreement with Ability Pharmaceuticals SL grants us a license and the exclusive rights to develop, manufacture and commercialize ABTL-0812 in China, Macau, Hong Kong, Taiwan, and Vietnam. ABTL-0812 is a first-in-class P13K/Akt/mTOR signaling pathway inhibitor for solid tumors, important in regulating the cell cycle. We are currently preparing for a phase 1 proof-of-concept trial in Taiwan and Mainland China.

### ***Governmental Policy Changes in China***

Governmental policy changes in China have eliminated national regulation of the maximum retail drug prices for most drugs effective as of June 1, 2015. Decisions by provincial authorities appear to be emerging as the primary governmental mechanism for price controls. As an example, the Zhejiang provincial authority announced a price limitation for sales of ZADAXIN in the province in April 2015 that became effective in May 2015. We were able to mitigate the impact of this price limitation by shifting an equitable portion of the burden of the price reduction and the benefit of higher pricing in provinces with higher tender prices with our distributor in our sales channel. Under our new contractual arrangement with Sinopharm, effective January 1, 2016, the lower tender price is reflected in a lower base invoice price to Sinopharm, as further described in the following section under "Results of Operations, Revenues". We anticipate that provincial pricing decisions will continue to be a significant factor in the China pharmaceutical market for the foreseeable future.

Recently, Guangdong and Fujian provinces have each announced maximum prices for ZADAXIN that are approximately six and four percent lower, respectively, than the reference (baseline) tender price. We expect these provincial decisions to affect the pricing of ZADAXIN in these provinces with respect to sales made pursuant to contracts dated on and after March 2017 for Guangdong and Fujian, and to affect pricing in other provinces, but the exact timing and consequences to our pricing, especially in other provinces, is uncertain. For the quarter ended June 30, 2017, Guangdong and Fujian represented a approximately 13.4% and 3%, respectively, of our ZADAXIN volumes in China. We have estimated for the second quarter that \$0.8 million of price compensation will be payable to distributors for ZADAXIN product to be sold at prices in these two provinces below the reference tender price under a provision in the agreement with the Company's China distributor. This amount, therefore, was recorded as a reduction to revenue in our second quarter results of operations. The impact of such pricing decisions on our future results is unpredictable, but we expect that pricing pressures on revenue in 2017 will be offset through sharing of the burden with our China distributor and potentially through volume increases. However, in the future, prices could be reduced to levels significantly below those that would prevail in an unregulated market, which may limit the growth of our revenues or cause them to decline.

In February 2017, a new National Reimbursement Drug List ("NRDL") was issued by Chinese government authorities, and included thymalfasins as "Type B" drugs which are partially reimbursed; however, Hepatitis B was not listed as an indication for thymalfasins in the new NRDL. Partial reimbursement for Hepatitis B and other indications could also be obtained by provinces determining to list thymalfasins on Provincial Reimbursement Drug Lists ("PRDLs") which we expect to be released in the second half of 2017. The Company will be seeking to have thymalfasins listed in PRDLs including for the Hepatitis B and cancer indication. Although thymalfasin is no longer covered under the Basic Medical Insurance, reimbursement under worker's compensation coverage remains in place.

We believe our cash and cash equivalents as of June 30, 2017 and ongoing revenue generating business operations will be sufficient to support our current operating plan for at least the next 12 months beyond the issuance date. Our results may fluctuate from quarter to quarter and we may report losses in the future.

**Results of Operations****Revenues :**

The following table summarizes the period over period change in our product sales and promotion services (*in thousands*):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2017	2016	Change	2017	2016	Change
Product sales, net	\$ 43,369	\$ 37,869	15%	\$ 85,006	\$ 73,189	16%
Promotion services	1,151	1,122	3%	2,406	2,301	5%
Total net revenues	\$ 44,520	\$ 38,991	14%	\$ 87,412	\$ 75,490	16%

Product sales were \$43.4 million for the three month period ended June 30, 2017 compared to \$37.9 million for the corresponding period in 2016, an increase of \$5.5 million, or 15%. ZADAXIN sales were \$41.6 million in the second quarter of 2017, compared to \$36.5 million for the same period in 2016, a \$5.1 million or 14% increase. An increase of \$4.4 million was attributed to an increase in volumes of 12%, an increase of \$3.3 million was attributed to revenues from sales generated in the first quarter of 2017 but recognized only in the second quarter of 2017 that were above the reference tender price under a provision in the agreement with the Company's China distributor, a revenue decrease of \$0.8 million was attributed to ZADAXIN products sold in the second quarter that we estimate will be ultimately sold at prices below the reference tender price under a provision in the agreement with the Company's China distributor, and a revenue decrease of \$1.8 million was attributed to an unfavorable exchange rate since last year.

Product sales were \$85.0 million for the six month period ended June 30, 2017 compared to \$73.2 million for the corresponding period in 2016, an increase of \$11.8 million, or 16%. ZADAXIN sales were \$81.1 million for the six month period ended June 30, 2017, compared to \$70.1 million for the corresponding period of 2016, an increase of \$11.0 million or 16%. An increase of \$10.2 million was attributed to an increase in volumes of 15%, an increase of \$7.5 million was attributed to revenues from sales generated in the fourth quarter of 2016 and in the first quarter of 2017 but recognized only in the first and second quarters of 2017 that were both above the reference tender price under a provision in the agreement with the Company's China distributor, a revenue decrease of \$0.8 million was attributed to ZADAXIN products sold in the second quarter that we estimate will be ultimately sold at prices below the reference tender price under a provision in the agreement with the Company's China distributor, and a revenue decrease of \$5.9 million was attributed to an unfavorable exchange rate since last year.

As of June 30, 2017, approximately \$44.7 million, or 93%, of the Company's accounts receivable was attributable to one customer, Sinopharm, in China. The Company generally does not require collateral from its customers. The Company maintains reserves for potential credit losses and such actual losses may vary significantly from its estimates.

Our contractual arrangement with Sinopharm which commenced January 1, 2016 is resulting in the later recognition (relative to practices prevailing through December 31, 2015) of a portion of our revenue invoiced to Sinopharm in situations where the provincial tender price is greater relative to a reference (baseline) tender price. This is due to a price adjustment mechanism in the new contractual arrangement whereby Sinopharm is invoiced at a lower base price relative to that prevailing in the previous agreement. The lower base price (reduced by estimated price compensation payable to the distributor for situations where the provincial tender price is lower than the reference (baseline) tender price) is recorded as revenue at the time the sale is completed the goods arrive at destination. Sinopharm is invoiced for the portion of the price that may result from situations where the provincial tender price is greater than the reference (baseline) tender price at a later time, and that portion will be recognized as revenue after the amount has been agreed upon with them. Although we do not expect this new arrangement to have a significant impact on annual revenue or the amount recognized on an annual basis, it has and may continue to impact our current and future quarterly revenue amounts and timing. For example, the price compensation receivable due to us from Sinopharm for above-reference tender price provinces for products originally sold in the first quarter of 2016 was recognized in the third quarter of 2016, and the amount of price compensation receivable for products originally sold in the second and third quarters of 2016 was recognized in the fourth quarter of 2016. We expect that the price compensation receivable due to us from Sinopharm for above-reference tender price provinces for a quarter will be recognized on a one-to-two quarter delayed basis relative to the originating sales quarter going forward. We expect that such price compensation receivable, on an estimated basis, will be recognized in the originating sales quarter rather than a later quarter when it is agreed with the distributor under the provisions of ASU 2014-09 (the new revenue recognition guidance which takes effect from January 1, 2018 for us).

Per our previous contractual arrangement with Sinopharm through December 31, 2015, and the aforementioned renewed contractual arrangement with Sinopharm (our sole importer and distributor for ZADAXIN in China) which took effect January 1, 2016, our sales of ZADAXIN to Sinopharm were denominated in U.S. dollars through June 30, 2016. However, the established importer price was adjusted quarterly based upon exchange rate fluctuations between the U.S. dollar and RMB. Effective July 1, 2016, our sales of ZADAXIN to Sinopharm are and will be denominated in RMB going forward. Our China ZADAXIN sales revenues have been (under the prior adjustment mechanism which operated on a lag basis), currently are, and will be in the future (as invoiced directly in RMB) subject to exchange rate risk.



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We anticipate that ZADAXIN revenues in 2017 will be higher than 2016, although our revenues are subject to exchange rate fluctuations and provincial adjustments to tender (retail level, government approved) prices which we cannot predict.

Recent governmental policy changes in China have eliminated national regulation of the maximum retail drug prices for most drugs effective as of June 1, 2015. Decisions by provincial authorities appear to be emerging as the primary governmental mechanism for price controls. As an example, the Zhejiang provincial authority announced a price limitation for sales of ZADAXIN in the province in April 2015 that became effective in May 2015. Changes in provincial drug prices for ZADAXIN in the provinces could impact our future sales revenues. Recently, Guangdong and Fujian provinces have each announced maximum prices for ZADAXIN that are approximately six and four percent lower, respectively, than the reference (baseline) tender price. We expect these provincial decisions to affect the pricing of ZADAXIN in these provinces with respect to sales made pursuant to contracts dated on and after March 2017 for Guangdong and Fujian, and to affect pricing in other provinces, but the exact timing and consequences to our pricing, especially in other provinces, is uncertain.

In China, pharmaceutical products are imported and distributed through a tiered method of distribution. For our proprietary product ZADAXIN, we manufacture our product using our U.S. and European contract manufacturers, and we generate our product sales revenue through sales of ZADAXIN product to Sinopharm. Sinopharm acts as an importer, and also as the top “tier” of the distribution system (“Tier 1”) in China. Our ZADAXIN sales occur when Sinopharm purchases product from us without any right of return except for replacement of product in the event of damaged product or quality control issues. Passage of title and risk of loss are transferred to Sinopharm at the time of arrival of a shipment at its destination. After the sale, Sinopharm clears products through China import customs, sells directly to large hospitals and holds additional product it has purchased in inventory for sale to the next tier in the distribution system. The second-tier (“Tier 2”) distributors are responsible for the further sale and distribution of the products they purchase from the importer, either through sales of product directly to the retail level (hospitals and pharmacies), or to third-tier (“Tier 3”) local or regional distributors who, in turn, sell products to hospitals and pharmacies.

Promotion services revenues were \$ 1.2 million and \$1.1 million for the quarters ended June 30, 2017 and 2016, respectively, an increase of \$ 0.1 million, or 3%. Promotion services revenues were \$ 2.4 million and \$2.3 million for the six month periods ended June 30, 2017 and 2016, respectively, an increase of \$ 0.1 million, or 5%. The increases are related mainly to an increase in Endoxan™ product sales.

We continue to assess the financial performance of the products we promote and distribute under our agreements and their overall value within our entire portfolio of products. Over time, we anticipate the product mix that we promote will change, which may affect our revenues and profitability in the future. If any of these agreements are determined to no longer be beneficial to us and are allowed to expire, or if third parties will not renegotiate, renew or extend the agreements on terms acceptable to us, our revenues would be adversely affected and our profitability may be adversely or beneficially affected. On the other hand, if we are successful in negotiating better terms, there may be a positive impact on our revenues and profitability.

All of our promotion services revenue and a majority of our product revenues are related to our China segment. Total China revenues were \$ 42.6 million and \$ 37.3 million, or 96% and 96% of sales for the three months ended June 30, 2017 and 2016, respectively. Rest of the World segment revenues were \$ 2.0 million and \$ 1.7 million, or 4% and 4% for the three months ended June 30, 2017 and 2016, respectively, and related to sales of ZADAXIN product.

Total China revenues were \$ 82.5 million and \$72.1 million, or 94% and 96% of sales for the six months ended June 30, 2017 and 2016, respectively. Rest of the World segment revenues were \$ 4.9 million and \$ 3.4 million, or 6% and 4% for the six months ended June 30, 2017 and 2016, respectively, and related to sales of ZADAXIN product.

For the three months ended June 30, 2017 and 2016, sales to Sinopharm in China accounted for approximately 93% and 93% of our revenues, respectively. For the six months ended June 30, 2017 and 2016, sales to Sinopharm in China accounted for approximately 92% and 92% of our revenues, respectively. Our experience with our largest customer has been good and we anticipate that we will continue to sell a majority of our product to them.

### **Cost of Product Sales:**

The following table summarizes the period over period change in our cost of product sales (*in thousands*):

	Three Months Ended June 30,			Change	Six Months Ended June 30,			Change
	2017	2016			2017	2016		
Cost of product sales	\$ 5,654	\$ 5,712	-1%	\$ 11,819	\$ 11,525	3%		

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Cost of product sales was \$5.7 million for the three month period ended June 30, 2017, compared to \$5.7 million for the corresponding period in 2016, a decrease of \$0.1 million, or 1%. ZADAXIN cost of sales decreased \$0.2 million for the three month period ended June 30, 2017, compared to the same period of last year, benefiting from lower production costs from increased volumes and larger production lot sizes, partially offset by a \$0.1 million increase in DC Bead cost of sales for the three month period ended June 30, 2017, compared to the same period of last year.

Cost of product sales was \$11.8 million for the six month period ended June 30, 2017, compared to \$11.5 million for the corresponding period in 2016, an increase of \$0.3 million, or 3%. Cost of product sales for the six month period ended June 30, 2017, compared to the same period of last year related to oncology products increased by \$0.4 million due to combination of a 13% volume increase and from product mix, and increased by \$0.1 million related to DC Bead sales due to increased volumes, and partially offset by a \$0.2 million decrease in ZADAXIN cost of sales benefiting from lower production costs from increased volumes and larger production lot sizes.

We expect our ZADAXIN cost of product sales and gross margins to fluctuate from period to period depending on the level of sales and price of our products, the absorption of product-related fixed costs, currency exchange fluctuations, any charges associated with excess or expiring finished product inventory, and the timing of other inventory period costs such as manufacturing process improvements for the goal of future cost reductions.

Overall, we expect our gross margin percentages in 2017 to be lower than 2016, based on lower selling prices in certain provinces, with indications of others to follow, as well as the unfavorable impact of currency exchange fluctuations.

### **Sales and Marketing (“S&M”):**

The following table summarizes the period over period change in our sales and marketing expenses (*in thousands*):

	Three Months Ended			Six Months Ended		
	June 30,			June 30,		
	2017	2016	Change	2017	2016	Change
Sales and marketing	\$ 15,509	\$ 14,432	7%	\$ 28,274	\$ 26,784	6%

S & M expenses for the three months ended June 30, 2017 increased by \$ 1.1 million, or 7 %, compared to the corresponding period in 2016. S&M expenses for the six months ended June 30, 2017 increased by \$ 1.5 million, or 6 %, compared to the corresponding period in 2016. The increases for both periods in 2017 primarily related to increases in salaries and benefits, mainly from annual increases, and to increased sales commissions based on increased Z ADAXIN sales.

We anticipate total S&M expenses for the year ending December 31, 2017 to be higher than those incurred for the year ended December 31, 2016 related to growth in our S&M efforts for ZADAXIN and other products including higher post-marketing clinical trial expenses and expenses related to our e-commerce strategies to widen our market.

### **Research and Development (“R&D”):**

The following table summarizes the period over period change in our R&D expenses (*in thousands*):

	Three Months Ended			Six Months Ended		
	June 30,			June 30,		
	2017	2016	Change	2017	2016	Change
Research and development	\$ 2,828	\$ 4,765	-41%	\$ 5,323	\$ 6,232	-15%

R&D expenses for the three months ended June 30, 2017 decreased \$ 2.0 million, or 41 %, compared to the corresponding period in 2016. For the three months ended June 30, 2016, we recorded \$2.0 million related to in-license arrangements with certain licensees, but none in the three months ended June 30, 2017. For the three months ended June 30, 2017 and 2016, we spent \$2.8 million and \$2.8 million, respectively, related to R&D activities in China for development expenses of product candidates in-licensed from certain business partners.

R&D expenses for the six months ended June 30, 2017 decreased \$1.0 million, or 15%, compared to the corresponding period in 2016. For the six months ended June 30, 2016, we recorded \$2.0 million related to in-license arrangements with certain licensees, but none in the six months ended June 30, 2017. For the six months ended June 30, 2017 and 2016, we spent \$5.3 million and \$4.2 million, respectively, related to R&D activities in China for development expenses of product candidates in-licensed from certain business partners.

We anticipate our R&D expenses to increase in 2017 compared to 2016 related to potential license fee payments, milestone payments expected to occur under current license arrangements, and related to research and development activities in China.

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### **General and Administrative (G&A) :**

The following table summarizes the period over period changes in our general and administrative expenses (*in thousands*):

	Three Months Ended			Six Months Ended		
	June 30,			June 30,		
	2017	2016	Change	2017	2016	Change
General and administrative	\$ 8,286	\$ 8,129	2%	\$ 15,516	\$ 15,572	0%

For the three months ended June 30, 2017, compared to the corresponding period of the prior year, general and administrative expenses were \$0.9 million higher, predominantly as a result of annual increases in salaries and benefits and strategic review expenses, partially offset by a foreign currency gain of \$0.7 million on re-measuring operational monetary assets.

For the six months ended June 30, 2017, compared to the corresponding period of the prior year, general and administrative expenses were \$56 thousand higher, predominantly as a result of foreign currency gain of \$1.5 million on re-measuring operational monetary assets, and lower legal fees, partially offset by higher share-based compensation expenses, higher professional consulting fees, increases in salaries and benefits, and the nonrecurring effect of a reversal of bad debt provision in the prior year.

### **Other Income (Expense), Net :**

The following table summarizes the period over period changes in our other income (expense), net (*in thousands*):

	Three Months Ended			Six Months Ended		
	June 30,			June 30,		
	2017	2016	Change	2017	2016	Change
Other income (expense), net	\$ 167	\$ (249)	-167%	\$ 1,242	\$ (121)	-1126%

Other income (expense), net for the three months ended June 30, 2017 increased by \$0.4 million compared to the corresponding period in 2016 primarily as a result of foreign exchange re-measurement. Other income (expense), net for the six months ended June 30, 2017 increased by \$1.3 million compared to the corresponding period last year was primarily driven by the receipt of a \$1.0 million government subsidy related to our China operations which had no future performance obligations and was recognized upon receipt as other income.

### **Provision for Income Tax :**

The following table summarizes the period over period changes in our provision for income tax (*in thousands*):

	Three Months Ended			Six Months Ended		
	June 30,			June 30,		
	2017	2016	Change	2017	2016	Change
Provision for income tax	\$ 589	\$ (371)	-259%	\$ 1,601	\$ 1,576	2%

The provision for income taxes for the three months ended June 30, 2017, was approximately \$0.6 million compared with \$0.4 million of income tax benefits for the three months ended June 30, 2016. In the three months ended June 30, 2017, we booked \$1.1 million of additional tax expense representing expected deferred tax liabilities which arose as a consequence of a change in our position regarding reinvestment of certain offshore undistributed earnings of our foreign subsidiaries, which is further described in Note 11 – Income Taxes. Without this \$1.1 million of additional tax expense, we would have approximately \$0.5 million income tax benefit for the three months ended June 30, 2017 compared to \$0.4 million income tax benefit for the three months ended June 30, 2016. The benefit for income taxes relate to a reduction in the Company's liabilities for uncertain tax positions in China due to certain tax years becoming closed to assessment due to the statute of limitations.

The provision for income taxes for the six months ended June 30, 2017, was approximately \$1.6 million compared with \$1.6 million for the six months ended June 30, 2016. In the six months ended June 30, 2017 we booked \$1.1 million of additional tax expense representing expected deferred tax liabilities which arose as a consequence of a change in our position regarding reinvestment of certain offshore undistributed earnings of our foreign subsidiaries, which is further described in Note 11 – Income Taxes. In the six months ended June 30, 2016 we booked \$1.2 million of additional income tax expense, and recorded a corresponding accrual in accrued and other current liabilities, to correct an error. The error correction reflected the recognition of a previously unrecognized liability for an uncertain tax position related to the potential non-deductibility, under PRC tax regulations, of certain marketing costs related to the Company's China operations, which is described in further detail in Note 1, "Error Corrections."

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We had previously concluded, up to the second quarter of 2017, that our offshore undistributed accumulated earnings as of December 31, 2016 of \$249 million were indefinitely reinvested and had therefore provided no taxes thereon. We had also previously concluded, in conjunction with this assertion, that a portion of its earnings expected to be generated by foreign subsidiaries in 2017 would be repatriated to the parent company in order to address the parent company's liquidity needs.

We entered into a definitive merger agreement (subject to stockholder approval and other customary closing conditions) in the second quarter of 2017 with a consortium of buyers intending to acquire us in a "going private" transaction (announced via a Form 8-K filed with the SEC on June 8, 2017). The terms of the definitive merger agreement, among other provisions regarding the funding of the acquisition, provide that we may distribute funds from our foreign subsidiaries (Cayman Islands entities) to our United States parent company in order to commit a portion of the merger funds necessary to effect the "going private" transaction and repurchase common shares. As a result of this contractual provision, we concluded in Q2 that the likelihood of distribution of offshore undistributed earnings cast doubt upon the ability to indefinitely reinvest of offshore undistributed earnings. Accordingly, following consideration of amounts specified in the merger agreement and related agreements, it was concluded that \$123 million of the unremitted earnings are no longer indefinitely reinvested as a result of expected distribution before the close of the announced merger in late 2017. We determined, after further analysis, that our parent company's available tax net operating loss carryforwards, which had been fully reserved via valuation allowances, are available to eliminate tax liability associated with substantially all of the Federal taxable dividend income of \$123 million that would arise from a planned remittance. After determination of the amount, we recorded additional net tax expense of approximately \$1.1 million as a discrete tax charge in the second quarter of 2017 for the full estimated US tax cost associated with the expected remittance of such earnings. The net expense represents the Federal deferred tax liability associated with the planned remittance, substantially offset by the reversal of the associated valuation allowance on the tax net operating loss carryforwards expected to be utilized. No withholding taxes are anticipated for the planned remittance due to the jurisdictions in which the cash expected to be remitted is held.

We evaluated its remaining offshore undistributed earnings of \$126 million (after excluding the anticipated \$123 million dividend distribution) and after further consideration of business needs in our foreign subsidiaries and the lack of further needs by our parent company concluded it has the intent and ability to indefinitely reinvest the remainder. Accordingly, no deferred taxes have been provided for the remaining unremitted earnings; determination of the amount of such taxes on the remainder is not practicable given substantial complexity stemming from the various jurisdictions involved, tax attributes to be considered, time periods involved, and withholding taxes that may need to be considered.

### **Liquidity and Capital Resources**

We continue to closely manage our liquidity and capital resources. We rely on our operating cash flows, and cash and cash equivalents to provide for our liquidity requirements. We believe that we have the ability to meet our liquidity needs for at least the next 12 months to fund our working capital requirements of our operations, including investments in our business, and to fund our business development activities.

The following tables summarize our cash and cash equivalents and our cash flow activities as of the end of, and for each of, the periods presented (in thousands):

	As of June 30, 2017	As of December 31, 2016
Cash, cash equivalents and investments	\$ 157,328	\$ 134,395

As of June 30, 2017, we had \$ 157.3 million in cash and cash equivalents, of which \$ 147.3 million was located in subsidiaries of the Company outside the US. Cash and cash equivalents held by subsidiaries outside the U.S. are held primarily in U.S. dollars. Such cash and cash equivalents are used to fund the operating activities of our foreign subsidiaries and for further investment in foreign operations, which may include in-licensing new products, particularly for China, and for potential acquisitions.

We have determined that as of December 31, 2016, \$211 million of accumulated undistributed earnings of foreign subsidiaries, after the payment of a 2016 dividend in the amount of \$10 million and a 2015 dividend in the amount of \$12.8 million, which were satisfied entirely out of the respective year's current earnings and profits, were indefinitely reinvested outside of the US. In making this determination, the following attributes were considered: (i) the expected future needs of the foreign subsidiaries, including working capital, capital expenditures, as well as additional investments to support the infrastructure in our China subsidiaries and (ii) additional investments to support our expansion in the China market as well as planned product licensing transactions. Upon distribution of our foreign undistributed earnings, we may be subject to U.S. federal and state income taxes.

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Our current expectation is that any amounts repatriated to supplement our parent company's liquidity will be offset by tax-deductible expenses or available tax benefits such as accumulated net operating losses. We will accrue for U.S. income taxes on future foreign earnings that we anticipate repatriating from our foreign subsidiaries.

	Six Months Ended June 30,	
	2017	2016
Cash provided by (used in):		
Operating activities	\$ 20,339	\$ 19,125
Investing activities	\$ (674)	\$ (54)
Financing activities	\$ 3,183	\$ (2,888)

Net cash provided by operating activities was \$ 20.3 million for the six months ended June 30, 2017 and primarily reflected the net income for the period, adjusted for non-cash items such as stock-based compensation expense, depreciation and amortization expense, and changes in operating assets and liabilities. Accounts receivable levels increased during the six months ended June 30, 2017 principally as a result of additional revenue earned but not yet collected for amounts due from Sinopharm for price compensation receivable. Accounts payable and accrued liabilities decreased \$ 3.3 million mainly related to compensation and benefits payables, and professional fees and R&D accruals during the six months ended June 30, 2017.

Net cash provided by operating activities was \$ 19.1 million for the six months ended June 30, 2016 and primarily reflected the net income for the period, adjusted for non-cash items such as stock-based compensation expense, depreciation and amortization expense, and changes in operating assets and liabilities. Accounts receivable decreased \$ 3.9 million related to payments received from customers during the six months ended June 30, 2016. Accounts payable and accrued liabilities decreased \$ 2.9 million mainly related to a decrease in compensation and benefits and sales and marketing accruals for payments made during the six months ended June 30, 2016.

Net cash used in investing activities was approximately \$ 0.7 million and \$ 0.1 million, respectively, for the six months ended June 30, 2017 and 2016, and related to purchases of property and equipment.

Net cash provided by (used in) financing activities was \$ 3.2 million and (\$ 2.9) million for the six months ended June 30, 2017 and 2016, respectively. For the six months ended June 30, 2017, we received net proceeds from the issuances of common stock made pursuant to options exercised, or shares otherwise issued for cash, under our stock award plans. For the six months ended June 30, 2016 we paid \$ 2.9 million, mainly related to employee individual income tax obligations which was reimbursed by such employee to us in the form of shares in a cashless exercise.

The following summarizes our future obligations including uncertain tax positions as of June 30, 2017 (*in thousands*):

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Operating leases (1)	\$ 2,561	\$ 1,970	\$ 454	\$ 137	\$ —
Purchase obligations (2)	18,784	18,784	—	—	—
Uncertain tax positions (3)	3,900	—	—	—	—
Total	<u>\$ 25,245</u>	<u>\$ 20,754</u>	<u>\$ 454</u>	<u>\$ 137</u>	<u>\$ —</u>

- (1) These are future minimum rental commitments for office space and copiers leased under non-cancelable operating lease arrangements.
- (2) These consist of purchase obligations with manufacturers and distributors.
- (3) As we are not able to reasonably estimate the timing of the payments or the amount by which our obligations for unrecognized tax benefits will increase or decrease over time, the related balances have not been reflected in the "Payments Due by Period" section of the table.

Under our license agreements with third parties we have agreed to various milestone payments related to regulatory and commercial success and other achievements that may require substantial payments in the future.

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We believe that our existing cash and cash equivalents and ongoing revenue generating business operations will be sufficient to support our current operating plan for at least the next 12 months from the issuance of the financial statements. We have no current commitments to offer and sell any securities that may be offered or sold pursuant to a registration statement. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may subject us to restrictive covenants and significant interest costs. To the extent that we raise additional funds through collaboration and licensing arrangements, we would be required to relinquish some rights to our technologies, product candidates or marketing territories. Additional financing or collaboration and licensing arrangements may not be available when needed either at all or on favorable terms.

We intend to continue to explore alternatives for financing to provide additional flexibility in managing our operations, in-licensing new products, particularly for China, and potential acquisitions, as may be required. The unavailability or the inopportune timing of any financing could prevent or delay our long-term product development and commercialization programs, either of which could hurt our business. We cannot assure you that funds from financings, if any, will be sufficient to in-license additional products. The need, timing and amount of any such financing would depend upon numerous factors, including the status of the pending regulatory investigations and pending litigations, the level and price of our products, the timing and amount of manufacturing costs related to our products, the availability of complementary products, technologies and businesses, the initiation and continuation of preclinical and clinical trials and testing, the timing of regulatory approvals, developments in relationships with existing or future collaborative parties, the status of competitive products, and various alternatives for financing. We have not determined the timing or structure of any transaction.

### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements.

### **Critical Accounting Estimates and Assumptions**

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make judgments, estimates and assumptions in the reporting of our unaudited condensed consolidated financial statements and accompanying notes. There can be no assurance that actual results will not differ from those estimates.

Our revenue recognition policy is as follows.

#### ***Revenue Recognition***

We recognize revenue when persuasive evidence of an arrangement exists, services have been rendered or delivery has occurred, the price to the buyer is fixed or determinable and collectability is reasonably assured.

***Product Revenue*** . We recognize product revenue from selling manufactured ZADAXIN product at the time of delivery. Sales of ZADAXIN to Sinopharm are recognized upon arrival of a shipment to its destination, which marks the point when title and risk of loss to product are transferred. We also earn product revenue from purchasing medical products from pharmaceutical companies and selling them directly to importers or distributors. We recognize revenue related to these products based on the “sell-in” method, when the medical products have been delivered to the importers or distributors. Payments by the importing agents and distributors are not contingent upon sale to the end user by the importing agents or distributors.

Effective January 1, 2016, our contractual arrangement with our China importer and distributor for ZADAXIN, Sinopharm, is resulting in the later recognition (relative to practices prevailing under the old contractual arrangement through December 31, 2015) of a portion of our revenue due from Sinopharm related to situations where the provincial tender price is greater relative to a reference (baseline) tender price. The tender price is the ultimate retail end price approved by provincial authorities. There is a price mechanism in the new contractual arrangement whereby Sinopharm is invoiced at a lower base price relative to that prevailing in the previous agreement. The lower base price (reduced by estimated price compensation payable to Sinopharm for situations where the provincial tender price is lower than the reference (baseline) tender price) is recorded as revenue at the time the sale is completed upon arrival at destination. Sinopharm is invoiced for the portion of the price that results from situations where the provincial tender price is greater than the reference (baseline) tender price at a later time, and such amount is recognized as revenue after the amount has been agreed with them. It is expected that the price compensation due to us related to sales in a quarter under the price adjustment mechanism for provinces with tender prices above the reference (baseline) tender price will be recognized on a rolling one-to-two quarter delayed basis relative to the originating sales quarter.

***Promotion Services Revenue***. We recognize promotion services revenue after designated medical products are delivered to the distributors as specified in the promotion services contracts, which marks the period when marketing and promotion services have been rendered, and the revenue recognition criteria are met.

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**Revenue Reserve.** We maintain a revenue reserve for product returns based on estimates of the amount of product to be returned by our customers which is based on historical patterns, analysis of market demand and/or a percentage of sales based on industry trends, and management's evaluation of specific factors that may increase the risk of product returns. Importing agents or distributors do not have contractual rights of return except under limited terms regarding product quality. However, we are expected to replace products that have expired or are deemed to be damaged or defective when delivered. The calculation of the product returns reserve requires estimates and involves a high degree of subjectivity and judgment. As a result of the uncertainties involved in estimating the product returns reserve, there is a possibility that materially different amounts could be reported under different conditions or using different assumptions. As of June 30, 2017 and December 31, 2016, our revenue reserves were approximately \$0.3 and \$0.3 million, respectively.

We evaluate our returns reserve quarterly and adjust it when events indicate that a change in estimate is appropriate. Changes in estimates could materially affect our results of operations or financial position. It is possible that we may need to adjust our estimates in future periods.

### **New Accounting Standards Updates**

Please refer to Note 1 to our unaudited condensed consolidated financial statements appearing under Part I, Item 1 for a discussion of new accounting standards updates that may impact the Company.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

There have been no material changes in our market risk for the six months ended June 30, 2017 compared to the disclosure in Part II, Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2016.

### **Item 4. Controls and Procedures**

#### **Evaluation of Disclosure Controls and Procedures**

Under the supervision and with the participation of our management, including our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), we evaluated the effectiveness of the design and operation of our disclosure controls and procedures, as such term is defined in Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended. Based on their evaluation at the end of the period covered by this quarterly report on Form 10-Q, our CEO and CFO have concluded that our disclosure controls and procedures were effective and were operating at the reasonable assurance level as of the end of the period covered by this quarterly report.

#### **Changes in Internal Controls**

Our management, including our CEO and CFO, has evaluated any changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2017, and has concluded that there was no change during such quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

#### **Limitations of the Effectiveness of Internal Controls**

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the internal control system are met. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We are continuously seeking to improve the efficiency and effectiveness of our operations and of our internal controls. This results in refinements to processes throughout our organization.



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**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings**

None.

**Item 1A. Risk Factors**

Consider these risks and uncertainties before investing in our common stock. We have marked with an asterisk (\*) those risk factors below that reflect changes from the risk factors included in our Annual Report on Form 10-K filed with the SEC on March 9, 2017.

**Risks Related to Our Business**

**The announcement and pendency of our agreement to be acquired by the Buyer Consortium could have an adverse effect on our business.\***

On June 7, 2017 we entered into an Agreement and Plan of Merger, or the Merger Agreement (the “Merger Agreement”), with Silver Biotech Investment Limited, a company organized under the laws of the Cayman Islands (“Holdco”), and Silver Delaware Investment Limited, a Delaware corporation and wholly owned subsidiary of Holdco (“Merger Sub”), under which Merger Sub will be merged with and into us (the “Merger”), with us continuing as the surviving corporation and subsidiary of Holdco after the Merger. Upon the terms and subject to the conditions set forth in the Merger Agreement, at the effective time of the merger, each share of common stock of SciClone issued and outstanding immediately prior to the effective time of the Merger will be cancelled and automatically converted into the right to receive \$11.18 in cash, without interest.

Uncertainty about the effect of the proposed Merger on our employees, partners and customers may have an adverse effect on our business and operations that may be material to our company. Our employees may experience uncertainty about their roles following the Merger. There can be no assurance we will be able to attract and retain key talent, including senior leaders, to the same extent that we have previously been able to attract and retain employees. Any loss or distraction of such employees could have a material adverse effect on our business and operations. In addition, we have diverted, and will continue to divert, significant management resources towards the completion of the Merger, which could materially adversely affect our business and operations.

Our partners, suppliers and customers may experience uncertainty associated with the Merger. This uncertainty may affect their current or future business relationships with us. Uncertainty may cause vendors or customers to refrain from purchasing our products, and suppliers may seek to change existing business relationships, which could result in an adverse effect on our business, operations and financial position in a way that may be material to our company.

Pursuant to the terms of the Merger Agreement, we are subject to certain restrictions on the conduct of our business, including the ability in certain cases to enter into contracts, acquire or dispose of assets, incur indebtedness or incur capital expenditures, until the merger becomes effective or the Merger Agreement is terminated. These restrictions may prevent us from taking actions with respect to our business that we may consider advantageous and result in our inability to respond effectively to competitive pressures and industry developments, and may otherwise harm our business and operations.

**The failure to complete the merger with the Buyer Consortium could adversely affect our business and stock price.\***

Completion of the merger with the Buyer Consortium is subject to several conditions beyond our control that may prevent, delay or otherwise adversely affect its completion in a material way, including receipt of funding by the Buyer Consortium and the approval of our stockholders. In addition, we may receive lawsuits on various matters relating to the merger, including seeking, among other things, to preliminarily and/or permanently enjoin the proposed merger and/or rescind the merger in the event it is consummated. If the merger or a similar transaction is not completed, the share price of our common stock may drop to the extent that the current market price of our common stock reflects an assumption that a transaction will be completed. In addition, under circumstances specified in the Merger Agreement, we may be required to pay a termination fee in the event the merger is not consummated. Further, a failure to complete the merger may result in negative publicity and a negative impression of us in the investment community. Any disruption to our business resulting from the announcement and pendency of the merger, including any adverse changes in our relationships with our shareholders, customers and suppliers, could continue or accelerate in the event of a failure to complete the merger. There can be no assurance that our business, these relationships or our financial condition will not be adversely affected, as compared to the condition prior to the announcement of the merger, if the merger is not consummated.



**Our stock price may be volatile, and an investment in our stock could suffer a decline in value.\***

Although we reported net income of \$12.1 million and \$6.3 million for the three months ended June 30, 2017 and 2016, respectively, and have reported full year annual net income since fiscal 2009, we have experienced occasional quarterly losses and as a result of accumulated annual operating losses prior to fiscal 2009, we have an accumulated deficit of approximately \$61 million as of June 30, 2017. If our operating expenses were to increase or if we were not able to increase or sustain revenue, we may not maintain profitability over the next 12 months.

The market price of our common stock has experienced, and may continue to experience, substantial volatility due to many factors, some of which we have no control over, including:

- our substantial dependence on our sales of ZADAXIN in China;
- our revenues are dependent on our obtaining or maintaining regulatory licenses and compliance with other country-specific regulations, including renewing our China Import Drug License for ZADAXIN, which must be renewed every 5 years (and is presently under renewal as the current license expires in December 2017);
- Chinese government actions intended to reduce pharmaceutical prices such as the reduction in some provinces of the governmentally permitted maximum listed price for our products and increased oversight of the health care market and pharmaceutical industry;
- government regulatory action affecting our Company or our drug products or our competitors' drug products in China, the U.S. and other foreign countries, including the effect of government initiatives in China, particularly the Chinese government's increasing regulation of the pharmaceutical industry through anti-corruption activities;
- compliance by our employees and agents with regulations that are applicable to sales and marketing activities, including the Foreign Corrupt Practices Act;
- actual or anticipated fluctuations in our quarterly operating results, some of which may result from undertaking new clinical development projects, or from licensing or acquisition-related expenses including up-front fees, milestone payments, and other items;
- announcement and completion of corporate acquisition, merger, licensing or marketing arrangements, or sales of assets;
- changes in assessments of our internal control over financial reporting;
- progress and results of clinical trials and the regulatory approval process for our product candidates;
- timing and achievement of our corporate objectives;
- charges related to expired inventory or bad debt;
- terminations of, or changes in our agreements or relationships with collaborative partners;
- announcements of technological innovations or new products by us or our competitors;
- developments or disputes concerning patent or proprietary rights;
- changes in the composition of our management team or Board of Directors;
- changes in company assessments or financial estimates by securities analysts;
- general stock market conditions and fluctuations for the emerging growth and pharmaceutical market sectors;
- unanticipated increases in our G&A expense due to legal and accounting expenses, including expenses relating to strategic initiatives, or arising out of matters relating to any additional or uncorrected control deficiency or related matters;
- economic and political conditions in the U.S. or abroad, particularly in China;
- currency fluctuations between the RMB and U.S. dollar ("USD");
- broad financial market fluctuations in the U.S., Europe or Asia;
- more aggressive action by the government in the U.S., China or other foreign jurisdictions in changing taxation policy; and
- unanticipated changes in key personnel.

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We have acquired products, product licenses and other companies in the past and expect to continue such acquisitions. We may not realize all the anticipated benefits of such acquisitions due to various risks, including risks similar to those stated above as well as to risks that could result if we:

- issue common stock that would dilute our current shareholders' percentage ownership;
- assume liabilities, some of which may be unknown at the time of such acquisitions;
- record goodwill and intangible assets that would be subject to impairment testing and potential periodic impairment charges;
- incur amortization expenses related to certain intangible assets; and
- incur large and immediate write-offs of in-process research and development costs; or become subject to litigation.

### **Our revenue is substantially dependent on our sales of ZADAXIN in China and competition or other factors could adversely affect our sales. \***

Our product revenue is highly dependent on the sales of ZADAXIN in China. We anticipate that sales of ZADAXIN will continue to be a majority of our revenue for at least the next two years. For the three months ended June 30, 2017 and 2016, approximately 96% and 95% of our ZADAXIN sales, respectively, were to customers in China. Sales of ZADAXIN in China may be limited due to the low average personal income, lack of patient cost reimbursement, poorly developed infrastructure and competition from other products, including generics. ZADAXIN sales growth in recent years has benefited from the rapidly growing Chinese economy and growing personal disposable income. Sales of ZADAXIN in China could be adversely affected by a slowing or downturn of the Chinese economy and from the recent and future decisions of provincial agencies' pricing reform. Any decrease in the sales of ZADAXIN in China may have a material adverse effect on our revenue and results of operations.

In China, ZADAXIN is approved for the treatment of hepatitis B virus ("HBV") and as an immune system enhancer. We face competition from pharmaceutical companies who are aggressively marketing competing products for the treatment of HBV and for other indications where we believe ZADAXIN may be used on an off-label basis. In addition, several local companies are selling lower-priced, locally manufactured generic thymalfasin, which is a competitive product and is selling in substantial and increasing quantities. While generic products outsell ZADAXIN in unit volumes, we have been able to maintain a pricing advantage through the reputation of our imported, branded product. We believe such competition will continue with added new local manufacturers of generic thymalfasin and there could be a negative impact on the price and the volume of ZADAXIN sold in China, which would harm our business.

Sales of ZADAXIN may fluctuate significantly from quarter to quarter due to financing limitations on importers, changes in inventory levels at our customers, and surges in sales and inventories. Importers and distributors of ZADAXIN borrow funds in China from banks to purchase, hold and distribute ZADAXIN. Substantial increases in restrictions on fund availability and/or increases in borrowing costs could limit the ability of our importers and distributors to finance their import and distribution process. Additionally, in the past, there have been situations where our suppliers or customers hold a higher level of inventory than expected, which decreased demand for ZADAXIN during that period. Further, our customers tend to purchase large orders, and inventory levels may fluctuate significantly as a result, or as a result of changes in the distribution channel, potentially affecting quarterly periodic results. Fluctuation in our sales of ZADAXIN may negatively impact our revenues and results of operations.

We are attempting to expand our business beyond ZADAXIN and outside of China. However, our efforts to in-license or acquire other pharmaceutical products for marketing in China and other markets may be unsuccessful or even if successful may not have a meaningful effect on our dependence on ZADAXIN sales in those markets.

### **Our revenues are dependent on our obtaining or maintaining regulatory licenses and compliance with other country-specific regulations, including renewing our drug import license for ZADAXIN, and compliance with the Chinese Pharmacopoeia.**

Our revenue is dependent on receipt and maintenance of regulatory licenses and compliance with other country-specific regulations. For example, we have received regulatory approvals to import and market ZADAXIN in China and to manufacture ZADAXIN and export the product from Italy. In order to continue our sales to China, we need to maintain these approvals, known as Import Drug Licenses which allow for the importation and commercial sale of a product manufactured outside of China. Our Import Drug License for ZADAXIN needs to be renewed every five years and the next renewal is required before December 2017 in order for us to continue our ability to import and sell ZADAXIN into China. Although Import Drug License renewals in the past were obtained successfully, there is no assurance that SciClone will receive renewals in the future when applied for or that the renewals will not be conditioned or limited in ways that limit our ability to import and sell ZADAXIN into China.

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Our licenses to manufacture and export ZADAXIN from Italy are dependent upon our continuing compliance with regulations in Italy. Our business would be adversely affected if we are not able to maintain these approvals. In order to sell ZADAXIN to the licensed importers in China, our manufacturers must 1) be approved by the Italian Ministry of Health (“AIFA”) and 2) be accepted by the CFDA. Some manufacturing changes may require: 1) approval by AIFA in Italy and/or 2) acceptance by the CFDA. ZADAXIN registration in Italy has been essential to the renewal of our Import Drug License from the CFDA permitting the importation of ZADAXIN into China.

Our ability to obtain a renewal of our Import Drug License from the CFDA could be adversely affected due to changes in policies and practices at CFDA in the review process, including with respect to potential requirements for additional technical information and product specification changes regarding ZADAXIN.

The CFDA, AIFA and other regulatory agencies may, and have, changed their internal administrative rules in ways that may delay or complicate the regulatory approval process. Those changes are not always disclosed or known to us and we may experience unexpected delays or additional costs as a result of such changes. Any change in our ability to obtain or renew regulatory licenses or approvals could have an adverse effect on our revenue and results of operations.

Our products are subject to rigorous regulation in the jurisdictions where they are sold, including the standards established by the Chinese Pharmacopoeia, or ChP, in China. The ChP is an official compendium of drugs in China and sets the standards of purity, description, test, dosage, precaution, storage and the strength for each drug in China. If our products fail to meet relevant specifications, including ChP specifications, during routine customs testing as such specifications may be revised from time to time, our Import Drug Licenses, which allow the importation for commercial sale, may be revoked, which would result in a significant loss of revenue and materially adversely affect our business.

**Chinese provincial government regulations mandating price controls have been imposed on ZADAXIN and several of our other products. If we experience difficulties in our sales efforts as a result of price restrictions or other policies intended to reduce health care costs, our operating results and financial condition will be harmed.\***

Our products are subject to increasing pricing pressures, particularly in China. Government regulations mandating price controls and limitations on patient access to our products impact our business, and our future results could be adversely affected by changes in such regulations or policies.

The Chinese government is increasing its efforts to reduce overall health care costs, including pricing controls on pharmaceutical products. Individual provinces in China and, in some cases, individual hospitals can and have established pricing requirements for a product to be included on formulary lists or imposed price reductions as part of the provincial tender process. In some cases, these price limits have been significantly lower than prices at which our distributors have been selling ZADAXIN, in which case we have been removed from formulary lists, which consequently has reduced sales to certain hospitals and could adversely affect our future sales.

Recent governmental policy changes in China have eliminated national regulation of the maximum retail drug prices for most drugs, effective June 1, 2015. Decisions by provincial authorities are emerging as the primary governmental mechanism for price controls. As an example, the Zhejiang provincial authority announced a price limitation for sales of ZADAXIN in the province in April 2015 that became effective in May 2015. However, we were able to mitigate, in part, the impact of this price limitation by sharing the burden of the price reduction and the benefit of higher pricing in provinces with higher tender prices with our distributor. Recently, Guangdong and Fujian provinces have each announced maximum prices for ZADAXIN that are approximately six and four percent lower, respectively, than the reference (baseline) tender price. We expect these provincial decisions to affect the pricing of ZADAXIN in these provinces with respect to sales made pursuant to contracts dated on and after March 2017 for Guangdong and Fujian, and to affect pricing in other provinces, but the exact timing and consequences to our pricing, especially in other provinces, is uncertain.

The pricing regulations in China, whether operating at a national, provincial or institutional level, as well as regulation of the importation of pharmaceutical products, have reduced retail prices of, and our own revenue from, ZADAXIN and our other products, and we expect that pricing pressure will continue. While the regulatory mechanisms are changing and the ultimate outcome is uncertain, and while we have been able to mitigate the impact of prior price reductions on our overall business, prices could be reduced to levels significantly below those that would prevail in an unregulated market, limit the volume of product which may be imported and sold or place high import duties on the product, any of which may limit the growth of our revenues or cause them to decline.

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Other emerging measures intended to reduce health care costs may also adversely affect our sales. Chinese provincial or local government agencies may limit or prohibit the use of pharmaceuticals they consider to be and designate as adjuvants as part of a policy to reduce spending on pharmaceuticals. None of our products has received such a designation to date from Chinese provincial or local government agencies. A few hospitals have designated our product as an adjuvant, but our revenues have not been materially affected. However, if any of our products are designated as an adjuvant by governments or local agencies in provinces where we have significant sales, or in hospitals where we have significant sales, sales of that product in such locations or hospitals would be significantly adversely affected.

**If we fail to achieve or maintain an effective system of internal controls, we may not be able to accurately report our financial results. As a result, current and potential stockholders could lose confidence in our financial reporting, which would harm our business and the trading price of our stock.**

Effective internal controls are necessary for us to provide reliable financial reports and to protect from fraudulent, illegal or unauthorized transactions. If we cannot establish effective controls and provide reliable financial reports, our business and operating results could be harmed. Moreover, as a U.S.-based corporation doing business internationally, these controls often need to satisfy the requirements of foreign law as well as the requirements of U.S. law which frequently differ in certain aspects. We have in the past discovered, and may in the future discover, areas of our internal controls that need improvement. For example, in 2012, our management identified two separate instances of a material weakness in internal control over financial reporting which were fully remediated prior to December 31, 2014. We continuously work on improvements to our internal controls and there can be no assurance that these or other material weaknesses will not occur in the future, or otherwise cause us to inaccurately report our financial statements. For example, the restatement of our financial statements for each of our first, second, and third quarters of 2012, and our financial statements for each of the second and third quarters of 2011 and the year ended December 31, 2011, were in part caused by the material weakness related to the design and operation of our controls disclosed as of December 31, 2012 discussed above. Any failure to implement and maintain controls over our financial reporting or difficulties encountered in the implementation of improvements in our controls, could cause us to fail to meet our reporting obligations. Any failure to improve our internal controls or to address identified weaknesses in the future, if they were to occur, could also cause investors to lose confidence in our reported financial information, which could have a negative impact on the trading price of our stock.

**We are subject to U.S. and foreign anti-bribery and anti-corruption and similar laws, and could face substantial penalties if we fail to fully comply with such regulations and laws.**

We are subject to U.S., Chinese and other foreign anti-bribery and anti-corruption laws and regulations. As a U.S. reporting company, we are subject to Foreign Corrupt Practices Act (“FCPA”) which prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA has been interpreted to include interactions with certain healthcare professionals in many countries. Other countries have enacted similar anti-corruption laws and/or regulations and the Chinese government in particular has increased its anti-corruption measures, particularly in the pharmaceutical and health care markets.

In 2010 the SEC and DOJ commenced investigations of the Company regarding a range of matters, including the possibility of violations of the FCPA, primarily related to certain historical sales and marketing activities with respect to our China operations. A Special Committee of our Board undertook an independent investigation as to matters reflected in and arising from the SEC and DOJ investigations in order to evaluate whether any violation of the FCPA or other laws occurred. In 2016, we announced a settlement agreement with the SEC fully resolving the SEC’s investigation into possible violations of the FCPA. The DOJ has also completed its investigation and has declined to pursue any action. Under the terms of the settlement with the SEC, we paid to the SEC a total of \$12.8 million, including disgorgement, pre-judgment interest and a penalty as final settlement. We are also required to give status reports to the SEC through the first quarter of 2019 on our continued remediation and implementation of anti-corruption compliance measures.

We expended substantial resources on the investigations and our internal remediation and compliance efforts, and continue to expend substantial resources on compliance. However, given the high level of complexity of the anti-bribery laws, there is a risk that we may inadvertently breach these regulations, for example through fraudulent or negligent behavior of individual employees, our failure to comply with record keeping requirements, or otherwise. Our success depends, in part, on our ability to anticipate risks and manage compliance through policies, procedures and internal controls. We have a large, dispersed sales force and we use third-party agents as well as distributors in various aspects of our business, including reliance on exclusive distributors for ZADAXIN in South Korea and Vietnam, all of which present risks to our effort to ensure that our practices comply with anti-bribery and similar regulations.

**Our independent registered public accounting firm serving as our external auditor is an audit firm which is not inspected by the Public Company Accounting Oversight Board (“PCAOB”), and, although they may be subject to other inspections, you do not have the benefits of PCAOB inspections.**

Our incumbent independent auditors’ system of quality control and their individual audits are subject to review, inspection, or other outside assurance from time to time by member firms in the network of firms to which they belong, by peer accounting firms, or by regulatory or industry bodies in China (such as China’s securities regulator or the Chinese body representing certified public accountants). However, these various bodies or parties are distinct from the PCAOB, and their efforts may not be concentrated on audits of SEC registrants. Their reviews or inspections may be substantially different, or not comparable to, an inspection by the PCAOB. Auditors of companies that are registered with the SEC and traded publicly in the U.S., including our independent registered public accounting firm, must be registered with the PCAOB, and are required by the laws of the U.S. to undergo regular inspections by the PCAOB to assess their compliance with the laws of the U.S. and professional standards. Because our auditors are located in the People’s Republic of China, a jurisdiction where the PCAOB is currently unable to conduct inspections without the approval of the Chinese authorities, our auditors are not currently inspected by the PCAOB. This lack of PCAOB inspections in China prevents the PCAOB from regularly evaluating audits and quality control procedures of any auditors operating in China, including our auditors. As a result, investors in our equity securities may be deprived of the benefits of PCAOB inspections. The inability of the PCAOB to conduct inspections of auditors in China makes it more difficult to evaluate the effectiveness of our auditors’ audit procedures or quality control procedures as compared to other public company auditors outside of China that are subject to PCAOB inspections. As a result, investors in our stock may lose confidence in our reported financial information and procedures and the quality of our financial statements.

**Proceedings instituted by the SEC against certain PRC-based accounting firms, including our independent registered public accounting firm, could result in financial statements being determined to not be in compliance with the requirements of the Securities Exchange Act of 1934, as amended.**

In December 2012, the SEC brought administrative proceedings against five accounting firms, including our independent registered public accounting firm, in China, alleging that they had refused to produce audit work papers and other documents related to certain other China-based related companies under investigation by the SEC. On January 22, 2014, an initial administrative law decision was issued, censuring these accounting firms and suspending four of these firms from practicing before the SEC for a period of six months. The decision is neither final nor legally effective unless and until reviewed and approved by the SEC. On February 12, 2014, four of these PRC-based accounting firms, including our registered public accounting firm, appealed to the SEC against this sanction decision. In February 2015, the four PRC-based accounting firms agreed to a censure and to pay \$500,000 each to the SEC to settle the dispute and avoid suspension of their ability to practice before the SEC and audit U.S.-listed companies. The settlement requires the firms to follow detailed procedures to seek to provide the SEC with access to Chinese firms’ audit documents via the China Securities Regulatory Commission. If the firms don’t follow the procedures, the SEC could impose penalties such as suspensions, or it could restart the current enforcement case administrative proceedings.

In the event that the SEC restarts the enforcement administrative proceedings, depending upon the final outcome, listed companies in the U.S. with major PRC operations may find it difficult or impossible to retain auditors in respect of their operations in the PRC, which could result in financial statements being determined to not be in compliance with the requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Moreover, any negative news about the proceedings against these audit firms may cause investor uncertainty regarding China-based, U.S.-listed companies and the market price of our stock may be adversely affected.

If our independent registered public accounting firm were denied the ability to practice before the SEC and we were unable to timely find another registered public accounting firm to audit and issue an opinion on our financial statements, our financial statements could be determined not to be in compliance with the requirements of the Exchange Act of 1934. Such a determination could ultimately lead to the delisting of our shares from the NASDAQ Global Select Market or deregistration by the SEC, or both, which would substantially reduce or effectively terminate the trading of our stock in the U.S.

**We may incur unexpected charges relating to our operations.**

Although we have generally experienced minimal product returns and our customers have historically paid all invoiced amounts, we could incur future charges relating to inventory that expires or as a result of customer failures to pay invoiced amounts timely or in full. For example, from time to time we have recorded bad debt expense or write offs of uncollectible accounts receivable. While the amounts of the write offs have historically been immaterial, we may have more significant bad debt expenses or write offs in the future. We have had and could also experience additional charges for potential inventory obsolescence related to other products if we are unable to sell units that are nearing their expiration dates, or for bad debt if other distributors do not pay outstanding receivables in full. Those or similar future events would have an adverse impact upon our operating results.

**We are at risk of additional securities class action and derivative lawsuits.**

Securities class action and derivative lawsuits are often filed against public companies following a decline in the market price of their securities. After our announcement regarding SEC and DOJ investigations in 2010, we and certain of our officers and directors were named as parties in purported stockholder class actions and derivative lawsuits. Those class action lawsuits were dismissed and we have settled those derivative lawsuits. Our stock price declined following the announcement of a restatement of our financial statements for fiscal 2011 and the first three quarters of fiscal 2012, and that our predecessor independent auditing firm had elected not to stand for reappointment for the 2013 fiscal year. Soon after that announcement, we and certain of our officers and directors were named as parties in a purported derivative lawsuit relating to the restatement, which was subsequently dismissed in its entirety. We may experience stock price volatility in the future related to other matters. This risk is especially relevant for us because biotechnology companies have experienced greater than average stock price volatility in recent years. We may be named in additional litigation, which could require significant management time and attention and result in significant legal expenses and may result in an unfavorable outcome, which could have a material adverse effect on our business, financial condition, results of operations and cash flows. Such litigation could result in additional substantial costs and a diversion of management's and the Board of Directors' attention and resources, which could harm our business.

**We may not be able to successfully develop or commercialize our products.**

We have numerous product candidates under development, some of which we own and others which were in-licensed to us.

Clinical trials are inherently risky and may reveal that our product candidates are ineffective or have unanticipated side effects and/or drug interactions that may significantly decrease the likelihood of regulatory approval. The regulatory approval processes in the U.S., Europe and China are demanding, lengthy and expensive. We have committed significant resources, including capital and time, to develop and seek approval for products under development, and if we do not obtain approvals we are seeking, we may be unable to achieve any revenue from these products. All new drugs, including our product candidates, are subject to extensive and rigorous regulation by the FDA, CFDA and similar regulatory agencies. These regulations govern, among other things, the development, testing, manufacturing, labeling, storage, pre-market approval, importation, advertising, promotion, sale and distribution of our products. These regulations may change from time to time and new regulations may be adopted.

Satisfaction of government regulations may take several years and the time needed to satisfy them varies substantially based on the type, complexity and novelty of the pharmaceutical product. As a result, government regulation may cause us to delay the introduction of, or prevent us from marketing, our existing or potential products for a considerable period of time and impose costly procedures on our activities. We have experienced delays in the regulatory process, and there exists risk that we may not receive approval of in-licensed products currently in the regulatory process.

To fully develop these products and other products we may acquire, substantial resources are required for extensive research, development, pre-clinical testing, clinical trials, and manufacturing scale-up and regulatory approval prior to the potential products being ready for sale. We cannot assure that our efforts will produce commercially viable products. We are obligated to make a milestone payment upon regulatory approval of certain products under development. If any of our products, even if developed and approved, cannot be successfully commercialized in a timely manner, our business will be harmed and the price of our stock may decline.

Market acceptance of any product that is successfully developed and approved will depend on many factors, including our ability to convince prospective customers to use our products as an alternative to other treatments and therapies. In addition, doctors must opt to use treatments involving our products. If doctors elect to use a different course of treatment, demand for our drug products would be reduced. In addition, for certain products we may need to convince partners to manufacture or market our products. Our success will also depend upon pricing restrictions and reimbursement policies that will be imposed, and upon our ability to properly anticipate those. Failure to do any of the above will lead to an unfavorable outcome on the results of our operations.



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### **Our sales are concentrated in China and we face risks relating to operating in China, including risks due to changes in the regulatory environment, slow payment cycles and exposure to fluctuations in the Chinese economy.**

A significant portion of our revenue and profit is derived from operations in China. Consequently, our overall financial results are dependent on this market, and our business is exposed to risks there. A downturn in the Chinese economy could materially and adversely affect our revenues and results of operations. In addition to the risks relating to pricing previously discussed above, these risks also include changes in economic conditions (including wage and cost inflation, currency exchange rates, consumer spending and employment levels), tax rates, laws, changes in the regulatory environment, increased competition and potential noncompliance with local laws and regulations. Risks also include changing consumer product preferences and preferred sales channels, as well as our ability to accommodate such changing preferences. Certain risks and uncertainties of doing business in China are solely within the control of the Chinese government, and Chinese law regulates the scope of our foreign investments and business conducted within China. Any significant or prolonged deterioration in China's relations with the United States and other countries could adversely affect our China business. There are also uncertainties regarding the interpretation and application of laws and regulations and the enforceability of intellectual property and contract rights in China. There can be no assurance as to the future effect of any such risks and uncertainties on our results of operations, financial condition or cash flows.

We experience other issues with managing sales operations in China including long payment cycles, potential difficulties in timely accounts receivable collection and, especially from significant customers, fluctuations in the timing and amount of orders and the adverse effect of any of these issues on our business could be increased due to the concentration of our business with a small number of distributors. Problems with collections from, or sales to, any one of those distributors could materially adversely affect our results.

Our future results could be adversely affected by changes in laws and regulations, including, among others, changes in accounting standards, taxation requirements (including tax rate changes, new tax laws and revised tax law and regulatory interpretations, including changes affecting the taxation by the U.S. of income earned outside the U.S. that may result from pending and possible future proposals), competition laws, privacy laws and environmental laws in the U.S. and other countries.

The PRC State Council has promulgated rules, officially effective in April 2016, applicable to the distribution of drugs, and started with certain pilot provinces. The rules are known as the "two-invoice-system", which embodies a key principle that there should be no more than two invoices issued between the manufacturer and the hospital or pharmacy (starting with the first manufacturer or distributor in the PRC). The "two-invoice-system" addresses the government's objectives to reduce the high prices of pharmaceutical products and to eliminate potential corruption. The "two-invoice-system" may affect the way in which future sales of ZADAXIN are distributed. The Company is monitoring the launch and development of the "two-invoice-system" in different provinces, including the pilots, as to any potential future impact to the Company's business.

Compliance with changing regulations concerning corporate governance and public disclosure has resulted in and may continue to result in additional expenses. Changing laws, regulations and standards relating to corporate governance and public disclosure, are creating uncertainty for companies such as ours and costs are increasing as a result of this uncertainty and other factors. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment has and may continue to result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

### **The Company could be subject to changes in its tax rates, the adoption of new U.S. or international tax legislation or exposure to additional tax liabilities which could have a negative impact on our financial position and results of operations.**

Currently all of our revenue is generated from customers located outside the U.S., and a substantial portion of our assets, including employees, are located outside the U.S. U.S. income taxes and foreign withholding taxes have not been provided on certain undistributed earnings of non-U.S. subsidiaries, because such earnings are intended to be indefinitely reinvested in the operations of those subsidiaries. The U.S. government may propose initiatives that would substantially reduce our ability to defer U.S. taxes including: repealing deferral of U.S. taxation of foreign earnings, eliminating utilization or substantially reducing our ability to claim foreign tax credits, and eliminating various tax deductions until foreign earnings are repatriated to the U.S. If any of these proposals are constituted into legislation, they could increase our U.S. income tax liability and as a result have a negative impact on our financial position and results of operations.

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**Because of China's tiered method of importing and distributing finished pharmaceutical products, our quarterly results may vary substantially from one period to the next; we are dependent upon Sinopharm as the exclusive importer of ZADAXIN.**

Imported products in China, including ZADAXIN and other imported products, are distributed through a tiered method to import and distribute finished pharmaceutical products. Promoted products are typically sold from our partner companies within China to the primary distributor with the following distribution being the same for imported as well as promoted products. At each port of entry, and prior to moving the product forward to the distributors, government-licensed importing agents must process and evaluate each imported product shipment to determine whether it satisfies China's quality assurance requirements. In order to efficiently manage this process, the importing agents typically place large, and therefore relatively few, orders within an annual period. Therefore, sales to an importing agent can vary substantially from quarter to quarter depending on the size and timing of the orders, which has in the past and may in the future cause our quarterly results to fluctuate. We rely on Sinopharm to supply our ZADAXIN sales in China. Our receivables from Sinopharm are material, and if we were unable to collect receivables from Sinopharm or any other importer, our business and cash-flow would be adversely affected.

Generally, our importers are not obligated to place purchase orders for our product, and if they determined for any reason not to place purchase orders, we would need to seek alternative licensed importers, which could cause fluctuations in our revenue. As a result of our agreement granting certain exclusive importation rights to Sinopharm for ZADAXIN, we are dependent upon Sinopharm's performance of its obligations under that agreement. We have a long-standing and, we believe excellent, relationship with Sinopharm; however, if Sinopharm were unable to adequately perform its obligations under, or breached, the agreement our business would be adversely affected.

**The existence of counterfeit pharmaceutical products in China's pharmaceutical retail market may damage our brand and reputation and have a material adverse effect on our business, financial condition, results of operations and prospects.**

Certain medicine products distributed or sold in China's pharmaceutical retail market, including those appearing to be ZADAXIN, may be counterfeit. Counterfeit products are products sold under the same or very similar brand names and/or have a similar appearance to genuine products. Counterfeit products, including counterfeit pharmaceutical products, are a significant problem in China and we have experienced counterfeiting of ZADAXIN. Such counterfeit products divert sales from genuine products, often are of lower cost, often are of lower quality (having different ingredients or formulations, for example), and have the potential to damage the reputation for quality and effectiveness of the genuine product. The counterfeit pharmaceutical product regulation control and enforcement system in China is not able to completely eliminate production and sale of counterfeit pharmaceutical products. To increase our ability to prevent counterfeiting, we have taken several actions, including enhancements of our ZADAXIN product labeling to implement industry-leading labeling technology and implementation of product tracking applications. However we cannot eliminate counterfeiting. Any sale of counterfeit products resulting in adverse side effects to consumers may subject us to negative publicity and expenses. It could have a material adverse effect on our business, financial condition, results of operations and prospects.

**We are subject to currency exchange rate fluctuations, which could adversely affect our financial performance. \***

Although our financial statements are reported in U.S. dollars, a significant portion of our revenues and costs are realized in other currencies. Our profitability is affected by movement of the U.S. dollar against other currencies. Fluctuations in exchange rates between the U.S. dollar and other currencies may also affect the reported value of our assets and liabilities, as well as our cash flows. Some foreign currencies are subject to government exchange controls.

The majority of our sales through June 30, 2016 were in U.S. dollars, although a portion of our sales were denominated in RMB. Per our previous contractual arrangement with Sinopharm through December 31, 2015, and a renewed contractual arrangement with Sinopharm (our sole importer and distributor for ZADAXIN in China) which took effect January 1, 2016, our sales of ZADAXIN to Sinopharm were denominated in U.S. dollars. However, the established importer price could be adjusted quarterly based upon exchange rate fluctuations between the U.S. dollar and RMB. Effective July 1, 2016, sales to Sinopharm are and will be denominated in RMB, linking our sales directly to the foreign currency (as opposed to a less-correlated basis via lagging adjustments).

Our purchases with contract manufacturers are denominated in U.S. dollars and euros and costs of our marketing efforts in China are paid in local currency. In addition, we have certain cash balances and other assets and liabilities denominated in euros, RMB and Hong Kong dollars. A stronger U.S. dollar vis-à-vis the local currency would tend to have an adverse effect on sales and potentially on collection of accounts receivable and a positive effect on expenses. China currently maintains the value of the RMB in a narrow currency trading band that may or may not fluctuate based on government policy. For example, in August 2015, the Chinese government devalued the RMB and may further devalue the RMB at any time. This devaluation has resulted in the strengthening of the U.S. dollar and may reflect a weakening of the Chinese economy. Depending on market conditions and the state of the Chinese economy, China has intervened in the foreign exchange market in the past to prevent significant short-term fluctuations in the RMB exchange rate, and it could make future adjustments, including moving to a managed float system, with opportunistic interventions. This reserve diversification may negatively impact the U.S. dollar and U.S. interest rates. Changes in exchange rates could unpredictably and adversely affect our operating results and could result in exchange losses. To date, we have not hedged against the risks associated with fluctuations in exchange rates and, therefore, exchange rate fluctuations could have a material adverse impact on our future operating results and stock price.



**We cannot predict the safety profile of the use of ZADAXIN or other drugs we may develop or market particularly when used in combination with other drugs.**

While ZADAXIN has an excellent safety profile, we cannot predict whether ZADAXIN or any product we market may have unexpected safety issues in a particular patient population or when used in new indications. In addition, we cannot predict how ZADAXIN or other drugs we may develop or market will work with other drugs, including causing possible adverse side effects not directly attributable to the other drugs that could compromise the safety profile of ZADAXIN or other drugs we may develop or market when used in certain combination therapies. We are exploring new indications for ZADAXIN and there is a risk that new safety issues could appear in these new patient populations.

As we introduce new products, there may be adverse safety events related to those products. Adverse safety events may have a negative impact on our business. Discovery of safety issues with our products could create product liability and could cause additional regulatory scrutiny and requirements for additional labeling, withdrawal of products from the market, and the imposition of fines or criminal penalties. Adverse safety events may also damage physician and patient confidence in our products and our reputation. Any of these could result in liabilities, loss of revenue, material write-offs of inventory, material impairments of goodwill and fixed assets, material restructuring charges and other adverse impacts on our results of operations.

Regulatory authorities are making greater amounts of stand-alone safety information directly available to the public through periodic safety update reports, patient registries and other reporting requirements. The reporting of adverse safety events involving our products or products similar to ours and public rumors about such events may increase claims against us and may also cause our product sales or stock price to decline or experience periods of volatility.

**If third-party reimbursement is not available or patients cannot otherwise pay for ZADAXIN or other drugs we may develop, we may not be able to successfully market them. \***

Significant uncertainty exists as to the reimbursement status of therapeutic products, such as ZADAXIN or other drugs we may develop. We cannot assure you that third-party insurance coverage and reimbursement will be available for therapeutic products we might develop. Although ZADAXIN receives some limited reimbursement in China, we cannot assure you that we will be able to maintain existing reimbursements or increase third-party payments for ZADAXIN or obtain third-party payments for other products that we sell or develop in China. In February 2017, a new National Reimbursement Drug List (“N R D L”) was issued by Chinese government authorities, included thymalfasins as “Type B” drugs which are partially reimbursed; however, Hepatitis B was not listed as an indication for thymalfasins in the new N R D L. Partial reimbursement for Hepatitis B could also be obtained by provinces determining to list thymalfasins on Provincial Reimbursement Drug Lists (“PRDLs”), which we expect to be released in the second half of 2017. The Company will be seeking to have thymalfasins listed in PRDLs, including for the Hepatitis B and cancer indication. Although thymalfasin is no longer covered under the BMI reimbursement its coverage under worker’s compensation insurance remains in place. The failure to maintain third-party reimbursement for our products would harm our business. In many emerging markets where we have marketing rights to ZADAXIN, but where government resources and per capita income may be so low that our products will be prohibitively expensive, we may not be able to market our products on economically favorable terms, if at all.

Recent efforts by governmental and third-party payers to contain or reduce health care costs and the announcement of legislative proposals and reforms to implement government controls has caused us to reduce the prices at which we market our drugs in China, and additional reforms, if they were to occur, could cause us to further reduce our prices which could reduce our gross margins and may harm our business.

**We rely on third parties who are our sole source suppliers for our clinical trial and commercial products and their inability to deliver products that meet our quality-control standards could delay or harm one or more important areas of our business including our sales, clinical trials or the regulatory approval process.**

We rely on third parties, who are subject to regulatory oversight, to supply our commercial products. Any deficiencies or shortages in supply of our commercial products would adversely affect our ability to realize our sales plans. For example, the manufacturing of the raw material and the processing to finished product of ZADAXIN is done in few batches in any given three month period and any manufacturing errors have the potential to require a product recall. We currently have only one approved finished vial manufacturer and two approved active pharmaceutical ingredient (“API”) suppliers. Similarly, ONXEO (formerly BioAlliance) is the sole supplier of Loramyc and each of the products that are marketed through our NovaMed Shanghai and our SciClone Pharmaceuticals (Jiangsu) Co. Ltd. subsidiaries are manufactured by, or obtained from, a single source.

If we experience a problem with a sole source manufacturer or our suppliers, our sales may suffer. We have experienced difficulties with obtaining product from manufacturers in the past. In addition, manufacturing interruptions or failure to comply with regulatory requirements by suppliers of our product candidates in clinical trial, or other could delay the trials or detract from the integrity of the trial data and its potential use in future regulatory filings.

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During 2012, we experienced limitations on supply of several products we were promoting (each of which we no longer market) and the growth in the sales of those products was affected. During 2011, we experienced manufacturing delays related to repairs for general, non-production-related facilities equipment at one of our API suppliers. During 2010, we experienced difficulties validating upgrades to equipment with one of our API manufacturers. Although we are taking steps to ensure that such problems do not continue, there is no assurance that we will either be successful in doing so with our current supplier or be able to timely and cost-effectively qualify new suppliers for this component.

### **If our thymalfasin API or ZADAXIN products are not shipped and stored at precision temperatures, the products could become damaged, which could negatively affect our sales and operating results.**

Thymalfasin API and ZADAXIN are temperature sensitive products. SciClone relies on third-party organizations to provide controlled temperature shipping logistics services from the point of ownership transfer from the API contract manufacturer to the point where thymalfasin API is converted to ZADAXIN drug product, and from the ZADAXIN drug product manufacturing site to our storage locations in Hong Kong and then to China. Although some temperature excursions are allowable and thymalfasin and ZADAXIN are relatively stable when exposed to temperatures higher than recommended, if any third-party logistics or equipment provider fails to perform their required oversight duties with respect to temperature control or a shipment is delayed in transit for a prolonged period of time, the thymalfasin API or ZADAXIN drug product could become unsuitable for subsequent processing or commercial use. Although we have not experienced cold chain interruptions in the past and our distributor in China may maintain several months' supply of our product, were our cold chain distribution or warehouse capability to be interrupted, our ability to timely deliver finished product to China could be adversely affected, which in turn could materially adversely affect our sales and operating results.

### **We rely on third parties for development, commercialization and other aspects of our business, and the inability of any of these parties to reliably, timely or cost-effectively provide us with their obligated services could materially harm the timing of bringing our products to market and accordingly adversely affect our business.**

We rely on third parties, such as collaboration partners, contract research organizations, medical institutions, clinical investigators, and contract laboratories, in the research and development of our product candidates and in the conduct of clinical trials for our product candidates. We are also dependent upon third parties for the commercialization or distribution of products or product candidates, including our exclusive distributors for ZADAXIN in South Korea and Vietnam. If these parties, whom we do not control, do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, or if our collaboration partners do not have the ability or the resources to successfully complete their objectives, or choose not to continue their relationship with us, our development efforts could be delayed, suspended or terminated, or our commercialization efforts may be delayed, impaired or terminated. If the quality or accuracy of the data they obtain by third parties is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical or clinical activities could be delayed and we may not be able to obtain regulatory approval for our product candidates.

### **Our rights to develop, market and sell our products and future product candidates are held under license and other agreements, and the third parties to those agreements might elect not to renew them.**

Except for ZADAXIN, our rights to develop, market and sell our products including licensed products and products currently promoted or sold, are held by us under license, promotion, distribution or marketing agreements with third parties. These agreements for products include products in the regulatory review process, including products in clinical trials that are held under license, distribution or marketing agreements. In addition, our success in the future may be dependent on entering into similar agreements with other parties and the renewal of any such agreements. The third parties to these agreements are generally not under an obligation to renew the agreements, and in some cases have not renewed the agreements, which has affected our revenues. If any of these agreements are terminated, or if they are not renewed, our ability to develop or distribute the products or product candidates could be terminated and our business could be affected.

### **If we are unable to retain our key personnel, or are unable to attract and retain additional, highly skilled and experienced personnel, including the ability to expand our sales staff, our business will suffer.**

We are highly dependent upon our ability to attract and retain qualified personnel because of the specialized, scientific and worldwide nature of our business. We are also dependent on our ability to appropriately staff these personnel in appropriate positions as our business fluctuates. Further, our efforts to in-license or acquire, develop and commercialize product candidates in current or new jurisdictions may require the addition of clinical and regulatory personnel and the expansion of, or changes in our sales and marketing operation. In addition, we assign numerous key responsibilities to a limited number of individuals, and we would experience difficulty in finding immediate replacements for any of them were any one of them to choose to leave employment with us. There is intense competition for qualified management, scientific, clinical, regulatory, and sales and marketing personnel in the pharmaceutical industry.

There is significant turnover in the industry, in China in particular, and we have also experienced turnover in our sales personnel and key employees. We may not be able to attract and retain the qualified personnel we need to grow and develop our business globally.

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We have terminated personnel for violations of our policies and procedures as well as for lack of performance. Our future success will depend in part on our retaining key personnel and on recruiting additional senior sales and other personnel in China. We are continuously recruiting executives and other level personnel to address departures and to expand and strengthen our China operations.

Conversely, if we need to reduce the size of a particular aspect of our business, including if we have contracts that are not renewed or renegotiated for products we market or promote, we are also dependent on our ability to make such adjustments while retaining suitably skilled personnel. If we were unable to attract and retain qualified personnel as needed or promptly replace those employees who are critical to our sales, development and other operations, and in particular senior executives, our financial results and operations would be adversely affected. At this time, we do not maintain “key person” life insurance for any of our personnel.

### **We may need to obtain additional funding to support our long-term product development, including funding of in-licensed products, and commercialization programs. \***

We believe our existing cash and cash equivalents and ongoing revenue generating business operations will be sufficient to support our current operating plan for at least the next 12 months. We may use cash to acquire additional product rights or for future acquisitions, and we may seek additional funding through offering securities, including, without limitation, pursuant to our S-3 registration statement. Our ability to achieve and sustain operating profitability is dependent on numerous factors including our ability to achieve increasing sales of ZADAXIN in China, and for our other products and the execution and successful completion of clinical trials in China. Further, we may use cash to fund products we in-license. We cannot assure you that such funds from operating activities will be sufficient, or that we will attain profitable operations in future periods. In addition, we intend to develop other products and we may need additional funds in the future to support such development and to support future growth and achieve profitability. If we need to raise additional funds in the future and such funds are not available on reasonable terms, if at all, our commercialization efforts may be impeded, our revenues may be limited and our operating results may suffer.

### **We are subject to the risk of increased income taxes which could reduce our future income.**

We have structured our operations in a manner designed to maximize income in countries where:

- tax incentives have been extended to encourage foreign investment; or
- income tax rates are low.

Our taxes could increase if certain tax holidays or incentives are not renewed upon expiration, or if tax rates applicable to us in such jurisdictions are otherwise increased. In addition, the Company and its subsidiaries are regularly subject to tax return audits and examinations by various taxing jurisdictions, particularly in the U.S. and China. In determining the adequacy of our provision for income taxes, we regularly assess the likelihood of adverse outcomes resulting from tax examinations. While it is often difficult to predict the final outcome or the timing of the resolution of a tax examination, we believe that our reserves for uncertain tax positions reflect the outcome of tax positions that are more likely than not to occur. However, we cannot be certain that the final determination of any tax examinations will not be materially different than that which is reflected in our income tax provisions and accruals. Should additional taxes be assessed as a result of a current or future examination, there could be a material adverse effect on our tax provision, operating results, financial position and cash flows in the period or periods for which that determination is made.

Our taxes could also increase if our ability to defer U.S. federal taxes under current tax laws were to change as a result of changes in tax law that prevent us from asserting indefinite reinvestment of offshore undistributed earnings or as a result of a change in our intention regarding distribution of these offshore undistributed earnings.

**If we fail to protect our products, technologies and trade secrets, we may not be able to successfully use, manufacture, market or sell our products, or we may fail to advance or maintain our competitive position, and we have limited intellectual property protection in China.**

Our success depends significantly on our ability to obtain and maintain meaningful patent protection for our products and technologies and to preserve our trade secrets. Our pending patent applications may not result in the issuance of patents in the future. Our patents or patent applications may not have priority over others' applications. Our existing patents and additional patents that may be issued, if any, may not provide a competitive advantage to us or may be invalidated or circumvented by our competitors. Others may independently develop similar products or design around patents issued or licensed to us. Patents issued to, or patent applications filed by, other companies could harm our ability to use, manufacture, market or sell our products or maintain our competitive position with respect to our products. Although many of our patents relating to thymalfasin have expired, including composition of matter patents, we have rights to other patents and patent applications relating to thymalfasin and thymalfasin analogues, including method of use patents with respect to the use of thymalfasin for certain indications. Additionally, thymalfasin has received Orphan Drug designation in the U.S. for the treatment of stage 2b through stage 4 melanoma, for the treatment of chronic active hepatitis B, for the treatment of DiGeorge anomaly with immune defects, and for the treatment of hepatocellular carcinoma. If other parties develop generic forms of thymalfasin for other indications, including conducting clinical trials for such indications, our patents and other rights might not be sufficient to prohibit them from marketing and selling such generic forms of thymalfasin or their brands of thymalfasin. If other parties develop analogues or derivatives of thymalfasin, our patents and other rights might not be sufficient to prohibit them from marketing these analogues or derivatives.

Pharmaceutical products are either not patentable or have only recently become patentable in some of the countries in which we market or may market thymalfasin. We do not have composition patent claims directed to the thymalfasin that is currently marketed in China, our largest market, although we do have other type of patent claims, pending or issued, directed to other aspects of thymalfasin therapy. Other companies market generic thymalfasin in China, potentially in violation of our patent, trademark or other rights which, to date, we have defended by informing physicians and hospitals of the practice. Past enforcement of intellectual property rights in many of these countries, including China in particular, has been limited or non-existent. Future enforcement of patents and proprietary rights in many other countries will likely be problematic or unpredictable. Moreover, the issuance of a patent in one country does not assure the issuance of a similar patent in another country. Claim interpretation and infringement laws vary by nation, so the extent of any patent protection is uncertain and may vary in different jurisdictions.

**If we are involved in intellectual property claims and litigation, the proceedings may divert our resources and subject us to significant liability for damages, substantial litigation expense and the loss of our proprietary rights.**

Our commercial success depends in part on our not infringing valid, enforceable patents or proprietary rights of third parties, and not breaching any licenses that may relate to our technologies and products. In addition, we may not be aware of all patents or patent applications that may impact our ability to make, use or sell any of our potential products. For example, U.S. patent applications may be kept confidential for 12 or more months while pending in the Patent and Trademark Office, and patent applications filed in foreign countries are often first published nine months or more after filing. It is possible that we may unintentionally infringe these patents or other patents or proprietary rights of third parties. We may in the future receive notices claiming infringement from third parties as well as invitations to take licenses under third-party patents. Any legal action against us or our collaborative partners claiming damages and seeking to enjoin commercial activities relating to our products and processes affected by third-party rights may require us or our collaborative partners to obtain licenses in order to continue to manufacture or market the affected products and processes. Our efforts to defend against any of these claims, regardless of merit, would require us to devote resources and attention that could have been directed to our operations and growth plans. In addition, these actions may subject us to potential liability for damages. We or our collaborative partners may not prevail in a patent action and any license required under a patent may not be made available on commercially acceptable terms, or at all. Any conflicts resulting from the patent rights of others could significantly reduce the coverage of our patents and limit our ability to obtain meaningful patent protection.

If other companies obtain patents with conflicting claims, we may be required to obtain licenses to those patents or develop or obtain alternate technology to manufacture or market the affected products and processes. We may not be able to obtain any such licenses on acceptable terms or at all. Any failure to obtain such licenses could delay or prevent us from pursuing the development or commercialization of our potential products. Our efforts to defend against any of these claims would require us to devote resources and attention that could have been directed to our operations and growth plans.

We may need to initiate litigation, which could be time-consuming and expensive, to enforce our proprietary rights or to determine the scope and validity of others' rights. If litigation results, a court may find our patents or those of our licensors invalid or may find that we have infringed on a competitor's rights. If any of our competitors have filed patent applications in the U.S. that claim technology we also have invented, the Patent and Trademark Office may require us to participate in expensive interference proceedings to determine who has the right to a patent for the technology. These actions may subject us to potential liability for damages. We or our collaborative partners may not prevail in a patent action and any license required under a patent may not be made available on commercially acceptable terms, or at all.

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### **Substantial sales of our stock or securities convertible into shares of our stock or the exercise or conversion of options may impact the market price of our common stock.**

We may conduct future offerings of our common stock, preferred stock or other securities convertible into our common stock to fund acquisitions, finance operations and for other purposes. Future issuances of substantial amounts of our common stock could adversely affect the market price of our common stock. Similarly, if we raise additional funds through the issuance of common stock or securities convertible into or exercisable for common stock or sell equity in a subsidiary, the percentage ownership of our present stockholders of the respective entities will be reduced and the price of our common stock may fall.

### **Our cash, cash equivalents and investment in common stock are subject to certain risks which could materially adversely affect our overall financial position.**

We invest our cash and cash equivalents in accordance with an established internal policy and customarily in instruments which historically have been highly liquid and carried relatively low risk. However, in recent years, similar types of investments have experienced losses in value or liquidity issues which differ from their historical pattern. For example, we routinely have invested in money market funds with large financial institutions. One or more of these funds could experience losses or liquidity problems and, although to date some of the largest financial institutions who sponsor such funds have offset similar losses, there is no assurance that our financial institutions would either not incur losses or would offset any losses were they to occur.

Any adjustment to decrease the ratings of our investments by a statistical rating organization (such as Moody's or Standard and Poor's) may have a negative impact on the value of our investments.

Should any of our cash investments permanently lose value or have their liquidity impaired, it would have a material and adverse effect on our overall financial position by imperiling our ability to fund our operations and forcing us to seek additional financing sooner than we would otherwise and such financing may not be available on commercially attractive terms.

If our common stock investment in Soligenix were to permanently lose value on an other-than-temporary basis, our financial position could be negatively impacted with a charge to operations.

In addition, financial instruments may subject us to a concentration of credit risk. Most of our cash and cash equivalents are held by a limited number of financial institutions. To date, we have not experienced any losses on our deposits of cash and cash equivalents. However, if any of these instruments permanently lost value or have their liquidity impaired, it would also have a material and adverse effect on our overall financial position by imperiling our ability to fund our operations and forcing us to seek additional financing sooner than we would otherwise and such financing may not be available on commercially attractive terms.

We expect that we may need to transfer capital to certain of our China subsidiaries from time to time to fund their operations. We need to obtain regulatory approval from China's State Administration of Foreign Exchange ("SAFE") in order to make such transfers and there can be no assurance that we will be able to obtain such approval in a timely manner. We were able to fund the operations of NovaMed Shanghai to date through commercial credit facilities or through intercompany loans, but we could face difficulties in the future if our efforts to improve profitability and cash flow in NovaMed Shanghai or our other China subsidiaries are not successful, or if we are unable to obtain SAFE approval or obtain further funding for them.

Furthermore, a majority of our cash is held by our foreign subsidiaries. Such cash is used to fund the operating activities of our foreign subsidiaries and for further investment in foreign operations. Based on our current operating plan, we do not anticipate the need to repatriate undistributed earnings of our foreign subsidiaries accumulated through December 31, 2016. We plan to repatriate a portion of expected foreign earnings to be generated in future years to fund our U.S. operations. We have provided for U.S. income taxes on a portion of recent years' foreign earnings that we have repatriated from our foreign subsidiaries, and our annual effective tax rate for the respective periods reflects both the provisions as well as benefits associated with our operations. We plan to indefinitely reinvest outside of the U.S. remaining unrepatriated future foreign earnings expected to be generated in 2017 and beyond.

### **Our loans receivable are subject to certain risks which could materially adversely affect our financial position.**

As part of our May 2013 license and supply agreement with Zensun, we agreed to loan up to \$12 million to Zensun, of which \$12 million had been loaned as of June 30, 2017. The proceeds of the loans are to be used for working capital and general corporate purposes by Zensun. As security for the loan agreements, Zensun pledged its entire equity interest in its subsidiary Shanghai Dongxin Biochemical Technology Co. Ltd. (whose assets include real property) to us. If the real property which comprises the majority of the value of all of the assets pledged as security were to suffer a decrease in its value due to macroeconomic conditions or local market-specific factors impacting commercial real estate market values, such a fact may represent an indication of loan impairment. If these loans were to become impaired and the loans could not be collected, our financial position could be negatively impacted with a charge to operations for the amount of any unpaid principal and interest.

**Our ability to utilize our tax attributes may be limited by an “ownership change”.**

Our ability to use our tax attributes, such as our U.S. federal income tax net operating loss carryforwards and our tax credit carryforwards, may be substantially restricted if we have had in the past, or have in the future, an “ownership change” as defined in Section 382 of the U.S. Internal Revenue Code. An ownership change occurs if increases in the percentage of our stock held by “5-percent shareholders” (within the meaning of Section 382, which provides that certain public groups can be treated as 5-percent shareholders) collectively exceed more than fifty percent, comparing the lowest percentage of stock owned by each 5-percent shareholder at any time during the testing period (which is generally a three-year rolling period) to the percentage of stock owned by the 5-percent shareholder immediately after the close of any owner shift testing date. Our repurchases of our common stock, issuances of any additional significant amounts of our common stock for future acquisitions or other transactions and trading in our stock by stockholders, may have increased the possibility that in the future we could experience an ownership change. Trading by our stockholders, stock repurchases or other transactions could, in the future, cause an ownership change, resulting in an annual limitation on utilization of our tax attributes. If our tax attribute usage is subject to limitation and if we are profitable, our future cash flows could be adversely affected due to an increased tax liability.

**Our business could be negatively affected as a result of actions of stockholders.**

The actions of stockholders could adversely affect our business. Specifically, certain actions of certain types of stockholders, including without limitation public proposals, requests to pursue a strategic combination or other transaction or special demands or requests, could disrupt our operations, be costly and time-consuming or divert the attention of our management, directors and employees. In addition, perceived uncertainties as to our future direction in relation to the actions of our stockholders may result in the loss of potential business opportunities or the perception that we are unstable and need to make changes, which may be exploited by our competitors and make it more difficult to attract and retain personnel as well as customers, service providers and partners. Actions by our stockholders may also cause fluctuations in our stock price based on speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

**We may be subject to product liability lawsuits, and our insurance may be inadequate to cover damages.**

Clinical trials of any of our current and potential products or the actual commercial sales of our product may expose us to liability claims from the use of these products. We currently carry product liability insurance. However, we cannot be certain that we will be able to maintain insurance on acceptable terms, if at all, for clinical and commercial activities, that any insurance we have will cover any particular claim that is asserted, or that the insurance would be sufficient to cover any potential product liability claim or recall. If we fail to have sufficient coverage, our business, results of operations and cash flows could be adversely affected.

**If we are unable to comply with environmental and other laws and regulations, our business may be harmed.**

We are subject to various federal, state and local laws, regulations and recommendations relating to the use, manufacture, storage, handling and disposal of hazardous materials and waste products (including radioactive compounds and infectious disease agents), as well as safe working conditions, laboratory and manufacturing practices and the experimental use of animals. The extent of government regulation that might result from future legislation or administrative action in these areas cannot be accurately predicted.

We do not currently maintain hazardous materials at our facilities. While we outsource our research and development programs involving the controlled use of biohazardous materials, if in the future we conduct these programs ourselves, we might be required to incur significant cost to comply with environmental laws and regulations. Further, in the event of an accident, we would be liable for any damages that result, and the liability could exceed our resources.

**Our business and operations are subject to the risks of being based in particular locations known for earthquakes, other natural catastrophic disasters and service interruptions.**

Our corporate headquarters are located in the Silicon Valley area of Northern California, a region known for seismic activity. Although we maintain a disaster recovery policy that includes storage of important corporate data in a different geographic region of the U.S., all of our significant corporate data is stored in our headquarters facility and accordingly, a significant natural disaster, such as an earthquake, could have a material adverse impact on our business, operating results, and financial condition. Most of our sales are into China for which we maintain our warehouses for finished goods in Hong Kong, which can experience severe typhoon storms, earthquakes or other natural catastrophic disasters. Although our distributors in China may maintain several months’ supply of our product, were our warehouse capability to be interrupted, either through a natural disaster such as flooding or through a service interruption, such as a lack of electricity to power required air conditioning, our ability to timely deliver finished product to China could be adversely affected which in turn would materially adversely affect our sales and ensuing operating results.



**We may be affected by climate change and market or regulatory responses to climate change.**

Climate change, including the impact of global warming, could have a material adverse effect on our results of operations, financial condition, and liquidity if it were to disrupt the demand, supply or delivery of product, management of our business, or result in cost increases as a result of government regulation.

**Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.**

In the ordinary course of our business, we store sensitive data, including intellectual property, our proprietary business information, certain information regarding our business partners, and personally identifiable information of our employees, in our computer networks. The secure maintenance and transmission of this information is critical to our operations and reputation. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Although we have not been adversely affected in any significant manner, we have experienced problems with information security in the past which we believe is primarily due to breaches of security by current or former employees gaining access to restricted information. Any such breach could compromise our computer networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Although we have purchased cyber liability insurance, any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and regulatory penalties, and damage our reputation, any of which could adversely affect our business and competitive position.



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**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

Not applicable.

**Item 3. Defaults Upon Senior Securities**

Not applicable.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

Not applicable.

**Item 6. Exhibits**

<u>Exhibit Number</u>	<u>Description</u>
2.1 <sup>(1)</sup>	Agreement and Plan of Merger by and among Company, Holdco and Merger Sub dated June 7, 2017
3.2 <sup>(2)</sup> **	Amended and Restated Bylaws of SciClone Pharmaceuticals, Inc.
10.1 <sup>(1)</sup> **	Voting Agreement by and between GL Capital and Company dated June 7, 2017
31.1 <sup>(3)</sup>	Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2 <sup>(3)</sup>	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1 <sup>(3)</sup>	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2 <sup>(4)</sup>	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101 <sup>(3)</sup>	The following materials from Registrant's Quarterly Report on Form 10-Q for the three months ended June 30, 2017, formatted in Extensible Business Reporting Language (XBRL) includes: (i) Unaudited Condensed Consolidated Balance Sheets as of June 30, 2017 and December 31, 2016, (ii) Unaudited Condensed Consolidated Statements of Income for the three months ended June 30, 2017 and 2016, (iii) Unaudited Condensed Consolidated Statements of Comprehensive Income for the three months ended June 30, 2017 and 2016, (iv) Unaudited Condensed Consolidated Statements of Cash Flows for the three months ended June 30, 2017 and 2016, and (v) Notes to Unaudited Condensed Consolidated Financial Statements.

\*\* Management compensatory plan or arrangement

- (1) Incorporated by reference from the Company's Current Report on Form 8-K filed on June 8, 2017.
- (2) Incorporated by reference from the Company's Current Report on Form 8-K filed on May 9, 2017.
- (2) Filed herewith.
- (2) Furnished herewith.

**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

SCICLONE PHARMACEUTICALS, INC.

Date: August 9, 2017

/s/ Wilson W. Cheung

Wilson W. Cheung  
Senior Vice President, Finance and Chief Financial Officer

INDEX TO EXHIBITS

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(3) Filed herewith.

(4) Furnished herewith.

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE  
SARBANES-OXLEY ACT OF 2002

I, Friedhelm Blobel, Ph.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of SciClone Pharmaceuticals, Inc. (the "Registrant");
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 registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant 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 registrant, 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant'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
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

Date: August 9 , 2017

/s/ Friedhelm Blobel, Ph.D.  
Friedhelm Blobel, Ph.D.  
Chief Executive Officer and President  
(Principal Executive Officer)

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CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-  
OXLEY ACT OF 2002

I, Wilson W. Cheung, certify that:

1. I have reviewed this quarterly report on Form 10-Q of SciClone Pharmaceuticals, Inc. (the "Registrant");
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 registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant 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 registrant, 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant'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
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

Date: August 9 , 2017

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/s/ Wilson W. Cheung  
Wilson W. Cheung  
Senior Vice President, Finance and Chief Financial Officer  
(Principal Financial Officer)

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CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906  
OF THE SARBANES-OXLEY ACT OF 2002

I, Friedhelm Blobel, Chief Executive Officer and President, of SciClone Pharmaceuticals, Inc. (the "Registrant"), do hereby certify in accordance with 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

- (1) the Quarterly Report on Form 10-Q of the Registrant, to which this certification is attached as an exhibit (the "Report"), fully complies with the requirements of section 13(a) of the Securities Exchange Act of 1934 (15 U.S.C. 78m); and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: August 9 , 2017

/s/ Friedhelm Blobel, Ph.D.

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Friedhelm Blobel, Ph.D.

Chief Executive Officer and President  
(Principal Executive Officer)

*A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to SciClone Pharmaceuticals, Inc. and will be retained by SciClone Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.*

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CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906  
OF THE SARBANES-OXLEY ACT OF 2002

I, Wilson W. Cheung, Senior Vice President, Finance and Chief Financial Officer, of SciClone Pharmaceuticals, Inc. (the "Registrant"), do hereby certify in accordance with 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

- (1) the Quarterly Report on Form 10-Q of the Registrant, to which this certification is attached as an exhibit (the "Report"), fully complies with the requirements of section 13(a) of the Securities Exchange Act of 1934 (15 U.S.C. 78m); and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: August 9, 2017

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/s/ Wilson W. Cheung  
Wilson W. Cheung  
Senior Vice President, Finance and Chief Financial Officer  
(Principal Financial Officer)

*A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to SciClone Pharmaceuticals, Inc. and will be retained by SciClone Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.*

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