

SCICLONE PHARMACEUTICALS INC

FORM 10-Q (Quarterly Report)

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2016

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

SCICLONE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

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

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)

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, or a smaller reporting company. See definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller Reporting Company

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 November 2, 2016, 51,053,583 shares of the registrant's Common Stock, \$0.001 par value, were issued and outstanding.

SCICLONE PHARMACEUTICALS , INC.

TABLE OF CONTENTS

	PAGE NO.	
PART I.	<u>FINANCIAL INFORMATION</u>	
Item 1.	<u>Financial Statements (Unaudited)</u>	
	<u>Condensed Consolidated Balance Sheets as of September 30, 2016 and December 31, 2015</u>	3
	<u>Condensed Consolidated Statements of Income for the three- and nine - month periods ended September 30, 2016 and 2015</u>	4
	<u>Condensed Consolidated Statements of Comprehensive Income for the three- and nine - month periods ended September 30, 2016 and 2015</u>	5
	<u>Condensed Consolidated Statements of Cash Flows for the nine -month periods ended September 30, 2016 and 2015</u>	6
	<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	7
Item 2.	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	21
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	34
Item 4.	<u>Controls and Procedures</u>	34
PART II.	<u>OTHER INFORMATION</u>	
Item 1.	<u>Legal Proceedings</u>	35
Item 1A.	<u>Risk Factors</u>	36
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	58
Item 3.	<u>Defaults Upon Senior Securities</u>	58
Item 4.	<u>Mine Safety Disclosures</u>	58
Item 5.	<u>Other Information</u>	58
Item 6.	<u>Exhibits</u>	59
	<u>Signature</u>	60

[Table of Contents](#)**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements (Unaudited)****SCICLONE PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)**

	September 30, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 130,113	\$ 101,403
Restricted cash in escrow for SEC settlement (Note 9)	—	12,826
Accounts receivable, net of allowances of \$91 and \$594 as of September 30, 2016 and December 31, 2015, respectively	37,749	39,363
Inventories	13,751	10,976
Prepaid expenses and other current assets	2,529	3,654
Deferred tax assets	94	299
Total current assets	184,236	168,521
Property and equipment, net	1,826	2,651
Investments in third party (Note 10)	2,718	—
Goodwill	32,101	32,979
Other assets	12,480	12,468
Total assets	\$ 233,361	\$ 216,619
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 4,736	\$ 4,495
Accrued and other current liabilities	19,882	32,151
Deferred revenue	—	174
Total current liabilities	24,618	36,820
Other long-term liabilities	78	87
Commitments and contingencies (Note 9)		
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; 50,872,875 and 49,533,835 shares issued and outstanding as of September 30, 2016 and December 31, 2015, respectively	51	50
Additional paid-in capital	301,433	296,086
Accumulated other comprehensive income	1,357	2,070
Accumulated deficit	(94,176)	(118,494)
Total stockholders' equity	208,665	179,712
Total liabilities and stockholders' equity	\$ 233,361	\$ 216,619

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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenues:				
Product sales, net	\$ 39,457	\$ 41,986	\$ 112,646	\$ 112,356
Promotion services	1,087	894	3,388	2,038
Total net revenues	40,544	42,880	116,034	114,394
Operating expenses:				
Cost of product sales	5,585	6,853	17,110	17,131
Sales and marketing	13,320	15,073	40,104	39,746
Research and development	3,288	1,039	9,520	8,708
General and administrative	7,900	7,294	23,472	20,762
SEC settlement expense	—	26	—	10,826
Total operating expenses	30,093	30,285	90,206	97,173
Income from operations	10,451	12,595	25,828	17,221
Non-operating income (expense):				
Interest and investment income	270	252	792	614
Other income (expense), net	451	(281)	330	(305)
Income before provision for income tax	11,172	12,566	26,950	17,530
Provision for income tax	1,056	587	2,632	611
Net income	\$ 10,116	\$ 11,979	\$ 24,318	\$ 16,919
Basic net income per share				
Basic net income per share	\$ 0.20	\$ 0.24	\$ 0.49	\$ 0.34
Diluted net income per share				
Diluted net income per share	\$ 0.19	\$ 0.23	\$ 0.46	\$ 0.32
Weighted average shares used in computing:				
Basic net income per share	50,379	49,869	49,957	49,920
Diluted net income per share	52,595	52,126	52,482	52,344

See accompanying notes to unaudited condensed consolidated financial statements.

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

	<u>Three Months Ended</u> <u>September 30,</u>		<u>Nine Months Ended</u> <u>September 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Net income	\$ 10,116	\$ 11,979	\$ 24,318	\$ 16,919
Other comprehensive loss, net of income tax				
Foreign currency translation	(123)	(661)	(713)	(618)
Total other comprehensive loss	(123)	(661)	(713)	(618)
Total comprehensive income	<u>\$ 9,993</u>	<u>\$ 11,318</u>	<u>\$ 23,605</u>	<u>\$ 16,301</u>

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2016	2015
Operating activities:		
Net income	\$ 24,318	\$ 16,919
Adjustments to reconcile net income to net cash provided by operating activities:		
Non-cash expense related to stock-based compensation	4,576	3,437
Provision for doubtful accounts	—	541
Provision for expiring inventory	34	—
Depreciation and amortization	737	802
Loss on disposal of fixed assets	1	2
Deferred income taxes	199	12
Changes in operating assets and liabilities:		
Accounts receivable, net	1,572	(526)
Inventories	641	1,215
Prepaid expenses and other assets	686	692
Accounts payable	(2,470)	(4,076)
Accrued and other current liabilities	845	11,822
Deferred revenue	(174)	(394)
Other long-term liabilities	(8)	(80)
Net cash provided by operating activities	30,957	30,366
Investing activities:		
Investments in third party (Note 10)	(2,718)	—
Loans to third party (Note 4)	—	(7,250)
Proceeds from the sale of short-term investments	—	75
Purchases of property and equipment	(141)	(1,152)
Net cash used in investing activities	(2,859)	(8,327)
Financing activities:		
Repurchase of common stock including commissions	—	(12,811)
Proceeds related to issuances of common stock, net	610	3,696
Net cash provided by (used in) financing activities	610	(9,115)
Effect of exchange rate changes on cash and cash equivalents	2	72
Net increase in cash and cash equivalents	28,710	12,996
Cash and cash equivalents, beginning of period	101,403	86,228
Cash and cash equivalents, end of period	\$ 130,113	\$ 99,224
Supplemental disclosure of non-cash operating activities:		
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 generally accepted accounting principles in the United States (“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, 2015 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, 2015 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 judgments, assumptions and estimates that affect the amounts reported in the unaudited condensed consolidated financial statements and accompanying notes. Actual results could differ significantly 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 US 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 92% and 98% of the Company’s total net revenue for the three-month periods ended September 30, 2016 and 2015, respectively, which revenues related to the Company’s China segment. Sinopharm contributed 92% of the Company’s total net revenue for both the nine-month periods ended September 30, 2016 and 2015, which revenues related to

Table of Contents

the Company's China segment. There were no other customers that exceeded 10% of the Company's total net revenue in the periods presented.

Total ZADAXIN product sales were \$37.8 million or 93% of total net revenues, and were \$39.2 million or 91% of total net revenues, for the three months ended September 30, 2016 and 2015, respectively. Total ZADAXIN product sales were \$107.9 million or 93% of total net revenues, and were \$105.9 million or 93% of total net revenues, for the nine months ended September 30, 2016 and 2015, respectively. As of September 30, 2016, approximately \$34.8 million, or 92%, 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 were denominated in US dollars through June 30, 2016. However, the established importer price was adjusted quarterly based upon exchange rate fluctuations between the US dollar and Chinese Yuan Renminbi ("RMB"). Effective July 1, 2016, the Company's sales of ZADAXIN to Sinopharm are and will 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 and months, the RMB has experienced devaluation. Such devaluation negatively affects the US dollar value of revenues while it positively affects the US 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 December 31, 2015, the Company had a receivable reserve of \$0.5 million related to accounts receivable from one customer that was more than one year past due. During 2014, the Company's subsidiary, SciClone Pharmaceuticals International China Holding Ltd ("SPIL China") executed an agreement with this customer providing for settlement of the receivable balance, which at the time was \$1.9 million, of which \$1.0 million was paid in 2014. SPIL China collected \$0.4 million under this agreement in May 2015 and this gain on recovery was recorded as a \$0.4 million reduction to general and administrative expense for the nine-month period ended September 30, 2015. In March 2016, SPIL China collected the remaining \$0.5 million from this customer and this gain on recovery was recorded as a reduction to general and administrative expense for the first quarter of 2016. The Company recognized \$0.5 million of bad debt expense in general and administrative expense during the first quarter of 2015 related to past due receivables from another customer, due to uncertainty regarding the collectability of the customer's outstanding receivable balance. The Company wrote-off the \$0.5 million of past due accounts receivable from this customer during the fourth quarter of 2015 as uncollectible. As of September 30, 2016, the Company had a receivable reserve of \$0.1 million.

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

Table of Contents

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.

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 mechanism in the new contractual arrangement whereby the customer is invoiced at a lower base price relative to that prevailing in the previous agreement. The lower base price (as well as estimated price compensation payable due 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 upon arrival at destination. To date, there are no situations where a provincial tender price is less than the reference (baseline) tender price. The distributor 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 the distributor. It is expected that the price compensation 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 be recognized on a rolling two-to-three 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 which 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 September 30, 2016 and December 31, 2015, the Company’s revenue reserves were \$0.1 million.

Investments

As of September 30, 2016, the Company’s investment portfolio included an available-for-sale investment in the common stock of a third party (Note 10) categorized within Level 2 of the fair value hierarchy. This investment security was acquired in early September 2016. The Company records unrealized gains or losses on available-for-sale investments in other comprehensive income (loss). Realized gains and losses and declines in value judged to be other-than temporary on available-for-sale investments are included in earnings.

Available-for sale investments are evaluated for impairment each reporting period. An investment is considered impaired if the fair value of the investment is less than its cost. If after consideration of all available evidence to evaluate the realizable value of its investment, impairment is determined to be other-than-temporary, then an impairment loss is recognized in the condensed consolidated statement of operations.

Table of Contents

Inventories

Inventories consist of raw materials, work in progress and finished products. Inventories are valued at the lower of cost or market (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, including pharmaceutical products approaching their expiration dates. 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. For the three- and nine - month periods ended September 30, 2016 , the Company recorded inventory write-downs to cost of product sales of approximately \$0 and \$34,000 , respectively, related to ZADAXIN inventory expected to expire. For the three- and nine -month periods ended September 30, 2015, the Company recorded no write-downs related to inventory.

Loans Receivable

Loans receivable are due from a single third party (see Note 4). Loans are initially recorded, and continue to be carried, at unpaid principal balances under “other assets” on the unaudited condensed consolidated balance sheet. 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.

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 September 30, 2016 and December 31, 2015, 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		Nine Months Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
Numerator:				
Net income	\$ 10,116	\$ 11,979	\$ 24,318	\$ 16,919
Denominator:				
Weighted-average shares outstanding used to compute basic net income per share	50,379	49,869	49,957	49,920
Effect of dilutive securities	2,216	2,257	2,525	2,424
Weighted-average shares outstanding used to compute diluted net income per share	52,595	52,126	52,482	52,344
Basic net income per share	\$ 0.20	\$ 0.24	\$ 0.49	\$ 0.34
Diluted net income per share	\$ 0.19	\$ 0.23	\$ 0.46	\$ 0.32

Table of Contents

For the three months ended September 30, 2016 and 2015, outstanding stock options and awards for 2,394,941 and 1,514,534 shares 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 September 30, 2016 and 2015, outstanding stock options and awards for 275,000 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.

For the nine months ended September 30, 2016 and 2015, outstanding stock options and awards for 2,151,751 and 1,043,815 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 nine months ended September 30, 2016 and 2015, outstanding stock options and awards for 275,000 and 325,137 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.

Error Corrections

The Company revised its condensed consolidated statement of income for the nine months ended September 30, 2015 by reducing general and administrative expense and increasing sales and marketing expense by \$0.7 million for costs incurred related to marketing events.

The Company provided \$1.3 million of additional income tax expense, and recorded a corresponding accrual in accrued and other current liabilities, during the nine months ended September 30, 2016 to correct an error. The error corrected reflected the recognition of a previously unrecognized liability for an uncertain tax position related to the potential nondeductibility, under the People's Republic of China ("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 \$0.4 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 projected results for full year 2016 and concluded the impact is not expected to be material to the projected annual results. Accordingly, the total adjustment was recorded out-of-period in the first nine months of 2016. Management also concluded that the relevant amounts were not material to current liabilities or stockholders' equity in any prior period or the current period.

New Accounting Standards Updates

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, with early application permitted provided that the effective date is not earlier than the original effective date. The Company is in the process of determining what impact, if any, the adoption of ASU 2014-09 will have on its financial statements and related disclosures. The standard permits the use of either the full retrospective or modified retrospective transition method. The Company has not yet selected a transition method nor has it determined the effect of the standard on its ongoing financial reporting.

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

Table of Contents

are effective for annual reporting periods beginning after December 15, 2016, and interim periods within those annual periods. Earlier application is permitted as of the beginning of an interim or annual period. Additionally, the new guidance may be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. The Company has not yet selected an adoption method. The impact of adopting this guidance is not expected to be material to the consolidated financial statements given the Company's deferred tax amounts.

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 is evaluating the impact of adoption of this update on its consolidated financial statements and related disclosures.

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 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 currently plans to implement this ASU as required in the first quarter of calendar 2017. The Company does not expect that the adoption will have a material impact on its consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, "*Financial Instruments – Credit Losses (Topic 326), Measurement of Credit Losses on Financial Statements*." 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. As the likelihood of the Company experiencing one or more of the eight

[Table of Contents](#)

particular specified transactions is low, ASU 2016-15 is not expected to have a material impact on the Company's consolidated financial statements.

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 investments) measured at fair value on a recurring basis (*in thousands*):

Fair Value Measurements as of September 30, 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 September 30, 2016
Money market funds	\$ 19,693	\$ —	\$ —	\$ 19,693
Common stock investments in third party (Note 10)	—	2,718	—	2,718
Total	\$ 19,693	\$ 2,718	\$ —	\$ 22,411

Fair Value Measurements as of December 31, 2015 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, 2015
Money market funds	\$ 19,678	\$ —	\$ —	\$ 19,678
Total	\$ 19,678	\$ —	\$ —	\$ 19,678

[Table of Contents](#)

Note 3 — Inventories

Inventories consisted of the following (*in thousands*) :

	September 30, 2016	December 31, 2015
Raw materials	\$ 4,367	\$ 3,871
Work in progress	258	535
Finished goods	9,126	6,570
	<u>\$ 13,751</u>	<u>\$ 10,976</u>

Included in the Company's inventory as of September 30, 2016 and December 31, 2015 was \$3.0 million and \$3.3 million, respectively, in inventory held at distributors related to non-ZADAXIN products.

Note 4 — Loans Receivable

As part of the Company's May 2013 license and supply agreement with Zensun (Shanghai) Science & Technology Co. Ltd ("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 quarterly report on Form 10-Q for the second quarter of 2013.

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\$ 232,000 as of September 30, 2016) 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 US-dollar denominated borrowings up to \$11.75 million. As of September 30, 2016, 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 mature on September 26, 2017, with an option (granted at loan origination) exercisable by the borrower to extend for two additional years provided certain conditions are met. As of September 30, 2016, the borrower had notified the Company of its intent to exercise its option to extend the borrowings for two additional years. 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,

[Table of Contents](#)

concluded there were no indications of loan impairment as of September 30, 2016 or December 31, 2015; accordingly, there is no allowance for losses.

The two loans are included in “other assets” on the Company’s unaudited condensed consolidated balance sheet as of September 30, 2016 and December 31, 2015. Interest income on the loans amounted to \$0.2 million for both the three months ended September 30, 2016 and 2015. Interest income on the loans amounted to \$0.7 million and \$0.5 million for the nine months ended September 30, 2016 and 2015, respectively, and is included in interest and investment income in the unaudited condensed consolidated statements of income.

Note 5 — Goodwill

The following table represents the change in goodwill for the nine months ended September 30, 2016 (*in thousands*):

Balance as of December 31, 2015	\$	32,979
Translation adjustments		(878)
Balance as of September 30, 2016	\$	<u>32,101</u>

Note 6 — Accrued and Other Current Liabilities

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

	September 30, 2016	December 31, 2015
Accrued SEC settlement loss (Note 9)	\$ —	\$ 12,826
Accrued sales and marketing expenses	7,300	8,511
Accrued taxes, tax reserves and interest	5,772	4,323
Accrued compensation and benefits	3,881	4,341
Accrued professional fees	1,241	1,130
Accrued manufacturing costs	1,173	444
Other	515	576
	<u>\$ 19,882</u>	<u>\$ 32,151</u>

Note 7 — Accumulated Other Comprehensive Income (Loss)

Changes in the composition of accumulated other comprehensive income (loss) for the three and nine months ended September 30, 2016 and 2015 are as follows (*in thousands*):

Balances as of July 1, 2016	\$	1,480
Other comprehensive loss related to foreign currency translation		(123)
Balances as of September 30, 2016	\$	<u>1,357</u>
Balances as of July 1, 2015	\$	3,307
Other comprehensive loss related to foreign currency translation		(661)
Balances as of September 30, 2015	\$	<u>2,646</u>
Balances as of January 1, 2016	\$	2,070
Other comprehensive loss related to foreign currency translation		(713)
Balances as of September 30, 2016	\$	<u>1,357</u>

Table of Contents

Balances as of January 1, 2015	\$	3,264
Other comprehensive loss related to foreign currency translation		(618)
Balances as of September 30, 2015	\$	<u>2,646</u>

Note 8 — Stockholders' Equity

Stock-based Compensation

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

	<u>Three Months Ended</u> <u>September 30,</u>		<u>Nine Months Ended</u> <u>September 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Sales and marketing	\$ 286	\$ 217	\$ 728	\$ 685
Research and development	92	65	200	159
General and administrative	1,729	1,079	3,648	2,593
	<u>\$ 2,107</u>	<u>\$ 1,361</u>	<u>\$ 4,576</u>	<u>\$ 3,437</u>

Stock Options

During the nine months ended September 30, 2016, the Company granted options to purchase a total of 1,390,000 shares of common stock and options to purchase 1,630,359 shares of common stock were exercised. As of September 30, 2016, there was approximately \$ 7 . 4 million of unrecognized compensation expense, net of forfeitures, related to non-vested stock options, which is expected to be recognized over a weighted-average remaining period of approximately 2. 5 0 years.

Restricted Stock Units (RSUs)

During the nine months ended September 30, 2016, 315 ,000 RSUs were granted at a grant date fair value per share of \$ 10 . 01 and 150,500 RSUs vested. As of September 30, 2016, there was approximately \$ 4 . 3 million of unrecognized compensation cost, net of forfeitures, related to non-vested RSUs, which is expected to be recognized over a weighted-average remaining period of approximately 1.48 years.

Repurchase of Common Stock

The Company repurchased and retired 1,526,306 shares at a cost of \$12.8 million during the nine -month period ended September 30, 2015 under its share repurchase program that expired December 31, 2015.

Note 9 — Commitments and Contingencies

Legal Matters

The Company is a party to various legal proceedings and was subject to government investigations, as noted in this section below. All legal proceedings and any government investigations are subject to inherent uncertainties, unfavorable rulings or other adverse events which could occur. Unfavorable outcomes could include substantial monetary damages or awards, injunctions or other remedies, and if any of these were to occur, the possibility exists for a material adverse impact on the Company's business, results of operations, financial position, and overall trends. The Company might also conclude that settling one or more such matters is in the best interests of its stockholders and its business, and any such settlement could include substantial payments.

As previously disclosed, since 2010 the SEC and the US Department of Justice ("DOJ") had each been conducting formal investigations of the Company regarding a range of matters, including the possibility of violations of the Foreign Corrupt Practices Act ("FCPA"), primarily related to certain historical sales and marketing activities with respect to the Company's

[Table of Contents](#)

China operations. In response to these matters, the Company's Board appointed a Special Committee of independent directors (the "Special Committee") to oversee its response to the government inquiry. Based on an initial review, the Special Committee decided to undertake 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.

The Company previously recorded a charge to operating expenses in the fourth quarter of 2013 in the amount of \$ 2.0 million for the accrual of an estimated loss associated with the SEC and DOJ investigations based on the available information at the time. In the second quarter of 2015, the Company recorded an additional charge to operating expenses of \$10.8 million based on an agreement in principle reached with the SEC which had not yet been finalized at that time, bringing the accrued liability to \$12.8 million.

On October 7, 2015, the Company deposited \$12.8 million in an interest-bearing escrow account that it established related to the agreement in principle regarding a proposed settlement of FCPA-related matters with the staff of the SEC, creating a cash restriction at the time of deposit. On February 4, 2016, the Company announced that it entered into a settlement agreement with the SEC fully resolving the SEC's investigation into possible violations of the FCPA. Under the terms of the settlement agreement, in February 2016 the Company paid to the SEC a total of \$12.8 million which was released from its escrow account, including disgorgement, pre-judgment interest and a penalty as final settlement. This payment was in line with the charges the Company previously recorded and disclosed as summarized above. As part of the agreement the Company neither admitted nor denied engagement in any wrongdoing and the Company agreed to give status reports to the SEC for the next three years on its continued remediation and implementation of anti-corruption compliance measures. The DOJ has also completed its related investigation and has declined to pursue any action.

NovaMed Pharmaceuticals (Shanghai) Co. Ltd. ("NovaMed Shanghai") 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. NovaMed Shanghai filed an application for binding arbitration with the China International Economic and Trade Arbitration Commission ("CIETAC") on July 26, 2012. On April 2, 2014, CIETAC issued the final Award of the Arbitral Tribunal. The Arbitral Tribunal found that MEDA did have a right to terminate the agreement upon a change of control, but that MEDA must make reasonable reimbursement to NovaMed Shanghai before any product rights are returned to MEDA. The amount that must be paid includes \$333,333 as "unjust enrichment" plus an amount for reasonable compensation for such services provided by NovaMed Shanghai to MEDA. The amount of such payment for services was not determined by the Arbitral Tribunal, but was left to be determined by NovaMed Shanghai. On April 30, 2014, NovaMed Shanghai informed MEDA that its determination of reasonable compensation for its services was \$ 3,314,629, including the \$333,333 for unjust enrichment. MEDA made a counter offer and the parties were attempting to resolve the matter without an additional arbitration proceeding. In December 2014, NovaMed Shanghai filed a "Request for Second Arbitration" with CIETAC in order to enforce its right to compensation. The arbitration case is pending with CIETAC. On April 20, 2016, the Second Arbitral Tribunal ordered the bifurcation of the proceedings. The first stage of the proceedings will deal with the question whether NovaMed Shanghai in principle has claims against MEDA. A first oral hearing took place on July 6 and 7, 2016. The parties were originally invited to comment on the issues raised at the first hearing until October 14, 2016. Due to ongoing settlement negotiations between the parties this deadline has been extended to December 23, 2016. If one party feels the need to then respond to the other party's submission, the Second Arbitral Tribunal will at its discretion grant such opportunity to file an additional submission until February 6, 2017. The parties are further expected to file cost submissions by February 13, 2017. In parallel, the parties are in settlement discussions. The date for the next hearing has not yet been scheduled. The amount of any final payment to NovaMed Shanghai remains uncertain, and as such the Company has not recognized it as a gain contingency.

Table of Contents

Purchase Obligations

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 September 30, 2016, the Company did not have any material unmet purchase obligations.

Note 10 — Investments in Third Party

On September 9, 2016, the Company and Soligenix, Inc. (trading under ticker "SNGX D" on the OTCQB over-the-counter market) 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, including Hong Kong and Macau, as well as 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 cost of \$2.7 million representing publicly available quoted prices. As of September 30, 2016, the fair value of the Soligenix common stock investment was \$2.7 million and unrealized gains (losses) on the investment were zero. 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 will be adjusted to fair value at each reporting date with unrealized gains (losses) reported as a component of other comprehensive income (loss). The residual cash consideration of \$0.3 million related to the expanded territorial rights was recorded as research and development expense for the three- and nine-month periods ended September 30, 2016.

Note 11 — In-License Costs

For the three- and nine-month periods ended September 30, 2016, the Company recognized \$0.3 million and \$2.3 million of research and development ("R&D") expenses for upfront and milestone payments related to in-license agreements. For the three- and nine-month periods ended September 30, 2015, the Company recognized \$0 and \$5.5 million, respectively, in R&D expenses related to upfront and milestone payments for its in-license agreements, primarily with Theravance Biopharma, Inc.

Note 12 — Income Taxes

The provision for income taxes primarily relates to taxable income of the Company's China operations. The provision for income tax was \$1.1 million and \$0.6 million for the three-month periods ended September 30, 2016 and 2015, respectively. The lower tax for the three-month period ended September 30, 2015 primarily related to the restructuring of the Company's China business. The provision for income tax was \$2.6 million and \$0.6 million for the nine-month periods ended September 30, 2016 and 2015, respectively. For the nine-month period ended September 30, 2016, the Company's tax provision included

[Table of Contents](#)

\$1.3 million of additional tax expense representing the correction of an error related to a previously unrecognized liability for an uncertain tax position in China (refer also to Note 1, “**Error Corrections**”). In addition, the tax provision for the nine -month period ended September 30, 2015 was lower, compared to the nine -month period ended September 30, 2016, due to lower tax related to restructuring the Company’s China business. The Company’s statutory tax rate in China was 25% in 2016 and 2015.

The Company has concluded that its offshore undistributed accumulated earnings as of December 31, 2015 were indefinitely reinvested, and has therefore provided no taxes thereon. The Company concluded that a portion of its earnings expected to be generated by foreign subsidiaries in 2016 will be repatriated to the parent company in order to address the parent company’s liquidity needs. A dividend distribution was already made to the parent company in early 2016 and further distributions may be made. The actual repatriation year-to - date and any further anticipated repatriations, however, are not expected to result in any additional US federal or state tax liability for 2016 as ongoing tax-deductible corporate expenses already incurred and expected to be incurred by the parent company more than offset the amount of the taxable income represented by the dividend distributions. These actual amounts and expectations have been reflected in the Company’s estimated annual effective tax rate for 2016.

Note 1 3 — 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 US and Hong Kong.

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 nine -month periods ended September 30, 2016 and 2015 is as follows (*in thousands*):

[Table of Contents](#)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue:				
China	\$ 38,315	\$ 40,676	\$ 110,442	\$ 109,388
Rest of the World (including the US and Hong Kong)	2,229	2,204	5,592	5,006
Total net revenues	\$ 40,544	\$ 42,880	\$ 116,034	\$ 114,394
Income (loss) from operations:				
China	\$ 14,500	\$ 14,649	\$ 41,154	\$ 34,650
Rest of the World (including the US and Hong Kong)	(4,049)	(2,054)	(15,326)	(17,429)
Total income from operations	\$ 10,451	\$ 12,595	\$ 25,828	\$ 17,221
Non-operating income (expense), net:				
China	\$ 719	\$ (44)	\$ 1,113	\$ 288
Rest of the World (including the US and Hong Kong)	2	15	9	21
Total non-operating income (expense), net	\$ 721	\$ (29)	\$ 1,122	\$ 309
Income (loss) before provision for income tax:				
China	\$ 15,219	\$ 14,605	\$ 42,267	\$ 34,938
Rest of the World (including the US and Hong Kong)	(4,047)	(2,039)	(15,317)	(17,408)
Total income before provision for income tax	\$ 11,172	\$ 12,566	\$ 26,950	\$ 17,530

Long-lived assets as of September 30, 2016 and December 31, 2015 by operating segment are as follows (*in thousands*):

	September 30, 2016	December 31, 2015
China	\$ 47,755	\$ 46,315
Rest of the World (including the US and Hong Kong)	1,370	1,783
	\$ 49,125	\$ 48,098

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;
- government regulatory action affecting our Company or our drug products or our competitors' drug products in China, the US 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 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 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; 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 resolution of the SEC and 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;
- 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

Table of Contents

- other factors discussed in this Report under Part I, Item 2 “Management’s 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. We undertake no obligation to revise or update publicly any forward-looking statements for any reason.

Overview

SciClone Pharmaceuticals, Inc. (NASDAQ: SCLN) is a United States (“US”)-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® (thymalfasin). In addition, we have an established business model with large pharmaceutical partners to promote and sell products and we are focused on establishing profitability in all of these collaborations. We believe our sales and marketing strengths position us to benefit from the long-term expansion of the pharmaceutical market in China. According to Globe Newswire, the Chinese pharmaceutical market currently ranks second among the global pharmaceutical markets, and had an estimated worth of \$105 billion in 2014. It is forecasted to increase significantly to \$200 billion by 2020. 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.

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 US 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®, a product for the embolization of malignant hypervascularized tumors, for which we initiated sales and recorded product revenue beginning in the third quarter of 2015, and products from Pfizer International Trading (Shanghai) Ltd. (“Pfizer”). Through June 30, 2015, our product sales revenues also included Aggrastat®, an intervention cardiology product launched in China in 2009, in-licensed from Cardiome Pharma Corp (“Cardiome”). In August 2015, we and Cardiome mutually agreed to end our collaboration for Aggrastat, thereby terminating our exclusive distribution rights in China, and returning all rights to the product to Cardiome. We recorded Aggrastat revenues of \$1.8 million for the nine months ended September 30, 2015, none thereafter, and we do not expect to generate any further Aggrastat revenues. We do not anticipate that the termination of this agreement will adversely affect our profitability.

ZADAXIN has the highest margins in our portfolio as it is a premium product sold exclusively by SciClone. In addition, we anticipate that new marketed products, when and if introduced, can increase the future revenues and profitability of our pharmaceutical business in China over the coming years. Our “promotion services revenues” result from fees we receive for exclusively promoting 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. Over time, as additional proprietary or in-licensed products come to the market, we aim to shift our product mix towards those products providing higher margins for us.

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

[Table of Contents](#)

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 on September 26, 2016, we announced the first patient has been treated in the investigat or- initiated clinical trial in 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, and we believe our oncology sales team and academic marketing liaisons have established high quality relationships with medical professionals and institutions that specialize in cancer treatment, which we believe will be a valuable asset as we continue commercial sales of DC Bead. BioCompatibles UK Ltd. ("BTG") and SciClone previously entered into an agreement granting SciClone exclusive licensing and distribution rights to DC Bead in China. Under the agreement, we are purchasing DC Bead product from BTG.

We are also pursuing the registration of Loramyc[®], a mucoadhesive tablet formulation of miconazole laurid to treat oropharyngeal candidiasis.

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 are pursuing additional agreements to generate additional revenue. 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. Our objective is to in-license products that provide us with higher margins, augmenting our product sales revenue and profitability, and we continue to explore opportunities to optimize our promotion services revenues.

On September 26, 2016, we also 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 to PT-112 from Phosplatin Therapeutics for Greater China (mainland China, Hong Kong, and Macau) and Vietnam, along with option rights in South Korea and Taiwan.

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 People's Republic of China, including Hong Kong and Macau, as well as 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 Phase 2 preliminary 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 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.

Table of Contents

In May 2015, Theravance Biopharma, Inc. (“Theravance Biopharma”) granted SciClone exclusive development and commercialization rights to VIBATIV[®] (telavancin) in China, as well as the Hong Kong SAR, the Macao SAR, 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.

In December 2014, we entered into a strategic partnership with The Medicines Company for two cardiovascular products in China. The partnership includes an agreement granting us a license and the exclusive rights in China to promote two 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 for which a Phase 3 registration trial was completed in China and is currently under review by the China Food and Drug Administration for marketing approval, 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 which a clinical trial application (CTA) for China was filed in 2013. We received CTA approval from the China Food and Drug Administration (“CFDA”) in early 2016 and are preparing a clinical study. As 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 will now be working together with Chiesi and The Medicines Company to progress the Cleviprex clinical study going forward. Under the terms of the agreement, which apply to Chiesi for Cleviprex, we 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 have also agreed to participate in the China registration process for both products. Financial terms of the agreement, in addition to net sales royalties payable to The Medicines Company, include the following additional payments to The Medicines Company and 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.

Our license agreement with Taiwan Liposome Company (“TLC”) grants us a license and the exclusive rights in China to promote, market, distribute and sell ProFlow[®] for the treatment of peripheral arterial disease (“PAD”) and other indications. In November 2014, TLC was notified by the CFDA that ProFlow did not receive clinical trial approval. TLC appealed the decision and the CFDA has not rendered a final decision.

In May 2013, we entered into a framework agreement with Zensun (Shanghai) Science & Technology Co., Ltd. (“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 a New Drug Application (“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 September 30, 2016 (refer to Note 4 to the unaudited condensed consolidated financial statements appearing under Part I, Item 1 for further information regarding the Zensun loans).

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. We were able to mitigate the impact of this price limitation by shifting an equitable portion of the burden of the price reduction to our distributor in our sales channel; accordingly, the impact of the price reduction for the year ended December 31, 2015 was \$2.8 million. The impact of the 2015 tender price reduction in Zhejiang province does not require providing for estimated price compensation payable under our new contractual arrangement with Sinopharm, which took effect January 1, 2016, as the lower tender price is reflected in a

Table of Contents

lower base invoice price to our customer under the new contractual arrangement. We anticipate that provincial pricing decisions will continue to be a significant factor in the China pharmaceutical market for the foreseeable future. The impact of such decisions on our future results is unpredictable, but we expect that pricing pressures on revenue in 2016 will be offset at least in significant part 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 addition, our new contractual arrangement with Sinopharm Holding Lingyun Biopharmaceutical (Shanghai) Co. Ltd (Sinopharm), our China distributor for ZADAXIN, which commenced January 1, 2016 is resulting in the later recognition (relative to practices prevailing through December 31, 2015 under the expired prior contractual arrangement) of a portion of our revenue invoiced to Sinopharm in situations where the provincial tender price (ultimate retail end price approved by provincial authorities) is greater relative to a reference (baseline) tender price. This is due to a price adjustment mechanism in the new contractual arrangement whereby the customer is invoiced at a lower base price relative to that prevailing in the previous agreement. The lower base price (as well as estimated price compensation payable due to the distributor for situations where the provincial tender price is lower than the referenced (baseline) tender price) is recorded as revenue at the time the sale is completed upon arrival at destination. Currently, there are no provinces with lower-than-reference tender prices leading to price compensation payable. The distributor is then 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 such amount will be recognized as revenue after the amount has been agreed upon with the distributor. 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, we expect that the price compensation receivable due to us from the distributor for higher tender price provinces for a quarter will be recognized on a two-to-three quarter delayed basis relative to the originating sales quarter going forward.

As previously disclosed, since 2010 the US Securities and Exchange Commission (“SEC”) and the US Department of Justice (“DOJ”) had each been conducting formal investigations of us regarding a range of matters, including the possibility of violations of the Foreign Corrupt Practices Act (“FCPA”). On February 4, 2016, we announced that we entered into a settlement agreement with the SEC fully resolving the SEC’s investigation into possible violations of the FCPA. Under the terms of the settlement agreement, in February 2016 we paid a total of \$12.8 million, including disgorgement, pre-judgment interest and a penalty as final settlement which was released from our restricted escrow account which we funded in the fourth quarter of 2015. This payment is in line with the charges we previously recorded and disclosed in our Form 10-Q filed with the SEC on August 10, 2015. As part of the agreement we neither admitted nor denied engagement in any wrongdoing and we agreed to give status reports to the SEC for the next three years on our continued remediation and implementation of anti-corruption compliance measures. The DOJ has also completed its related investigation and has declined to pursue any action (refer to Note 9 to the unaudited condensed consolidated financial statements appearing under Part I, Item 1 and “Legal Proceedings” in Part II, Item 1 for further information regarding the SEC and DOJ investigations).

In early February 2016, we announced that our Board of Directors had initiated a process to identify, examine and consider a range of strategic alternatives available to us with a view to enhancing stockholder value and had engaged Lazard as its financial advisor to assist the Board in evaluating strategic alternatives. In July 2016, we announced that our Board is no longer continuing active discussions with potential acquirers which were undertaken as part of its strategic review process and that the Board will continue to evaluate additional strategic opportunities while continuing to focus on growing the Company’s business.

We believe our cash and cash equivalents as of September 30, 2016 and ongoing revenue generating business operations will be sufficient to support our current operating plan for at least the next 12 months. 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 changes in our product sales and promotion services revenues (in thousands):

	Three Months Ended			Nine Months Ended		
	September 30,			September 30,		
	2016	2015	Change	2016	2015	Change
Product sales, net	\$ 39,457	\$ 41,986	-6%	\$ 112,646	\$ 112,356	0%
Promotion services	1,087	894	22%	3,388	2,038	66%
Total net revenues	\$ 40,544	\$ 42,880	-5%	\$ 116,034	\$ 114,394	1%

Product sales were \$ 39.5 million for the three-month period ended September 30, 2016 compared to \$ 42.0 million for the corresponding period in 2015, a decrease of \$ 2.5 million, or 6%. ZADAXIN sales were \$ 37.8 million for the three-month period ended September 30, 2016, compared to \$39.2 million for the corresponding period of 2015, a decrease of \$ 1.4 million or 3%, which mainly related to a 12% increase in volume sold, offset by a 9% decrease in selling price related to a decrease in the list price of ZADAXIN in Zhejiang province since May 2015 and related to a lower base invoice price in our new arrangement with Sinopharm that became effective January 1, 2016 discussed below as well as a 6% unfavorable exchange rate impact. DC Bead product sales were \$0 and \$1.0 million, respectively, for the three months ended September 30, 2016 and 2015.

Product sales were \$ 112.6 million for the nine-month period ended September 30, 2016 compared to \$ 112.4 million for the corresponding period in 2015, an increase of \$ 0.3 million, or 0%. ZADAXIN sales were \$ 107.9 million for the nine-month period ended September 30, 2016, compared to \$ 105.9 million for the corresponding period of 2015, an increase of \$2.0 million or 2%, which mainly related to a 15% increase in volume sold, offset partially by a 7% decrease in selling price related to a decrease in the list price of ZADAXIN in Zhejiang province since May 2015 and related to a lower base invoice price in our new arrangement with Sinopharm that became effective January 1, 2016 discussed below as well as a 6% unfavorable exchange rate impact. DC Bead product sales were \$0 and \$1.0 million, respectively, for the nine months ended September 30, 2016 and 2015, respectively. Product sales increased \$1.0 million for the nine months ended September 30, 2016, compared to the corresponding period of 2015, related to our oncology product sales. Aggrastat® product sales were zero and \$ 1.8 million for the nine-month periods ended September 30, 2016 and 2015, respectively, due to the termination of our agreement with Cardiome as discussed below.

Our new 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 the customer is invoiced at a lower base price relative to that prevailing in the previous agreement. The lower base price (as well as estimated price compensation payable due 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 (arrived at destination). There are presently no provinces with tender prices below the reference (baseline) tender price, and therefore no price compensation payable situations. The distributor is then 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 such amount will be recognized as revenue after the amount has been agreed upon with the distributor. 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 the distributor for higher tender price provinces for amounts sold in the first quarter of 2016 was recognized in the third quarter of 2016 in the amount of \$0.2 million. We expect that the price compensation receivable due to us from the distributor for higher tender price provinces for a quarter will be recognized on a two-to-three quarter delayed basis relative to the originating sales quarter going forward.

Table of Contents

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 US dollars through June 30, 2016. However, the established importer price was adjusted quarterly based upon exchange rate fluctuations between the US 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) and will be in the future (as invoiced directly in RMB) subject to exchange rate risk. In recent months the RMB has experienced devaluation.

We anticipate that ZADAXIN revenues in 2016 will be higher than 2015, 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.

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 US 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 revenue was \$ 1.1 million and \$0.9 million for the quarters ended September 30, 2016 and 2015, respectively, an increase of \$ 0.2 million, or 22%. Promotion services revenue was \$ 3.4 million and \$2.0 million for the nine-month periods ended September 30, 2016 and 2015, respectively, an increase of \$1.4 million, or 66%. The increases related to increased sales of Endoxan™ and Holoxan™ product promoted under our agreements with Baxter.

Our Baxter promotion agreement is for a 5-year term, through December 2017. Our Pfizer product distribution agreement is for a 5-year term, through June 2019. In August 2015, we and Cardiome, from whom we licensed Aggrastat, mutually agreed to end our collaboration for Aggrastat, and we returned all rights to the product to Cardiome. We recorded Aggrastat revenues of \$1.8 million for the nine months ended September 30, 2015, and none thereafter. We do not expect to generate any further Aggrastat revenues. We do not anticipate that the termination of this agreement will adversely affect our profitability.

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, related to our China segment. Total China revenues were \$38.3 million and \$ 40.7 million, respectively, or 95% of sales, for both the three months ended September 30,

[Table of Contents](#)

2016 and 2015. Rest of the World segment revenues were \$2.2 million, or 5%, for both the three months ended September 30, 2016 and 2015, and related to sales of ZADAXIN product.

Total China revenues were \$110.4 million and \$109.4 million, or 95% and 96% of sales, respectively, for the nine months ended September 30, 2016 and 2015. Rest of the World segment revenues were \$5.6 million and \$5.0 million, or 5% and 4%, for the nine months ended September 30, 2016 and 2015, respectively, and related to sales of ZADAXIN product.

For the three months ended September 30, 2016 and 2015, sales to Sinopharm in China accounted for approximately 92% and 98% of our revenues, respectively. For both the nine-month periods ended September 30, 2016 and 2015, sales to Sinopharm in China accounted for approximately 92% of our revenues. 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 tables summarize the period over period changes in our cost of product sales (*in thousands*):

	Three Months Ended			Nine Months Ended		
	September 30,			September 30,		
	2016	2015	Change	2016	2015	Change
Cost of product sales	\$ 5,585	\$ 6,853	-19%	\$ 17,110	\$ 17,131	0%

Cost of product sales for the three months ended September 30, 2016 decreased \$1.3 million or 19%, compared to the corresponding period in 2015 mainly related to reductions in DC Bead, Methotrexate[®] and Aggrastat cost of product sales primarily related to a reduction in sales of those products. In addition, cost of product sales of ZADAXIN decreased due to manufacturing overhead volume efficiencies. Cost of product sales was \$17.1 million for both the nine-month periods ended September 30, 2016 and 2015.

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 2016 to be slightly lower than 2015, 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 tables summarize the period over period changes in our S&M expenses (*in thousands*):

	Three Months Ended			Nine Months Ended		
	September 30,			September 30,		
	2016	2015	Change	2016	2015	Change
Sales and marketing	\$ 13,320	\$ 15,073	-12%	\$ 40,104	\$ 39,746	1%

S&M expenses for the three months ended September 30, 2016 decreased by \$1.8 million, or 12%, compared to the corresponding period in 2015. The decrease in S&M expense for the three months ended September 30, 2016, compared to the corresponding period in 2015, primarily related to decreases in sales and marketing events and lower DC Bead-related launch costs. S&M expenses for the nine months ended September 30, 2016 increased by \$0.4 million, or 1%, compared to the corresponding period in 2015, related to growth in our S&M efforts for ZADAXIN.

We anticipate total S&M expenses for the year ending December 31, 2016 to be higher than those incurred for the year ended December 31, 2015 related to growth in our S&M efforts for ZADAXIN.

Table of Contents

Research and Development (“R&D”):

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

	Three Months Ended September 30.			Nine Months Ended September 30.		
	2016	2015	Change	2016	2015	Change
Research and development	\$ 3,288	\$ 1,039	216%	\$ 9,520	\$ 8,708	9%

R&D expenses for the three months ended September 30, 2016, increased \$2.2 million, or 216 %, compared to the corresponding period in 2015. For the three months ended September 30, 2016 and 2015, we recorded \$0.3 million and \$0 million, respectively, related to in-license arrangements with certain licensors and \$2.8 million and \$1.0 million, respectively, related to R&D expenses for clinical and preclinical R&D activities with certain licensors.

R&D expenses for the nine months ended September 30, 2016 increased \$0.8 million, or 9 %, compared to the corresponding period in 2015. For the nine months ended September 30, 2016 and 2015, we recorded \$2.3 million and \$5.5 million, respectively, related to in-license arrangements, and \$7.0 million and \$3.2 million, respectively, related to R&D expenses for clinical and preclinical R&D activities with certain licensors.

The major components of R&D expenses include salaries and other personnel-related expenses, including associated stock-based compensation, facility-related expenses, depreciation of facilities and equipment, license-related fees, services performed by clinical research organizations and research institutions and other outside service providers.

We anticipate our R&D expenses to increase in 2016 compared to 2015 related to potential license fee payments, milestone payments expected to occur under license arrangements, and related to research and development activities with certain licensors.

General and Administrative (“G&A”):

The following table s summarize the period over period changes in our G&A expenses (*in thousands*):

	Three Months Ended September 30.			Nine Months Ended September 30.		
	2016	2015	Change	2016	2015	Change
General and administrative	\$ 7,900	\$ 7,294	8%	\$ 23,472	\$ 20,762	13%

G&A expenses for the three-month period ended September 30, 2016 increased by \$0.6 million, or 8 %, compared to the corresponding period in 2015. Costs related to the Company’s strategic review to maximize stockholder value and stock-based compensation increased for the three-month period ended September 30, 2016, compared to the corresponding period in 2015.

G&A expenses for the nine-month period ended September 30, 2016, increased by \$2.7 million, or 13 %, compared to the corresponding period in 2015. Costs related to the Company’s strategic review to maximize stockholder value increased for the nine-month period ended September 30, 2016, compared to the corresponding period in 2015 by approximately \$2.0 million including higher legal, tax and other professional costs. In addition, during the nine months ended September 30, 2016, the Company recorded higher professional fees related to other tax matters as well as higher stock-based compensation expense, offset partially by \$0.5 million of lower bad debt expense. This bad debt expense was recorded to reserve accounts receivable from a customer that were uncertain of collection during the nine months ended September 30, 2015; this amount did not recur in the corresponding 2016 period.

We expect our G&A expenses in 2016 to increase compared to 2015 related to growth in our business and related to our strategic review. As previously announced, our Board is no longer continuing active discussions with potential acquirers which were undertaken as part of the Company’s strategic review process, and determined that at this time remaining an independent publicly traded company is the best path forward to maximize long-term value. However, the Board intends to continue to

[Table of Contents](#)

review and refine the Company's corporate strategy and evaluate new opportunities and we may continue to incur certain G&A expenses in connection with this evaluation.

SEC Settlement Expense:

We previously recorded a charge of \$2.0 million in the fourth quarter of 2013 related to the possibility of a settlement with the SEC and DOJ regarding their investigation into possible violations of the FCPA by us, and we recorded an additional charge of \$10.8 million associated with the proposed settlement with the SEC in the second quarter of 2015. In February 2016, we entered into a settlement agreement with the SEC fully resolving the SEC's investigation into possible violations of the FCPA. Under the terms of the settlement agreement, in February 2016 we paid \$12.8 million, including disgorgement, pre-judgement interest and a penalty as final settlement. As part of the agreement, we neither admitted nor denied engagement in any wrongdoing and we agreed to give status reports to the SEC for the next three years on our continued remediation and implementation of anti-corruption compliance measures. The DOJ has also completed its related investigation and has declined to pursue any actions. Refer to Part I, Item 1, Note 9 "Contingencies" and Part II, Item 1 "Legal Proceedings" for further information on this matter.

Provision for Income Tax:

The provision for income taxes primarily relates to taxable income of our China operations. The provision for income tax was \$ 1.1 million and \$0.6 million for the three-month periods ended September 30, 2016 and 2015, respectively. The lower tax for the three-month period ended September 30, 2015 related to the restructuring of the Company's China business.

The provision for income tax was \$2.6 million and \$0.6 million for the nine-month periods ended September 30, 2016 and 2015, respectively. For the nine-month period ended September 30, 2016, our tax provision included \$1.3 million of additional tax expense representing the correction of an error related to a previously unrecognized liability for an uncertain tax position in China (refer also to Note 1, "***Error Corrections***"). In addition, the tax provision for the nine-month period ended September 30, 2015 was lower, compared to the nine-month period ended September 30, 2016, due to lower tax related to restructuring our China business.

Our statutory tax rate in China was 25% in 2016 and 2015. We expect the provision for income tax to increase for the year ending December 31, 2016, compared to the year ended December 31, 2015, due to growth in our China operations and related to an uncertain tax position in China.

We have concluded that our offshore undistributed accumulated earnings as of December 31, 2015 were indefinitely reinvested, and have therefore provided no taxes thereon. We concluded that a portion of our earnings expected to be generated by foreign subsidiaries in 2016 will be repatriated to the parent company in order to address the parent company's liquidity needs. A dividend distribution in this regard already occurred in early 2016, and we may have another. This actual distribution and any future anticipated repatriations, however, are not expected to result in any additional US federal or state tax liability for 2016 as ongoing tax-deductible corporate expenses already incurred and expected to be incurred by the parent company more than offset the amount of the actual and any further expected dividend distributions. These actual and expected amounts have been reflected in our estimated annual effective tax rate for 2016.

Liquidity and Capital Resources

We 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 continue to 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 our cash flow activities as of the end of, and for each of, the periods presented (*in thousands*):

[Table of Contents](#)

	As of September 30, 2016	As of December 31, 2015
Cash and cash equivalents	\$ 130,113	\$ 101,403

As of September 30, 2016, we had \$ 130.1 million in cash and cash equivalents, of which \$ 124.2 million was located in subsidiaries of the Company outside the US. Cash and cash equivalents held by subsidiaries outside the US are held primarily in US 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 concluded that as of December 31, 2015, \$ 176.2 million of accumulated undistributed earnings of foreign subsidiaries continue to be 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 US federal and state income taxes.

Based on our current operating plan, we do not anticipate the need to repatriate undistributed earnings held by foreign subsidiaries accumulated as of December 31, 2015. We have repatriated (via a dividend distribution in early 2016) and we plan to repatriate a further portion of current year expected foreign earnings generation to fund our limited US operations. We have provided and are providing for US income taxes on the portion of current year actual and expected foreign earnings generation that we have repatriated and anticipate repatriating from our foreign subsidiaries, and our estimated annual effective tax rate for the quarter reflects both the provisions as well as benefits associated with our operations. We do not anticipate having to record any US tax liability related to the actual and any further repatriations, because US actual and forecasted corporate expenses more than offset the actual and anticipated dividend income. We plan to indefinitely reinvest outside of the US the remaining unrepatriated expected current year foreign earnings generated in 2016.

	Nine Months Ended September 30.	
	2016	2015
Cash provided by (used in):		
Operating activities	\$ 30,957	\$ 30,366
Investing activities	\$ (2,859)	\$ (8,327)
Financing activities	\$ 610	\$ (9,115)

Net cash provided by operating activities was \$ 31.0 million for the nine -months ended September 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 \$1.6 million related to payments received from customers during the nine months ended September 30, 2016. Accounts payable and accrued liabilities decreased \$1.6 million mainly related to a decrease in compensation and benefits and sales and marketing accruals for payments made during the nine months ended September 30, 2016.

Net cash provided by operating activities was \$ 30.4 million for the nine months ended September 30, 2015 and primarily reflected the net income for the period adjusted for non-cash items such as stock-based compensation expense, provision for doubtful accounts, depreciation and amortization expense and changes in operating assets and liabilities.

Net cash used in investing activities was approximately \$2.9 million and \$8.3 million for the nine months ended September 30, 2016 and 2015, respectively. As further discussed in Note 10 to the notes to the unaudited condensed consolidated financial statements, on September 9, 2016, we and Soligenix entered into an exclusive license agreement (the "License Agreement"), pursuant to which Soligenix granted rights to the Company to develop, promote, market, distribute and sell SGX942 in the People's Republic of China, including Hong Kong and Macau, as well as Taiwan, South Korea and Vietnam. In connection with the execution of the License Agreement, we entered into a common stock purchase agreement

[Table of Contents](#)

with Soligenix pursuant to which we bought 3,529,412 shares of Soligenix common stock valued at \$2.7 million as of September 30, 2016.

As part of our license and supply agreement with Zensun, we agreed to loan up to \$12 million in total to Zensun under two separate loan agreements (such lendings are further described in Note 4 to the unaudited condensed consolidated financial statements appearing under Part I, Item 1). Pursuant to these agreements, in the second half of 2014, we loaned \$4.75 million to Zensun, and in April 2015, we loaned \$7.25 million to Zensun, bringing the total amount loaned to Zensun to \$12.0 million. The proceeds of the 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 our subsidiary, SciClone Pharmaceuticals International China Holding Ltd.

For the nine months ended September 30, 2016 and 2015, we also purchased \$ 0.1 million and \$1.1 million of property and equipment, respectively.

Net cash provided by financing activities and net cash used in financing activities was \$0.6 million and \$ 9.1 million for the nine months ended September 30, 2016 and 2015, respectively. For the nine months ended September 30, 2016 and 2015, we received \$0.6 million and \$ 3.7 million, respectively, of 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 nine months ended September 30, 2015, we used \$ 12.8 million to repurchase and retire 1,526,306 shares of our common stock under our stock repurchase program that expired December 31, 2015.

The following summarizes our future obligations including uncertain tax positions as of September 30, 2016 (*in thousands*):

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Operating leases (1)	\$ 4,334	\$ 2,412	\$ 1,872	\$ 50	\$ —
Purchase obligations (2)	18,600	18,600	—	—	—
Uncertain tax positions (3)	3,878	—	—	—	—
Total	\$ 26,812	\$ 21,012	\$ 1,872	\$ 50	\$ —

- (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 upfront and milestone payments related to regulatory and commercial success and other achievements that may require substantial payments in the future.

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. 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.

Table of Contents

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. In addition, as previously disclosed, our Board intends to continue to review and refine the Company's corporate strategy and evaluate new strategic opportunities to enhance stockholder value. 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 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 preparation of our unaudited condensed consolidated financial statements and accompanying notes. Actual results could differ materially 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 the arrival of a shipment to its destination when title and risk of loss to the 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 new contractual arrangement with our China importer and distributor for ZADAXIN, Sinopharm, is resulting in the later recognition (relative to practices prevailing through December 31, 2015 under an expired older contractual arrangement) of a portion of the Company's revenue invoiced to Sinopharm related to 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 the customer is invoiced at a lower base price relative to that prevailing in the previous agreement. The lower base price (as well as estimated price compensation payable due 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 (arrived at destination). There currently are no situations involving provinces with tender prices below the reference (baseline) tender price. The distributor is then 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 such amount is recognized as revenue after the amount has been agreed upon with the distributor. We expect that price compensation receivable will be recognized in the quarters following the original sale pursuant to the price adjustment mechanism on a two or three-quarter delayed basis. For example, we recognized price compensation receivable related to sales by Sinopharm in the first quarter of 2016 in our third quarter product sales revenue.

[Table of Contents](#)

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.

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 September 30, 2016 and December 31, 2015, our revenue reserves were approximately \$0.1 million; the reserves were recorded as accrued liabilities on our unaudited condensed consolidated balance sheets.

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.

For a discussion of the Company's other significant accounting policies, please see our Annual Report on Form 10-K for the fiscal year ended December 31, 2015. There have been no material changes in our critical accounting policies, estimates and judgments for the three or nine months ended September 30, 2016 compared to the disclosures in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2015, other than (i) the changes in our revenue recognition practices for sales of ZADAXIN to Sinopharm effective from January 1, 2016 as discussed in the foregoing paragraphs under the subcaption "Product Revenue" and (ii) our adoption of accounting policies for our available-for-sale investment in a third party as discussed in Note 1 and Note 10 to our unaudited condensed consolidated financial statements appearing under Part 1, Item 1.

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 compared to the disclosure in Part II, Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2015.

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, evaluated any changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2016, and concluded that there was no change during such quarter that has

[Table of Contents](#)

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.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

As previously disclosed, since 2010 the SEC and the DOJ had each been conducting formal investigations of us regarding a range of matters, including the possibility of violations of the Foreign Corrupt Practices Act (“FCPA”), primarily related to certain historical sales and marketing activities with respect to our China operations. In response to these matters, our Board appointed a Special Committee of independent directors (the “Special Committee”) to oversee our response to the government inquiry. Based on an initial review, the Special Committee decided to undertake 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.

As previously disclosed, on February 4, 2016, we entered into a settlement agreement with the SEC that fully resolved the SEC’s investigation. Under the terms of the settlement agreement, we paid a total of \$12.8 million in February 2016, including disgorgement, pre-judgment interest and a penalty. The payment was in line with the charges we previously recorded and disclosed in our Form 10-Q filed with the SEC on August 10, 2015. As part of the agreement, we neither admitted nor denied engagement in any wrongdoing and we agreed to give status reports to the SEC for the next three years on our continued remediation and implementation of anti-corruption compliance measures. The DOJ has also completed its related investigation and has declined to pursue any action.

As previously disclosed, we have taken, and continue to take certain steps to enhance our existing anti-bribery compliance efforts, including (i) evaluating and expanding our training of employees regarding understanding of and compliance with laws including the FCPA and other anti-bribery laws and regulations, (ii) evaluating existing compliance and anti-bribery policies and guidelines and preparing new, more detailed policies and guidelines for implementation after review by our Board of Directors and/or committees of the Board of Directors, (iii) implementing a pre-approval policy for certain expenses including payments for, or reimbursement of, travel and entertainment expenses, and sponsorships of certain third-party events, (iv) establishing an automated system for recording and approving travel and entertainment expenditures, and (v) hiring a Vice President of Compliance and an Internal Audit Director to monitor and enforce compliance with our policies. Also, upon the recommendation of the Special Committee, the Audit Committee of the Board retained a third-party consultant to observe and make recommendations regarding our FCPA compliance. We will continue to emphasize the importance of compliance and ethical business conduct.

NovaMed Pharmaceuticals (Shanghai) Co. Ltd. (“NovaMed Shanghai”) was a party to a Distribution and Supply Agreement with MEDA originally entered into in 2007. Following our acquisition of NovaMed Shanghai in 2011, 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. NovaMed Shanghai filed an application for binding arbitration with the China International Economic and Trade Arbitration Commission (“CIETAC”) on July 26, 2012. On April 2, 2014, CIETAC issued the final Award of the Arbitral Tribunal. The Arbitral Tribunal found that MEDA did have a right to terminate the agreement upon a change of control, but that MEDA must make reasonable reimbursement to NovaMed Shanghai before any

Table of Contents

product rights are returned to MEDA. The amount that must be paid includes \$333,333 as “unjust enrichment” plus an amount for reasonable compensation for such services provided by NovaMed Shanghai to MEDA. The amount of such payment for services was not determined by the Arbitral Tribunal, but was left to be determined by NovaMed Shanghai. On April 30, 2014, NovaMed Shanghai informed MEDA that its determination of reasonable compensation for its services was \$3,314,629, including the \$333,333 for unjust enrichment. MEDA made a counter offer and the parties were attempting to resolve the matter without an additional arbitration proceeding. In December 2014, NovaMed Shanghai filed a “Request for Second Arbitration” with CIETAC in order to enforce its right to compensation. The arbitration case is pending with CIETAC. On April 20, 2016, the Second Arbitral Tribunal ordered the bifurcation of the proceedings. The first stage of the proceedings will deal with the question whether NovaMed Shanghai in principle has claims against MEDA. A first oral hearing took place on July 6 and 7, 2016. The parties were originally invited to comment on the issues raised at the first hearing until October 14, 2016. Due to ongoing settlement negotiations between the parties, this deadline has been extended to December 23, 2016. If one party feels the need to then respond to the other party's submission, the Second Arbitral Tribunal will at its discretion grant such opportunity to file an additional submission until February 6, 2017. The parties are further expected to file cost submissions by February 13, 2017. In parallel, the parties are in settlement discussions. The date for the next hearing has not yet been scheduled. The amount of any final payment to NovaMed Shanghai remains uncertain, and as such the Company has not recognized it as a gain contingency.

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 11, 2016.

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

Although we reported net income of \$ 24.3 million and \$16.9 million for the nine months ended September 30, 2016 and 2015, 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 \$ 94 million as of September 30, 2016. 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:

- government regulatory action affecting our Company or our drug products or our competitors' drug products in China, the US 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;
- government regulatory action intended to reduce pharmaceutical prices such as the reduction in the governmentally permitted maximum listed price for our products and increased oversight of the health care market and pharmaceutical industry;
- compliance by our employees 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;
- market perceptions of our strategic review process;
- progress and results of clinical trials and the regulatory approval process in Europe and in China;
- timing and achievement of our corporate objectives;

Table of Contents

- 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;
- announcement and completion of corporate acquisition, merger, licensing or marketing arrangements, or sales of assets;
- 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;
- changes in assessments of our internal control over financial reporting;
- 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 our strategic review, our dispute with MEDA, and arising out of matters relating to any additional or uncorrected control deficiency or related matters;
- economic and political conditions in the US or abroad, particularly in China;
- currency fluctuations between the RMB and US Dollar (“USD”) including recent RMB devaluation that has led to, and may continue to lead to, downward adjustments in our importer price if further devaluation continues;
- broad financial market fluctuations in the US, Europe or Asia; and
- more aggressive action by the government in China in changing taxation policy.

Any acquisitions we may undertake involve a number of risks, and we may not realize all the anticipated benefits of an acquisition. We may acquire other companies or products that present risks similar to those stated above.

We may enter into other company or product acquisition transactions in the future which could present integration or other risks similar to those stated above and may also cause us to:

- 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 will continue to be substantially dependent on our sales of ZADAXIN in China. *

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 nine months ended September 30, 2016 and 2015, approximately 93 % 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.

Table of Contents

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. 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.

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 due to epidemics. 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. 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.

During the third quarter of 2012, we estimated that there was a substantial increase in ZADAXIN channel inventory levels and we believe that our sales to our customers exceeded the pace at which our customers were able to sell the ZADAXIN through to other parties, primarily hospital pharmacies. As a result, ZADAXIN revenues were lower in the first half of 2013, as compared to the same period of 2014. We believe channel inventory has returned to normal levels, and we continue to believe that we will grow demand for ZADAXIN through increased penetration in the market; however, we may not be successful or we may experience future fluctuations in channel inventory either of which could adversely affect our future ZADAXIN revenue.

We could experience fluctuations in channel inventory due to actual or expected epidemics. For example, during the second quarter of 2009, we experienced a strong upsurge in ZADAXIN sales, which we believe was attributable both to the increasing penetration of ZADAXIN within the Chinese market, as well as concerns in China from the H1N1 influenza virus. If distributors and hospitals that purchase ZADAXIN stockpile more ZADAXIN than needed for current use, our subsequent sales of ZADAXIN may suffer as distributors and hospitals use ZADAXIN already in their inventory before purchasing additional product from us. This could lead to uneven future revenue results for ZADAXIN and in turn materially impact our cash flows and business condition.

The Chinese government has previously imposed price restrictions on ZADAXIN and several of our oncology 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. *

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. 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; we were able to mitigate the impact of this price limitation by sharing the burden of the price reduction with our distributor. We anticipate that provincial pricing decisions will continue to be a significant factor in the China pharmaceutical market for the foreseeable future. The impact of such decisions on our

[Table of Contents](#)

future results is unpredictable, but we expect that pricing pressures in 2016 will be offset at least in significant part through sharing of any potential further 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.

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.

While over the long term, we believe that the price reductions may positively affect our sales volumes and result in broader penetration into Tier 3 and Tier 2 cities in target geographies, potentially increasing our total sales revenues from these products, the process and timing for any price restrictions is unpredictable and further price reduction could be imposed that could adversely affect our business. In addition, our new contractual arrangement with our China distributor, Sinopharm, which commenced January 1, 2016, is resulting in the later recognition (relative to practices prevailing through December 31, 2015 under the expired older contractual arrangement) 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 the customer is invoiced at a lower base price relative to that prevailing in the previous agreement. The lower base price (as well as estimated price compensation payable due 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 (arrived at destination). Currently, there are no situations involving provinces with tender prices lower than the reference (baseline) tender price. The distributor is then 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 such amount is recognized as revenue after the amount has been agreed upon with the distributor. 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.

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.

Our business strategy is dependent in part on our agreements with third parties for the rights to develop and commercialize products, or promote products, particularly in China. We have experienced challenges in maintaining some of our agreements and if we fail to enter into additional agreements, our business will suffer. *

Our sales and marketing strategy in China depends significantly on agreements with third parties, and potentially on entering into additional agreements with third parties, or renegotiating agreements with third parties. Except for ZADAXIN, our rights to develop, market and sell our products in China, 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 DC Bead, a product which we launched commercially in the third quarter of 2015, and 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. If

[Table of Contents](#)

any of these agreements are terminated, or if they are not renewed, our ability to distribute, or develop, the products or product candidates could be terminated and our business could be affected.

All of our products were originally obtained by us under licenses, promotion, distribution or similar third-party agreements. We do not conduct product discovery and our ability to bring new products to market is dependent upon our entering into additional acquisition, in-licensing, promotion or distribution agreements, particularly in China. The competition for attractive products is intense, and we cannot be certain that we will be able to negotiate in-license, promotion or distribution agreements for additional products in the future.

While in June 2013 we renewed our promotion agreement with Baxter for a 5-year term through December 2017 and in July 2014 we renewed our product distribution agreement with Pfizer for a 5-year term through June 2019, our promotion agreements with Sanofi Aventis S.A. (“Sanofi”) were not renewed and expired on December 31, 2013. In addition, in August 2015, we and Cardiome mutually agreed to end our collaboration for Aggrastat, and return all rights to the product to Cardiome. We continue to assess the financial performance of the products we promote 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. Terminations or failures to renew these or any other agreement as to some or all of the products covered by the agreement could result in a decline in revenue and in other costs including restructuring charges if a resulting revenue decline required us to reduce costs. On the other hand, if we are successful in negotiating better terms there may be a positive impact on our revenues and profitability.

If our products do not meet standards established by the Chinese Pharmacopoeia, we could lose our license to import products to China for commercial sale, which could negatively affect our revenues and operating results .

Our products are subject to standards established by the Chinese Pharmacopoeia, or ChP. 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. The ChP is revised from time to time, with the most recent revisions set forth in a 2015 edition. If our products fail to meet ChP specifications during routine customs testing as such specifications may be revised from time to time, our Import Drug Licenses (IDLs), 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.

Our revenue will continue to be substantially dependent on our maintaining regulatory licenses and compliance with other country-specific regulations. *

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. Our IDL to import ZADAXIN into China 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 IDL 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.

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 IDL from the CFDA permitting the importation of ZADAXIN into China.

Our ability to obtain a renewal of our IDL 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 regarding ZADAXIN to CFDA.

Table of Contents

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. We have initiated planning and work related to the China IDL renewal and expect to be able to obtain a renewal, as we have in the past. However, if we are unable to renew our IDL, we would not be able to continue to import ZADAXIN into China and we would not be able to continue sales in China once our inventory in China had been sold.

Our resolution with government agencies in connection with violations by us of the US Foreign Corrupt Practices Act could have a material adverse effect on our business, results of operations and financial condition. *

As previously disclosed, since 2010 the SEC and the DOJ had each been conducting formal investigations of us regarding a range of matters, including possible violations of the FCPA, primarily related to certain historical sales and marketing activities with respect to our China operations. In response to these matters, our Board appointed the Special Committee to oversee our response to the government inquiry. Based on an initial review, the Special Committee decided to undertake 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.

On February 4, 2016, we announced that we entered into a settlement agreement with the SEC fully resolving the SEC's investigation into possible violations of the FCPA and that the DOJ had also completed its related investigation and has declined to pursue any action. Under the terms of the settlement agreement with the SEC, SciClone paid a total of \$12.8 million, including disgorgement, pre-judgment interest and a penalty. The payment was in line with the charges the Company previously recorded and disclosed in its Form 10-Q filed with the SEC on August 10, 2015. As part of the agreement, we neither admitted nor denied engagement in any wrongdoing and we agreed to give status reports to the SEC for the next three years on our continued remediation and implementation of anti-corruption compliance measures.

While we have resolved the previously pending matters with the SEC and DOJ whether by virtue of announcement of the settlement agreement and the SEC Order or otherwise, we may be subject to investigations by foreign governments or further claims by third parties arising from conduct subject to the investigation or our other international operations. In addition, the remedial actions we have taken or may take as a result of such investigations may adversely affect our business in China and other countries, including adversely affecting our ability to obtain license renewals or other administrative approvals we require to conduct business in China and other countries.

Despite the resolution of the SEC and DOJ matters, we may be subject to additional investigations or regulatory actions in the future.

Despite the settlement of our SEC and DOJ matters, we may be subject to additional investigations in the future. We are unable to predict what ultimate consequences any investigation by any regulatory or law enforcement agency may have on us. Regulatory investigations that might be initiated in the future could result in substantial expenses, management diversion of attention, and harm to our business. If we fail to comply with regulations or to carry out controls on our Chinese or other foreign operations in a manner that satisfies all applicable laws, our business would be harmed. Any civil or criminal action commenced against us by a regulatory or law enforcement agency, including in China, could result in administrative orders against us, the imposition of significant penalties and/or fines against us, and/or the imposition of civil or criminal sanctions against certain of our officers, directors and/or employees.

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 US-based corporation doing business in China, these controls often need to

Table of Contents

satisfy the requirements of Chinese law as well as the requirements of US 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, during the third quarter of 2012, our management determined that we had a material weakness in internal control over financial reporting related to the design and operation of our controls primarily associated with product returns reserves and the override of certain controls in the financial statement close process related to our NovaMed Pharmaceuticals, Inc. (“NovaMed”) subsidiary. Furthermore, during the fourth quarter of 2012, our management determined that we had an additional indicator of the same material weakness related to the timing of revenue recognition for our Pfizer products and the override of related controls at our NovaMed subsidiary, and the corporate monitoring thereof. During fiscal 2014, we designed and implemented procedures to address the material weakness disclosed in our Annual Reports on Form 10-K for the years ended December 31, 2013 and 2012 related to the design and operating effectiveness of certain corporate monitoring controls. Management designed and implemented corporate monitoring controls and other controls that provided increased oversight over our China operations, and remediated the material weakness 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.

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, including the Sarbanes-Oxley Act of 2002, new SEC regulations and The NASDAQ Stock Market rules, 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.

There can be no assurance that our review of strategic opportunities will result in pursuing or completing a particular transaction. *

In early February 2016, we announced that our Board of Directors had initiated a process to identify, examine and consider a range of strategic alternatives available to us with a view to enhancing stockholder value and had engaged Lazard as its financial advisor to assist the Board in evaluating strategic alternatives. In July 2016, we announced that our Board is no longer continuing active discussions with potential acquirers which were undertaken as part of its strategic review process and that the Board will continue to evaluate additional strategic opportunities while continuing to focus on growing the Company's business. This announcement had adverse effects on our stock price, and may have adverse effects on our customer relationships and retention of key employees. In addition, there can be no assurance that the evaluation of potential strategic opportunities will result in either pursuing any different strategic operational approach or completing any particular transaction. We also may not accurately assess the risks and uncertainties associated with engaging or not engaging in a strategic opportunity, and the anticipated benefits from pursuing any such opportunity may not materialize. In addition, undertaking a strategic process could divert management's time and focus from operating our business, potentially having adverse effects on our existing business relationships and our key employees.

We may not be able to effectively manage our employees and distribution network, and our reputation, business, prospects and brand may be materially and adversely affected by actions taken by our distributors and third-party marketing firms.

Table of Contents

Our company policies prohibit our employees from making improper payments to hospitals or otherwise engaging in improper activities to influence the procurement decisions of hospitals, and we take remedial actions, including termination, when employees do not adhere to our policies. However, we may not be able to effectively ensure that every employee complies at all times with our policies. The compensation of our sales and marketing personnel is partially linked to their sales performance. Although we have made numerous changes to ensure compliance with our policies and to attempt to avoid any violation of law, we cannot assure you that employees will not violate the anticorruption laws of China, the US and other countries. Such violations, or allegations of such violations, could have a material adverse effect on our reputation, business, prospects and brand.

Furthermore, we have identified from time to time certain instances of improperly submitted expense reporting by our employees. Our employees may seek to create additional opportunities to engage in misappropriation or other employee malfeasance. If our controls and procedures to prevent such activities fail or are circumvented, our business would be negatively affected by, among other things, the related financial losses, diminished reputation and threat of litigation and regulatory inquiry and investigation.

We do not control, and therefore have limited ability to manage, the activities of third-parties who assist us in marketing and distributing our products. Our distributors or other third parties with whom we do business could take actions which violate the anti-corruption laws of China, the US or other countries. Failure to adequately manage our employees, and third parties and, or their non-compliance with employment, distribution or marketing agreements, could harm our corporate image among hospitals and end users of our products and disrupt our sales, resulting in a failure to meet our sales goals. Furthermore, we could be liable for actions taken by our employees, distributors or third-party marketing or third-party firms, including any violations of applicable law in connection with the marketing or sale of our products, including China's anticorruption laws and the FCPA of the US. In particular, if our employees, distributors or third-party marketing firms make any payments that are forbidden under China's anticorruption laws or the FCPA, we could be subject to civil and criminal penalties imposed by the Chinese or US government.

Recently, the Chinese government has increased its anti-corruption measures. In the pharmaceutical industry, corrupt practices include, among others, acceptance of kickbacks, bribes or other illegal gains or benefits by the hospitals and medical practitioners from pharmaceutical manufacturers and distributors in connection with the prescription of certain pharmaceuticals. Our employees, affiliates, distributors or third-party marketing firms may violate these laws or otherwise engage in illegal practices with respect to their sales or marketing of our products or other activities involving our products. If our employees, affiliates, distributors or third-party marketing firms violate these laws, or are alleged to have violated these laws, we could be required to pay damages or fines, be subject to administrative actions or suffer additional consequences which could materially and adversely affect our ability to conduct business in China and our financial condition. In addition, Chinese laws regarding what types of payments to promote or sell our products are impermissible are not always clear, and local regulatory authorities enforcing these laws are not always consistent. As a result, we, our employees, affiliates, our distributors or third-party marketing firms could make certain payments in connection with the promotion or sale of our products or other activities involving our products which at the time are considered by us or them to be legal but are later deemed impermissible by the Chinese government, or we may be asked to make payments by local government authorities that may not be permissible under China's anticorruption laws or the FCPA. Furthermore, our brand and reputation, our sales activities or the price of our common stock could be adversely affected if we become the target of any negative publicity as a result of actions taken by our employees, affiliates, distributors or third-party marketing firms.

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

[Table of Contents](#)

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 US, including our independent registered public accounting firm, must be registered with the PCAOB, and are required by the laws of the US to undergo regular inspections by the PCAOB to assess their compliance with the laws of the US 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 US-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 US 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, US-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 US.

Our compliance with the Foreign Corrupt Practices Act may put us at a competitive disadvantage, while our failure to comply with the Foreign Corrupt Practices Act may result in substantial penalties.

As a US reporting company, we are required to comply with the FCPA. If our employees or other agents are found to have engaged in practices in violation of the FCPA, we could suffer severe penalties. Non-US companies, including some of our competitors, are not subject to the provisions of the FCPA. Corruption, extortion, bribery, pay-offs, theft and other fraudulent practices occur from time to time in mainland China. If our competitors engage in these practices, they may receive

[Table of Contents](#)

preferential treatment from personnel of some companies, giving our competitors an advantage in securing business or from government officials who might give them priority in their business dealings, which would put us at a disadvantage.

Retaliation from terminated employees may damage our reputation or lead to claims that could subject us to further regulatory action.

From time to time we have terminated the employment of certain employees for performance-related reasons, including, in particular, our policies intended to prevent corruption. Employees who are terminated may seek more favorable terms of separation by threatening to damage our reputation in the marketplace. Further, they may seek to retaliate against us by making so-called “whistleblower” claims under the provisions enacted by the Dodd-Frank Act that may entitle persons who report alleged wrong-doing to the SEC to cash rewards. We anticipate that these provisions will result in a significant increase in whistleblower claims across our industry, and dealing with such claims could generate significant expenses and take up significant management time, even for frivolous and non-meritorious claims. Any investigations of whistleblower claims may impose additional expense on us, may require the attention of senior management and members of the Board of Directors and may result in fines, adverse administrative sanctions or rulings and/or reputational damage whether or not we are deemed to have violated any regulations. Furthermore, terminated employees may also seek to retaliate against us by making claims against us to other regulatory agencies, including local regulatory authorities. Inquiries by local regulatory agencies about such claims, even if frivolous and non-meritorious, could also generate significant expenses and take up significant management and Board of Directors’ time.

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, we recorded \$0.5 million of bad debt expense in general and administrative expense for the first quarter of 2015 related to one customer whose accounts receivable were uncertain of collection, and subsequently wrote off the bad debt in the fourth quarter of 2015. In addition, we recorded \$2.4 million to bad debt expense for the year ended December 31, 2013 related to one customer whose accounts receivable were significantly past due and for which collectability was uncertain at that time. We subsequently collected \$1.5 million of these receivables in fiscal 2014, a further \$0.4 million in the second quarter of 2015, and the final \$0.5 million in the first quarter of 2016. We recorded charges of \$2.1 million during the year ended December 31, 2014 for potential inventory obsolescence related to Aggrastat. 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 products under development in China, some of which were acquired in the NovaMed acquisition and others which were in-licensed by us. In recent years, we have in-licensed several additional product candidates for each of which our future development expenses and milestone payments could be material.

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. For example, in March 2012, we announced the discontinuation of our phase 2b clinical trial evaluating SCV-07 for the delayed onset of oral mucositis. This decision was based on the results of a pre-planned interim analysis that indicated that the trial would not meet the pre-specified efficacy endpoints, and we have no plans to proceed with further development of SCV-07 at this time.

The regulatory approval processes in the US, 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. In addition, the Chinese government is increasing its efforts to reduce overall health care costs, including pricing controls on pharmaceutical products. We cannot determine what the potential government pricing constraints are likely to be for products in development in advance. Therefore, we may be required to abandon the development or commercialization of a product after significant effort and expense if we determine at any time that trends in government pricing constraints will make the commercialization of a product unprofitable.

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 face significant technological risks inherent in developing these products. We may also abandon some or all of our proposed products before they become commercially viable. 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. Failure to do any of the above will lead to an unfavorable outcome on the results of our operations.

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. In addition to the risks relating to pricing previously discussed above, these risks also include changes in economic conditions (including wage and cost inflation,

Table of Contents

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.

In addition to the risk relating to pricing regulations and other risks related to operating in China, as discussed above, 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. Operations in foreign countries including China also expose us to risks relating to difficulties in enforcing our proprietary rights, currency fluctuations and adverse or deteriorating economic conditions. If we experience problems with these matters, or if significant regulatory limitations are imposed on our ability to terminate employees and on the related costs, political, economic or regulatory changes occur, our results could be adversely affected. For example, during the third quarter of 2014, we wrote-off \$1.1 million of \$3.5 million in fully reserved accounts receivable related to one customer in China, and subsequently collected the remaining \$2.4 million.

Our operations throughout the world including China are potentially subject to the laws and regulations of the US including the FCPA, in addition to the laws and regulations of the other countries. Regulation in China of the activities in the pharmaceutical industry has increased and may continue to undergo significant and unanticipated changes. A number of companies have faced significant expenses or fines as a result of the increasing regulation of, and enforcement activity regarding, the pharmaceutical industry. The Chinese government has recently made arrests of pharmaceutical company employees for allegedly illegal sales and marketing activities. Recent or future arrests of sales personnel, doctors or others in the pharmaceutical industry, whether or not the individuals violated laws or regulations, could impact the operations and results of pharmaceutical companies in China, including our own. The Chinese government has also been investigating the costs to manufacture approximately 40 pharmaceutical products sold in China. While SciClone was not involved in either of these actions, these actions may be an indication of heightened Chinese government oversight of the pharmaceutical industry, and of multinational pharmaceutical companies in particular. Such activities could have long-term implications for the pharmaceutical industry in China including increased pricing pressure and a heightened level of government oversight and investigations, either of which could adversely affect the industry as a whole or individual companies, including SciClone.

Our business is sensitive to the economy in China. A downturn in the Chinese economy could materially and adversely affect our revenues and results of operations.

Any slowdown in China's economic development might lead to tighter credit markets, increased market volatility, sudden drops in business and consumer confidence and dramatic changes in business and consumer behaviors. Economic growth rates in China are slowing and there has been significant volatility in the stock indexes within China. The Chinese government is believed to take an active role in influencing stock indexes and in many other areas, but there is no assurance that growth rates will not continue to decline. Slowing growth in China, stock market volatility and uncertainty in economic conditions, may cause a decline in sales of ZADAXIN or negatively impact our other products. A decline in demand for our products in China could materially and adversely affect our revenues and results of operations.

[Table of Contents](#)

The Company could be subject to changes in its tax rates, the adoption of new US 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 US, and a substantial portion of our assets, including employees, are located outside the US. US income taxes and foreign withholding taxes have not been provided on certain undistributed earnings of non-US subsidiaries, because such earnings are intended to be indefinitely reinvested in the operations of those subsidiaries. The US government may propose initiatives that would substantially reduce our ability to defer US taxes including: repealing deferral of US 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 US. If any of these proposals are constituted into legislation, they could increase our US income tax liability and as a result have a negative impact on our financial position and results of operations.

Chinese healthcare regulation and the Chinese market are changing rapidly and we may modify our strategy in response to those changes and we cannot assure you that we will be successful in implementing changes.

The Chinese healthcare and regulatory environment have changed and are likely to continue to change in response to Chinese government policies and other factors. We intend to evaluate and make modifications to our strategy in response to these changes. We intend to continue our strategies of growing business in China by expanding ZADAXIN sales, entering into new promotional agreements, and seeking of products that have been approved outside China, but we may implement additional strategies, including expanding our capabilities in China to develop earlier stage products in-licensed from third parties in China or elsewhere. If we make significant additions or changes to our strategy, we may not be successful in implementing such changes, or the Chinese market may change in unexpected directions to which we are not able to respond timely.

We may lose market share or otherwise fail to compete effectively in the intensely competitive pharmaceutical industry.

Competition in the pharmaceutical industry in China is intense, and we believe that competition will increase. Our success depends on our ability to compete in this industry, but we cannot assure you that we will be able to successfully compete with our competitors. Increased competitive pressure could lead to intensified price-based competition resulting in lower prices and margins, which would hurt our operating results. We cannot assure you that we will compete successfully against our competitors or that our competitors, or potential competitors, will not develop drugs or other treatments for our targeted indications that will be superior to ours.

We depend on sales to China, and global conditions could negatively affect our operating results or limit our ability to expand our operations in and outside of China. Changes in China's political, social, regulatory and economic environment may affect our financial performance.

Our business is concentrated in China. Heightened tensions resulting from the current geopolitical conditions in the Middle East, North Korea and elsewhere could worsen, causing disruptions in foreign trade, which would harm our sales. In particular, our commercial product is manufactured in Europe and distributed by us from our operations in Hong Kong. Any disruption of our supply and distribution activities due to geopolitical conditions could decrease our sales and harm our operating results. In addition, while we continue our efforts to expand our operations in and outside of China, disruptions in our marketing or distribution efforts could delay or limit our ability to expand. We have had distributors with whom our accounts receivable collectability has become uncertain where, in addition to the charges that may result from the collectability of the accounts receivable, we may experience delays in our efforts to expand our operations and lose business to our competitors from any resulting disruption.

With respect to China, our financial performance may be affected by changes in China's political, social, regulatory and economic environment. The role of the Chinese central and local governments in the Chinese economy is significant. Chinese policies toward economic liberalization, and laws and policies affecting foreign companies, currency exchange rates and other

[Table of Contents](#)

matters could change, resulting in greater restrictions on our ability to do business in China. Any imposition of surcharges or any increase in Chinese tax rates could hurt our operating results. The Chinese government could revoke, terminate or suspend our license for national security and similar reasons or in the event our employees, affiliates, distributors or third-party marketing firms violate Chinese anticorruption laws, or are alleged to have violated these laws, without compensation to us. If the government of China were to take any of these actions, we would be prevented from conducting all or part of our business. Any failure on our part to comply with governmental regulations could result in the loss of our ability to market our products in China.

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 NovaMed's 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. 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 our products, 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 our products. 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 product labeling to implement industry-leading labeling technology and implementation of product tracking applications. However we cannot eliminate counterfeiting and, 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. *

The majority of our sales through June 30, 2016 were in US 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 US dollars. However, the established importer price could be adjusted quarterly based upon exchange rate fluctuations between the US 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). In recent months the RMB has experienced devaluation exposing us to increased foreign exchange risk and our revenues were adversely impacted by those fluctuations in the three and nine month periods ended September 30, 2016.

Our purchases with contract manufacturers are denominated in US 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 US dollar vis-à-vis the local currency would tend to have an adverse effect on sales and potentially on collection of accounts receivable. 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 US 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 US dollar and US interest rates. A weaker US dollar would increase our in-country China operating expenses. We are subject to currency exchange rate fluctuations as a result of expenses incurred by our foreign operations. In particular, one of our supply arrangements under which we purchase finished products is denominated in euros and costs of our operations in China are paid in local currency. Consequently, 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, such as DC Bead, to the market in China, 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.

[Table of Contents](#)

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. The Chinese government reviews reimbursement decisions periodically and we believe that a review is in process and will be concluded in late 2016 or early 2017. 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. If we experience a problem with the manufacturer or our suppliers, our sales may suffer. We have experienced difficulties with obtaining product from manufacturers in the past. 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. Manufacturing interruptions or failure or delay of product to meet quality assurance specifications could adversely affect shipments and recognition of sales of our products in any period and impair our relationships with customers and our competitive position and may increase the cost of material produced. In addition, each of the products that are marketed through our NovaMed Shanghai subsidiary is manufactured by, or obtained from, a single source.

We also rely on third parties, who are subject to regulatory oversight, to supply drug product. For example, ONXEO (formerly BioAlliance) is the sole supplier of Loramyc . Any unanticipated deficiencies in this supplier, or the suppliers of our raw materials, and/or recall of the manufacturing lots could also impede commercialization of our products and impair our competitive position. In addition, any unanticipated deficiencies in suppliers used in our clinical trials could delay the trials or detract from the integrity of the trial data and its potential use in future regulatory filings. In addition, manufacturing interruptions or failure to comply with regulatory requirements by any of these suppliers could significantly delay clinical development of potential products and reduce third-party or clinical researcher interest and support of proposed trials.

[Table of Contents](#)

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 of our products 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 contract research organizations, medical institutions, clinical investigators, contract laboratories, and collaborative partners in the conduct of clinical trials for our product candidates. If these parties, whom we do not control, do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines or choose not to continue their relationship with us, if the third parties need to be replaced, or if the quality or accuracy of the data they obtain 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 may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize our product candidates.

Commercialization of some of our products depends on collaborations with others. If our collaborators are not successful, or if we are unable to find future collaborators, we may not be able to properly develop and commercialize our products.

We depend in part on our distributors and business partners to develop or promote our drugs, and if they are not successful in their efforts or fail to do so, our business will suffer. We generally do not have control over the amount and timing of resources that our business partners devote to our collaborative efforts, and some have not always performed as or when expected. If they do not perform their obligations as we expect, particularly obligations regarding clinical trials, our development expenses would increase and the development or sale of our products could be limited or delayed, which could hurt our business and cause our stock price to decline. In addition, our relationships with these companies may not be successful. Disputes may arise with our collaborators, including disputes over ownership rights to intellectual property, know-how or technologies developed with our collaborators. We may not be able to negotiate similar additional arrangements in the future to develop and commercialize ZADAXIN or other products.

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 for China 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.

Table of Contents

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.

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. For example, we reduced the size of our sales force as a result of the expiration of our agreement with Sanofi at the end of 2013. In addition, we have taken corrective measures based on the findings of our Special Committee relating to its investigation of matters relating to the FCPA and have taken, and expect to continue to take, corrective measures relating to managements' evaluation of internal control over financial reporting which could have adverse effects on our business, including the loss of personnel, and changes in marketing, sales and educational practices or programs. 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. 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. For example, on March 16, 2007, the Chinese government passed a unified enterprise income tax law which became effective on January 1, 2008. Among other things, the law cancels many income tax incentives previously applicable to one of our subsidiaries in China. The law provides a transition rule which increased the tax rate of one of our subsidiaries in China over a 5-year period to 25% by 2012. The law also increased the standard withholding rate on earnings distributions to between 5% and 10% depending on the residence of the shareholder. The ultimate effect of these and other changes in Chinese tax laws on our overall tax rate will be affected by, among other things, our China income, the manner in which China interprets, implements and applies the new tax provisions, and by our ability to qualify for any exceptions or new incentives.

[Table of Contents](#)

In addition, the Company and its subsidiaries are regularly subject to tax return audits and examinations by various taxing jurisdictions, particularly in the US 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.

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 US 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, US 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

Table of Contents

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 US 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.

Substantial sales of our stock or the exercise or conversion of options may impact the market price of our common stock.

While we do not have any plans to issue common stock other than with respect to equity compensation, 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 investments 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, with turmoil in the credit markets, 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.

Table of Contents

If our common stock investment in Soligenix were to permanently lose value, 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, 2015. We plan to repatriate, and have repatriated year-to-date, a portion of actual and expected current year foreign earnings generated or to be generated to fund our US operations. We have provided and are providing for US income taxes on a portion of current year foreign earnings that we have repatriated and anticipate repatriating from our foreign subsidiaries, and our estimated annual effective tax rate for the quarter reflects both the provisions as well as benefits associated with our operations. We plan to indefinitely reinvest outside of the US the remaining unrepatriated current year foreign earnings generated and expected to be generated in 2016.

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 September 30, 2016. 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 US 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 US 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

[Table of Contents](#)

is subject to limitation and if we are profitable, our future cash flows could be adversely affected due to an increased tax liability.

Anti-takeover provisions in our charter documents and under Delaware law may make an acquisition of us, which may be beneficial to our stockholders, more difficult.

Certain anti-takeover provisions of Delaware law and our charter documents as currently in effect may make a change in control of our company more difficult, even if a change in control would be beneficial to our stockholders. Our charter documents contain certain anti-takeover provisions, including provisions in our certificate of incorporation providing that stockholders may not cumulate votes, stockholders' meetings may be called by stockholders only if they hold 25% or more of our common stock and provisions in our bylaws providing that the stockholders may not take action by written consent. Additionally, our Board of Directors has the authority to issue 10 million shares of preferred stock and to determine the terms of those shares of stock without any further action by the stockholders. The rights of holders of our common stock are subject to the rights of the holders of any preferred stock that may be issued. The issuance of preferred stock could make it more difficult for a third-party to acquire a majority of our outstanding voting stock. Delaware law also prohibits corporations from engaging in a business combination with any holders of 15% or more of their capital stock until the holder has held the stock for three years unless, among other possibilities, the Board of Directors approves the transaction. Our Board of Directors may use these provisions to prevent changes in the management and control of our company. Also, on December 18, 2006, our Board of Directors declared a dividend distribution of one Preferred Stock Purchase Right (collectively, the "Rights") for each outstanding share of our Common Stock, each Right which entitles the registered holder to purchase from the Company one one-thousandth of a share of the Company's Series D Preferred Stock, \$0.001 par value, at a price of \$25.00 pursuant to a Rights Agreement dated as of December 19, 2006, between the Company and Mellon Investor Services LLC, that expires December 19, 2016. The Rights have certain anti-takeover effects. Under certain circumstances the Rights could cause substantial dilution to a person or group who attempts to acquire the Company on terms not approved by our Board of Directors. Although the Rights should not interfere with an acquisition of the Company approved by the Board, the Rights may have the effect of delaying and perhaps improving the terms of an acquisition for our stockholders, or deterring an acquisition of the Company. Also, under applicable Delaware law, our Board of Directors may adopt additional anti-takeover measures in the future.

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.

[Table of Contents](#)

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 US, 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.

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.

[Table of Contents](#)

Item 6. Exhibits

<u>Exhibit Number</u>	<u>Description</u>
31.1 ⁽¹⁾	Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2 ⁽¹⁾	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1 ⁽²⁾	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2 ⁽²⁾	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101 ⁽¹⁾	The following materials from Registrant's Quarterly Report on Form 10-Q for the three- and nine -months ended September 30, 2016, formatted in Extensible Business Reporting Language (XBRL) includes: (i) Unaudited Condensed Consolidated Balance Sheets as of September 30, 2016 and December 31, 2015, (ii) Unaudited Condensed Consolidated Statements of Income for the three- and nine -months ended September 30, 2016 and 2015, (iii) Unaudited Condensed Consolidated Statements of Comprehensive Income for the three- and nine -months ended September 30, 2016 and 2015, (iv) Unaudited Condensed Consolidated Statements of Cash Flows for the nine -months ended September 30, 2016 and 2015, and (v) Notes to Unaudited Condensed Consolidated Financial Statements.

* Certain information in this exhibit has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request under 17 C.F.R. Sections 200.80(b)(4), 200.83 and 230.46.

(1) Filed herewith.

(2) Furnished herewith.

INDEX TO EXHIBITS

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* Certain information in this exhibit has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request under 17 C.F.R. Sections 200.80(b)(4), 200.83 and 230.46.

- (1) Filed herewith.
- (2) 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: November 9, 2016

/s/ Friedhelm Blobel, Ph.D.

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

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: November 9, 2016

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

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: November 9, 2016

/s/ Friedhelm Blobel, Ph.D.

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.

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: November 9, 2016

/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.
