UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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 June 30, 2017

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38112

ATHENEX, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**43-1985966**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1001 Main Street, Suite 600 Buffalo, NY	**14203**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code:
(716) 427-2950

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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒ (Do not check if a small reporting company)	Small reporting company	☐

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

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

As of August 9, 2017, the registrant had 57,063,609 shares of common stock, $0.001 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements.

ATHENEX, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(unaudited)
(In thousands, except share and per share data)

	June 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 55,150	$ 33,125
Short-term investments	30,150	8,628
Accounts receivable, net of chargebacks, allowance for doubtful accounts, and other deductions of $1,860 and $155, respectively	3,783	2,777
Inventories, net	9,260	4,240
Prepaid expenses and other current assets	3,978	3,153
Total current assets	102,321	51,923
Property and equipment, net	8,321	5,810
Goodwill	37,600	37,552
Intangible assets, net	9,242	8,464
Other long-term assets	330	2,141
Total assets	$ 157,814	$ 105,890
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 7,315	$ 7,174
Accrued expenses	17,886	18,956
Current portion of long-term debt - related parties	1,064	1,123
Current portion of long-term debt	832	766
Total current liabilities	27,097	28,019
Long-term liabilities:		
Deferred compensation	2,052	2,174
Deferred rent	1,328	904
Deferred income tax liability	98	206
Capital lease obligation	191	-
Long-term debt - related parties	-	496
Convertible bonds	5,042	14,498
Convertible bonds - related parties	-	16,129
Derivative liability	1,632	8,795
Total liabilities	37,440	71,221
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Common stock, par value $0.001 per share, 250,000,000 shares authorized at June 30, 2017 and December 31, 2016; 58,736,529 and 42,342,706 shares issued at June 30, 2017 and December 31, 2016, respectively; 57,063,609 and 40,685,786 shares outstanding at June 30, 2017 and December 31, 2016, respectively	59	42
Additional paid-in capital	402,267	237,581
Accumulated other comprehensive loss	(658)	(1,304)
Accumulated deficit	(274,719)	(195,106)
Less: treasury stock, at cost; 1,672,920 and 1,656,920 shares at June 30, 2017 and December 31, 2016, respectively	(7,406)	(7,406)
Total Athenex, Inc. stockholders' equity	119,543	33,807
Non-controlling interests	831	862
Total stockholders' equity	120,374	34,669
Total liabilities and stockholders' equity	$ 157,814	$ 105,890

The accompanying notes are an integral part of these condensed consolidated financial statements.

ATHENEX, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(In thousands, except share and per share data)

	Three months ended June 30,		Six months ended June 30,	
	2017	2016	2017	2016
Revenue:				
Product sales, net	$ 4,416	$ 4,820	$ 8,316	$ 9,308
License fees and consulting revenue	98	71	696	166
Grant revenue	81	302	164	348
Total revenue	4,595	5,193	9,176	9,822
Costs and operating expenses:				
Cost of product sales	4,137	4,834	6,976	8,976
Research and development expenses	17,597	8,645	44,005	15,391
Selling, general, and administrative expenses	13,632	4,567	23,431	8,904
Total costs and operating expenses	35,366	18,046	74,412	33,271
Operating loss	(30,771)	(12,853)	(65,236)	(23,449)
Interest expense	3,281	49	5,657	3
Unrealized loss on derivative liability	4,587	-	8,863	-
Loss before income tax expense (benefit)	(38,639)	(12,902)	(79,756)	(23,452)
Income tax expense (benefit)	29	(403)	(63)	(303)
Net loss	(38,668)	(12,499)	(79,693)	(23,149)
Less: net loss attributable to non-controlling interests	(43)	(78)	(80)	(110)
Net loss attributable to Athenex, Inc.	$ (38,625)	$ (12,421)	$ (79,613)	$ (23,039)
Unrealized (loss) gain on investment, net of income taxes	(37)	67	(34)	63
Foreign currency translation adjustment, net of income taxes	181	(393)	680	(427)
Comprehensive loss	$ (38,481)	$ (12,747)	$ (78,967)	$ (23,403)
Net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted	$ (0.88)	$ (0.31)	$ (1.89)	$ (0.59)
Weighted-average shares used in computing net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted	43,741,096	39,775,112	42,208,612	39,321,739

The accompanying notes are an integral part of these condensed consolidated financial statements.

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ATHENEX, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Stockholders' Equity
(unaudited)
(In thousands, except share data)

	Common Stock		Additional paid-in	Accumulated	Accumulated other comprehensive	Treasury Stock		Total Athenex, Inc.	Non-controlling	Total stockholders'
	Shares	Amount	capital	deficit	loss	Shares	Amount	stockholders' equity	interests	equity
Balance at December 31, 2015	40,330,124	$ 40	$ 206,679	$ (107,391)	$ (223)	(422,328)	$ (1,545)	$ 97,560	$ 484	$ 98,044
Issuance of common stock	1,133,332	1	8,499	-	-	-	-	8,500	-	8,500
Issuance of common stock in connection with satisfaction of contingent consideration	315,810	1	2,842	-	-	-	-	2,843	-	2,843
Stock-based compensation cost	-	-	3,877	-	-	-	-	3,877	-	3,877
Restricted stock expense	-	-	2,166	-	-	-	-	2,166	-	2,166
Repurchase of common stock, at cost	-	-	-	-	-	(246,200)	(2,216)	(2,216)	-	(2,216)
Stock options exercised	5,440	-	14	-	-	-	-	14	-	14
Non-controlling interests	-	-	-	-	-	-	-	-	519	519
Net loss	-	-	-	(23,039)	-	-	-	(23,039)	(110)	(23,149)
Other comprehensive loss, net of tax	-	-	-	-	(364)	-	-	(364)	-	(364)
Balance at June, 2016 (unaudited)	41,784,706	$ 42	$ 224,077	$ (130,430)	$ (587)	(668,528)	$ (3,761)	$ 89,341	$ 893	$ 90,234

	Common Stock		Additional paid-in	Accumulated	Accumulated other comprehensive	Treasury Stock		Total Athenex, Inc.	Non-controlling	Total stockholders'
	Shares	Amount	capital	deficit	loss	Shares	Amount	stockholders' equity	interests	equity
Balance at December 31, 2016	42,342,706	$ 42	$ 237,581	$ (195,106)	$ (1,304)	(1,656,920)	$ (7,406)	$ 33,807	$ 862	$ 34,669
Sale of common stock, net of costs and discounts of $11,706	6,900,000	7	64,187	-	-	-	-	64,194	-	64,194
Conversion of bonds	7,727,273	8	84,992	-	-	-	-	85,000	-	85,000
Stock-based compensation cost	400,000	-	7,740	-	-	-	-	7,740	-	7,740
Research and development licensing fee satisfied with stock	568,182	1	6,249	-	-	-	-	6,250	-	6,250
Vesting of restricted stock	391,982	1	1,079	-	-	-	-	1,080	-	1,080
Stock options and warrants exercised	406,386	-	439	-	-	-	-	439	-	439
Repurchase of common stock	-	-	-	-	-	(16,000)	-	-	-	-
Non-controlling interests	-	-	-	-	-	-	-	-	49	49
Net loss	-	-	-	(79,613)	-	-	-	(79,613)	(80)	(79,693)
Other comprehensive income, net of tax	-	-	-	-	646	-	-	646	-	646
Balance at June 30, 2017 (unaudited)	58,736,529	$ 59	$ 402,267	$ (274,719)	$ (658)	(1,672,920)	$ (7,406)	$ 119,543	$ 831	$ 120,374

The accompanying notes are an integral part of these condensed consolidated financial statements.

ATHENEX, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows
(unaudited)
(In thousands)

	Six months ended June 30,	
	2017	**2016**
Cash flows from operating activities:		
Net loss	$ (79,693)	$ (23,149)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,664	752
Stock-based compensation expense	8,820	6,043
Change in fair value of contingent consideration	-	53
Change in fair value of derivative liability	8,863	-
Amortization of debt discount	3,040	-
Deferred rent expense	424	-
Loss on disposal of assets	80	-
Research and development license fees settled with convertible bond and stock	13,250	-
Interest incurred on converted bonds	3,350	-
Deferred income taxes	(108)	(435)
Changes in operating assets and liabilities, net of effects of acquisitions:		
Receivables, net	(1,006)	32
Prepaid expenses and other assets	(824)	193
Inventories, net	(5,020)	(1,081)
Accounts payable and accrued expenses	(1,643)	(2,457)
Net cash used in operating activities	(48,803)	(20,049)
Cash flows from investing activities:		
Purchase of property and equipment	(3,442)	(506)
Payment of refundable deposit	-	1,000
Payments for licenses	(1,550)	-
Purchases of short-term investments	(33,202)	(7,750)
Sale of short-term investments	11,657	6,900
Net cash used in investing activities	(26,537)	(356)
Cash flows from financing activities:		
Proceeds from sale of stock	75,900	8,500
Proceeds from issuance of convertible bonds	30,000	-
Costs incurred related to the sale of stock	(9,044)	-
Proceeds from exercise of stock options	439	14
Investment from non-controlling interest	49	519
Payment of contingent consideration	-	(3,100)
Repayment of long-term debt	(553)	(536)
Purchase of treasury stock	-	(2,216)
Net cash provided by financing activities	96,791	3,181
Net increase (decrease) in cash and cash equivalents	21,451	(17,224)
Cash and cash equivalents, beginning of period	33,125	43,495
Effect of exchange rate changes on cash and cash equivalents	574	(131)
Cash and cash equivalents, end of period	$ 55,150	$ 26,140
Non-cash investing and financing activities:		
Stock issued in connection with the acquisition of QuaDPharma	$ -	$ 343
Stock issued in connection with the acquisition of Polymed	$ -	$ 2,500
Accrued purchases of property and equipment	$ 80	$ 76
Cost of equity raise in accounts payable and accrued expenses	$ 1,124	$ -
Convertible bond issued in lieu of licensing cash payment	$ 7,000	$ -
Common stock issued in lieu of licensing cash payment	$ 6,250	$ -
Common stock issued upon the conversion of bonds	$ 85,000	$ -
Property and equipment financed under capital lease	$ 234	$ -

The accompanying notes are an integral part of these condensed consolidated financial statements.

1. Company and Nature of Business

Organization and Description of Business

Athenex, Inc. (the "Company" or "Athenex"), originally under the name Kinex Pharmaceuticals LLC ("Kinex"), formed in November 2003, commenced operations on February 5, 2004, and operated as a limited liability company until it was incorporated in the State of Delaware under the name Kinex Pharmaceuticals, Inc. on December 31, 2012. The Company changed its name to Athenex, Inc. on August 26, 2015.

Athenex is a global biopharmaceutical company dedicated to the discovery, development and commercialization of novel therapies for the treatment of cancer. The Company's mission is to improve the lives of cancer patients by creating more effective, safer and tolerable treatments. The Company has generated its clinical product candidates through its Orascovery and Src Kinase Inhibition research platforms, which are based on its understanding of human absorption biology and novel approaches to inhibiting kinase activity, respectively. The Company has assembled a leadership team and has established operations in the U.S. and China across the pharmaceutical value chain to execute its mission to become a global leader in bringing innovative cancer treatments to the market and improving health outcomes. The Company's primary activities since commencement have been conducting research and development internally and through corporate collaborators, in-licensing and out-licensing pharmaceutical compounds and technology, and conducting clinical trials.

Significant Risks and Uncertainties

The Company has incurred operating losses since its inception and, as a result, as of December 31, 2016 and June 30, 2017 had an accumulated deficit of $195.1 million and $274.7 million, respectively. Operations have been funded primarily through the sale of common stock and convertible bonds and, to a lesser extent, through revenue generated from our Global Supply Chain Platform and Commercial Platform. The Company will require significant additional funds in order to conduct clinical trials and to fund its operations. There can be no assurances, however, that additional funding will be available on favorable terms, or at all. If adequate funds are not available, the Company may be required to delay, modify, or terminate its research and development programs or reduce its planned commercialization efforts. The Company believes that it will be able to obtain additional working capital through equity financings or other arrangements to fund operations; however, there can be no assurance that such additional financing, if available, can be obtained on terms acceptable to the Company. If the Company is unable to obtain such additional financing, the Company will need to reevaluate future operating plans. Accordingly, there is substantial doubt regarding the Company's ability to continue as a going concern.

These consolidated financial statements have been prepared on a going concern basis, which implies the Company will continue to realize its assets and discharge its liabilities in the normal course of the business. The Company's recurring losses from operations and negative cash flows from operations have raised substantial doubt regarding its ability to continue as a going concern. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Athenex is subject to a number of risks similar to other biopharmaceutical companies, including, but not limited to, the lack of available capital, possible failure of preclinical testing or clinical trials, inability to obtain marketing approval of product candidates, competitors developing new technological innovations, market acceptance of the Company's products, and protection of proprietary technology. If the Company does not successfully commercialize or partner any of its product candidates, it will be unable to generate sufficient product revenue to achieve profitability.

Initial Public Offering

On June 13, 2017, the Company's Registration Statement on Form S-1 (File No. 333-217928) relating to the initial public offering ("IPO") of its common stock was declared effective by the Securities and Exchange Commission ("SEC"). Pursuant to such Registration Statement, the Company sold an aggregate of 6,900,000 shares of its common stock at a price of $11.00 per share for cash proceeds of $64.2 million, net of underwriting discounts and commissions of $6.1 million and offering costs of $5.6 million.

On June 14, 2017, the day of the IPO, convertible bonds with an aggregate principal value of $68.0 million, and a carrying value of $55.8 million, were converted into 7,727,273 shares of common stock. The IPO closed on June 19, 2017.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted in the United States of America for interim financial information (Accounting Standards Codification ("ASC") 270, *Interim Reporting*) and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, these financial statements do not include all of the information necessary for a full presentation of financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America ("GAAP"). In the opinion of management, the condensed consolidated financial statements reflect all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the results of the Company for the periods presented. These condensed consolidated financial statements reflect the accounts and operations of the Company and those of its subsidiaries in which the Company has a controlling financial interest. Intercompany transactions and balances have been fully eliminated in consolidation.

Results of the operations for the three and six months ended June 30, 2017 are not necessarily indicative of the results expected for the full fiscal year or for any future annual or interim period. These financial statements should be read in conjunction with the consolidated financial statements and related footnotes included in the Company's Form S-1 covering the years ended December 31, 2015 and 2016.

The Company's accounting policies have not changed materially from those included in the Company's Form S-1 covering the years ended December 31, 2015 and 2016, unless described herein.

Use of Estimates

These condensed consolidated financial statements have been prepared in conformity with GAAP. The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the condensed consolidated financial statements and the reported amount of revenue and expenses during the reporting period. Such management estimates include those relating to assumptions used in contract research accruals, measurement of acquired assets and assumed liabilities in business combinations, allowance for doubtful accounts, inventory reserves, the valuation of derivative liability, income taxes, the estimated useful life and recoverability of long-lived assets, and the valuation of stock-based awards. Actual results could differ from those estimates.

Revenue Recognition

Product Sales, Chargebacks, Returns, and Discounts

The Company recognizes product revenue when there is persuasive evidence of an arrangement, the price is fixed or determinable, collectability is reasonably assured, and upon shipment to or delivery and acceptance by customers. Service revenue is recognized in the period such services have been rendered.

The Company's specialty products sold through its Commercial Platform are distributed through independent pharmaceutical wholesalers. The wholesalers then generally sell to an end user, normally a hospital, alternative healthcare facility, or an independent pharmacy, at a lower price previously established by the end user and the Company. Sales are initially recorded at the list price sold to the wholesaler. Because these prices will be reduced for the end user, the Company records a contra-asset and reduction to revenue at the time of the sale, using the difference between the list price and the estimated end-user contract price. Upon the sale by the wholesaler to the end user, the wholesaler will chargeback the difference between the original list price and price at which the product was sold to the end user and such chargeback is offset against the initial estimated contra asset. The Company reviews the chargebacks to ensure that the initial list-price sales less the estimated chargebacks are accurate. As of June 30, 2017, the Company's chargeback accrual totaled $1.5 million.

The Company offers cash discounts, which approximate 2% of the gross sales price as an incentive for prompt customer payment, and, consistent with industry practice, the Company's return policy permits customers to return products within a window of time before and after the expiration of product dating, most often 2% of gross purchases. The Company expects that its wholesale customers will make timely payments and take advantage of the cash discounts, and expects customers to use their right of return. Therefore, at the time of sale, net revenue and accounts receivable are reduced by the full amount of the discount offered and the return expected. The Company considers payment performance and historical return rates and adjusts the accrual to reflect actual experience. As of June 30, 2017, the Company's accrual for cash discounts and return accrual were not material to the financial statements.

Concentration of Credit Risk, Other Risks and Uncertainties

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents and investments. Cash equivalents are deposited in interest-bearing money market accounts and certificates of deposit. Although the Company deposits the cash with multiple financial institutions, cash balances may occasionally be in excess of the amounts insured by the Federal Deposit Insurance Corporation. The Company also has significant assets and liabilities held in its overseas manufacturing facility in China, Taihao, and therefore is subject to foreign currency fluctuation. Also, due to government restrictions on transferring funds out of China, the total restricted net assets of the Company's consolidated subsidiaries was $15.3 and $15.7 million as of June 30, 2017 and December 31, 2016, respectively.

Recent Accounting Pronouncements Not Yet Adopted

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update ("ASU") No. 2014-09, "*Revenue from Contracts with Customers (Topic 606)*", which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The new standard will be effective for the Company on January 1, 2018. The standard permits the use of either the retrospective or cumulative effect transition method. The Company's evaluation of the effects of ASU 2014-09 and the selection of a transition method is ongoing and not yet complete. The Company anticipates that the standard may impact the accounting related to its out-license agreements, however, such agreements are not currently significant to the consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, "*Leases (Topic 842)*" which requires that lessees distinguish between finance and operating leases and recognize the assets and liabilities that arise from the leases on the balance sheet. This ASU is required to be adopted retrospectively and is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, and is required to be applied on a modified retrospective basis. The Company is evaluating the effect of this standard on its consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, "*Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*," which modifies the measurement of expected credit losses of certain financial instruments. ASU 2016-13 is required to be adopted retrospectively and is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. The Company is evaluating the effect of this standard on its consolidated financial statements.

In November 2016, the FASB issued ASU 2016-18, "*Statement of Cash Flows (Topic 230): Restricted Cash*." The primary purpose of this ASU is to reduce the diversity in practice that exists in the classification and presentation of changes in restricted cash on the statement of cash flows. This ASU will require that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. This ASU is effective for fiscal years beginning after December 15, 2017. This ASU is required to be applied retrospectively. Early adoption is permitted, including adoption in an interim period. The Company is evaluating the effect of this standard on its consolidated financial statements.

Recently Adopted Accounting Pronouncements

In July 2015, the FASB issued ASU No. 2015-11, "*Inventory (Topic 330): Simplifying the Measurement of Inventory*." This ASU requires inventory to be measured at the lower of cost or net realizable value. The provisions of this ASU are effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. The amendment is required to be applied prospectively. The Company adopted ASU 2015-11 effective January 1, 2017. Adoption of ASU 2015-11 did not have a significant impact on the consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, "*Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*" which simplifies the accounting for share-based payment award transactions including: income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. Effective January 1, 2017, the Company adopted ASU 2016-09. The standard eliminated the requirement to defer recognition of excess tax benefits related to employee share-based awards until they are realized through a reduction to income taxes payable. The Company applied the modified retrospective method and there was no net cumulative effect adjustment to retained earnings on January 1, 2017 as the increase in deferred income tax assets for previously unrecognized excess tax benefits was fully offset by a valuation allowance. As permitted by the ASU, the Company will continue to use an estimated forfeiture rate in determining stock-based compensation expense.

In August 2016, the FASB issued ASU No. 2016-15, "*Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*," which addresses the classification of certain cash transactions on the statement of cash flows. ASU 2016-15 is effective for fiscal years beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2019. The Company early adopted ASU 2016-15 as of January 1, 2016 and applied its provisions retrospectively through the earliest period presented, which did not have a significant impact on its consolidated financial statements.

In January 2017, the FASB issued ASU 201704, "*Intangibles—Goodwill and Other (Topic 350) Simplifying the Test for Goodwill Impairment*." The primary purpose of the ASU is to simplify the subsequent measurement of goodwill by eliminating Step 2 from the goodwill impairment test. The ASU also applies the same test of goodwill to all reporting units, now including those with a zero or negative carrying amount of net assets. This ASU is required to be adopted on a prospective basis and is effective for any goodwill impairment tests in fiscal years beginning after December 15, 2019, although early adoption is permitted for any impairment tests performed after January 1, 2017. The Company has adopted the new guidance on a prospective basis during the first quarter of 2017. The adoption of this ASU has not impacted the Company's consolidated financial statements.

3. Inventories, net

Inventories, net, consist of the following (in thousands):

	June 30, 2017	December 31, 2016
Raw materials and purchased parts	$ 776	$ 977
Work in progress	3,792	2,727
Finished goods	4,692	536
Total inventories, net	$ 9,260	$ 4,240

4. Intangible Assets, net

Intangible Assets, Net

The Company's identifiable intangible assets, net, consist of the following (in thousands):

	December 31, 2016			
	Cost/Fair Value	Accumulated Amortization	Impairments	Net
Amortizable intangible assets:				
Licenses	$ 3,100	$ 315	$ -	$ 2,785
QuaDPharma customer list	204	58	146	-
Polymed customer list	1,593	414	-	1,179
Polymed technology	3,712	437	-	3,275
Indefinite-lived intangible assets:				
CDE in-process research and development (IPR&D)	1,884	-	248	1,636
Effect of currency translation adjustment	(411)	-	-	(411)
Total intangible assets, net	$ 10,082	$ 1,224	$ 394	$ 8,464

	June 30, 2017 (unaudited)			
	Cost/Fair Value	Accumulated Amortization	Impairments	Net
Amortizable intangible assets:				
Licenses	$ 4,650	$ 731	$ -	$ 3,919
QuaDPharma customer list	-	-	-	-
Polymed customer list	1,593	545	-	1,048
Polymed technology	3,712	583	-	3,129
Indefinite-lived intangible assets:				-
CDE in-process research and development (IPR&D)	1,636	66	80	1,490
Effect of currency translation adjustment	(405)	(61)	-	(344)
Total intangible assets, net	$ 11,186	$ 1,864	$ 80	$ 9,242

As of December 31, 2016, licenses at cost include an Orascovery license of $0.4 million and a license purchased from Gland Pharma Ltd ("Gland") of $2.7 million. The Orascovery license with Hanmi Pharmaceuticals Co. Ltd. ("Hanmi") was purchased directly from Hanmi and is being amortized on a straight-line basis over a period of 12.75 years, the remaining life of the license agreement at the time of purchase. The license purchased from Gland is being amortized on a straight-line basis over a period of 5 years, the remaining life of the license agreement at the time of purchase. During the six months ended June 30, 2017, the Company purchased additional licenses from Gland for $1.6 million which are being amortized over a period of 5 years.

The remaining intangible assets were acquired in connection with the acquisitions of Athenex Pharma Solutions (formerly referred to as QuaDPharma), Polymed, and CDE. Intangible assets are amortized using an economic consumption model over their useful lives. The Athenex Pharma Solutions customer list was being amortized on a straight-line basis over 7 years. The Polymed customer list and technology are amortized on a straight-line basis over 6 and 12 years, respectively. The CDE in-process research and development, or IPR&D, will not be amortized until the related projects are completed. IPR&D will be tested annually for impairment, unless conditions exist causing an earlier impairment test (i.e. abandonment of project). During the six months ended June 30, 2017, the Company abandoned a project within IPR&D and therefore, the related balance of $0.1 million was written-off as impaired and is included within research and development expenses in the condensed consolidated statement of operations and comprehensive loss for the six months ended June 30, 2017. The weighted-average useful life for all intangible assets was 7.87 years as of June 30, 2017.

The Company recorded $0.4 million and $0.1 million of amortization expense for the three months ended June 30, 2017 and 2016, respectively, and $0.8 million and $0.3 million of amortization expense for the six months ended June 30, 2017 and 2016, respectively.

5. Fair Value Measurements

Financial instruments consist of cash and cash equivalents, short-term investments, an equity investment, accounts receivable, accounts payable, accrued liabilities, and debt. Short-term investments, the equity investment, and the embedded derivative liability are stated at fair value. Cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities, and debt, are stated at their carrying value, which approximates fair value due to the short time to the expected receipt or payment date of such amounts.

ASC 820, Fair Value Measurements, establishes a framework for measuring fair value. That framework provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurements) and the lowest priority to unobservable inputs (level 3 measurements). The three levels of the fair value hierarchy under the ASC 820 are described as follows:

Level 1—Inputs to the valuation methodology are unadjusted quoted prices for identical assets or liabilities inactive markets that the plan has the ability to access.

Level 2—Inputs to the valuation methodology include:

- Quoted prices for similar assets or liabilities in active markets;
- Quoted prices for identical or similar assets or liabilities in inactive markets;
- Inputs other than quoted prices that are observable for the asset or liability;
- Inputs that are derived principally from or corroborated by observable market data by correlation or other means; and
- If the asset or liability has a specified (contractual) term, the level 2 input must be observable for substantially the full term of the asset or liability.

Level 3—Inputs to the valuation methodology are unobservable, supported by little or no market activity, and that are significant to the fair value measurement.

Transfers between levels, if any, are recorded as of the beginning of the reporting period in which the transfer occurs; there were no transfers between Levels 1, 2 or 3 for any of the periods presented.

The following tables represent the fair value hierarchy for those assets and liabilities that the Company measures at fair value on a recurring basis (in thousands):

	Fair Value Measurements at December 31, 2016 Using:			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds	$ 6,522	$ 6,522	$ -	$ -
Short-term investments - certificates of deposit	8,628	8,628	-	-
Investment	340	340	-	-
Total assets	$ 15,490	$ 15,490	$ -	$ -
Liabilities:				
Derivative liability	$ 8,795	$ -	$ -	$ 8,795
Total liabilities	$ 8,795	$ -	$ -	$ 8,795

	Fair Value Measurements at June 30, 2017 (unaudited) Using:			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds	$ 22,169	$ 22,169	$ -	$ -
Short-term investments - commercial paper	19,945	-	19,945	-
Short-term investments - corporate notes	10,017	-	10,017	-
Short-term investments - U.S. government bonds	17,177	-	17,177	-
Investment	330	330	-	-
Total assets	$ 69,638	$ 22,499	$ 47,139	$ -
Liabilities:				
Derivative liability	$ 1,632	$ -	$ -	$ 1,632
Total liabilities	$ 1,632	$ -	$ -	$ 1,632

The Company classifies its certificates of deposit and money market funds within Level 1 because it uses quoted market prices to determine their fair value. The Company classifies its commercial paper, corporate notes, and U.S. government bonds within Level 2 because it uses quoted prices for identical or similar assets or liabilities in inactive markets and each has a specified term and all level 2 inputs are observable for substantially the full term of each instrument.

The Company owns 68,000 shares of PharmaEssentia, a company publicly traded on the Taiwan OTC Exchange ("TWO"). As of June 30, 2017 and December 31, 2016, the Company's investment in PharmaEssentia is valued at the closing price reported on the TWO. This investment is classified as a level 1 investment.

The Company bifurcated the embedded derivative feature from its convertible bonds and recorded such as a long-term liability. The derivative liability was measured at fair value as of the issuance date and remeasured at fair value at the end of the reporting period. The liability is measured at fair value using level 3 inputs. The derivative liability is discussed further in Note 7—*Debt*.

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 financial instruments (in thousands):

	Derivative Liability
Balance as of December 31, 2016	$ 8,795
Issuance of convertible bonds with embedded derivative	13,172
Change in fair value	8,863
Conversion of derivative liability to common stock	(29,198)
Balance as of June 30, 2017 (unaudited)	$ 1,632

6. Income Taxes

The Company did not record a provision for federal income taxes for the six months ended June 30, 2017 because it expects to generate a loss for the year ending December 31, 2017 and the Company's net deferred tax assets continue to be offset by a full valuation allowance. Tax benefit to date relates to foreign tax benefit on losses in the Peoples Republic of China ("PRC") offset by state franchise taxes and amortization of long-lived intangible assets in the U.S. and PRC.

7. Debt

As of June 30, 2017 and December 31, 2016, the balances of this debt are as follows (in thousands):

	June 30, 2017	December 31, 2016
	(unaudited)	
Current portion of promissory notes to related parties	$ 1,064	$ 1,123
Current portion of mortgage	789	766
Current portion of capital lease obligation	43	-
Long-term portion of promissory notes to related parties	-	496
Long-term portion of capital lease obligation	191	-
Convertible bonds	5,042	14,498
Convertible bonds - related parties	-	16,129
Derivative liability	1,632	8,795
Total	$ 8,761	$ 41,807

The promissory notes have a 36-month term beginning on July 1, 2015 and ending on June 1, 2018 with a 6% stated interest rate. The mortgage payments extend through July 30, 2017. Future minimum principal payments on these promissory notes and mortgage consist of $1.4 million and $0.5 million due in the remaining six months in 2017 and 2018, respectively.

In 2016 and 2017, the Company issued convertible bonds with an aggregate principal value of $75.0 million and a maturity date of October 1, 2018. Of the convertible bonds issued, an aggregate principal of $24.0 million were issued to related parties. On June 14, 2017, the IPO date, $68.0 million of these bonds, which had a carrying value of $55.8 million, were converted into 7,727,273 shares of common stock.

In March 2017, the Company signed an amendment to its license agreement with Hanmi, under which the Company received the rights to develop and sell drugs under the Orascovery program in additional territories, including Japan. This license amendment required an upfront fee of $7.0 million payable to Hanmi upon the execution of the agreement. In lieu of the payment, the Company issued a convertible bond to Hanmi with a par value of $7.0 million. This bond carries an interest rate of 10% per annum and a maturity date of October 1, 2018. Hanmi has the option to convert the bond to shares of common stock at discounted rates from 20% to 22% at various dates up to the maturity date. This amendment includes additional regulatory milestone payments and royalties based on sales. The occurrence of any milestone triggering events have not been deemed to be probable and no sales have yet occurred. Hanmi did not elect to convert this bond into common stock on the IPO date.

8. Related Party Transactions

During the three and six months ended June 30, 2017 and 2016, the Company entered into transactions with individuals and other companies that have financial interests in the Company. Related party transactions included the following:

a. The Company sold 2,520,000 shares of restricted stock to the executives of the Company: 1,200,000 in 2015 and 1,320,000 in 2014. To fund these stock purchases, the executives signed promissory notes in the amount of $6.6 million in 2015 and $6.0 million in 2014. The notes in 2015 purchased 1,200,000 shares at $5.50 share and the notes in 2014 purchased 1,320,000 shares at $4.55 per share. In an effort to retain the executives, it was negotiated that, based on the continued employment of those executives, the Company will forgive the notes over a three year period. Accordingly, the restricted shares vest and become non-restricted equally over the three-year period. The Company has accounted for this related party transaction as a restricted stock offering, recognizing as an expense the value of the vested shares and the forgiveness of the notes over the three-year period, contingent on the continued employment of the executive. The notes are reported as a reduction to additional paid-in capital. The Company accelerated the forgiveness of these promissory notes in 2016 and forgave the notes in full. The stock-based compensation expense recognized from these transactions was $0 and $1.0 million, for the three months ended June 30, 2017 and 2016, respectively, and $0 and $2.1 million for the six months ended June 30, 2017 and 2016, respectively.

b. In 2015, CDE signed an agreement with Avalon BioMedical (Management) ("Avalon") under which Avalon will receive certain administrative services and will occupy space at CDE's research location. Avalon reimburses CDE for these administrative services as incurred and pays CDE 30% of the total rent payment for the Hong Kong research and development facility (See Note 13—*Commitments and Contingencies*). Certain members of the Company's board and management collectively have a controlling interest in Avalon. The Company does not hold any interest in Avalon and does not have any obligations to absorb losses or any rights to receive benefits from Avalon. As of June 30, 2017 and December 31, 2016, Avalon held 678,880 shares of the Company's common stock, which represents 1.2% and 1.7%, respectively of the Company's total issued shares. Balances due from Avalon recorded on the condensed consolidated balance sheets were not significant.

c. The Company receives consulting and licensing revenue from PharmaEssentia, a company in which Athenex has an investment classified as available-for-sale (see Note 5—*Fair Value Measurements*). Revenue recorded from PharmaEssentia amounted to $0 for both the three months ended June 30, 2017 and 2016, and $0.5 million and $0 for the six months ended June 30, 2017 and 2016, respectively.

d. The Company purchases certain pharmaceutical ingredients from Chongqing Taisheng Biotechnology Co., Ltd. ("Taisheng"), a company which is owned by a member of Athenex's management. Purchases from Taisheng amounted to $0 for both the three months ended June 30, 2017 and 2016, and $0, and $0.2 million for the six months ended June 30, 2017 and 2016, respectively. Amounts owed to Taisheng were $0 as of June 30, 2017 and December 31, 2016.

e. The Company receives certain clinical development services from ZenRx Limited and subsidiaries ("ZenRx"), a company for which one of our executive officers serves on the board of directors. In connection with such services, the Company made payments to ZenRx of $0.1 million and less than $0.1 million during the three months ended June 30, 2017 and 2016, respectively, and $0.2 million and less than $0.1 million during the six months ended June 30, 2017 and 2016, respectively. As of June 30, 2017 and December 31, 2016, amounts owed to ZenRx were less than $0.1 million and $0.1 million, respectively. In April 2013, the Company entered into a license agreement with ZenRx pursuant to which the Company granted an exclusive, sublicensable license to use certain of our intellectual property to develop and commercialize Oratecan and Oraxol in Australia and New Zealand, and a non-exclusive license to manufacture a certain compound, but only for use in Oratecan and Oraxol. ZenRx is responsible for all development, manufacturing and commercialization, and the related costs and expenses, of any product candidates resulting from the agreement. No revenue was earned from this license agreement in the periods presented in these condensed consolidated financial statements.

f. The Company receives certain consulting services from RSJ Consulting LLC ("RSJ"), a limited liability company for which one of our executive officers serves as the principal. Services incurred from RSJ amounted to less than $0.1 million and less than $0.1 million for the three months ended June 30, 2017 and 2016, respectively, and $0.1 million and $0.2 million for the six months ended June 30, 2017 and 2016, respectively.

g. The Company issued and sold $24.0 million in convertible bonds in 2016 and 2017 to related parties. One of the holders of more than 5% of our outstanding common stock as of December 31, 2016, and an entity affiliated with one of our directors, each purchased $10.0 million in convertible bonds during 2016. Additionally, during the first quarter of 2017, the Company issued and sold $4.0 million in convertible bonds to two related parties. One of the holders of more than 5% of our outstanding common stock as of March 31, 2017 and a director of the Company each purchased $2.0 million in convertible bonds. On June 14, 2017, the IPO date, these bonds were converted into 2,727,273 shares of common stock.

9. Stockholders' Equity

Common Stock

As of June 30, 2017 and 2016, 250 million common shares, par value $0.001, were authorized by the Company's Board of Directors. The common shares are entitled to one vote per share and to receive dividends as declared.

On June 14, 2017, the Company completed an IPO of its common stock (refer to Note 1 – *Company and Nature of Business* for additional information). During the six months ended June 30, 2017, the Company issued 6,900,000 shares of common stock at $11.00 per share in connection with the IPO, 7,727,273 shares of common stock from the conversion of the convertible bonds into common stock, 568,182 shares of common stock upon the IPO in connection with a licensing agreements, 406,386 shares from the exercise of warrants and options, and 791,982 shares from the vesting of restricted stock units and the grant of shares in connection with an executive's employment agreement for cumulative increase to equity of $164.7 million.

Treasury Stock

During the six months ended June 30, 2017, the Company purchased 16,000 shares of common stock for a de minimis amount as the result of the cancellation of shares issued in connection with a restricted stock agreement.

Cost of Equity Raise

Costs incurred in raising equity, whether paid with cash or through the issuance of securities, are charged against the equity raised. These costs include underwriting discounts and commissions, legal fees, accounting services and amounts paid to consultants and amounted to $11.7 million, cumulatively, as of the IPO date. $1.8 million of these costs were deferred and included within other long-term assets on the consolidated balance sheet as of December 31, 2016. The total amount of $11.7 million was charged against the capital raised through the IPO.

Common Stock Option Plans

The Company has three common stock option plans adopted in 2013, 2007 and 2004 (the "Plans") which authorize the grant of up to 11,800,000 common stock options to employees, directors, and consultants. Additionally, on June 14, 2017, the Company adopted its 2017 Omnibus Incentive Plan and 2017 Employee Stock Purchase Plan (the "2017 Plans"). Under the 2017 Plans, 5,200,000 shares of common stock are reserved for future issuance to employees, directors, and consultants, including 1,000,000 reserved for an Employee Stock Purchase Plan, which was established at IPO but no shares have as yet been issued. Management has valued the options at their grant date using the Black-Scholes option pricing model. See Note 10—*Stock-Based Compensation* for more information.

10. Stock-Based Compensation

Stock Options

The Company recognizes stock-based compensation based on the grant date fair value of stock options granted to employees, officers, and directors. The Company uses the Black-Scholes option pricing model to calculate the grant date fair value of stock options and warrants. The Black-Scholes option pricing model requires inputs for risk-free interest rate, dividend yield, volatility, fair value of common stock, and expected lives of the options. The risk-free rate for periods within the expected life of the option is based on the U.S. Treasury yield curve in effect at the time of the grant. No dividend yield is used, consistent with the Company's history. Expected volatility is based on historical volatilities of the stock prices of peer biopharmaceutical companies. Historically, the fair value of common stock has been based on the most recent sale price of the Company's common stock and is now valued based on market price at the date of issuance. The Company uses the simplified method for determining the expected lives of options. The Company recognizes compensation expenses based on the grant date fair value of stock options on a straight-line basis over the requisite service period, which is generally the vesting period.

Options granted have a contractual term of 10 years and generally vest over a 2-4 year period. A limited number of options vest immediately in certain circumstances. The following table summarizes the status of the Company's stock option activity granted under the Plans to employees, directors, and consultants (in thousands, except stock option amounts):

	Stock Options	Weighted-Average Exercise price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2016	9,280,689	$ 6.26	7.26	$ 43,994
Granted	1,626,532	11.00	-	
Exercised	(72,320)	6.06	-	
Forfeited	(70,042)	9.29	-	
Expired	(9,273)	3.54	-	
Outstanding at June 30, 2017 (unaudited)	10,755,586	$ 6.96	7.25	$ 99,376
Vested and exercisable at June 30, 2017 (unaudited)	7,547,480	$ 5.85	6.46	$ 78,092

The total fair-value of stock options vested and recorded as compensation expense during the three months ended June 30, 2017 and 2016 and the six months ended June 30, 2017 and 2016 was $1.7 million, $2.0 million, $3.3 million, and $3.9 million, respectively. As of June 30, 2017 and December 31, 2016, $17.9 million and $11.0 million of unrecognized cost related to non-vested stock options is expected to be recognized over a weighted-average period of approximately 1.9 years and 1.6 years, respectively. The total intrinsic value of options exercised was approximately $0.4 million and less than $0.1 million for the six months ended June 30, 2017 and 2016, respectively.

The Company determines the fair value of stock-based awards on the grant date using the Black-Scholes option pricing model, which is impacted by assumptions regarding a number of highly subjective variables. The following table summarizes the weighted-average assumptions used as inputs to the Black-Scholes model during the periods indicated:

	Six months ended June 30, 2017	Six months ended June 30, 2016
Weighted average grant date fair value	$ 6.49	$ 5.29
Expected dividend yield	-%	-%
Expected stock price volatility	66%	65%
Risk-free interest rate	1.74%	1.20%
Expected life of options (in years)	6.2	6.0

Stock Grants

The Company grants common stock to key officers and directors as additional compensation in certain circumstances. The fair value of these grants is recorded as compensation expense throughout the requisite service period. Compensation cost recorded for the stock grants amounted to $4.4 million and $1.0 million for the three months ended June 30, 2017 and 2016, respectively, and $4.4 million and $2.1 million for the six months ended June 30, 2017 and 2016, respectively.

Awards granted to non-employees

The Company has accounted for equity instruments issued to non-employees in accordance with the provisions of ASC 718, *Compensation—Stock Compensation*, and ASC 505, *Equity*. All transactions in which goods or services are received in exchange for equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable. The expense is recognized in the same manner as if the Company had paid cash for the services provided by the non-employees.

Restricted Stock

The following table summarizes restricted stock activity:

	Shares of Restricted Stock	Weighted Average Fair Value
Nonvested at December 31, 2016	661,982	$ 9.00
Granted	-	9.00
Vested	(391,982)	9.00
Nonvested at June 30, 2017 (unaudited)	270,000	$ 9.00

Warrants

The Company has granted warrants to purchase common stock. The Company determined the fair value of the warrants on the grant date using the Black-Scholes option pricing model, consistent with the valuations of stock options described above. All warrants were fully vested and 344,000 were outstanding as of December 31, 2016. During June 2017, the holder exercised their warrants and as of June 30, 2017, there were no outstanding warrants.

Stock-Based Compensation Cost

The components of stock-based compensation and the amounts recorded within research and development expenses and selling, general, and administrative expenses in the Company's consolidated statements of operations and comprehensive loss consisted of the following for the three and six months ended June 30, 2017 and 2016 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Stock options	$ 1,736	$ 2,013	$ 3,340	$ 3,877
Vesting of restricted stock grants	540	1,120	1,080	2,166
Stock awarded to directors and officers	4,400	-	4,400	-
Total stock-based compensation expense	$ 6,676	$ 3,133	$ 8,820	$ 6,043
Cost of product sales	$ 26	$ -	$ 48	$ -
Research and development expenses	447	1,610	908	3,165
Selling, general, and administrative expenses	6,203	1,523	7,864	2,878
Total stock-based compensation expense	$ 6,676	$ 3,133	$ 8,820	$ 6,043

11. Net Loss Per Share Attributable to Athenex, Inc. Common Stockholders

Basic net loss per share is calculated by dividing net loss attributable to common stockholders by the weighted-average number of common shares issued, outstanding, and vested during the period. Diluted net loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common share and common shares equivalents for the period using the treasury-stock method. For the purposes of this calculation, warrants for common stock and stock options are considered common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

The following outstanding shares of common stock equivalents were excluded from the calculation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have been antidilutive:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(unaudited)			
Stock options and other common stock equivalents	9,819,089	11,136,500	9,749,264	11,016,552
Unvested restricted shares	596,651	1,053,887	629,317	1,158,887
Total potential dilutive shares	10,415,740	12,190,387	10,378,581	12,175,439

12. Business Segment, Geographic, and Concentration Risk Information

The Company has three operating segments, which are organized based mainly on the nature of the business activities performed and regulatory environments in which they operate. The Company also considers the types of products from which the reportable segments derive their revenue (only applicable to two reportable segments). Each operating segment has a segment manager who is held accountable for operations and has discrete financial information that is regularly reviewed by the Company's chief operating decision-maker. The Company's operating segments are as follows:

Oncology Innovation Platform—This primary operating segment performs research and development on certain of the Company's proprietary drugs, from the preclinical development of its chemical compounds, to the execution and analysis of its several clinical trials. This segment focuses specifically on the oral absorption cancer drug platform, the Src Kinase inhibitors, and the transmucosal drug delivery system. This segment performs research in the United States, Taiwan, Hong Kong, and mainland China.

Global Supply Chain Platform—This operating segment includes Athenex Pharma Solutions and Polymed. Athenex Pharma Solutions is a contract manufacturing company that provides small to mid-scale cGMP manufacturing of clinical and commercial products for pharmaceutical and biotech companies. Athenex Pharma Solutions also performs microbiological and analytical testing for raw material and formulated products and is expanding to manufacture and sell pharmaceutical products under 503B regulations set forth by the U.S. Food and Drug Administration ("FDA"). Polymed markets and sells API and medical devices in North America, Europe, and Asia from its locations in Texas and China. Polymed also develops new compounds, processing techniques, and manufactures API at Taihao, a cGMP facility in Chongqing, China. Currently, a majority of the Company's revenue is generated by this segment.

Commercial Platform—This operating segment includes Athenex Pharmaceutical Division, a newly-formed component that is focused on the manufacturing, distribution, and sales of generic pharmaceuticals. This segment provides services and products to external customers based mainly in the United States.

The segments operate in North America and Asia. The Company's Oncology Innovation Platform segment operates and holds long-lived assets located in the United States, Taiwan, Hong Kong, and mainland China. The Commercial Platform segment operates and holds long-lived assets located in the United States. The Global Supply Chain Platform segment operates and holds long-lived assets located in the United States and China. For geographic segment reporting, product sales have been attributed to countries based on the location of the customer.

Segment information is as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
Net (loss) income attributable to Athenex, Inc.:				
Oncology Innovation Platform	$ (33,018)	$ (12,037)	$ (61,277)	$ (22,452)
Global Supply Chain Platform	(1,981)	428	(3,129)	225
Commercial Platform	(3,626)	(812)	(15,207)	(812)
Total consolidated net loss attributable to Athenex, Inc.	$ (38,625)	$ (12,421)	$ (79,613)	$ (23,039)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
Total revenue:				
Oncology Innovation Platform	$ 270	$ 404	$ 1,003	$ 546
Global Supply Chain Platform	4,509	6,249	10,806	11,605
Commercial Platform	1,820	-	1,896	-
Total revenue for reportable segments	6,599	6,653	13,705	12,151
Intersegment revenue	(2,004)	(1,460)	(4,529)	(2,329)
Total consolidated revenue	$ 4,595	$ 5,193	$ 9,176	$ 9,822

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
Total revenue by product group:				
API sales	$ 2,024	$ 3,726	$ 5,023	$ 7,688
Medical device sales	232	519	567	876
Contract manufacturing revenue	247	544	684	712
Commercial product sales	1,913	31	2,042	32
License fees and consulting revenue	98	71	696	166
Grant revenue	81	302	164	348
Total consolidated revenue	$ 4,595	$ 5,193	$ 9,176	$ 9,822

Intersegment revenue is recorded by the selling segment when it is realized or realizable and all revenue recognition criteria are met. Upon consolidation, all intersegment revenue and related cost of sales are eliminated from the selling segment's ledger.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
Total depreciation and amortization:				
Oncology Innovation Platform	$ 120	$ 51	$ 212	$ 98
Global Supply Chain Platform	495	284	1,021	654
Commercial Platform	233	-	431	-
Total consolidated depreciation and amortization	$ 848	$ 335	$ 1,664	$ 752

	June 30, 2017	December 31, 2016
	(unaudited)	
Total assets:		
Oncology Innovation Platform	$ 97,562	$ 53,022
Global Supply Chain Platform	47,052	48,560
Commercial Platform	13,200	4,308
Total consolidated assets	$ 157,814	$ 105,890

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
Total revenue:				
United States	$ 2,227	$ 1,011	$ 2,940	$ 1,513
India	790	1,252	2,261	3,208
Austria	716	1,792	1,718	3,184
China	417	655	729	1,111
Taiwan	-	-	500	-
Other foreign countries	445	483	1,028	806
Total consolidated revenue	$ 4,595	$ 5,193	$ 9,176	$ 9,822

	June 30, 2017	December 31, 2016
	(unaudited)	
Total property and equipment, net:		
United States	$ 4,280	$ 2,177
China	4,041	3,633
Total consolidated property and equipment, net	$ 8,321	$ 5,810

Customer revenue and accounts receivable concentration amounted to the following for the identified periods. All customers relate to the Global Supply Chain Platform Segment.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
Percentage of total revenue by customer:				
Customer A	17%	24%	22%	33%
Customer B	15%	31%	18%	31%

	June 30, 2017	December 31, 2016
	(unaudited)	
Percentage of total accounts receivable by customer:		
Customer A	19%	50%
Customer B	9%	9%

13. Commitments and Contingencies

Future minimum payments under the non-cancelable leases consists of the following as of June 30, 2017 (in thousands):

Year ending December 31:	Minimum payments
2017 (remaining six months)	$ 473
2018	1,298
2019	1,650
2020	1,659
2021	1,668
Thereafter	6,202
	$ 12,950

Legal Proceedings

The Company is not a party to any pending or known threatened legal proceedings that, in the opinion of the Company, would have a material impact on the Company's condensed consolidated financial statements.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and the related notes included in Part I, item I of this report and with our audited consolidated financial statements and related notes thereto for the year ended December 31, 2016, included in our final prospectus dated June 2, 2017, filed with the Securities and Exchange Commission pursuant to Rule 424(b) under the Securities Act of 1933, as amended, or the Prospectus. This discussion and other parts of this report contain forward-looking statements that involve risks and uncertainties, such as our plans, objectives, expectations, intentions and beliefs. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section entitled "Risk Factors" beginning on page 30 in this report.

NOTE ABOUT FORWARD-LOOKING STATEMENTS

This quarterly report contains forward-looking statements. All statements other than statements of historical fact are "forward-looking statements" for purposes of this Quarterly Report on Form 10-Q. These forward-looking statements may include, but are not limited to, statements regarding our future results of operations and financial position, business strategy, market size, potential growth opportunities, clinical development activities, the timing and results of clinical trials and potential regulatory approval and commercialization of product candidates. In some cases, forward-looking statements may be identified by terminology such as "believe," "may," "will," "should," "predict," "goal," "strategy," "potentially," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "expect," "seek" and similar expressions and variations thereof. These words are intended to identify forward-looking statements.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to actual results or to changes in our expectations, except as required by law.

As used in this Quarterly Report on Form 10-Q, the terms "Athenex," "the Company," "we," "us," and "our" refer to Athenex, Inc. and, where appropriate, its consolidated subsidiaries, unless the context indicates otherwise.

Overview

We are a global biopharmaceutical company dedicated to the discovery, development and commercialization of novel therapies for the treatment of cancer. Our mission is to improve the lives of cancer patients by creating more effective, safer and tolerable treatments. We have generated our clinical product candidates through our Orascovery and Src Kinase Inhibition research platforms, which are based on our understanding of human absorption biology and novel approaches to inhibiting kinase activity, respectively. We believe that our ability to overcome the challenges of oral delivery of chemotherapy and limitations associated with IV delivery, via our P-gp inhibitor, offers significant potential benefits to patient outcomes by allowing patients to stay on therapy longer and extending the potential opportunities to combine with other agents, including targeted therapies and immunotherapies that would otherwise be too toxic in combination with IV chemotherapy. We have assembled a leadership team and have established operations in the U.S. and China across the pharmaceutical value chain to execute our mission to become a global leader in bringing innovative cancer treatments to the market and improve health outcomes.

We have three segments operating in North America and Asia: our Oncology Innovation Platform, our Commercial Platform and our Global Supply Chain Platform. Our Oncology Innovation Platform include two core research and development centers, one in Hong Kong, China and one in the U.S.

Since inception, we have devoted substantially all of our resources to research and development of our lead product candidates under our Orascovery and Src Kinase Inhibition platforms. We have incurred significant net losses since inception. As of June 30, 2017, we had an accumulated deficit of approximately $274.7 million. Our recurring losses from operations and negative cash flows from operations have raised substantial doubt regarding our ability to continue as a going concern, and as a result, our independent registered public accounting firm has noted this in their opinion on our consolidated financial statements for the year ended December 31, 2016, which was issued prior to our raising $64.2 million of net proceeds in our June 2017 IPO described below. As a result of the acquisitions of Athenex Pharma Solutions in 2014 and Polymed in 2015, we started to generate revenue from those businesses. Our Commercial Platform launched sales of generic injectable products in 2017. Product sales totaled $8.3 million and $9.3 million for the six months ended June 30, 2017 and 2016, respectively. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- Continue investment in acquiring or in-licensing other drugs and technologies;
- Continue preclinical and clinical development of our programs;
- Continue investment in our manufacturing facilities;
- Hire additional research, development and business personnel;
- Maintain, expand and protect our intellectual property portfolio; and
- Incur additional costs associated with operating as a public company.

We have funded our operations to date primarily from the issuance and sale of our common stock and convertible bonds and, to a lesser extent, through revenue generated from our Global Supply Chain Platform and Commercial Platform. Cash used in operations for the six months ended June 30, 2017 was $48.8 million compared with cash used in operations of $20.0 million for the six months ended June 30, 2016. As of June 30, 2017, we had cash and cash equivalents of $55.2 million and short-term investments of $30.2 million.

On June 14, 2017, we completed the initial public offering (IPO) of our common stock pursuant to a registration statement on Form S-1. In the IPO, we sold an aggregate of 6,900,000 shares of our common stock, which included 900,000 shares of common stock purchased by the underwriters upon the full exercise of their options to purchase additional common stock, at a price to the public of $11.00 per share. We received aggregate cash proceeds of approximately $64.2 million from the IPO, net of underwriting discounts and commissions and offering expenses.

Key Components of Results of Operations

Revenue

We derive our consolidated revenue primarily from (i) the sales of API and medical devices by our Global Supply Chain Platform; (ii) the sales of generic injectable products by our Commercial Platform, (iii) licensing and collaboration projects conducted by our Oncology Innovation Platform, which generates revenue in the form of upfront payments, milestone payments and payments received for providing research and development services for our collaboration projects and for other third parties; and (iv) grant awards from government agencies and universities for our continuing research and development efforts.

We do not anticipate revenue being generated from sales of our product candidates conducted by our Oncology Innovation Platform until we have obtained regulatory approval. We cannot assure you that we will succeed in achieving regulatory approval for our drug candidates as planned, or at all.

Cost of Product Sales

We manufacture our clinical products in our cGMP facility in New York and APIs at our cGMP facility in China. Cost of product sales primarily includes the cost of raw materials, labor costs, manufacturing overhead expenses, reserves for expected scrap, as well as transportation costs. Cost of product sales also includes depreciation expense for production equipment, amortization of certain licenses, changes to our excess and obsolete inventory reserves, and certain direct costs such as shipping costs, net of costs charged to customers.

Research and Development Expenses

Research and development expenses consist of the costs associated with our research and development activities, conducting preclinical studies and clinical trials and activities related to regulatory filings. Our current research and development activities mainly relate to the clinical development of the following programs:

Orascovery platform—Comprised of our in-licensed and novel P-gp inhibitor, HM30181A, that is combined with various chemotherapeutic agents and enables them to be absorbed into the blood when given orally:

- Oraxol, combining HM30181A with an oral dosage form of paclitaxel;
- Oratecan, combining HM30181A with an oral dosage form of irinotecan;
- Oradoxel, combining HM30181A with an oral dosage form of docetaxel; and
- Oratopo, combining HM30181A with an oral dosage form of topotecan.

Src Kinase Inhibition platform—Targets the tyrosine kinase protein in regulating cell growth that leads to blockade of metastasis:

- KX-01 ointment, Src kinase inhibitor that is being topically administered to treat skin cancers and pre-cancers;
- KX-01 oral, Src kinase inhibitor that is being orally administered to treat certain solid and liquid tumors; and
- KX-02, Src kinase inhibitor that is orally administered to treat brain cancer, such as glioblastoma multiforme (GBM).

We expense research and development costs as incurred. We record costs for certain development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment or clinical site activations. We do not allocate employee related costs, depreciation, rental and other indirect costs to specific research and development programs because these costs are deployed across multiple product programs under research and development.

We cannot determine with certainty the duration, costs and timing of the current or future preclinical or clinical studies of our drug candidates. The duration, costs, and timing of clinical studies and development of our drug candidates will depend on a variety of factors, including:

- The scope, rate of progress, and costs of our ongoing, as well as, any additional clinical studies and other research and development activities;
- Clinical study results;
- Clinical study enrollment rates;
- Significant and changing government regulation; and
- The timing and receipt of any regulatory approvals.

A change in the outcome of any of these variables with respect to the development of a drug candidate could mean a significant change in the costs and timing associated with the development of that drug candidate.

Research and development activities are central to our business model. We expect our research and development expenses to continue to increase for the foreseeable future as we continue to support the clinical trials of Oraxol, Oratecan, Oradoxel, Oratopo, KX-01 ointment, KX-01 oral and KX-02, as well as initiate and prepare for additional clinical and preclinical studies. We also expect spending to increase in the research and development for API and specialty products. There are numerous factors associated with the successful commercialization of any of our drug candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

Selling, General and Administrative Expenses

Selling, general and administrative, or SG&A, expenses primarily consist of compensation, including salary, employee benefits and stock-based compensation expenses for sales and marketing personnel, and for administrative personnel that support our general operations such as, executive management, legal counsel, financial accounting, information technology, and human resources personnel. SG&A expenses also includes professional fees for legal, patents, consulting, auditing and tax services, as well as other direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies used in the selling, marketing, general and administrative activities. We expect to incur additional SG&A expenses in connection with our becoming a public company, which may increase further when we are no longer able to rely on the “emerging growth company” exemption pursuant to the JOBS Act.

We anticipate that our SG&A expenses will increase in future periods to support increases in our research and development and commercialization activities. We expect these increases will likely result in increased headcount, increased share compensation charges, expanded infrastructure and increased costs for insurance. We also anticipate increases to legal, compliance, accounting and investor and public relations expenses associated with being a public company.

Results of Operations

Three Months Ended June 30, 2017 Compared to Three Months Ended June 30, 2016

The following table sets forth a summary of our unaudited condensed consolidated results of operations for the three months ended June 30, 2017 and 2016, together with the changes in those items in dollars and percentage. This information should be read together with our consolidated financial statements and related notes included elsewhere in this document. Our operating results in any period are not necessarily indicative of the results that may be expected for any future period.

	Three Months Ended June 30,			
	2017	2016	Change	
	(in thousands)	(in thousands)	(in thousands)	%
Revenue	$ 4,595	$ 5,193	$ (598)	-12%
Cost of product sales	(4,137)	(4,834)	$ 697	-14%
Research and development expenses	(17,597)	(8,645)	$ (8,952)	104%
Selling, general, and administrative expenses	(13,632)	(4,567)	$ (9,065)	198%
Interest expense	(3,281)	(49)	$ (3,232)	NM
Unrealized loss on derivative liability	(4,587)	-	$ (4,587)	NM
Income tax (expense) benefit	(29)	403	$ (432)	-107%
Net loss	(38,668)	(12,499)	(26,169)	
Less: net loss attributable to non-controlling interests	(43)	(78)	35	-45%
Net loss attributable to Athenex, Inc.	$ (38,625)	$ (12,421)	$ (26,204)	

Revenue

Net revenue of the three months ended June 30, 2017 totaled $4.6 million, a decrease of $0.6 million, or 12%, as compared to $5.2 million for the three months ended June 30, 2016. These results in the three months ended June 30, 2017 included decreases in API sales of $1.7 million, medical devices sales of $0.3 million, contract manufacturing revenue of $0.3 million and grant revenue of $0.2 million compared to the same period in the prior year. This was offset by a $1.9 million increase in revenue from our Commercial Platform.

Cost of Product Sales

Cost of product sales for the three months ended June 30, 2017 totaled $4.1 million, a decrease of $0.7 million, or 14%, as compared to $4.8 million for the three months ended June 30, 2016. This was primarily due to the decrease of $1.6 million API and medical devices' cost of product sales, offset by the increase of $1.1 million in the generic drugs' cost of product sales. APS cost of product sales decreased by $0.2 million due to the decrease of contract manufacturing revenue.

Research and Development Expenses

Research and development expenses for the three months ended June 30, 2017 totaled $17.6 million, an increase of $9.0 million, or 104%, as compared to $8.6 million for the three months ended June 30, 2016. This was primarily due to increased licensing fees and increased payment for our proprietary drug programs, and included the following:

- $6.9 million increase in the costs of drug licensing fees to Hanmi and Gland;
- $3.2 million increase in the costs of clinical studies related primarily to Oraxol;
- $0.5 million increase in product development for the 503B business;
- $0.2 million increase in API R&D expenses; and
- Offset by a $1.2 million decrease in employee and executive compensation and a $0.6 million in the costs of preclinical studies.

Selling, General, and Administrative Expenses

Selling, general and administrative expenses for the three months ended June 30, 2017, totaled $13.6 million, an increase of $9.1 million, or 198%, as compared to $4.6 million for the three months ended June 30, 2016. This was primarily due to a stock grant to an executive at the IPO date and the establishment of our Commercial Platform in the third quarter of 2016, as well as additional costs associated with being a public company, and included the following:

- $6.4 million increase in employee and executive compensation;
- $1.9 million in selling and marketing expenses related to the Commercial Platform; and
- $0.8 million increase in professional fees.

Interest Expenses

Interest expense for the three months ended June 30, 2017 totaled $3.3 million, an increase of $3.2 million as compared to the three months ended June 30, 2016. The increase was due to the interest incurred on convertible bonds we issued between the third quarter of 2016 and the second quarter of 2017.

Unrealized Loss on Derivative Liability

Unrealized loss on derivative liability for the three months ended June 30, 2017 totaled $4.6 million compared to the three months ended June 30, 2016. This increase was due to the change in the fair value of the derivatives embedded within the convertible bonds we issued between the third quarter of 2016 and the second quarter of 2017.

Six Months Ended June 30, 2017 Compared to Six Months Ended June 30, 2016

The following table sets forth a summary of our unaudited condensed consolidated results of operations for the six months ended June 30, 2017 and 2016, together with the changes in those items in dollars and percentage. This information should be read together with our consolidated financial statements and related notes included elsewhere in this document. Our operating results in any period are not necessarily indicative of the results that may be expected for any future period.

	Six Months Ended June 30,			
	2017	2016	Change	
	(in thousands)	(in thousands)	(in thousands)	%
Revenue	$ 9,176	$ 9,822	$ (646)	-7%
Cost of product sales	(6,976)	(8,976)	$ 2,000	-22%
Research and development expenses	(44,005)	(15,391)	$ (28,614)	186%
Selling, general, and administrative expenses	(23,431)	(8,904)	$ (14,527)	163%
Interest expense	(5,657)	(3)	$ (5,654)	NM
Unrealized loss on derivative liability	(8,863)	-	$ (8,863)	NM
Income tax benefit	63	303	$ (240)	-79%
Net loss	(79,693)	(23,149)	(56,544)	
Less: net loss attributable to non-controlling interests	(80)	(110)	30	-27%
Net loss attributable to Athenex, Inc.	$ (79,613)	$ (23,039)	$ (56,574)	

Revenue

Our revenue decreased by $0.6 million, from $9.8 million for the six months ended June 30, 2016 to $9.2 million for the six months ended June 30, 2017. Sales of API and medical devices decreased by $2.7 million and $0.3 million, respectively, offset by a $1.9 million increase in revenue from our Commercial Platform, which launched 8 generic drug sales in 2017 and a $0.5 million increase of licensing fees from our Oncology Innovation Platform.

Cost of Product Sales

Cost of product sales totaled $7.0 million for the six months ended June 30, 2017, a decrease of $2.0 million, or 22%, from the six months ended June 30, 2016. This was primarily due to a $1.0 million decrease in Polymed as a result of the decrease in API and medical device sales and a $1.4 million decrease in APS cost of product sales due to the increase of internal clinical study supply services, which led to lesser costs incurred for external sales. This was offset by a $0.2 million increase in the labor costs and a $0.2 million increase in the amortization of our licensing fees and depreciation of machine and production equipment.

Research and Development Expenses

Our research and development expenses increased by $28.6 million, or 187%, to $44.0 million for the six months ended June 30, 2017 from $15.4 million for the six months ended June 30, 2016, primarily due to the increased costs of drug licensing and the advancement of our clinical pipeline, and included the following:

- $21.9 million increase as a result of the drug licensing fees to Hanmi, Gland and Amphastar;
- $7.1 million increase in the costs of clinical studies, primarily for Oraxol, KX01 ointment, and Oratecan;
- $1.0 million increase in general product development and supplies related to 503B products; and
- $1.0 million increase in API and other research and development expenses;
- Offset by a $1.6 million decrease in employee compensation expenses as a result of the allocation of executive compensation and a $0.8 million decrease in preclinical study costs as our proprietary drugs entered the clinical stages.

Selling, General, and Administrative Expenses

Our selling, general and administrative expenses increased by $14.5 million, or 163%, from $8.9 million for the six months ended June 30, 2016 to $23.4 million for the six months ended June 30, 2017 primarily due to an increase in employee compensation, and included the following:

- $10.0 million increase in employee and executive compensation, including wages and benefits, as well as stock-based compensation, primarily attributable to increased headcount in our Commercial Platform;
- $2.2 million increase in office expenses, rent and utilities, and other expenses related to the expansion of our business operations;
- $1.2 million increase in selling and marketing expenses related to the Commercial Platform;
- $0.6 million increase in professional fees, which included accounting, legal and consulting fees; and
- $0.5 million increase in IT expenses, which included new ERP system and other hardware and software costs.

Interest Expenses

Interest expenses increased by $5.7 million for the six months ended June 30, 2017. This was primarily due to the interest incurred on the convertible bonds issued between the third quarter of 2016 and the second quarter of 2017.

Unrealized Loss on Derivative Liability

Unrealized loss on derivative liability increased by $8.9 for the six months ended June 30, 2017. This was primarily due to the change in the fair value of the derivatives embedded within the convertible bonds we issued between the third quarter of 2016 and the second quarter of 2017.

Liquidity and Capital Resources

Capital Resources

Since our inception, we have incurred net losses and negative cash flows from our operations. Substantially all of our losses have resulted from funding our research and development programs and selling, general and administrative costs associated with our operations. We incurred net losses of $79.7 million and $23.1 million for the six months ended June 30, 2017 and 2016, respectively. As of June 30, 2017, we had an accumulated deficit of $274.7 million. Our primary use of cash is to fund research and development costs. Our operating activities used $48.8 million and $20.0 million of cash during the six months ended June 30, 2017 and 2016, respectively. Our principal sources of liquidity as of June 30, 2017 were cash and cash equivalents totaling of $55.2 million and short-term investments totaling $30.2 million, which are generally U.S. government or high quality investment grade corporate debt securities.

Pursuant to our IPO in June 2017, the Company sold an aggregate of 6,900,000 shares of its common stock at a price of $11.00 per share for cash proceeds of $64.2 million, net of underwriting discounts and commissions of $6.1 million and offering costs of $5.6 million.

Based on our current operating plan, we expect that our existing cash, cash equivalents and short-term investments as of June 30, 2017, will enable us to fund our operating expenses and capital expenditures requirements through at least March 2018. We expect that our expenses will increase substantially as we continue to fund clinical development of our Orascovery and Src Kinase Inhibition research programs, fund new and ongoing research and development activities and working capital and other general corporate purposes. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our drug candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development and commercialization of our drug candidates.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section.

Our future capital requirements will depend on many factors, including:

- the costs, timing and outcome of regulatory reviews and approvals;
- the ability of our drug candidates to progress through clinical development successfully;
- the initiation, progress, timings, costs and results of nonclinical studies and clinical trials for our other programs and potential drug candidates;
- the number and characteristics of the drug candidate we pursue;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property related claims;
- the extent to which we acquire or in-license other products and technologies; and
- our ability to maintain and establish collaboration arrangements on favorable terms, if at all.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and government grants. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect rights of holders of common stock. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could potentially dilute the ownership interest of holders of common stock. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or research programs or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or drug candidates that we would otherwise prefer to develop and market ourselves.

We believe that the existing cash and cash equivalents will not be sufficient to enable us to complete all necessary development or commercially launch our proprietary drug candidates. If we are unable to raise capital when needed or on attractive terms, we will be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts. Our inability to obtain additional funding when needed could seriously harm our business.

Cash Flows

The following table provides information regarding our cash flows for the six months ended June 30, 2017 and 2016:

	Six Months Ended June 30,	
	2017	2016
	(in thousands)	
Net cash (used in) operating activities	$ (48,803)	$ (20,049)
Net cash (used in) investing activities	(26,537)	(356)
Net cash provided by financing activities	96,791	3,181
Net effect of foreign exchange rate changes	574	(131)
Net increase (decrease) in cash and cash equivalents	$ 22,025	$ (17,355)

Net Cash Used in Operating Activities

The use of cash was primarily resulted from our net loss adjusted for non-cash charges and changes in components of working capital. The primary use of our cash in the periods presented was to fund our research and development, regulatory and other clinical trial costs, drug licensing costs, inventory purchase, and other related supporting administration.

Net cash used in operating activities was $48.8 million for the six months ended June 30, 2017. This resulted principally from our net loss of $79.7 million, adjusted for non-cash charges of $39.4 million, and by cash used in our operating assets and liabilities of $8.5 million. Our net non-cash charges during the six months ended June 30, 2017 primarily consisted of $13.3 million of licensing fees settled by bonds and equity, $8.9 million of fair value change in derivative liabilities, $8.8 million of stock-based compensation expense, $3.4 million of convertible bonds interest, $3.0 million amortization of debt discount, and $1.7 million depreciation and amortization expense.

Net cash used in operating activities was $20.0 million for the six months ended June 30, 2016. The resulted principally from our net loss of $23.1 million, adjusted for non-cash charges of $6.4 million, and offset by cash used in our operating assets and liabilities of $3.3 million. Our non-cash charges during the six months ended June 30, 2016 primarily consisted of $6.0 million of stock-based compensation expense.

Net Cash Used in Investing Activities

Net cash used in investing activities was $26.5 million for the six months ended June 30, 2017, compared to $0.4 million used in investing activities for the six months ended June 30, 2016. The increased use in cash from investing activities was primarily due to cash used in purchasing short-term investments, including commercial paper, corporate notes, and U.S. government bonds.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $96.8 million for the six months ended June 30, 2017, including $75.9 million from the issuance of common stock, which included net proceeds of $69.3 million from IPO net of $6.1 million underwriting discounts and commissions and $0.5 million certain offering costs, and $30.0 million from the issuance of convertible bonds, compared with $3.1 million for the six months ended June 30, 2016, which included $8.5 million from the issuance of common stock, offset by $3.1 million payment of contingent consideration and $2.2 million purchase of treasury stock.

Contractual Obligations

A summary of our contractual obligations as of June 30, 2017 is as follows:

	Payments Due by Period				
	Remainder of 2017	1 to 3 years	3 to 5 years	More than 5 years	Total Amounts Committed
	(in thousands)				
Operating leases	$ 473	$ 2,948	$ 3,327	$ 6,202	$ 12,950
Long-term debt	789	-	-	-	$ 789
Long-term debt - related parties	570	494	-	-	$ 1,064
Capital lease obligation	22	212	-	-	$ 234
Convertible bonds	-	7,000	-	-	$ 7,000
Licensing fees	1,509	4,400	-	-	$ 5,909
	$ 3,363	$ 15,054	$ 3,327	$ 6,202	$ 27,946

The operating leases include (1) the rental of our global headquarters in the Conventus Center for Collaborative Medicine in Buffalo, NY and (2) the rental of our research and development facility in the Integrated Circuit Development Centre in Hong Kong and (3) the rental of the Commercial Platform headquarters in Chicago, IL. Of the total amounts committed, $9.5 million are committed for the rental of our Buffalo, NY global headquarters, $0.5 million are committed for our research and development center in New Jersey, $0.3 million are committed for our Hong Kong research and development facility, and $5.3 million are committed for our Commercial Platform headquarters. The above amounts do not include the interest that will incurred on our debt.

Off Balance Sheet Arrangements

We do not maintain any off balance sheet partnerships, arrangements, or other relationships with unconsolidated entities or others, often referred to as structured finance or special purpose entities, which are established for the purpose of facilitating off balance sheet arrangements or other contractually narrow or limited purposes.

Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements and the reported amounts of revenue and expenses during the periods. We evaluate our estimates and judgments on an ongoing basis, including but not limited to, estimating the useful lives of long-lived assets, assessing the impairment of long-lived assets, stock-based compensation expenses, and the realizability of deferred income tax assets. We base our estimates on historical experience, known trends and events, contractual milestones and other various factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Changes in the accounting estimates are likely to occur from period to period. Actual results could be significantly different from these estimates. There have been no significant changes in our critical accounting policies and estimates as compared to the critical accounting policies and estimates disclosed in Management's Discussion and Analysis of Financial Condition and Operations included in our prospectus filed on June 15, 2017 with the SEC, except for the determination of the fair value of our common stock, which was used in estimating the fair value of stock-based awards at grant date. Prior to IPO, our stock was not publicly traded, therefore we estimated the fair value of our common stock as discussed in the prospectus. Following our IPO, we established a policy, using the closing sale price per share of our common stock as quoted on the NASDAQ Global Market on the date of grant for purposes of determining the exercise price per share of our share-based awards to purchase common stock.

Recent Accounting Pronouncements

In the normal course of business, we evaluate all new accounting pronouncements issued by the Financial Accounting Standards Board ("FASB"), Securities and Exchange Commission, or other authoritative accounting bodies to determine the potential impact they may have on our condensed consolidated financial statements. See Note 2 of the Notes to Condensed Consolidated Financial Statements contained in Item 1 of this report for additional information about these recently issued accounting standards and their potential impact on our financial condition or results of operations.

JOBS Act

Under Section 107(b) of the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, an "emerging growth company" can delay the adoption of new or revised accounting standards until such time as those standards would apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, as a result, we will adopt new or revised accounting standards at the same time as other public companies that are not emerging growth companies. There are other exemptions and reduced reporting requirements provided by the JOBS Act that we are currently evaluating. For example, as an emerging growth company, we are exempt from Sections 14A(a) and (b) of the Exchange Act which would otherwise require us to (1) submit certain executive compensation matters to shareholder advisory votes, such as "sayonpay," "sayonfrequency" and "golden parachutes;" and (2) disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparisons of our chief executive officer's compensation to our median employee compensation. We also rely on an exemption from the rule requiring us to provide an auditor's attestation report on our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and the rule requiring us to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will continue to remain an "emerging growth company" until the earliest of the following: (1) the last day of the fiscal year following the fifth anniversary of the date of the completion of our initial public offering, (2) the last day of the fiscal year in which our total annual gross revenue is equal to or more than $1 billion, (3) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years, or (4) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Foreign Currency Exchange Risk

A significant portion of our business is located outside the United States and, as a result, we generate revenue and incur expenses denominated in currencies other that the U.S. dollar, a majority of which is denominated in Renminbi. In the six months

ended June 30, 2017 and 2016, approximately 7.9% and 11.7%, respectively, of our sales, excluding intercompany sales, were denominated in foreign currencies. As a result, our revenue can be significantly impacted by fluctuations in foreign currency exchange rates. We expect that foreign currencies will represent a lower percentage of our sales in the future due to the anticipated growth of our U.S. business. Our international selling, marketing, and administrative costs related to these sales are largely denominated in the same foreign currencies, which somewhat mitigates our foreign currency exchange risk rate exposure.

Currency Convertibility Risk

A portion of our revenues and expenses, and a portion of our assets and liabilities are denominated in RMB. On January 1, 1994, the PRC government abolished the dual rate system and introduced a single rate of exchange as quoted daily by the People's Bank of China, or PBOC. However, the unification of exchange rates does not imply that the RMB may be readily convertible into U.S. dollars or other foreign currencies. All foreign exchange transactions continue to take place either through the PBOC or other banks authorized to buy and sell foreign currencies at the exchange rates quoted by the PBOC. Approvals of foreign currency payments by the PBOC or other institutions require submitting a payment application form together with suppliers' invoices, shipping documents and signed contracts.

Additionally, the value of the RMB is subject to changes in central government policies and international economic and political developments affecting supply and demand in the PRC foreign exchange trading system market.

Interest Rate Sensitivity

We had cash and cash equivalents of $55.2 million as of June 30, 2017, which consisted primarily of bank deposits and money market funds. In addition, we also had short term investments of $30.2 million as of June 30, 2017. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our condensed consolidated financial condition or results of operations. We do not believe that our cash or cash equivalents have significant risk of default or illiquidity.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2017. The term "disclosure controls and procedures," as defined in Rule 13a15(e) under the Exchange Act means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well-designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2017, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a15(d) and 15d15(d) of the Exchange Act that occurred during the quarter ended June 30, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, results of operations, financial condition or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should consider carefully the following risk factors, as well as the other information in this report, including our condensed financial statements and related notes and management's discussion and analysis of financial condition and results of operations, before you decide to purchase our common stock. If any of the following risks actually occur, our business, financial condition and results of operations could be materially adversely affected, the value of our common stock could decline and you may lose all or part of your investment.

Risks Related to Our Financial Position and Need for Additional Capital

Our primary clinical candidates are still in the development stage and have not yet received regulatory approval, which may make it difficult to evaluate our current business and predict our future performance.

We are a globally-focused biopharmaceutical company formed in November 2003. Our operations to date have focused on organizing and staffing our Company, business planning, raising capital, establishing our intellectual property portfolio and conducting preclinical studies and clinical trials of our drug candidates. We have not yet successfully completed large-scale, pivotal clinical trials, or obtained regulatory approvals for our drug candidates and have not yet established sales and marketing activities necessary for successful commercialization. Consequently, any predictions you make about our future success or viability may not be accurate. In addition, as a developing business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges.

We are focused on the discovery and development of innovative drugs for the treatment of cancers. The fact that we have not yet, among other things, demonstrated our ability to initiate or complete large-scale clinical trials or manufacture drugs at commercial scale, particularly in light of the rapidly evolving cancer treatment field, may make it difficult to evaluate our current business and predict our future performance. These constraints make any assessment of our future success or viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage companies in rapidly evolving fields as we seek to transition to a company capable of supporting commercial activities. If we do not address these risks and difficulties successfully, our business will suffer.

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

Investment in pharmaceutical product development is highly speculative because it entails substantial upfront costs and expenses and significant risk that a drug candidate will fail to gain regulatory approval or become commercially viable. Since our formation, the Company has relied on a combination of securities offerings, public-private partnerships, and public grants to fund our operations. We have devoted most of our financial resources to research and development, including our non-clinical development activities and clinical trials. We have not generated substantial revenue from product sales to date, and we continue to incur significant development and other expenses related to our ongoing operations. As a result, we incurred significant losses since inception. For the six months ended June 30, 2017 and June 30, 2016, we reported net losses of $79.6 million and $23.1 million, respectively, and had an accumulated deficit of $274.7 million as of June 30, 2017. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from selling, general and administrative expenses associated with our operations.

We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our drug candidates, and begin to commercialize approved drugs, if any. Typically, it takes many years to develop a new drug before it is available for treating patients. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses, our ability to generate revenue and the timing and amount of milestones and other required payments to third parties in connection with our potential future arrangements with third parties. If any of our drug candidates fail in clinical trials or do not gain regulatory approval, or if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our shareholders' equity and working capital.

We expect our research and development expenses to continue to be significant in connection with our continued investment in our drug candidates and our ongoing and planned clinical trials for our drug candidates. Furthermore, if we obtain regulatory approval for our drug candidates, we expect to incur increased selling, general and administrative expenses. In addition, since we became a public company in 2017, we will incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows from operations for the foreseeable future. These losses have had and will continue to have a material adverse effect on our stockholders' equity, financial position, cash flows and working capital.

Our ability to continue as a going concern will require us to obtain additional financing to fund our current operations, which may be unavailable on acceptable terms, or at all.

Our recurring losses from operations and our current operating plans raise substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our consolidated financial statements as of and for the year ended December 31, 2016 with respect to this uncertainty. Even after our June 2017 IPO, our ability to continue as a going concern will require us to obtain additional financing to fund our current operating plans. We believe that our existing cash and cash equivalents and short-term investments will be sufficient to fund our current operating plans through at least the next 7 months. We have based these estimates, however, on assumptions that may prove to be wrong, and we could spend our available financial resources much faster than we currently expect and need to raise additional funds sooner than we anticipate. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate our research and drug development programs or commercialization efforts.

We currently do not generate substantial revenue from product sales and may never become profitable.

Our ability to generate revenue and become profitable depends upon our ability to successfully complete the development of, and obtain the necessary regulatory approvals for, our proprietary drug candidates, as we currently only have commercialized our API products and specialty products. Our product sales totaled $8.3 million and $9.3 million in the six months ended June 30, 2017 and June 30, 2016, respectively. We expect to continue to incur substantial and increasing losses through the projected development and commercialization of our drug candidates. None of our proprietary drug candidates has been approved for marketing in the U.S., China or any other jurisdiction, and they may never receive such approval. Our ability to achieve revenue and profitability is dependent on our ability to complete the development of our proprietary drug candidates, obtain necessary regulatory approvals, and have our proprietary drugs manufactured and successfully marketed.

Even if we receive regulatory approval of our proprietary drug candidates for commercial sale, we do not know when they will generate revenue, if at all. Our ability to generate revenue from product sales of our drug candidates depends on a number of factors, including our ability to:

- complete research regarding, and non-clinical and clinical development of, our proprietary drug candidates;
- formulate appropriate dosing protocols, drug preparations and capsule encapsulation methods;
- obtain regulatory approvals and marketing authorizations for drug candidates for which we complete clinical trials;
- develop a sustainable and scalable manufacturing processes, including establishing and maintaining commercially viable supply relationships with third parties and establishing our own manufacturing capabilities and infrastructure;
- compliantly launch and commercialize proprietary drug candidates for which we obtain regulatory approvals and marketing authorizations, either directly or with a collaborator or distributor;
- obtain market acceptance of our proprietary drug candidates and their routes of administration as viable treatment options;
- obtain adequate coverage and reimbursement for our proprietary drug candidates from government (including U.S. federal healthcare programs) and private payors;
- identify, assess, acquire and/or develop new proprietary drug candidates;
- address any competing technological and market developments;
- negotiate and maintain favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintain, protect and expand our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- successfully commercialize our 503B outsourced facility products and U.S. specialty pharmaceutical products;

- further develop our API business; and
- attract, hire and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we are required by the FDA, CFDA, or regulatory authorities in other jurisdictions to perform studies in addition to those that we currently anticipate. Even if our proprietary drug candidates are approved for commercial sale, we anticipate incurring significant costs associated with the commercial launch of these drugs.

Our ability to become and remain profitable depends on our ability to generate revenue. Even if we are able to generate revenue from the sale of our drug candidates, API we manufacture for others, and from the sales of our generic injectable drugs, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce our operations. Even if we do achieve profitability, we may not be able to sustain or increase profitability. Our failure to become and remain profitable would decrease the value of our Company and could impair our ability to raise capital, expand our business or continue our operations. Failure to become and remain profitable may adversely affect the market price of our common stock and our ability to raise capital and continue operations. A decline in the value of our Company could also cause you to lose all or part of your investment.

We will need to obtain additional financing to fund our operations, and if we are unable to obtain such financing, we may be unable to complete the development and commercialization of our drug candidates.

We have financed our operations with a combination of securities offerings, public-private partnerships, public grants. Our drug candidates will require the completion of regulatory review, significant marketing efforts and substantial investment before they can provide us with any product sales revenue.

Our operations have consumed substantial amounts of cash since inception. The net cash used for our operating activities was $48.8 million and $20.0 million for the six months ended June 30, 2017 and 2016, respectively. We expect to continue to spend substantial amounts on advancing the clinical development of our proprietary drug candidates, and launching and commercializing any proprietary drug candidates for which we receive regulatory approval, including building our own commercial organizations to address certain markets.

We will need to obtain additional financing to fund our future operations, including completing the development and commercialization of our proprietary drug candidates. We also need to obtain additional financing to conduct additional clinical trials for the approval of our proprietary drug candidates if requested by regulatory bodies, and completing the development of any additional proprietary drug candidates we might discover. Moreover, our research and development expenses and other contractual commitments are substantial and are expected to increase in the future.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this “Risk Factors” section. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

- the progress, timing, scope and costs of our clinical trials, including the ability to timely enroll patients in our planned and potential future clinical trials;
- the outcome, timing and cost of regulatory approvals by the FDA, CFDA and regulatory authorities in jurisdictions where we seek such approvals, including the possibility that the FDA, CFDA or regulatory authorities may require that we perform more studies than those that we currently expect;
- our ability to secure adequate coverage and reimbursement for our proprietary drug candidates from government (including U.S. federal health care programs) and private payors;
- the number and characteristics of drug candidates that we may in-license and develop;
- our ability to successfully and compliantly launch commercialize our drug candidates;
- the amount of sales and other revenues from drug candidates that we may commercialize, if any, including the selling prices for such potential products and the availability of adequate reimbursement by third-party payors;

- the amount of rebates or other price concessions we may owe under U.S. federal health care programs that cover and reimburse our proprietary drug candidates;
- the amount and timing of the milestone and royalty payments we receive from our collaborators under our licensing arrangements;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- selling and marketing costs associated with our potential products, including the cost and timing of expanding our marketing and sales capabilities;
- the terms and timing of any potential future collaborations, licensing or other arrangements that we may establish;
- cash requirements of any future acquisitions and/or the development of other drug candidates;
- the costs of operating as a public company;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities;
- the time and cost necessary to respond to technological and market developments; and
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

Until we can generate a sufficient amount of revenue, we may finance future cash needs through public equity offerings, debt financings, collaborations and strategic alliances. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. General market conditions or the market price of our common stock may not support capital raising transactions such as an additional public offering of our common stock or other securities. In addition, our ability to raise additional capital may be dependent upon obtaining shareholder approval to issue a sufficient number of shares of our common stock. There can be no assurance that we will be able to satisfy the criteria for continued listing on the NASDAQ stock market or that we will be able to obtain shareholder approval of such stock issuances if it is necessary. If adequate funds are not available to us on acceptable terms, or at all, we may be required to delay or reduce the scope of, or eliminate, one or more of our research or development programs or our commercialization efforts. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. In addition, if we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or drug candidates or to grant licenses on terms that may not be favorable to us.

We believe that the existing cash and cash equivalents will not be sufficient to enable us to complete all necessary development or commercially launch our proprietary drug candidates. If we are unable to raise capital when needed or on attractive terms, we will be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts. Our inability to obtain additional funding when needed could seriously harm our business.

Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.

We may seek additional funding through a combination of equity offerings, debt financings, collaborations and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our common stock. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the market price of our common stock to decline. In the event that we enter into collaborations or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party on unfavorable terms our rights to technologies or proprietary drug candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms.

Certain of our executive officers and employees have received grants of stock options and shares of restricted stock which vest over time. Under certain circumstances, such vesting may be accelerated. The accelerated vesting of stock options and shares of restricted stock could result in dilution to our existing stockholders and lower the market price of our common stock.

An impairment of goodwill could have a material adverse effect on our results of operations.

Acquisitions frequently result in the recording of goodwill and other intangible assets. As of June 30, 2017, goodwill represented $37.6 million, or 23.8% of our total assets, primarily as a result of our acquisitions of Athenex Pharma Solutions, LLC, Comprehensive Drug Enterprises Limited, or CDE, and Polymed Therapeutics, Inc. and Chongqing Taihao Pharmaceutical Co Ltd, collectively Polymed. Goodwill is not amortized and is subject to impairment testing at least annually using a fair value based approach. The identification and measurement of goodwill impairment involves the estimation of the fair value of our reporting units. The estimates of fair value of reporting units are based on the best information available as of the date of the assessment and incorporate management assumptions about expected future cash flows and other valuation techniques. Future cash flows can be affected by changes in industry or market conditions, among other factors. The recoverability of goodwill is evaluated at least annually or more frequently when events or changes in circumstances indicate that the fair value of a reporting unit has more likely than not declined below its carrying value.

We cannot accurately predict the amount and timing of any future impairment of assets, and, going forward, we may be required to take goodwill or other asset impairment charges relating to certain of our reporting units. Any such charges would have an adverse effect on our financial results.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred operating losses that are treated as taxable losses for U.S. federal income tax purposes. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an ownership change (generally defined as a greater than 50 percentage points change (by value) in its equity ownership over a rolling three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post- change income may be limited. We believe that we have experienced an ownership change in the past, which may affect our ability to utilize our net operating loss carryforwards. In addition, we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. As of June 30, 2017, we had federal net operating loss carryforwards of approximately $183.6 million that could be limited by our past and any future ownership change, which could have an adverse effect on our future results of operations. Similar limitations will apply to our ability to carry forward any unused tax credits to offset future taxable income.

Risks Related to Clinical Development of Our Proprietary Drug Candidates

We depend substantially on the success of our proprietary drug candidates, which are in pre-clinical and clinical development.

As of June 30, 2017, we had a total of more than 40 planned, ongoing and completed clinical trials for our drug candidates, including a Phase 2 and a Phase 3 clinical trial for KX-01 ointment and Oraxol, respectively. Our business and the ability to generate revenue related to product sales from our proprietary drug candidates will depend on the successful development, regulatory approval and commercialization for the treatment of patients with cancer of our drug candidates, which are still in development, and other drugs we may develop. Clinical development is a lengthy and expensive process with an uncertain outcome. The results of pre- clinical studies and early clinical trials of our drug candidates may not be predictive of the results of later-stage clinical trials. In the case of any trials we conduct, results have in the past, and may in the future, fail to meet the desired safety and efficacy endpoints, or differ from earlier trials due to the larger number of clinical trial sites and additional countries and populations involved in such trials. We have invested a significant portion of our efforts and financial resources in the development of our existing drug candidates. The success of our proprietary drug candidates will depend on several factors, including:

- successful enrollment in, and completion of, clinical studies;
- receipt of regulatory approvals from the FDA, CFDA and other regulatory authorities for our drug candidates;
- establishing commercial manufacturing capabilities, either by using our own facilities or making arrangements with third-party manufacturers;
- conducting our clinical trials safely and efficiently, and in many cases, relying on third parties to do so;
- obtaining, maintaining and protecting our rights in our intellectual property, including patent, trade secrets, know-how and regulatory exclusivity;
- ensuring we do not infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property rights of third parties;

- competition with other drug candidates and drugs, including existing IV chemotherapy treatments, potential oncology biologics and other oral dosing technologies developed or being developed by competitors; and
- continued acceptable safety profile for our drug candidates following regulatory approval, if and when received.

If we do not achieve one or more of these requirements in accordance with our business plans or at all, we could experience significant delays in our ability to obtain approval for and/or to successfully commercialize our drug candidates, which would materially harm our business and we may not be able to generate sufficient revenues and cash flows to continue our operations.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. For example, our current lead product candidate, Oraxol, currently in Phase 3 clinical trials, has been in development by us since 2011. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our drug candidates may not be predictive of the results of later- stage clinical trials. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, including genetic differences, patient adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. In the case of any trials we conduct, results may differ from early trials due to the larger number of patients, clinical trial sites and additional countries and populations involved in such trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our future clinical trial results may not be favorable.

We may not be successful in our efforts to identify or discover additional drug candidates. Due to our limited resources and access to capital, we must and have in the past decided to prioritize development of certain product candidates; these decisions may prove to have been wrong and may adversely affect our business.

To date, we have focused our drug discovery efforts on developing our cancer platform, particularly our Orascovery and Src Kinase Inhibition product candidates. If our cancer platform fails to identify potential drug candidates, our business could be materially harmed. Additionally our management, at the direction of our board of directors, has discretion in prioritizing which product candidates to develop.

Research programs to pursue the development of our drug candidates for additional indications and to identify new drug candidates and disease targets require substantial technical, financial and human resources whether or not we ultimately are successful. Our research programs may initially show promise in identifying potential indications and/or drug candidates, yet fail to yield results for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential indications and/or drug candidates;
- potential drug candidates may, after further study, be shown to lack efficacy, have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or
- it may take greater human and financial resources to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs than we possess, thereby limiting our ability to diversify and expand our drug portfolio.

Because we have limited financial and managerial resources, we focus on research programs and drug candidates for specific indications. As a result, we may forego or delay pursuit of opportunities with other drug candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Accordingly, there can be no assurance that we will be able to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential drug candidates or other potential programs that ultimately prove to be unsuccessful.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We and our research partners have from time to time and may in the future experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including:

- the availability of a sizeable population of eligible patients;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapeutics;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the drug candidate being studied in relation to other available therapies,
- our ability to obtain and maintain patient consents;
- the failure of patients to complete a clinical trial; and
- the availability of approved therapies that are similar in mechanism to our drug candidates.

In addition, our clinical trials will compete with other clinical trials for drug candidates that are in the same therapeutic areas as our drug candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators is limited, we have conducted and expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites.

Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our drug candidates.

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

Some of our drug candidates, particularly those developed through our Orascovery platform, represent a departure from more commonly used methods for cancer treatment, and therefore represent a novel approach that carries inherent development risks. For instance, our Orascovery platform intends to facilitate the delivery of chemotherapy agents orally, as opposed to IV, while our Src Kinase inhibitor candidates operate by a new mechanism of action. To develop our Orascovery platform, we must successfully develop oral formulations of the active ingredients and ensure they can be delivered safely and consistently in capsule form. The need to further develop or modify in any way the protocols related to our drug candidates to demonstrate safety or efficacy may delay the clinical program, regulatory approval or commercialization, if approved. Our Src Kinase inhibitor platform is based on a novel molecule with an additional mechanism of action that is not found in other Src Kinase inhibitors. Because of this, unexpected safety and tolerability concerns may arise during the development process.

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

Our products and product candidates may cause undesirable, or an increase in the frequency of, side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, CFDA or other regulatory authorities. Further, if a product candidate receives marketing approval and we or others identify undesirable side effects caused by the product after the approval, or if drug abuse is determined to be a significant problem with an approved product, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of the product;
- regulatory authorities may require the addition of labeling statements, such as a "Black Box warning" or a contraindication;
- we may be required to change the way the product is distributed or administered, conduct additional clinical trials or change the labeling of the product;
- we may decide to remove the product from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking the product; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing an affected product or product candidate and significantly impact our ability to successfully commercialize or maintain sales of our product or product candidates and generate revenues.

If clinical trials of our drug candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA, CFDA or other regulatory authorities or do not otherwise produce positive results, we may incur costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our drug candidates.

We may experience various unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our drug candidates, including:

- regulators, institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, enrollment may be insufficient or slower than we anticipate or patients may drop out at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials of our drug candidates for various reasons, including a finding of a lack of clinical response or a finding that participants are being exposed to unacceptable health risks;
- regulators, IRBs or ethics committees may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- the cost of clinical trials of our drug candidates may be greater than we anticipate;
- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate; and
- our drug candidates may cause adverse events, have undesirable side effects or other unexpected characteristics, causing us or our investigators to suspend or terminate the trials.

If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our drug candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if they raise safety concerns, we may:

- be delayed in obtaining regulatory approval for our drug candidates;

- not obtain regulatory approval at all;
- obtain approval for indications that are not as broad as intended;
- have the drug removed from the market after obtaining regulatory approval;
- be subject to additional post-marketing testing requirements;
- be subject to restrictions on how the drug is distributed or used; or
- be unable to obtain reimbursement for use of the drug.

Delays in testing or approvals may result in increases in our drug development costs. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all.

Significant clinical trial delays also could shorten any periods during which we have the exclusive right to commercialize our drug candidates or allow our competitors to bring drugs to market before we do and impair our ability to commercialize our drug candidates and may harm our business and results of operations.

Manufacturing risks, including our inability to manufacture API and clinical products used in the clinical trials of our proprietary product candidates could adversely affect our ability to commercialize our product candidates.

Our business strategy depends on our ability to manufacture API in sufficient quantities and on a timely basis so as to meet our needs to manufacture our product candidates for our clinical trials and to meet consumer demand for our future products, while adhering to product quality standards, complying with regulatory requirements and managing manufacturing costs. We are subject to numerous risks relating to our manufacturing capabilities, including:

- Our inability to manufacture API and clinical products in sufficient quantities to meet the needs of our clinical trials or to commercialize our products;
- our inability to secure product components in a timely manner, in sufficient quantities or on commercially reasonable terms;
- our failure to increase production of products to meet demand;
- our inability to modify production lines to enable us to efficiently produce future products or implement changes in current products in response to regulatory requirements;
- difficulty identifying and qualifying alternative suppliers for components in a timely manner; and
- potential damage to or destruction of our manufacturing equipment or manufacturing facility.

In addition, we conduct manufacturing operations at our facility in Chongqing, China to manufacture our proprietary product candidates. As a result, our business is subject to risks associated with doing business in China, including:

- adverse political and economic conditions, particularly those negatively affecting the trade relationship between the U.S. and China;
- trade protection measures, such as tariff increases, and import and export licensing and control requirements;
- potentially negative consequences from changes in tax laws;
- difficulties associated with the Chinese legal system, including increased costs and uncertainties associated with enforcing contractual obligations in China;
- historically lower protection of intellectual property rights;
- unexpected or unfavorable changes in regulatory requirements;
- possible patient or physician preferences for more established pharmaceutical products and medical devices manufactured in the U.S.; and
- difficulties in managing foreign relationships and operations generally.

These risks are likely to be exacerbated by our limited experience with our current products and manufacturing processes. If, as we expect, our need for API increases, or demand for our products increase, we will have to invest additional resources to purchase components, hire and train employees, and enhance our manufacturing processes. If we fail to increase our production capacity efficiently, our sales may not increase in line with our forecasts and our operating margins could fluctuate or decline. Any of these factors may affect our ability to manufacture our product and could reduce our revenues and profitability.

Risks Related to Obtaining Regulatory Approval for Our Drug Candidates

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

The time required to obtain approval by the FDA, CFDA and other regulatory authorities in jurisdictions where we seek such approval is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a drug candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any drug candidate, and it is possible that none of our existing drug candidates or any drug candidates we may discover, in-license or acquire and seek to develop in the future will ever obtain regulatory approval.

Our drug candidates could fail to receive regulatory approval from the FDA, CFDA or a regulatory authority for many reasons, including:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that a drug candidate is safe and effective or safe, pure, and potent for its proposed indication;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- failure to demonstrate that a drug candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of our drug candidates to support the submission and filing of a new drug application, or NDA, or other submission or to obtain regulatory approval;
- the FDA, CFDA or regulatory authority's finding of deficiencies related to the product, manufacturing processes or facilities of ours or of third-party manufacturers with whom we contract for clinical and commercial supplies; and
- changes in approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA, CFDA or a regulatory authority may require more information, including additional preclinical or clinical data, to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve any of our drug candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a drug candidate with a label that is not desirable for the successful commercialization of that drug candidate. In addition, if our drug candidate produces undesirable side effects or safety issues, the FDA may require the establishment of Risk Evaluation Mitigation Strategies, or REMS, or the CFDA or a regulatory authority may require the establishment of a similar strategy, that may, for instance, restrict distribution of our drug candidates and impose burdensome implementation requirements on us. Any of the foregoing scenarios could materially harm the commercial prospects of our drug candidates.

The approval process for pharmaceutical products outside the U.S. varies among countries and may limit our ability to develop, manufacture and sell our products internationally. Failure to obtain marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad.

In order to market and sell our products internationally, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and may involve additional testing. We may conduct clinical trials for, and seek regulatory approval to market, our product candidates in countries other than the U.S. and the PRC. Depending on the results of clinical trials and the process for obtaining regulatory approvals in other countries, we may decide to first seek regulatory approvals of a product candidate in countries other than the U.S., or we may simultaneously seek regulatory approvals in the U.S. and other countries. If we seek marketing approval for a product candidate outside the U.S., we will be subject to the regulatory requirements of health authorities in each country in which we seek approval. With respect to marketing authorizations in China, we will be required to seek regulatory approval from the CFDA. The approval procedure varies among regions and countries and may involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval.

Obtaining regulatory approvals from health authorities in countries outside the U.S. is likely to subject us to all of the risks associated with obtaining FDA approval described above. In addition, marketing approval by the FDA does not ensure approval by the health authorities of any other country, and marketing approvals by foreign health authorities do not ensure a similar approval by the FDA.

We are conducting, and may in the future conduct, clinical trials for our product candidates in sites outside the U.S. and the FDA may not accept data from trials conducted in such locations.

We have conducted, and may in the future conduct, certain of our clinical trials outside of the U.S. Although the FDA may accept data from clinical trials conducted outside the U.S., acceptance of this data is subject to certain conditions imposed by the FDA. There can be no assurance the FDA will accept data from any clinical trials we conduct outside of the U.S. If the FDA does not accept the data from any of our clinical trials conducted outside the U.S., it would likely result in the need for additional clinical trials in the U.S., which would be costly and time-consuming and could delay or prevent the commercialization of any of our product candidates.

Regulatory approval may be substantially delayed or may not be obtained for one or all of our drug candidates for a variety of reasons.

We may be unable to complete development of our drug candidates on schedule, if at all. The completion of the studies for our drug candidates will require funding beyond our existing cash reserves. In addition, if regulatory authorities require additional time or studies to assess the safety or efficacy of our drug candidates, we may not have or be able to obtain adequate funding to complete the necessary steps for approval for any or all of our drug candidates. Preclinical studies and clinical trials required to demonstrate the safety and efficacy of our drug candidates are time consuming and expensive and together take several years or more to complete. For example, our current lead product candidate, Oraxol, currently in Phase 3 clinical trials, has been in development since 2011. Delays in clinical trials, regulatory approvals or rejections of applications for regulatory approval in the U.S., Taiwan, New Zealand, China or other markets may result from many factors, including:

- our inability to obtain sufficient funds required for a clinical trial;
- regulatory requests for additional analyses, reports, data, non-clinical and preclinical studies and clinical trials;
- regulatory questions regarding interpretations of data and results and the emergence of new information regarding our drug candidates or other products;
- clinical holds, other regulatory objections to commencing or continuing a clinical trial or the inability to obtain regulatory approval to commence a clinical trial in countries that require such approvals;
- failure to reach agreement with the FDA, CFDA or other regulators regarding the scope or design of our clinical trials;
- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;
- our inability to enroll a sufficient number of patients who meet the inclusion and exclusion criteria in a clinical trial;
- our inability to conduct a clinical trial in accordance with regulatory requirements or our clinical protocols;
- clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication;
- failure of our third-party clinical trial managers to satisfy their contractual duties or meet expected deadlines;
- delay or failure in adding new clinical trial sites;
- ambiguous or negative interim results, or results that are inconsistent with earlier results;
- unfavorable or inconclusive results of clinical trials and supportive non-clinical studies, including unfavorable results regarding effectiveness of drug candidates during clinical trials;
- feedback from the FDA, CFDA, an IRB, data safety monitoring boards, or comparable entities, or results from earlier stage or concurrent preclinical studies and clinical trials, that might require modification to the protocol;
- unacceptable risk-benefit profile or unforeseen safety issues or adverse side effects;
- decision by the FDA, CFDA, an IRB, comparable entities, or the company, or recommendation by a data safety monitoring board or comparable regulatory entity, to suspend or terminate clinical trials at any time for safety issues or for any other reason;

- failure to demonstrate a benefit from using a drug or biologic;
- lack of adequate funding to continue the clinical trial due to unforeseen costs or other business decisions;
- our inability to reach agreements on acceptable terms with prospective contract research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- our inability to obtain approval from IRBs or ethics committees to conduct clinical trials at their respective sites;
- manufacturing issues, including problems with manufacturing or timely obtaining from third parties sufficient quantities of a drug candidate for use in a clinical trial; and
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data.

Changes in regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Amendments may require us to resubmit clinical trial protocols to IRBs or ethics committees for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

According to the Provisions for Drug Registration and the Reform Plan Regarding the Category of the Registration of Chemical Medicines promulgated by the CFDA, the registrations of chemical medicines in China are divided into five categories, among which, Category 1 means the registration of innovative drugs that are not marketed either domestically or abroad, and Category 5 for the registration of drugs that have been marketed abroad and are being registered for marketing in the PRC for the first time. Our drug candidates are all new therapeutic agents and we have built both research and development, clinical trial capacities, and commercial manufacturing facilities in China. As a result, we expect all of our current drug candidates to fall within the Category 1 application process, but cannot be sure we will be granted or be able to maintain Category 1 designation. We believe the local drug registration pathway, Category 1, is a faster and more efficient path to obtain approval in the Chinese market than the drug registration pathway for imported drugs under Category 5. Category 5 drug candidates may not qualify to benefit from fast track review with priority at the Clinical Trial Application stage. Category 1 drugs receive special examination and approval treatment. The advantages of such treatment include a separate pathway for Category 1 application to queue up for examination by the Center for Drug Evaluation of the CFDA, or the CDE, and a working mechanism for communication with the applicants for discussion of relevant technical issues. The applications for Category 1 drugs are handled with higher priority and enhanced communications with the CDE. Compared with Category 5 drugs, Category 1 drugs are qualified to apply for special examination and approval at both the Clinical Trial Application stage and the production registration application stage. If the special examination and approval are granted at the Clinical Trial Application stage, such treatment will apply to the production registration application stage without further approval. During the Clinical Trial Application stage, reduction or exemption of clinical trial may be available if Category 1 drugs are for orphan diseases or other special diseases. The advantages also include, by providing priority resources, shortening time limits to review and exam applications of Category 1 drugs' clinical trials and of production registration, and to handle document submission and approval process. We cannot be sure that the CFDA will grant such priority treatment to any of our drugs candidates.

If we experience delays in the completion of, or the termination of, a clinical trial, of any of our drug candidates, the commercial prospects of our drug candidates will be harmed, and our ability to generate revenues from the sale of any of those drug candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our drug candidate development and approval process, and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug candidates.

Our drug candidates have caused and may cause undesirable adverse events or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any regulatory approval.

Undesirable adverse events caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, CFDA or other regulatory authority. Results of our trials could reveal a high and unacceptable severity or prevalence of adverse events. In such an event, our trials could be suspended or terminated and the FDA, CFDA or other regulatory authorities could order us to cease further development of, or deny approval of, our drug candidates for any or all targeted indications. Drug-related adverse events could affect patient recruitment or the ability of enrolled subjects to complete the trial, and could result in potential product liability claims. Any of these occurrences may significantly harm our reputation, business, financial condition and prospects.

In our clinical studies to date, we have observed the following serious adverse effects with respect to each of our product candidates:

- Oraxol - severe neutropenia, febrile neutropenia, sepsis, septic shock, altered state of consciousness, hypokalemia and cardiac arrest, dehydration, pneumonia, tracheal obstruction, nausea, vomiting, diarrhea, fatigue, abdominal and breast pain, anorexia, acute gastroenteritis, atrioventricular block, bacteremia, cerebral hemorrhage, constipation, disease progression, hematuria, liver dysfunction, neoplasm, pain, pancytopenia, pyrexia, syncope, urinary tract infection, urinary tract obstruction and death;
- Oratecan - diarrhea, rash, gastrointestinal hemorrhage, vomiting, nausea, increased bilirubin, leukopenia, pulmonary embolism asthenia, neutropenia, anorexia, increased alanine aminotransferase, increased aspartate aminotransferase, enteritis and acute kidney injury;
- KX-01 oral - allergic reaction, bacteremia, fatigue, rash, syncope, tremor, dermatitis, neutropenic fever, hyponatremia, failure to thrive, lower extremity edema, mucositis, neutropenia, pancytopenia, thrombocytopenia, seizure and motor vehicle accident, embolic stroke, pneumonitis, fever, acute kidney injury, lung infection and increased blood platelet, albumin and bilirubin levels, abdominal pain, arm pain, pyrexia, rigors, tachypenia, oxygen desaturation pneumonia, anemia, elevated ALT and AST, dehydration and leukopenia; and
- KX-02 - thromboembolic event.

Additionally, if one or more of our drug candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such drugs, a number of potentially significant negative consequences could result, including:

- we may suspend marketing of the drug;
- regulatory authorities may withdraw approvals of the drug;
- regulatory authorities may require additional warnings on the label;
- we may be required to develop a REMS for the drug or, if a REMS is already in place, to incorporate additional requirements under the REMS, or to develop a similar strategy as required by a regulatory authority;
- we may be required to conduct post-marketing studies;
- we could be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular drug candidate, if approved, and could significantly harm our business, results of operations and prospects.

We may seek Orphan Drug Exclusivity for some of our drug candidates, and we may be unsuccessful.

We have received Orphan Drug Designation from the FDA for our KX-02 proprietary product candidate. As part of our business strategy, we may seek Orphan Drug Designation for our product candidates and we may be unsuccessful. Regulatory authorities in some jurisdictions, including the U.S. and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a disease with a patient population of fewer than 200,000 individuals in the U.S., or a patient population greater than 200,000 in the U.S. where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U.S.

Generally, if a drug with an Orphan Drug Designation subsequently receives the first regulatory approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same indication during the period of exclusivity, with certain limited exceptions. The applicable period is seven years in the U.S. and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for Orphan Drug Designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan Drug Exclusivity may be lost if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we obtain Orphan Drug Exclusivity for a drug candidate, exclusivity may not effectively protect the drug candidate from competition because different drugs can be approved for the same condition and the same drugs can be approved for a different condition but used off-label for any orphan indication we may obtain. Even after an orphan drug is approved, the FDA can subsequently approve a different drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

Risks Related to Commercialization of Our Drug Candidates

If we are not able to obtain, or experience delays in obtaining, required regulatory approvals, we will not be able to commercialize our drug candidates, and our ability to generate revenue will be materially impaired.

We currently do not have any proprietary drug candidates that have gained regulatory approval for sale in the U.S., China or any other country, and we cannot guarantee that we will ever obtain regulatory approval for marketable proprietary drugs. Our business is substantially dependent on our ability to complete the development of, obtain regulatory approval for and successfully commercialize drug candidates in a timely manner. We cannot commercialize drug candidates without first obtaining regulatory approval to market each drug from the FDA, CFDA or regulatory authorities in the relevant jurisdictions. Our proprietary drug candidates are currently undergoing various phases of FDA clinical trials. We cannot predict whether these trials and future trials will be successful or whether regulators will agree with our conclusions regarding the preclinical studies and clinical trials we have conducted to date.

Before obtaining regulatory approvals for the commercial sale of any drug candidate for a target indication, we must demonstrate in preclinical studies and well-controlled clinical trials, and, with respect to approval in the U.S., to the satisfaction of the FDA, that the drug candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. An NDA must include extensive preclinical and clinical data and supporting information to establish the drug candidate's safety and effectiveness. The NDA must also include significant information regarding the chemistry, manufacturing and controls for the drug. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and approval may not be obtained. If we submit an NDA to the FDA, the FDA decides whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA.

Regulatory authorities outside of the U.S., such as the regulatory authorities in emerging markets, also have requirements for approval of drugs for commercial sale with which we must comply prior to marketing in those areas. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our drug candidates. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking non-U.S. regulatory approval could require additional non-clinical studies or clinical trials, which could be costly and time-consuming. The non-U.S. regulatory approval process may include all of the risks associated with obtaining FDA approval and other risks specific to the relevant jurisdiction. For all of these reasons, we may not obtain non-U.S. regulatory approvals on a timely basis, if at all.

If we are unable to obtain regulatory approval for our drug candidates in one or more jurisdictions, or any approval contains significant limitations, our target market will be reduced and our ability to realize the full market potential of our drug candidates will be harmed. Furthermore, if we are not able to obtain, or experience delays in obtaining, required regulatory approvals, we will not be able to commercialize our drug candidates, and our ability to generate revenue will be materially impaired.

Even if any of our drug candidates receives regulatory approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any of our drug candidates receives regulatory approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current cancer treatments like chemotherapy and radiation therapy are well established in the medical community, and doctors may continue to rely on these treatments to the exclusion of our drug candidates. In addition, physicians, patients and third-party payors may prefer other novel products to ours, and we may experience difficulties gaining acceptance for our orally administered drug candidates. If our drug candidates do not achieve an adequate level of acceptance, we may not generate significant product sales revenues and we may not become profitable. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which our drug candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our drug candidates as a safe and effective treatment;

- the potential and perceived advantages of our drug candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA, CFDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA, CFDA or other regulatory authorities;
- the timing of market introduction of our drug candidates as well as competitive drugs;
- the cost of treatment in relation to alternative treatments;
- the amount of upfront costs or training required for physicians to administer our drug candidates;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities (including U.S. federal healthcare programs);
- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third- party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If our drug candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue. Even if our drugs achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our drugs, are more cost effective or render our drugs obsolete.

Even if we receive regulatory approval for our drug candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our drug candidates.

If our drug candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post- marketing studies, and submission of safety, efficacy, and other post-marketing information, including both federal and state requirements in the U.S. and requirements of regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive requirements of the FDA, CFDA and regulatory authorities, including, in the U.S., ensuring that quality control and manufacturing procedures conform to current cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA or other marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our drug candidates may be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the drug candidate. The FDA may also require a REMS program as a condition of approval of one or more of our drug candidates, which could entail requirements for long-term patient follow- up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA, CFDA or a regulatory authority approves our drug candidates, we will have to comply with requirements including, for example, submissions of safety and other post-marketing information and reports, registration, and continued compliance with cGMPs and Good Clinical Practices, or GCPs, for any clinical trials that we conduct post-approval.

The FDA may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the drug reaches the market. Later discovery of previously unknown problems with our drug candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-marketing studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our drugs, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, untitled or warning letters, or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our drug candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA, CFDA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. The policies of the FDA, CFDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained and we may not achieve or sustain profitability.

In addition, if we were able to obtain accelerated approval of any of our drug candidates, the FDA would require us to conduct a confirmatory study to verify the predicted clinical benefit and additional safety studies. Other regulatory authorities outside the U.S., such as the CFDA, may have similar requirements. The results from the confirmatory study may not support the clinical benefit, which would result in the approval being withdrawn. While operating under accelerated approval, we will be subject to certain restrictions that we would not be subject to upon receiving regular approval.

We market certain medical devices that, if modified, may be subject to FDA clearance and failure to obtain such clearance could adversely affect our financial condition or results of operations.

Through our subsidiary, Polymed, we currently market in-vitro diagnostic rapid test kits used in the performance of clinical laboratory tests (limited to drugs of abuse and pregnancy testing in the U.S.) under clearance by the FDA pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act. These products and our operations are subject to extensive regulation by the FDA and other federal and state authorities in the United States, as well as comparable authorities in foreign jurisdictions. After a device receives 510(k) marketing clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) marketing clearance or, depending on the modification, Premarket Approval, or PMA. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review that decision and disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) marketing clearance or PMA approval is obtained. Also, in these circumstances, we may be subject to significant regulatory fines or penalties. In the event we make additional product enhancements to our 510(k)-cleared products, we cannot be assured that the FDA would agree with any of our decisions to not submit 510(k) premarket notifications for these modified devices.

Our manufacturing experience is limited and any failure by us to manufacture our products for commercial sale after receiving FDA approval would materially impact our revenue and financial condition.

The manufacture of drugs for commercial sale is subject to regulation by the FDA under cGMP regulations and by other regulators under other laws and regulations. We cannot assure you that we will continue to manufacture our products under cGMP regulations or other laws and regulations in sufficient quantities for commercial sale, or in a timely or economical manner.

Our manufacturing facilities require specialized personnel and are expensive to operate and maintain. Any delay in the regulatory approval or market launch of product candidates to be manufactured in these facilities will require us to continue to operate these expensive facilities and retain specialized personnel, which may increase our expected losses.

Through our public-private partnerships, additional cGMP manufacturing facilities for our use are currently being built in Dunkirk, New York and Chongqing, China. Our facility in Dunkirk, New York is being built pursuant to an agreement with Fort Schuyler Management Corporation, or FSMC, a not-for-profit corporation organized by the State of New York. Under the current arrangement, we will select and hire contractors for the project and oversee the development of the Dunkirk facility. Empire State Development, or ESD, the parent entity of FSMC, is responsible for the costs of construction and all equipment for the facility, up to an aggregate of $200 million, and ESD, not us, will own the facility and equipment. We have limited experience in overseeing the development of such a facility and we may not be able to complete the development within the timeframe expected, within the expected budget, or at all. If development of the Dunkirk facility is delayed or not completed it could materially adversely affect our operations and financial results.

Additionally, upon completion, both the Dunkirk and Chongqing facilities will need to be cGMP validated prior to operating. Validation is a lengthy process that must be completed before we can manufacture under cGMP guidelines. We cannot guarantee that the FDA or foreign regulatory agencies will approve any of the other facilities or, once they are approved, that such facilities will remain in compliance with cGMP regulations.

The manufacture of pharmaceutical products is a highly complex process in which a variety of difficulties may arise from time to time. We may not be able to resolve any such difficulties in a timely fashion, if at all. If anything were to interfere with the continuing manufacturing operations in our facilities, it could materially adversely affect our business and financial condition.

Currently, many of our product candidates are manufactured in small quantities for use in clinical trials. We cannot assure you that we will be able to successfully scale up the manufacture of each of our product candidates in a timely or economical manner, or at all. If any of these product candidates are approved by the FDA or other drug regulatory authorities for commercial sale, we will need to manufacture them in larger quantities. If we are unable to successfully scale up our manufacturing capacity, the regulatory approval or commercial launch of such product candidate may be delayed or there may be a shortage in supply of such product candidate.

If we fail to develop manufacturing capacity and experience, fail to continue to contract for manufacturing on acceptable terms, or fail to manufacture our product candidates economically on a commercial scale or in accordance with cGMP regulations, our development programs will be materially adversely affected. This may result in delays in receiving FDA or foreign regulatory approval for one or more of our product candidates or delays in the commercial production of a product that has already been approved. Any such delays could materially adversely affect our business and financial condition.

The manufacture of API is highly regulated by FDA, CFDA and other regulatory bodies and is subject to current good manufacturing practice requirements and to inspection by such regulators, which may result in adverse findings and actions against certain API manufacturing facilities.

API manufacturing facilities are subject to regulation by the applicable regulatory bodies in the place of manufacture as well as the regulatory agency in the country to which the product is exported. For instance, FDA's cGMP regulations apply to these facilities and violation of these, or other, regulations may result in adverse action against the facility, including cessation of manufacturing activities. Our API manufacturing facilities in Chongqing are also subject to regulation by the CFDA. If the FDA, CFDA or other regulators discover a problem at one facility, we may be subject to increased scrutiny and/or adverse actions across our operations, including fines or orders to cease manufacturing, which could have a material impact on our operations, clinical development, business strategy or results of operations.

We have limited experience in marketing proprietary drug products. If we are unable to establish such marketing and sales capabilities or enter into agreements with third parties to market and sell our proprietary drug candidates, we may not be able to generate sales revenue from such products.

We have limited sales, marketing and commercial product experience. We intend to continue to develop our in-house commercial organization and sales force for such products, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable to establish internal sales, marketing and commercial distribution capabilities for our proprietary drug candidates, we will need to pursue collaborative arrangements for the sales and marketing of our proprietary drugs. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they

will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized our proprietary drug candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our proprietary drug candidates.

There can be no assurance that we will be able to develop our in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any proprietary product, and as a result, we may not be able to generate sales revenue from such products.

We face substantial competition, and our competitors may discover, develop or commercialize competing drugs before or more successfully than we do.

The development and commercialization of new drugs is highly competitive. We face competition with respect to our current drug candidates, and will face competition with respect to any drug candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell drugs or are pursuing the development of drugs for the treatment of the types of cancer for which we are developing our drug candidates. Some of these competitive drugs and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we may develop. Our competitors also may obtain approval from the FDA, CFDA or other regulatory authorities for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market and/or slow our regulatory approval.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Even if we are able to commercialize any drug candidates, the drugs may become subject to unfavorable pricing regulations, third party reimbursement practices or healthcare reform initiatives, which could harm our business.

Successful sales of our drug candidates, if approved, depend on the availability of adequate coverage and reimbursement from third-party payors. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the U.S., and commercial payors are critical to new drug acceptance.

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or licensing approval is granted. In some non-U.S. markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a drug in a particular country, but be subject to price regulations that delay our commercial launch of the drug and negatively impact the revenues we are able to generate from the sale of the drug in that country. For example, according to the guidance issued in March 2015 by the central government of the PRC, each province will decide which drugs to include in its provincial major illness reimbursement lists and the percentage of reimbursement, based on local funding. Adverse pricing limitations may hinder our ability to recover our investment in one or more drug candidates, even if our drug candidates obtain regulatory approval. For example, in China, according to a statement, *Opinions on reforming the review and approval process for pharmaceutical products and medical devices*, issued by the State Council in August 2015, the enterprises applying for new drug approval will be required to undertake that the selling price of new drug on PRC mainland market shall not be higher than the comparable market prices of the product in its country of origin or PRC's neighboring markets, as applicable.

Our ability to commercialize any drugs successfully also will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a drug is:

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

We cannot be sure that reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any drug for which we obtain regulatory approval. Obtaining reimbursement for our drugs may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidate that we successfully develop.

In the U.S., no uniform policy of coverage and reimbursement for drugs exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a drug from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our drugs on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given drug, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, although Medicare Part D – Medicare's outpatient prescription drug benefit – has protections in place to ensure coverage and reimbursement for oncology products and all Part D prescription drug plans are required to cover substantially all anti-cancer agents, third-party payors might not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our drugs.

The State Council required central and provincial authorities across the PRC to promote a medical insurance program for major illnesses, which targets covering at least 50% of the medical cost as incurred by treating major illnesses, but falls out of the coverage of the basic insurance programs. The State Council requires provincial authorities to increase reimbursement rates over the next three years.

We intend to seek approval to market our drug candidates in the U.S., China, and in other selected jurisdictions. If we obtain approval in one or more non-U.S. jurisdictions for our drug candidates, we will be subject to rules and regulations in those jurisdictions. In some non-U.S. countries, the pricing of drugs and biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining regulatory approval of a drug candidate. In addition, market acceptance and sales of our drug candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our drug candidates and may be affected by existing and future health care reform measures.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain regulatory approval of and commercialize our drug candidates and affect the prices we may obtain.

In the U.S., PRC and certain other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our drug candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any drug candidates for which we obtain regulatory approval.

In the U.S., the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

More recently, in March 2010, President Obama signed into law the Affordable Care Act, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the Affordable Care Act of importance to our potential drug candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologics;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service Act pharmaceutical pricing program;
- new requirements to report payments and other transfers of value made to physicians and teaching hospitals;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted in the U.S. since the Affordable Care Act was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding.

We expect that the Affordable Care Act, as well as other healthcare reform measures that have been since adopted or may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs. In particular, we expect that the new presidential administration and U.S. Congress will seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. Since taking office, President Trump has continued to support the repeal of all or portions of the ACA. President Trump has also issued an executive order in which he stated that it is his administration's policy to seek the prompt repeal of the ACA and directed executive departments and federal agencies to waive, defer, grant exemptions from, or delay the implementation of the provisions of the ACA to the maximum extent permitted by law. There is still uncertainty with respect to the impact President Trump's administration and the U.S. Congress may have, if any, and any changes will likely take time to unfold. Such reforms could have an adverse effect on anticipated revenues from therapeutic candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop therapeutic candidates. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

Other legislative and regulatory proposals have been made to expand post-approval requirements and restrict coverage and reimbursement and sales and promotional activities, for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether agencies such as the FDA or Centers for Medicare and Medicaid Services will issue new regulations, guidance or interpretations that may impact our drug candidates. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent regulatory approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

We may be subject, directly or indirectly, to applicable U.S. federal and state anti-kickback, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. If we obtain FDA approval for any of our drug candidates and begin commercializing those drugs in the U.S., our operations may be subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act and physician sunshine laws and regulations. These laws may impact, among other things, our proposed sales and marketing programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, such as the federal False Claims Act which imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval from Medicare, Medicaid or other third-party payors that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- provisions of the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- provisions of HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;
- the federal transparency requirements under the Affordable Care Act, including the provision commonly referred to as the Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we are subject to state and non-U.S. equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the Federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not just governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amends the intent requirement of the federal Anti-Kickback and criminal healthcare fraud statutes. As a result of such amendment, a person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation.

Moreover, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the U.S. government under the Federal False Claims Act as well as under the false claims laws of several states.

Law enforcement authorities are increasingly focused on enforcing these laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our drug candidates outside the U.S. will also likely subject us to non-U.S. equivalents of the healthcare laws mentioned above, among other non-U.S. laws.

If any of the physicians or other providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

We expect that the new presidential administration and U.S. Congress will seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA, which could impact provisions of the existing fraud and abuse, privacy and security or other health care laws and regulations. There is still uncertainty with respect to the impact President Trump's administration and the U.S. Congress may have, if any, and any changes will likely take time to unfold. Such reforms could have an adverse effect on anticipated revenues from therapeutic candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop therapeutic candidates. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

Lastly, political, economic, and regulatory influences are subjecting the health care industry in the United States to fundamental change. Initiatives to reduce the federal budget and debt and to reform health care coverage are increasing cost-containment efforts. We anticipate that federal agencies, Congress, state legislatures, and the private sector will continue to review and assess alternative health care benefits, controls on health care spending, and other fundamental changes to the healthcare delivery system. Any proposed or actual changes could limit coverage for or the amounts that federal and state governments will pay for health care products and services, which could also result in reduced demand for our products or additional pricing pressures, and limit or eliminate our spending on development projects and affect our ultimate profitability.

We intend to market our drugs, if approved, in a variety of international markets and we are exploring the licensing of commercialization rights or other forms of collaboration worldwide, which exposes us to additional risks of conducting business in additional international markets.

We conduct business operations in regions including the U.S., China, Taiwan and New Zealand, and non-

U.S. markets are an important component of our growth strategy. If we fail to obtain licenses or enter into collaboration arrangements with third parties in these markets, or if these parties are not successful, our revenue- generating growth potential will be adversely affected.

Moreover, international business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- initiatives to develop an international sales, marketing and distribution organization may increase our expenses, divert our management's attention from the acquisition or development of drug candidates or cause us to forgo profitable licensing opportunities in these geographies;
- efforts to enter into collaboration or licensing arrangements with third parties in connection with our international sales, marketing and distribution efforts may increase our expenses or divert our management's attention from the acquisition or development of drug candidates;

- changes in a specific country's or region's laws, regulations or political and cultural climate or economic condition;
- differing regulatory requirements for drug approvals and marketing internationally;
- difficulty of effective enforcement of contractual provisions and intellectual property rights in local jurisdictions;
- potentially reduced protection for intellectual property rights;
- potential third-party patent rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements, such as Export Administration Regulations promulgated by the U.S. Department of Commerce and fines, penalties or suspension or revocation of export privileges;
- economic weakness, including inflation or political instability, particularly in non-U.S. economies and markets;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- the effects of applicable non-U.S. tax structures and potentially adverse tax consequences;
- currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incidental to doing business in another country;
- workforce uncertainty and labor unrest, particularly in non-U.S. countries where labor unrest is more common than in the U.S.;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a non-U.S. market with low or lower prices rather than buying them locally;
- failure of our employees and contracted third parties to comply with Office of Foreign Asset Control rules and regulations and the Foreign Corrupt Practices Act;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

These and other risks may materially adversely affect our ability to obtain or sustain revenue from international markets.

The use of legal, regulatory, and legislative strategies by both brand and generic competitors, including but not limited to "authorized generics" and regulatory petitions, as well as the potential impact of proposed and newly enacted legislation, may increase costs associated with the introduction or marketing of our generic products, could delay or prevent such introduction, and could adversely affect our results of operations.

Our competitors, both branded and generic, often pursue strategies to prevent, delay, or eliminate competition from generic alternatives to branded products. These strategies include, but are not limited to:

- entering into agreements whereby other generic companies will begin to market an authorized generic, a generic equivalent of a branded product, at the same time or after generic competition initially enters the market;
- launching a generic version of their own branded product prior to or at the same time or after generic competition initially enters the market;
- filing petitions with the FDA or other regulatory bodies seeking to prevent or delay approvals, including timing the filings so as to thwart generic competition by causing delays of our product approvals;
- seeking to establish regulatory and legal obstacles that would make it more difficult to demonstrate bioequivalence or to meet other requirements for approval, and/or to prevent regulatory agency review of applications, such as through the establishment of patent linkage (laws and regulations barring the issuance of regulatory approvals prior to patent expiration);
- initiating legislative or other efforts to limit the substitution of generic versions of brand pharmaceuticals;
- filing suits for patent infringement and other claims that may delay or prevent regulatory approval, manufacture, and/or scale of generic products;
- introducing "next-generation" products prior to the expiration of market exclusivity for the reference product, which often materially reduces the demand for the generic or the reference product for which we seek regulatory approval;

- persuading regulatory bodies to withdraw the approval of brand name drugs for which the patents are about to expire and converting the market to another product of the brand company on which longer patent protection exists;
- obtaining extensions of market exclusivity by conducting clinical trials of brand drugs in pediatric populations or by other methods; and
- seeking to obtain new patents on drugs for which patent protection is about to expire.

If any other actions by our competitors and other third parties to prevent or delay activities necessary to the approval, manufacture, or distribution of our products are successful, our entry into the market and our ability to generate revenues associated with new products may be delayed, reduced, or eliminated, which could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

Our compounded preparations and the pharmacy compounding industry are subject to regulatory and customer scrutiny, which may impair our growth and sales.

Formulations prepared and dispensed by compounding pharmacies contain FDA-approved ingredients, but are not themselves approved by the FDA. As a 503B outsourcing facility, our compounded formulations are not subject to the FDA approval process. Certain compounding pharmacies have been the subject of widespread negative media coverage in recent years, and the actions of these pharmacies have resulted in increased scrutiny of compounding pharmacy activities from the FDA and state governmental agencies. For example, the FDA has in the past requested that a number of compounding pharmacies conduct a recall of all non-expired, purportedly sterile drug products and cease sterile compounding operations due to lack of sterility assurance, and additional compounding pharmacies have suspended sterile production or voluntarily recalled certain sterile compounding products after an FDA inspection of the relevant facilities. As a result of this exercise of caution, some physicians may be hesitant to prescribe, and some patients may be hesitant to purchase and use, these compounded formulations.

If a compounded drug formulation provided through our compounding services leads to patient injury or death or results in a product recall, we may be exposed to significant liabilities and reputational harm.

The production, labeling and packaging of compounded drugs is inherently risky. The success of our compounded formulations and pharmacy operations depends to a significant extent upon perceptions of the safety and quality of our products. We could be adversely affected if our formulations are subject to negative publicity. We could also be adversely affected if any of our formulations or other products, any similar products sold by other companies, or any products sold by other compounding outsourcing facilities, prove to be, or are asserted to be, harmful to patients. There are a number of factors that could result in the injury or death of a patient who receives one of our compounded formulations, including quality issues, manufacturing or labeling flaws, improper packaging or unanticipated or improper uses of the products, any of which could result from human or other error. Any of these situations could lead to a recall of, or safety alert relating to, one or more of our products. Similarly, to the extent any of the components of approved drugs or other ingredients used by us to produce compounded formulations have quality or other problems that adversely affect the finished compounded preparations, our sales could be adversely affected. In addition, in the ordinary course of business, we may voluntarily retrieve products in response to a customer complaint. Because of our dependence upon medical and patient perceptions, any adverse publicity associated with illness or other adverse effects resulting from the use or misuse of our products, any similar products sold by other companies or any other compounded formulations, could have a material adverse impact on our business, results of operations and financial condition.

Risks Related to Our Intellectual Property

A significant portion of our intellectual property portfolio currently comprises pending patent applications that have not yet been issued as granted patents, and if our pending patent applications fail to issue our business will be adversely affected. If we are unable to obtain and maintain patent protection for our technology and drugs, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the U.S., the PRC and other countries with respect to our proprietary technology and drug candidates. We have sought to protect our proprietary position by filing patent applications in the U.S., the PRC and other countries related to novel technologies and drug candidates that we consider are important to our business. As of June 30, 2017, we own more than 100 issued patents and more than 40 pending patent applications worldwide. In addition, we own one pending international patent application under the Patent Cooperation Treaty, or PCT, which we plan to file nationally in the U.S. and other jurisdictions. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. There

can be no assurance that our pending patent applications will result in issued patents in the U.S. or non-U.S. jurisdictions in which such applications are pending. Moreover, even our issued patents do not guarantee us the right to practice our technology in relation to the commercialization of our platforms' product candidates. The area of patent and other intellectual property rights in biotechnology is an evolving one with many risks and uncertainties, and third parties may have blocking patents that could be used to prevent us from commercializing our patented technologies, platforms and product candidates and practicing our proprietary technology. There can also be no assurance that a third party will not challenge the validity of our patents or that we will obtain sufficient claim scope in those patents to prevent a third party from competing successfully with our drug candidates.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our technology or drug candidates, or that effectively prevent others from commercializing competitive technologies and drug candidates. Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Under the America Invents Act enacted in 2011, the U.S. moved to a first-to-file system in early 2013 from the previous system under which the first to make the claimed invention was entitled to the patent. Assuming the other requirements for patentability are met, the first to file a patent application is entitled to the patent.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or drug candidates in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the U.S. and abroad, which proceedings are time-consuming, costly and of uncertain outcome. We may become involved in interference, *inter partes* review, post grant review, *ex parte* reexamination, derivation, opposition or similar other proceedings challenging our patent rights or the patent rights of others. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and drug candidates, or limit the duration of the patent protection of our technology and drug candidates. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drug candidates similar or identical to ours.

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

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the field of immunotherapy has emerged in the U.S. The patent situation outside of the U.S. is even more uncertain. Changes in the patent laws and rules, either by legislation, judicial decisions, or regulatory interpretation in the U.S. and other countries may diminish our ability to protect our inventions and enforce our intellectual property rights, and more generally could affect the value of our intellectual property.

In addition, the laws of certain non-U.S. countries do not protect intellectual property rights to the same extent as U.S. federal and state laws do. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing drugs made using our inventions in and into the U.S. or non-U.S. jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs and further, may export otherwise infringing drugs to non-U.S. jurisdictions where we have patent protection, but where enforcement rights are not as strong as those in the U.S. These drugs may compete with our drug candidates and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain jurisdictions, including China. The legal systems of some countries do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biopharmaceutical products, which could make it difficult in those jurisdictions for us to stop the infringement or misappropriation of our patents or other intellectual property rights, or the marketing of competing drugs in violation of our proprietary rights. Proceedings to enforce our patent and other intellectual property rights in non-U.S. jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business.

Furthermore, such proceedings could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims of infringement or misappropriation against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and our patent rights relating to our drug candidates could be found invalid or unenforceable if challenged in court or before the U.S. Patent and Trademark Office or comparable non-U.S authority.

Competitors may infringe our patent rights or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Such litigation can be expensive and time- consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and/or defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that patent rights or other intellectual property rights owned by us are invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent rights or other intellectual property rights do not cover the technology in question. An adverse result in any litigation proceeding could put our patent, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

If we initiate legal proceedings against a third party to enforce any patent, or any patents that may issue in the future from our patent applications, that relates to one of our drug candidates, the defendant could counterclaim that such patent rights are invalid or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include *ex parte* re-examination, *inter partes* review, post-grant review, derivation and equivalent proceedings in non-U.S. jurisdictions, such as opposition proceedings. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our drug candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our drug candidates. Such a loss of patent protection could have a material adverse impact on our business.

We may not be able to prevent misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the U.S. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

Although we are not currently experiencing any claims challenging the inventorship of our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as inventors or co- inventors. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our drug candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose rights such as exclusive ownership of, or right to use, our patent rights or other intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time-consuming and could prevent or delay us from developing or commercializing our drug candidates.

Our commercial success depends in part on our avoiding infringement of the patents and other intellectual property rights of third parties. There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including litigation in the U.S. courts, *inter partes* review, post grant review, interference and *ex parte* reexamination proceedings before the U.S. Patent and Trademark Office, or USPTO, or oppositions and other comparable proceedings in non-U.S. jurisdictions. Numerous issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing drug candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our drug candidates or manufacturing processes may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our drug candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our drug candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our drug candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to prevent us from commercializing such drug candidate unless we obtain a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the applicable drug candidate unless we obtain a license, limit our uses, or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all.

Third parties who bring successful claims against us for infringement of their intellectual property rights may obtain injunctive or other equitable relief, which could prevent us from developing and commercializing one or more of our drug candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee resources from our business. In the event of a successful claim of infringement or misappropriation against us, we may have to pay substantial damages, including treble damages and attorneys' fees in the case of willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing drug candidates, which may be impossible or require substantial time and monetary expenditure and undertaking additional preclinical studies, clinical trials or regulatory review. In the event of an adverse result in any such litigation, or even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our drug candidates. We cannot predict whether any required license would be available at all or whether it would be available on commercially reasonable terms, and we may fail to obtain any of these licenses on commercially reasonable terms, if at all. In the event that we are unable to obtain such a license, we would be unable to further develop and commercialize one or more of our drug candidates, which could harm our business significantly. We may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation and any such license agreements may require us to pay royalties and other fees that could significantly harm our business.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical personnel, management personnel, or both from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If our products conflict with the intellectual property rights of third parties, we may incur substantial liabilities and we may be unable to commercialize products in a profitable manner or at all.

We seek to launch generic pharmaceutical products either where patent protection or other regulatory exclusivity of equivalent branded products has expired, where patents have been declared invalid or where products do not infringe on the patents of others. However, at times, we may seek approval to market generic products before the expiration of patents relating to the branded versions of those products, based upon our belief that such patents are invalid or otherwise unenforceable or would not be infringed by our products. Our success depends in part on our ability to operate without infringing the patents and proprietary rights of third parties.

The manufacture, use and sale of generic versions of products has been subject to substantial litigation in the pharmaceutical industry. These lawsuits relate to the validity and infringement of patents or proprietary rights of third parties. If our products were found to be infringing on the intellectual property rights of a third-party, we could be required to cease selling the infringing products, causing us to lose future sales revenue from such products and face substantial liabilities for patent infringement, in the form of either payment for the innovator's lost profits or a royalty on our sales of the infringing product. These damages may be significant and could materially adversely affect our business. Any litigation, regardless of the merits or eventual outcome, would be costly and time-consuming and we could incur significant costs and/or a significant reduction in revenue in defending the action and from the resulting delays in manufacturing, marketing or selling any of our products subject to such claims.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other patent agencies in several stages over the lifetime of the patent. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

The terms of our patents may not be sufficient to effectively protect our drug candidates and business.

In most countries in which we file patent applications, including the U.S., the term of an issued patent is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. With respect to any issued patents in the U.S., we may be entitled to obtain a patent term extension or extend the patent expiration date provided we meet the applicable requirements for obtaining such patent term extensions. Although various such extensions may be available, the life of a patent and the protection it affords is by definition limited. Even if patents covering our drug candidates are obtained, we may be open to competition from other companies as well as generic medications once the patent life has expired for a drug. If patents are issued on our currently pending patent applications, the resulting patents will be expected to expire on dates ranging from 2025 to 2038, excluding any potential patent term extension or adjustment. Upon the expiration of our issued patent or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

In addition, the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies. For these reasons, we may have competition for our technologies, platforms and product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

If we do not obtain additional protection under the Hatch-Waxman Amendments and similar legislation in other countries extending the terms of our patents, if issued, relating to our drug candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA regulatory approval for our drug candidates, one or more of our U.S. patents, if issued, may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years as compensation for patent term lost during drug development and the FDA regulatory review process. Patent term extensions, however, cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval by the FDA, and only one patent can be extended for a particular drug.

The application for patent term extension is subject to approval by the USPTO, in conjunction with the FDA. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain a patent term extension for a given patent or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our drug will be shortened and our competitors may obtain earlier approval of competing drugs, and our ability to generate revenues could be materially adversely affected.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our drug candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patent rights. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and is therefore costly, time-consuming, and inherently uncertain. In addition, the U.S. has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained, if any. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in a recent case, *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that certain claims to naturally-occurring substances are not patentable. Although we do not believe that our currently-issued patents and any patents that may issue from our pending patent applications directed to our drug candidates if issued in their currently pending forms, as well as patent rights licensed by us, will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patent rights. There could be similar changes in the laws of foreign jurisdictions that may impact the value of our patent rights or our other intellectual property rights.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

In addition to our issued patents and pending patent applications, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drug candidates. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to them, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In many cases our confidentiality and other agreements with consultants, outside scientific collaborators, sponsored researchers and other advisors require them to assign to us or grant us licenses to inventions they invent as a result of the work or services they render under such agreements or grant us an option to negotiate a license to use such inventions. However, any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

Furthermore, many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, including each member of our senior management, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. Although we have confidence in these individuals, organizations, and systems, agreements or security measures may be breached and we may not have adequate remedies for any breach. To the extent that our employees, contractors, consultants, collaborators, and advisors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

We may not be successful in obtaining or maintaining necessary rights for our development pipeline through acquisitions and in-licenses.

Because our programs may involve additional drug candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire and maintain licenses or other rights to use these proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, or other third-party intellectual property rights from third parties that we identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third- party intellectual property rights, our business, financial condition and prospects for growth could suffer.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could be required to pay monetary damages or could lose license rights that are important to our business.

We have entered into license agreements with third parties providing us with rights under various third- party patents and patent applications, including the rights to prosecute patent applications and to enforce patents. Certain of these license agreements impose and, for a variety of purposes, we may enter into additional licensing and funding arrangements with third parties that also may impose diligence, development or commercialization timelines and milestone payment, royalty, insurance and other obligations on us. Certain of these license agreements provide us with the exclusive right to practice technologies in major markets including North America, South America, European Union, Australia, New Zealand, Eastern Europe, China, Taiwan, Hong Kong, Macau and parts of Southeast Asia, although the right to practice the technologies and any inventions arising out of such technologies outside of these territories may be reserved to the licensing company. In addition, under certain of our existing licensing agreements, we are obligated to pay royalties on net product sales of our drug candidates once commercialized, pay a percentage of sublicensing revenues, make other specified payments relating to our drug candidates or pay license maintenance and other fees. We also have diligence and clinical development obligations under certain of these agreements that we are required to satisfy. If we fail to comply with our obligations under our current or future license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any drug or drug candidate that is covered by the licenses provided for under these agreements or we may face claims for monetary damages or other penalties under these agreements. Such an occurrence could diminish the value of these products and our company. Termination of the licenses provided for under these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

In particular, our ability to stop third parties from making, using, selling, offering to sell, or importing any of our patented inventions, either directly or indirectly, will depend in part on our success in obtaining, defending, and enforcing patent claims that cover our technology, inventions, and improvements. With respect to both licensed and company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our platforms and product candidates and the methods used to manufacture those platforms and product candidates. Our issued patents and those that may issue in the future may be challenged, invalidated, or circumvented, which could limit our ability to stop competitors from marketing related platforms or product candidates or limit the length of the term of patent protection that we may have for our technologies, platforms, and product candidates.

We also rely on trade secret protection for our confidential and proprietary information. Although we take steps to protect our confidential and proprietary information as trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us.

If our licensing and sublicensing activities result in non-compliance with our licensing agreements, our business relationships with our licensing partners may suffer and we may be required to pay monetary damages or rescind or amend existing agreements which are important to our business.

We have entered into agreements with third parties under which we have granted licenses to use certain of our patents and patent applications, including the rights to develop, seek regulatory approval for and sell products using our KX-01 and KX-02 products. We have also entered into similar agreements sublicensing the intellectual property for the Orascovery platform, which we have licensed from Hanmi. We have granted exclusive patent rights to certain of these partners and have granted them certain additional rights with respect to the intellectual property we have licensed to them. From time to time we may engage in other licensing transactions in which we acquire licenses to certain intellectual property or sublicense intellectual property rights. If we fail to comply with or are found to have violated the terms of any of our licenses, we may be required to rescind or amend our license agreements or pay damages to license counterparties or other rightsholders. This may also negatively impact our relationships with our licensing and sublicensing partners for our candidate platforms.

Risks Related to Our Reliance on Third Parties

We depend on our agreements with Hanmi Pharmaceutical Co. Ltd, or Hanmi, to provide rights to the intellectual property relating to certain of our lead product candidates. Any termination or loss of significant rights under those agreements would adversely affect our development or commercialization of our lead product candidates.

We have licensed the intellectual property rights related to HM30181A, an integral part of our current product candidates, from Hanmi pursuant to two license agreements. If, for any reason, our license agreements are terminated or we otherwise lose those rights, it would adversely affect our business. Our license agreements with Hanmi impose on us obligations relating to exclusivity, territorial rights, development, commercialization, funding, payment, diligence, sublicensing, insurance, intellectual property protection and other matters. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages to Hanmi and Hanmi may have the right to terminate our license, which could result in us being unable to develop, manufacture and sell our product candidates that incorporate HM30181A.

In addition, under our 2013 license agreement with Hanmi, we have granted Hanmi a one-time right of first negotiation that, at Hanmi's discretion, requires us to negotiate in good faith the sale of our rights in Oraxol and Oratecan under such agreement to Hanmi at a purchase price determined by an internationally-recognized investment banking firm with an office in Hong Kong at any time prior to the earlier of (i) our first commercial sale of products using such technology or (ii) receipt by Hanmi of written notice from our Company of the sublicense of the rights in an applicable product to a third party. If Hanmi exercises this right of first negotiation and we reach an agreement to sell our rights under that licensing agreement, our ability to continue to develop certain of our product candidates would be significantly impaired and would adversely affect our business and results of operations.

Each of our license agreements with Hanmi expires on the earlier of (i) expiration of the last of Hanmi's patent rights licensed under the agreement or (ii) invalidation of Hanmi's patent rights which are the subject of the agreement, provided that the term will automatically be extended for consecutive one year periods unless either party gives notice to the other at least 90 days prior to expiration of the patent rights licensed under the agreement or before the then current annual expiration date of the agreement. The patent rights licensed to us under the agreements with Hanmi have expiry dates ranging from 2023 to 2033, unless the terms of such licensed patents are able to be extended in accordance with applicable laws and regulations. Subject to certain conditions, Hanmi may also terminate the license agreements if we fail to comply with certain development milestones set out in each of the agreements. The agreements also contain customary termination rights for either party, such as in the event of a breach of the agreement or the initiation of bankruptcy proceedings by the other party or by mutual agreement.

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

We have relied upon and may, in the future, rely upon third-party CROs to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, and regulatory requirements and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCPs, which are regulations and guidelines enforced by the FDA, CFDA and other regulatory authorities for all of our drugs in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, CFDA or regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that

upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, non-clinical and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements, environmental, health and safety laws and regulations, or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, our results of operations and the commercial prospects for our drug candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Our total API revenue is highly dependent on a limited number of API customers, and the loss of, or any significant decrease in business from, any one or more of our major API customers could adversely affect our financial condition and results of operations.

We have in the past derived, and, until we further diversify our sources of revenue from the sales of new products and drugs, we believe that we will continue to derive, a significant portion of our revenue from a limited number of customers. We generated 40.6% and 63.2% for the six months ended June 30, 2017 and 2016, respectively, of our total revenue from our two largest customers, Intas Pharmaceuticals and Ebewe Pharmaceuticals, during those periods. No other customer accounted for 10% or more of our total revenue during those periods. While our business model relies on API sales to generate the substantial majority of our revenue, we expect our total revenue will continue to be highly dependent on a limited number of API customers.

There are a number of factors that could cause us to lose major customers. We do not enter into long-term sales contracts with customers, but sell API to them based on short-term purchase orders. Accordingly, these customers may choose to use other suppliers with little or no notice, based upon considerations of price, quality, shipping time, competitive or other reasons. In addition, our API customers use the API to manufacture drugs, and they are subject to regulation and oversight by the FDA and other relevant regulatory agencies. If for any reason, any such customer violates an FDA regulation that results in their being prohibited from manufacturing drugs, they would no longer purchase API from us. Such sanctions or regulatory action against drug manufacturers could happen without notice, and our revenue stream could be adversely affected without notice.

The loss of any of our major API customers could materially and adversely affect our financial condition and results of operations.

Additionally, Polymed, our wholly owned subsidiary, sells API to third parties for use in those third parties' products, which may be manufactured in cGMP facilities. In the event Polymed's customers fail to remain in compliance with cGMP regulations, their operations may be adversely impacted, causing them to cancel or cease API orders from Polymed. Any decrease in orders by Polymed's customers may impact Polymed's revenue and, as a result, our overall financial condition.

If our Global Supply Chain Platform is insufficient, we may rely on third parties to manufacture at least a portion of our drug candidate supplies, and for at least a portion of the manufacturing process of our drug candidates, if approved. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices.

Although we currently have a facility that may be used as our clinical-scale manufacturing and processing facility, we partially rely on outside vendors to manufacture supplies and process our drug candidates. We have not yet begun to manufacture or process our drug candidates on a commercial scale and may not be able to do so for any of our drug candidates.

We have limited experience in managing the manufacturing process, and our process may be more difficult or expensive than the approaches currently in use.

Although we do intend to further develop our manufacturing facilities, and those leased to us under our public-private partnerships, we may also use third parties as part of our manufacturing process. Our reliance on third-party manufacturers may expose us to the following risks:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA, CFDA or other regulatory authorities must approve any manufacturers. This approval would require

new testing and cGMP-compliance inspections by FDA, CFDA or other regulatory authorities. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our drugs.

- our manufacturers may have little or no experience with manufacturing our drug candidates, and therefore may experience quality issues or require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to manufacture our drug candidates.
- our third-party manufacturers might be unable to timely manufacture our drug or produce the quantity and quality required to meet our clinical and commercial needs, if any.
- contract manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately.
- our future contract manufacturers may not perform as agreed, may not devote sufficient resources to our drugs, or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our drugs.
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our drugs.
- our third-party manufacturers could breach or terminate their agreement with us.
- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects.
- our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters.
- our contract manufacturers may have unacceptable or inconsistent product quality success rates and yields.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our drug candidates by the FDA, CFDA or other regulatory authorities, result in higher costs or adversely impact commercialization of our drug candidates. In addition, we will rely on third parties to perform certain specification tests on our drug candidates prior to delivery to patients. If these tests are not conducted appropriately and test data are not reliable, patients could be put at risk of serious harm and the FDA, CFDA or other regulatory authorities could place significant restrictions on our Company until deficiencies are remedied.

The manufacture of drug and biological products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls.

Currently, raw materials used in our manufacturing activities, including the pacific yew used in many of the API products we manufacture, are supplied by multiple suppliers. We have agreements for the supply of such raw materials with manufacturers or suppliers that we believe have sufficient capacity to meet our demands. In addition, we believe that adequate alternative sources for such supplies exist. However, there is a risk that, if supplies are interrupted, it would materially harm our business.

Manufacturers of drug and biological products often encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process (including the absence of contamination). These problems include logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, product testing, operator error, availability of qualified personnel, as well as compliance with strictly enforced federal, state and non-U.S. regulations. Furthermore, if contaminants are discovered in our supply of our drug candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability failures or other issues relating to the manufacture of our drug candidates will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our drug candidate to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely.

If third-party manufacturers fail to comply with pharmaceutical manufacturing regulations, our financial results and financial condition will be adversely affected.

Before a third party can begin commercial manufacture of our drug candidates and potential drugs, contract manufacturers are subject to regulatory inspections of their manufacturing facilities, processes and quality systems. Due to the complexity of the processes used to manufacture drug and biological products and our drug candidates, any potential third-party manufacturer may be unable to initially pass federal, state or international regulatory inspections in a cost effective manner in order for us to obtain regulatory approval of our drug candidates. If our contract manufacturers do not pass their inspections by the FDA, CFDA or other regulatory authorities, our commercial supply of drug product or substance will be significantly delayed and may result in significant additional costs, including the delay or denial of any marketing application for our drug candidates. In addition, drug and biological manufacturing facilities are continuously subject to inspection by the FDA, CFDA and other regulatory authorities, before and after drug approval, and must comply with cGMPs. Our contract manufacturers may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. In addition, contract manufacturers' failure to achieve and maintain high manufacturing standards in accordance with applicable regulatory requirements, or the incidence of manufacturing errors, could result in patient injury, product liability claims, product shortages, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously harm our business, reputation or corporate image. If a third-party manufacturer with whom we contract is unable to comply with manufacturing regulations, we may also be subject to fines, unanticipated compliance expenses, recall or seizure of our drugs, product liability claims, total or partial suspension of production and/or enforcement actions, including injunctions, and criminal or civil prosecution. These possible sanctions could materially adversely affect our financial results and financial condition.

Furthermore, changes in the manufacturing process or procedure, including a change in the location where the product is manufactured or a change of a third-party manufacturer, could require prior review by the FDA, CFDA or other regulatory authorities and/or approval of the manufacturing process and procedures in accordance with the FDA or CFDA's regulations, or comparable requirements. This review may be costly and time consuming and could delay or prevent the launch of a product. The new facility will also be subject to pre- approval inspection. In addition, we have to demonstrate that the product made at the new facility is equivalent to the product made at the former facility by physical and chemical methods, which are costly and time consuming. It is also possible that the FDA, CFDA or other regulatory authorities may require clinical testing as a way to prove equivalency, which would result in additional costs and delay.

We have entered into collaborations and may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We have partnered with companies such as Hanmi, Gland Pharma Limited and SunGen Pharma LLC and may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our drug candidates and any future drug candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing shareholders, or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our drug candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third party for development and commercialization of a drug candidate, we can expect to relinquish some or all of the control over the future success of that drug candidate to the third party.

Further, collaborations involving our drug candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our drug candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive drugs, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a drug candidate, repeat or conduct new clinical trials, or require a new formulation of a drug candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, drugs that compete directly or indirectly with our drugs or drug candidates;

- a collaborator with marketing and distribution rights to one or more drugs may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our drug candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable drug candidates; and
- collaborators may own or co-own intellectual property covering our drugs that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into collaboration agreements and strategic partnerships or license our drugs, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a drug candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our drug candidates or bring them to market and generate product sales revenue, which would harm our business prospects, financial condition and results of operations.

We have engaged and will rely on a single vendor to manage our order to cash cycle and our distribution activities in the U.S., and the loss or disruption of service from this vendor could adversely affect our operations and financial condition.

Our U.S. customer management, order processing, invoicing, cash application, chargeback and rebate processing and distribution and logistics activities will be managed by Dohmen Life Science Services, or DLSS, a managed services provider with a focus on life sciences companies. If we were to lose the availability of DLSS's services due to a dispute, termination of or inability to renew the contract, or other factors such as fire, natural disaster or other disruption, such loss could have a material adverse effect on our operations. Although multiple providers of such services exist, there can be no assurance that we could secure another source to handle these transactions on acceptable terms or otherwise to our specifications in the event of a disruption of services at operational centers.

Risks Related to Our Industry, Business and Operation

Our future success depends on our ability to retain our Chief Executive Officer and other key executives and to attract, retain and motivate qualified personnel. Additionally, certain members of our leadership may engage in other business ventures that may have interests in conflict with ours.

We are highly dependent on Dr. Lau, our Chief Executive Officer, and the other principal members of our management and scientific teams. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

To induce valuable employees to remain at our Company, in addition to salary and cash incentives, we have provided stock option grants that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by changes in the price of our common stock that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with our key employees, any of our employees could leave our employment at any time, with or without notice.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel or consultants will also be critical to our success. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery and preclinical development and commercialization strategy. The loss of the services of our executive officers or other key employees and consultants could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

Furthermore, replacing executive officers and key employees or consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel or consultants on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel.

We may choose to hire part-time employees or use consultants. As a result, certain of our employees, officers, directors and consultants may not devote all of their time to our business, and may from time to time serve as officers, directors and consultants of other companies. These other companies may have interests in conflict with ours. For instance, Dr. Johnson Lau, who serves as our Chief Executive Officer and Chairman, Dr. Manson Fok and Mr. Song-Yi Zhang, who serve on our board of directors, and another of our employees are also directors of Avalon Global Holdings Limited, or Avalon, a shareholder of ours. In addition, Dr. David Hangauer, our former Chief Scientific Officer and one of our founders, recently retired in December 2016, and now maintains an advisory relationship with our company.

We also face competition for the hiring of scientific and clinical personnel from universities and research institutions. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We are substantially dependent on our public-private partnerships and if we or our counterparties fail to meet the obligations of those agreements and we lose the benefits of those partnerships, it would materially impact our development, operations and prospects.

Our long-term public-private partnerships with governments and government agencies, including in certain emerging markets, include agreements to build and/or maintain manufacturing facilities for us. For example, we entered into an agreement with Fort Schuyler Management Corporation, or FSMC, a not-for-profit corporation organized by the State of New York, whereby FSMC agreed to fund the costs of construction of a new manufacturing facility in Dunkirk, New York. FSMC is responsible for the costs of construction and of all equipment for the facility, up to an amount not to exceed $225 million, and shall retain ownership of the facility and the equipment. We are entitled to lease the facility and all equipment at a rate of $1.00 per year for an initial 10-year term, and for the same rate if we elect to extend the lease for an additional 10-year term. We are responsible for all operating costs and expenses for the facility. In exchange, we have committed to spending $1.5 billion on operational expenses in the Dunkirk facility in our first 10-year term in the facility, and an additional $1.5 billion on operational expenses if we elect to extend the lease for a second 10-year term. We have also committed to hiring 450 permanent employees within the first 5 years at the Dunkirk facility. We have also entered into similar arrangements with FSMC relating to our headquarters, and Chongqing Maliu Riverside Development & Investment Co., Ltd. relating to a plant in Chongqing, PRC, under which we have committed to achieving certain operating, revenue and tax generation milestones. If we are unable to comply with our obligations under these arrangements, including the milestones we have committed to achieve, we may lose access to the properties covered by such arrangements which could disrupt our operations and manufacturing activities, cause us to divert resources to finding alternative facilities, which would not have any subsidies, and would have a significant impact on our operations and financial performance. Furthermore, there is no guarantee that the counterparties to our public-private partnerships will comply with the terms of the agreements, including that their ability to fund their capital commitments under the agreements may be subject to their ability to raise additional capital and that construction timetables may not be met, nor is there guarantee that the successors to such counterparties will continue to comply with terms of the agreements, regardless of existence of such government stipulations as a guideline released on November 4, 2016 by the State Council of China, which provides that, among others governments and relevant departments at all levels shall strictly keep policy commitments lawfully made to society and administrative counterparties, shall carefully perform all the contracts lawfully entered into with investment subjects in activities like attraction of investment and public-private partnership, shall not breach contracts with such excuses as government transition and replacement of leaders, and shall bear legal and economic liability in event of their infringements and contract breaches. If our public- private partnership counterparties or their successors fail to comply with their obligations under these arrangements, our development programs and prospects will be materially adversely affected. Public- private partnerships are also subject to risks associated with government and government agency counterparties, including risks related to government relations compliance, sovereign immunity, shifts in the political environment, changing economic and legal conditions and social dynamics.

We will need to increase the size and capabilities of our organization, and we may experience difficulties in managing our growth.

As of June 30, 2017, we had over 450 employees and consultants and most of our employees are full- time. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we must add a significant number of additional managerial, operational, sales, marketing, financial and other personnel. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA or other comparable authority review process for our drug candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our drug candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities. In addition, we expect to incur additional costs in hiring, training and retaining such additional personnel.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our drug candidates and, accordingly, may not achieve our research, development and commercialization goals.

We previously identified material weaknesses in our internal control over financial reporting. If we fail to maintain effective internal control over financial reporting, we may not be able to accurately report our consolidated financial results.

In connection with the preparation of our consolidated financial statements as of and for the years ended December 31, 2014 and 2015, we and our independent registered public accounting firm identified material weaknesses related to our internal controls regarding: (1) the thoroughness of review and determination of appropriate accounting treatment for complex, non-routine transactions, including consideration of fair value concepts, notably for purchase price allocation and accounting for stock options; (2) the precision of review and application of available information through retrospective review to record accounting estimates accurately based on known, available information; and (3) the precision of review and evaluation of capitalization policies to ensure amounts capitalized as assets related to items for which an identifiable benefit has been received and will be realizable. We have concluded that such material weaknesses were remediated as of December 31, 2016.

Management believes that we did not have the appropriate resources or personnel to provide a full review of complex transactions to allow us, in the normal course of business, to prevent or identify a material misstatement on a timely basis and that constituted material weaknesses in our internal control over financial reporting under the standards established by the U.S. Public Company Accounting Oversight Board. Under standards established by the Public Company Accounting Oversight Board, a deficiency in internal control over financial reporting exists when the design or operation of a control does not allow management or personnel, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely basis. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected and corrected on a timely basis. Management implemented a remediation plan to address these material weaknesses identified. In addition, management has hired additional accounting personnel with appropriate experience to assist us in applying U.S. GAAP technical accounting guidance and financial reporting, with a particular emphasis on events outside the ordinary course of business and complex transactions including estimates. As a newly public company, we will also need to establish and maintain effective disclosure and financial controls and make changes in our corporate governance practices. We cannot assure that there will not be additional material weaknesses and significant deficiencies that our independent registered public accounting firm or we will identify in the future. If we identify such issues or if we are unable to produce accurate and timely financial statements, our stock price may be adversely affected and we may be unable to maintain compliance with applicable listing requirements. Moreover, there is no assurance that we will be able to recruit additional accounting and financial personnel or maintain such personnel. Even if we are able to hire appropriate personnel, our existing operating expenses and operations will be impacted by the direct costs of their employment and the indirect consequences relating to the diversion of management resources from product development efforts.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the laws of the FDA and other similar non-U.S. regulatory authorities; provide true, complete and accurate information to the FDA and other similar non-U.S. regulatory authorities; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the U.S. and similar non-U.S. fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our drug candidates and begin commercializing those drugs in the U.S., our potential exposure under U.S. laws will increase significantly and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing drugs or drug candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Our business is subject to applicable laws and regulations relating to sanctions, anti-money laundering and anti-bribery practices, the violation of which could adversely affect our operations.

We must comply with all applicable economic sanctions, anti-money laundering and anti-bribery laws and regulations of the U.S. and other foreign jurisdictions where we operate, including the PRC. U.S. laws and regulations applicable to us include the economic trade sanctions laws and regulations administered by the U.S. Department of the Treasury's Office of Foreign Assets Control, or OFAC, as well as certain laws administered by the U.S. Department of State. Our business is also subject to anti-money laundering laws and regulations, including the Proceeds of Crime Act 2002, the Terrorism Act 2000 and the Money Laundering Regulations 2007 in the U.K., the Bank Secrecy Act of 1970, the Money Laundering Control Act of 1986 and the USA PATRIOT Act of 2001 in the U.S. and equivalent or similar legislation in the other countries where we do business. In addition, we are subject to the Foreign Corrupt Practices Act of 1977, or FCPA, and other anti-bribery laws such as the U.K. Bribery Act 2010 that generally prohibit the corrupt provision of anything of value to foreign governments and their officials and political parties for the purpose of influencing official conduct or obtaining or retaining an undue business advantage. Applicable anti-bribery laws also may prohibit commercial bribery.

We have operations, conduct clinical trials, deal with government entities, including hospitals and public health regulators, and have contracts in countries known to experience corruption and commercial bribery. Our activities in these countries create the risk of unauthorized payments or offers of payments by our employees, brokers or agents that could be in violation of various laws, including the FCPA, even though these parties are not always subject to our control and supervision. There is no assurance that our existing safeguards and procedures will be completely effective in ensuring compliance with such laws, and our employees, brokers or agents may engage in conduct for which we may be held responsible. Violations of the FCPA or other anti-bribery laws may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could negatively affect our reputation, business, operating results, and financial condition.

Regulations administered by OFAC govern transactions with countries and persons subject to U.S. trade sanctions. We are also subject to U.S. Government restrictions on transactions with specific entities and individuals, including, without limitation, those set forth on the Entity List, the Specially Designated Nationals List, the Denied Persons List, the Unverified List, and the U.S. State Department's lists of debarred parties and sanctioned entities, and we may also be subject to restrictions on transactions with specific entities and individuals subject to the sanctions administered by the United Nations Security Council, the European Union, Her Majesty's Treasury, or other relevant sanctions authority. These regulations prohibit us from entering into or facilitating unlicensed transactions with, for the benefit of, or in some cases involving the property and property interests of such persons, governments, or countries designated by the relevant sanctions authority under one or more sanctions regimes. Failure to comply with these sanctions and embargoes may result in material fines, sanctions or other penalties being imposed on us or other governmental investigations. In addition, various state and municipal governments, universities and other investors maintain prohibitions or restrictions on investments in companies that do business involving sanctioned countries or entities.

International economic and trade sanctions are complex and subject to frequent change, including jurisdictional reach and the lists of countries, entities, and individuals subject to the sanctions. Current or future economic and trade sanctions regulations or developments might have a negative impact on our business or reputation, and we may incur significant costs related to current, new, or changing sanctions programs, as well as investigations, fines, fees or settlements, which may be difficult to predict. In addition, companies subject to SEC reporting obligations are required under Section 13 of the Exchange Act to disclose in their periodic reports specified dealings or transactions involving Iran or other individuals and entities targeted by certain sanctions promulgated by OFAC that the reporting company or any of its affiliates engaged in during the period covered by the relevant periodic report. In some cases Section 13 requires companies to disclose transactions even if they are permissible under U.S. law. The SEC is required to post this notice of disclosure pursuant to Section 13 on its website and report to the President and certain congressional committees regarding such filings.

On January 16, 2016, OFAC issued General License H, which authorized certain transactions relating to Iran. Pursuant to General License H, certain of our non-U.S. subsidiaries may conduct business relating to Iran. SEC guidance to date indicates that activities authorized by General License H generally are not subject to disclosure under Section 13, but should applicable SEC guidance or disclosure requirements change, or should our non-U.S. subsidiaries engage in activities subject to disclosure under Section 13, we may be required to disclose certain Iran-related transactions in future periodic reports with the SEC. Even if such activity is permitted under applicable law, disclosure could harm our reputation and have a negative impact on our business. Our non-U.S. subsidiaries also remain subject to OFAC secondary sanctions governing trade with Iran, and any violations of OFAC secondary sanctions regulations could negatively affect our reputation, business, operating results, and financial condition.

Although we have policies and controls in place that are designed to ensure compliance with these laws and regulations, it is possible that an employee or intermediary could fail to comply with applicable laws and regulations. In such event, we could be exposed to civil penalties, criminal penalties and other sanctions, including fines or other punitive actions, and the government may

seek to impose modifications to business practices, including cessation of business activities in sanctioned countries, and modifications to compliance programs, which may increase compliance costs. In addition, such violations could damage our business and/or our reputation. Such criminal or civil sanctions, penalties, other sanctions, and damage to our business and/or reputation could have a material adverse effect on our financial condition and results of operations.

Any failure to comply with applicable regulations and industry standards or obtain various licenses and permits could harm our reputation and our business, results of operations and prospects.

A number of governmental agencies or industry regulatory bodies in the U.S., and in non-U.S. jurisdictions including the PRC, impose strict rules, regulations and industry standards governing pharmaceutical and biotechnology research and development activities, which apply to us. Our failure to comply with such regulations could result in the termination of ongoing research, administrative penalties imposed by regulatory bodies or the disqualification of data for submission to regulatory authorities. This could harm our reputation, prospects for future work and operating results. For example, if we were to treat research animals inhumanely or in violation of international standards set out by the Association for Assessment and Accreditation of Laboratory Animal Care, it could revoke any such accreditation and the accuracy of our animal research data could be questioned.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of or exposure to hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use or disposal of biological or hazardous materials.

In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

If we face allegations of noncompliance with the law and encounter sanctions, our reputation, revenues and liquidity may suffer, and our drugs could be subject to restrictions or withdrawal from the market.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenues from our drugs. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our Company and our operating results will be adversely affected. Additionally, if we are unable to generate revenues from our product sales, our potential for achieving profitability will be diminished and the capital necessary to fund our operations will be increased.

Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we partially rely on our third-party research institution collaborators for research and development of our drug candidates and other third parties for the manufacture of our drug candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. Certain data breaches must be reported to affected individuals and the government, and in some cases to the media, under provisions of HIPAA, other U.S. federal and state law, and requirements of non-U.S. jurisdictions, and financial penalties may also apply. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and reputational damage, and the further development and commercialization of our drug candidates could be delayed.

We are aware of a security breach that occurred in March 2017. That incident occurred when the credentials of an approved consultant were compromised, and the consultant's credentials were used to access the remote desktop server and active directory server of our wholly-owned subsidiary, Athenex Pharma Solutions, or APS. Upon discovery of the breach, we immediately took steps to void the compromised credentials and reset all credentials having access to APS' systems. These particular APS information systems are independent of ours, and did not contain any drug candidate, clinical trial or patient-specific data. However, information stored on APS' systems may have been vulnerable during the intrusion. To help mitigate future incidents we have put in place enhanced security measures required for access by consultants. Notwithstanding such measures, we cannot be certain that no future security breaches will occur or that future breaches will not result in a material disruption of our development programs and our business operations.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our third-party research institution collaborators, CROs, suppliers and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. In addition, we partially rely on our third-party research collaborators for conducting research and development of our drug candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our ability to obtain clinical supplies of our drug candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. Damage or extended periods of interruption to our corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our drug candidates. Although we maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our drug candidates or our 503B products.

We face an inherent risk of product liability as a result of the clinical testing of our drug candidates and will face an even greater risk if we commercialize any of our clinical candidates. For example, we may be sued if our drug candidates or 503B products we plan to manufacture cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the drug, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our drugs;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any drug candidate; and
- a decline in the price of our common stock.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of drugs we develop, alone or with collaborators. Although we currently carry clinical trial insurance, which we believe to be adequate for our current operations, the amount of such insurance coverage may not be adequate now, or in the future, and we may be unable to maintain such insurance, or we may not be able to obtain additional or replacement insurance at a reasonable cost, if at all. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Additionally, we may be sued if the products that we commercialize, market or distribute for our partners cause or are perceived to cause injury or are found to be otherwise unsuitable, and may result in:

- decreased demand for the those products;
- damage to our reputation;
- costs incurred related to product recalls;
- limiting our opportunities to enter into future commercial partnership; and
- a decline in the price of our common stock.

We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.

We maintain property insurance policies covering physical damage to, or loss of, our buildings and their improvements, equipment, office furniture and inventory. We hold employer's liability insurance generally covering death or work-related injury of employees. We hold public liability insurance covering certain incidents involving third parties that occur on or in the premises of the company. We hold directors and officers liability insurance. We do not maintain key-man life insurance on any of our senior management or key personnel, or business interruption insurance. Our insurance coverage may be insufficient to cover any claim for product liability, damage to our fixed assets or employee injuries. Any liability or damage to, or caused by, our facilities or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.

We may increasingly become a target for public scrutiny, including complaints to regulatory agencies, negative media coverage, including social media and malicious reports, all of which could severely damage our reputation and materially and adversely affect our business and prospects.

We focus on the development of drugs used in the treatment of cancers, and such drugs may be the subject of regulatory, watchdog and media scrutiny and coverage, which also the possibility of heightened attention from the public, the media and our participants. In addition, members of our management and board include high- profile public figures who may be the subject of media and public scrutiny and attention. From time to time, these objections or allegations, regardless of their veracity, may result in public protests or negative publicity, which could result in government inquiry or harm our reputation. Corporate transactions we or related parties undertake may also subject us to increased media exposure and public scrutiny. There is no assurance that we would not become a target for public scrutiny in the future or such scrutiny and public exposure would not severely damage our reputation as well as our business and prospects.

In addition, our directors and management have been in the past, and may continue to be, subject to scrutiny by the media and the public regarding their activities in and outside our Company, which may result in unverified, inaccurate or misleading information about them being reported by the press. Negative publicity about our directors or management, even if untrue or inaccurate, may harm our reputation.

Our business, financial condition and results of operations may be adversely affected by global economic conditions.

Our business and operating results could be affected by global economic conditions. When global economic conditions deteriorate or economic uncertainty continues, customers and potential customers may delay or cancellation of plans to purchase our products, governments may reduce healthcare expenditures, and other payors may reduce their reimbursement coverage or reimbursement rates. Our sensitivity to economic cycles and any related fluctuations in the businesses of our customers or potential customers could have a material adverse impact on our business and financial results. Although we are uncertain about the extent to which global financial market disruptions or a slowdown of the U.S. or Chinese economy would impact our business in the long term, there is a risk that our business, results of operations and prospects would be materially and adversely affected by any global economic downturn or the slowdown of the U.S. or Chinese economy.

If our manufacturing facilities are damaged or destroyed or production at such facilities is otherwise interrupted, our business and prospects would be negatively affected.

If our manufacturing facilities or the equipment in them is damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of the facilities or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time- consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need FDA, CFDA or and other comparable regulatory agency approval before selling any drugs manufactured at that facility. Such an event could delay our clinical trials or reduce our product sales if and when we are able to successfully commercialize one or more of our drug candidates.

Any interruption in manufacturing operations at our manufacturing facilities could result in our inability to satisfy the demands of our clinical trials or commercialization. A number of factors could cause interruptions, including:

- equipment malfunctions or failures;
- malfunctions or compromise by third party actors of our technology systems;
- work stoppages;
- damage to or destruction of either facility due to natural disasters;
- regional power shortages;
- product tampering; or
- terrorist activities.

Any disruption that impedes our ability to manufacture our drug candidates in a timely manner could materially harm our business, financial condition and operating results.

Currently, we maintain insurance coverage against damage to our property and equipment. However, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. We may be unable to meet our requirements for our drug candidates if there were a catastrophic event or failure of our manufacturing facilities or processes.

Risks Related to Our Doing Business in the PRC

The pharmaceutical industry in China is highly regulated and such regulations are subject to change which may affect approval and commercialization of our drugs.

Certain of our research operations and manufacturing facilities are in China. The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. In recent years, the regulatory framework in China regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in increased compliance costs on our business or cause delays in or prevent the successful development or commercialization of our drug candidates in China and reduce the current benefits we believe are available to us from developing and manufacturing drugs in China. Chinese authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry and any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in China. We believe our strategy and approach is aligned with the Chinese government's policies, but we cannot ensure that our strategy and approach will continue to be aligned.

Fluctuations in exchange rates could result in foreign currency exchange losses, which may adversely affect our financial condition, results of operations and cash flows.

We incur portions of our expenses, and may in the future derive revenues, in currencies other than U.S. dollars, in particular, the Renminbi. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates. For example, a portion of our clinical trial activities are conducted outside of the U.S., and associated costs may be incurred in the local currency of the country in which the trial is being conducted, which costs could be subject to fluctuations in currency exchange rates. We currently do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the U.S. dollar. A decline in the value of the U.S. dollar against currencies in countries in which we conduct clinical trials could have a negative impact on our research and development costs.

The value of the Renminbi against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in political and economic conditions and the foreign exchange policy adopted by the PRC and other non-U.S. governments. Specifically in the PRC, on July 21, 2005, the PRC government changed its policy of pegging the value of the Renminbi to the U.S. dollar. Following the removal of the U.S. dollar peg, the Renminbi appreciated more than 20% against the U.S. dollar over the following three years. Between July 2008 and June 2010, this appreciation halted and the exchange rate between the Renminbi and the U.S. dollar remained within a narrow band. Since June 2010, the PRC government has allowed the Renminbi to appreciate slowly against the U.S. dollar again, and it has appreciated more than 10% since June 2010. In April 2012, the PRC government announced that it would allow more Renminbi exchange rate fluctuation and in August 2015, China's central bank executed a 2% devaluation in the Renminbi. From December 2015 to December 2016, the Renminbi depreciated approximately 4.6% against the U.S. dollar. It remains unclear what further fluctuations may occur or what impact this will have on the currency.

It is difficult to predict how market forces or PRC, U.S. or other government policies may impact the exchange rate between the Renminbi, U.S. dollar and other currencies in the future. There remains significant international pressure on the PRC government to adopt a more flexible currency policy, which could result in greater fluctuation of the Renminbi against the U.S. dollar. Substantially all of our revenues are denominated in U.S. dollars and our costs are denominated in U.S. dollars and Renminbi, and a large portion of our financial assets is denominated in U.S. dollars. To the extent that we need to convert U.S. dollars into Renminbi for our operations, appreciation of the Renminbi against the U.S. dollar would have an adverse effect on the Renminbi amount we would receive. Conversely, if we decide to convert our Renminbi into U.S. dollars for other business purposes, appreciation of the U.S. dollar against the Renminbi would have a negative effect on the U.S. dollar amount we would receive. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our financial condition, results of operations and cash flows.

Changes in the political and economic policies of the PRC government may materially and adversely affect our business, financial condition and results of operations and may result in our inability to sustain our growth and expansion strategies.

A significant portion of our operations are in the PRC. Accordingly, our financial condition and results of operations are affected to a large extent by economic, political and legal developments in the PRC.

The PRC economy differs from the economies of most developed countries in many respects, including the extent of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. Although the PRC government has implemented measures emphasizing the utilization of market forces for economic reform, the reduction of state ownership of productive assets, and the establishment of improved corporate governance in business enterprises, a substantial portion of productive assets in China is still owned by the government. In addition, the PRC government continues to play a significant role in regulating industry development by imposing industrial policies. The PRC government also exercises significant control over China's economic growth by allocating resources, controlling payment of foreign currency-denominated obligations, setting monetary policy, regulating financial services and institutions and providing preferential treatment to particular industries or companies.

While the PRC economy has experienced significant growth in the past three decades, growth has been uneven, both geographically and among various sectors of the economy. The PRC government has implemented various measures to encourage economic growth and guide the allocation of resources. Some of these measures may benefit the overall PRC economy, but may also have a negative effect on us. Our financial condition and results of operation could be materially and adversely affected by government control over capital investments or changes in tax regulations that are applicable to us and consequently have a material adverse effect on our businesses, financial condition and results of operations.

There are uncertainties regarding the interpretation and enforcement of PRC laws, rules and regulations.

A portion of our operations are conducted in the PRC through our PRC subsidiaries, and are governed by PRC laws, rules and regulations. Our PRC subsidiaries are subject to laws, rules and regulations applicable to foreign investment in China. The PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions may be cited for reference but have limited precedential value.

In 1979, the PRC government began to promulgate a comprehensive system of laws, rules and regulations governing economic matters in general. The overall effect of legislation over the past three decades has significantly enhanced the protections afforded to various forms of foreign investment in China. However, China has not developed a fully integrated legal system, and recently enacted laws, rules and regulations may not sufficiently cover all aspects of economic activities in China or may be subject to significant degrees of interpretation by PRC regulatory agencies. In particular, because these laws, rules and regulations are relatively new, and because of the limited number of published decisions and the nonbinding nature of such decisions, and because the laws, rules and regulations often give the relevant regulator significant discretion in how to enforce them, the interpretation and enforcement of these laws, rules and regulations involve uncertainties and can be inconsistent and unpredictable. In addition, the PRC legal system is based in part on government policies and internal rules, some of which are not published on a timely basis or at all, and which may have a retroactive effect. As a result, we may not be aware of our violation of these policies and rules until after the occurrence of the violation.

Any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention. Since PRC administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy than in more developed legal systems. These uncertainties may impede our ability to enforce the contracts we have entered into and could materially and adversely affect our business, financial condition and results of operations.

Substantial uncertainties exist with respect to the enactment timetable, the final version, interpretation and implementation of draft PRC Foreign Investment Law and how it may impact the viability of our current corporate governance.

The Ministry of Commerce published a discussion draft of the proposed Foreign Investment Law in January 2015 aiming to, upon its enactment, replace the trio of existing laws regulating foreign investment in China, namely, the Sino-foreign Equity Joint Venture Enterprise Law, the Sino-foreign Cooperative Joint Venture Enterprise Law and the Wholly Foreign-invested Enterprise Law, together with their implementation rules and ancillary regulations. The draft Foreign Investment Law embodies an expected PRC regulatory trend to rationalize its foreign investment regulatory regime in line with prevailing international practice and the legislative efforts to unify the corporate legal requirements for both foreign and domestic investments. The Ministry of Commerce has solicited comments on this draft and substantial uncertainties exist with respect to its enactment timetable, the final version, interpretation and implementation. The draft Foreign Investment Law, if enacted as proposed, may materially impact the viability of our current corporate governance if we, in the future, have PRC shareholders.

Among other things, the draft Foreign Investment Law expands the definition of foreign investment and introduces the principle of "actual control" in determining whether a company is considered a foreign-invested enterprise, or an FIE. The draft Foreign Investment Law specifically provides that entities established in China but "controlled" by foreign investors will be treated as FIEs, whereas an entity set up in a foreign jurisdiction would nonetheless be, upon market entry clearance by the Ministry of Commerce or its local counterparts, treated as a PRC domestic investor provided that the entity is "controlled" by PRC entities and/or citizens. In this connection, "control" is broadly defined in the draft law to cover the following summarized categories:

(1) holding 50% of more of the shares, equity or voting rights of the subject entity; (2) holding less than 50% of the voting rights of the subject entity but having the power to secure at least 50% of the seats on the board or other equivalent decision making bodies, or having the voting power to exert material influence on the board, the shareholders' meeting or other equivalent decision making bodies; or (3) having the power to exert decisive influence, via contractual or trust arrangements, over the subject entity's operations, financial matters or other key aspects of business operations. Once an entity is determined to be an FIE, it will be subject to the foreign investment restrictions or prohibitions, if the FIE is engaged in the industry listed in the "negative list" which will be separately issued by the State Council later. Unless the underlying business of the FIE falls within the negative list, which calls for market entry clearance by the Ministry of Commerce or its local counterparts, prior approval from the government authorities as mandated by the existing foreign investment legal regime would no longer be required for establishment of the FIE.

The draft Foreign Investment Law, if enacted as proposed, may also materially impact our corporate governance practice and increase our compliance costs. For instance, the draft Foreign Investment Law imposes stringent ad hoc and periodic information reporting requirements on foreign investors and the applicable FIEs. Aside from investment implementation report and investment amendment report that are required at each investment and alteration of investment specifics, an annual report is mandatory, and large foreign investors meeting certain criteria are required to report on a quarterly basis. Any company found to be non-compliant with these information reporting obligations may potentially be subject to fines and/or administrative or criminal liabilities, and the persons directly responsible may be subject to criminal liabilities.

PRC regulations relating to investments in offshore companies by PRC residents may subject our future PRC- resident beneficial owners or our PRC subsidiaries to liability or penalties, limit our ability to inject capital into our PRC subsidiaries or limit our PRC subsidiaries' ability to increase their registered capital or distribute profits.

The State Administration of Foreign Exchange, or SAFE promulgated the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment through Special Purpose Vehicles, or SAFE Circular 37, on July 4, 2014, which replaced the former circular, commonly known as SAFE Circular 75, promulgated by SAFE on October 21, 2005. SAFE Circular 37 and other SAFE rules require PRC residents to register with banks or local branches of SAFE (only in the case of supplement registration) in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with such PRC residents' legally owned assets or equity interests in domestic enterprises or offshore assets or interests, referred to in SAFE Circular 37 as a "special purpose vehicle". SAFE Circular 37 further requires amendment to the registration in the event of any significant changes with respect to the special purpose vehicle, such as increase or decrease of capital contributed by PRC individuals, share transfer or exchange, merger, division or other material events. In the event that a PRC shareholder holding interests in a special purpose vehicle fails to fulfill the required

registration, the PRC subsidiaries of that special purpose vehicle may be prohibited from making profit distributions to the offshore parent and from carrying out subsequent cross-border foreign exchange activities, and the special purpose vehicle may be restricted in its ability to contribute additional capital into its PRC subsidiary. Moreover, failure to comply with the various registration requirements described above could result in liability under PRC law for evasion of foreign exchange controls.

We believe that certain of our shareholders are PRC residents under SAFE Circular 37. These certain shareholders have undertaken to (i) apply to register with local SAFE branch or its delegated commercial bank as soon as possible after exercising their options, and (ii) indemnify and hold harmless us and our subsidiaries against any loss suffered arising from their failure to complete the registration. We do not have control over the shareholders and our other beneficial owners and cannot assure you that all of our PRC-resident beneficial owners have complied with, and will in the future comply with, SAFE Circular 37 and subsequent implementation rules. The failure of PRC-resident beneficial owners to register or amend their SAFE registrations in a timely manner pursuant to SAFE Circular 37 and subsequent implementation rules, or the failure of future PRC-resident beneficial owners of our Company to comply with the registration procedures set forth in SAFE Circular 37 and subsequent implementation rules, may subject such beneficial owners or our PRC subsidiaries to fines and legal sanctions. Furthermore, SAFE Circular 37 is unclear how this regulation, and any future regulation concerning offshore or cross-border transactions, will be interpreted, amended and implemented by the relevant PRC government authorities, and we cannot predict how these regulations will affect our business operations or future strategy. Failure to register or comply with relevant requirements may also limit our ability to contribute additional capital to our PRC subsidiaries and limit our PRC subsidiaries' ability to distribute dividends to us. These risks could in the future have a material adverse effect on our business, financial condition and results of operations.

We may be treated as a resident enterprise for PRC tax purposes under the PRC Enterprise Income Tax Law, and we may therefore be subject to PRC income tax on our global income.

Under the PRC Enterprise Income Tax Law and its implementing rules, both of which came into effect on January 1, 2008, enterprises established under the laws of jurisdictions outside of China with "de facto management bodies" located in China may be considered PRC tax resident enterprises for tax purposes and may be subject to the PRC enterprise income tax at the rate of 25% on their global income. "De facto management body" refers to a managing body that exercises substantive and overall management and control over the production and business, personnel, accounting books and assets of an enterprise. The State Administration of Taxation has issued guidance, known as Circular 82 that provides certain specific criteria for determining whether the "de facto management body" of a Chinese-controlled offshore-incorporated enterprise is located in China. Although Circular 82 only applies to offshore enterprises controlled by PRC enterprises, not those, such as us, controlled by foreign enterprises or individuals, the determining criteria set forth in Circular 82 may reflect the State Administration of Taxation's general position on how the "de facto management body" test should be applied in determining the tax resident status of offshore enterprises, regardless of whether they are controlled by PRC enterprises. Currently, our management is located in the U.S., and we generate a portion of our revenues within the PRC and a portion outside the PRC. We believe that neither we nor any of our subsidiaries outside of China is a PRC resident enterprise for PRC tax purposes. However, the tax resident status of an enterprise is subject to determination by the PRC tax authorities and uncertainties remain with respect to the interpretation of the term "de facto management body". If we were to be considered a PRC resident enterprise, we would be subject to PRC enterprise income tax at the rate of 25% on our global income. In such case, our profitability and cash flow may be materially reduced as a result of our global income being taxed under the PRC Enterprise Income Tax Law.

Dividends payable to our foreign investors and gains on the sale of our common stock by our foreign investors may become subject to PRC tax law.

Under the PRC Enterprise Income Tax Law and its implementing rules issued by the State Council, in general, a 10% PRC withholding tax is applicable to dividends payable to investors that are non-resident enterprises that do not have an establishment or place of business in the PRC or which have such establishment or place of business but the dividends are not effectively connected with such establishment or place of business, to the extent such dividends are derived from sources within the PRC. Similarly, any gain realized on the transfer of shares of our common stock by such investors is also subject to PRC tax at a current rate of 10%, subject to any reduction or exemption set forth in relevant tax treaties, if such gain is regarded as income derived from sources within the PRC. If we are deemed a PRC resident enterprise, dividends paid on our common stock, and any gain realized from the transfer of our common stock, would be treated as income derived from sources within the PRC and would as a result be subject to PRC taxation. Furthermore, if we are deemed a PRC resident enterprise, dividends payable to individual investors who are non-PRC residents and any gain realized on the transfer of common stock by such investors may be subject to PRC tax at a current rate of 20%, subject to any reduction or exemption set forth in applicable tax treaties. It is unclear whether if we or any of our subsidiaries established outside China are considered a PRC resident enterprise, holders of our common stock would be able to claim the benefit of income tax treaties or agreements entered into between China and other countries or areas. If dividends payable to our non-PRC investors, or gains from the transfer of our common stock by such investors are subject to PRC tax, the value of your investment in our common stock may decline significantly.

We and our shareholders face uncertainties with respect to indirect transfers of equity interests in PRC resident enterprises by their non-PRC holding companies.

Pursuant to a notice, or Circular 698, issued by the State Administration of Taxation, where a non-resident enterprise conducts an "indirect transfer" by transferring the equity interests of a PRC resident enterprise indirectly via disposing of the equity interests of an overseas holding company, and such overseas holding company is located in a tax jurisdiction that: (1) has an effective tax rate less than 12.5%; or (2) does not tax foreign income of its residents, the non-resident enterprise, being the transferor, shall report to the relevant tax authority of the PRC resident enterprise such indirect transfer. Using a "substance over form" principle, the PRC tax authority may disregard the existence of the overseas holding company if it lacks a reasonable commercial purpose and was established for the purpose of reducing, avoiding or deferring PRC tax. As a result, gains derived from such indirect transfer may be subject to PRC enterprise income tax, currently at a rate of 10%. In 2015, the State Administration of Taxation issued a circular, known as Circular 7, which replaced or supplemented certain previous rules under Circular 698. Circular 7 sets out a wider scope of indirect transfer of PRC assets that might be subject to PRC enterprise income tax, and more detailed guidelines on the circumstances when such indirect transfer is considered to lack a bona fide commercial purpose and thus regarded as avoiding PRC tax. The conditional reporting obligation of the non-PRC investor under Circular 698 is replaced by a voluntary reporting by the transferor, the transferee or the underlying PRC resident enterprise being transferred. Furthermore, if the indirect transfer is subject to PRC enterprise income tax, the transferee has an obligation to withhold tax from the sale proceeds, unless the transferor reports the transaction to the PRC tax authority under Circular 7. Late payment of applicable tax will subject the transferor to default interest. Gains derived from the sale of shares by investors through a public stock exchange are not subject to the PRC enterprise income tax pursuant to Circular 7 where such shares were acquired in a transaction through a public stock exchange.

As newly implemented, there is uncertainty as to the application of Circular 7. Circular 7 may be determined by the tax authorities to be applicable to our offshore restructuring transactions or sale of the shares of our offshore subsidiaries where non-resident enterprises, being the transferors, were involved. The PRC tax authorities may pursue such non-resident enterprises with respect to a filing regarding the transactions and request our PRC subsidiaries to assist in the filing. As a result, we and our non-resident enterprises in such transactions may become at risk of being subject to filing obligations or being taxed under Circular 7, and may be required to expend valuable resources to comply with Circular 7 or to establish that we and our non-resident enterprises should not be taxed under Circular 7, for our previous and future restructuring or disposal of shares of our offshore subsidiaries, which may have a material adverse effect on our financial condition and results of operations.

Restrictions on currency exchange may limit our ability to utilize our revenue effectively.

The PRC government imposes controls on the convertibility of Renminbi into foreign currencies and, in certain cases, the remittance of currency out of China. A portion of our revenue may in the future be denominated in Renminbi. Shortages in availability of foreign currency may then restrict the ability of our PRC subsidiaries to remit sufficient foreign currency to our offshore entities for our offshore entities to pay dividends or make other payments or otherwise to satisfy our foreign currency denominated obligations. The Renminbi is currently convertible under the "current account," which includes dividends, trade and service-related foreign exchange transactions, but not under the "capital account", which includes foreign direct investment and loans, including loans we may secure from our onshore subsidiaries. Currently, our PRC subsidiaries, which are wholly-foreign owned enterprises, may purchase foreign currency for settlement of "current account transactions," including payment of dividends to us, without the approval of SAFE by complying with certain procedural requirements. However, the relevant PRC governmental authorities may limit or eliminate our ability to purchase foreign currencies in the future for current account transactions. Since a portion of our future revenue may be denominated in Renminbi, any existing and future restrictions on currency exchange may limit our ability to utilize revenue generated in Renminbi to fund our business activities outside of the PRC or pay dividends in foreign currencies to our shareholders, including holders of our common stock. Foreign exchange transactions under the capital account remain subject to limitations and require approvals from, or registration with, SAFE and other relevant PRC governmental authorities. This could affect our ability to obtain foreign currency through debt or equity financing for our subsidiaries.

Recent litigation and negative publicity surrounding China-based companies listed in the U.S. may result in increased regulatory scrutiny of us and negatively impact the trading price of our common stock and could have a material adverse effect upon our business, including its results of operations, financial condition, cash flows and prospects.

We believe that litigation and negative publicity surrounding companies with operations in China, including concerning the directors and officers of such companies, that are listed in the U.S. have negatively impacted stock prices for such companies. Various equity-based research organizations have published reports on China- based companies after examining, among other things, their corporate governance practices, related party transactions, sales practices and financial statements that have led to special investigations and stock suspensions on national exchanges. Any similar scrutiny of us, regardless of its lack of merit, could result in a diversion of management resources and energy, potential costs to defend ourselves against rumors, decreases and volatility in the trading price of our common stock, and increased directors and officers insurance premiums and could have a material adverse effect upon our business, including its results of operations, financial condition, cash flows and prospects.

Risks Related to Our Common Stock

The trading price of our common stock is likely to be volatile, which could result in substantial losses to you.

The trading price of our common stock is likely to be volatile and could fluctuate widely in response to a variety of factors, many of which are beyond our control. In addition, the performance and fluctuation of the market prices of other companies with a portion of their business operations located in China that have listed their securities in the U.S. may affect the volatility in the price of and trading volumes for our common stock. Some of these companies have experienced significant volatility, including significant price declines after their initial public offerings. The trading performances of these companies' securities after their offerings may affect the overall investor sentiment towards other companies with significant China operations listed in the U.S. and consequently may impact the trading performance of our common stock.

In addition to market and industry factors, the price and trading volume for our common stock may be highly volatile for specific business reasons, including:

- announcements of regulatory approval or a complete response letter, or specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- announcements of therapeutic innovations or new products by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- any adverse changes to our relationship with manufacturers or suppliers;
- the results of our testing and clinical trials;
- the results of our efforts to acquire or license additional drug candidates;
- variations in the level of expenses related to our existing drug candidates or preclinical and clinical development programs;
- any intellectual property infringement actions in which we may become involved;
- announcements concerning our competitors or the pharmaceutical industry in general;
- achievement of expected product sales and profitability;
- manufacture, supply or distribution shortages;
- variations in our results of operation, including volatility related to our efforts to address drug shortages, which may lead to sharp decreases in sales and margins as such shortages abate;
- announcements about our earnings that are not in line with analyst expectations, the risk of which is enhanced because it is our policy not to give guidance on earnings;
- publication of operating or industry metrics by third parties, including government statistical agencies, that differ from expectations of industry or financial analysts;
- changes in financial estimates by securities research analysts;
- announcements made by us or our competitors of new product and service offerings, acquisitions, strategic relationships, joint ventures or capital commitments;
- press reports or other negative publicity, whether or not true, about our business;
- additions to or departures of our management;
- fluctuations of exchange rates between the Renminbi and the U.S. dollar;
- release or expiry of lock-up or other transfer restrictions on our outstanding common stock;
- sales or perceived potential sales of additional common stock;
- sales of our common stock by us, our executive officers and directors or our shareholders in the future;
- general economic and market conditions and overall fluctuations in the U.S. equity markets;

- changes in accounting principles; and
- changes or developments in the PRC or global regulatory environment.

Any of these factors may result in large and sudden changes in the volume and trading price of our common stock. In the past, following periods of volatility in the market price of a company's securities, shareholders have often instituted securities class action litigation against that company. If we were involved in a class action suit, it could divert the attention of management, and, if adversely determined, have a material adverse effect on our financial condition and results of operations.

In addition, the stock market, in general, and small pharmaceutical and biotechnology companies have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. Further, the current decline in the financial markets and related factors beyond our control may cause our common stock price to decline rapidly and unexpectedly.

We may be subject to securities litigation, which is expensive and could divert management attention.

The price of our common stock may be volatile, and in the past companies that have experienced volatility in the market price of their common stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the U.S. Securities Exchange Act of 1934, as amended, or the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the U.S. Securities and Exchange Commission, or SEC.

We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Substantial future sales or perceived potential sales of our common stock or other equity securities in the public market could cause the price of our common stock to decline significantly.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

Substantially all of the stockholders who held shares of our capital stock prior to our initial public offering are subject to lock-up agreements with the underwriters of our IPO that restrict such stockholders' ability to transfer shares of our common stock. Upon the expiration of the lock-up periods, subject to volume and other restrictions as applicable under Rules 144 and 701 under the Securities Act, the shares of our common stock outstanding will be available for sale. In addition, shares issued or issuable upon exercise of options or warrants vested as of the expiration of the lock-up period will be eligible for sale at that time. Sales of stock by these stockholders could have a material adverse effect on the trading price of our common stock.

In the future, we may issue additional shares or other equity or debt securities convertible into shares in connection with a financing, acquisition, litigation settlement, employee arrangement, or otherwise. Any such issuance could result in substantial dilution to our existing shareholders and could cause the market price to decline.

We are currently an "emerging growth company." As a result of the reduced disclosure requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are currently an "emerging growth company," as defined in the JOBS Act. For so long as we remain an emerging growth company, we are permitted and intend to rely on some of the exemptions from certain reporting requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include but are not limited to not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We cannot predict whether investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and the price of our common stock may be more volatile.

Because we do not expect to pay dividends in the foreseeable future, you must rely on price appreciation of our common stock for return on your investment.

We intend to retain most, if not all, of our available funds and earnings to fund the development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future. Therefore, you should not rely on an investment in our common stock as a source for any future dividend income.

Our board of directors has significant discretion as to whether to distribute dividends. Even if our board of directors decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on, among other things, our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our board of directors. Accordingly, the return on your investment in our common stock will likely depend entirely upon any future price appreciation of our common stock. There is no guarantee that our common stock will appreciate in value or even maintain the price at which you purchased our common stock. You may not realize a return on your investment in our common stock and you may even lose your entire investment in our common stock.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, the market price for our common stock and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If research analysts do not establish and maintain adequate research coverage or if one or more of the analysts who covers us downgrades our common stock or publishes inaccurate or unfavorable research about our business, the market price for our common stock would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which, in turn, could cause the market price or trading volume for our common stock to decline significantly.

Our directors, executive officers and principal stockholders will continue to have substantial control over us after this offering, which could limit your ability to influence the outcome of key transactions, including a change of control.

Our directors and officers together with their affiliates, beneficially owned, in the aggregate, approximately 38.12% of our outstanding common stock as of June 30, 2017. As a result, these stockholders, if acting together, will be able to influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. In addition, these stockholders, acting together, would have the ability to control the management and affairs of our company. They may also have interests that differ from yours and may vote in a way with which you disagree and which may be adverse to your interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company and might ultimately affect the market price of our common stock.

Anti-takeover provisions in our charter documents may discourage our acquisition by a third party, which could limit our shareholders' opportunity to sell their shares at a premium.

Our amended and restated certificate of incorporation and bylaws include provisions that could limit the ability of others to acquire control of our Company, could modify our structure or could cause us to engage in change-of-control transactions. These provisions could have the effect of depriving our shareholders of an opportunity to sell their shares at a premium over prevailing market prices by discouraging third parties from seeking to obtain control in a tender offer or similar transaction.

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

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the NASDAQ Stock Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time- consuming and costly.

We are evaluating these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices

Pursuant to Section 302 and 906 of the Sarbanes-Oxley Act of 2002, our CEO and CFO will be required to certify that the Company's financial statements are accurate, comply with the requirements of the exchange acts, and information reported is fairly presented for the year ending December 31, 2017. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

Unregistered Sales of Equity Securities

From April 1, 2017 to June 30, 2017, we granted to our directors, employees, and consultants options to purchase 1,611,032 shares of common stock under of 2017 Omnibus Incentive Plan with a per share exercise price of $11.00. Additionally, we granted 400,000 shares of common stock to a certain executive pursuant to an employment agreement. These transactions were exempt from the registration requirements of the Securities Act in reliance upon Rule 701 promulgated under the Securities Act of Section 4(a)(2) of the Securities Act.

On June 14, 2017, we issued 7,727,273 shares through the conversion of our convertible bonds with a principal amount of $68 million. Additionally, we issued 568,182 shares of common stock to a licensor and collaborator pursuant to the licensing agreement executed between the Company and the licensor These transactions were exempt from the registration requirements of the Securities act in reliance upon Section 4(a)(2) of the Securities Act.

Use of Proceeds

On June 14, 2017, our Registration Statement on Form S-1 (File No. 333-217928) relating to the IPO of our common stock was declared effective by the SEC. Pursuant to the IPO, we sold an aggregate of 6,900,000 shares of our common stock at a price of $11.00 per share. Credit Suisse, J.P. Morgan, Deutsche Bank Securities, and ICBC International acted as underwriters. The offering did not terminate before all of the securities registered in the registration statement were sold. Pursuant to such Registration Statement, the Company sold an aggregate of 6,900,000 shares of its common stock at a price of $11.00 per share for cash proceeds of $64.2 million, net of underwriting discounts and commissions of $6.1 million and offering costs of $5.6 million. No payments were made by us to directors, officers, or persons owning ten percent or more of our common stock or to their associates, or to our affiliates.

There has been no material change in the expected use of the net proceeds from our IPO, as described in our final prospectus filed with the SEC on June 15, 2017 pursuant to Rule 424(b)

Item 3. Defaults upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable

Item 5. Other Information.

Not applicable

Item 6. Exhibits.

The exhibits filed or furnished as part of this Quarterly Report on Form 10Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

SIGNATURES

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

Athenex, Inc.

Date: August 14, 2017

By: /s/ Johnson Y.N. Lau
Chief Executive Officer
(Board Chairman and
Principal Executive Officer)

Date: August 14, 2017

By: /s/ J. Nicholas Riehle
Chief Financial Officer
(Principal Financial Officer and
Principal Accounting Officer)

EXHIBIT INDEX

Exhibit Number	Exhibit Title	Incorporated by Reference (Unless Otherwise Indicated)			
		Form	File	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Company, effective as of June 19, 2017.	8-K	001-38112	3.1	June 22, 2017
3.2	Amended and Restated Bylaws of the Company, effective as of June 19, 2017.	8-K	001-38112	3.2	June 22, 2017
10.5+	2017 Omnibus Incentive Plan and Form of Stock Option Agreement.	S-1/A	333-217928	10.5	June 2, 2017
10.6+	2017 Employee Stock Purchase Plan.	S-1/A	333-217928	10.6	June 2, 2017
10.14.3^	Binding Term Sheet for License effective as of May 5, 2017, by and between Athenex Pharmaceutical Division, LLC and Gland Pharma Limited.	S-1/A	333-217928	10.14.3	June 2, 2017
10.29.1+	Amendment to Letter Agreement by and between Athenex, Inc. and Flint Besecker, dated April 17, 2017.	S-1	333-217928	10.29.1	May 12,2017
31.1	Certification of the Chief Executive Officer and Chairman of the Board of Directors pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	—	—	—	Filed herewith
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	—	—	—	Filed herewith
32.1	Certification of the Chief Executive Officer and Chairman of the Board of Directors and the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	—	—	—	Filed herewith
101.INS	XBRL Instance Document.	—	—	—	Filed herewith
101.SCH	XBRL Taxonomy Extension Schema Document.	—	—	—	Filed herewith
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	—	—	—	Filed herewith
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	—	—	—	Filed herewith
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	—	—	—	Filed herewith
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	—	—	—	Filed herewith

+ Indicates management contract or compensatory plan.

^ Confidential treatment is requested for certain confidential portions of this exhibit pursuant to Rule 406 under the Securities Act. In accordance with Rule 406, these confidential portions have been omitted from this exhibit and filed separately with the Commission.

Exhibit 31.1

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

I, Johnson Y.N. Lau, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Athenex, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a–15(e) and 15d–15(e)) for the 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2017

/s/ Johnson Y.N. Lau
Johnson Y.N. Lau
Chief Executive Officer and Chairman of the Board of Directors
(Principal executive officer)

Exhibit 31.2

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

I, J. Nick Riehle, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Athenex, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a–15(e) and 15d–15(e)) for the 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2017

/s/ J. Nick Riehle
J. Nick Riehle
Chief Financial Officer
(Principal financial and accounting officer)

Exhibit 32.1

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

In accordance with 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Johnson Y.N. Lau, Chief Executive Officer and Chairman of the Board of Directors (principal executive officer) of Athenix, Inc. (the "registrant"), and J. Nick Riehle, Chief Financial Officer (principal financial and accounting officer) of the registrant, each hereby certifies that, to the best of their knowledge:

1. The registrant's Quarterly Report on Form 10-Q for the period ended June 30, 2017, to which this Certification is attached as Exhibit 32.1 (the "Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition of the registrant at the end of the period covered by the Report and results of operations of the registrant for the periods covered by the Report.

Date: August 14, 2017

/s/ Johnson Y.N. Lau
Johnson Y.N. Lau
Chief Executive Officer and Chairman of the Board of Directors
(Principal executive officer)

/s/ J, Nick Riehle
J. Nick Riehle
Chief Financial Officer
(Principal financial and accounting officer)