TESARO, Inc.
Form 10-Q
October 30, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2015

OR

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

For the transition period from to

Commission File #001-35587

TESARO, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**27-2249687**
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)
1000 Winter Street, Suite 3300 Waltham, Massachusetts	**02451**
(Address of Principal Executive Offices)	(Zip Code)

(339) 970-0900

(Registrant s Telephone Number, Including Area Code)

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 x No o

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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer , accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer x
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

As of October 26, 2015, there were 40,090,327 shares of the registrant s Common Stock, par value $0.0001 per share, outstanding.

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TESARO, INC.

FORM 10-Q
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2015

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements.

TESARO, INC.

Condensed Consolidated Balance Sheets

(all amounts in 000 s, except share and per share data)

(Unaudited)

	December 31, 2014	September 30, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 256,861	$ 302,518
Accounts receivable		1,105
Inventories		476
Other current assets	1,735	4,435
Total current assets	258,596	308,534
Property and equipment, net	1,022	2,555
Other assets	4,284	3,778
Total assets	$ 263,902	$ 314,867
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 6,089	$ 5,617
Accrued expenses	16,750	33,473
Deferred revenues, current		500
Other current liabilities	1,526	3,061
Total current liabilities	24,365	42,651
Convertible notes, net	115,481	121,863
Deferred revenues, non current		413
Total liabilities	139,846	164,927
Commitments and contingencies *(Note 8)*		
Stockholders equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at both December 31, 2014 and September 30, 2015; no shares issued or outstanding at both December 31, 2014 and September 30, 2015		

Common stock, $0.0001 par value; 100,000,000 shares authorized at both December 31, 2014 and September 30, 2015; 36,110,082 and 40,072,877 shares issued and outstanding at December 31, 2014 and September 30, 2015, respectively		4		4
Additional paid-in capital		474,562		676,095
Accumulated deficit		(350,510)		(526,159)
Total stockholders equity		124,056		149,940
Total liabilities and stockholders equity	$	263,902	$	314,867

See accompanying notes to condensed consolidated financial statements.

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TESARO, INC.

Condensed Consolidated Statements of Operations and

Comprehensive Loss

(all amounts in 000 s, except per share data)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	**2015**	**2014**	**2015**
License revenue	$	$ 87	$	$ 87
Expenses:				
Research and development	29,925	40,063	88,611	112,538
Selling, general and administrative	6,263	22,766	16,538	50,791
Acquired in-process research and development			17,900	1,000
Total expenses	36,188	62,829	123,049	164,329
Loss from operations	(36,188)	(62,742)	(123,049)	(164,242)
Interest expense	(42)	(3,853)	(42)	(11,432)
Interest income	4	9	14	25
Net loss	$ (36,226)	$ (66,586)	$ (123,077)	$ (175,649)
Net loss per share applicable to common stockholders - basic and diluted	$ (1.01)	$ (1.66)	$ (3.45)	$ (4.49)
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	36,029	40,038	35,627	39,129
Comprehensive loss	$ (36,226)	$ (66,586)	$ (123,077)	$ (175,649)

See accompanying notes to condensed consolidated financial statements.

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TESARO, INC.

Condensed Consolidated Statements of Cash Flows

(all amounts in 000 s)

(Unaudited)

	Nine Months Ended September 30,	
	2014	**2015**
Operating activities		
Net loss	$ (123,077)	$ (175,649)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development	17,900	1,000
Depreciation expense	254	437
Stock-based compensation expense	8,538	17,510
Non-cash interest expense	26	6,888
Loss on disposal of property and equipment	80	
Changes in operating assets and liabilities:		
Accounts receivable		(1,105)
Other assets	1,851	(2,683)
Inventories		(476)
Accounts payable	2,246	(509)
Accrued expenses	7,009	16,642
Deferred revenue		913
Other liabilities	1	1,535
Net cash used in operating activities	(85,172)	(135,497)
Investing activities		
Acquisition of product candidate and technology licenses and milestone payments	(17,900)	(1,000)
Purchase of property and equipment	(969)	(1,869)
Net cash used in investing activities	(18,869)	(2,869)
Financing activities		
Proceeds from issuance of convertible notes, net of issuance costs	195,193	
Purchase of capped call options	(20,829)	
Proceeds from sale of common stock, net of issuance costs	94,199	179,753
Proceeds from exercise of stock options	960	4,223
Proceeds from issuance of common stock under Employee Stock Purchase Plan	120	248
Payment of minimum tax withholdings on share-based awards		(201)
Net cash provided by financing activities	269,643	184,023
Increase in cash and cash equivalents	165,602	45,657
Cash and cash equivalents at beginning of period	130,310	256,861
Cash and cash equivalents at end of period	$ 295,912	$ 302,518
Non-cash investing and financing activities		
Convertible note issuance costs unpaid as of period end	$ 475	$
Purchase of property and equipment - cash not paid as of period end	$	$ 118

Supplemental cash flow information		
Interest paid	$	$ 3,052

See accompanying notes to condensed consolidated financial statements.

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TESARO, INC.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Description of Business

TESARO, Inc., or the Company or TESARO, was incorporated in Delaware on March 26, 2010 and commenced operations in May 2010. Headquartered in Waltham, Massachusetts, TESARO is an oncology-focused biopharmaceutical company dedicated to improving the lives of cancer patients. TESARO acquires, in-licenses and develops oncology product candidates and, if approved for marketing, intends to commercialize these products. Since incorporation, primary activities have consisted of acquiring product candidates, advancing development of these product candidates, developing intellectual property, recruiting personnel and raising capital. The Company intends to in-license or acquire additional product candidates across various stages of development, operates in one segment and to date, has not earned any revenues from product sales and has earned only immaterial license revenues. The Company is subject to a number of risks, including dependence on key individuals, the need to develop commercially viable products, competition from other companies, many of which are larger and better capitalized, and the need to obtain adequate additional financing to fund the development and potential commercialization of its product candidates and further its in-licensing and acquisition activities.

On September 1, 2015, the Company s first commercial product, VARUBITM (oral formulation of rolapitant), was approved by the United States Food and Drug Administration, or FDA, in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. The Company expects to commence sales of VARUBI during the fourth quarter of 2015.

The Company has incurred significant operating losses since inception and has relied on its ability to fund its operations through private and public equity and debt financings. Management expects operating losses and negative operating cash flows to continue for the foreseeable future. As the Company continues to incur losses, transition to profitability is dependent upon the successful development, approval, and commercialization of its product candidates and the achievement of a level of revenues adequate to support its cost structure. The Company may never achieve profitability, and unless and until it does, the Company will continue to need to raise additional capital. Management intends to fund future operations in part through additional public or private equity or debt offerings and may seek additional capital through arrangements with strategic partners or from other sources.

2. Basis of Presentation and Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements are unaudited and have been prepared by TESARO in conformity with accounting principles generally accepted in the United States of America, or GAAP.

The Company s condensed consolidated financial statements reflect the operations of the Company and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation. The Company currently operates in one business segment, which is the identification, acquisition, development and commercialization of oncology therapeutics and supportive care product candidates, and has a single reporting and operating unit structure.

Certain information and footnote disclosures normally included in the Company s annual financial statements have been condensed or omitted. These interim financial statements, in the opinion of management, reflect all normal recurring adjustments necessary for a fair presentation of the Company s financial position and results of operations for the interim periods ended September 30, 2014 and 2015.

The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full fiscal year. These interim financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2014 and the notes thereto, which are included in the Company s Annual Report on Form 10-K for the year ended December 31, 2014.

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Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets, liabilities and expenses, other comprehensive income and the related disclosures. On an ongoing basis, management evaluates its estimates, including estimates related to accrued clinical trial and manufacturing development expenses, which form part of the Company s research and development expenses, and stock-based compensation expense. Significant estimates in these condensed consolidated financial statements include estimates made in connection with accrued research and development expenses, stock-based compensation expense and valuation of convertible notes. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

Cash and Cash Equivalents

The Company considers all highly-liquid investments with original or remaining maturity from the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents include bank demand deposits and money market funds that invest primarily in certificates of deposit, commercial paper and U.S. government and U.S. government agency obligations. Cash equivalents are reported at fair value.

Fair Value of Financial Instruments

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. The fair value hierarchy prioritizes valuation inputs based on the observable nature of those inputs. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of investment credit quality. The hierarchy defines three levels of valuation inputs:

Level 1 inputs	Quoted prices in active markets for identical assets or liabilities
Level 2 inputs	Observable inputs other than Level 1 inputs, including quoted prices in active markets for similar assets or liabilities and quoted prices for identical assets or liabilities in markets that are not active
Level 3 inputs	Unobservable inputs that reflect the Company s own assumptions about the assumptions market participants would use in pricing the asset or liability

The following table presents information about the Company s financial assets and liabilities that have been measured at fair value as of December 31, 2014 and September 30, 2015 and indicates the fair value hierarchy of the valuation inputs utilized to determine such fair value (in thousands):

Description	Balance Sheet Classification	December 31, 2014 Total	Level 1	Level 2	Level 3
Assets:					
Money market funds	Cash and cash equivalents	$ 254,840	$ 254,840	$	$
Total assets		$ 254,840	$ 254,840	$	$

Description	Balance Sheet Classification	September 30, 2015 Total	Level 1	Level 2	Level 3
Assets:					
Money market funds	Cash and cash equivalents	$ 294,713	$ 294,713	$	$
Total assets		$ 294,713	$ 294,713	$	$

The carrying amounts of accounts payable and accrued expenses approximate their fair values due to their short-term maturities.

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In September 2014, the Company issued $201.3 million aggregate principal amount of 3.00% convertible senior notes due October 1, 2021, or the Convertible Notes. Interest is payable semi-annually in arrears on April 1 and October 1 of each year, beginning on April 1, 2015. As of September 30, 2015, the carrying value of the Convertible Notes, net of unamortized discount, was $121.9 million and the estimated fair value of the Convertible Notes was $273.0 million. The Convertible Notes are discussed in more detail in Note 4, Convertible Notes.

Research and Development Expenses

Research and development costs are charged to expense as incurred and include:

- pre-commercial license fees and milestone payments related to the acquisition of in-licensed product candidates, which are reported on the statements of operations as acquired in-process research and development;

- employee-related expenses, including salaries, bonuses, benefits, travel and stock-based compensation expense;

- fees and expenses incurred under agreements with contract research organizations, investigative sites, research consortia and other entities in connection with the conduct of clinical trials and preclinical studies and related services, such as data management, laboratory and biostatistics services;

- the cost of acquiring, developing and manufacturing active pharmaceutical ingredients for product candidates that have not received regulatory approval, clinical trial materials and other research and development materials;

- fees and costs related to regulatory filings and activities;

- facilities, depreciation and other expenses, which include direct and allocated expenses for rent, utilities, maintenance of facilities, insurance and other supplies; and

- other costs associated with clinical and preclinical activities.

Costs for certain development activities, such as clinical trials and manufacturing development activities, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to the Company by its vendors on their actual costs incurred or level of effort expended. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated balance sheets as prepaid or accrued research and development expenses.

Acquired In-Process Research and Development Expense

The Company has acquired the rights to develop and commercialize new product candidates. Up-front payments that relate to the acquisition of a new drug compound, as well as milestone payments, are immediately expensed as acquired in-process research and development in the period in which they are incurred, provided that the acquisition did not also include processes or activities that would constitute a business, as defined under GAAP, the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no alternative future use. Royalties owed on future sales of the products licensed pursuant to the agreements are expensed in the period the related revenues are recognized.

Stock-Based Compensation Expense

Stock-based compensation is recognized as expense for each stock-based award based on its estimated fair value. The Company determines the fair value of each stock option award at its grant date using the Black-Scholes option pricing model. The Company determines the fair value of each restricted stock unit at its grant date based on the fair market value of its common stock. The value of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service period. The cumulative effect of any changes to the estimated forfeiture rates are accounted for as an adjustment to expense in the period of the change.

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Inventory

Beginning in the third quarter of 2015, the Company began to capitalize inventory costs associated with VARUBI when it was determined that the inventory had a probable future economic benefit. Inventories are stated at the lower of cost or estimated net realizable value, on a first-in, first-out, or FIFO, basis. Prior to the regulatory approval of its product candidates, the Company incurs expenses for the manufacture of drug product that could potentially be available to support the commercial launch of its products. Until the first reporting period when regulatory approval has been received or is otherwise considered probable, the Company records all such costs as research and development expense. The Company periodically analyzes its inventory levels, and writes down inventory that has become obsolete, inventory that has a cost basis in excess of its estimated realizable value and inventory in excess of expected sales requirements as cost of product revenues. Expired inventory would be disposed of and the related costs would be written off as cost of product revenues.

License Revenue

The Company may enter into arrangements under which it licenses certain rights to its product candidates to third parties. Activities under licensing agreements are evaluated to determine if they represent a multiple element arrangement. The Company identifies the deliverables included within the agreement and evaluates which deliverables represent separate units of accounting. The Company accounts for those components as separate units of accounting if the following two criteria are met:

- the delivered item or items have stand-alone value to the customer; and

- if the arrangement includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in the control of the Company.

Factors considered in this determination include, among other things, whether any other vendors sell the items separately and if the licensee could use the delivered item for its intended purpose without the receipt of the remaining deliverables. When multiple deliverables are combined and accounted for as a single unit of accounting, the Company bases its revenue recognition on the last element to be delivered using the straight-line or proportional performance method depending on the Company s ability to estimate the performance obligation. Amounts received or recorded as receivable prior to satisfying the associated revenue recognition criteria are recorded as deferred revenue in the condensed consolidated balance sheets. Amounts not expected to be recognized within one year following the balance sheet date are classified as non-current deferred revenue.

If a future milestone payment under a license agreement is contingent upon the achievement of a substantive milestone, license revenue is recognized in its entirety in the period in which the milestone is achieved. A milestone is substantive if:

- it can only be achieved based in whole or in part on either the Company s performance or the occurrence of a specific outcome resulting from the Company s performance;

- there is substantive uncertainty at the date an arrangement is entered into that the event will be achieved; and

- it would result in additional payments being due to the Company.

The commercial milestone payments and royalty payments received under license agreements, if any, will be recognized as license revenue when they are earned.

The Company has entered into one license agreement with a third party pursuant to which it has licensed the rights to develop, manufacture and commercialize rolapitant in China, including Hong Kong and Macao. For this arrangement, the Company has determined that there is only one unit of accounting that includes the licensed patents and the licensed know-how, which will be delivered over a period of time. The Company recorded $0.1 million of license revenue related to a $1.0 million up-front payment under this arrangement during the three and nine months ended September 30, 2015, and recorded $0.9 million as deferred revenue as of September 30, 2015. This $1.0 million payment is being recognized as license revenue over the two-year period of performance relating to the Company s obligations to provide the licensed know-how to the licensee. Under the terms of the agreement, the Company would be entitled to additional payments of up to $2.0 million contingent on the achievement of certain regulatory milestones, as well as royalties on product sales at percentage rates in the low teens.

New Accounting Pronouncements - Recently Issued

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-09, which amends the guidance for accounting for revenue from contracts with customers. This ASU supersedes the revenue recognition requirements in Accounting Standards Codification, or ASC, Topic 605, *Revenue Recognition*, and creates a new Topic 606, *Revenue from Contracts with Customers*. Two adoption methods are permitted: retrospectively to all prior reporting periods presented, with certain practical expedients permitted; or retrospectively with the cumulative effect of initially adopting the ASU recognized at the date of initial application. On August 12, 2015, the FASB issued ASU No. 2015-14, which defers the effective date by one year to December 15, 2017 for annual reporting periods beginning after that date, including interim periods within those periods. The FASB also approved permitting early adoption of the standard, but not before the original effective date of December 15, 2016. The Company has not yet determined which adoption method it will utilize or the effect that the adoption of this guidance will have on its potential future revenue streams and consolidated financial statements.

In June 2014, the FASB issued ASU No. 2014-12. The amendments in this ASU apply to reporting entities that grant their employees share-based payments in which the terms of the award provide that a performance target can be achieved after a requisite service period. The amendments require an entity to treat a performance target that affects vesting, and that could be achieved after the requisite service period, as a performance condition. A reporting entity should apply existing guidance in ASC Topic 718 relating to awards with performance conditions that affect vesting to account for such

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awards. The performance target should not be reflected in estimating the grant-date fair value of the award. Compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. The amendments in this ASU are effective for annual reporting periods and interim periods within those annual reporting periods beginning after December 15, 2015, and early adoption is permitted. The Company does not expect the adoption of this guidance to have a material impact on its consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, which is intended to define management s responsibility to evaluate whether there is substantial doubt about an organization s ability to continue as a going concern and to provide related footnote disclosures. Substantial doubt about an entity s ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued (or are available to be issued). ASU No. 2014-15 provides guidance to an organization s management, with principles and definitions intended to reduce diversity in the timing and content of disclosures commonly provided by organizations in the footnotes of their financial statements. ASU No. 2014-15 is effective for annual reporting periods ending after December 15, 2016, and for annual and interim periods thereafter. Early adoption is permitted. The Company is currently in the process of evaluating the impact of adoption of this guidance on its consolidated financial statements and related disclosures.

In April 2015, the FASB issued ASU No. 2015-03, which amends existing guidance to require the presentation of debt issuance costs in the balance sheet as a deduction from the carrying amount of the related debt liability instead of a deferred charge. ASU No. 2015-03 is effective for annual reporting periods beginning after December 15, 2015, and early adoption is permitted. The amendment must be applied retrospectively such that the balance sheet of each individual period presented is adjusted to reflect the period-specific impact of using the new guidance. Upon transition, a business must adhere to the appropriate disclosures for an adjustment in an accounting principle. Such disclosures include why the change in accounting principle is occurring, the transition method, an explanation of the prior period information that was retrospectively adjusted, and how the change impacts the financial statement line items (i.e., debt issuance cost asset and the debt liability). The Company is currently in the process of evaluating the timing of adoption. If the Company had adopted this guidance as of September 30, 2015, the impact would have been to decrease Other assets and Convertible notes, net by $3.0 million as of September 30, 2015.

In April 2015, the FASB issued ASU No. 2015-05, which provides guidance to customers about whether a cloud computing arrangement includes a software license. If a cloud computing arrangement includes a software license, then the customer should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the customer should account for the arrangement as a service contract. The guidance will not change GAAP for a customer s accounting for service contracts. ASU 2015-05 is effective for annual periods, including interim periods within those annual periods, beginning after December 15, 2015. Early adoption is permitted. An entity can elect to adopt the amendments either (1) prospectively to all arrangements entered into or materially modified after the effective date, or (2) retrospectively. For prospective transition, the only disclosure requirements at transition are the nature of and reason for the change in accounting principle, the transition method, and a qualitative description of the financial statement line items affected by the change. For retrospective transition, the disclosure requirements at transition include the requirements for prospective transition and quantitative information about the effects of the accounting change. The Company does not expect the adoption of this guidance to have a material impact on its consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, which amends existing guidance for measurement of inventory. Current inventory guidance requires an entity to measure inventory at the lower of cost or market. Market could be replacement cost, net realizable value, or net realizable value less an approximately normal profit margin. The amendments do not apply to inventory that is measured using last-in, first-out (LIFO) or the retail inventory method. The amendments apply to all other inventory, which includes inventory that is measured using first-in, first-out or average cost. An entity should measure all inventory to which the amendments apply at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. Subsequent measurement is unchanged for inventory measured using LIFO or the retail inventory method. The amendments in this ASU more closely align the measurement of inventory in GAAP with the measurement of inventory in International Financial Reporting Standards. The amendments are effective for fiscal years beginning after December 15, 2016, and interim periods within fiscal years beginning

after December 15, 2017. The amendments should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. The Company does not expect the adoption of this guidance to have a material impact on its consolidated financial statements.

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3. Net Loss per Share

Basic and diluted net loss per common share is calculated by dividing net loss applicable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. The Company s potentially dilutive shares, which include outstanding stock options, unvested restricted stock, restricted stock units, and shares issuable upon conversion of the Convertible Notes, are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

The following table presents amounts that were excluded from the calculation of diluted net loss per share, due to their anti-dilutive effect (in thousands):

	Three and Nine Months Ended September 30,	
	2014	2015
Outstanding stock awards	3,663	6,044
Unvested restricted stock	13	
Shares issuable upon conversion of Convertible Notes		663
	3,676	6,707

In September 2014, the Company issued Convertible Notes, which provide in certain situations for the conversion of the outstanding principal amount of the Convertible Notes into shares of the Company s common stock at a predefined conversion rate. See Note 4, Convertible Notes , for additional information. In conjunction with the issuance of the Convertible Notes, the Company entered into capped call option transactions, or Capped Calls, with certain counterparties. The Capped Calls are expected generally to reduce the potential dilution, and/or offset, to an extent, the cash payments the Company may choose to make in excess of the principal amount, upon conversion of the Convertible Notes.

As provided by the terms of the indenture underlying the Convertible Notes, the Company has a choice to settle the conversion obligation for the Convertible Notes in cash, shares or any combination of the two. The Company currently intends to settle the par value of the Convertible Notes in cash and any excess conversion premium in shares. Accordingly, the par value of the Convertible Notes will not be included in the calculation of diluted income per share, but the dilutive effect of the conversion premium will be considered in the calculation of diluted net income per share using the treasury stock method. The Convertible Notes first became convertible during the calendar quarter beginning on April 1, 2015. The share figure in the table above represents the estimated incremental shares that would be issued, after the consideration of the Capped Calls, assuming conversion of all of the outstanding Convertible Notes as of September 30, 2015.

4. Convertible Notes

On September 29, 2014, in a registered underwritten public offering, the Company completed the issuance of $201.3 million aggregate principal amount of the Convertible Notes. In conjunction with the sale of the Convertible Notes, the Company used $20.8 million of the net proceeds to enter into separate Capped Calls.

The Convertible Notes bear interest at a rate of 3.00% per annum, payable semi-annually on April 1 and October 1, beginning from April 1, 2015, and will be convertible into cash, shares of the Company s common stock or a combination of cash and shares of the Company s common stock, at the Company s election. The Convertible Notes will mature on October 1, 2021, unless earlier converted or repurchased in accordance with their terms. Prior to the close of business on the business day immediately preceding April 1, 2021, the Convertible Notes will be convertible only upon the occurrence of certain events and during certain periods as discussed below, and thereafter, at any time until the close of business on the second scheduled trading day immediately preceding the maturity date. The initial conversion price of the Convertible Notes is approximately $35.13 per share of common stock at an initial conversion rate of 28.4627 shares of the Company s common stock per $1,000 principal amount of Convertible Notes.

The conversion rate is subject to adjustment from time to time upon the occurrence of certain events, including, but not limited to, the issuance of stock dividends and payment of cash dividends. At any time prior to the close of business on the business day immediately preceding April 1, 2021, holders may convert their Convertible Notes at their option only under the following circumstances:

(1) during any calendar quarter commencing after the calendar quarter ending on December 31, 2014 (and only during such calendar quarter), if the closing sale price of the Company s common stock for at least 20 trading

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days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter in which the conversion occurs is greater than 130% of the conversion price on each applicable trading day;

(2) during the five business day period after any ten consecutive trading day period, or the measurement period, in which the trading price per $1,000 principal amount of the Convertible Notes for each trading day of the measurement period was less than 98% of the product of the closing sale price of the Company s common stock and the conversion rate on each such trading day; or

(3) upon the occurrence of specified corporate events.

The following table sets forth total interest expense recognized related to the Convertible Notes during the three and nine months ended September 30, 2015 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2015	2014	2015
Contractual interest expense	$ 17	$ 1,509	$ 17	$ 4,544
Amortization of debt discount	24	2,178	24	6,383
Amortization of debt issuance costs	1	166	1	505
Total interest expense	$ 42	$ 3,853	$ 42	$ 11,432

During the nine months ended September 30, 2015 the Company paid $3.1 million in interest related to the Convertible Notes.

5. Stock-Based Compensation

The Company maintains several equity compensation plans, including the 2012 Omnibus Incentive Plan, or the 2012 Incentive Plan, the 2010 Stock Incentive Plan, or the 2010 Incentive Plan, the 2015 Non-Employee Director Stock Incentive Plan, or the 2015 Director Plan, and the 2012 Employee Stock Purchase Plan, or the 2012 ESPP.

On April 27, 2012, the stockholders of the Company approved the 2012 Incentive Plan, which had been previously adopted by the board of directors. Upon effectiveness of the 2012 Incentive Plan, the Company ceased making awards under the 2010 Incentive Plan. The 2012 Incentive Plan allows the Company to grant awards for up to 1,428,571 shares of common stock plus the number of shares of common stock available for grant under the 2010 Incentive Plan as of the effectiveness of the 2012 Incentive Plan (an additional 6,857 shares) plus the number of shares of common stock related to awards outstanding under the 2010 Incentive Plan that terminate by expiration, forfeiture, cancellation, cash settlement or otherwise. In addition, each year starting with 2014, the number of shares available for grants of awards under the 2012 Incentive Plan is increased automatically on January 1 by a number of shares of common stock equal to the lesser of 4% of the shares of common stock outstanding at such time or the number of shares determined by the Company s board of directors. Accordingly, effective January 1, 2014 and 2015, the number of shares authorized for issuance under the 2012 Incentive Plan was increased by 1,309,560 shares and

1,444,403 shares, respectively. On May 14, 2015, the stockholders of the Company approved an increase of 2,000,000 shares of common stock available for grant under the 2012 Incentive Plan. Awards under the 2012 Incentive Plan may include the following award types: stock options, which may be either incentive stock options or nonqualified stock options; stock appreciation rights; restricted stock; restricted stock units; dividend equivalent rights; performance shares; performance units; cash-based awards; other stock-based awards, including unrestricted shares; or any combination of the foregoing. The exercise price of stock options granted under the 2012 Incentive Plan is equal to the closing price of a share of the Company s common stock on the grant date.

On May 14, 2015, the stockholders of the Company approved the 2015 Director Plan, which had been previously adopted by the board of directors in order to have a plan in addition to the 2012 Incentive Plan for purposes of granting awards to non-employee directors. The 2015 Director Plan allows the Company to grant awards for up to 500,000 shares of common stock. Awards under the 2015 Director Plan may include the following award types: stock options; stock appreciation rights; restricted stock; restricted stock units; unrestricted stock; or any combination of the foregoing. The exercise price of stock options granted under the 2015 Director Plan is equal to the closing price of a share of the Company s common stock on the grant date.

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Stock-based compensation expense as reflected in the Company s condensed consolidated statements of operations and comprehensive loss was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2015	2014	2015
Research and development	$ 1,187	$ 3,783	$ 3,551	$ 7,808
Selling, general and administrative	1,711	4,346	4,987	9,702
Total stock-based compensation expense	$ 2,898	$ 8,129	$ 8,538	$ 17,510

Stock Options

The following table presents a summary of the Company s stock option activity and related information:

	Shares	Weighted-average exercise price per share
Outstanding at December 31, 2014	3,726,329	$ 18.82
Granted	2,719,292	54.79
Exercised	(188,752)	22.38
Cancelled	(274,843)	35.71
Outstanding at September 30, 2015	5,982,026	$ 34.28
Vested at September 30, 2015	2,352,409	$ 15.59
Vested and expected to vest at September 30, 2015 (a)	5,565,442	$ 33.00

(a) This represents the number of vested options as of September 30, 2015, plus the number of unvested options expected to vest as of September 30, 2015, based on the unvested options at September 30, 2015, adjusted for the estimated forfeiture rate.

At September 30, 2015, there was approximately $95.0 million of total unrecognized compensation cost related to unvested stock options, which the Company expects to recognize over a remaining weighted-average period of 3.1 years.

Restricted Stock Units

During the three and nine months ended September 30, 2015, the Company issued 10,000 and 60,000 restricted stock units, or RSUs, to certain employees, respectively. These RSUs are subject to time-based vesting. At September 30, 2015, there was approximately $3.2 million of unrecognized compensation cost related to the time-based RSUs, which the Company expects to recognize over a remaining weighted-average period of 3.8 years. All 60,000 RSUs remain outstanding at

September 30, 2015.

In August 2014, the Company issued 19,500 performance-based RSUs to certain employees, of which 3,900 vested during 2014 and 12,000 vested during the three months ended September 30, 2015. During the nine months ended September 30, 2015, 3,600 of these RSUs were cancelled. These stock awards performance conditions made vesting contingent on the occurrence of certain milestone events. As a result, the related compensation cost was recognized as an expense when the probability of the milestone was deemed probable. The last of these events occurred during the three months ended September 30, 2015, resulting in $0.3 million of compensation cost. At September 30, 2015, there was no remaining unrecognized compensation cost related to the performance-based RSU grants.

ESPP

Under the Company s 2012 ESPP, an aggregate of 275,000 shares of common stock have been reserved for issuance pursuant to purchase rights granted to the Company s employees or to employees of the Company s designated subsidiaries. As of September 30, 2015, 249,801 shares remained available for issuance. During the nine months ended September 30,

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2014 and 2015, the Company issued 5,372 and 7,523 shares, respectively, under the 2012 ESPP, and recognized approximately $0.1 million and $0.2 million in related stock-based compensation expense, respectively.

6. Common Stock Transactions

In February 2014, the Company sold 3,200,000 shares of common stock, in an underwritten public offering at a price to the public of $31.50 per share, resulting in gross proceeds of approximately $100.8 million. Net proceeds to the Company after deducting fees, commissions and other expenses related to the offering were approximately $94.2 million. The shares were issued pursuant to an automatic shelf registration statement on Form S-3.

In March 2015, the Company sold 3,755,000 shares of common stock, in an underwritten public offering at a price to the public of $51.00 per share, resulting in gross proceeds of approximately $191.5 million. Net proceeds to the Company after deducting fees, commissions and other expenses related to the offering were approximately $179.8 million. The shares were issued pursuant to an automatic shelf registration statement on Form S-3.

7. Income Taxes

Deferred tax assets and deferred tax liabilities are determined based on temporary differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some portion or all of the deferred tax assets will not be realized.

For the three and nine months ended September 30, 2014 and 2015, the Company did not record any current or deferred income tax provisions or benefits. Due to the uncertainty surrounding the future realization of the favorable tax attributes, the Company has recorded full valuation allowances against its otherwise recognizable net deferred tax assets at both December 31, 2014 and September 30, 2015.

8. Commitments and Contingencies

The Company leases office space in Waltham, Massachusetts under a non-cancelable operating lease agreement. In April 2015, the Company amended its lease to add an additional 17,700 square feet to its existing leased office space of 53,200 square feet, increasing the total to approximately 70,900 square feet. The term of the lease commenced April 1, 2013 and continues through June 30, 2017. The lease agreement provides for one month of free rent with respect to a portion of the leased premises and a tenant improvement allowance of $0.1 million. The Company recognizes rental expense on a straight-line basis over the respective lease term including any free rent periods and tenant allowances.

Future minimum rental commitments under the lease as of September 30, 2015 were $0.6 million, $2.3 million and $1.2 million for the remainder of the year ending December 31, 2015, and the years ending December 31, 2016 and 2017, respectively.

The Company has entered into agreements with certain vendors for the provision of services, including services related to data management, clinical and commercial operation support and companion diagnostic development, that the Company is not contractually able to terminate for convenience and avoid any and all future obligations to the vendors. Under such agreements, the Company is contractually obligated to make certain minimum payments to the vendors, with the exact amounts in the event of termination to be based on the timing of the termination and the exact terms of the agreement.

The Company has certain obligations under licensing agreements with third parties that are contingent upon achieving various development, regulatory and commercial milestones. Pursuant to these license agreements, the Company is required to make milestone payments if certain development, regulatory and commercial sales milestones are achieved, and may have certain additional research funding obligations. Also, pursuant to the terms of each of these license agreements, when and if commercial sales of a product commence, the Company will pay royalties to its licensors on net sales of the respective products.

Legal Proceedings

The Company may periodically become subject to legal proceedings and claims arising in connection with ongoing business activities, including claims or disputes related to patents that have been issued or that are pending in the field of

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research on which the Company is focused. The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities.

9. Collaboration Arrangements

In May 2015, the Company entered into a research agreement with Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., or Merck, to perform a trial to evaluate the preliminary safety and efficacy of niraparib plus KEYTRUDA® in patients with triple negative breast cancer and patients with ovarian cancer. Under the terms of this agreement, the Company is responsible for providing niraparib study materials and for carrying out clinical research activities. The Company and Merck will share in the external costs of the study equally, with certain exceptions. The Company records cost-sharing payments received from Merck as reductions of research and development expense. During the three and nine months ended September 30, 2015, the Company incurred $0.6 million in external costs related to this study, of which $0.3 million is reimbursable by Merck. At September 30, 2015, the $0.3 million of cost-sharing receivable from Merck has been recorded in accounts receivable on the condensed consolidated balance sheet.

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

The following information should be read in conjunction with the unaudited financial information and the notes thereto included in this Quarterly Report on Form 10-Q and the audited financial information and the notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2014.

Except for the historical information contained herein, the matters discussed in this Quarterly Report on Form 10-Q may be deemed to be forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. In this Quarterly Report on Form 10-Q, words such as may, will, expect, anticipate, estimate, intend, and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements.

Examples of forward looking statements contained in this report include statements regarding the following: our commercialization plans for rolapitant, including the potential timing of commercial launch of both VARUBITM (the oral formulation) and the IV formulation; our intent to in-license or acquire additional product candidates; our expectation that research and development and selling, general and administrative expenses will increase in the future; our expectations regarding the timing and design of our development plans, the timing of regulatory filings, and the timing of data from clinical trials, with respect to each of our IV rolapitant, niraparib, and TSR-042 programs; our expectations regarding the winding-down of our TSR-011 program; our expectations regarding our discovery and development plans for immunotherapy antibodies, including the expected timing; our anticipated royalty payments; our expectation that we will continue to incur significant expenses, including increases in our selling, general and administrative expenses, and that our operating losses and negative cash flows will continue to increase for the foreseeable future; the expected impact of recent accounting pronouncements and guidance on our financial statements; and our needs for additional capital and the forecast of the period of time through which our financial resources will be adequate to support our operations.

Our actual results and the timing of certain events may differ materially from the results discussed, projected, anticipated or indicated in any forward-looking statements. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report on Form 10-Q. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report on Form 10-Q, they may not be predictive of results or developments in future periods.

These forward-looking statements involve substantial risks and uncertainties that could cause actual future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the launch of any new pharmaceutical product or the execution and completion of clinical trials, uncertainties surrounding the timing of availability of data from our clinical trials, ongoing discussions with and actions by regulatory authorities, patient accrual rates for clinical trials, and other matters that could affect the timing of data, the potential regulatory approval, or the commercial availability of the Company s product candidates. The following information and any forward-looking statements should be considered in light of these factors and the factors discussed elsewhere in this Quarterly Report on Form 10-Q, including under the heading Risk Factors, and in light of factors discussed in our Annual Report on Form 10-K for the year ended December 31, 2014.

We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Overview

We are an oncology-focused biopharmaceutical company dedicated to improving the lives of cancer patients. We were founded in March 2010 by former executives of MGI PHARMA, Inc., an oncology and acute-care focused biopharmaceutical company. We have in-licensed and are currently developing oncology-related product candidates, including both rolapitant and niraparib, and we expect to commence commercial sales of VARUBITM, which is the oral formulation of rolapitant, during the fourth quarter of 2015.

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On September 1, 2015, the Company s first commercial product, VARUBI, was approved by the United States Food and Drug Administration, or FDA, in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy.

In March 2014, we added immuno-oncology programs to our portfolio of product candidates by entering into a collaboration and exclusive license agreement with AnaptysBio, Inc., or AnaptysBio, for the discovery and development of antibodies for several immuno-oncology targets. We expect to file an investigational new drug application for our first immuno-oncology antibody, TSR-042, which targets PD-1, by the end of 2015.

- *Rolapitant* is a potent and long-acting neurokinin-1, or NK-1, receptor antagonist for the prevention of chemotherapy induced nausea and vomiting, or CINV. The oral form of rolapitant, VARUBI, has been approved for commercialization in the United States, and we are also developing an intravenous, or IV, formulation of rolapitant, which has completed various Phase 1 clinical trials. As part of a registration program for IV rolapitant, we have successfully completed a clinical study comparing the exposure of IV rolapitant and oral rolapitant, as well as a clinical study evaluating the safety of IV rolapitant to support an NDA submission, which we expect to submit to the FDA in the first quarter of 2016. We also plan to submit a Marketing Authorization Application, or MAA, for oral rolapitant to the European Medicines Agency, or EMA, in the second quarter of 2016.

- *Niraparib* is an orally active and potent poly (ADP-ribose) polymerase, or PARP, inhibitor. In July 2013, we dosed the first patient in a Phase 3 clinical trial evaluating niraparib for the treatment of patients with high grade serous, platinum sensitive, relapsed ovarian cancer. We refer to this Phase 3 trial as our NOVA trial. In April 2015, enrollment was completed for the NOVA trial. In April 2014, we dosed the first patient in a Phase 3 clinical trial evaluating niraparib in breast cancer patients with germline BRCA mutations. We refer to this Phase 3 trial as our BRAVO trial. In the first quarter of 2015, we initiated a Phase 2 clinical trial evaluating niraparib as a therapy for patients with ovarian cancer who have previously been treated with three or more regimens of therapy. We dosed the first patient in this trial, which we refer to as our QUADRA trial, in April 2015. In May 2015, we entered into a research agreement with Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., or Merck, to perform a trial to evaluate the preliminary safety and efficacy of niraparib plus KEYTRUDA® in patients with triple negative breast cancer and patients with ovarian cancer. We also are collaborating with the Sarcoma Alliance for Research through Collaboration, or SARC, to evaluate niraparib in combination with chemotherapy for the treatment of Ewing s sarcoma, as well as the Nordic Society of Gynecologic Oncology (in collaboration with the European Network for Gynaecological Oncological Trial groups) in their trial evaluating niraparib plus bevacizumab in ovarian cancer patients in a Phase 1/2 trial referred to as the AVANOVA trial. Additionally, we intend to evaluate niraparib in the first-line setting in ovarian cancer patients. Based on research related to PARP inhibitors generally, we believe that niraparib may also be active in the treatment of several other tumor types.

- *Immuno-Oncology Platform*: PD-1, or programmed cell death protein 1, is a key immune checkpoint molecule that can limit T-cell-mediated immune responses. The presence of the PD-1 ligand, or PD-L1, has been identified on many tumor types, and expression of PD-L1 has been linked to poor clinical outcomes in a variety of

cancers. Anti-PD-1 antibodies have demonstrated in vivo efficacy in tumor models and have shown promising results in several clinical studies. In 2014, the FDA approved KEYTRUDA and OPDIVO®, the first two approved anti-PD-1 antibodies, for the treatment of certain melanomas. In 2015, the FDA further approved both KEYTRUDA and OPDIVO for the treatment of certain forms of NSCLC. As part of our collaboration with AnaptysBio, we received exclusive rights to monospecific antibody product candidates targeting TIM-3, LAG-3 and PD-1 and bi-specific antibody product candidates targeting PD-1/TIM-3, PD-1/LAG-3 and an additional bi-specific combination. We anticipate beginning clinical trials using TSR-042, the lead anti-PD-1 antibody product candidate that we have in-licensed as part of the agreement with AnaptysBio, in 2016. With respect to the TIM-3 and LAG-3 targets, we have identified the lead anti-TIM-3 compound, TSR-022, and we expect to identify the lead anti-LAG-3 compound by the end of 2015. We intend to select lead and backup compounds for the bi-specific PD-1/TIM-3 and PD-1/LAG-3 targets during 2016. In addition, we are evaluating our immuno-oncology anti-tumor agents, such as TSR-042, in combination preclinical pharmacology studies with niraparib and other anti-tumor agents.

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In March 2011, we entered into a license agreement with Amgen, Inc., or Amgen, to obtain exclusive worldwide rights to research, develop, manufacture, market and sell certain licensed ALK inhibitor compounds, including TSR-011. In October 2015, our Board of Directors determined not to continue to pursue the development of TSR-011, and we intend to terminate the license agreement with Amgen. TSR-011 is an orally available targeted anti-cancer agent that is a potent inhibitor of both anaplastic lymphoma kinase, or ALK, and tropomyosin-related kinase, or TRK, currently in a Phase 1/2a dose escalation clinical trial in cancer patients. In August 2015, enrollment was completed for this trial. In connection with terminating the license agreement with Amgen, we expect to orderly wind down our clinical work on TSR-011, including the ongoing Phase 1/2a study.

We commenced business operations in May 2010. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring and developing product candidates, identifying potential product candidates, undertaking preclinical studies, clinical trials, manufacturing activities related to our product candidates and preparing for the commercialization of VARUBI. To date, we have not generated any revenues from product sales, and only received limited revenue from a license related to rolapitant. We have financed our operations with net proceeds from public offerings of our common stock, private placements of our preferred stock and the issuance of convertible notes.

As of September 30, 2015, we had an accumulated deficit of $526.2 million. Our net losses were $175.6 million, $171.0 million, $92.4 million, and $61.8 million for the nine months ended September 30, 2015 and the years ended December 31, 2014, 2013 and 2012, respectively. We expect to incur significant expenses and operating losses for the foreseeable future. Overall, we expect operating expenses to continue to increase in the fourth quarter of 2015 over current levels as we incur increased costs related to the advancement of our ongoing commercialization activities, executing related marketing and promotional programs, and hiring consultants for the commercialization of VARUBI, costs related to the advancement of clinical trial and other development activities under our current development programs, such as IV rolapitant and niraparib, costs related to the immuno-oncology development activities under our collaboration with AnaptysBio, costs related to expanding our international operations, costs related to orderly winding down our work for TSR-011, and costs related to potential future collaborative or in-licensed development programs. In addition, future license payments or milestone payments could cause our total operating expenses and cash usage to fluctuate. For example, upon our first commercial sale of VARUBI, we are obligated to make a $15.0 million milestone payment to OPKO Health, or OPKO. If we obtain regulatory approval for any of our product candidates in addition to VARUBI, or in anticipation of obtaining regulatory approval, we expect that we will incur significant additional commercialization expenses related to product sales, marketing, manufacturing and distribution. Furthermore, we expect to incur increasing selling, general and administrative costs associated with our anticipated growth and continuing operation as a public company, and we will continue to incur substantial interest expense related to our outstanding convertible debt. The actual amount of many of the expenditures described above will depend on numerous factors, including the timing of expenses and the timing and progress of our clinical trial activity and commercialization efforts for VARUBI. Accordingly, until we can generate a sufficient amount of revenue from our products, if ever, we expect to finance our operations in part through additional public or private equity or debt offerings and may seek additional capital through arrangements with strategic partners or from other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenues to achieve profitability, and we may never do so.

Rolapitant. In December 2010, we entered into a license agreement with OPKO to obtain exclusive worldwide rights to research, develop, manufacture, market and sell rolapitant. The license agreement also extended to an additional, backup compound, SCH900978, to which we have similar rights and obligations as rolapitant, but which we are not currently advancing. We are required to make development milestone payments to OPKO of up to an aggregate of $30.0 million, of which we have paid $5.0 million to date, if specified regulatory and initial commercial sales milestones are achieved in the U.S. and Europe, which includes a payment of $15.0 million due to OPKO upon our first commercial sale of VARUBI. In addition, we are required to make milestone payments to OPKO of up to an aggregate of $85.0 million if specified levels of annual net sales of rolapitant are achieved. When commercial sales of rolapitant commence, we are required to pay OPKO tiered royalties on the amount of annual net sales achieved in the United States and Europe at percentage rates that range from the low teens to the low twenties, which we expect will

result in an effective royalty rate in the low teens. The royalty rate on annual net sales outside of the United States and Europe is slightly above the single digits. We will pay royalties on rolapitant until the later of (i) the date that all of the patent rights licensed from OPKO and covering rolapitant expire, are invalidated or are not enforceable, and (ii) 12 years from the first commercial sale of the product, in each case, on a country-by-country and product-by-product basis. If we elect to develop and commercialize rolapitant in Japan through a third-party licensee, we will share equally with OPKO all amounts received by us in connection with such activities under our agreement with such third party, subject to certain exceptions and deductions. OPKO also retains an option to become the exclusive distributor of such products in Latin America, provided that OPKO exercises that option within a defined period following

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specified regulatory approvals in the United States. We are responsible for all preclinical, clinical, regulatory and other activities necessary to develop and commercialize rolapitant.

Rolapitant Intravenous Formulation. We are also developing a single dose IV rolapitant formulation with respect to which we have selected a single intravenous dose of 185mg for further development. We have completed a multiple ascending dose study of IV rolapitant that confirmed the safety and tolerability profiles and linear pharmacokinetics of repeat daily doses. As part of a registration program for IV rolapitant, we have successfully completed a clinical study comparing the exposure of IV rolapitant and oral rolapitant, as well as a clinical study evaluating the safety of IV rolapitant to support an NDA submission, which we expect to submit to the FDA in the first quarter of 2016.

Niraparib. In May 2012, we entered into a license agreement with Merck, under which we obtained exclusive, worldwide rights to certain patents and non-exclusive rights to certain Merck know-how, to research, develop, manufacture, market and sell niraparib and a backup compound, MK-2512, for all therapeutic and prophylactic uses in humans. We are not currently advancing MK-2512. Under the terms of the license agreement, we have made two milestone payments to Merck, one in the amount of $1.9 million upon dosing of the first patient in our NOVA trial in July 2013 and one in the amount of $0.9 million upon dosing of the first patient in our BRAVO trial in April 2014. We are required to make total milestone payments to Merck of up to $57.0 million in U.S. and European development and regulatory milestones for the first indication, up to $29.5 million in development and regulatory milestones for each successive indication, and up to $87.5 million in one-time sales milestones based on the achievement of annual sales objectives. If commercial sales of niraparib commence, we will pay Merck tiered royalties at percentage rates in the low teens based on worldwide annual net sales, until the later of the expiration of the last patent licensed from Merck covering or claiming niraparib, or the tenth anniversary of the first commercial sale of niraparib, in either case, on a country-by-country basis.

We are responsible for all clinical, regulatory and other activities necessary to develop and commercialize niraparib. At the time of the license transaction, niraparib had completed a Phase 1 clinical trial in cancer patients as a monotherapy. We are evaluating niraparib for the treatment of patients with high grade serous, platinum sensitive, relapsed ovarian cancer in our NOVA trial, which we initiated in July 2013. In April 2015, enrollment was completed for the NOVA trial. We also initiated our QUADRA trial during the first quarter of 2015. QUADRA is a Phase 2 clinical trial of niraparib for the treatment of patients with ovarian cancer who have previously been treated with three or more regimens of therapy. This trial is a single arm, open label study, targeted to enroll 225 patients who have previously received three or more lines of chemotherapy. Endpoints include objective response rate and duration of response across platinum sensitive, platinum resistant, $gBRCA_{mut}$ and HRD patient subsets. We further intend to initiate a clinical trial of niraparib in the first-line ovarian cancer setting, which we refer to as our PRIMA trial, during the first quarter of 2016. The PRIMA trial will include patients who have responded to first-line platinum chemotherapy. We are also evaluating niraparib in breast cancer patients with germline BRCA mutations in our BRAVO trial, which we initiated in April 2014. We are also participating in certain investigator sponsored trials investigating the use of niraparib in various other tumor types.

In May 2015, we entered into a research agreement with Merck to perform a trial to evaluate the preliminary safety and efficacy of niraparib plus KEYTRUDA in patients with triple negative breast cancer and patients with ovarian cancer. We intend to initiate this trial during the first

quarter of 2016.

Immuno-Oncology Platform. In March 2014, we entered into a collaboration and exclusive license agreement with AnaptysBio, a privately-held therapeutic antibody company, which we expanded by amending the agreement in November 2014. Under the terms of this agreement, we obtained an exclusive, royalty-bearing, sublicensable worldwide license to research, develop, manufacture, market and sell products based on AnaptysBio s proprietary technology for the discovery, generation and optimization of immunotherapy antibody product candidates targeting TIM-3 (TSR-022), LAG-3 and PD-1 (TSR-042) and bi-specific antibody product candidates targeting PD-1/TIM-3, PD-1/LAG-3 and an additional bi-specific combination. Under this amended agreement, AnaptysBio is responsible for performing initial discovery and development of therapeutic antibodies against immune checkpoint proteins, with the goal of generating immunotherapy antibodies for use in the treatment of cancer. We are responsible for all subsequent preclinical, clinical, regulatory, manufacturing and other activities necessary to develop and commercialize antibodies selected under each of four development programs, and we are obligated to use commercially reasonable efforts to research, develop or commercialize at least one product under each development program.

Under the terms of the amended agreement, we are required to reimburse AnaptysBio on a quarterly basis for specified costs incurred by AnaptysBio in its initial discovery and development activities covered by the agreement. For each of the four development programs, we will be required to make milestone payments to AnaptysBio of up to $18.0 million if certain research and development milestone events are achieved, of which we have incurred $1.0 million to date, and up to an additional $90.0 million of milestone payments if certain U.S. and non-U.S. regulatory submissions and approvals occur in initial and subsequent indications. We will also be required to pay AnaptysBio tiered single-digit

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royalties, on a product-by-product basis, on worldwide annual net sales, and additional commercial milestone payments if specified levels of annual net sales of a product are attained.

TSR-011. We intend to wind-down our TSR-011 program. In March 2011, we entered into a license agreement with Amgen to obtain exclusive worldwide rights to research, develop, manufacture, market and sell certain licensed ALK inhibitor compounds, including TSR-011. Under the terms of the license agreement, we have made a milestone payment of $1.0 million. We expect to work to orderly wind down our clinical activities and return all rights related to TSR-011 under the license agreement to Amgen.

Public Offerings of Common Stock, Private Placements of Securities and Issuance of Convertible Notes. As of September 30, 2015, our principal source of liquidity was cash and cash equivalents, which totaled $302.5 million. Since our inception on March 26, 2010, we have funded our operations primarily through public offerings of our common stock, the private placement of our equity securities and issuance of convertible notes. From inception through December 31, 2014, we received $383.9 million in proceeds, net of underwriting discounts and commissions and offering expenses, from public offerings of common stock and private placements of convertible preferred stock. In March 2015, we completed a public offering of our common stock whereby we sold an additional 3,755,000 shares of our common stock at a price to the public of $51.00 per share and received approximately $179.8 million in proceeds, net of underwriting discounts and commissions and offering expenses. On September 29, 2014, we issued $201.3 million aggregate principal amount of Convertible Notes, with net proceeds of $194.7 million, and we used $20.8 million of the proceeds from this transaction to enter into capped call option transactions, or Capped Calls, associated with the Convertible Notes.

Financial Operations Overview

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- pre-commercial license fees and milestone payments related to the acquisition of in-licensed product candidates, which are reported on our statements of operations as acquired in-process research and development;

- employee-related expenses, including salaries, bonuses, benefits, travel and stock-based compensation expense;

- fees and expenses incurred under agreements with contract research organizations, investigative sites, research consortia and other entities in connection with the conduct of clinical trials and preclinical studies and related services, such as administrative, data management, laboratory and biostatistics services;

- the cost of acquiring, developing and manufacturing active pharmaceutical ingredients for product candidates that have not received regulatory approval, clinical trial materials and other research and development materials;

- fees and costs related to regulatory filings and operations;

- facilities, depreciation and other expenses, which include direct and allocated expenses for rent, utilities, maintenance of facilities, insurance and other supplies; and

- other costs associated with clinical and preclinical activities.

Research and development costs are expensed as incurred. License fees and development milestone payments related to in-licensed products and technology are expensed as acquired in-process research and development if it is determined that they have no alternative future use. Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to us by our vendors.

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Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials and manufacturing costs. We expect that our total future research and development costs will continue to increase over current levels, depending on the progress of our clinical development programs as well as expected increasing costs associated with our collaborations with AnaptysBio and Merck, manufacturing related costs, and potential development milestone payments. More specifically, we expect costs to increase as we: continue our currently ongoing Phase 2 and 3 trials for, and initiate additional investigative and collaborative studies related to, niraparib; continue clinical and other development activities for the IV formulation of rolapitant; incur potential research and development related milestones; incur increased discovery, development and manufacturing related expenses associated with our immuno-oncology platform; and hire additional development and scientific personnel.

We cannot determine with certainty the duration and completion costs of the current or future clinical trials of our product candidates or if, when, or to what extent we will generate revenues from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our currently unapproved product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including the uncertainties of future clinical and preclinical studies, uncertainties in clinical trial enrollment rates and significant and changing government regulation. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate s commercial potential.

The following table presents research and development expenses and acquired in-process research and development expenses on a program-specific basis for our in-licensed products and product candidates for the nine months ended September 30, 2014 and 2015 (in thousands):

	Nine Months Ended September 30,	
	2014	**2015**
Rolapitant Expenses		
Acquired in-process research and development	$	$
Research and development	24,940	20,114
Rolapitant total	24,940	20,114
Niraparib Expenses		
Acquired in-process research and development	900	
Research and development	35,590	42,805
Niraparib total	36,490	42,805
TSR-011 Expenses		
Acquired in-process research and development		
Research and development	4,760	3,623
TSR-011 total	4,760	3,623
Immuno-Oncology Platform Expenses		
Acquired in-process research and development	17,000	1,000
Research and development	3,500	14,960
Immuno-Oncology Platform total	20,500	15,960
Personnel and Other Expenses	19,821	31,036

Total	**$**	**106,511**	**$**	**113,538**

For further discussion of the changes in our research and development expenses with respect to the nine months ended September 30, 2015 and the corresponding period of 2014, see Results of Operations Comparison of the Nine Months Ended September 30, 2014 and 2015 Research and Development Expenses below.

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Personnel-related costs, depreciation and stock-based compensation are not allocated to any programs, as they are deployed across multiple projects under development and, as such, are separately classified as personnel and other expenses in the table above.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist principally of salaries and related costs, including stock-based compensation, for the Company s commercial personnel, including its recently hired field sales force, medical education professionals and other commercial support personnel, as well as personnel in executive and other administrative or non-research and development functions. Other selling, general and administrative expenses include certain facility-related costs, communication expenses, pre-commercialization and other activities necessary to prepare for and support the launch of VARUBI, and professional fees for legal, patent review, consulting and accounting services.

We anticipate that our selling, general and administrative expenses will continue to increase in the future in support of our commercial activities related to VARUBI and continued research and development activities, as well as the continued costs of operating as a public company. These increases will likely include increased costs related to the hiring of additional personnel, executing marketing and promotional programs, hiring consultants, and legal and other professional fees, among other expenses. Additionally, we anticipate that we will continue to incur significant increases in payroll and other expenses relating to the sales and marketing of VARUBI.

Other Income and Expense

Other income and expense consists primarily of interest expense related to the Convertible Notes and interest income earned on cash and cash equivalents.

Results of Operations

Comparison of the Three Months Ended September 30, 2014 and 2015

	Three Months Ended September 30,		Increase/ (Decrease)
	2014	2015	
		(in thousands)	
License revenue	$	$ 87	$ 87
Expenses:			
Research and development	29,925	40,063	10,138
Selling, general and administrative	6,263	22,766	16,503
Total expenses	36,188	62,829	26,641
Loss from operations	(36,188)	(62,742)	(26,554)

Other income (expense), net	(38)	(3,844)	(3,806)
Net loss	$ (36,226)	$ (66,586)	$ (30,360)

License Revenue. License revenue of $0.1 million during 2015 relates to the Company s license agreement with a third party pursuant to which the third party has licensed the rights to develop, manufacture and commercialize rolapitant in China, including Hong Kong and Macao. At September 30, 2015, the Company was entitled to an up-front payment of $1.0 million and recorded $0.1 million of license revenue during the three months ended September 30, 2015. The Company received the cash payment from the licensee subsequent to September 30, 2015.

Research and Development Expenses. Research and development expenses were $40.1 million for the three months ended September 30, 2015, compared to $29.9 million for the three months ended September 30, 2014, an increase of $10.1 million. The increase was primarily due to higher expenses related to external costs associated with the development of our immuno-oncology platform, as well as higher personnel and related costs. Significant changes resulting in this increase included:

- an increase of $4.2 million in costs associated with our immuno-oncology platform due to increased costs related to biologics manufacturing as well as non-clinical and other immuno-oncology program research activities; and

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- an increase of $2.7 million in personnel and other costs (excluding stock-based compensation), primarily related to increased research and development headcount supporting the growth of our development activities.

In addition, stock-based compensation expense included in research and development expenses increased by $2.6 million, primarily related to increased awards of employee stock options and higher grant-date fair values of those awards.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $22.8 million for the three months ended September 30, 2015, compared to $6.3 million for the three months ended September 30, 2014, an increase of $16.5 million. The increase was primarily due to increases of: $9.5 million in salaries, benefits and other personnel-related costs, primarily due to the hiring of sales, marketing, medical affairs and other support personnel associated with the commercialization of VARUBI; $4.3 million in professional and consulting fees and other expenses to support corporate operational and pre-commercialization activities; and $2.6 million in stock-based compensation expense.

Other Income (Expense), Net. Other income (expense) is primarily comprised of interest expense related to our Convertible Notes and interest income earned on cash and cash equivalents. Interest expense increased by $3.8 million in the three months ended September 30, 2015, due to there being a full three months of expense in the 2015 period compared to two days of interest in the 2014 period. Interest income increased from $4,000 in the three months ended September 30, 2014 to $9,000 in the three months ended September 30, 2015.

Comparison of the Nine Months Ended September 30, 2014 and 2015

	Nine Months Ended September 30,		Increase/ (Decrease)
	2014	2015	
	(in thousands)		
License revenue	$	$ 87	$ 87
Expenses:			
Research and development	88,611	112,538	23,927
Selling, general and administrative	16,538	50,791	34,253
Acquired in-process research and development	17,900	1,000	(16,900)
Total expenses	123,049	164,329	41,280
Loss from operations	(123,049)	(164,242)	(41,193)
Other income (expense), net	(28)	(11,407)	(11,379)
Net loss	$ (123,077)	$ (175,649)	$ (52,572)

Research and Development Expenses. Research and development expenses were $112.5 million for the nine months ended September 30, 2015, compared to $88.6 million for the nine months ended September 30, 2014, an increase of

$23.9 million. The increase was primarily due to higher expenses related to the development of our immuno-oncology platform and niraparib, partially offset by lower expenses associated with the development of rolapitant and TSR-011. Significant changes resulting in this increase included:

- an increase of $11.5 million in costs associated with our immuno-oncology platform due to increased costs related to biologics manufacturing and non-clinical research activities. In addition, the current year expense represented nine months of effort on all of the current antibody candidates; the expense for the prior year period reflected effort only on those candidates identified in the initial collaboration and exclusive license agreement with AnaptysBio, which was executed during March 2014;

- an increase of $7.2 million in costs associated with niraparib development activities, primarily related to increased costs of our various ovarian cancer clinical trials, partially offset by lower costs relating to drug process development and manufacturing;

- an increase of $7.0 million in personnel and other costs (excluding stock-based compensation), primarily related to increased research and development headcount supporting the growth of our development activities; and

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- a decrease of $4.8 million in costs associated with rolapitant development activities, primarily due to lower costs related to the oral rolapitant Phase 3 clinical trials, which were completed in 2014, partially offset by increased costs relating to drug process development and manufacturing and costs relating to IV rolapitant development activities.

In addition, stock-based compensation expense included in research and development expenses increased by $4.3 million, primarily related to increased awards of employee stock options and higher grant-date fair values of those awards.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $50.8 million for the nine months ended September 30, 2015, compared to $16.5 million for the nine months ended September 30, 2014, an increase of $34.3 million. The increase was primarily due to increases of: $19.4 million in salaries, benefits and other personnel-related costs, primarily due to the hiring of sales, marketing, medical affairs and other support personnel associated with the commercialization of VARUBI; $10.2 million in professional and consulting fees and other expenses to support corporate operational and pre-commercialization activities; and $4.7 million in stock-based compensation expense.

Acquired In-Process Research and Development Expenses. We recorded $1.0 million in acquired in-process research and development expenses for the nine months ended September 30, 2015, due to a milestone related to the initiation of the first Good Laboratory Practices, or GLP, toxicology study under our immuno-oncology platform. We recorded $17.9 million in acquired in-process research and development expenses for the nine months ended September 30, 2014. This amount consisted of the $17.0 million up-front payment related to the collaboration and exclusive license agreement with AnaptysBio, and a $0.9 million milestone payment related to the initiation of the Phase 3 clinical trial of niraparib in breast cancer patients with germline BRCA mutations in April 2014.

Other Income (Expense), Net. Other income (expense) is primarily comprised of interest expense related to our Convertible Notes, and interest income earned on cash and cash equivalents. Interest expense increased by $11.4 million in the nine months ended September 30, 2015, due to there being a full nine months of expense in the 2015 period compared to two days of interest in the 2014 period. Interest income increased from $14,000 in the nine months ended September 30, 2014 to $25,000 in the nine months ended September 30, 2015.

Liquidity and Capital Resources

Sources of Liquidity

To date, we have not generated any revenue, other than $0.1 million of license revenue related to an up-front payment for which the Company has also recorded $0.9 million of deferred revenue as of September 30, 2015. As of September 30, 2015, our principal source of liquidity was cash and cash equivalents, which totaled $302.5 million. Since our inception on March 26, 2010, we have funded our operations primarily through public offerings of our common stock, the private placement of our equity securities and the issuance of convertible notes. From inception through December 31, 2014, including our 2012 initial public offering, we raised a total of $383.9 million in net cash proceeds from private placements of convertible preferred stock and public offerings of common stock. In March 2015, we completed a public offering of our common stock whereby we sold an additional 3,755,000 shares of our common stock at a price to the public of $51.00 per share and received approximately $179.8 million in proceeds, net of underwriting discounts and commissions and offering expenses.

On September 29, 2014, we completed the issuance of $201.3 million aggregate principal amount of senior convertible notes, generating proceeds, net of underwriting discounts, commissions and offering expenses, of $194.7 million. In conjunction with the sale of the Convertible Notes, we used approximately $20.8 million of the net proceeds to enter into Capped Calls with certain counterparties. The Capped Calls are expected generally to reduce the potential dilution, and/or offset, to an extent, the cash payments we may choose to make in excess of the principal amount, upon conversion of the Convertible Notes.

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Cash Flows

The following table sets forth the primary sources and uses of cash for each of the periods below (in thousands):

	Nine Months Ended September 30,	
	2014	**2015**
Net cash provided by (used in):		
Operating activities	$ (85,172)	$ (135,497)
Investing activities	(18,869)	(2,869)
Financing activities	269,643	184,023
Increase in cash and cash equivalents	$ 165,602	$ 45,657

Cash Flows from Operating Activities

The use of cash in operating activities during both the nine months ended September 30, 2014 and 2015 resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital. Net cash used in operating activities increased by $50.3 million for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014, primarily due to increased external expenses related to pre-commercialization activities and increased external research and development expenses as we continued to progress the niraparib development program and the immuno-oncology platform. Higher costs associated with increased employee headcount related to pre-launch commercial preparation activities also contributed to the increase in cash used in operating activities. These factors were partially offset by lower external costs associated with our oral rolapitant and TSR-011 programs.

Cash Flows from Investing Activities

The decrease of $16.0 million in net cash used in investing activities for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014 was due primarily to the $17.0 million up-front payment made in the nine months ended September 30, 2014 in connection with the collaboration and exclusive license agreement with AnaptysBio for our immuno-oncology platform. We also made a $0.9 million milestone payment in the second quarter of 2014 related to the initiation of the Phase 3 clinical trial of niraparib in breast cancer patients with germline BRCA mutations. In June 2015 we incurred a $1.0 million milestone payment under the agreement with AnaptysBio, which we paid in July 2015.

Cash Flows from Financing Activities

The decrease of $85.6 million in net cash provided by financing activities for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014 was primarily due to the issuance of convertible notes in September 2014. In the nine months ended September 30, 2014, cash proceeds of $174.4 million, net of issuance costs and the purchase of capped call options were received, compared to no proceeds in the current year period. In addition, the current year period included cash proceeds of $179.8 million from the closing of our March 2015 public offering of common stock, compared to cash proceeds of $94.2 million in the prior year period from the closing of our

February 2014 public offering of common stock (both amounts net of underwriting discounts and commissions and offering expenses). Also, cash proceeds from exercises of employee stock options and ESPP purchases increased by $3.4 million during the current year period.

Operating Capital Requirements

We expect to incur significant expenses and operating losses for the foreseeable future. Overall, we expect 2015 operating expenses to continue to increase for the remainder of 2015 as we incur increased costs related to the advancement of our ongoing commercialization activities, having a commercial sales operation in place for a full quarter, executing related marketing and promotional programs, and hiring consultants in preparation for the launch of VARUBI, costs related to the advancement of clinical trials and other development activities under our current development programs, such as IV rolapitant and niraparib, costs related to the immuno-oncology development activities under our collaboration with AnaptysBio, and costs related to potential future in-licensed development programs. We are subject to the risks incident in the development of new biopharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business and cause increased uses of cash.

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We believe that our existing cash and cash equivalents, coupled with the cash we expect to generate from sales of VARUBI, will be sufficient to fund our cash flow requirements, including any license payments or milestone obligations that may arise, required costs relating to our March 2014 collaboration and exclusive license agreement with AnaptysBio and cash interest obligations related to our Convertible Notes, through at least the 12 months following the filing of this Quarterly Report on Form 10-Q. However, we expect to require additional capital for the commercialization of VARUBI, further development and potential commercialization of our other product candidates and we may also need to raise additional funds to pursue our strategy of in-licensing or acquiring additional product candidates and to meet our obligation to repay the Convertible Notes at maturity or, at our election, upon conversion.

Unless and until we can generate a sufficient amount of revenue from our products, we expect to finance future cash needs through public or private equity or debt offerings and may seek additional capital through arrangements with strategic partners or from other sources. Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we would have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. Raising additional funds through the issuance of equity or debt securities could result in dilution to our existing stockholders, increased fixed payment obligations, or both. Furthermore, these securities may have rights senior to those of our common stock and Convertible Notes and could contain covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

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. 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, both short and long-term, will depend on many factors, including:

- our ability to generate revenues from sales of VARUBI and future products;

- the cost of establishing sales, marketing and distribution capabilities for VARUBI or any product candidates for which we may receive regulatory approval;

- the outcome, timing and cost of regulatory approvals by the FDA and comparable non-U.S. regulatory authorities, including the potential that the FDA or comparable non-U.S. regulatory authorities may require that we perform more studies than those that we currently expect;

- the initiation, progress, timing, costs and results of clinical trials for our product candidates and any future product candidates we may in-license, including our current and potential future Phase 2 and 3 clinical trials for niraparib;

- the winding-down of our clinical development plans for TSR-011;

- the cost and timing of completion of commercial-scale outsourced manufacturing activities;

- the discovery, preclinical and clinical development plans that are or will be established for potential product candidates under our collaboration with AnaptysBio;

- the attainment of milestones and our obligations to make milestone payments, royalty payments, or both to OPKO, Merck, Amgen or AnaptysBio or to any other future product candidate licensor, if any, under our in-licensing agreements;

- the number and characteristics of product candidates that we in-license and develop;

- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

- the amount and timing of potential conversion requests, if any, and interest expense associated with our Convertible Notes; and

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- the effect of competing technological and market developments.

If we lack sufficient capital to expand our operations or otherwise capitalize on our business opportunities, our business, financial condition and results of operations could be materially adversely affected.

Contractual Obligations and Commitments

There have been no material changes to our contractual obligations and commitments included in our Annual Report on Form 10-K for the year ended December 31, 2014.

Off-Balance Sheet Arrangements

As of September 30, 2015, we did not have any off-balance sheet arrangements as defined in Item 303(a)(4)(ii) of Regulation S-K.

Critical Accounting Policies

Our management s discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued research and development expenses and stock-based compensation expense. We base our estimates on historical experience, known trends and events and various other 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. Actual results may differ from these estimates under different assumptions or conditions. In making estimates and judgments, management employs critical accounting policies.

For a description of our critical accounting policies, please see Management s Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2014. There have not been any material changes to our critical accounting policies since December 31, 2014.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. As of September 30, 2015 and December 31, 2014, we had cash and cash equivalents of $302.5 million and $256.9 million, respectively, consisting primarily of money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of United States interest rates, particularly because our investments are in short-term securities. Our securities are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio. There has been no material change to our interest rate sensitivity during the nine months ended September 30, 2015.

Item 4. Controls and Procedures.

Management s Evaluation of our Disclosure Controls and Procedures

Our principal executive officer and our principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act, Rule 13a-15(e) or Rule 15d-15(e)), with the participation of our management, has concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures are effective and are designed to ensure that information we are required to disclose in the reports that we file or submit under the Exchange Act is accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure, and is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms. It should be noted that any system of controls is designed to provide reasonable, but not absolute, assurances that the system will achieve its stated goals under all reasonably foreseeable

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circumstances. Our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures are effective at a level that provides such reasonable assurances.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the fiscal quarter covered by this report that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II **OTHER INFORMATION**

Item 1. Legal Proceedings.

We are not currently a party to any material legal proceedings.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the following discussion of risk factors, in its entirety, in addition to the other information contained in this Quarterly Report on Form 10-Q, our Annual Report on Form 10-K for the year ended December 31, 2014 and the other filings we make with the Securities and Exchange Commission, as well the information in our financial statements and the related notes. We cannot assure you that any of the events discussed in the risk factors below will not occur. These risks, or other events that we do not currently anticipate or that we currently deem immaterial, may have a material adverse effect on our business, prospects, financial condition and results of operations.

Risks Related to Our Financial Position and Capital Needs

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

We are a biopharmaceutical company with a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. We have not generated any 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 are not profitable and have incurred losses in each period since our inception in 2010. For the year ended December 31, 2014, we reported a net loss of $171.0 million and had an accumulated deficit of $350.5 million as of December 31, 2014. For the nine month period ended September 30, 2015, we reported a net loss of $175.6 million and had an accumulated deficit of $526.2 million as of September 30, 2015.

Although we obtained approval from the U.S. Food and Drug Administration, or FDA, for VARUBI™ (rolapitant) tablets in September 2015 and plan to launch VARUBI in the U.S. market during the fourth quarter of 2015, we expect to continue to incur losses for the foreseeable future, and these losses may increase as we continue to invest in a sales and marketing organization and other commercialization infrastructure for VARUBI and continue our development of, and seek regulatory approvals for, our product candidates. 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 revenues from VARUBI and any product candidates for which we obtain regulatory approval, and the timing and amount of

milestones and other required payments to third parties. If any of our product 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 stockholders equity and working capital.

We have a very limited operating history, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We were incorporated in March 2010. Our operations to date have been focused on organizing and staffing our company, acquiring product and technology rights, and conducting product development activities for our product candidates. We obtained FDA approval for VARUBI in September 2015 but have not yet demonstrated an ability to commercialize VARUBI or any of our other product candidates. Consequently, any predictions about our future success, performance or viability may not be as accurate as they could be if we had a longer operating history, approved products that have been marketed for some time, or both.

We currently have no sales of our products and may never become profitable.

To date, we have not generated any revenues from sales of VARUBI or our clinical-stage product candidates. We also have not generated any revenues from the other product candidates that we have in-licensed. Our ability to generate revenue and become profitable depends upon our ability to successfully commercialize products, including VARUBI, any of our clinical-stage product candidates, or the other product candidates that we have or may in-license or acquire in the future.

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Even if we are able to successfully achieve regulatory approval for our product candidates, we do not know when any of these products will generate revenue for us, if at all. Our ability to generate revenue from VARUBI and our current or future product candidates also depends on a number of additional factors, including our ability to:

- successfully complete development activities, including clinical trials for IV rolapitant and niraparib;
- complete and submit new drug applications, or NDAs, or biologic license applications, or BLAs, to the FDA and obtain regulatory approval for indications for which there is a commercial market
- complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities;
- set a commercially viable price for our products;
- obtain commercial quantities of VARUBI, IV rolapitant, niraparib, and any of our other product candidates at acceptable cost levels;
- develop a commercial organization capable of sales, marketing and distribution;
- find suitable partners to help us market, sell and distribute our approved products; and
- obtain adequate reimbursement from third-party payors, including government payors.

In addition, because of the numerous risks and uncertainties associated with product development, including the risk that our product candidates may not advance through development or achieve the endpoints of applicable clinical trials, 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. Even if we are able to complete the process described above, we anticipate incurring significant costs associated with commercializing these products.

Even if we are able to generate revenues from the sale of our products, 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, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

If we require additional capital to fund our operations and we fail to obtain necessary financing, we may be unable to complete the development and commercialization of our product candidates.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to advance the clinical development of our product candidates and to launch and commercialize VARUBI and any product candidates for which we receive regulatory approval, including building our own commercial organizations to address certain markets. We believe that our existing cash and cash equivalents will be sufficient to fund our projected operating requirements for at least the twelve-month period following the date of this Quarterly Report on Form 10-Q. However, we expect to require additional capital for the further development and commercialization of VARUBI and our product candidates and to pursue our strategy of in-licensing or acquiring additional product candidates.

Until we can generate a sufficient amount of revenue from our products, if ever, we expect to finance future cash needs through additional public or private equity or debt offerings and may seek additional capital through arrangements with strategic partners or from other sources. Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of VARUBI or one or more of our product candidates. Raising additional funds through the issuance of debt or equity securities could result in dilution to our existing stockholders, increased fixed payment obligations, or both. Furthermore, these securities may have rights senior to those of our common stock and could contain covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

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

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that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements, both short and long-term, will depend on many factors, including:

- the cost of establishing sales, marketing and distribution capabilities for VARUBI or any product candidates for which we may receive regulatory approval;

- the outcome, timing and cost of regulatory approvals by the FDA and comparable foreign regulatory authorities, including the potential that the FDA or comparable foreign regulatory authorities may require that we perform more studies than those that we currently expect;

- the initiation, progress, timing, costs and results of clinical trials for our current product candidates and any future product candidates we may in-license;

- the cost and timing of completion of commercial-scale outsourced manufacturing activities;

- the preclinical and clinical development plans we and our collaborator, AnaptysBio, Inc., or AnaptysBio, establish for our monospecific antibody product candidates targeting PD-1 (TSR-042), TIM-3 (TSR-022) and LAG-3 and our bi-specific antibody product candidates targeting PD-1/TIM-3, PD-1/LAG-3 and an additional bi-specific combination;

- the attainment of milestones and our obligations to make milestone payments, royalty payments, or both to OPKO, Merck, Amgen, or AnaptysBio or to any other future product candidate licensor, if any, under our in-licensing agreements;

- the number and characteristics of product candidates that we in-license and develop;

- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

- the amount and timing of potential conversion requests, if any, and interest expense associated with our Convertible Notes; and

- the effect of competing technological and market developments.

If we lack the capital to expand our operations or otherwise capitalize on our business opportunities, our business, financial condition and results of operations could be materially adversely affected.

Risks Related to Our Business and Industry

Our future success is dependent primarily on our ability to successfully commercialize VARUBI and to obtain regulatory approvals for and successfully commercialize our portfolio of product candidates.

The success of our business depends heavily upon our ability to develop and commercialize product candidates. We are preparing to launch sales of VARUBI, and our only clinical-stage product candidates are IV rolapitant and niraparib. IV rolapitant is our most advanced product candidate, and our other product candidates are at earlier stages of development. Niraparib is currently in Phase 3 clinical trials in ovarian and breast cancer patients that commenced during 2013 and 2014, respectively. Our antibody product candidates targeting PD-1, TIM-3 and LAG-3 are still in preclinical development.

We cannot commercialize product candidates in the United States without first obtaining regulatory approval for the product from the FDA. Similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate with substantial evidence gathered in preclinical and well-controlled clinical studies, and, with respect to approval in the United States, to the satisfaction of the FDA, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. The process to develop, obtain regulatory approval for and commercialize product candidates is long, complex and costly both inside and outside of the United States. Even if a product candidate were to successfully obtain approval from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations, including use restrictions for certain patient populations; warnings, precautions or contraindications; or burdensome post-approval study or risk management requirements.

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Our current business plan relies on the successful commercialization of VARUBI, which was approved by the FDA in September 2015, and VARUBI may not achieve market acceptance and may not be commercially successful.

Our ability to successfully commercialize VARUBI, our first FDA-approved product, is important to the execution of our business strategy. VARUBI may not achieve market acceptance among physicians, patients, and third-party payors, and may not be commercially successful. The degree of market acceptance and commercial success of VARUBI will depend on a number of factors, including the following:

- maintaining compliance with all regulatory requirements applicable to VARUBI;

- the acceptance of VARUBI by patients and the medical community and the availability, perceived advantages and relative cost, safety and efficacy of alternative and competing treatments;

- the effectiveness of our marketing, sales and distribution strategy and operations;

- the ability of our third-party manufacturer(s) to manufacture commercial supplies of VARUBI, to remain in good standing with regulatory agencies, and to develop, validate and maintain commercially viable manufacturing processes that are, to the extent required, compliant with current good manufacturing practice (cGMP) regulations;

- our ability to obtain marketing approvals from foreign regulatory authorities, where and as applicable;

- the degree to which the approved labeling supports promotional initiatives for commercial success;

- the availability of reimbursement from managed care plans and other third-party payors and the willingness and ability of patients to pay for VARUBI;

- a continued acceptable safety profile of VARUBI;

- any unexpected results from further analysis of clinical data of our completed clinical trials;

- whether we are required by foreign regulatory agencies to conduct additional clinical trials;

- our ability to enforce our intellectual property rights in and to VARUBI; and

- our ability to avoid third party patent interference or patent infringement claims.

As many of these factors are beyond our control, we cannot assure you that we will ever be able to generate meaningful revenue through the sale of VARUBI. Any inability on our part to successfully commercialize VARUBI in the United States and any international territories where it may be approved, or any significant delay, could have a material adverse impact on our ability to execute upon our business strategy.

Failure to obtain regulatory approval for the intravenous formulation of rolapitant could limit our commercial success.

Although our recent development efforts have been focused on an oral formulation of rolapitant, resulting in FDA approval of VARUBI in September 2015, we are also carrying out development activities related to the IV formulation of this product, including a Phase 1 trial of IV rolapitant intended to demonstrate the bioequivalence of IV rolapitant to VARUBI. Notwithstanding VARUBI s FDA approval, the FDA will require approval of a separate NDA for an IV formulation, and there can be no assurance that we will be able to obtain regulatory approval of the IV formulation. To support an NDA for the IV formulation, we will have to provide data specific to the IV formulation. The FDA may not accept our bioequivalence strategy for IV rolapitant and may require efficacy studies to support the NDA. We expect the IV formulation of rolapitant to serve what we believe is a larger portion of the market for NK-1 receptor antagonists and potentially generate more revenue than the oral formulation. If we do not obtain regulatory approval for the IV formulation or do not obtain such approval in a timely manner, it would negatively affect our revenue and growth prospects.

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If we are unable to successfully establish sales, marketing and distribution capabilities for VARUBI or our product candidates for which we obtain marketing approval, we may be unable to generate revenue from sales of our products.

We have not yet commercialized any drug products as a company. To achieve commercial success for VARUBI and any product candidate that may be approved by the FDA or comparable foreign regulatory authorities, we must continue to expand our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. We will be competing with companies that currently have extensive, well-funded, and more experienced sales and marketing operations. We may be unable to compete successfully against these more established companies.

We have built and are continuing to expand a field organization and other capabilities for the sales, marketing and distribution of VARUBI. As an organization, we have no prior experience in the marketing, sale and distribution of pharmaceutical products, and there are significant risks involved with building and managing a sales organization. In addition, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. Factors that may inhibit our efforts to commercialize VARUBI on our own include:

- our inability to recruit, train, retain and incentivize adequate numbers of qualified and effective sales and marketing personnel;

- the inability of sales personnel to generate sufficient sales leads and to obtain access to physicians or persuade adequate numbers of physicians to use or prescribe VARUBI;

- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and

- our inability to effectively manage a geographically dispersed sales and marketing team.

If we are unable to establish adequate sales, marketing and distribution capabilities for VARUBI or any product candidate for which we obtain marketing approval, whether independently or with third parties, we may not be able to generate product revenue or may not become profitable. If the cost of establishing and maintaining a sales and marketing organization exceeds the cost-effectiveness of doing so, we may not become profitable.

We face substantial competition for VARUBI and our product candidates, and others may discover, develop or commercialize products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face substantial competition with respect to VARUBI and if approved, our IV rolapitant product would also face substantial competition. If VARUBI is successfully commercialized, we expect it to compete with EMEND, an NK-1 receptor antagonist marketed by Merck, as well as AKYNZEO, an oral combination NK-1 receptor antagonist and 5-HT3 receptor antagonist (netupitant plus ALOXI (palonosetron HCl)) that is marketed by Helsinn and Eisai. We also expect that in the short term there will be one or more generic versions of EMEND with which we will compete. VARUBI would face additional competition if other products were developed and approved for the treatment and prevention of CINV, or an IV formulation of AKYNZEO is developed.

We also face competition with respect to our current clinical-stage product candidates, including niraparib and our antibody product candidates targeting PD-1 (TSR-042), TIM-3 (TSR-022) and LAG-3. We will face competition with respect to any product 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 products or are pursuing the development of products for the treatment of the disease indications for which we are developing our clinical-stage product candidates. If niraparib is successfully commercialized, it will compete with Lynparza® (olaparib), a PARP inhibitor approved by the FDA and EMA in December 2014 and that is currently marketed by AstraZeneca. Niraparib may also face competition from other PARP inhibitors if they are successfully developed and receive regulatory approval in the same market. We are aware of several PARP inhibitors in clinical development, including AbbVie s ABT-888 (veliparib), Eisai, Inc. s E-7016, Teva Pharmaceutical Industries, Ltd. s CEP-9722, Clovis Oncology, Inc. s CO-338 (rucaparib) and Medivation, Inc. s MDV3800 (talazoparib).

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There are also a number of pharmaceutical and biotechnology companies pursuing the development of cancer immunotherapies that may compete with our immunotherapy product candidates, which are in preclinical development. We are aware of several companies that have antibody-based products on the market or in clinical development that are directed at the same biological targets as some of our collaboration programs with AnaptysBio. These include: Bristol-Myers Squibb, which has an approved anti-PD-1 antibody, OPDIVO (nivolumab), and an anti-LAG-3 antibody in development; Merck, which has an approved anti-PD-1 antibody that is commercially available under the trade name KEYTRUDA (pembrolizumab), formerly called MK-3475; and Pfizer, Genentech, MedImmune (AstraZeneca), Medivation and EMD Serono (Merck KGaA), which have anti-PDL-1 and/or anti-PD-1 modulators in development. We are also aware of several other companies with immuno-oncology antibodies or programs in the preclinical or research phase.

Our product candidates are being developed for cancer therapeutics and oncology supportive care. There are a variety of available therapies and supportive care products marketed for cancer patients. In many cases, these drugs are administered in combination to enhance efficacy or to reduce side effects. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis. Many of these approved drugs are well established therapies or products and are widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic products, including one or more generic versions of EMEND. This may make it difficult for us to execute our business strategy of using our product candidates in combination with existing therapies or replacing existing therapies with our product candidates.

In addition to pharmaceutical and biotechnology companies, our 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. More established companies, as well as institutions, agencies and organizations, may have a competitive advantage over us due to their greater size, cash flows and institutional experience. Compared to us, many of our competitors may have significantly greater financial, technical and human resources.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more widely used and less costly than ours, and may also be more successful than us in manufacturing and marketing their products.

Even if our product candidates receive regulatory approval, as VARUBI has, they may still face future development and regulatory difficulties.

Even after regulatory approval is obtained, products are still subject to ongoing requirements of the FDA and comparable foreign regulatory authorities, including requirements related to manufacturing, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. The safety profile of any product will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information about VARUBI or of any of our product candidates after approval, those authorities may require labeling changes or establishment of a Risk Evaluation and Mitigation Strategy, or REMS, or similar strategy, impose restrictions on a product s indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of drug and biological products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our approved products or product candidates, or the manufacturing facilities for our approved products or product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;

- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;

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- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;

- seek an injunction or impose civil or criminal penalties or monetary fines;

- suspend or withdraw regulatory approval;

- suspend any ongoing clinical studies;

- refuse to approve pending applications or supplements to applications filed by us;

- suspend or impose restrictions on operations, including costly new manufacturing requirements; and

- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue.

Advertising and promotion of VARUBI and any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the Department of Justice, the Department of Health and Human Services Office of Inspector General, state attorneys general, members of Congress, and the public. Violations of applicable advertising and promotion laws and regulations, including promotion of our products for unapproved (or off-label) uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA. Advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign regulatory authorities.

In the United States, engaging in impermissible promotion of approved products, such as VARUBI, for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. These false claims statutes include the federal civil False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment of government funds, and the individual could share in any judgment or settlement funds. Since 2004, False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements based on certain sales practices promoting off-label drug uses.

This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay treble damages and penalties, or agree to comply with burdensome reporting and compliance obligations pursuant to a Corporate Integrity Agreement with the U.S. Department of Health and Human Services Office of Inspector General to avoid exclusion from the Medicare, Medicaid, and other federal and state healthcare programs. We may become subject to such litigation and, if we are not successful in defending against such actions, those actions may have a material adverse effect on our business, financial condition and results of operations.

Because the results of preclinical testing or earlier clinical studies are not necessarily predictive of future results, niraparib, which is currently in Phase 3 clinical trials, or any other product candidate we advance into clinical trials may not have favorable results in later clinical trials or receive regulatory approval.

Success in preclinical testing and early clinical studies does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of an investigational drug, or the safety, purity, and potency of an investigational biological product. A number of companies in the pharmaceutical and biotechnology industries, including many with greater resources and experience than us, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier clinical trials. Despite the results reported in earlier clinical trials for niraparib, we do not know whether the clinical trials we may conduct will demonstrate adequate efficacy and safety, or safety, purity, and potency, to result in regulatory approval to market any of our product candidates in any particular jurisdiction or jurisdictions. If later-stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates may be adversely impacted.

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Clinical drug development involves a lengthy and expensive process with an uncertain outcome.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process.

We have various ongoing clinical trials related to our development programs for IV rolapitant and niraparib. We may experience delays in our ongoing or future clinical trials, and we do not know whether planned clinical trials will begin or enroll subjects on time, need to be redesigned, or be completed on schedule, if at all. Clinical trials may be delayed, suspended or prematurely terminated for a variety of reasons, such as:

- delay or failure in reaching agreement with the FDA or comparable foreign regulatory authority on a trial design that we are able to execute;

- 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 study;

- delay or failure in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- delay or failure in obtaining institutional review board, or IRB, approval or the approval of other reviewing entities, including comparable foreign entities, to conduct a clinical trial at each site;

- 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;

- delay or failure in recruiting and enrolling suitable subjects to participate in a trial;

- delay or failure in having subjects complete a trial or return for post-treatment follow-up;

- clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;

- 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;

- feedback from the FDA, an IRB, a data safety monitoring board, or comparable foreign entities; or results from earlier stage or concurrent preclinical and clinical studies, that might require modification to the protocol;

- decision by the FDA, an IRB, comparable foreign regulatory entities, or the Company; or recommendation by a data safety monitoring board or comparable foreign regulatory entity, to suspend or terminate clinical trials at any time for safety issues or for any other reason;

- unacceptable risk-benefit profile or unforeseen safety issues or adverse side effects;

- failure to demonstrate a benefit from using a drug or biologic;

- manufacturing issues, including problems with manufacturing or obtaining from third parties sufficient quantities of a product candidate for use in clinical trials; and

- changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

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Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of subjects to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, the ability to obtain and maintain patient consents, whether enrolled subjects drop out before completion, competing clinical trials, and clinicians and patients perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their activities, we have limited influence over their actual performance.

If we experience delays in the completion of, or the termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product 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 product candidates.

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

The time required to obtain approval by the FDA and comparable foreign regulatory authorities 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 product candidate s clinical development and may vary among jurisdictions. Although we have obtained FDA regulatory approval for VARUBI, it is possible that none of our current product candidates or any product candidates we may in-license or acquire and seek to develop in the future will ever obtain regulatory approval.

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

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that a product 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 product 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 product candidates to support the submission and filing of an NDA, BLA or other submission or to obtain regulatory approval;

- disapproval of the manufacturing processes or facilities 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 or a comparable foreign 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 product 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 product candidate with a label that is not desirable for the successful commercialization of that product candidate. In addition, if our product candidate produces undesirable side effects or safety issues, the FDA may require the establishment of REMS, or a comparable foreign regulatory authority may require the establishment of similar strategies, that may, for instance, restrict distribution of our product and impose

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burdensome implementation requirements on us. Any of the foregoing scenarios could materially harm the commercial prospects of our product candidates.

VARUBI or our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial viability of any approved product, or result in significant negative consequences following any marketing approval.

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 or other comparable foreign regulatory authority. Drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete a clinical trial, and could result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if one or more of our product candidates receives marketing approval, as VARUBI has, and we or others later identify undesirable side effects caused by VARUBI or such other products, a number of potentially significant negative consequences could result, including:

- we may suspend marketing of such product;
- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to develop a REMS for such product 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 comparable foreign regulatory authority;
- we may be required to conduct post-market studies;
- we could be sued and held liable for harm caused to subjects or patients; or
- our reputation may suffer.

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

Failure to obtain regulatory approval in international jurisdictions would prevent VARUBI and our product candidates from being marketed abroad.

In order to market and sell VARUBI or any of our product candidates in the European Union and other jurisdictions, including China, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of any of our product candidates by regulatory authorities in the European Union, China or other countries, the commercial prospects of that product candidate may be significantly diminished and our business prospects could decline.

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Our product VARUBI, as well as any product candidates we are able to commercialize, may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business.

Our ability to successfully market VARUBI and commercialize other products will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Our future revenues and profitability will be adversely affected if these third-party payors do not sufficiently cover and reimburse the cost of our products and related procedures or services. If these entities do not provide sufficient coverage and reimbursement for VARUBI, or any future drug product we may market, these products may be too costly for general use, and physicians may prescribe them less frequently.

The Medicare program and certain government pricing programs, including the Medicaid drug rebate program, the 340B/PHS drug pricing program and the VHC Act pricing program, impact the revenues we may derive from VARUBI. Any future legislation or regulatory actions altering these programs or imposing new ones could have a significant adverse effect on our business. There have been, and we expect there will continue to be, a number of legislative and regulatory actions and proposals to control and reduce health care costs. These measures may, among other things: negatively impact the level of reimbursement for pharmaceutical products; require higher levels of cost-sharing by beneficiaries; change the discounts required to be provided by pharmaceutical manufacturers to government payors and/or providers; extend government discounts to additional government programs and/or providers; or reduce the level of reimbursement for health care services and other non-drug items. Any such measures could indirectly impact demand for pharmaceutical products because they can cause payors and providers to apply heightened scrutiny and/or austerity actions to their entire operations, including pharmacy budgets.

Also, the trend toward managed health care in the U.S., as well as the implementation of the Affordable Care Act, and the concurrent growth of organizations such as managed care organizations, accountable care organizations and integrated delivery networks, may result in increased pricing pressures for pharmaceutical products, including any products that may be offered by us in the future. Cost-cutting measures that health care providers are instituting, and the implementation of health care reform, could materially adversely affect our ability to sell any drug products that are successfully developed or acquired by us. In addition, third-party payors, in an effort to control costs, are increasingly making patients responsible for a higher percentage of the total cost of drugs in the outpatient setting. This can lower the demand for our products if the increased patient cost sharing obligations are more than they can afford. Individual states responses to ongoing financial pressures could also result in measures designed to limit reimbursement, restrict access, or impose broader or deeper discounts on branded pharmaceutical products utilized for Medicaid patients, including VARUBI, or any future drug product we may market. We are unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation or regulation would have on our business.

There may be significant delays in obtaining coverage and reimbursement for VARUBI and other newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacturing, selling and distribution costs. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary.

If we fail to comply with our reporting and payment obligations under U.S. governmental pricing and contracting programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by manufacturers, governmental or regulatory agencies, and the courts. We will be required to submit a number of different pricing calculations and failure to comply with our reporting and payment obligations under U.S. governmental pricing and contracting programs may have material adverse effects on the company. The Medicaid rebate amount for each manufacturer is computed each quarter based on the manufacturer s submission to CMS of its current AMP and, in the case of innovator products like VARUBI, best price figures, for the quarter. If we participate in the Medicaid drug rebate program and become aware that our reporting for a prior quarter was incorrect, or has changed, we will be obligated to resubmit the corrected data for a period not to exceed twelve quarters from the quarter in which the data originally were due. Such restatements and recalculations would increase our costs for complying with the laws and regulations governing the Medicaid drug rebate program. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. Price recalculations also may affect the ceiling price at which we would be required to offer our products to certain covered entities, such as safety-net providers, under the 340B drug discount program.

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If we participate in the Medicaid drug rebate program or our products are covered under Medicare Part B, we will be liable for errors associated with our submission of ASP pricing data. In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted false AMP, ASP, or best price information to the government, we may be liable for civil monetary penalties in the amount of $100,000 per item of false information. If we are found to have made a misrepresentation in the reporting of our ASP, the Medicare statute provides for civil monetary penalties of up to $10,000 for each misrepresentation for each day in which the misrepresentation was applied. Our failure to submit monthly/quarterly AMP, ASP, and best price data on a timely basis could result in a civil monetary penalty of $10,000 per day for each day the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we would participate in the Medicaid program. In the event that CMS terminates our rebate agreement, federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs that we are able to successfully commercialize. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid.

We are required to calculate and report certain pricing data to the U.S. federal government in connection with federal drug pricing programs. Compliance with these federal drug pricing programs is a pre-condition to: (i) the availability of federal funds to pay for our products under Medicaid and Medicare Part B; and (ii) procurement of our products by the VA, and by covered entities under the 340B/PHS program. The pricing data reported are used as the basis for establishing FSS and 340B/PHS program contract pricing and payment and rebate rates under the Medicare Part B and Medicaid programs, respectively. Pharmaceutical manufacturers have been prosecuted under federal and state false claims laws for submitting inaccurate and/or incomplete pricing information to the government, which has resulted in overcharges or underpayments under these programs. The rules governing the calculation of certain reported prices are highly complex. Although it is our intention to maintain and follow strict procedures to ensure the maximum possible integrity for our federal price calculations, the process for making the required calculations involves subjective judgments and the risk of errors always exists, which creates the potential for exposure under the false claims laws. If we become subject to investigations or other inquiries concerning our compliance with price reporting laws and regulations, and our methodologies for calculating federal prices are found to include flaws or to have been incorrectly applied, we could be required to pay or be subject to additional reimbursements, penalties, sanctions or fines, which could have a material adverse effect on our business, financial condition and results of operations.

To be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs as well as to be purchased by certain federal agencies and certain federal grantees, we also must participate in the VA FSS pricing program. To participate, we are required to enter into an FSS contract with the VA, under which we must make our innovator covered drugs available to the Big Four federal agencies the VA, the DoD, the Public Health Service, and the Coast Guard at pricing that is capped pursuant to a statutory federal ceiling price, or FCP, formula set forth in Section 603 of the Veterans Health Care Act of 1992, or VHCA. The FCP is based on a weighted average wholesaler price known as the Non-FAMP which manufacturers are required to report on a quarterly and annual basis to the VA. If we misstate Non-FAMPs or FCPs, we must restate these figures. Pursuant to the VHCA, knowing provision of false information in connection with a Non-FAMP filing can subject us to penalties of $100,000 for each item of false information. If we overcharge the government in connection with our FSS contract or Section 703 Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which

we market, sell and distribute VARUBI and any other products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

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- the federal healthcare Anti-Kickback Statute prohibits any person from, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchasing, leasing, ordering or arranging for or recommending of any good or service for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid. The term remuneration has been broadly interpreted to include anything of value. The Anti-Kickback Statute is subject to evolving interpretation and has been applied by government enforcement officials to a number of common business arrangements in the pharmaceutical industry. The government can establish a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of the statute or specific intent to violate it. There are a number of statutory exemptions and regulatory safe harbors protecting some common activities from prosecution; however, those exceptions and safe harbors are drawn narrowly. Failure to meet all of the requirements of a particular statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute, but the legality of the arrangement will be evaluated on a case-by-case basis based on the totality of the facts and circumstances. We seek to comply with the exemptions and safe harbors whenever possible, but our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, there are no safe harbors for many common practices, such as educational and research grants or patient assistance programs;

- the federal civil False Claims Act imposes civil penalties, and provides for whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment of government funds that are false or fraudulent, or knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim to avoid, decrease, or conceal an obligation to pay money to the federal government. In recent years, several pharmaceutical and other healthcare companies have faced enforcement actions under the federal False Claims Act for, among other things, allegedly submitting false or misleading pricing information to government health care programs and providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have faced enforcement actions for causing false claims to be submitted because of the company s marketing the product for unapproved, and thus non-reimbursable, uses. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties of $5,500 to $11,000 per false claim or statement. Because of the potential for large monetary exposure, healthcare and pharmaceutical companies often resolve allegations without admissions of liability for significant and material amounts to avoid the uncertainty of treble damages and per claim penalties that may awarded in litigation proceedings. They may be required, however, to enter into corporate integrity agreements with the government, which may impose substantial costs to companies to ensure compliance. Criminal prosecution is possible for making or presenting a false or fictitious or fraudulent claim to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, among other things, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HIPAA also prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using

any false writing or document knowing the same to contain any materially false fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services;

- the federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, imposes annual reporting requirements on certain manufacturers of drugs, devices, or biologics for payments and other transfers of value by them, directly or indirectly, to physicians (including physician family members) and teaching hospitals, as well as ownership and investment interests held by physicians. A manufacturer s failure to submit timely, accurately and completely the required information for all payments, transfers of value or ownership or investment interests may result in civil monetary penalties of up to an aggregate of $150,000 per year, and up to an aggregate of $1 million per year for knowing failures. Manufacturers must submit reports by the 90th day of each calendar year; and

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- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. Several states also require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products in those states and to report gifts and payments to individual health care providers in those states. Some of these states also prohibit certain marketing-related activities, including the provision of gifts, meals, or other items to certain health care providers. In addition, several states require pharmaceutical companies to implement compliance programs or marketing codes.

The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance or reporting requirements in multiple jurisdictions increase the possibility that a healthcare or pharmaceutical company may fail to comply fully with one or more of these requirements. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with applicable fraud and abuse or other healthcare laws and regulations or guidance. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Our revenues also depend on the availability outside the U.S. of adequate pricing and reimbursement from third-party payors for our current and future drug products, if any.

Outside the U.S., certain countries, including a number of EU Member States, set prices and reimbursement for pharmaceutical products, or medicinal products as they are commonly referred to in the EU, with limited participation from the marketing authorization holders. We cannot be sure that such prices and reimbursement will be acceptable to us or our collaborators. If the regulatory authorities in these foreign jurisdictions set prices or reimbursement that are not commercially attractive for us or our collaborators, our revenues from sales by us or our collaborators, and the potential profitability of our drug products, in those countries would be negatively affected. An increasing number of countries are taking initiatives to attempt to reduce large budget deficits by focusing cost-cutting efforts on pharmaceuticals for their state-run health care systems. These international price control efforts have impacted all regions of the world, but have been most drastic in the EU.

Additionally, some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country

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

In the United States and foreign jurisdictions, legislative and regulatory changes and proposed changes regarding the healthcare system could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

In recent years, Congress has considered reductions in Medicare reimbursement levels for drugs administered by physicians. CMS also has authority to revise reimbursement rates and to implement coverage restrictions for some drugs. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products, which in turn would affect the price we can receive for those products. While Medicare regulations apply only 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 federal legislation or regulation may result in a similar reduction in payments from private payors.

In March 2010, the President signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, together the Affordable Care Act. This law substantially changes the

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way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Affordable Care Act is 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 healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms. The Affordable Care Act expanded manufacturers rebate liability under the Medicaid program from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well; increased the minimum Medicaid rebate due for most innovator drugs in general from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP; and capped the total rebate amount for innovator drugs at 100% of AMP. The Affordable Care Act and subsequent legislation also changed the definition of AMP. The Affordable Care Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government. Each such manufacturer pays a prorated share of the branded prescription drug fee of $3.0 billion in 2015, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners. The Affordable Care Act also expanded the 340B program to include additional types of covered entities.

In 2012, CMS issued proposed regulations to implement the changes to the Medicaid program under the Affordable Care Act but has not yet issued final regulations. CMS is currently expected to release final regulations later in 2015. It appears likely that the Affordable Care Act will continue the pressure on pharmaceutical pricing, especially under the Medicare and Medicaid programs, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. Beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologics, were reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. The Bipartisan Budget Act of 2013 extended the 2% reduction to 2023, and the Protecting Access to Medicare Act of 2014 extended the 2% reduction, on average, to 2024. If Congress does not take action in the future to modify these sequestrations, Medicare Part D plans could seek to reduce their negotiated prices for drugs. Other legislative or regulatory cost containment provisions, as described below, could have a similar effect.

We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be.

If we breach the license agreements for our product candidates, we could lose the ability to continue the development and commercialization of our product candidates.

In December 2010, we entered into a license agreement with OPKO to obtain exclusive worldwide rights to research, develop, manufacture, market and sell rolapitant. The license agreement also extended to an additional, backup compound, SCH900978, to which we have the same rights and obligations as rolapitant, but which we are not currently advancing. In May 2012, we entered into a license agreement with Merck, under which we obtained exclusive, worldwide rights to certain patents and non-exclusive rights to certain Merck know-how, to research, develop, manufacture, market and sell niraparib and a backup compound, MK-2512, for all therapeutic and prophylactic uses in humans. We are

not currently advancing MK-2512. In March 2011, we entered into a license agreement with Amgen to obtain exclusive worldwide rights to research, develop, manufacture, market and sell an ALK/TRK inhibitor product. In March 2014, we entered into a collaboration and exclusive license agreement with AnaptysBio, under which we obtained exclusive, worldwide rights to certain patents and intellectual property of AnaptysBio to research, develop, manufacture, market and sell antibody product candidates targeting PD-1, TIM-3 and LAG-3 and non-exclusive rights to certain other patents and intellectual property of AnaptysBio necessary to utilize the intellectual property exclusively licensed to us.

Our agreements with our licensors require us to use diligent or commercially reasonable efforts to develop and commercialize such products in accordance with such agreements, and also generally require us to make timely milestone, royalty and other payments, provide certain information regarding our activities with respect to such products, maintain the confidentiality of information we receive and indemnify our licensors with respect to our development and commercialization activities under the terms of the agreements.

If we fail to meet these obligations, our licensors have the right to terminate our exclusive licenses and upon the effective date of such termination, have the right to re-obtain the licensed technology as well as aspects of any intellectual property controlled by us and developed during the period the agreements were in force that relate to the licensed technology. This means that our licensors could effectively take control of the development and commercialization of our product

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candidates after an uncured, material breach of our license agreements by us. This would also be the case if we voluntarily terminate the agreements. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve our rights under the patents licensed to us, we may not be able to do so in a timely manner, at an acceptable cost or at all. Any uncured, material breach under the licenses could result in our loss of exclusive rights and may lead to a complete termination of our product development and any commercialization efforts for the applicable product or product candidate.

We may not be successful in obtaining necessary rights to product candidates for our development pipeline through acquisitions and in-licenses.

We do not intend to develop product candidates from our own original research. Our business model is predicated, in part, on our ability to successfully identify and acquire or in-license product candidates for the treatment and support of cancer patients. However, we may be unable to acquire or in-license any product candidates from third parties for various reasons, including because we are focusing on a specific area of care, and we may be unable to identify product candidates that we believe are an appropriate strategic fit for our company.

The in-licensing and acquisition of product candidates is a competitive area, and a number of more established companies are also pursuing strategies to in-license or acquire product candidates that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to in-license or acquire the relevant product candidate on terms that would allow us to generate an appropriate return on our investment.

In addition, we expect that competition for the in-licensing or acquisition of product candidates that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing prices. If we are unable to successfully obtain rights to suitable product candidates, our business, financial condition and prospects for growth could suffer.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk with the commercialization of VARUBI or any of our current or future product candidates. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trial sites or entire trial programs;

- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any products that we may develop.

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We currently hold $10 million in product liability insurance coverage in the aggregate, which may not be adequate to cover all liabilities that we may incur. We expect to increase our insurance coverage when we begin to commercialize our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could consume significant amounts of our cash and adversely affect our business.

We intend to market our products outside of the United States, and we will be subject to the risks of doing business outside of the United States.

Because we intend to market VARUBI and our product candidates, if approved, outside of the United States, our business is subject to risks associated with doing business outside of the United States. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including:

- efforts to develop an international sales, marketing and distribution organization may increase our expenses, divert our management s attention from the acquisition or development of product candidates or cause us to forgo profitable licensing opportunities in these geographies;

- changes in a specific country s or region s political and cultural climate or economic condition;

- unexpected changes in foreign laws and regulatory requirements;

- difficulty of effective enforcement of contractual provisions in local jurisdictions;

- inadequate intellectual property protection in foreign countries;

- trade-protection measures, import or export licensing requirements such as Export Administration Regulations promulgated by the U.S. Department of Commerce and fines, penalties or suspension or revocation of export privileges;

- the effects of applicable foreign tax structures and potentially adverse tax consequences; and

- significant adverse changes in foreign currency exchange rates.

In addition to FDA and related regulatory requirements in the U.S. and abroad, we are subject to extensive additional federal, state and foreign anti-bribery regulation, which include the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act, and similar laws in other countries outside of the U.S. We have developed and implemented a corporate compliance program based on what we believe are current best practices in the pharmaceutical industry, but we cannot guarantee that we, our employees, our consultants or our third-party contractors are or will be in compliance with all federal, state and foreign regulations regarding bribery and corruption. Moreover, our partners and third party contractors located outside the U.S. may have inadequate compliance programs or may fail to respect the laws and guidance of the territories in which they operate. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could also have an adverse effect on our business, financial condition and results of operations

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended 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, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of

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information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, 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 be in compliance with such 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 and results of operations, including the imposition of significant fines or other sanctions.

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

As of September 30, 2015, we had 275 full-time employees compared to 108 at the end of December 2014. As our development and commercialization plans and strategies develop, or as a result of any in-licenses or acquisitions of new product candidates, we will continue to need additional managerial, operational, sales, marketing, financial and other resources. Our management, personnel and systems currently in place may not be adequate to support our recent or future growth. Such growth will impose significant added responsibilities on members of management, including:

- managing our clinical trials effectively;
- expanding and maintaining a sales and marketing organization and developing our distribution capabilities;
- identifying, recruiting, maintaining, motivating and integrating additional employees;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- improving our managerial, development, operational and finance systems; and
- expanding our facilities.

As our operations expand, we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to commercialize VARUBI and our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

If we are unable to attract and retain highly qualified employees, we may not be able to grow effectively.

Our future growth and success depend on our ability to recruit, retain, manage and motivate our employees. The loss of the services of any member of our senior management team or the inability to hire or retain experienced management personnel could adversely affect our ability to execute our business plan and harm our operating results.

Because of the specialized scientific and managerial nature of our business, we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel. Our ability to compete and grow depends in large part upon the continued service of our senior management team. In particular, the loss of one or more of our senior executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the biopharmaceutical field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

Our future success depends on our ability to retain our co-founding executive officers.

We are highly dependent on Leon O. Moulder, Jr., our Chief Executive Officer, and Mary Lynne Hedley, Ph.D., our President and Chief Operating Officer. Although we have offer letter agreements with Mr. Moulder and Dr. Hedley, these agreements are at-will and do not prevent them from terminating their employment with us at any time. We do not maintain key person insurance for any of our executives or other employees. The loss of the services of either of these persons could impede the achievement of our research, development and commercialization objectives.

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In addition to in-licensing or acquiring product candidates, we may engage in future acquisitions that could disrupt our business, cause dilution to our stockholders and harm our financial condition and operating results.

While we currently have no specific plans to acquire any other businesses, we have, from time to time, evaluated acquisition opportunities and may, in the future, make acquisitions of, or investments in, companies that we believe have products or capabilities that are a strategic or commercial fit with our current product candidates and business or otherwise offer opportunities for our company. In connection with these acquisitions or investments, we may:

- issue stock that would dilute our stockholders percentage of ownership;
- incur debt and assume liabilities; and
- incur amortization expenses related to intangible assets or incur large and immediate write-offs.

We also may be unable to find suitable acquisition candidates and we may not be able to complete acquisitions on favorable terms, if at all. If we do complete an acquisition, we cannot assure you that it will ultimately strengthen our competitive position or that it will not be viewed negatively by customers, financial markets or investors. Further, future acquisitions could also pose numerous additional risks to our operations, including:

- problems integrating the purchased business, products or technologies;
- increases to our expenses;
- the failure to have discovered undisclosed liabilities of the acquired asset or company;
- diversion of management s attention from their day-to-day responsibilities;
- harm to our operating results or financial condition;

- entrance into markets in which we have limited or no prior experience; and

- potential loss of key employees, particularly those of the acquired entity.

We may not be able to complete one or more acquisitions or effectively integrate the operations, products or personnel gained through any such acquisition without a material adverse effect on our business, financial condition and results of operations.

Our therapeutic product candidates, including niraparib, may be approved only in combination with companion diagnostics to support certain uses. We may have difficulty receiving approval for our therapeutic product candidates for those uses from FDA and comparable foreign regulatory agencies if applicable companion diagnostics are not commercially available.

For certain of our cancer therapeutic product candidates, including niraparib, we believe we have acquired product candidates for which diagnostic tests or specific clinical criteria will allow us to identify cancer patients who will be more likely to respond. We plan to rely on diagnostic tests to help us more accurately identify patients with those criteria both during our clinical trials and in connection with the commercialization of our product candidates. Diagnostic tests, including companion diagnostics, are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and require separate regulatory approval prior to commercialization. We do not develop diagnostic tests internally. We are therefore dependent on the sustained cooperation and effort of third-party collaborators in developing and obtaining approval for these tests. For example, our niraparib product candidate will use a test owned and administered by a third party to identify breast cancer patients with a BRCA gene mutation during clinical testing. We are also evaluating niraparib in patients with certain homologous recombinant deficiency, or HRD, scores. The test to determine this HRD score is owned and administered by the same third party that administers the BRCA gene mutation test. Therefore, it is possible that niraparib will be approved for these indications only in combination with one of these diagnostic tests. This third party may encounter difficulties in developing and obtaining approval for its test, or may fail to support the clinical development of niraparib for breast cancer as we expect, or may fail to keep the test on the market even if it is approved. Any such delay or

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failure could delay or prevent approval of niraparib for breast cancer, or products we may later acquire with similar characteristics.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems, and those of our collaborators, our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. 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 liabilities and the further development of our product candidates could be delayed.

Our failure to comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

We are subject to U.S. data protection laws and regulations (i.e., laws and regulations that address privacy and data security) at both the federal and state levels. The legislative and regulatory landscape for data protection continues to evolve, and in recent years there has been an increasing focus on privacy and data security issues. Numerous federal and state laws, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, and disclosure of health-related and other personal information. In addition, we may obtain health information from third parties (e.g., healthcare providers who prescribe our products) that are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA other than potentially with respect to providing certain employee benefits we could be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. Finally, a data breach affecting sensitive personal information, including health information, could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

EU Member States, Switzerland and other countries have also adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EU Data Protection Directive, as implemented into national laws by the EU Member States, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. Data protection authorities from the different EU Member States may interpret the EU Data Protection Directive and national laws differently, which adds to the complexity of processing personal data in the EU, and guidance on implementation and compliance practices are often updated or otherwise revised. For example, due to a recent judgment by the European Court of Justice, a practice by many US entities of relying on safe harbor certification as a demonstration that they provide a level of data protection equivalent to that required by the EU Data Protection Directive was determined to be invalid. Our failure to comply with these laws, or changes in the way in which these laws are implemented, could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results. If the currently proposed revised draft EU Data Protection Regulation is adopted in its current form it may also increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new EU data protection rules.

Risks Related to Our Dependence on Third Parties

We have no experience manufacturing VARUBI on a commercial scale or our product candidates on a large clinical scale and have no manufacturing facility. We are dependent on a limited number of third-party manufacturers for the manufacture of VARUBI and our product candidates as well as on third parties for our supply chain, and if we experience problems with any of these third parties, the manufacturing of VARUBI or our product candidates could be delayed, which could harm our results of operations.

We do not own or operate facilities for the manufacture of VARUBI or our product candidates. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. We currently work with one contract manufacturing organization, or CMO, Hovione, for the production of rolapitant drug substance used for VARUBI and IV rolapitant, and one other CMO, Patheon, for commercial production of VARUBI. We also currently work with a CMO for the production of IV rolapitant drug product for clinical use.

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As our drug development pipeline matures and we begin to commercialize VARUBI, we will have a greater need for clinical study and commercial manufacturing capacity. We have no experience manufacturing pharmaceutical products on a commercial scale and some of our suppliers will need to increase their scale of production to meet our projected needs for commercial manufacturing. Specifically, to meet our projected needs for commercial manufacturing of VARUBI, Patheon will need to increase scale of production. The development of commercial-scale manufacturing capabilities may require our third-party manufacturers to invest substantial additional funds and hire and retain the technical personnel who have the necessary manufacturing experience. Our third-party manufacturers may not successfully complete any required increase to existing manufacturing capacity in a timely manner, or at all. Because of the complex nature of our compounds, our manufacturers may not be able to manufacture our compounds at an acceptable cost or in sufficient quantities or in a timely manner necessary to make commercially successful products, or may require us to pay significant costs, including for capital improvements to their facilities. Therefore, successful commercialization of VARUBI or any of our product candidates may require us to establish large-scale commercial manufacturing capabilities. If our contract manufacturers or other third parties fail to deliver VARUBI for commercial sale on a timely basis, with sufficient quality, and at commercially reasonable prices, and we fail to find replacement manufacturers or to develop our own manufacturing capabilities, we may be required to delay or suspend commercialization of VARUBI.

Existing inventory for niraparib drug substance and drug product from Merck provided the initial clinical trial material needed for our niraparib clinical program. We have agreements in place with CMOs for the further production of niraparib to meet our clinical supply needs. For preclinical development of our antibody product candidates targeting PD-1 (TSR-042), TIM-3 (TSR-022) and LAG-3, we currently work with one CMO for the production of biologics. For each of our product candidates, we may elect to pursue arrangements with other CMOs for manufacturing clinical supplies for later-stage trials and for commercialization. We have not yet qualified alternate suppliers in the event the current CMOs we utilize are unable to scale production, or if we otherwise experience any problems with them. If we are unable to arrange for alternative third-party manufacturing sources, or to do so on commercially reasonable terms or in a timely manner, we may not be able to complete development of our product candidates, or market or distribute them.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates or products ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to synthesize and manufacture our product candidates or any products we may eventually commercialize in accordance with our specifications) and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates and approved products, such as VARUBI, be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, such failure could be the basis for the FDA to issue a warning or untitled letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention of product, refusal to permit the import or export of products, injunction, or imposition of civil and criminal penalties.

Any significant disruption in our supplier relationships could harm our business. We source key materials from third parties, either directly through agreements with suppliers or indirectly through our manufacturers who have agreements with suppliers. There are a small number of suppliers for certain capital equipment and key materials that are used to manufacture our drugs. Such suppliers may not sell these key materials to our manufacturers at the times we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of these key materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production

of these key materials. Any significant delay in the supply of a product candidate or its key materials for an ongoing clinical study could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these key materials for VARUBI or for our product candidates after regulatory approval, the commercial launch of VARUBI or our product candidates could be delayed or there could be a shortage in supply, which would impair our ability to generate revenues from the sale of VARUBI or our product candidates.

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

We rely upon AnaptysBio to discover and conduct preclinical research and development on antibody product candidates targeting PD-1, TIM-3 and LAG-3 in accordance with the research programs that we jointly establish for those candidates. Although we participate in the planning of these programs, we do not directly control the amount or timing of resources devoted by AnaptysBio to activities related to these product candidates. AnaptysBio may not commit sufficient resources to our research and development programs for these candidates. If AnaptysBio fails to commit sufficient resources to any of our antibody product candidates, our preclinical programs related to the candidate could be delayed, terminated, or unsuccessful. Furthermore, if we fail to make required payments to AnaptysBio, including up-front, milestone, reimbursement or royalty payments, or to observe other obligations in our agreement with AnaptysBio, AnaptysBio may not be required to perform its obligations under the agreement and may have the right to terminate the agreement.

We also have relied upon and plan to continue to 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 and clinical trials, and we 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 and legal, regulatory and scientific standards, and our reliance on collaborators and CROs does not relieve us of our regulatory responsibilities. We also rely on these third parties to assist in conducting our preclinical studies in accordance with good laboratory practices and Animal Welfare Act requirements. We and our collaborators and CROs are required to comply with good clinical practices, or GCP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the EEA, and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our collaborators or CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP requirements. Failure to comply with these regulations may require us to repeat preclinical and clinical trials, which would delay the regulatory approval process.

AnaptysBio and our CROs are not our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical programs. If our collaborators and CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our preclinical and clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Because we have relied and rely on third parties for these functions, our internal capacity to perform these functions is limited. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results in a timely manner, or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a limited number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. Although we carefully manage

our relationships with AnaptysBio and our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

If we lose our relationships with CROs, our drug development efforts could be delayed.

We rely on third-party vendors and CROs for preclinical studies and clinical trials related to our drug development efforts. Switching or adding additional CROs involves additional cost and requires management time and focus. Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. Identifying, qualifying and managing the performance of third-party service providers can be difficult, time consuming and cause delays in our development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the

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original provider. If any of our relationships with our third-party CROs terminates, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms.

To supplement our in-house sales and marketing efforts, we may sell VARUBI through a network of specialty distributors. If we are unable to train, maintain and expand our network of specialty distributors, we may not be able to successfully commercialize VARUBI or any other product candidates for which we obtain marketing approval.

To supplement our in-house sales and marketing efforts, we may sell VARUBI through a network of specialty distributors across the United States. As a result, our revenues from sales of VARUBI may be, at least in part, dependent upon the sales and marketing efforts of these specialty distributors. As VARUBI will be a newly marketed product, we would need to expend significant time and resources to train the specialty distributors.

Our relationships with distributors will be non-exclusive and our distributors will simultaneously sell products on behalf of third parties, including products that may compete directly or indirectly with VARUBI or our product candidates. If our specialty distributors fail to devote sufficient time to the sale of VARUBI, or if they otherwise fail to adequately promote, market and sell VARUBI, our ability to generate revenues from the sale of VARUBI will be impaired. We may face significant challenges and risks in managing our geographically dispersed distribution network and retaining the team that makes up that network. If a substantial number of our specialty distributors, or any significant specialty distributor, were to cease to do business with us within a short period of time, our sales could be adversely affected. In such a situation, we may need to seek alternative specialty distributors. Because of competition for their services, we may be unable to recruit additional qualified specialty distributors to work with us. We may also not be able to enter into agreements with them on favorable or commercially reasonable terms, if at all. Failure to retain qualified specialty distributors would prevent us from successfully commercializing VARUBI or any other product candidates for which we obtain marketing approval.

Risks Related to Our Intellectual Property

If we are unable to protect our intellectual property rights, our competitive position could be harmed and we could be required to incur significant expenses to enforce our rights.

We depend on our ability to protect our proprietary technology. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. Where we have the right to do so under our license agreements, we seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and products that are important to our business. The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patents, including those patent rights licensed to us by third parties, are highly uncertain.

The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside the United States. The rights already granted under any of our currently

issued patents and those that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and products may be adversely affected. Further, under our agreement with Merck for niraparib, Merck is responsible, subject to certain exceptions, for prosecuting the licensed patents, and we are reliant on them to do so in a diligent fashion, subject to our right to review and approve their prosecution activities. If Merck fails to conduct such activities diligently or does not take approved actions, among other reasons, we may not obtain or maintain broad proprietary protection for niraparib. Similarly, under our agreement with AnaptysBio, during preclinical development of our antibody product candidate, AnaptysBio has primary responsibility for prosecuting certain licensed patents at our expense, subject in certain circumstances to our right to prior approval of expenses. If AnaptysBio fails to conduct such activities diligently or does not take approved actions, among other reasons, we may not obtain or maintain broad proprietary protection for antibody product candidates targeting PD-1, TIM-3 and LAG-3. Following the clearance of an IND for an antibody product candidate targeting PD-1, TIM-3 or LAG-3 or any bi-specific antibody product candidate targeting some combination thereof, we become responsible for prosecuting certain licensed patents related to that candidate.

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With respect to patent rights, we do not know whether any of the pending patent applications for any of our licensed compounds will result in the issuance of patents that protect our technology or products, or which will effectively prevent others from commercializing competitive technologies and products. Although we have a number of issued patents under our licensing agreements covering our technology, our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Further, the examination process may require us or, in the case of niraparib and our antibody product candidates during preclinical development, our licensor, to narrow the claims, which may limit the scope of patent protection that may be obtained. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we own or have licensed from third parties may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents, or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection for our technology and products. Protecting against the unauthorized use of our patented technology, trademarks and other intellectual property rights is expensive, difficult and, may in some cases not be possible. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult.

The patent prosecution process is expensive and time-consuming, and we, or in the case of niraparib and our antibody product candidates during preclinical development, our licensor, 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 or our licensors will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them. Further, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms where they are available in any countries where we are prosecuting patents. This includes in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984, which permits a patent term extension of up to five years beyond the expiration of the patent. However the applicable authorities, including the FDA in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and these foreign laws may also be subject to change. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions typically are not published until 18 months after filing, or in some cases not at all. Therefore we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

Previously, in the United States, assuming the other requirements for patentability are met, the first to make the claimed invention was entitled to the patent. Outside the United States, the first to file a patent application is entitled to the patent. In March 2013, the United States transitioned to a first to file system in which the first inventor to file a patent application will be entitled to the patent. Under either the previous or current system, third parties will be allowed to submit prior art prior to the issuance of a patent by the United States Patent and Trademark Office, and may become involved in opposition, derivation, reexamination, inter-partes review or interference proceedings challenging our patent rights or

the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, which could adversely affect our competitive position with respect to third parties.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents 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. This can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to 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

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our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents 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.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates, and to use our proprietary technologies without infringing the proprietary rights of third parties. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference proceedings before the U.S. Patent and Trademark Office. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party s intellectual property rights, we could be required to obtain a license from such third party to continue developing and commercializing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

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 members 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.

Intellectual property disputes could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

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 we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to

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protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, 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 is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Risks Related to Ownership of Our Common Stock

The price of our stock has been, and may continue to be, volatile, and you could lose all or part of your investment

The trading price of our common stock is highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. Since our initial public offering, which occurred in June 2012, the price of our common stock on the NASDAQ Global Select Market has ranged from $11.05 per share to $66.95 per share. In addition to the factors discussed in this Risk Factors section and elsewhere in this Quarterly Report on Form 10-Q, these factors include:

- the success of competitive products or technologies;
- regulatory actions with respect to our products or our competitors products;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- results of clinical trials of our product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;

- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to in-license or acquire additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- changes in the structure of healthcare payment systems;

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- market conditions in the pharmaceutical and biotechnology sectors; and

- general economic, industry and market conditions.

In addition, the stock market in general, and the NASDAQ Global Select Market and biotechnology companies in particular, 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. The realization of any of the above risks or any of a broad range of other risks, including those described in these Risk Factors, could have a dramatic and material adverse impact on the market price of our common stock.

Forecasting sales of VARUBI may be difficult and if our revenue projections are inaccurate, our business may be harmed and our stock price may decline.

Our sales of VARUBI will be difficult to forecast. Factors that increase the difficulty of forecasting sales of VARUBI include the following:

- the cost and availability of reimbursement for the product;

- treatment guidelines issued by government and non-government agencies;

- timing of market entry relative to competitive products;

- availability of alternative therapies;

- price of VARUBI relative to alternative therapies, including generic versions of products that compete with our product;

- rates of returns and rebates;

- uncertainty about the pace of acceptance of VARUBI;

- the ability of our third-party manufacturers to manufacture and deliver VARUBI in commercially sufficient quantities;

- the ability of our third-party distributors in the United States to process orders in a timely manner and satisfy their obligations to us;

- the extent and success of our marketing efforts; and

- potential side effects or unfavorable publicity concerning our product or similar products.

The extent to which any of these or other factors individually or in the aggregate may impact future sales of VARUBI is uncertain and difficult to predict. Our management must make forecasting decisions regarding future revenue in the course of business planning despite this uncertainty, and actual results of operations may deviate materially from projected results. If our revenues from VARUBI sales are lower than we anticipate, we will incur costs in the short term that will result in losses that are unavoidable. A shortfall in revenue would have a direct impact on our expected cash flow, our stock price and on our business generally. Furthermore, to the extent that any projections we disclosed publicly regarding future sales of VARUBI or our financial performance are incorrect, including as a result of the challenges in forecasting sales of VARUBI, our stock price could be adversely affected and we could be subject to an increased risk of litigation. In addition, fluctuations in our quarterly results can adversely and significantly affect the market price of our common stock.

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

The market price of our common stock may be volatile, and in the past, some companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this

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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 principal stockholders and management own a significant percentage of our stock and are able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors and their or our respective affiliates beneficially owned approximately 34.6% of our voting stock as of September 30, 2015. This group of stockholders has the potential ability to control us through their ownership position. These stockholders may be able to determine the outcomes of certain matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

If we fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. Commencing with our next Annual Report on Form 10-K, we are required, under Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment must include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a control deficiency, or combination of control deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 of the Sarbanes-Oxley Act also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting.

Our compliance with Section 404 requires that we incur substantial accounting expense and expend significant management efforts. We have limited experience complying with Section 404, and if in the future we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. Furthermore, we cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the NASDAQ, the U.S. Securities and Exchange Commission, or the SEC, or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

We are incurring 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.

We incur significant legal, accounting and other expenses as a public company, and these expenses will increase even more as our compliance obligations increase, including as a result of the requirement to obtain an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC and the NASDAQ Stock Market. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have substantially increased, and will continue to increase, our legal and financial compliance costs and have made and will make some activities more time-consuming and costly. These increased costs have increased, and will continue to increase, our consolidated net loss. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. We cannot predict or estimate

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the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

As of September 30, 2015, we have 40,072,877 shares of common stock outstanding. Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Of these outstanding shares, 13,865,010 are currently held by directors, executive officers and other parties that may be deemed to be their or our affiliates and are available for sale subject to volume limitations, other restrictions under securities laws and, in some cases, vesting schedules. We also have registered shares of common stock that we may issue under our equity compensation plans. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

Furthermore, certain persons who were stockholders prior to our initial public offering are entitled to registration rights under the Securities Act with respect to shares they hold, which includes 12,727,272 shares held by our directors, executive officers and other parties that may be deemed to be their or our affiliates. Registration of these shares under the Securities Act would result in such shares becoming freely tradable without restrictions under the Securities Act, except with respect to shares purchased by affiliates. Any sales of shares by these stockholders could have a material adverse effect on the trading price of our common stock.

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 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, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the 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 or

insufficient disclosure due to error or fraud may occur and may not be detected.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that we will need significant additional capital in the future to continue our planned operations. To raise capital, we may sell substantial amounts of common stock or securities convertible into or exchangeable for common stock. These future issuances of common stock or common stock-related securities, together with the exercise of outstanding stock options and any additional shares issued in connection with acquisitions, if any, may result in material dilution to our investors. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock.

Pursuant to our equity incentive plans, our compensation committee is authorized to grant equity-based incentive awards to our directors, executive officers and other employees and service providers, including officers, employees and

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service providers of our subsidiaries and affiliates. The initial number of shares of our common stock available for future grant under our 2012 Omnibus Incentive Plan, or the 2012 Incentive Plan, which became effective in April 2012, was 1,428,571 plus the number of shares of our common stock reserved for issuance under our 2010 Stock Incentive Plan, or the 2010 Incentive Plan, as of the effective date of the 2012 Incentive Plan (which is an additional 6,857 shares). On May 14, 2015, our stockholders approved an additional 2,000,000 shares for issuance under our 2012 Incentive Plan. The number of shares of our common stock reserved for issuance under our 2012 Incentive Plan will be increased (i) from time to time by the number of shares of our common stock forfeited upon the expiration, cancellation, forfeiture, cash settlement or other termination of awards under our 2010 Incentive Plan following the effective date of the 2012 Incentive Plan, and (ii) on January 1 of each year, by a number of shares of common stock equal to the lesser of (x) 4% of the shares of common stock outstanding at such time, or (y) the number of shares determined by our board of directors. As of September 30, 2015, there were 1,527,313 shares of our common stock reserved for issuance under our 2012 Incentive Plan. On May 14, 2015, our stockholders approved our 2015 Non-Employee Director Stock Incentive Plan, or the 2015 Director Plan. The number of shares of our common stock available for future grant under our 2015 Director Plan is 500,000. Future stock option grants and issuances of common stock under our equity plans may have an adverse effect on the market price of our common stock.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These provisions include:

- authorizing the issuance of blank check preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;

- prohibiting cumulative voting in the election of directors, which would otherwise allow for less than a majority of stockholders to elect director candidates;

- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;

- eliminating the ability of stockholders to call a special meeting of stockholders; and

- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under Delaware law, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Any provision of our amended and restated certificate of incorporation or amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price 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 one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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Risks Related to Our Indebtedness

Servicing our debt will require significant amounts of cash, and we may not have sufficient cash flow from our business to pay our debt.

Our ability to make scheduled payments of the principal of, to pay interest on, to pay any cash due upon conversion of, or to refinance, our indebtedness, including our 3.00% convertible senior notes due October 1, 2021, or the Convertible Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

Despite our current debt levels, we may still incur additional debt; if we incur substantial additional debt, these higher levels of debt may affect our ability to pay the principal of and interest on the Convertible Notes.

We and our subsidiaries may be able to incur substantial additional debt in the future, some of which may be secured debt. The indenture governing the Convertible Notes does not restrict our ability to incur additional indebtedness or require us to maintain financial ratios or specified levels of net worth or liquidity. If we incur substantial additional indebtedness in the future, these higher levels of indebtedness may affect our ability to pay the principal of and interest on the Convertible Notes, or any fundamental change in purchase price or any cash due upon conversion, and our creditworthiness generally.

The conditional conversion feature of the Convertible Notes, if triggered, may adversely affect our financial condition and operating results.

In the event the conditional conversion feature of the Convertible Notes is triggered, holders of notes will be entitled to convert their notes at any time during specified periods at their option. If one or more holders elect to convert their notes, unless we satisfy our conversion obligation by delivering solely shares of our common stock (other than cash in lieu of any fractional share), we would be required to settle all or a portion of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Convertible Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

The accounting method for convertible debt securities that may be settled in cash, such as the Convertible Notes, could have a material effect on our reported financial results.

Pursuant to Accounting Standards Codification Subtopic 470-20, *Debt with Conversion and Other Options*, which we refer to as ASC 470-20, an entity must separately account for the liability and equity components of the convertible debt instruments (such as the Convertible Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer s economic interest cost. The effect of ASC

470-20 on the accounting for the Convertible Notes is that the equity component is required to be included in the additional paid-in capital caption of stockholders equity on our consolidated balance sheet and the value of the equity component would be treated as original issue discount for purposes of accounting for the debt component of the Convertible Notes. As a result, we will be required to record a greater amount of non-cash interest expense in current periods presented as a result of the amortization of the discounted carrying value of the Convertible Notes to their face amount over the term of the Convertible Notes. We will report greater losses in our financial statements because ASC 470-20 will require interest to include both the current period s amortization of the debt discount and the instrument s coupon interest, which could adversely affect our reported or future financial results, the market price of our common stock and the trading price of the Convertible Notes.

In addition, under certain circumstances, convertible debt instruments (such as the Convertible Notes) that may be settled entirely or partly in cash are currently accounted for utilizing the treasury stock method, the effect of which is that the shares issuable upon conversion of the Convertible Notes are not included in the calculation of diluted earnings per share except to the extent that the conversion value of the Convertible Notes exceeds their principal amount. Under the treasury stock method, for diluted earnings per share purposes, the transaction is accounted for as if the number of shares of common stock that would be necessary to settle such excess, if we elected to settle such excess in shares, are issued. We cannot be sure that the accounting standards in the future will continue to permit the use of the treasury stock method. If we are unable

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to use the treasury stock method in accounting for the shares issuable upon conversion of the Convertible Notes, then our diluted earnings per share would be adversely affected.

To the extent we issue shares of our common stock to satisfy all or a portion of our conversion obligation, conversions of the Convertible Notes may dilute the ownership interest of our existing stockholders.

Upon conversion of the Convertible Notes, we have the option to pay or deliver, as the case may be, either cash, shares of our common stock, or a combination of cash and shares of our common stock. To the extent we issue shares of our common stock to satisfy all or a portion of our conversion obligation, the conversion of some or all of the Convertible Notes will dilute the ownership interests of our existing stockholders. Any sales in the public market of our common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the Convertible Notes may encourage short selling by market participants because the conversion of the Convertible Notes could depress the price of our common stock.

The fundamental change purchase feature of the Convertible Notes may delay or prevent an otherwise beneficial attempt to take over our Company.

The terms of the Convertible Notes require us to offer to purchase the Convertible Notes for cash in the event of a fundamental change. A non-stock takeover of our Company may trigger the requirement that we purchase the Convertible Notes. This feature may have the effect of delaying or preventing a takeover of our Company that would otherwise be beneficial to investors.

Item 6. Exhibits.

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

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

TESARO, INC.

By:	/s/ Leon O. Moulder, Jr. Leon O. Moulder, Jr. *Chief Executive Officer* *(principal executive officer)*
Date:	October 30, 2015
By:	/s/ Timothy R. Pearson Timothy R. Pearson *Executive Vice President and Chief Financial Officer* *(principal financial officer)*
Date:	October 30, 2015

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EXHIBIT INDEX

Exhibit Number	Exhibit Description
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
EX-101.INS	XBRL Instance Document
EX-101.SCH	XBRL Taxonomy Extension Schema Document
EX-101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
EX-101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
EX-101.LAB	XBRL Taxonomy Extension Label Linkbase Document
EX-101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document