TESARO, Inc.
Form 10-K
February 29, 2016
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended December 31, 2015

or

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

For the transition period from to

Commission file number 001-35587

TESARO, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

(339) 970-0900

(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act: Common Stock, par value $0.0001 per share, NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

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

Indicate by check mark whether the registrant has submitted electronically 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 No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K

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

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

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

The aggregate market value of the registrant's voting stock held by non-affiliates as of June 30, 2015 was approximately $1,521,158,000 based on the closing price of $58.79 of the Common Stock of the registrant as reported on the NASDAQ Global Select Market on such date. As of February 24, 2016, there were 40,283,470 shares of the registrant's Common Stock, par value $0.0001 per share, outstanding.

Table of Contents

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's Definitive Proxy Statement for its 2016 Annual Meeting of Stockholders, which is expected to be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the registrant's fiscal year ended December 31, 2015, are incorporated by reference into Part III of this Annual Report on Form 10-K.

Table of Contents

TESARO, INC.

ANNUAL REPORT ON FORM 10-K

For the Fiscal Year Ended December 31, 2015

TABLE OF CONTENTS

3

Table of Contents

PART I

Except for the historical information contained in this Annual Report on Form 10-K, the matters discussed herein 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 Annual Report on Form 10-K, 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 progress of the commercial launch of VARUBI® (the oral formulation) and the potential timing of the launch of 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 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.

Forward-looking statements are not guarantees of future performance. Actual future results, performance, achievements or the timing of certain events may differ significantly from those expressed or implied by the forward-looking statements. Risks and uncertainties involved in the forward-looking statements include, among others, the uncertainties inherent in the development or launch of any new pharmaceutical product, the execution and completion of clinical trials, the timing and availability of data from 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 or the success of any product. Forward-looking statements contained in this Annual Report on Form 10-K should be considered in light of these factors and the factors discussed elsewhere in this Annual Report on Form 10-K, including under the heading “Risk Factors”. You should read carefully the factors described in the “Risk Factors” section to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. You are also advised to consult any further disclosures we make on related subjects in our Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and our website.

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.

TESARO, the TESARO logo and VARUBI are trademarks of TESARO, Inc. in the United States and in other selected countries. All other brand names or trademarks appearing in this report are the property of their respective holders. Unless the context requires otherwise, references in this report to "TESARO", the "Company," "we," "us," and "our" refer to TESARO, Inc.

ITEM 1. BUSINESS

Overview

We are an oncology-focused biopharmaceutical company dedicated to improving the lives of cancer patients. We were founded in March 2010 and have in-licensed and are developing oncology-related product candidates, including rolapitant and niraparib, as well as product candidates under our immuno-oncology platform.

On September 1, 2015, our first commercial product, VARUBI® (rolapitant), was approved by the United States Food and Drug Administration, or FDA, for use 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

Table of Contents

to, highly emetogenic chemotherapy. We commenced shipments of VARUBI, which is the oral formulation of rolapitant, to distributors during the fourth quarter of 2015.

A summary description of our current products and product candidates is as follows:

- 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. We expect to submit a new drug application, or NDA, to the FDA for IV rolapitant 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. We have several ongoing clinical trials evaluating niraparib for the treatment of ovarian or breast cancers, and we expect to initiate dosing in further clinical trials of niraparib during 2016. We are also collaborating with various other organizations to evaluate niraparib in combination with other therapeutics for the treatment of various cancers. Based on research related to PARP inhibitors generally, we believe that niraparib may also be active in the treatment of several other tumor types. We expect top-line data from our NOVA and QUADRA trials of niraparib to become available during the second quarter of 2016, and we are currently planning to submit an NDA and an MAA for niraparib in the second half of 2016.

- Immuno-Oncology Platform: 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 submitted an investigational new drug application, or IND, for our first immuno-oncology antibody, TSR-042, which targets PD-1, in December 2015, and we plan to initiate a Phase 1 clinical trial of TSR-042 in the first quarter of 2016. As part of our collaboration with AnaptysBio, we received exclusive rights to monospecific antibody product candidates targeting PD-1, TIM-3, and LAG-3 and bi-specific antibody product candidates targeting PD-1/TIM-3, PD-1/LAG-3 and an additional bi-specific combination. In addition, we plan to evaluate our immuno-oncology anti-tumor agents, such as TSR-042, in combination preclinical pharmacology studies with niraparib and other anti-tumor agents.

In addition to potential candidates arising from our agreement with AnaptysBio, we intend to continue to leverage the experience and competencies of our senior management team to identify, acquire, develop and commercialize cancer therapeutics, including those that are potentially safer and more effective than existing treatments.

Upon successful development and regulatory approval of any of our product candidates, we intend to pursue commercialization of them in key product markets, including North America, Europe and China. At this time, we intend to focus on commercializing our products directly in North America, and directly or in partnership with established companies in Europe and China. In addition to developing commercial capabilities within these

geographic areas, we intend to establish a network of licensees and distributors for our products in other geographic areas.

Since our founding, we have relied on private and public financing sources to fund our operations. As of December 31, 2015, our principal source of liquidity was cash and cash equivalents, which totaled $230.1 million. From inception through December 31, 2015, including through our 2012 initial public offering, we have raised a total of $758.3 million in net cash proceeds from private placements of convertible preferred stock and public offerings of common stock and convertible notes. This total includes the sale in March 2015 of 3,755,000 shares of common stock in an underwritten public offering pursuant to a registration statement on Form S-3, at a price of $51.00 per share, resulting in net proceeds of approximately $179.8 million, which is net of underwriting discounts and commissions and estimated offering expenses. On February 24, 2016, we entered into a Stock Purchase Agreement with certain accredited investors, including funds affiliated with three of our directors, pursuant to which we agreed to issue an aggregate of 4,404,658 shares of our common stock, at a price per share of $35.19 for an aggregate purchase price of approximately $155.0 million. This private placement transaction is subject to the satisfaction of certain closing conditions that we expect will occur prior to April 30, 2016, but no earlier than March 18, 2016.

Our common stock trades on the NASDAQ Global Select Market, or NASDAQ, under the trading symbol “TSRO.”

Table of Contents

Our Strategy

Our strategy is to leverage the experience and competencies of our management team to identify, acquire and develop promising drug candidates and to commercialize cancer therapeutics that are potentially safer and more effective than existing treatments.

The key components of our strategy are:

Successfully Commercialize Rolapitant for the Prevention of CINV. On September 1, 2015, our first commercial product, VARUBI, was approved by the FDA, for use 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. We launched VARUBI in mid-November 2015. Our rolapitant program also includes the development of an IV formulation, 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 and 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 plan to submit an MAA for oral rolapitant to the EMA in the second quarter of 2016. We believe that we are well positioned to maximize the commercial potential of rolapitant. At MGI PHARMA, in 2003 our founding senior management team successfully launched and commercialized ALOXI® (palonosetron HCl injection), a 5-HT3 receptor antagonist for the prevention of CINV, in the United States. ALOXI, based on revenues, became the largest product in its class in 2006, despite being the fourth 5-HT3 receptor antagonist to market in the United States and competing with products sold by GlaxoSmithKline plc, Roche Holding Ltd. and Sanofi S.A. We intend to leverage the experience that our founding senior management team gained at MGI PHARMA to establish rolapitant as part of the standard of care for the prevention of CINV in patients who, per established treatment guidelines, could benefit from an NK-1 receptor antagonist, in addition to treatment with a 5-HT3 receptor antagonist plus a corticosteroid.

Continue the Clinical Development of and Successfully Commercialize Niraparib for the Treatment of Cancers that are Susceptible to PARP Inhibition. We are evaluating niraparib for the treatment of patients with high-grade serous, platinum sensitive, relapsed ovarian cancer in the NOVA Phase 3 clinical study, for which we initiated dosing in July 2013 and for which planned enrollment was completed in April 2015. We are evaluating niraparib in breast cancer patients with germline BRCA mutations in the BRAVO Phase 3 clinical trial, which we commenced in April of 2014. In the first quarter of 2015, we commenced 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. The first patient was dosed in this trial, which we refer to as the 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 temozolomide for the treatment of Ewing's sarcoma, as well as the Nordic Society of Gynecologic Oncology, or NSGO (in collaboration with the European

Network for Gynaecological Oncological Trial groups, or ENGOT) 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 commence a clinical trial of niraparib in the first-line setting in ovarian cancer patients during the first quarter of 2016. Based on research related to PARP inhibitors generally, we believe that niraparib may also be active in the treatment of several other tumor types. As further described below, we are also evaluating niraparib in combination preclinical pharmacology studies with our immuno-oncology anti-tumor agents.

Identify and Advance Potential Antibody Product Candidates Under Our Collaboration and Exclusive License Agreement with AnaptysBio. Under our collaboration and exclusive license agreement with AnaptysBio, we received exclusive rights to products based on AnaptysBio's proprietary technology for the discovery, generation and optimization of antibodies targeting certain immune checkpoint proteins. Specifically, 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 candidate. The IND for TSR-042, our lead anti-PD-1 antibody candidate, became effective in January 2016. We intend to initiate dosing in a Phase 1 clinical trial in the first quarter of 2016. We intend to submit an IND for TSR-022,

Table of Contents

the lead anti-TIM-3 compound, in the second quarter of 2016, and we expect to identify the lead anti-LAG-3 compound in the first half of 2016. We also 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. We believe that these therapeutic antibodies will form the basis of a strategic platform that will potentially enable us to develop novel monotherapy and combination-based approaches with immuno-oncology, including combinations of anti-PD-1 plus anti-TIM-3, and anti-PD-1 plus anti-LAG-3, and other anti-cancer agents in a variety of indications. Specifically, we believe this platform will enable us to initiate clinical development in new tumor indications not addressed with our current product candidates, and to study combination approaches in the clinic, potentially both with our existing product candidates and new candidates that we either in-license or access through collaborative transactions with others.

In-license or Acquire Additional Product Candidates to Create a Balanced Product Portfolio. We intend to in-license or acquire additional product candidates across various stages of development. We do not have, nor do we intend to build, drug discovery capabilities. We intend to focus on product candidates that we believe are differentiated from existing cancer therapeutics and that have well-defined, and potentially expeditious, clinical and regulatory pathways. Our criteria for selecting therapeutic product candidates for acquisition include consideration of potential diagnostics or specific clinical criteria that we believe would allow us to enrich our clinical study population for cancer patients who are more likely to respond to the compound. We believe that rolapitant, niraparib, and potential product candidates under our collaboration with AnaptysBio have these characteristics. We believe that our ability to execute on this strategy is due in part to our founding senior management team's experience with in-licensing and acquiring cancer therapeutics and oncology supportive care products on advantageous terms, and their prior success in developing and obtaining regulatory approval for these compounds and developing markets for and commercializing these products. Our objective is to build a portfolio of cancer therapeutics that is balanced by stage of development, resource requirements and development risk. We categorize acquisition or in-licensing targets as follows:

- Lower risk, later-stage assets that serve as a foundation for building a commercial business. We continue to seek, and may in-license or acquire, late-stage product candidates, such as rolapitant, that have well-defined regulatory and clinical development paths. By doing so, we believe that we can minimize to some degree the risks of development and regulatory approval. Having multiple products at, or near, a commercial stage will allow us to utilize our sales and marketing and medical affairs teams in a cost-effective manner.

- Mid-stage assets supported by early clinical study results indicating activity and adequate safety. We continue to seek, and may in-license or acquire, mid-stage product candidates and seek to advance them to final clinical testing, regulatory approval and commercialization. In identifying mid-stage assets, we intend to focus on assets that we believe demonstrate activity and adequate safety based on early clinical testing (i.e., Phase 1 or 2 clinical trials). Assets at this stage generally have more risk of not achieving eventual success than later-stage assets. We believe that niraparib was representative of this type of asset when we acquired rights to it in May 2012.

- Early-stage, potentially transformational assets associated with signals of effectiveness or patient selection approaches, by use of tools such as biomarkers. We continue to seek, and may in-license or acquire, early-stage assets that we can develop from preclinical status to commercialized products. For this category of assets, we intend

to focus on those compounds for which signals of effectiveness are demonstrated during in vitro or in vivo preclinical testing. Ideally, the early stage assets we in-license or acquire will exhibit signals of effectiveness for identifiable subpopulations of cancer patients, thereby allowing for the selection of cancer patients during clinical testing who are most likely to respond to treatment. We believe this will lead to more efficient and effective clinical trials and, if approved, better prescription patterns, providing for the best potential patient outcomes. We believe that this more personalized medicine approach to cancer therapy will allow for a more rapid and efficient path to product candidate development, registration and commercialization. We believe that the immuno-oncology portfolio of assets is representative of this category of assets.

· Currently marketed products and soon to be marketed products which allow us to utilize our sales and marketing and medical affairs organizations in a cost effective manner. We continue to seek, and may

Table of Contents

in-license or acquire, assets that have received regulatory approval and are, or are about to be, marketed to the same treatment centers and healthcare professionals as those to whom we market VARUBI and would market our product candidates, if approved. Having multiple marketed products can lead to efficiencies of scale in sales and marketing and medical affairs, and can drive faster market penetration for future products.

Build Global Capabilities to Maximize the Value of Our Product Candidates. We have exclusive worldwide rights to all of our current product candidates (rolapitant, niraparib, and any future product candidates that may result from our collaboration with AnaptysBio), and we intend to develop and commercialize our product candidates globally. We will also try to acquire global rights for product candidates we acquire or in-license in the future.

- Develop Our Products Globally. We are developing rolapitant and niraparib, and plan to develop our immuno-oncology assets, on a global basis, and intend to develop any future product candidates globally, in order to more rapidly enroll patients and support regulatory submissions to health authorities outside of the United States. We believe that global development programs will result in shortened development timelines, earlier submission of marketing authorization applications and, if the clinical results warrant, earlier regulatory approvals than would be expected if we were to conduct clinical development programs only in the United States.

- Commercial Operations in North America and Other Key Markets. We plan to commercialize our portfolio of cancer therapeutics and oncology supportive care products by deploying a fully integrated sales and marketing organization in North America. In the key markets of Europe and China, we expect to either deploy our own sales and marketing organizations or to collaborate with established third parties under arrangements that provide us with a significant portion of the economic value of our products in those markets. We believe that we can execute on this strategy for these geographies due to the past experience of our management team commercializing oncology products in those markets. Further, we believe that this strategy for Europe and China will provide us a better economic benefit than merely out-licensing substantial rights to our products for those regions to third parties for future development and commercialization, which may provide us with limited opportunities to impact the commercial success of our products. To this end, in July 2015 we entered into an agreement with Jiangsu Hengrui Medicine Co., Ltd., or Hengrui, for the development, registration, manufacture and commercialization of rolapitant in China.

Overview of the Market for Cancer Therapeutics and Oncology Supportive Care Products

Cancer is a group of diseases characterized by uncontrolled growth and spread of abnormal cells. In January 2016, the American Cancer Society projected that there will be an estimated 1,685,210 new cancer cases diagnosed and 595,690 cancer deaths in the United States in 2016. Current treatments for cancer include surgery, radiation therapy, chemotherapy, hormone therapy, targeted therapy and immunotherapy. The IMS Institute for Healthcare Informatics reported in 2015 that total global spending on oncology medicines, including therapeutic treatments and supportive care, reached the $100 billion threshold in 2014.

Many marketed products and product candidates for treating cancer patients that are currently being developed by biopharmaceutical companies are cytotoxic chemotherapies that exert their toxic effect on cancer generally through nonspecific damage to cellular components with the goal of causing cancer cell malfunction and cell death. Other products and product candidates alter cell metabolism or internal repair mechanisms leading to the demise of the cancer cell. More recently, targeted anti-cancer agents have been designed by scientists to inhibit the action of specific molecules within cancer cells that are driving the aberrant growth responsible for tumor development. Some of these targeted agents are developed in conjunction with companion diagnostic tests that are used by clinicians to determine if a patient's cancerous tumor contains these specific molecules and is, therefore, more likely to respond to a particular targeted therapy. Recent advances in cancer immunology have led to the development and availability of effective immunotherapies for the treatment of certain cancers. For our current cancer therapeutics, we believe we have acquired product candidates where diagnostics or specific clinical criteria will allow us to identify cancer patients who will be more likely to respond to the therapeutic. In the future, our preference will be to in-license or acquire cancer therapeutics that can be developed in a targeted patient population enriched for those who may respond to the drug candidate. We expect that the characteristics of these compounds will permit us to design clinical trials

Table of Contents

that, if successful, may allow us to achieve clinical outcomes that will support regulatory approval for targeted patient groups and reimbursement by healthcare payors due to attractive risk/benefit metrics in the targeted population.

All of these approaches may be associated with various side effects experienced by cancer patients that result from the treatments having an adverse impact on normal functioning cells and organ systems. Some of the more common side effects of cancer therapy include nausea, vomiting or emesis, infections, fatigue and diarrhea. Supportive care products are frequently prescribed or administered to cancer patients to prevent or treat these side effects thereby allowing the patients to continue to receive potentially life prolonging cancer therapies.

Treatment centers (such as hospitals and community cancer centers) and the healthcare professionals who treat cancer patients (physicians, nurses, physician assistants and pharmacists) utilize various combinations of cancer therapeutics and oncology supportive care products to extend and improve the quality of life of these patients. Our strategy is aligned with these trends in cancer care; that is, to acquire, in-license and develop product candidates and to commercialize products that selectively treat cancers and those that address the side effects from such treatments.

Our Product

VARUBI is an oral substance P/NK-1 receptor antagonist marketed in the United States for use in combination with other antiemetic agents in adults for the prevention of delayed (24 to 120 hours after chemotherapy administration) nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. VARUBI received FDA approval on September 1, 2015, and we commenced shipments of VARUBI in November 2015. The National Comprehensive Cancer Network, or NCCN®, has added VARUBI to the NCCN Clinical Practice Guidelines in Oncology, or NCCN Guidelines®, Antiemesis Version 2.2015 as a recommended option, in combination with other antiemetic agents, for patients receiving both high emetic risk intravenous chemotherapy, or HEC, and moderate emetic risk intravenous chemotherapy, or MEC. Category 1, the highest level category of evidence and consensus, was granted to VARUBI for both HEC and MEC. VARUBI is available to patients receiving emetogenic chemotherapy in hospitals and community cancer centers.

We demonstrated in three Phase 3 trials that a single oral dose of rolapitant, when administered along with the current standard of care for CINV (a 5-HT_3 receptor antagonist plus a corticosteroid), significantly decreased vomiting and the use of rescue medication for nausea over the delayed-phase period of risk for cancer patients receiving emetogenic chemotherapy as compared to the current standard of care alone. We obtained the exclusive worldwide rights to research, develop, manufacture, market and sell rolapitant from OPKO in December 2010. OPKO had acquired certain NK-1 receptor related assets, including rolapitant, in 2010 from Schering-Plough Corporation, or Schering-Plough, as part of a U.S. Federal Trade Commission, or FTC, requirement to divest certain assets in connection with Schering-Plough's combination with Merck. Prior to its divestiture of rolapitant, Schering-Plough evaluated rolapitant in over 1,000 subjects, including studies for the prevention of post-operative nausea and vomiting, or PONV, and chronic cough, and completed a Phase 2 clinical trial in patients at high risk for CINV. We are also developing an IV formulation of rolapitant, which has completed various Phase 1 clinical trials.

We believe the U.S. market will expand based upon market research that suggests physicians are not currently utilizing NK-1 receptor antagonists in many situations where it is recommended by practice guidelines, combined with the sales and marketing activities and enhanced educational initiatives associated with three companies marketing NK-1 receptor antagonists. Overall trends in the market, growing awareness of supportive care issues and the implementation of guidelines for patient care, including the prevention of CINV, that are developed and published by oncology organizations, may also lead to greater use of NK-1 receptor antagonists.

Table of Contents

Our Product Candidates

Our in-licensed product candidates and our immuno-oncology platform are consistent with our strategy to develop and commercialize cancer therapeutics and oncology supportive care products. The following table summarizes the status of these product candidates.

Rolapitant—Intravenous Formulation

We are developing a single dose IV formulation of rolapitant to address what we believe is the market need for this dosage form. We believe this formulation will provide physicians with an additional route of administering rolapitant, while also alleviating certain concerns associated with payor pre-approval, logistics and pharmacy availability that are sometimes associated with oral formulations of drugs utilized by cancer patients. We have selected a single intravenous dose of 185mg for 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. We expect that any NDA we submit to the FDA for the IV formulation of rolapitant will rely heavily on, and reference data in, our NDA submission for oral rolapitant. We plan to submit an NDA to the FDA in the first quarter of 2016, and we expect to launch an IV formulation of rolapitant, if approved, approximately one year following submission.

Niraparib—Poly (ADP-ribose) Polymerase (PARP) Inhibitor

Overview

Niraparib is an orally active and potent poly (ADP-ribose) polymerase, or PARP, inhibitor. Niraparib has demonstrated promising results in a Phase 1 clinical trial in advanced cancer patients. In the trial, a maximum tolerated dose of 300mg of niraparib was determined, and anti-tumor activity in BRCA-deficient cancers was also observed. BRCA1 and BRCA2 belong to a class of human genes, the mutation of which has been linked to certain types of cancers, including breast, ovarian and lung. PARP is a family of proteins involved in many functions in a cell, including DNA repair, gene expression, cell cycle control, intracellular trafficking and energy metabolism. PARP inhibitors have shown preclinical efficacy as a monotherapy against tumors with existing defects, such as BRCA1 and BRCA2, by compromising their ability to repair DNA, and as a combination therapy when administered together with anti-cancer agents that induce DNA damage. Results to date for

10

Table of Contents

clinical trials of PARP inhibitors indicate anti-cancer activity, which is particularly noteworthy in patients with germline BRCA mutations.

Background on PARP Inhibitors

One well-studied area of PARP activity relates to DNA repair. DNA contains genetic instructions used in the development and functioning of most known living organisms. DNA can be damaged by many sorts of mutagens, including oxidizing agents, alkylating agents, ultraviolet light and X-rays. An important property of DNA is that it can replicate, or make copies of itself. This is critical when cells divide because each new cell needs to have an exact copy of the DNA present in the old cell. It is also critical to the integrity and survival of cells that DNA damage can be repaired. Cells have evolved multiple mechanisms to enable such DNA repair, and these mechanisms are complementary to each other, each driving repair of specific types of DNA damage. If a cell's DNA damage repair system is overpowered, then the cell is programmed to die.

Radiation and certain chemotherapies such as alkylating agents and topoisomerase inhibitors induce significant damage to tumor cells, which results in programmed cell death. DNA repair mechanisms may reduce the activity of these anti-cancer therapies but, conversely, inhibition of DNA repair processes may enhance the effects of DNA-damaging anti-cancer therapy. PARP is essential for some DNA repair processes and therefore may be an important target in cancer therapy. Clinical trial results to date suggest that PARP inhibitors may be effective as a monotherapy in cancer patients with mutations in genes such as BRCA1 and BRCA2. PARP inhibitors have also been explored in numerous clinical trials as potentiators of chemotherapy, including in combination with temozolomide, cisplatin, carboplatin, gemcitabine and topotecan.

Key Characteristics of Niraparib

Niraparib is an investigational, orally active and potent PARP inhibitor that we believe has certain desirable characteristics. Based upon our review of the data, we believe that niraparib has the potential to inhibit growth of solid tumors in cancer patients. The nonclinical and Phase 1 clinical data suggest that niraparib may have advantages as a treatment for certain cancers, including:

- potent inhibition of PARP and demonstrated tumor growth inhibition in tumor models;
- dose-responsive pharmacokinetics in humans;

demonstrated reduction of PARP activity in human subjects;

amenable dosage formulation for further clinical and commercial development;

clinical activity with once daily oral administration as a monotherapy; and

tolerability in a Phase 1 combination trial with full doses of another chemotherapy agent, temozolomide, and a biologically active dose of niraparib.

Based upon these key characteristics, as well as the data discussed below, we believe that niraparib has the potential to be effective in patients with several tumor types.

Niraparib Preclinical Development

In vitro, niraparib increased the radiosensitivity of non-small cell lung cancer, or NSCLC, cell lines. Furthermore, niraparib was shown to dramatically reduce PARP activity in these same cancer cell lines within two hours of treatment. In testing conducted in mice, treatment of tumor cells with niraparib resulted in the prolonged inhibition of PARP. Niraparib treatment sensitized tumor cells to subsequent radiotherapy and chemotherapy in xenograft models. As a monotherapy, niraparib inhibited the growth of tumors bearing a BRCA1 mutation.

Niraparib Clinical Development

In 2011, Merck reported preliminary results from a two-part Phase 1 clinical study of niraparib to determine its toxicity and tolerability, pharmacokinetic and pharmacodynamic profiles, and preliminary anti-tumor activity. In June 2013,

Table of Contents

we presented updated Phase 1 data at the American Society of Clinical Oncology, or ASCO, annual meeting. Overall conclusions from this trial were that niraparib dosing was well tolerated, demonstrated linear pharmacokinetics, and provided evidence of target modulation and promising anti-tumor activity in patients with either BRCA mutated or non-BRCA mutated cancers.

We have commenced or intend to commence the following clinical trials of niraparib:

- NOVA: In July 2013, the first patient was dosed in this Phase 3 clinical trial evaluating niraparib for the treatment of patients with high-grade serous, platinum sensitive, relapsed ovarian cancer. In April 2015, planned enrollment was completed for the NOVA trial. The NOVA trial is an international, randomized, double-blind, multi-center trial that assesses the effectiveness of niraparib compared with placebo to delay progression following a platinum containing chemotherapy regimen. Patients enrolled into one of two independent cohorts based on germline BRCA mutation status. Within each cohort, patients are randomized 2:1 to receive niraparib or placebo, and are continuously treated with placebo or 300mg of niraparib until progression. The primary endpoint of this study is progression free survival, or PFS. Secondary endpoints include patient reported outcomes, chemotherapy free interval length, and overall survival.

- BRAVO: The first patient was dosed in this trial in April 2014. The BRAVO trial is an international, randomized, multi-center trial that assesses the effectiveness of niraparib compared with physician's choice of either eribulin, capecitabine, vinorelbine or gemcitabine to delay progression in metastatic breast cancer patients who have germline BRCA mutations. The primary endpoint of this trial is progression free survival and the key secondary endpoint of this trial is overall survival. Enrollment in this study is expected to continue through 2016.

- QUADRA: In March 2015, we commenced a potential registration trial of niraparib for the treatment of patients with ovarian cancer who have previously been treated with three or more regimens of therapy. The first patient was dosed in this trial in April 2015. QUADRA is a single arm, open label study. Endpoints include objective response rate and duration of response across platinum sensitive, platinum resistant, gBRCAmut and homologous recombination deficiency, or HRD, patient subsets.

- PRIMA: We expect to initiate dosing in a Phase 3 clinical trial of niraparib in the first-line setting in ovarian cancer patients in the first quarter of 2016. This study will include patients who have responded to first-line platinum chemotherapy. Patients will be randomized 2:1 to receive niraparib or placebo. The endpoints for this study include progression free survival, progression free survival in subsequent therapy and overall survival and safety.

We expect top-line data from the NOVA and QUADRA trials to become available during the second quarter of 2016, and we plan to submit an NDA and an MAA for niraparib in the second half of 2016.

We are also collaborating on the following niraparib studies:

- In February 2014, we began collaborating with SARC to evaluate niraparib in combination with temozolomide for the treatment of Ewing's sarcoma.

- AVANOVA: In November 2014, we began collaborating with NSGO (in collaboration with ENGOT) in their trial evaluating niraparib plus bevacizumab in ovarian cancer patients in a Phase 1/2 trial.

- 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 dosing in this trial during the first quarter of 2016.

The development of cancer in certain patients involves the dysfunction of a key DNA repair pathway known as homologous recombination. While cancer cells can maintain viability despite disruption of the homologous recombination pathway, they become particularly vulnerable to chemotherapy if an alternative DNA repair pathway is disrupted. This is known as synthetic lethality, a situation where the individual loss of either repair pathway is compatible with cell viability, but the simultaneous loss of both pathways results in cancer cell deaths. Since PARP inhibitors block DNA repair, in the context

Table of Contents

of cancer cells with the BRCA mutation, PARP inhibition results in synthetic lethality. For this reason, patients with germline mutations in a BRCA gene show marked clinical benefit that follows treatment with a PARP inhibitor. In 2014 we entered into a collaboration with Myriad Genetics, Inc., or Myriad, for the use and development of a HRD diagnostic test. Subsequently, we increased the enrollment of our NOVA trial to incorporate the Myriad HRD assay with the goal of potentially enriching the target population for potential responders to niraparib. Under the agreement, Myriad will provide testing services and pursue necessary regulatory approvals of a companion diagnostic in support of our development of niraparib. Under certain circumstances, we may be required to make milestone payments to Myriad based on the achievement of certain development and regulatory milestone events with regard to the development of a companion diagnostic.

Immuno-Oncology Platform

Background on Immuno-Oncology Platform

Antibodies to immune checkpoint receptors have recently demonstrated promise in the treatment of certain solid tumors, including metastatic melanoma, renal cell carcinoma and NSCLC. Although the normal function of immune checkpoint receptors is to maintain immune homeostasis, they are co-opted by certain tumors to evade immune surveillance. PD-1, TIM-3 and LAG-3 are each checkpoint regulators that modulate the function of the immune system via different mechanisms and, when activated and interacting with their respective ligands, may limit the ability of the immune system to respond effectively to tumors. By blocking the interaction of PD-1, TIM-3 and LAG-3 with their respective ligands, antibodies targeting these checkpoint regulators aim to restore immune anti-cancer function in patients across a variety of tumor types. We believe that therapeutic antibodies selected from the programs within our collaboration with AnaptysBio will form the basis of a strategic platform that will potentially enable us to develop novel monotherapy and combination-based approaches with immuno-oncology and other anti-cancer agents in a variety of new tumor indications, not addressed with our current product candidates, and to study combination approaches in the clinic, both with our existing product candidates and potentially with new candidates we either in-license or access through collaborative transactions with others. As further discussed below, antibody candidates from these programs are expected to enter clinical trials starting in the first half of 2016.

Anti-PD-1 Antibodies

Programmed cell death protein 1 (PD-1, CD279) is a well-validated target for tumor immunotherapy. PD-1 operates as a negative regulator of T-cell function and interacts with two ligands, PD-L1 and PD-L2. Many tumor types up-regulate PD-L1 on the cell surface as a means of modulating the host immune system and avoiding anti-tumor responses. Antibodies to PD-1 have now been studied in a number of clinical trials in several tumor types including, but not limited to, melanoma, NSCLC, prostate, renal and colorectal carcinoma. Anti-tumor responses of long duration have been noted, which may be further promoted through combination therapy with additional immuno-regulatory therapeutics.

AnaptysBio has generated a number of potent antibodies to PD-1 with demonstrated functionality in in vitro assays. We have selected a lead monospecific antibody for the PD-1 program, TSR-042, to which we have exclusive rights. We submitted an IND for TSR-042 in December 2015 which became effective in January 2016, and we expect to begin clinical trials using TSR-042 in the first half of 2016. In addition, we plan to evaluate our immuno-oncology anti-tumor agents, such as TSR-042, in combination preclinical pharmacology studies with niraparib and potentially other anti-tumor agents.

Anti-TIM-3 and Bi-Specific Anti-PD-1/TIM-3 Antibodies

T-cell immunoglobulin domain and mucin domain-3 (TIM-3), initially identified on activated Th1 cells, has been shown to be a negative regulator of the immune response. Blockade of TIM-3 promotes T-cell mediated anti-tumor immunity and has anti-tumor activity in a range of mouse tumor models. Combinations of TIM-3 blockade with other immunotherapeutic agents such as TSR-042 (our lead anti-PD-1 antibody), anti-CD137 antibodies and others, can be additive or synergistic in increasing anti-tumor effects. TIM-3 expression has been associated with a number of different tumor types including melanoma, NSCLC and renal cancer, and additionally, expression of intratumoral TIM-3 has been shown to correlate with poor prognosis across a range of tumor types including NSCLC, cervical, and gastric cancers. Blockade of TIM-3 is also of interest in promoting increased immunity to a number of chronic viral diseases. TIM-3 has also been shown to interact with a number of ligands including galectin-9, phosphatidylserine and HMGB1, although which of these, if any, are relevant in regulation of anti-tumor responses is not clear at present.

The aim of the TIM-3 program is to generate human or humanized antibodies to TIM-3 that have functional antagonist activity. Such activity would be expected to block the negative signaling of TIM-3, enhance T-cell responses, and

Table of Contents

promote anti-tumor immune responses. A number of fully-human anti-TIM-3 antibodies have been generated by AnaptysBio with demonstrated functional activity and to which we have exclusive rights. We have selected TSR-022 as our lead anti-TIM-3 candidate for clinical development and plan to submit an IND for TSR-022 in the second quarter of 2016. In addition, several bi-specific antibodies to PD-1 and TIM-3 have been isolated and are in the process of being advanced into functional activity testing.

Anti-LAG-3 and Bi-Specific Anti-PD-1/LAG-3 Antibodies

Lymphocyte-activation gene-3 (LAG-3) is a CD4 related transmembrane protein expressed on activated T-cells and regulatory T-cells. Following T-cell activation and up-regulation of LAG-3, LAG-3 binds MHC Class II and results in down-regulation of the immune response. Affinity of LAG-3 for MHC class II is higher than that of CD4, allowing for potent dampening of T-cell activation via direct blocking of the interaction as well as direct signaling. Blockade of LAG-3 promotes T-cell mediated anti-tumor immunity and has anti-tumor activity in a range of mouse tumor models. Simultaneous blockade of LAG-3 with PD-1 appears to be synergistic with enhanced anti-tumor effects.

The aim of the LAG-3 program is to generate human or humanized antibodies to LAG-3 that have functional antagonist activity. Such activity would be expected to block the negative signaling of LAG-3 and promote anti-tumor immune responses. Monospecific anti-LAG-3 antibodies have been generated by AnaptysBio from both mouse immunization techniques, as well as from the proprietary libraries, and those antibodies are currently being characterized and affinity matured to reach certain design goals. From this effort, we expect to identify a clinical candidate targeting LAG-3 in the first half of 2016. In addition, AnaptysBio is progressing toward screening and isolation of bi-specific antibodies to PD-1 and LAG-3.

TSR-011

In 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 anaplastic lymphoma kinase, or ALK, inhibitor compounds, including TSR-011. We initiated a Phase 1/2a dose escalation clinical trial of TSR-011 in cancer patients in November 2012. In October 2015, our Board of Directors determined to discontinue the development of TSR-011, and we notified Amgen of our intention to terminate the license agreement pursuant to the terms of the agreement. The license agreement with Amgen was terminated in January 2016. In connection with terminating the license agreement with Amgen, we expect the ongoing wind down of clinical and other activities related to TSR-011 to continue through 2016.

Licensing Agreements

License for Rolapitant

In December 2010, we entered into a license agreement with OPKO to obtain an exclusive, royalty bearing, sublicensable worldwide license, to research, develop, manufacture, market and sell rolapitant. The license agreement also extends to an additional, backup compound, SCH900978, to which we have the same rights and obligations as rolapitant, but which we are not currently advancing. Under the OPKO license, we are obligated to use commercially reasonable efforts to conduct all preclinical, clinical, regulatory and other activities necessary to develop and commercialize rolapitant.

Under the terms of the OPKO license, upon signing of the agreement, we paid OPKO $6.0 million and issued convertible preferred stock then valued at $0.6 million, which has since been converted to common stock. We are also required to make development milestone payments to OPKO of up to an aggregate of $30.0 million, of which we have paid $20.0 million to date, if specified regulatory and initial commercial sales milestones are achieved. In addition, we are required to make additional milestone payments to OPKO of up to an aggregate of $85.0 million if specified levels of annual net sales of rolapitant are achieved. Upon the commencement of commercial sales of rolapitant, we are required to pay OPKO tiered royalties on the amount of annual net sales of rolapitant 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 the date that all of the patent rights licensed from OPKO and covering rolapitant expire, are invalidated or are not enforceable and 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.

Table of Contents

The license with OPKO will remain in force until the expiration of the royalty term in each country, unless OPKO has cause to terminate the license earlier for our material breach of the license or bankruptcy. We have a right to terminate the license at any time during the term for any reason on three months' written notice to OPKO.

License for 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 Merck license, we are obligated to use diligent efforts to develop and commercialize a licensed product.

Under the terms of the license agreement, we made an up-front payment to Merck of $7.0 million in June 2012. We have made two milestone payments to Merck to date totaling $2.8 million. We are required to make total milestone payments to Merck of up to $57.0 million in 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.

The license with Merck will remain in effect until the expiration of the royalty term in such country, unless terminated earlier by the mutual agreement of the parties or due to the material breach or bankruptcy of a party. In addition, beginning upon completion of the first Phase 2 clinical trial of a licensed product candidate, we may terminate the license without cause by giving 180 days written notice.

In October 2012, we also entered into two license agreements with AstraZeneca UK Limited, having aggregate upfront payments of $0.4 million. These agreements provide us with the exclusive right to certain methods of treating patients with PARP inhibitors solely with respect to niraparib. Under certain circumstances, we may be required to make milestone and royalty payments to AstraZeneca UK Limited based on the achievement of certain development and regulatory milestone events with regard to niraparib, and on net sales of niraparib.

License for Immuno-Oncology Platform

In March 2014, we entered into a collaboration and exclusive license agreement with AnaptysBio, a privately-held therapeutic antibody company. We executed an amendment in November 2014 to add an additional bi-specific antibody product candidate. Under the terms of the amended 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 certain specified immunotherapy antibodies. Specifically, we received exclusive rights to monospecific antibody product candidates targeting PD-1 (TSR-042), TIM-3 (TSR-022) and LAG-3 and three bi-specific antibody product candidates targeting PD-1/TIM-3, PD-1/LAG-3 and an additional bi-specific combination. Under the amended agreement, AnaptysBio is responsible for performing initial discovery and development of therapeutic antibodies 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 this agreement, we made up-front, non-creditable and non-refundable cash payments of $19.0 million to AnaptysBio during 2014. 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 also be required to make milestone payments to AnaptysBio of up to $18.0 million if certain research and development milestone events are achieved, 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 have made $2.0 million in development milestone payments to date. We will also be required to pay AnaptysBio tiered single-digit 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.

Table of Contents

This agreement expires on the earliest date after which no further payments are due to AnaptysBio, unless earlier terminated. Either party may terminate the agreement in the event of an uncured material breach by the other party. We may terminate the agreement at any time upon 90 days prior written notice to AnaptysBio.

Competition

Our industry is highly competitive and subject to rapid and significant technological change. While we believe that our development experience and scientific knowledge provide us with competitive advantages, we may face competition from large pharmaceutical and biotechnology companies, smaller pharmaceutical and biotechnology companies, including specialty pharmaceutical companies and generic drug companies, academic institutions, government agencies and research institutions, and others.

The acquisition or licensing of pharmaceutical products is also very competitive, and a number of more established companies, which have acknowledged strategies to in-license or acquire products, may have competitive advantages as may other emerging companies taking similar or different approaches to product acquisitions. The more established companies may have a competitive advantage over us due to their size, cash flows and institutional experience.

Compared to TESARO, many of our competitors may have significantly greater financial, technical and human resource capabilities. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Our commercial opportunity could be reduced or eliminated if our competitors develop or market products or other novel technologies that are more effective, safer or less costly than any that will be commercialized by us, or obtain regulatory approval for their products more rapidly than we may obtain approval for ours. Our success will be based in part on our ability to identify, develop, and manage a portfolio of drugs that are safer and more effective in the treatment and support of cancer patients.

Rolapitant Competition

In addition to VARUBI, there are two other commercially available NK-1 receptor antagonists. Oral aprepitant and its IV pro-drug fosaprepitant, which are both known by the brand name EMEND®, are marketed by Merck, and a combination of netupitant and palonosetron, which is known by the brand name AKYNZEO®, is marketed by Helsinn Healthcare, or Helsinn, and Eisai Inc., or Eisai, as a combination of NK-1 and 5-HT_3 receptor antagonists. AKYNZEO was introduced in capsule form in October 2014. A single-dose version of the IV formulation of EMEND was approved by the FDA in February 2016. Based on Merck's announcement of its financial results for the year ended December 31, 2015, EMEND generated $535 million (unaudited) in global revenues in 2015. We believe the IV formulation of EMEND accounted for greater than 80% of all EMEND usage in the U.S. in 2015.

Niraparib Competition

There is currently one PARP inhibitor that is commercially available, AstraZeneca Plc's LYNPARZATM (olaparib), which was approved in December 2014 by the FDA for use by ovarian cancer patients with a germline BRCA mutation who have been treated with three or more prior lines of chemotherapy and also by the European Commission following a positive opinion by the EMA for use as a monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed BRCA-mutated (germline and/or somatic) high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to platinum-based chemotherapy. We believe the products in clinical development targeting the PARP pathway consist of Medivation's talazoparib/MDV3800, AbbVie's ABT-888 (veliparib), and Clovis Oncology, Inc.'s CO-338 (rucaparib), each currently in Phase 3 clinical trials, Eisai, Inc.'s E-7016 and E-7449, currently in Phase 2 and Phase 1/2 clinical trials, respectively, and AbbVie's ABT-767, BeiGene/EMD Serono (Merck KgaA)'s BGB-290, Teva Pharmaceutical Industries, Ltd.'s CEP-9722 and Hengrui's fluzoparib, each currently in Phase 1 clinical trials. Both LYNPARZA and rucaparib have received "orphan drug designation" from the EMA, which provides certain benefits including market exclusivity for up to ten years in the approved indication post-approval.

Immuno-Oncology Competition

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. There are currently two anti-PD-1 antibody products being marketed. In 2014 Bristol-Myers Squibb received approval for OPDIVO® (nivolumab) and Merck received approval for KEYTRUDA® (pembrolizumab) for injection, for use by patients with melanoma who have who

Table of Contents

have progressed on YERVOY® (ipilimumab). KEYTRUDA and OPDIVO have also been approved for the treatment of certain non-small cell lung cancers, and OPDIVO has been approved for the treatment of certain renal cell carcinomas. We are aware of several companies that are developing or co-developing anti-PDL-1 and/or anti-PD-1 modulators for various indications, including Pfizer, Roche, Medimmune (AstraZeneca), EMD Serono (Merck KGaA), Novartis, Hengrui/Incyte, GlaxoSmithKline, BeiGene and Regeneron/Sanofi.

There are currently no anti-TIM-3 antibody products or anti-LAG-3 antibody products being marketed. We are aware that one company, Novartis, has an anti-TIM-3 modulator antibody in Phase 1 clinical development for various indications. We are also aware of several companies that have anti-LAG-3 modulators in development for various indications, including Novartis, which has an anti-LAG-3 antibody that is in Phase 1/2 clinical development, and Bristol-Myers Squibb, which has an anti-LAG-3 antibody in Phase 1 clinical development. We are also aware of several other companies with immuno-oncology antibodies or programs in the preclinical or research phase.

For more information on the market for cancer therapeutics and oncology supportive care products, our competitors and the products that may compete with our product candidates, see "—Overview of the Market for Cancer Therapeutics and Oncology Supportive Care Products", "—Our Product", "—Our Product Candidates—Rolapitant—IV Formulation", "—C Candidates—Niraparib—Poly (ADP-ribose) Polymerase (PARP) Inhibitor" and "—Our Product Candidates— Immuno-Oncol Platform."

Commercial Operations

Our U.S.-based commercial operations team, hired primarily in 2015, consists of approximately 100 employees. The commercial infrastructure includes a targeted, oncology sales force to establish relationships with a focused group of oncologists, oncology nurses and pharmacists. The sales force is supported by sales management, internal sales support, an internal marketing group and distribution support. Additionally, the sales and marketing teams manage relationships with key accounts such as managed care organizations, group-purchasing organizations, hospital systems, oncology group networks, and government accounts. To further develop our commercial infrastructure in the event that any of our other product candidates receives regulatory approval, we will have to invest significant amounts of financial and management resources, some of which will be committed prior to any confirmation that any such product candidate will be approved, and we could invest resources and then later learn that a particular product candidate is not being approved.

Government Regulation

As a biopharmaceutical company that operates in the United States, we are subject to extensive regulation by the FDA and other federal, state, and local regulatory agencies. The Federal Food, Drug, and Cosmetic Act, or the FD&C Act, and the Public Health Service Act, or PHSA, and their implementing regulations set forth, among other things,

requirements for the testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record keeping, reporting, distribution, import, export, advertising and promotion of our products and product candidates. Although the discussion below focuses on regulation in the United States, because that is currently our primary focus, we anticipate seeking approval for, and marketing, our products in other countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of regulation in the European Union, or the EU, are addressed in a centralized way through the EMA and the European Commission, but the specific regulation of EU Member States remains essential in many respects for certain types of authorization processes, pricing and reimbursement and promotional activities.

Development and Approval

Under the FD&C Act, FDA approval of an NDA is required before any new drug can be marketed in the United States. Under the PHSA, FDA licensure of a biologics license application, or BLA, is required before a biologic can be marketed in the United States. NDAs and BLAs require extensive studies and submission of a large amount of data by the applicant.

Preclinical Testing. Before testing any compound in human subjects in the United States, a company must generate extensive preclinical data. Preclinical testing generally includes laboratory evaluation of product chemistry and formulation, as well as toxicological and pharmacological studies in several animal species to assess the quality and safety of the product. Animal studies must be performed in compliance with the FDA's Good Laboratory Practice, or GLP, regulations and the United States Department of Agriculture's Animal Welfare Act.

Table of Contents

IND Application. Human clinical trials in the United States cannot commence until an IND application is submitted and becomes effective. A company must submit preclinical testing results to the FDA as part of the IND, and the FDA must evaluate whether there is an adequate basis for testing the drug in initial clinical studies in human volunteers. Unless the FDA raises concerns, the IND becomes effective 30 days following its receipt by the FDA. Once human clinical trials have commenced, the FDA may stop the clinical trials by placing them on "clinical hold" because of concerns about the safety of the product being tested, or for other reasons.

Clinical Trials. Clinical trials involve the administration of the drug to healthy human volunteers or to patients, under the supervision of a qualified investigator. The conduct of clinical trials is subject to extensive regulation, including compliance with the FDA's bioresearch monitoring regulations and Good Clinical Practice, or GCP, requirements, which establish standards for conducting, recording data from, and reporting the results of, clinical trials, and are intended to assure that the data and reported results are credible and accurate, and that the rights, safety, and well-being of study participants are protected. Clinical trials must be conducted under protocols that detail the study objectives, parameters for monitoring safety, and the efficacy criteria, if any, to be evaluated. Each protocol is reviewed by the FDA as part of the IND. In addition, each clinical trial must be reviewed, approved, and conducted under the auspices of an Institutional Review Board, or IRB, at the institution conducting the clinical trial. Companies sponsoring the clinical trials, investigators, and IRBs also must comply with regulations and guidelines for obtaining informed consent from the study subjects, complying with the protocol and investigational plan, adequately monitoring the clinical trial, and timely reporting of adverse events. Foreign studies conducted under an IND must meet the same requirements that apply to studies being conducted in the United States. Data from a foreign study not conducted under an IND may be submitted in support of an NDA or BLA if the study was conducted in accordance with GCP and the FDA is able to validate the data.

A study sponsor is required to publicly post certain details about active clinical trials and clinical trial results on government or independent websites (e.g., http://clinicaltrials.gov). Human clinical trials typically are conducted in three sequential phases, although the phases may overlap with one another:

- Phase 1 clinical trials include the initial administration of the investigational drug to humans, typically to a small group of healthy human subjects, but occasionally to a group of patients with the targeted disease or disorder. Phase 1 clinical trials generally are intended to determine the metabolism and pharmacologic actions of the drug, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.

- Phase 2 clinical trials generally are controlled studies that involve a relatively small sample of the intended patient population, and are designed to develop data regarding the product's effectiveness, to determine dose response and the optimal dose range, and to gather additional information relating to safety and potential adverse effects.

- Phase 3 clinical trials are conducted after preliminary evidence of effectiveness has been obtained, and are intended to gather the additional information about safety and effectiveness necessary to evaluate the drug's overall risk-benefit profile, and to provide a basis for physician labeling. Generally, Phase 3 clinical development programs

consist of expanded, large-scale studies of patients with the target disease or disorder to obtain statistical evidence of the efficacy and safety of the drug at the proposed dosing regimen, or the safety, purity, and potency of a biological product.

The sponsoring company, the FDA, or the IRB may suspend or terminate a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. Further, success in early-stage clinical trials does not assure success in later-stage clinical trials. Data obtained from clinical activities are not always conclusive and may be subject to alternative interpretations that could delay, limit or prevent regulatory approval.

NDA/BLA Submission and Review. After completing clinical testing of an investigational drug or biologic, a sponsor must prepare and submit an NDA or BLA for review and approval by the FDA. The NDA is a comprehensive, multi-volume application that includes, among other things, the results of preclinical and clinical studies, information about the drug's composition, and our plans for manufacturing, packaging, and labeling the drug. For certain candidates, such as immunotherapeutic antibodies, this information is submitted in a BLA. When an NDA or BLA is submitted, the FDA conducts a preliminary review to determine whether the application is sufficiently complete to be accepted for filing. If it is not, the FDA may refuse to file the application and request additional information, in which case the application must be resubmitted with the supplemental information, and review of the application is delayed.

Table of Contents

FDA performance goals generally provide for action on an application within 12 months of submission, but that deadline is extended in certain circumstances. Moreover, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA can expedite the review of new drugs and biologics that are intended to treat serious or life threatening conditions and demonstrate the potential to address unmet medical needs, such that the targeted action date is eight months from submission.

As part of its review, the FDA may refer an NDA or BLA to an advisory committee for evaluation and a recommendation as to whether the application should be approved. Although the FDA is not bound by the recommendation of an advisory committee, the agency usually has followed such recommendations. The FDA may determine that a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to ensure that the benefits of a new product outweigh its risks, and the product can therefore be approved. A REMS may include various elements, ranging from a medication guide or patient package insert to limitations on who may prescribe or dispense the drug, depending on what the FDA considers necessary for the safe use of the drug. Under the Pediatric Research Equity Act, certain applications for approval must include an assessment, generally based on clinical study data, of the safety and effectiveness of the subject drug or biological product in relevant pediatric populations. We have an agreed-upon pediatric plan to assess the effectiveness of rolapitant in the pediatric population.

After review of an NDA or BLA, the FDA may decide to not approve the application or issue a Complete Response letter outlining the deficiencies in the submission. The Complete Response letter also may request additional information, including additional preclinical or clinical data. Even if such additional information and data are submitted, the FDA may decide that the NDA still does not meet the standards for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than the sponsor. Obtaining regulatory approval often takes a number of years, involves the expenditure of substantial resources, and depends on a number of factors, including the severity of the disease in question, the availability of alternative treatments, and the risks and benefits demonstrated in clinical trials. Additionally, as a condition of approval, the FDA may impose restrictions that could affect the commercial success of a drug or require post-approval commitments, including the completion within a specified time period of additional clinical studies, which often are referred to as “Phase 4” or “post-marketing” studies.

Post-approval modifications to the drug or biologic product, such as changes in indications, labeling, or manufacturing processes or facilities, may require a sponsor to develop additional data or conduct additional preclinical or clinical trials, to be submitted in a new or supplemental NDA or BLA, which would require FDA approval.

Post-Approval Regulation

Once approved, products are subject to continuing regulation by the FDA. If ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market, the FDA may at any time withdraw product approval or take actions that would limit or suspend marketing. Additionally, the FDA may require post-marketing

studies or clinical trials if new safety information develops.

Good Manufacturing Practices. Companies engaged in manufacturing drug products or their components must comply with applicable current Good Manufacturing Practice, or cGMP, requirements and product-specific regulations enforced by the FDA and other regulatory agencies. Compliance with cGMP includes adhering to requirements relating to organization and training of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, quality control and quality assurance, packaging and labeling controls, holding and distribution, laboratory controls, and records and reports. The FDA regulates and inspects equipment, facilities, and processes used in manufacturing pharmaceutical or biologic products, prior to approval. If, after receiving approval, a company makes a material change in manufacturing equipment, location, or process (all of which are, to some degree, incorporated in the NDA or BLA), additional regulatory review and approval may be required. The FDA also conducts regular, periodic visits to re-inspect equipment, facilities, and processes following the initial approval of a product. Failure to comply with applicable cGMP requirements and conditions of product approval may lead the FDA to seek sanctions, including fines, civil penalties, injunctions, suspension of manufacturing operations, operating restrictions, withdrawal of FDA approval, seizure or recall of products, and criminal prosecution. Although we periodically monitor the FDA compliance of our third-party manufacturers, we cannot be certain that our present or future third-party manufacturers will consistently comply with cGMP and other applicable FDA regulatory requirements.

Table of Contents

Advertising and Promotion. The FDA and other federal regulatory agencies closely regulate the marketing and promotion of drugs and biologics through, among other things, standards and regulations for direct-to-consumer advertising, advertising and promotion to healthcare professionals, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet. A product cannot be commercially promoted before it is approved. After approval, product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling approved by the FDA. Healthcare providers are permitted to prescribe drugs and biologics for "off-label" uses—that is, uses not approved by the FDA and therefore not described in the product's labeling—because the FDA does not regulate the practice of medicine. However, FDA regulations impose stringent restrictions on manufacturers' communications regarding off-label uses. Broadly speaking, a manufacturer may not promote a drug or biologic for off-label use, but under certain conditions may engage in non-promotional, balanced, scientific communication regarding off-label use. Failure to comply with applicable FDA requirements and restrictions in this area may subject a company to adverse publicity and enforcement action by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug or biological products.

Other Requirements. In addition, companies that manufacture or distribute drug or biological products or that hold approved NDAs or BLAs must comply with other regulatory requirements, including submitting annual reports, reporting information about adverse drug experiences, and maintaining certain records.

Hatch-Waxman Act

The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, establishes two abbreviated approval pathways for pharmaceutical products that are in some way follow-on versions of already approved products.

Generic Drugs. A generic version of an approved drug is approved by means of an abbreviated new drug application, or ANDA, by which the sponsor demonstrates that the proposed product is the same as the approved, brand-name drug, which is referred to as the "reference listed drug," or RLD. Generally, an ANDA must contain data and information showing that the proposed generic product and RLD (1) have the same active ingredient, in the same strength and dosage form, to be delivered via the same route of administration, (2) are intended for the same uses, and (3) are bioequivalent. This is instead of independently demonstrating the proposed product's safety and effectiveness, which are inferred from the fact that the product is the same as the RLD, which the FDA previously found to be safe and effective.

505(b)(2) NDAs. If a product is similar, but not identical, to an already approved product, it may be submitted for approval via an NDA under FDC Act section 505(b)(2). Unlike an ANDA, this does not excuse the sponsor from demonstrating the proposed product's safety and effectiveness. Rather, the sponsor is permitted to rely to some degree

on the FDA's finding that the RLD is safe and effective, and must submit its own product-specific data of safety and effectiveness to an extent necessary because of the differences between the products.

RLD Patents. An NDA sponsor must identify to the FDA patents that claim the drug substance or drug product or a method of using the drug. When the drug is approved, those patents are among the information about the product that is listed in the FDA publication, Approved Drug Products with Therapeutic Equivalence Evaluations, which is referred to as the Orange Book. The sponsor of an ANDA or 505(b)(2) application seeking to rely on an approved product as the RLD must make one of several certifications regarding each listed patent. A "Paragraph III" certification is the sponsor's statement that it will wait for the patent to expire before obtaining approval for its product. A "Paragraph IV" certification is a challenge to the patent; it is an assertion that the patent does not block approval of the later product, either because the patent is invalid or unenforceable or because the patent, even if valid, is not infringed by the new product.

Regulatory Exclusivities. The Hatch-Waxman Act provides periods of regulatory exclusivity for products that would serve as RLDs for an ANDA or 505(b)(2) application. If a product is a "new chemical entity," or NCE—generally meaning that the active moiety has never before been approved in any drug—there is a period of five years from the product's approval during which the FDA may not accept for filing any ANDA or 505(b)(2) application for a drug with the same active moiety. An ANDA or 505(b)(2) application may be submitted after four years, however, if the sponsor makes a Paragraph IV certification challenging a listed patent. Because it takes time for the FDA to review and approve an application once it has been accepted for filing, five-year NCE exclusivity usually effectively means the ANDA or 505(b)(2) application is not approved for a period well beyond five years from approval of the RLD.

Table of Contents

A product that is not an NCE may qualify for a three-year period of exclusivity if the NDA contains clinical data that were necessary for approval. In that instance, the exclusivity period does not preclude filing or review of the ANDA or 505(b)(2) application; rather, the FDA is precluded from granting final approval to the ANDA or 505(b)(2) application until three years after approval of the RLD. Additionally, the exclusivity applies only to the conditions of approval that required submission of the clinical data. For example, if an NDA is submitted for a product that is not an NCE, but that seeks approval for a new indication, and clinical data were required to demonstrate the safety or effectiveness of the product for that use, the FDA could not approve an ANDA or 505(b)(2) application for another product with that active moiety for that use.

Once the FDA accepts for filing an ANDA or 505(b)(2) application containing a Paragraph IV certification, the applicant must within 20 days provide notice to the RLD NDA holder and patent owner that the application with patent challenge has been submitted, and provide the factual and legal basis for the applicant's assertion that the patent is invalid or not infringed. If the NDA holder or patent owner files suit against the ANDA or 505(b)(2) applicant for patent infringement within 45 days of receiving the Paragraph IV notice, the FDA is prohibited from approving the ANDA or 505(b)(2) application for a period of 30 months from the date of receipt of the notice. If the RLD has NCE exclusivity and the notice is given and suit filed during the fifth year of exclusivity, the 30-month stay does not begin until five years after the RLD approval. The FDA may approve the proposed product before the expiration of the 30-month stay if a court finds the patent invalid or not infringed or if the court shortens the period because the parties have failed to cooperate in expediting the litigation. At present, we anticipate that rolapitant and, if approved, niraparib will qualify for five-year NCE exclusivity.

Patent Term Restoration. A portion of the patent term lost during product development and FDA review of an NDA or BLA is restored if approval of the application is the first permitted commercial marketing of a drug containing the active ingredient. The patent term restoration period is generally one-half the time between the effective date of the IND and the date of submission of the NDA or BLA, plus the time between the date of submission of the NDA or BLA and the date of FDA approval of the product. The maximum period of restoration is five years, and the patent cannot be extended to more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval. The U.S. Patent and Trademark Office, or PTO, in consultation with the FDA, reviews and approves the application for patent term restoration. When any of our products is approved, we intend to seek patent term restoration for an applicable patent when it is appropriate. At present, we anticipate that rolapitant and, if approved, niraparib will qualify for patent term restoration. We have applied for patent term restoration for rolapitant.

The Biologics Price Competition and Innovation Act

The Biologics Price Competition and Innovation Act, or BPCI Act, authorizes the FDA to license a biological product that is biosimilar to an FDA-licensed biologic through an abbreviated pathway. The BPCI Act establishes criteria for determining that a product is biosimilar to an already-licensed biologic, or reference product, and establishes a process by which an abbreviated BLA for a biosimilar product is submitted, reviewed and approved. The BPCI Act provides

periods of exclusivity that protect a reference product from biosimilars competition. Under the BPCI Act, the FDA may not accept a biosimilar application for review until four years after the date of first licensure of the reference product, and the biosimilar may not be licensed until 12 years after the reference product's approval. Additionally, the BPCI Act establishes procedures by which the biosimilar applicant must provide information about its application and product to the reference product sponsor, and by which information about potentially relevant patents is shared and litigation over patents may proceed in advance of approval. The BPCI Act also provides a period of exclusivity for the first biosimilar to be determined by the FDA to be interchangeable with the reference product.

Because the BPCI Act is a relatively new law, we anticipate that its contours will be defined as the statute is implemented over a period of years. This likely will be accomplished by a variety of means, including FDA issuance of guidance documents and decisions in the course of considering specific applications. The FDA has to date issued various guidance documents and other materials indicating the agency's thinking regarding a number of issues implicated by the BPCI Act. Additionally, the FDA's approval in 2015 of the first biosimilar application helps define the agency's approach to certain issues.

Other Exclusivities

Pediatric Exclusivity. Section 505A of the FDC Act provides for six months of additional exclusivity and patent protection if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The

Table of Contents

data does not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or Orange Book listed patent protection that cover the drug are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve an ANDA or 505(b)(2) application owing to regulatory exclusivity or listed patents. The BPCI Act incorporates by reference many provisions of section 505A of the FDC Act, such that if pediatric studies for a biological product fairly respond to a written request from the FDA, are completed in a timely fashion, and otherwise comply with applicable requirements, the 12-year exclusivity period will be deemed to be 12 and a half years, and the four year period will be deemed to be four and a half years. However, six-month pediatric exclusivity does not attach to patents for a biological product under the BPCI Act. When any of our products is approved, we anticipate seeking pediatric exclusivity when it is appropriate.

Orphan Drug Exclusivity. The Orphan Drug Act provides incentives for the development of drugs and biological products intended to treat rare diseases or conditions, which generally are diseases or conditions affecting less than 200,000 individuals in the United States. If a sponsor demonstrates that a drug or biologic is intended to treat a rare disease or condition, the FDA grants orphan drug designation to the product for that use. The benefits of orphan drug designation include research and development tax credits and exemption from user fees. A drug or biologic that is approved for the orphan drug designated indication is granted seven years of orphan drug exclusivity. During that period, the FDA generally may not approve any other application for the same product for the same indication, although there are exceptions, most notably when the later product is shown to be clinically superior to the product with exclusivity. We intend to seek orphan drug designation and exclusivity for our products whenever it is available.

Foreign Regulation

In addition to laws and regulations in the United States, we are subject to a variety of laws and regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products.

Whether or not we obtain FDA approval for a product, we must obtain the requisite marketing authorizations from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of a product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application, or CTA, much like an IND, prior to the commencement of clinical trials. In the EU, for example, a CTA must be submitted to the national health authority of each EU Member State in which the clinical trial is to be conducted and to an independent ethics committee, much like the FDA and an IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases in EU Member States, for example, the clinical trials must be conducted in accordance with GCP, applicable regulatory requirements, and ethical principles that have their origin in the

Declaration of Helsinki.

In the EU, a marketing authorization for a medicinal product can be obtained through a centralized, mutual recognition, decentralized procedure, or national procedure (single EU Member State). In accordance with the centralized procedure, the applicant can submit a single application for marketing authorization to the EMA that will provide a positive opinion regarding the application if it meets certain quality, safety, and efficacy requirements. Following the opinion of the EMA, the European Commission makes a final decision to grant a centralized marketing authorization that permits the marketing of a product in all 28 EU Member States and three of the four European Free Trade Association, or EFTA, States, Iceland, Liechtenstein and Norway. The centralized procedure is mandatory for certain medicinal products, including orphan medicinal products, medicinal products derived from certain biotechnological processes, advanced therapy medicinal products and certain other medicinal products containing a new active substance for the treatment of certain diseases, and optional for certain other products, including medicinal products that are a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public or animal health. Under the centralized procedure in the EU, the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the EMA Committee for Medicinal Products for Human Use, or CHMP). Accelerated evaluation may be granted by the CHMP in exceptional cases. These are defined as circumstances in which a medicinal product is expected to be of a “major public health interest”. Three cumulative criteria must be fulfilled in such circumstances: the seriousness of the disease, such as heavy disabling or life-threatening diseases, to be treated; the absence or insufficiency of an appropriate alternative therapeutic

Table of Contents

approach; and anticipation of high therapeutic benefit. In these circumstances, the EMA ensures that the opinion of the CHMP is given within 150 days.

Unlike the centralized authorization procedure, the decentralized marketing authorization procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the European Commission, whose decision is binding on all EU Member States.

The mutual recognition procedure similarly is based on the acceptance by the competent authorities of the EU Member States of the marketing authorization of a medicinal product by the competent authorities of other EU Member States. The holder of a national marketing authorization may submit an application to the competent authority of an EU Member State requesting that this authority recognize the marketing authorization delivered by the competent authority of another EU Member State.

Once an applicant receives marketing authorization in an EU Member State, through any application route, the applicant is then required to engage in pricing discussions and negotiations with a separate pricing authority in that country. The legislators, policymakers and healthcare insurance funds in the EU Member States continue to propose and implement cost-containing measures to keep healthcare costs down, due in part to the attention being paid to health care cost containment and other austerity measures in the EU. Certain of these changes could impose limitations on the prices pharmaceutical companies are able to charge for their products. The amounts of reimbursement available from governmental agencies or third-party payors for these products may increase the tax obligations on pharmaceutical companies such as ours, or may facilitate the introduction of generic competition with respect to our products. Furthermore, an increasing number of EU Member States and other foreign countries use prices for medicinal products established in other countries as “reference prices” to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere. In addition, the ongoing budgetary difficulties faced by a number of EU Member States, including Greece and Spain, have led and may continue to lead to substantial delays in payment and payment partially with government bonds rather than cash for medicinal products, which could negatively impact our revenues and profitability. Moreover, in order to obtain reimbursement of our medicinal products in some countries, including some EU Member States, we may be required to conduct clinical trials that compare the cost-effectiveness of our products to other available therapies. There can be no assurance that our medicinal products will obtain favorable reimbursement status in any country.

The sole legal instrument at the EU level governing the pricing and reimbursement of medicinal products is Council Directive 89/105/EEC, or the “Transparency Directive.” The aim of this Directive is to ensure that pricing and reimbursement mechanisms established in the EU Member States are transparent and objective, do not hinder the free

movement and trade of medicinal products in the EU and do not hinder, prevent or distort competition on the market. The Transparency Directive does not provide any guidance concerning the specific criteria on the basis of which pricing and reimbursement decisions are to be made in individual EU Member States. Neither does it have any direct consequence for pricing nor reimbursement levels in individual EU Member States. The EU Member States are free to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices and/or reimbursement levels of medicinal products for human use. Certain individual EU Member States adopt policies according to which a specific price or level of reimbursement is approved for the medicinal product. Others adopt a system of reference pricing, basing the price or reimbursement level in their territories either on the pricing and reimbursement levels in other countries or on the pricing and reimbursement levels of medicinal products intended for the same therapeutic indication. Further, some EU Member States impose direct or indirect controls on the profitability of the company placing the medicinal product on the market.

Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States. These EU Member States include the United Kingdom, France, Germany, Ireland, Italy and Sweden. The HTA process in European Economic Area, or EEA, countries is governed by the national laws of these countries. HTA is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. HTA generally focuses on the clinical efficacy and effectiveness, safety, cost, and cost-

Table of Contents

effectiveness of individual medicinal products as well as their potential implications for the healthcare system. Those elements of medicinal products are compared with other treatment options available on the market.

The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product vary between EU Member States.

In 2011, Directive 2011/24/EU was adopted at EU level. This Directive concerns the application of patients' rights in cross-border healthcare. The Directive is intended to establish rules for facilitating access to safe and high-quality cross-border healthcare in the EU. Pursuant to the Directive, a voluntary network of national authorities or bodies responsible for HTA in the individual EU Member States was established. The purpose of the network is to facilitate and support the exchange of scientific information concerning HTAs. This may lead to harmonization of the criteria taken into account in the conduct of HTAs between EU Member States and in pricing and reimbursement decisions and may negatively affect price in at least some EU Member States.

In the EU, the advertising and promotion of our products will also be subject to EU Member States' laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices, as well as other EU Member State legislation that may apply to the advertising and promotion of medicinal products. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, as approved by the competent authorities. The SmPC is the document that provides information to physicians concerning the safe and effective use of the medicinal product. It forms an intrinsic and integral part of the marketing authorization granted for the medicinal product. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion. The off-label promotion of medicinal products is prohibited in the EU. The applicable laws at the EU level and in the individual EU Member States also prohibit the direct-to-consumer advertising of prescription-only medicinal products. Violations of the rules governing the promotion of medicinal products in the EU could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict communications concerning the advertising and promotion of our products to the general public and may also impose limitations on our promotional activities with healthcare professionals.

Failure to comply with the EU Member State laws implementing the Community Code on medicinal products, and EU rules governing the promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices, with the EU Member State laws that apply to the promotion of medicinal products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements can result in enforcement action by the EU Member State authorities, which may include any of the following: fines, imprisonment, orders forfeiting products or prohibiting or suspending their supply to the market, or requiring the manufacturer to issue public warnings, or to conduct a product recall.

Interactions between pharmaceutical companies and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct in the individual EU Member States. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the EU. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of the EU Member States. One example is the UK Bribery Act 2010. This act applies to any company incorporated in or "carrying on business" in the UK, irrespective of where in the world the alleged bribery activity occurs. This act could have implications for our interactions with physicians in and outside the UK. Violation of these laws could result in substantial fines and imprisonment.

The national laws of certain EU Member States require payments made to physicians to be publicly disclosed. Moreover, the European Federation of Pharmaceutical Industries and Associations, or EFPIA, Code on disclosure of transfers of value from pharmaceutical companies to healthcare professionals and healthcare organizations imposes a general obligation on members of the EFPIA or related national industry bodies to disclose transfers of value to healthcare professionals. In addition, agreements with physicians must often be the subject of prior notification and approval by the physician's employer, his/her competent professional organization, and/or the competent authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the EU Member States.

For other countries outside of the EU, such as countries in Eastern Europe, Central and South America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to

Table of Contents

country. In all cases, again, the clinical trials are conducted in accordance with GCP, applicable regulatory requirements, and ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, warning letters or untitled letters, injunctions, civil, administrative, or criminal penalties, monetary fines or imprisonment, suspension or withdrawal of regulatory approvals, suspension of ongoing clinical studies, refusal to approve pending applications or supplements to applications filed by us, suspension or the imposition of restrictions on operations, product recalls, the refusal to permit the import or export of our products or the seizure or detention of products.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we have or may obtain regulatory approval. Sales of VARUBI and, if approved, any of our product candidates, will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government healthcare programs such as Medicare and Medicaid, commercial health insurers and managed care organizations. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication.

In order to secure coverage and reimbursement for VARUBI or any other product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Third-party reimbursement may not be sufficient to enable us to maintain price levels high enough to realize an appropriate return on our investment in product development.

In the past, payors have implemented reimbursement metrics and periodically revised those metrics as well as the methodologies used as the basis for reimbursement rates, such as average sales price, or ASP, average manufacturer price, or AMP, and actual acquisition cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. The Centers for Medicare and Medicaid Services, or CMS, surveys and publishes retail pharmacy acquisition cost information in the form of National Average Drug Acquisition Cost, or NADAC, files to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates. It may be difficult to project the impact of these evolving reimbursement mechanics on the willingness of payors to cover our products for which we receive regulatory approval.

Our participation in the Medicaid rebate program established by the Omnibus Budget Reconciliation Act of 1990 and under multiple subsequent amendments of that law, including the Affordable Care Act, requires us to pay a rebate for each unit of drug reimbursed by Medicaid. The amount of the "basic" portion of the rebate for each product is set by law as the larger of: (i) 23.1% of quarterly AMP, or (ii) the difference between quarterly AMP and the quarterly best price available from us to any commercial or non-governmental customer, or Best Price. AMP must be reported on a monthly and quarterly basis and Best Price is reported on a quarterly basis only. In addition, the rebate also includes the "additional" portion, which adjusts the overall rebate amount upward as an "inflation penalty" when the drug's latest quarter's AMP exceeds the drug's AMP from the first full quarter of sales after launch, adjusted for increases in the Consumer Price Index—Urban. The upward adjustment in the rebate amount per unit is equal to the excess amount of the current AMP over the inflation-adjusted AMP from the first full quarter of sales. The rebate amount is required to be recomputed each quarter based on our report to CMS of current quarterly AMP and Best Price for our drug. The terms of our participation in the program impose a requirement for us to report revisions to AMP or Best Price within a period not to exceed 12 quarters from the quarter in which the data was originally due. Any such revisions could have the impact of increasing or decreasing our rebate liability for prior quarters, depending on the direction of the revision. The Affordable Care Act, in combination with other federal legislation passed in August 2010, made changes to the definition of AMP, effective October 1, 2010. In February 2016, final guidance and regulations were issued by the federal government clarifying these and certain other Affordable Care Act changes and which relate to the calculation of AMP and the related rebate liability for pharmaceutical products.

Federal law also requires that a company that participates in the Medicaid rebate program report ASP information each quarter to CMS for certain categories of drugs that are paid under Part B of the Medicare program. Manufacturers calculate ASP based on a statutorily defined formula and interpretations of the statute by CMS. CMS uses these submissions to determine payment rates for drugs under Medicare Part B and the resulting Medicare payment rate.

Table of Contents

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. Subsequent legislation extended the 2% reduction, on average, to 2025. 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.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. Government healthcare programs and other third-party payors are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. If these payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit. The United States government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. Adoption of such controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for products such as VARUBI and the product candidates that we are developing and could adversely affect our net revenues and operating results.

The marketability of VARUBI and any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on drug pricing. Coverage policies, third-party reimbursement rates and drug pricing regulation may change at any time.

In the United States, most outpatient prescription drugs may be covered under Medicare Part D. Medicare Part D is a voluntary prescription drug benefit, through which Medicare beneficiaries may enroll in prescription drug plans offered by private entities for coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans provided for under Medicare Part C.

Coverage and reimbursement for covered outpatient drugs under Part D are not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Although Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, they have some flexibility to establish those categories and classes and are not required to cover all of the drugs in each category or class. Medicare Part D prescription drug plans may use formularies to limit the number of drugs that will be covered in any therapeutic class and/or impose differential cost sharing or other utilization management

techniques.

The availability of coverage under Medicare Part D may increase demand for VARUBI and for products for which we receive marketing approval. However, in order for the products that we market to be included on the formularies of Part D prescription drug plans, we likely will have to offer pricing that is lower than the prices we might otherwise obtain. Changes to Medicare Part D that give plans more freedom to limit coverage or manage utilization, and/ or other cost reduction initiatives in the program could decrease the coverage and price that we receive for any approved products and could seriously harm our business.

In the physician office setting, Medicare Part B generally pays for covered drugs, which would include any eventual IV formulation of rolapitant and in limited circumstances could also include the oral formulation, at a rate of 106% of the drug's ASP. ASP is defined by statute based on sales and price concession data, including rebates and chargebacks, for a defined period of time and manufacturers submit the required information to CMS on a quarterly basis. Prior to the quarter in which the payment rate will go into effect, CMS calculates and publishes the ASP-based payment rate. Under this methodology, payment rates change on a quarterly basis, and significant downward fluctuations in ASP, and therefore reimbursement rates, could negatively impact sales of a product. Because the ASP-based payment rate is defined by statute, changes to Medicare payment methodologies require a legislative change. While the statute requires Medicare Part B payments for most drugs furnished in the physician office setting to be at 106% of ASP, the statute does not have a similar requirement for hospital outpatient departments. For that setting, the Medicare payment for many covered Part B drugs also is at 106% of ASP, provided that the product exceeds a per day cost threshold. For those products that do not meet the threshold,

Table of Contents

as is true for many oral anti-emetic products, there is no separate payment for the drug when furnished in a hospital outpatient department. For those products that meet the threshold, the current 106% of ASP payment rate could be changed by CMS in future years through regulations, without any intervening legislation. The 106% of ASP payment rates for the physician office and hospital outpatient settings are subject to the 2% sequestration cuts mandated by federal statute as described above.

Further, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, together the Affordable Care Act, a law that substantially changes the way healthcare is financed by both governmental and private insurers, contains provisions that may reduce the profitability of drug products. 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 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. On February 1, 2016, CMS issued final regulations to implement the changes to the Medicaid drug rebate program under the Affordable Care Act. These regulations become effective on April 1, 2016. We are evaluating the impact of these regulations on our business and operations.

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 2016, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. The Affordable Care Act also expanded the Public Health Service's 340B drug pricing program, or the 340B program (described below), to include additional types of covered entities. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners, and a significant number of provisions are not yet, or have only recently become, effective. 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. Even if favorable coverage and reimbursement status is attained for VARUBI or for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

We participate in the 340B program. Federal law requires that any company that participates in the Medicaid rebate program also participate in the 340B program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. In addition, in order to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies, a manufacturer also must participate in the Department of Veterans Affairs Federal Supply Schedule, or FSS, pricing program, established by Section 603 of the Veterans Health Care Act of 1992. Under this program, the manufacturer is obligated to make its product available for procurement on an FSS contract and charge a price to four federal agencies, Department of Veterans Affairs,

Department of Defense, Public Health Service and Coast Guard, that is at least 24% less than the Non-Federal Average Manufacturing Price, or non-FAMP, for the prior fiscal year. The requirements under the 340B and FSS programs could reduce the revenue we may generate from VARUBI and any products that are commercialized in the future and could adversely affect our business and operating results.

Fraud and Abuse Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback and false claims statutes.

The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any healthcare item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly and practices that involve

Table of Contents

remuneration to those who prescribe, purchase, or recommend pharmaceutical and biological products, including certain discounts, or engaging consultants as speakers or consultants, may be subject to scrutiny if they do not fit squarely within the exemption or safe harbor. 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 prohibits, among other things, any person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds, or knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing 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. Federal enforcement agencies also have showed increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement and co-pay support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. In addition, the Affordable Care Act amended federal law to provide that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Criminal prosecution is possible for making or presenting a false or fictitious or fraudulent claim to the federal government.

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, also created several new federal crimes, including healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

The majority of states also have statutes or regulations similar to the federal anti-kickback and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Several states now 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.

As of August 1, 2013, the federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, requires certain manufacturers of drugs, devices, biologics and medical supplies to engage in extensive tracking of payments and other transfers of value to physicians and teaching hospitals, including physician ownership

and investment interests, and public reporting of such data. Pharmaceutical and biological manufacturers with products for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program are required to have started tracking such payments on August 1, 2013, and must submit a report on or before the 90th day of each calendar year disclosing reportable payments made in the previous calendar year.

In addition, the United States Foreign Corrupt Practices Act prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any official of another country, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in that capacity.

Other countries, including a number of EU Member States, have laws of similar application.

Because of the breadth of these various fraud and abuse laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have material adverse effects on our business, financial condition and results of operations. In the event governmental authorities conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations, they may impose sanctions under these laws, which are potentially significant and may include civil monetary

Table of Contents

penalties, damages, exclusion of an entity or individual from participation in government health care programs, criminal fines and imprisonment, as well as the potential curtailment or restructuring of our operations. 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 harm our financial condition and divert the attention of our management from operating our business.

Patents and Proprietary Rights

We have in-licensed three patent portfolios, one each for our rolapitant, niraparib, and immunotherapeutic antibodies programs.

Our NK-1 receptor antagonist portfolio, which relates to rolapitant, consists of eight patent families currently being prosecuted or maintained, which include applications and patents directed to compositions of matter, formulations (including oral and IV), solid forms, methods of treatment (including both delayed and acute onset nausea and/or vomiting and timing of administration in relation to chemotherapy) and methods of preparing rolapitant. Rolapitant is a NK-1 receptor antagonist being developed for the prevention of chemotherapy induced nausea and/or vomiting. The portfolio licensed for rolapitant consists of 17 issued United States patents and 174 issued non-United States patents across the eight families. In the patent family covering the composition of matter, we have four issued United States patents and 72 issued non-United States patents.

Our PARP inhibitor portfolio includes five patent families relating to niraparib and two other patent families relating to MK-2512, the backup PARP inhibitor compound licensed from Merck that is not currently being developed. All seven of the patent families are being prosecuted or maintained by Merck in consultation with us. The five patent families relating to niraparib include applications and patents directed to compositions of matter, methods of treatment (including treatment of cancer and other diseases), particular salts of niraparib and methods of preparing niraparib. Of these five patent families, the first claims a broad genus of compounds that encompasses niraparib and uses thereof. This first family consists of applications pending in Europe, Canada and India and patents issued in Australia, Japan and China. The second family, which claims niraparib, presently comprises 92 issued patents worldwide, including a patent in the United States as well as patents in several European countries. This second family also has applications pending worldwide. The third patent family relating to niraparib is directed to particular salts of niraparib. This third family is being prosecuted worldwide, and patents have been issued in the United States, Australia, Israel, Russia, New Zealand, South Africa and several European countries. The fourth and fifth families relate to methods of preparing niraparib and comprise patent applications pending in the United States and Europe.

Our immunotherapeutic antibodies portfolio presently includes a United States patent application and applications pending in multiple jurisdictions, which cover particular lead antibodies to one identified target of interest. Two additional filings are pending and relate to other targets, and it is expected that worldwide filings will be pursued. We have rights to all patents owned or controlled by our collaborator, AnaptysBio, to the extent that they claim the manufacture, composition, or use of an antagonist antibody developed under the program.

Intellectual Property Protection Strategy

We seek and intend to continue seeking patent protection whenever available for any patentable aspects of our existing products or product candidates and related technology or any new products or product candidates we acquire in the future. Where our intellectual property is not protectable by patents, we seek to protect this through other means, including maintenance of trade secrets and careful protection of our proprietary information. Our license from Merck for niraparib requires Merck to, subject to certain exceptions, prosecute and maintain, upon consultation with us, its patent rights as they relate to the licensed compounds. If Merck decides to cease prosecution of the licensed patent rights, we have the right to take over such prosecution activities. Our license from OPKO for rolapitant grants us the right to control all prosecution and maintenance activities for the licensed compounds, at our sole discretion.

The patent positions of biopharmaceutical companies like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Consequently, we do not know whether any of the product candidates we in-license or acquire will be protectable or remain protected by enforceable patents. We cannot predict whether the patent applications we are pursuing will issue as patents in any particular jurisdiction, and furthermore, we cannot determine whether the claims of any issued patents will provide sufficient proprietary protection to protect us from competitors, or will be challenged, circumvented or invalidated by third parties. Because patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months, and since publication of discoveries in the scientific or patent

Table of Contents

literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. 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. Previously, in the United States, the first to make the claimed invention was entitled to the patent. Moreover, we may have to participate in interference proceedings declared by the PTO or a foreign patent office to determine priority of invention and/or in post-grant challenge proceedings (such as oppositions) that challenge priority of invention or other features of patentability. Such proceedings could result in substantial cost, even if the eventual outcome is favorable to us.

Although we have issued patents covering a number of different attributes of our products, and pending applications on others, there can be no assurance that any issued patents would be held valid by a court of competent jurisdiction. An adverse outcome could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using specific compounds or technology. To the extent prudent, we intend to bring litigation against third parties that we believe are infringing our patents.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the PTO in granting a patent, or may be shortened if a patent is terminally disclaimed over another patent.

In the United States, the term of a patent that covers an FDA-approved drug or biological product may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug or biologic is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Patent term extension is available only if the approval of the product represents the first permitted commercial marketing of the active ingredient. Similar provisions are available in the EU and other non-U.S. jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We intend to seek patent term adjustments and extensions to any of our issued patents in any jurisdiction where these are available; however, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such adjustments or extensions.

To protect our rights to any of our issued patents and proprietary information, we may need to litigate against infringing third parties, or avail ourselves of the courts or participate in hearings to determine the scope and validity of those patents or other proprietary rights. These types of proceedings are often costly and could be time-consuming to us, and we cannot be certain that the deciding authorities will rule in our favor. An unfavorable decision could result in the invalidation or a limitation in the scope of our patents or forfeiture of the rights associated with our patents or pending patent applications. Any such decision could result in our key technologies not being protectable, allowing

third parties to use our technology without being required to pay us licensing fees, or may compel us to license needed technologies from third parties to avoid infringing third-party patent and proprietary rights. Such a decision could even result in the invalidation or a limitation in the scope of our patents or could cause us to lose our rights under existing issued patents or not to have rights granted under our pending patent applications.

We also rely on trade secret protection for our confidential and proprietary information. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, no assurance can be given that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technology, or that we can meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual shall be our exclusive property. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

Table of Contents

NK-1 Receptor Antagonists

We have an exclusive, worldwide license from OPKO to a portfolio of patents related to rolapitant, including issued claims covering the composition of matter and certain formulations and methods of use.

United States Patent 7,049,320 claims composition of matter for the chemical composition of rolapitant, and a sister patent claims compositions of matter of related compounds. Corresponding applications and issued patents in multiple foreign jurisdictions have similar composition of matter claims. This family of patents and/or applications has a patent term of at least until December 2022. With the patent term adjustment, United States Patent 7,049,320 expires in December 2023.

Many jurisdictions also grant extensions of patent term, typically up to five years, for post-issuance regulatory delay. Only one patent may be extended per approved product. We believe that patent term extension under the Hatch-Waxman Act could be available to extend our patent exclusivity for rolapitant by up to five years in the United States depending on timing of our first approval. In Europe, we believe that patent term extension under supplementary protection certificate could also be available for an additional five years depending on timing of our first approval. There is no guarantee that the maximum allowable extension will be granted, and any extension granted may be shorter than this, or not granted at all.

United States Patent 7,563,801 claims oral pharmaceutical formulations of rolapitant, including capsule formulations. United States Patent 7,981,905, claims methods of treating nausea and/or emesis by administration of pharmaceutical formulations of rolapitant. United States Patent 8,404,702 claims methods of treating acute onset nausea and/or emesis. Corresponding patents and applications in multiple foreign jurisdictions similarly have claims directed to pharmaceutical formulations of rolapitant and uses thereof. This family of patents and/or applications has a patent term of at least until April 2027.

United States Patent 8,178,550 claims the hydrochloride monohydrate polymorphic form of the chemical composition of rolapitant. United States Patent 8,470,842 claims methods of treating or delaying the onset of nausea and emesis, as well as treating or delaying the onset of chemotherapy-induced nausea and/or chemotherapy-induced emesis, using the hydrochloride monohydrate polymorphic form of the chemical composition of rolapitant. Corresponding applications and issued patents in multiple foreign jurisdictions have similar claims to various polymorphic forms of rolapitant. This family of patents and/or applications has a patent term of at least until April 2027.

United States Patent 8,361,500 claims a powdered pharmaceutical formulation comprising at least one crystalline salt of rolapitant. Corresponding patent applications and issued patents in multiple other jurisdictions. This family of patents and/or applications has a patent term of at least until March 2028.

United States Patent 9,101,615 claims methods of treating nausea and/or emesis comprising administering an intravenous formulation of rolapitant. Corresponding applications and issued patents in multiple foreign jurisdictions have claims to IV formulations of rolapitant (including a micelle formulation) and methods of treating nausea and/or emesis. This family of patents and/or applications has a patent term of at least until 2030.

PARP Inhibitor

We have an exclusive, worldwide license from Merck to a portfolio of patents related to two inhibitors of poly (ADP-ribose) polymerase: niraparib and MK-2512. The five patent families that relate to niraparib include United States Patent 8,071,623, which claims composition of matter for the chemical composition of niraparib. This patent has a term of until March 2030. We have filed corresponding applications and have been issued 91 corresponding patents in multiple other jurisdictions worldwide. Unless their patent terms are extended due to delays by the responsible patent office or regulatory authority, or are shortened by terminal disclaimers, the patents in this family (other than United States Patent 8,071,623) will expire in approximately January 2028.

The second patent family relating to niraparib discloses and claims a broad genus of compounds that encompasses niraparib. This family includes applications pending in multiple jurisdictions and patents issued in Australia, China and Japan. Unless their patent terms are extended due to delays by the responsible patent office or regulatory authority, or shortened by terminal disclaimers, the patents in this family will expire approximately April 2027.

The third patent family relating to niraparib discloses and claims particular salts of niraparib. This family includes applications pending in multiple jurisdictions and patents issued in the United States, Australia, Israel, New Zealand, Russia

Table of Contents

and South Africa, as well as patents in several European countries. Unless their patent terms are extended due to delays by the responsible patent office or regulatory authority, or shortened by terminal disclaimers, the patents in this family will expire approximately January 2029.

The fourth and fifth families relating to niraparib disclose methods of preparing niraparib. These families include applications pending in the United States and Europe. Unless their terms are extended due to delays by the responsible patent office or regulatory authority, or shortened by terminal disclaimers, the patents resulting from the pending applications in these families will expire in approximately December 2033.

We believe that patent term extension under the Hatch-Waxman Act could be available to extend our patent exclusivity for niraparib by up to five years in the United States, depending on timing of our first approval. Such an extension would be available, if at all, on only one United States patent. With respect to Europe, we believe that supplementary protection certificates (which are issued on a country-by-country basis in Europe) could add up to five years to the patent term of a patent issued in each European country, depending on timing of our first approval. There is no guarantee that any extension will be granted, and even if granted, the extension may be less than the maximum allowable extension.

Immuno-Oncology

Pursuant to our Collaboration and Exclusive License Agreement with AnaptysBio, we have ownership and/or exclusive worldwide license rights in patent filings relating to certain antibodies that bind to PD-1, LAG-3, and/or TIM-3. Existing patent filings cover composition of matter for the relevant antibodies and binding fragments thereof, as well as their use individually and in combination; additional filings are contemplated.

No patents have yet issued from the relevant patent filings, but any such patents will be expected to have terms that extend into the 2030s; ultimate expiration dates, which may differ in different jurisdictions, may depend on, for example, extensions available for patent office and/or regulatory delays, payment of annuities and/or maintenance fees, and/or disclaimers of related cases.

Manufacturing

We contract with third parties for the manufacture of VARUBI and for the manufacture of our product candidates for preclinical studies and clinical trials, and we intend to continue to do so in the future. We currently work with Hovione Inter Limited, or Hovione, as a contract manufacturer, or CMO, for the production of rolapitant drug substance, with Patheon Inc., or Patheon, for the production of oral rolapitant drug product, and with another CMO for

the production of IV rolapitant drug product. To meet our needs with respect to further clinical development, we have contracted with additional CMOs for the manufacture of clinical supplies. We have agreements in place with multiple CMOs for the production of niraparib (both drug substance and drug product) to meet our ongoing clinical supply needs. We have contracted with one CMO for the manufacture of TSR-042, TSR-022 and other antibody products, and may contract with additional CMOs that have biologics capabilities. For each of our product candidates, we may elect to pursue relationships with other CMOs for manufacturing clinical supplies for later-stage trials and for commercialization. We do not own or operate manufacturing facilities for the production of clinical quantities of our product candidates. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. To meet our projected needs for clinical supplies to support our activities through regulatory approval and commercial manufacturing, the CMOs with whom we currently work will need to increase scale of production or we will need to secure alternate suppliers. We have not currently qualified alternate suppliers in the event the current CMOs we utilize are unable to scale production. We have personnel with pharmaceutical development and manufacturing experience who are responsible for the relationships with our CMOs.

In March 2012, we entered into a process development and manufacturing services agreement with Hovione, under which Hovione provides certain process development and manufacturing services in connection with the manufacture of rolapitant drug substance. The agreement also provides that if Hovione is successful in implementing the manufacturing process and the agreement is not terminated by us, Hovione would also manufacture certain commercial quantities of rolapitant. Hovione has implemented the manufacturing process successfully and is now manufacturing commercial quantities of rolapitant drug substance. Under the agreement, we pay Hovione for services in accordance with the terms of work plans, which we enter into from time to time. Each party to the agreement is subject to customary indemnification provisions. Unless terminated earlier, the agreement will continue until the later of the fifth anniversary of (i) all development services under the last work plan executed in accordance with the terms of the agreement or (ii) the first launch date of the product to occur in any of the following jurisdictions: Europe; Japan; or the United States. The agreement may be extended by agreement of the

Table of Contents

parties. We are permitted to terminate the agreement at the end of each phase of the initial work plan and to terminate any work plan executed after the initial work plan upon at least 30 days' prior written notice to Hovione.

In October 2015, we entered into a Master Manufacturing Services Agreement, or the Master Agreement, and a related Product Agreement (together with the Master Agreement, the Patheon Agreements) with Patheon. The Master Agreement governs the general terms under which Patheon or one of its affiliates will provide manufacturing services to us for drug products specified by us from time to time, and the Product Agreement relates specifically to the manufacture of VARUBI (rolapitant) tablets for sale in the United States.

Under the terms of the Patheon Agreements, Patheon will manufacture VARUBI 100 mg tablets for sale in the United States and provide related quality control, packaging and raw materials inventory and storage services. We will provide Patheon with the necessary active pharmaceutical ingredients for VARUBI. We are not required to purchase any minimum quantity of VARUBI or any other drug product under the Patheon Agreements, but have agreed to purchase from Patheon a significant majority of our requirements in a specified territory of any drug manufactured under the Master Agreement.

The term of each of the Patheon Agreements extends until December 31, 2019 and will automatically renew thereafter for successive two-year periods unless terminated by either party upon prior written notice. Each of the Patheon Agreements may also be terminated by either party for material, uncured breaches, in the event of the other party's bankruptcy, or upon prior notice if a governmental authority prevents us from importing, exporting, purchasing or selling the underlying product (VARUBI in the case of the Product Agreement). Patheon may terminate the Master Agreement or the Product Agreement if we assign any rights thereunder to a Patheon competitor. We may terminate packaging services upon prior written notice to Patheon and may terminate manufacturing services upon prior written notice if a product is discontinued in its specified territory.

Employees

As of December 31, 2015, we had 286 full-time employees, 59 of whom hold Ph.D. or M.D. degrees. Of these full-time employees, 119 were directly engaged in development activities and 103 were engaged in selling, marketing and related activities, with the remainder serving in primarily general and administrative and commercial support capacities. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Research and Development

We have dedicated a significant portion of our resources to our efforts to develop our product candidates, particularly rolapitant and niraparib. We incurred research and development expenses, including acquired in-process research and development, of $77.7 million, $143.3 million and $157.4 million during the years ended December 31, 2013, 2014 and 2015, respectively. We anticipate that a significant portion of our operating expenses will continue to be related to research and development in 2016 as we continue to advance our product candidates through clinical development and incur increasing costs under our immuno-oncology collaboration with AnaptysBio.

Available Information

Our internet website address is http://www.tesarobio.com. Through our website, we make available, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, any amendments to those reports, proxy and registration statements, and all of our insider Section 16 reports, as soon as reasonably practicable after such materials are electronically filed with, or furnished to, the U.S. Securities and Exchange Commission, or the SEC. These materials can be accessed through the “Investors” section of our website. The information found on our website is not part of this or any other report we file with, or furnish to, the SEC. Paper copies of our SEC reports are available free of charge upon request in writing to Investor Relations, TESARO, Inc., 1000 Winter Street, Suite 3300, Waltham, MA 02451. The content on any website referred to in this Form 10-K is not incorporated by reference into this Form 10-K unless expressly noted.

We currently operate in one segment. For additional information regarding our financial results, including measures of our accumulated deficit and information on our assets, refer to the Notes to Consolidated Financial Statements included in Part II, Item 8, “Financial Statements and Supplementary Data”, of this Annual Report on Form 10-K.

Table of Contents

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 Annual Report on Form 10-K, including the information in our financial statements and the related notes, and the other filings we make with the Securities and Exchange Commission. 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 and commercialization 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 recognized 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, 2015, we reported a net loss of $251.4 million and we had an accumulated deficit of $601.9 million as of December 31, 2015.

Although we obtained approval from the U.S. Food and Drug Administration, or FDA, for VARUBI® (rolapitant) tablets in September 2015 and launched 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, including niraparib and the IV formulation of rolapitant, and the timing and amount of milestones and other required payments to third parties in connection with such approvals. If any of our product candidates, such as niraparib, fails in clinical trials or does not gain regulatory approval, or if approved, fails 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 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 very limited experience commercializing 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 have not recognized any revenues from sales of our products, and we may never become profitable.

To date, we have not recognized any revenues from sales of VARUBI or generated any revenues from sales of 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, our existing clinical-stage product candidates, including niraparib and IV rolapitant, and any other product candidates that we have or may in-license or acquire in the future. 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 niraparib;

Table of Contents

- 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.

We will require additional capital to fund our operations, and if 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 in both the U.S. and in certain foreign markets, including Europe. We also expect to spend substantial amounts for any milestone obligations that may arise,

and for any additional product candidates that we may in-license. We will require additional capital for these and other needs. If such additional funding is not obtained on a timely basis, we would be required to change our current operating plans to reduce our future expenses.

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, niraparib, or one or more of our other 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 based 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:

Table of Contents

- the cost of establishing sales, marketing and distribution capabilities for VARUBI and any of our product candidates for which we may receive regulatory approval in the U.S. and in certain foreign markets, including Europe;

- the outcome, timing and cost of regulatory approvals by the FDA and comparable foreign regulatory authorities, including for niraparib and IV rolapitant, and 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, including for niraparib and IV rolapitant;

- the preclinical and clinical development plans we and our collaborator, AnaptysBio, Inc., or AnaptysBio, establish for our immuno-oncology platform;

- the likelihood and timing of attainment of milestones and our obligations to make milestone payments, royalty payments, or both 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 3.00% convertible senior notes due October 1, 2021, or the 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, including niraparib and

IV rolapitant.

The success of our business depends heavily upon our ability to develop and commercialize product candidates. We have launched but not recognized any revenue on sales of VARUBI, and our only other late clinical-stage product candidates are IV rolapitant and niraparib. Our other product candidates are at earlier stages of 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.

Table of Contents

Notwithstanding VARUBI's FDA approval, the FDA will require approval of a separate NDA for an IV formulation of rolapitant, 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. 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.

Despite the results reported in earlier clinical trials for niraparib, we do not know whether the clinical trials we are conducting or may in the future conduct will demonstrate adequate efficacy and safety, or safety to result in regulatory approval for niraparib in any particular jurisdiction or jurisdictions. If we do not obtain regulatory approval for niraparib, or do not obtain such approval in a timely manner or for anticipated patient populations, it would negatively affect our revenue and growth prospects.

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 manufacturers 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, or cGMP, regulations;
- 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;

- 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 foreign territories where it may be approved, or any significant delay in such approvals, could have a material adverse impact on our ability to execute upon our business strategy.

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.

Table of Contents

Prior to the launch of VARUBI in late 2015, we had not 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 recently built a field organization and other capabilities for the sales, marketing and distribution of VARUBI, and there are significant risks involved with building and managing a sales organization. Factors that may inhibit our efforts to effectively 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 currently offered by our 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 and maintain effective sales, marketing and distribution capabilities for VARUBI and any other 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. VARUBI competes with EMEND, an NK-1 receptor antagonist marketed by Merck, as well as AKYNZEO, an oral combination NK-1 receptor antagonist and 5-HT_3 receptor antagonist (netupitant plus ALOXI (palonosetron HCl)) that is marketed by Helsinn and Eisai. We are aware that Sandoz has received approval for a generic version of aprepitant that to our knowledge has not been launched commercially. VARUBI would face additional competition if such a generic version is introduced to the market or if other products were developed and

approved for the treatment and prevention of CINV or if an IV formulation of AKYNZEO is developed. There are a number of large pharmaceutical and biotechnology companies that market and sell products or are pursuing the development of products that we expect will compete with niraparib.

A number of pharmaceutical and biotechnology companies are also pursuing the development of cancer immunotherapies that may compete with our immunotherapy product candidates. 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, and several other companies with immuno-oncology antibodies or programs in the preclinical or research phase. For further detail on the specific competition that VARUBI and our product candidates face, see “Item 1. Business – Competition”.

Many of the approved drugs with which our products or product candidates may compete 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. If a generic formulation of aprepitant were to be introduced to the market, it may have a price that is lower than the price of VARUBI. If our other product candidates are approved, they may be priced at a significant premium over competitive generic products. 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.

Table of Contents

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, other regulatory authorities or comparable foreign 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;
- 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, vary 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,

Table of Contents

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 led 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. Equivalent laws and potential consequences exist in foreign jurisdictions.

Because the results of preclinical testing or earlier clinical studies are not necessarily predictive of future results, niraparib, which is 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 are conducting or may in the future conduct will demonstrate adequate efficacy and safety, or safety to result in regulatory approval for niraparib in any particular jurisdiction or jurisdictions. If we do not obtain regulatory approval for niraparib, or do not obtain such approval in a timely manner or for anticipated patient populations, it would negatively affect our revenue and growth prospects.

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;

Table of Contents

- 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 CROs, clinical sites, or clinical trial managers to satisfy their contractual duties or meet expected deadlines;

- 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 for a given study;

- a decision by the FDA, an IRB, comparable foreign regulatory entities, or the Company; or a recommendation by a data safety monitoring board or comparable foreign regulatory entity, to suspend or terminate a clinical trial 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 raw materials, active pharmaceutical ingredients or product candidates for use in clinical trials; and

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

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.

Table of Contents

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, including niraparib and IV rolapitant, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities for a product candidate 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, including niraparib and IV rolapitant, 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 a REMS, or a comparable foreign regulatory authority may require the establishment of similar strategies, that may, for instance, restrict distribution of our product or otherwise impose burdensome implementation requirements on us. Any of the foregoing scenarios could materially harm the commercial prospects of our product candidates.

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

Undesirable side effects caused by VARUBI or our product candidates, including niraparib and IV rolapitant, could cause us or regulatory authorities to interrupt, delay or halt clinical trials, could result in a more restrictive label, or could result in 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.

Table of Contents

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 such 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 for such product;
- 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 additional 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 or product candidate, and could significantly harm our business, results of operations and prospects.

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

In order to market and sell 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. In the EU, certain products or product candidates with

which niraparib may compete have received “orphan drug designation” from the EMA in an ovarian cancer indication, which provides certain benefits to such competitors, including market exclusivity for up to ten years in the approved indication post-approval. We will have to overcome those designations by demonstrating that niraparib is not a similar medicinal product, does not have the same therapeutic indication, or is clinically superior to the products that have received the orphan drug designation in order to obtain approval to market niraparib in the EU. We or our licensees 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.

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, including niraparib and IV rolapitant, 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, including niraparib and IV rolapitant, these products may be too costly for general use, and physicians may prescribe them less frequently.

Table of Contents

The Medicare program and certain government pricing programs, including the Medicaid drug rebate program, the Public Health Service's 340B drug pricing program, or the 340B program, and the pricing program under the Veterans Health Care Act of 1992, or the VHCA, impact the revenues we may derive from VARUBI and other future products that we may commercialize, including niraparib and IV rolapitant. Any future legislation or regulatory actions altering these programs or imposing new compliance requirements 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, together 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, including niraparib and IV rolapitant. 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 the Centers for Medicare and Medicaid Services, or CMS, of its current average manufacturer price, or AMP, and, in the case of innovator products like VARUBI, best price figures, for the quarter. If we become aware that our AMP or best price reporting for a prior quarter was incorrect, or has changed, we are 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 program.

We are liable for errors associated with our submission of average sales price, or ASP, pricing data under Medicare Part B. In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly

Table of Contents

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 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. 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 Department of Veterans Affairs, or the VA, and by covered entities under the 340B program. The pricing data reported are used as the basis for establishing Federal Supply Schedules, or FSS, drug pricing program and 340B 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. We cannot assure you that our pricing submissions will not be found to be incomplete or incorrect. 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 Department of Defense, 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 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. Additionally, 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 the Tricare Retail Pharmacy Program, 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, specialty distributors, specialty pharmacies, physicians and third-party payors play a primary role in the distribution, recommendation and prescription of any pharmaceutical product 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 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:

· 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

Table of Contents

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. Federal enforcement agencies also have showed increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement and co-pay support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. 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. Companies may be required, however, to enter into corporate integrity agreements with the government, which may impose substantial costs on companies to ensure compliance. Criminal prosecution is also 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

Table of Contents

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;

- 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; and

- similar restrictions imposed on the promotion and marketing of medicinal products in the EU and other countries, including restrictions prohibiting the promotion of a compound prior to its approval. Laws (including those governing promotion and marketing and anti-kickback provisions), industry regulations and professional codes of conduct often are strictly enforced. Even in those countries where we may decide not to directly promote or market our products, inappropriate activity by our any international distribution partners could have implications for us.

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 not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. 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 harm our financial condition and divert resources and the attention of our management from operating our business.

Our ability to successfully commercialize our products and generate revenues outside of the U.S. depends heavily on the availability of adequate pricing and reimbursement from government and other third-party payors.

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 levels 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.

Table of Contents

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

The Affordable Care Act substantially changes the 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 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 2016, 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. On February 1, 2016, CMS issued final regulations to implement the changes to the Medicaid drug rebate program under the Affordable Care Act. These regulations become effective on April 1, 2016. We are evaluating the impact of these regulations on our business and operations. 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. Subsequent legislation extended the 2% reduction, on average, to 2025. 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. Even if favorable coverage and reimbursement status is attained for our products, less favorable coverage policies and reimbursement rates may be implemented in the future.

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 (or in some instances current regulations, guidance or interpretations) on the marketing approvals of our product candidates, if any, may be.

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

Our agreements with our licensors, including OPKO, Merck, and AnaptysBio, require us, among other things, to use diligent or commercially reasonable efforts to develop and commercialize the products and product candidates licensed thereunder, make timely milestone, royalty and other payments, provide certain information regarding our activities with respect to such products and product candidates, maintain the confidentiality of information we receive thereunder, 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 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

Table of Contents

development and commercialization of our products and product candidates after an uncured, material breach of our license agreements by us. This would also generally be the case if we voluntarily terminated 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.

Table of Contents

We currently hold what we believe to be a commercially reasonable amount of product liability insurance coverage, which may not be adequate to cover all liabilities that we may incur. 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 for companies similar to ours, 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, failure to provide accurate information to the FDA or comparable foreign regulatory authorities, failure to comply with manufacturing standards, failure to 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, failure to report financial information or data accurately, violations of anti-bribery laws, or failure to 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

Table of Contents

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 confidential information obtained in the course of our business, which could result in civil or criminal legal actions, regulatory sanctions, or serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics and other corporate policies, 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 December 31, 2015, we had 286 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:

- 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, including our 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 personnel, 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. 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.

Table of Contents

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/or
- incur amortization expenses related to intangible assets or incur large and immediate write-offs.

We 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 or adoption of our therapeutic product candidates for those uses from FDA and comparable foreign regulatory agencies, or may have difficulty achieving adoption of our product candidates, if applicable companion diagnostics are not commercially available, or are restricted in their use by payors or other market forces.

For certain of our cancer therapeutic product candidates, including niraparib, we believe certain diagnostic tests or specific clinical criteria will allow us to identify cancer patients who will be more likely to respond to the drug. 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 certain of our product candidates, including niraparib. 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

Table of Contents

we expect, or may fail to keep the test on the market even if it is approved. Any such delay or failure could delay or prevent approval or adoption of niraparib, or other 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 collection and use of personal health data in the European Union is governed by the provisions of the EU Data Protection Directive, or the Directive. The Directive and the national implementing legislation of the EU Member States impose strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions concern the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. Data protection authorities from the different EU Member States may interpret the Directive and national laws differently and impose additional requirements, which add to the complexity of processing personal data in the EU.

Guidance on implementation and compliance practices are often updated or otherwise revised. For example, the EU Data Protection Directive prohibits the transfer of personal data to countries outside of the European Economic Area, or EEA, that are not considered by the European Commission to provide an adequate level of data protection. These countries include the United States. A recent judgment by the Court of Justice of the European Union determined the U.S.-EU Safe Harbor Framework, which was relied upon by many U.S. entities as a basis for transfer of personal data from the European Union to the U.S., to be invalid. U.S. entities therefore must use alternate procedures for such data transfer. In addition, the EU Data Protection Regulation, intended to replace the current Data Protection Directive, which will be officially adopted in the first quarter of 2016 and applicable two years after its publication in the Official Journal for the European Union, will introduce new data protection requirements in the EU and substantial fines for breaches of the data protection rules. The EU Data Protection Regulation will 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 data protection rules.

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.

Table of Contents

Risks Related to Our Dependence on Third Parties

We have no manufacturing facility, and we are dependent on a limited number of third-party manufacturers for the manufacture of VARUBI and our product candidates, as well as on a number of third parties for our supply chain. 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 ability to generate revenues from our approved products, our ability to obtain regulatory approval for our product candidates, and 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.

As our drug development pipeline matures and we continue to commercialize VARUBI and, if approved, our other product candidates, including niraparib and IV rolapitant, we will have a greater need for clinical study and commercial manufacturing capacity. We have limited 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. For example, 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, including niraparib and IV rolapitant, may require us to establish large-scale commercial manufacturing capabilities. If our contract manufacturers or other third parties fail to deliver VARUBI and our potential future products, including niraparib and IV rolapitant, 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 or our other potential future products.

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 immuno-oncology antibody product candidates, 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 similar foreign 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 or an equivalent foreign regulatory authority 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.

Table of Contents

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 drug products and product candidates. 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 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.

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 countries 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 you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies 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 and our ability to generate and grow revenues.

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 plan to continue to rely on third parties for the foregoing preclinical and clinical functions, our internal capacity to perform these functions is limited. Outsourcing these functions involves risks 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 have a limited number of employees, which limits the internal

Table of Contents

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, requires management time and focus, and could result in substantial delays in our development programs. 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 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 do so on commercially reasonable terms.

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, does not take approved actions, or otherwise fails to adequately protect our licensed patent rights, we may not obtain or maintain broad proprietary protection for niraparib. Similarly, under our agreement with AnaptysBio, during preclinical development of our antibody product candidates, 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, does not take approved actions, or otherwise fails to adequately protect our licensed patent rights, we may not obtain or maintain broad proprietary protection for antibody product candidates targeting PD-1, TIM-3 and LAG-3.

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 whether they 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

Table of Contents

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 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.

Table of Contents

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 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

Table of Contents

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 Annual Report on Form 10-K, 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;

- 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

Table of Contents

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;
- the timing of market entry relative to competitive products;
- the availability of alternative therapies;
- the price of VARUBI relative to alternative therapies, including generic versions of products that compete with our product;
- the 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 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 collectively able to exert significant control over matters subject to stockholder approval.

Table of Contents

Our executive officers, directors and their or our respective affiliates beneficially owned approximately 34.4% of our voting stock as of December 31, 2015. This group of stockholders has the potential ability to control us through their ownership position. Acting together, these stockholders may be able to determine the outcomes of certain matters requiring stockholder approval. For example, this group 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. We are required, under Section 404 of the Sarbanes-Oxley Act, to furnish an annual 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 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 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.

Table of Contents

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 December 31, 2015, we have 40,279,783 shares of common stock outstanding. Sales of a substantial number of shares of our common stock or other securities in the public market or in private placements 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 of 1933, or 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 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

Table of Contents

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 December 31, 2015, there were 1,437,159 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 411,571. 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.

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.

Table of Contents

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 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 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.

Table of Contents

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 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

As of December 31, 2015, our principal offices were located in a facility in Waltham, Massachusetts, where we leased office space totaling 70,900 square feet, which we use primarily for corporate functions. The term of the lease continues until June 30, 2017. We believe our facilities are adequate for our current needs. If we determine that additional or new facilities are needed in the future, we believe that sufficient options would be available to us on commercially reasonable terms.

ITEM 3. LEGAL PROCEEDINGS

We are not currently party to any material proceedings.

ITEM 4. MINE SAFETY DISCLOSURES

We are not an operator, and have no subsidiary that is an operator, of a coal or other mine.

Table of Contents

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information and Holders

Our common stock is traded on the NASDAQ Global Select Market under the symbol "TSRO." Trading of our common stock commenced on June 29, 2012, following the completion of our initial public offering. The following table sets forth, for the periods indicated, the high and low intraday sales prices of our common stock as reported on the NASDAQ Global Select Market.

	HIGH	LOW
Year Ended December 31, 2014:		
First quarter	$ 40.99	$ 24.37
Second quarter	$ 31.45	$ 22.15
Third quarter	$ 34.30	$ 25.06
Fourth quarter	$ 38.38	$ 23.00
Year Ended December 31, 2015:		
First quarter	$ 62.25	$ 36.14
Second quarter	$ 64.97	$ 50.55
Third quarter	$ 66.95	$ 38.14
Fourth quarter	$ 53.84	$ 38.01

On February 24, 2016, the last reported sale price of our common stock was $37.98 per share. As of the close of business on February 24, 2016, there were approximately 34 holders of record of our common stock. Because many of the common shares are registered in "nominee" or "street" names, we believe that the total number of beneficial owners is considerably higher.

Dividends

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other

factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Table of Contents

Performance Graph (1)

The following graph presents a comparison from June 28, 2012 through December 31, 2015 of cumulative total return on assumed investment of $100.00 in cash in our common stock, the NASDAQ Composite Index and the NASDAQ Biotechnology Index. Such returns are based on historical results and are not intended to suggest future performance. Data for the NASDAQ Composite Index and the NASDAQ Biotechnology Index assume reinvestment of dividends.

(1) This performance graph shall not be deemed "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities under that Section, and shall not be deemed incorporated by reference into any filing of TESARO, Inc. under the Securities Act of 1933, as amended.

Table of Contents

ITEM 6. SELECTED FINANCIAL DATA

The table below sets forth certain of our selected historical financial data at the dates and for the periods indicated. The selected historical statement of operations data presented below for the years ended December 31, 2013, 2014, and 2015 and the historical balance sheet data as of December 31, 2014 and 2015, have been derived from our audited consolidated financial statements, and should be read in conjunction with our audited consolidated financial statements and related notes that are included elsewhere in this Annual Report on Form 10-K. The historical statement of operations data for the years ended December 31, 2011 and 2012 and the historical balance sheet data as of December 31, 2011, 2012 and 2013 has been derived from financial statements not included in this Annual Report on Form 10-K.

All financial information presented has been consolidated and reflects the operations of TESARO, Inc. and its wholly-owned subsidiaries. Our historical results are not necessarily indicative of results expected in any future period.

The selected historical financial data presented in the table below should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and the related notes thereto, which are included elsewhere in this Annual Report on Form 10-K. The selected historical financial information in this section is not intended to replace our consolidated financial statements and the related notes thereto.

	Years Ended December 31,				
	2011	2012	2013	2014	2015
Statement of Operations Data:					
License revenue	$ —	$ —	$ —	$ —	$ 317
Expenses:					
Cost of sales - intangible asset amortization	—	—	—	—	268
Research and development	11,768	$ 47,200	75,725	118,425	155,390
Selling, general and administrative	3,158	6,715	14,780	23,935	78,701
Acquired in-process research and development	500	8,000	1,940	24,900	2,000
Total expenses	15,426	61,915	92,445	167,260	236,359
Loss from operations	(15,426)	(61,915)	(92,445)	(167,260)	(236,042)
Interest expense	—	—	—	(3,776)	(15,414)

Interest income	38	152	83	24	48
Other income (expense), net	(1,010)	—	—	—	—
Net loss	$ (16,398)	$ (61,763)	$ (92,362)	$ (171,012)	$ (251,408)
Net loss per share applicable to common stockholders - basic and diluted	$ (31.90)	$ (4.51)	$ (2.93)	$ (4.79)	$ (6.38)
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	514	13,696	31,559	35,739	39,387

	As of December 31,				
	2011	2012	2013	2014	2015
Balance Sheet Data:					
Cash and cash equivalents	$ 39,825	$ 125,445	$ 130,310	$ 256,861	$ 230,146
Working capital	38,835	114,902	121,916	234,231	189,810
Total assets	42,879	127,380	135,578	260,385	255,281
Convertible notes, net	—	—	—	111,964	121,325
Convertible preferred stock	64,348	—	—	—	—
Common stock and additional paid-in capital	305	202,798	302,650	474,566	688,792
Total stockholders' (deficit) equity	(25,068)	115,662	123,152	124,056	86,874

Table of Contents

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

We are an oncology-focused biopharmaceutical company dedicated to improving the lives of cancer patients. We have in-licensed and are developing several oncology-related product candidates, including rolapitant, niraparib, and the product candidates under our immuno-oncology platform.

On September 1, 2015, our first commercial product, VARUBI®, which is the oral formulation of rolapitant, was approved by the United States Food and Drug Administration, or FDA, for use 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. We commenced shipments of VARUBI to distributors in November 2015.

A summary description of our current products and product candidates is as follows:

- 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. We expect to submit a new drug application, or NDA, to the FDA for IV rolapitant 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. We currently have several ongoing clinical trials evaluating niraparib for the treatment of ovarian or breast cancers, and we expect to initiate further clinical trials of niraparib during 2016. We are also collaborating with various other organizations to evaluate niraparib in combination with other therapeutics for the treatment of various cancers. Based on research related to PARP inhibitors generally, we believe that niraparib may also be active in the treatment of several other tumor types. We expect top-line data from our NOVA and QUADRA trials of niraparib to become available during the second quarter of 2016, and we are currently planning to submit an NDA and an MAA for niraparib in the second half of 2016.

- Immuno-Oncology Platform: 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, for the discovery and development of antibodies for several immuno-oncology targets. We submitted an investigational new drug application, or IND, for our first immuno-oncology antibody, TSR-042, which targets PD-1, in December 2015, and

we will initiate a Phase 1 clinical trial of TSR-042 in the first quarter of 2016. As part of our collaboration with AnaptysBio, we received exclusive rights to monospecific antibody product candidates targeting PD-1, TIM-3, and LAG-3 and bi-specific antibody product candidates targeting PD-1/TIM-3, PD-1/LAG-3 and an additional bi-specific combination. In addition, we plan to evaluate our immuno-oncology anti-tumor agents, such as TSR-042, in combination preclinical pharmacology studies with niraparib and other anti-tumor agents.

We commenced business operations in May 2010. Our operations to date have been primarily focused on organizing and staffing our company, raising capital, identifying, acquiring and developing product candidates, undertaking preclinical studies and clinical trials, manufacturing activities related to our product candidates, and the commercialization of VARUBI. To date, we have recorded limited revenue from a license related to rolapitant and no revenues have been recorded related to sales of VARUBI, which we began to commercialize in the fourth quarter of 2015. For further discussion of our revenue recognition policy, see “Critical Accounting Policies and Significant Judgments and Estimates” below. 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 December 31, 2015, we had an accumulated deficit of $601.9 million. Our net losses were $251.4 million, $171.0 million, and $92.4 million for the years ended December 31, 2015, 2014 and 2013, respectively. We expect to incur significant expenses and operating losses for the foreseeable future. Overall, we expect 2016 operating expenses to increase over current levels as we incur increased costs related to niraparib and IV rolapitant, costs related to the immuno-oncology

Table of Contents

development activities under our collaboration with AnaptysBio, costs related to commercial activities associated with VARUBI, costs related to the advancement of clinical trial and other development activities under our current development programs, such as niraparib and the immuno-oncology activities under our collaboration with AnaptysBio, costs related to ongoing commercial activities, including our commercial sales force, executing marketing and promotional programs, and other commercialization costs associated with VARUBI, costs related to expanding our international operations, 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 acceptance of the submission of an NDA by the FDA related to niraparib, we would be obligated to make a $5.0 million milestone payment to Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., or Merck. If we obtain regulatory approval for any of our product candidates in addition to rolapitant, 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 $20.0 million to date, if specified regulatory and initial commercial sales milestones are achieved in the U.S. and Europe. This amount includes a $15.0 million milestone paid to OPKO in December 2015 which was triggered by our first commercial sale of VARUBI; we have recorded this amount as an intangible asset on the consolidated balance sheet. 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. 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. We are responsible for all preclinical, clinical, regulatory and other activities necessary to develop and commercialize rolapitant.

Rolapitant — Intravenous Formulation. We are developing a single dose IV formulation of rolapitant to address what we believe is the market need for this dosage form. If approved, this formulation will provide physicians with another

route of administering rolapitant, in addition to VARUBI, the oral formulation. We believe this formulation will alleviate certain concerns associated with payor pre-approval, logistics and pharmacy availability that are sometimes associated with oral formulations of drugs utilized by cancer patients. We plan to submit an NDA for the IV formulation of rolapitant 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 to date totaling $2.8 million. 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

Table of Contents

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, for which dosing was initiated in July 2013. In April 2015, planned enrollment was completed for the NOVA trial. We also commenced our QUADRA trial in March 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. We intend to initiate dosing in 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, in which the first patient was dosed in April 2014. We are also participating in several 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 Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in patients with triple negative breast cancer and patients with ovarian cancer. We intend to initiate dosing in 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 PD-1 (TSR-042), TIM-3 (TSR-022), and LAG-3 and bi-specific antibody product candidates targeting PD-1/TIM-3, PD-1/LAG-3 and an additional bi-specific combination. Under the 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, in 2014 we made up-front, non-creditable and non-refundable cash payments of $19.0 million to AnaptysBio. 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 paid $2.0 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 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. In 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. We initiated a Phase 1/2a dose escalation clinical trial of TSR-011 in cancer patients in November 2012. In October 2015, our Board of Directors determined to discontinue the development of TSR-011, and we notified Amgen of our intention to terminate the license agreement pursuant to the terms of the agreement. The license agreement with Amgen was terminated in January 2016. In connection with terminating the agreement, we expect the ongoing wind down of clinical and other activities related to TSR-011 to continue through 2016. Related costs are not expected to be material.

Public Offerings of Common Stock, Private Placements of Securities and Issuance of Convertible Notes. As of December 31, 2015, our principal source of liquidity was cash and cash equivalents, which totaled $230.1 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. 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

Table of Contents

Notes. 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 February 24, 2016, we entered into a Stock Purchase Agreement with certain accredited investors, pursuant to which we agreed to issue an aggregate of 4,404,658 shares of our common stock, at a price per share of $35.19 for an aggregate purchase price of approximately $155.0 million. This private placement transaction is subject to the satisfaction of certain closing conditions which we expect will occur prior to April 30, 2016, but no earlier than March 18, 2016, and is discussed in more detail under “Liquidity and Capital Resources – February 2016 Private Placement” below.

Financial Operations Overview

Revenue

To date, we have recorded limited revenue from a license related to rolapitant. No revenue has been recorded related to sales of any of our products, including VARUBI, which we began to commercialize in the fourth quarter of 2015. For further discussion of our revenue recognition policy, see “Critical Accounting Policies and Significant Judgments and Estimates” below. Our ability to generate revenue and become profitable depends upon our ability to successfully commercialize products, including any of our product candidates that we have in-licensed (rolapitant, niraparib, and products potentially resulting from our immuno-oncology collaboration with AnaptysBio) or other products or product candidates that we may in-license or acquire in the future. We expect to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, niraparib and IV rolapitant, continue commercial activities associated with VARUBI, continue to establish our commercial infrastructure, incur additional costs under our collaboration with AnaptysBio, incur costs associated with our anticipated growth, engage in pre-commercial activities relating to our product candidates, and incur increased interest expenses. Because of the numerous risks and uncertainties associated with product development and regulatory determinations, 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 when we begin to recognize revenue from sales of VARUBI and if we are able to generate revenues from the sale of our products, we may not become profitable. 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.

Research and Development Expenses

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

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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 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.

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

Table of Contents

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.

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, continue our manufacturing development and validation related to, and initiate additional investigative and collaborative studies related to, niraparib; continue clinical and other manufacturing, clinical and regulatory 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. 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 future ability to generate product revenues from any of these product candidates will be delayed or jeopardized. These occurrences would harm our business, financial condition and prospects, perhaps significantly, which would require us to alter our current operation plan and potentially delay, scale back, or discontinue the development or commercialization of one or more programs and/or other areas of the business in order to reduce our future expenses and continue to fund our remaining operations.

Table of Contents

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 years ended December 31, 2013, 2014 and 2015, respectively (in thousands).

	Year Ended December 31,		
	2013	2014	2015
Rolapitant Expenses			
Acquired in-process research and development	$ —	$ 5,000	$ —
Research and development	42,685	33,017	25,799
Rolapitant total	42,685	38,017	25,799
Niraparib Expenses			
Acquired in-process research and development	1,940	900	—
Research and development	15,742	46,694	60,982
Niraparib total	17,682	47,594	60,982
TSR-011 Expenses			
Acquired in-process research and development	—	—	—
Research and development	3,524	6,014	4,313
TSR-011 total	3,524	6,014	4,313
Immuno-Oncology Platform Expenses			
Acquired in-process research and development	—	19,000	2,000
Research and development	—	5,726	20,384
Immuno-Oncology Platform total	—	24,726	22,384
Personnel and Other Expenses	13,774	26,974	43,912
Total	$ 77,665	$ 143,325	$ 157,390

For further discussion of the changes in our research and development expenses with respect to the year ended December 31, 2015 and the corresponding period of 2014, see “Results of Operations — Comparison of the Year Ended December 31, 2015 to the Year Ended December 31, 2014 — Research and Development Expenses” below.

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 our commercial personnel, including our 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-commercial and commercial consulting, advertising, market research, 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.

Table of Contents

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. A portion of the interest expense on the Convertible Notes is non-cash expense relating to accretion of the debt discount and amortization of issuance costs.

Results of Operations

Comparison of the Year Ended December 31, 2015 to the Year Ended December 31, 2014

	Year Ended December 31,		Increase/
	2014	2015	(Decrease)
	(in thousands)		
License revenue	$ —	$ 317	$ 317
Expenses:			
Cost of sales - intangible asset amortization	—	268	268
Research and development	118,425	155,390	36,965
Selling, general and administrative	23,935	78,701	54,766
Acquired in-process research and development	24,900	2,000	(22,900)
Total expenses	167,260	236,359	69,099
Loss from operations	(167,260)	(236,042)	(68,782)
Other income (expense), net	(3,752)	(15,366)	(11,614)
Net loss	$ (171,012)	$ (251,408)	$ (80,396)

License Revenue. License revenue of $0.3 million during 2015 relates to our license agreement with Jiangsu Hengrui Medicine Co., Ltd., or Hengrui, pursuant to which Hengrui has licensed the rights to develop, manufacture and commercialize rolapitant in China, including Hong Kong and Macao. At December 31, 2015, we had received an up-front payment of $1.0 million and recorded $0.3 million of license revenue during the year ended December 31, 2015.

During the fourth quarter of 2015, and in connection with the launch of VARUBI, we shipped 6,170 units for stocking to distributors. The Wholesale Acquisition Cost, or WAC, which is the gross list price at which our customers purchase each unit of VARUBI, is $530 per unit, and we expect the average net sales price to TESARO (after accounting for all fees, rebates, chargebacks, and any other discounts or reserves) will be approximately 60% to 75%

of WAC on these units. We have not recognized product revenue during the year ended December 31, 2015 related to these shipments, as we have concluded that we did not meet the revenue recognition criteria under current accounting guidance. We anticipate recognizing revenue during 2016 on product sales once we have concluded that we have met all applicable revenue recognition criteria under current accounting guidance. For further discussion regarding our revenue recognition policy, see the "Critical Accounting Policies and Significant Judgments and Estimates" section below. As we have not recognized any product revenue, the corresponding costs of product sales have similarly not been recognized.

Cost of Sales - Intangible Asset Amortization. Cost of sales of $0.3 million for the year ended December 31, 2015 consists of amortization of the intangible asset recorded as a result of the $15.0 million milestone paid to OPKO upon the first commercial sale of VARUBI.

Research and Development Expenses. Research and development expenses were $155.4 million for the year ended December 31, 2015, compared to $118.4 million for the year ended December 31, 2014, an increase of $37.0 million. The increase was primarily due to higher expenses related to the development of our immuno-oncology platform, niraparib, and additional personnel, partially offset by lower expenses associated with the development of rolapitant and TSR-011. Significant changes resulting in this increase included:

- an increase of $14.7 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 a full year 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;

Table of Contents

- an increase of $14.3 million in costs associated with niraparib development activities, primarily related to increased costs of our ovarian cancer clinical trials, partially offset by lower costs relating to drug process development and manufacturing;

- an increase of $11.3 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

- a decrease of $7.2 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.

Inventory related costs of $1.9 million, $1.4 million and $5.1 million incurred prior to FDA approval of VARUBI were recorded as research and development expenses in our consolidated statements of operations and comprehensive loss for the years ended December 31, 2013, 2014 and 2015, respectively. We expect to use the remaining pre-commercialization inventory and materials through product sales over at least the next 24 months, and accordingly we would expect our cost of VARUBI product revenues to increase as a percentage of net sales of VARUBI in future periods.

In addition, stock-based compensation expense included in research and development expenses increased by $5.7 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 $78.7 million for the year ended December 31, 2015, compared to $23.9 million for the year ended December 31, 2014, an increase of $54.8 million. The increase was primarily due to increases of: $30.8 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; $15.8 million in professional and consulting fees and other expenses to support corporate operational, pre-commercialization and commercial market research, advertising and other activities; and $8.1 million in stock-based compensation expense.

Acquired In-Process Research and Development Expenses. We recorded $2.0 million in acquired in-process research and development expenses for the year ended December 31, 2015, comprised of two $1.0 milestones related to our immuno-oncology platform. We recorded $24.9 million in acquired in-process research and development expenses for the year ended December 31, 2014. This amount consisted of $19.0 million in total up-front payments under the agreement with AnaptysBio, a $5.0 million milestone payment to OPKO related to the acceptance of the oral rolapitant NDA for review by the FDA, and a $0.9 million milestone payment to Merck related to the niraparib program.

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 $11.6 million in the year ended December 31, 2015, due to there being a full year of expense related to the convertible notes in the 2015 period compared to three months of expense in the 2014 period.

Table of Contents

Comparison of the Year Ended December 31, 2014 to the Year Ended December 31, 2013

	Year Ended December 31,		Increase/
	2013	2014	(Decrease)
	(in thousands)		
Expenses:			
Research and development	$ 75,725	$ 118,425	$ 42,700
General and administrative	14,780	23,935	9,155
Acquired in-process research and development	1,940	24,900	22,960
Total expenses	92,445	167,260	74,815
Loss from operations	(92,445)	(167,260)	(74,815)
Other income (expense), net	83	(3,752)	(3,835)
Net loss	$ (92,362)	$ (171,012)	$ (78,650)

Revenues. We did not recognize any revenue for the years ended December 31, 2013 or 2014.

Research and Development Expenses. Research and development expenses were $118.4 million for the year ended December 31, 2014, compared to $75.7 million for the year ended December 31, 2013, an increase of $42.7 million. The increase was primarily due to higher expenses related to the development of niraparib and TSR-011, and our immuno-oncology platform, partially offset by lower expenses associated with the development of rolapitant. Significant changes resulting in this increase included:

- an increase of $31.0 million in costs associated with niraparib development activities, primarily related to the NOVA trial, which was initiated in July 2013, the BRAVO trial, which was initiated in April 2014, and costs relating to drug substance and drug product development and manufacturing as well as clinical supply distribution;

- an increase of $10.3 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;

- an increase of $8.2 million in costs associated with our immuno-oncology platform strategy and TSR-011 development activities; and

- a decrease of $9.7 million in costs associated with rolapitant development activities, due primarily to lower costs related to the recently completed oral rolapitant Phase 3 clinical trials, partially offset by increases in costs relating to regulatory filing fees and activities as well as IV rolapitant Phase 1 bioequivalence and other studies

In addition, stock-based compensation expense included in research and development expenses increased by $2.9 million, related to increased awards of employee stock options and higher grant-date fair values of those awards.

General and Administrative Expenses. General and administrative expenses were $23.9 million for the year ended December 31, 2014, compared to $14.8 million for the year ended December 31, 2013, an increase of $9.2 million. The increase was due primarily to increases of $4.8 million in salaries, benefits and other personnel-related costs related to additional hiring to support pre-commercialization activities and increased clinical activities; $3.3 million in professional and consulting fees and other expenses to support corporate operational and pre-commercialization activities; and $1.1 million in stock-based compensation expense, related to increased awards of employee stock options and higher average grant-date fair values of those awards.

Acquired In-Process Research and Development Expenses. We recorded $24.9 million in acquired in-process research and development expenses for the year ended December 31, 2014. This amount consisted of $19.0 million in total up-front payments related to the collaboration and exclusive license agreement and associated amendment with AnaptysBio, a $5.0 million milestone payment to OPKO related to the acceptance of the oral rolapitant NDA for review by the FDA and a $0.9 million milestone payment related to the initiation of the BRAVO trial in April 2014. We recorded $1.9 million in acquired in-process research and development expenses during the year ended December 31, 2013, representing a milestone payment made as a result of the first patient dosing in the NOVA trial, which occurred in July 2013.

Table of Contents

Other Income (Expense), Net. Other income (expense) for 2014 is primarily comprised of interest expense related to our 2014 issuance of $201.3 million aggregate principal of Convertible Notes. Interest income earned on cash and cash equivalents decreased from $83,000 in the year ended December 31, 2013 to $24,000 in the year ended December 31, 2014.

Liquidity and Capital Resources

Cash Flows

The following table presents a summary of the primary sources and uses of cash for the years ended December 31, 2013, 2014 and 2015 (in thousands):

	Year Ended December 31,		
	2013	2014	2015
Net cash provided by (used in):			
Operating activities	$ (84,888)	$ (117,485)	$ (194,531)
Investing activities	(2,340)	(25,911)	(19,805)
Financing activities	92,093	269,947	187,621
Increase (decrease) in cash and cash equivalents	$ 4,865	$ 126,551	$ (26,715)

Operating Activities. The use of cash in all periods resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital. The significant increases in cash used in operating activities for the years ended December 31, 2014 and 2015 were primarily due to increased external research and development expenses as we continued to progress the niraparib development program and the immuno-oncology platform and increased external expenses related to pre-commercial and other commercial activities related to the VARUBI approval and launch. Higher costs associated with increased employee headcount related to the VARUBI commercialization and expanded development 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 program.

Amounts recorded in the consolidated statements of operations as “Acquired in-process research and development” are included in the consolidated statements of cash flows as adjustments to reconcile net loss to net cash used in operating activities because these amounts are charged to expense as incurred in the respective periods, but the cash payments relating to these expenses are classified as investing activities in the consolidated statements of cash flows, as described below.

Investing Activities. Cash used in investing activities primarily consisted of the following amounts relating to the acquisition of product candidate licenses and milestone payments, which were recorded as acquired in-process research and development expense as incurred, except as noted:

- for the year ended December 31, 2013, a $1.9 million development milestone payment related to the niraparib program;

- for the year ended December 31, 2014, $19.0 million in total up-front payments for the immuno-oncology platform, a $5.0 million milestone payment for the rolapitant program and a $0.9 million milestone payment for the niraparib program; and

- for the year ended December 31, 2015, a $15.0 million commercial milestone payment to OPKO for the rolapitant program (recorded as an intangible asset), and $2.0 in milestone payments for the immuno-oncology platform.

Cash used in investing activities for the years ended December 31, 2013, 2014 and 2015 also included the use of $0.4 million, $1.0 million, and $2.3 million, respectively, for purchases of property and equipment.

Financing Activities. Cash provided by financing activities primarily consisted of the following amounts raised in issuances of equity and debt instruments:

- for the year ended December 31, 2013, net cash proceeds of $91.3 million (net of underwriting discounts and commissions and offering expenses) from a follow-on offering of common stock;

Table of Contents

- for the year ended December 31, 2014, net cash proceeds of $194.7 million (net of underwriting discounts and commissions and offering expenses) from the issuance of the Convertible Notes, partly offset by the use of $20.8 million in cash associated with the Capped Calls, as well as net cash proceeds of $94.2 million from a follow-on offering of common stock; and

- for the year ended December 31, 2015, net cash proceeds of $179.8 million from a follow-on offering of common stock.

Cash provided by financing activities during the years ended December 31, 2013, 2014 and 2015 also included $0.8 million, $1.9 million and $7.9 million, respectively, in proceeds from exercises of stock options under our 2010 Stock Incentive Plan and 2012 Omnibus Incentive Plan, and issuances of common stock under our 2012 Employee Stock Purchase Plan.

Operating Capital Requirements

We expect to incur significant expenses and operating losses for the foreseeable future. Overall, we expect 2016 operating expenses to increase over current levels as we incur increased costs related to IV rolapitant, costs related to the advancement of our clinical trials and other development activities under our current development programs, such as niraparib and the immuno-oncology activities under our collaboration with AnaptysBio, costs related to ongoing commercial activities, including our commercial sales force, executing marketing and promotional programs and other commercialization costs associated with VARUBI, costs related to expanding our international operations, 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.

We require additional capital for the continuing commercialization of VARUBI, further development and potential commercialization of our other product candidates, 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, and we may also need 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. On February 24, 2016, we entered into a Stock Purchase Agreement with certain accredited investors pursuant to which we agreed to issue an aggregate of 4,404,658 shares of our common stock, at a price per share of $35.19, for an aggregate purchase price of approximately $155.0 million. This private placement transaction is subject to the satisfaction of certain closing conditions and is discussed in more detail under “February 2016 Private Placement” below. Closing of this transaction is expected to occur by April 30, 2016. The funds that we expect to receive upon closing of the private placement, coupled with our existing cash and cash equivalents and the cash we expect to generate from sales of VARUBI, would be sufficient additional funds for us to meet our existing cash flow requirements and fund our existing operations at their currently planned levels through at least the 12 months following the filing of this Annual Report on Form 10-K. If this financing does

not timely close or any similar additional future funding is not obtained on a timely basis, we would be required to change our current operating plans to reduce our future expenses, which is within our control, in order to continue to meet our cash flow requirements and fund operations. In the event that we are unable to raise additional funds, we believe that at a reduced operating level, 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 through at least the 12 months following the filing of this Annual Report on Form 10-K.

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 and/or other areas of our business. 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.

Table of Contents

February 2016 Private Placement

On February 24, 2016, we entered into a Stock Purchase Agreement with certain accredited investors, or the Purchasers, including funds affiliated with three of our directors, or the Funds, pursuant to which we agreed to issue an aggregate of 4,404,658 shares of our common stock, or the Shares, at a price per share of $35.19, in a private placement transaction, or the Private Placement, in reliance on the exemption afforded by Section 4(a)(2) under the Securities Act of 1933, or the Securities Act, and Regulation D promulgated under the Securities Act. There were no placement agents used, or any underwriting discounts or commissions paid, in connection with the Private Placement. The price per share was calculated at the volume weighted average price for the 10-day period ending on February 22, 2016. The closing of the offering is subject to customary closing conditions, and expiration or early termination of any applicable waiting periods under the Hart-Scott-Rodino Act, and is expected to occur prior to the end of April 2016, but no earlier than March 18, 2016. If the closing has not occurred on or before September 30, 2016, the Stock Purchase Agreement may be terminated by us or any purchaser on a purchaser-by-purchaser basis. In addition, the agreement may be terminated on a purchaser-by-purchaser basis by mutual written agreement or upon uncured material breach.

Pursuant to the Stock Purchase Agreement, we also agreed to enter into an amendment to our Second Amended and Restated Investors' Rights Agreement, or the Existing IRA, with the Funds, and an Investor Agreement with Purchasers other than the Funds, in each case at or prior to the Closing. The amendment to the Existing IRA will extend to the Shares certain registration rights provided by the Existing IRA, including demand and piggyback registration rights, and will extend the term of those registration rights until three years following the date of the amendment to the Existing IRA. Under the Investor Agreement, TESARO will register the resale of the common stock issued in the private placement to the Purchasers who are a party to that agreement. Under the Investor Agreement, those Purchasers also will agree that their Shares will be subject to a lock-up restriction, such that those Purchasers will not, and will also cause their affiliates not to, without our prior approval, sell, transfer or otherwise dispose of the Shares until the earliest to occur of three months after the Closing or other specified events. In addition, pursuant to the terms of the Investor Agreement, the Purchasers will agree that the Shares will be subject to a standstill agreement, such that until the earliest to occur of May 29, 2017 or other specified events, neither such Purchasers nor their affiliates, will, without our written consent and subject to specified conditions, directly or indirectly, acquire more than 1% of any class of our securities, solicit proxies or consents or participate in such a solicitation, seek to control us or have called any meeting of our stockholders, make any proposal or public announcement regarding a tender or exchange offer for our securities or a fundamental transaction involving us, or undertake other specified actions.

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;

Table of Contents

- the attainment of milestones and our obligations to make milestone payments, royalty payments, or both to OPKO, Merck 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 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

The following table summarizes our contractual obligations as of December 31, 2015 (in thousands):

	Payments due by period				
	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Convertible Notes (a)	$ 235,966	$ 6,038	$ 12,075	$ 12,075	$ 205,778
Purchase commitments and other commitments	46,547	20,228	21,319	5,000	—
Operating lease obligations	3,496	2,345	1,151	—	—
Totals	$ 286,009	$ 28,611	$ 34,545	$ 17,075	$ 205,778

(a) See Note 7, "Convertible Notes", in the Notes to Financial Statements included in Part II, Item 8, "Financial Statements and Supplementary Data", of this Annual Report on Form 10-K for additional information. Amounts include both principal and interest.

Purchase and Other Commitments

Purchase commitments in the table above relate to agreements with certain vendors for the provision of services, including services related to commercial manufacturing, data management, clinical operation support and companion diagnostic development for which we are not contractually able to terminate for convenience and avoid any and all future obligations to the vendors. Certain agreements provide for termination rights subject to termination fees. Under such agreements, we are contractually obligated to make certain minimum payments to the vendors, mainly to reimburse the vendor for unrecoverable outlays incurred prior to cancellation; the exact amounts of which are dependent on the timing of termination and the exact terms of the relevant agreement and cannot be estimated with reasonable accuracy. In the table above, we have included our estimated commitments under such agreements as of December 31, 2015, assuming we do not terminate these agreements. These amounts do not represent our entire anticipated purchases in the future, but generally represent only our estimate of those items for which we are committed. The actual amounts we pay in the future to the vendors under such agreements may be less than the amounts shown in the table above.

Purchase commitments also include agreements to purchase goods or services that are enforceable and legally binding on us and that specify all significant terms, including: fixed or minimum quantities to be purchased; fixed, minimum or variable price provisions; and the approximate timing of the transaction. Such obligations are related principally to inventory purchase orders based on our current manufacturing needs and require significant lead times to be fulfilled by our vendors. Purchase commitments exclude agreements that are cancelable without penalty, including open purchase orders that represent authorizations to purchase rather than legally binding agreements. Other commitments relate principally to minimum royalty and milestone payments under certain licensing and collaboration agreements that we are obligated to pay even if we terminate such license agreements. Our license agreement with OPKO requires us to pay OPKO tiered royalties on the amount of annual net of rolapitant 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. However, in the table above, we have only

Table of Contents

included our minimum commitment to OPKO, which includes an annual minimum royalty payment of $2.5 million in each of the first five full calendar years of commercial sales of VARUBI.

As of December 31, 2015, we had several ongoing clinical studies in various clinical trial stages. Our most significant clinical trial expenditures are made to clinical research organizations, or CROs. Due to cancellation rights included in our contractual agreements with our CROs, we have not included any amounts related to our CRO contracts in the contractual obligations table above (other than those described in the preceding paragraph).

Our collaboration agreement with Myriad Genetics, Inc. allows us to terminate that agreement with proper written notice; however, we are required to pay any remaining unpaid milestones up to $5.5 million, which are included in the table above in the 1 to 3 years column, consistent with our product development expectations

The table above does not include a $4.0 million milestone owed to AnaptysBio in the first quarter of 2016. Our obligation to pay this milestone was triggered by the clearance of our IND for TSR-042, which occurred in January 2016.

Operating and Facility Lease Obligations

Operating lease obligations in the table above relate to operating leases for office facilities. We lease approximately 70,900 square feet of office space in Waltham, Massachusetts under a non-cancelable operating lease agreement. The term of the lease commenced April 1, 2013 and continues through June 30, 2017.

Product Licenses

In addition to the amounts set forth in the table above, we have certain obligations under licensing agreements with third parties that are contingent upon achieving various development, regulatory and commercial milestones. Pursuant to our license agreement with OPKO for the development and commercialization of rolapitant, we are required to make milestone payments to OPKO of up to an aggregate of $30.0 million if certain regulatory approvals and initial commercial sales milestones are achieved, of which $20.0 million has been paid as of December 31, 2015. Further, we are required to make additional milestone payments to OPKO of up to an aggregate of $85.0 million if specified levels of annual net sales of rolapitant are achieved. Pursuant to our license agreement with Merck for the development and commercialization of niraparib, we have made two milestone payments totaling $2.8 million to date, and we are required to make total milestone payments to Merck of up to $57.0 million in 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. Pursuant to our collaboration and exclusive license agreement and the associated amendment with AnaptysBio, we have made up-front, non-creditable and non-refundable cash payments of $19.0 million to AnaptysBio. 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 our four development programs, we will also be required to make milestone payments to AnaptysBio of up to $18.0 million if certain research and development milestone events are achieved, 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, and additional commercial milestone payments if specified levels of annual net sales of a product are attained. Finally, pursuant to the terms of each of these license agreements, when and if commercial sales of a product commence, we will pay royalties to our licensors on net sales of the respective products.

Technology Licenses

In October 2012, we entered into two license agreements with AstraZeneca UK Limited, under which we made aggregate upfront payments of $0.4 million. These agreements provide us with the exclusive right to certain methods of treating patients with PARP inhibitors solely with respect to niraparib. Under certain circumstances, we may be required to make milestone and royalty payments to AstraZeneca UK Limited based on the achievement of certain development and regulatory milestone events with regard to niraparib, and on net sales of niraparib. We have not included any amounts related to these agreements in the table above. We made milestone payments related to these agreements totaling $0.2 million and $0.1 million to AstraZeneca during the years ended December 31, 2013 and 2014, respectively, and no payments during the year ended December 31, 2015.

Table of Contents

Off-Balance Sheet Arrangements

As of December 31, 2015, we did not have any off-balance sheet arrangements as defined in Regulation S-K, Item 303(a)(4)(ii).

Critical Accounting Policies and Significant Judgments and Estimates

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, net product revenue 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.

While our significant accounting policies are described in more detail in the notes to our financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- CROs in connection with clinical studies;

- investigative sites in connection with clinical studies;

- vendors related to product manufacturing, development and distribution of clinical supplies;

- collaborator entities in connection with our collaboration agreements; and

- vendors in connection with preclinical development activities.

We record expenses related to clinical studies and manufacturing development activities based on our estimates of the services received and efforts expended pursuant to contracts with multiple CROs and manufacturing vendors that conduct and manage these activities on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of subjects and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed, enrollment of subjects, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrued or prepaid expense balance accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, we may report amounts that are too high or too low in any particular period. To date, there have been no material differences from our estimates to the amounts actually incurred.

Table of Contents

Stock-Based Compensation

We recognize compensation costs related to stock options, restricted stock units and restricted stock awards granted to employees based on the estimated fair value of the awards on the date of grant, net of estimated pre-vesting forfeitures. For awards with performance conditions the related compensation cost is recognized as an expense, starting when the milestone becomes probable of being met, over the remaining performance period. Described below is the methodology we utilize in measuring stock-based compensation expense. Following the consummation of our initial public offering, stock option, restricted stock units and restricted stock award fair values are determined utilizing the quoted market price of our common stock.

Since our inception in March 2010, we have applied the fair value recognition provisions of Financial Accounting Standards Board, or FASB, Accounting Standards Codification Topic 718, Compensation - Stock Compensation, or ASC 718. Determining the amount of stock-based compensation to be recorded requires us to estimate the fair value of a stock-based award as of its grant date. Stock-based compensation expense is recognized ratably over the requisite service period, which in most cases is the vesting period of the award. Estimating the fair value of stock-based awards requires us to make subjective assumptions. We use the Black-Scholes option pricing model to value our stock option awards. This valuation methodology requires us to make assumptions regarding the volatility of our common stock, the expected term of the stock option, the risk-free interest rate for a period that approximates the expected term of the stock option, and our expected dividend yield. Prior to June 2012, we were a privately-held company with a limited operating history and accordingly we utilized data from representative peer companies to estimate expected stock price volatility from our inception to our initial public offering. We selected peer companies from the biopharmaceutical industry with similar characteristics as us, including stage of product development, market capitalization and therapeutic focus. Since our initial public offering in June 2012, we have continued to use volatility data from a representative peer group, blended with our own actual volatility, to estimate expected stock price volatility, due to the limited public trading history of our common stock. To determine the expected term assumption, we use the simplified method as prescribed by U.S. Securities and Exchange Commission, or SEC, Staff Accounting Bulletin No. 107, Share-Based Payment, as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term of stock options granted to employees. We utilize a dividend yield of zero based on the fact that we have never paid cash dividends and have no current intention to pay cash dividends. The risk-free interest rate used for each stock option is based on the U.S. Treasury yield curve in effect at the time of grant for instruments with a similar expected term.

The following table presents the assumptions used in estimating the grant-date fair values of stock options granted during the years ended December 31, 2013, 2014 and 2015:

	Years Ended December 31,		
	2013	2014	2015
Dividend yield	—	—	—
Volatility	73% - 78%	69% - 76%	63% - 65%
Risk-free interest rate	1.07% - 2.05%	1.65% - 2.07%	1.35% - 1.95%

Expected term (years)	5.50 - 6.25	5.50 - 6.08	5.50 - 6.08

Stock-based compensation expense totaled $7.8 million, $11.7 million, and $25.9 million, respectively, for the years ended December 31, 2013, 2014 and 2015. As of December 31, 2015, we had $82.6 million of total unrecognized stock-based compensation expense, which is expected to be recognized over a weighted-average remaining vesting period of approximately 2.9 years. We expect stock-based compensation expense to increase in future periods due to expected increases in headcount and equity award grants, and the potential of increases in the market value of our common stock.

Under ASC 718, we are required to estimate the level of pre-vesting forfeitures expected to occur and record compensation expense only for those awards expected to vest. We estimate our forfeiture rate based on our actual forfeiture experience and accordingly have recorded expense net of forfeitures.

In-Process Research and Development

As part of our business strategy, we may in-license the rights to develop and commercialize product candidates. For each in-license transaction we evaluate whether we have acquired processes or activities along with inputs that would be sufficient to constitute a “business” as defined under GAAP. A “business” as defined under GAAP consists of inputs and processes applied to those inputs that have the ability to create outputs. Although businesses usually have outputs, outputs are not required for an integrated set of activities to qualify as a business. When we determine that we have not acquired sufficient processes or activities to constitute a business, any up-front payments, as well as pre-commercial milestone payments, are

Table of Contents

immediately expensed as acquired in-process research and development in the period in which they are incurred. Milestone payments made to third parties subsequent to regulatory approval are capitalized as intangible assets and amortized over the estimated remaining useful life of the related product.

Product Revenue

We are currently approved to sell VARUBI in the United States markets. We distribute our product principally through a limited number of specialty distributor and specialty pharmacy providers, collectively, our customers. Our customers subsequently resell our products to patients and health care providers. Separately, we have arrangements with certain payors and other third parties that provide for government-mandated and privately-negotiated rebates, chargebacks and discounts.

Revenues from product sales are recognized when persuasive evidence of an arrangement exists, delivery has occurred and title of the product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer has been reasonably assured and all performance obligations have been met and returns and allowances can be reasonably estimated. Product sales are recorded net of estimated rebates, chargebacks, discounts, co-pay assistance and other deductions as well as estimated product returns.

For the year ended December 31, 2015, we have concluded that we have not met certain of the above revenue recognition criteria, including the ability to estimate returns. One of the key elements to meet certain of the revenue recognition criteria is to have sufficient volume of activity which provides visibility into the distribution channel and the ultimate utilization of the product. We shipped our first units of VARUBI in November 2015, and due to the early stage of the product launch, we have determined that we do not have sufficient visibility to allow us to reliably make the various estimates necessary to recognize product sales and therefore cannot recognize revenue on the stocking shipments made to distributors during the fourth quarter of 2015. For those quantities shipped to our customers during 2015, the cost of the related units has been accounted for within Other Current Assets in the Consolidated Balance Sheet, and will be recorded to cost of goods sold upon recognition of the related revenue. We will continue to evaluate these criteria in future periods to determine if and when we have met the criteria for revenue recognition.

We expect to recognize product revenue during 2016 with respect to VARUBI once we have concluded that we have met all applicable revenue recognition criteria under current accounting guidance, which would include, among other criteria, a sufficient volume of activity and visibility into the distribution channel.

Intangible Assets

We maintain definite-lived intangible assets related to certain capitalized milestones. These assets are amortized on a straight-line basis over their remaining useful lives, which are estimated to be the remaining patent life. If our estimate of the product's useful life is shorter than the remaining patent life, then the shorter period is used. Amortization expense is recorded as a component of cost of sales in the consolidated statements of operations.

We assess our intangible assets for impairment if indicators are present or changes in circumstance suggest that impairment may exist. Events that could result in an impairment, or trigger an interim impairment assessment, include the receipt of additional clinical or nonclinical data regarding our drug candidate or a potentially competitive drug candidate, changes in the clinical development program for a drug candidate or new information regarding potential sales for the drug. In connection with each impairment assessment, we compare the fair value of the asset as of the date of the assessment with the carrying value of the asset on our consolidated balance sheet.

Recently Issued Accounting Pronouncements

For a discussion of new accounting pronouncements, see Note 2, "Summary of Significant Accounting Policies", in the Notes to Consolidated Financial Statements included in Part II, Item 8, "Financial Statements and Supplementary Data", of this Annual Report on Form 10-K.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates. As of December 31, 2014 and December 31, 2015, we had cash and cash equivalents of $256.9 million and $230.1 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

Table of Contents

United States interest rates, particularly because our investments are in short-term securities. Our securities are subject to interest rate risk and may fall in value if market interest rates increase.

Table of Contents

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

TESARO, Inc.

Consolidated Financial Statements

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Table of Contents

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

TESARO, Inc.

We have audited the accompanying consolidated balance sheets of TESARO, Inc. (the "Company") as of December 31, 2014 and 2015, and the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of TESARO, Inc. as of December 31, 2014 and 2015, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2 to the consolidated financial statements, the Company changed its presentation of debt issuance costs as a result of the adoption of the amendments to the FASB Accounting Standards Codification resulting from Accounting Standards Update No. 2015-03, Simplifying the Presentation of Debt Issuance Costs, effective December 31, 2015.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), TESARO, Inc.'s internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 26, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

February 26, 2016

Table of Contents

TESARO, Inc.

Consolidated Balance Sheets

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

	December 31, 2014	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 256,861	$ 230,146
Accounts receivable	—	679
Inventories	—	1,106
Other current assets	1,735	4,560
Total current assets	258,596	236,491
Intangible assets, net	—	14,732
Property and equipment, net	1,022	2,779
Restricted cash	—	500
Other assets	767	779
Total assets	$ 260,385	$ 255,281
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 6,089	$ 8,019
Accrued expenses	16,750	36,628
Deferred revenue, current	—	500
Other current liabilities	1,526	1,534
Total current liabilities	24,365	46,681
Convertible notes, net	111,964	121,325
Deferred revenue, non-current	—	288
Other non-current liabilities	—	113
Total liabilities	136,329	168,407
Commitments and contingencies (Notes 7 and 12)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at both December 31, 2014 and December 31, 2015; no shares issued or outstanding at both December 31, 2014 and December 31, 2015	—	—
	4	4

Common stock, $0.0001 par value; 100,000,000 shares authorized at both December 31, 2014 and December 31, 2015; 36,110,082 and 40,279,783 shares issued and outstanding at December 31, 2014 and December 31, 2015, respectively		
Additional paid-in capital	474,562	688,788
Accumulated deficit	(350,510)	(601,918)
Total stockholders' equity	124,056	86,874
Total liabilities and stockholders' equity	$ 260,385	$ 255,281

See accompanying notes to consolidated financial statements.

Table of Contents

TESARO, Inc.

Consolidated Statements of Operations and Comprehensive Loss

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

	Years Ended December 31,		
	2013	2014	2015
License revenue	$ —	$ —	$ 317
Expenses:			
Cost of sales – intangible asset amortization	—	—	268
Research and development	75,725	118,425	155,390
Selling, general and administrative	14,780	23,935	78,701
Acquired in-process research and development	1,940	24,900	2,000
Total expenses	92,445	167,260	236,359
Loss from operations	(92,445)	(167,260)	(236,042)
Interest expense	—	(3,776)	(15,414)
Interest income	83	24	48
Net loss	$ (92,362)	$ (171,012)	$ (251,408)
Net loss per share applicable to common stockholders - basic and diluted	$ (2.93)	$ (4.79)	$ (6.38)
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	31,559	35,739	39,387
Comprehensive loss	$ (92,362)	$ (171,012)	$ (251,408)

See accompanying notes to consolidated financial statements.

Table of Contents

TESARO, Inc.

Consolidated Statements of Stockholders' Equity

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

	Common Stock Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2012	27,136,329	$ 3	$ 202,795	$ (87,136)	$ 115,662
Issuance of common stock, net of issuance costs of $6,392	5,428,000	—	91,312	—	91,312
Issuance of common stock resulting from exercise of stock options	162,480	—	634	—	634
Issuance of common stock resulting from Employee Stock Purchase Plan	7,831	—	147	—	147
Issuance of common stock as payment of Board of Directors fees in lieu of cash	4,368	—	253	—	253
Stock-based compensation expense	—	—	7,506	—	7,506
Net loss	—	—	—	(92,362)	(92,362)
Balance at December 31, 2013	32,739,008	$ 3	$ 302,647	$ (179,498)	$ 123,152
Issuance of common stock, net of issuance costs of $6,601	3,200,000	1	94,198	—	94,199
Issuance of common stock resulting from exercise of stock options, net of shares withheld for taxes	159,747	—	1,630	—	1,630
Issuance of common stock resulting from Employee Stock Purchase Plan	9,845	—	249	—	249
Cancellation of unvested restricted stock	(8,929)	—	—	—	—
Issuance of common stock as payment of Board of Directors fees in lieu of cash	10,411	—	274	—	274
Conversion option of convertible notes - net of issuance costs of $2,859	—	—	84,984	—	84,984
Capped call options associated with convertible notes	—	—	(20,829)	—	(20,829)
Stock-based compensation expense	—	—	11,409	—	11,409
Net loss	—	—	—	(171,012)	(171,012)

Balance at December 31, 2014	36,110,082	$ 4	$ 474,562	$ (350,510)	$ 124,056
Issuance of common stock, net of issuance costs of $11,752	3,755,000	—	179,753	—	179,753
Issuance of common stock resulting from exercise of stock options	382,580	—	7,930	—	7,930
Issuance of common stock resulting from Employee Stock Purchase Plan	20,601	—	830	—	830
Issuance of common stock resulting from the vesting of restricted stock units, net of shares withheld for taxes	8,091	—	(201)	—	(201)
Issuance of common stock as payment of Board of Directors fees in lieu of cash	3,429	—	266	—	266
Stock-based compensation expense	—	—	25,648	—	25,648
Net loss	—	—	—	(251,408)	(251,408)
Balance at December 31, 2015	40,279,783	$ 4	$ 688,788	$ (601,918)	$ 86,874

See accompanying notes to consolidated financial statements.

Table of Contents

TESARO, Inc.

Consolidated Statements of Cash Flows

(all amounts in 000's)

	Years Ended December 31,		
	2013	2014	2015
Operating activities			
Net loss	$ (92,362)	$ (171,012)	$ (251,408)
Adjustments to reconcile net loss to net cash used in operating activities:			
Acquired in-process research and development	1,940	24,900	2,000
Depreciation & amortization expense	179	349	1,037
Stock-based compensation expense	7,759	11,683	25,914
Non-cash interest expense	—	2,249	9,360
Loss on disposal of property and equipment	—	80	—
Changes in operating assets and liabilities:			
Accounts receivable	—	—	(679)
Inventories	—	—	(1,106)
Other assets	(3,112)	2,327	(2,128)
Accounts payable	(1,301)	4,220	1,924
Accrued expenses	1,996	6,209	19,646
Deferred revenues	—	—	788
Other liabilities	13	1,510	121
Net cash used in operating activities	(84,888)	(117,485)	(194,531)
Investing activities			
Acquisition of product candidate and technology licenses and milestone payments	(1,940)	(24,900)	(17,000)
Purchase of property and equipment	(400)	(1,011)	(2,305)
Change in restricted cash	—	—	(500)
Net cash used in investing activities	(2,340)	(25,911)	(19,805)
Financing activities			
Proceeds from issuance of convertible notes, net of issuance costs	—	194,698	—
Purchase of capped call options	—	(20,829)	—
Proceeds from sale of common stock, net of issuance costs	91,312	94,199	179,753
Proceeds from exercise of stock options	634	1,663	7,239
Proceeds from issuance of common stock under Employee Stock Purchase Plan	147	249	830
Payment of minimum tax withholdings on share-based awards	—	(33)	(201)

Net cash provided by financing activities	92,093	269,947	187,621
Increase/(decrease) in cash and cash equivalents	4,865	126,551	(26,715)
Cash and cash equivalents at beginning of period	125,445	130,310	256,861
Cash and cash equivalents at end of period	$ 130,310	$ 256,861	$ 230,146
Non-cash investing and financing activities			
Stock option exercise proceeds receivable as of period end	$ —	$ —	$ 691
Purchase of property and equipment - cash not paid as of period end	$ —	$ —	$ 238
Supplemental disclosure of cash flow information			
Cash paid for interest	$ —	$ —	$ 6,071

See accompanying notes to consolidated financial statements.

Table of Contents

TESARO, Inc.

Notes to Consolidated Financial Statements

1. Nature of Business

The Company

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, commercializes 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 recognized 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, VARUBI® (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 commenced shipments of VARUBI during the fourth quarter of 2015.

Public Offerings of Common Stock

In March 2013, the Company sold 5,428,000 shares of common stock in an underwritten public offering pursuant to a registration statement on Form S-1, at a price of $18.00 per share, resulting in net proceeds of approximately $91.3 million, which is net of underwriting discounts and commissions and offering expenses.

In February 2014, the Company sold 3,200,000 shares of common stock in an underwritten public offering pursuant to an automatic shelf registration statement on Form S-3, at a price of $31.50 per share, resulting in net proceeds of approximately $94.2 million, which is net of underwriting discounts and commissions and offering expenses.

In March 2015, the Company sold 3,755,000 shares of common stock, in an underwritten public offering pursuant to an automatic shelf registration statement on Form S-3, at a price of $51.00 per share, resulting in net proceeds of approximately $179.8 million, which is net of underwriting discounts and commissions and offering expenses.

Liquidity

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, and 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 products and 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. On February 24, 2016, the Company entered into a Stock Purchase Agreement with certain accredited investors, pursuant to which the Company agreed to issue an aggregate of 4,404,658 shares of its common stock, at a price per share of $35.19 for an aggregate purchase price of approximately $155.0 million. This private placement transaction is subject to the satisfaction of certain closing conditions and is discussed in more detail in Note 15, “Subsequent Event”. The Company expects that closing of this financing will occur by April 30, 2016, however, there can be no assurances that it will close. Management intends to fund 2016 and future operations through the proceeds from this financing and additional public or private equity or debt offerings and may seek additional capital through arrangements with strategic partners or from other sources. If such funding is not obtained on a timely basis, the Company would be required to change its current operating plans to reduce its future expenses, which is

Table of Contents

within its control, in order to continue to fund operations, at such reduced levels through at least March 2017. See Note 15, “Subsequent Event”.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company’s 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 consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States, or GAAP. Certain amounts in the prior period financial statements have been reclassified to conform to the presentation of the current period financial statements. These reclassifications had no effect on the previously reported net loss.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment, which is the business of developing and commercializing safer and more effective oncology-focused therapeutics.

Use of Estimates

The preparation of 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, net product revenues, stock-based compensation expense and its intangible asset and related amortization. Significant estimates in these consolidated financial statements include estimates made in connection with accrued research and development expenses, stock-based compensation expense, revenue, valuation of convertible notes, intangible assets and related amortization. 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.

Concentrations of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash and cash equivalents. The Company maintains its cash and cash equivalent balances primarily in the form of money market fund accounts with financial institutions that management believes are creditworthy. The Company's investment policy includes guidelines on the quality of the institutions and financial instruments and defines allowable investments that the Company believes minimizes the exposure to concentration of credit risk. The Company has no financial instruments with off-balance-sheet risk of loss.

Revenue Recognition

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.

Table of Contents

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 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.

In July 2015, the Company entered into a license agreement with Jiangsu Hengrui Medicine Co., Ltd., or Hengrui, pursuant to which Hengrui 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 $0.3 million of license revenue related to a $1.0 million up-front payment under this arrangement during the year ended December 31, 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 Hengrui. 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.

Product Revenue

Revenues from product sales are recognized when persuasive evidence of an arrangement exists, delivery has occurred and title of the product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer has been reasonably assured and all performance obligations have been met and returns and allowances can be reasonably estimated. Product sales are recorded net of estimated rebates, chargebacks, discounts, co-pay assistance and other deductions as well as estimated product returns. The Company has not yet recorded any product revenue, as it has not yet concluded that it meets revenue recognition criteria under current accounting guidance.

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.

Restricted Cash

Restricted cash consists of cash balances held as collateral for the Company’s employee credit card program.

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

Table of Contents

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 at December 31, 2014 and 2015 and indicates the fair value hierarchy of the valuation inputs utilized to determine such fair value (in thousands):

		December 31, 2014			
Description	Balance Sheet Classification	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	$ —	$ —

		December 31, 2015			
Description	Balance Sheet Classification	Total	Level 1	Level 2	Level 3
Assets:					
Money market funds	Cash and cash equivalents	$ 224,885	$ 224,885	$ —	$ —
Total assets		$ 224,885	$ 224,885	$ —	$ —

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

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 December 31, 2015, the carrying value of the Convertible Notes was $121.3 million, net of unamortized discount and debt issuance costs and the fair value of the principal amount was

$338.8 million. The Convertible Notes are discussed in more detail in Note 7, “Convertible Notes.”

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets. Leasehold improvements are amortized over the economic life of the asset or the remaining lease term, whichever is shorter. Maintenance and repairs are expensed as incurred. The following estimated useful lives were used to depreciate the Company’s assets:

	Estimated Useful Life
Furniture and fixtures	5 years
Computer equipment and software	3 years
Manufacturing equipment	7 years
Leasehold improvements	Shorter of the useful life or the remaining lease term

Upon retirement or sale, the cost of the disposed asset and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is recognized in income.

The Company reviews long-lived assets when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparison of an asset’s book value to the estimated undiscounted future net cash flows that the asset is expected to generate. If the estimated future undiscounted net cash flows are less than the book value, the asset is considered to be impaired, and the impairment loss to be recognized in income is

Table of Contents

measured as the amount by which the book value of the asset exceeds its fair value, which is measured based on the estimated discounted future net cash flows that the asset is expected to generate. The Company recognized approximately $0.1 million of loss on the disposal of certain equipment during the year ended December 31, 2014. No other impairment losses have been recorded through December 31, 2015.

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 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 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. Certain clinical development costs incurred by the Company with respect to its niraparib program are reimbursed as part of a collaborative research agreement with Merck. Cost-sharing amounts received by the Company are recorded as a reduction to 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 pre-commercial milestone payments, are immediately expensed as acquired in-process research and development in the period in which they are incurred, provided that the new drug compound 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. Milestone payments made to third parties subsequent to regulatory approval are capitalized as intangible assets and amortized over the estimated remaining useful life of the related product. Royalties owed on sales of the products licensed pursuant to the agreements are expensed in the period the related revenues are recognized.

Comprehensive Loss

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss was equal to net loss for all periods presented.

Income Taxes

The Company accounts for income taxes under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of

Table of Contents

existing assets and liabilities and their respective tax bases using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Tax benefits are recognized when it is more likely than not that a tax position will be sustained during an audit. Deferred tax assets are reduced by a valuation allowance if current evidence indicates that it is considered more likely than not that these benefits will not be realized.

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 option award at its grant date using the Black-Scholes option pricing model. The fair value of each restricted stock or restricted stock unit award is equal to the closing market price of the Company's common stock on the grant date. 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.

Inventory

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. 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. 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. The determination of whether inventory costs will be realizable requires estimates by management and if actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required which would be recorded as a cost of product revenues in the consolidated statements of operations.

Intangible Assets

The Company maintains definite-lived intangible assets related to certain capitalized milestones. These assets are amortized on a straight-line basis over their remaining useful lives, which are estimated to be the remaining patent life. If the Company's estimate of the product's useful life is shorter than the remaining patent life, then the shorter

period is used. Amortization expense is recorded as a component of cost of sales in the consolidated statements of operations.

The Company assesses its intangible assets for impairment if indicators are present or changes in circumstance suggest that impairment may exist. Events that could result in an impairment, or trigger an interim impairment assessment, include the receipt of additional clinical or nonclinical data regarding our drug candidate or a potentially competitive drug candidate, changes in the clinical development program for a drug candidate, or new information regarding potential sales for the drug. In connection with any interim impairment assessment, the fair value of the asset as of the date of the assessment is compared with the carrying value of the asset on the consolidated balance sheet.

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, 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.

Table of Contents

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):

	Years Ended December 31,		
	2013	2014	2015
Outstanding stock awards	2,853	3,742	5,938
Unvested restricted stock	102	4	—
Shares issuable upon conversion of Convertible Notes	—	—	492
	2,955	3,746	6,430

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 7, "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 December 31, 2015.

New Accounting Pronouncements - Recently Adopted

In April 2015, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or 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 adopted this ASU at December 31, 2015, and has reclassified all prior periods to be consistent with the requirements outlined in the ASU. As a result, as of December 31, 2014, and December 31, 2015, the Company reclassified $3.5 million and $2.9 million, respectively, of net debt issuance costs from other assets to a reduction of the Convertible Notes in its consolidated balance sheets.

In November 2015, the FASB issued ASU No. 2015-17, Balance Sheet Classification of Deferred Taxes. This ASU requires entities to present deferred tax assets and deferred tax liabilities as noncurrent in a classified balance sheet. This ASU is effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period, and entities are permitted to apply either prospectively or retrospectively; early adoption is permitted. The Company adopted this ASU at December 31, 2015, on a prospective basis (prior periods were not retrospectively adjusted), and the adoption of this guidance did not have a material impact on its consolidated financial statements.

New Accounting Pronouncements - Recently Issued

In May 2014, the FASB issued 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

Table of Contents

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 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. If this standard had been adopted as of December 31, 2015, the Company believes that it would have concluded there was not substantial doubt about its ability to continue as a going concern. However, the Company faces certain risks and uncertainties, as further described in Note 1. "Nature of Business", that would have affected this analysis.

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.

Table of Contents

3. Inventories

The following table presents inventories (in thousands):

	December 31,	
	2014	2015
Raw materials	$ —	$ 364
Work in process	—	83
Finished goods	—	659
Total inventories	$ —	$ 1,106

We began capitalizing inventory during the year ended December 31, 2015 in connection with the FDA's approval of VARUBI, as the related costs were expected to be recoverable through the commercialization of the product.

4. Intangible Assets

The following table presents intangible assets (in thousands):

	December 31,		
	2014	2015	Estimated useful life
Intangible asset - OPKO milestone	$ —	$ 15,000	8 Years
Less accumulated amortization	—	(268)	
Total intangible asset, net	$ —	$ 14,732	

The Company recorded $0.3 million in amortization expense related to this intangible asset during the year ended December 31, 2015. Estimated future amortization expense for intangible assets as of December 31, 2015 is as follows (in thousands):

	Total
2016	$ 1,855
2017	1,855
2018	1,855
2019	1,855
2020	1,855
Thereafter	5,457
	$ 14,732

Table of Contents

5. Property and Equipment

The following table presents property and equipment, at cost, and related accumulated depreciation (in thousands):

	December 31,	
	2014	2015
Furniture and fixtures	$ 821	$ 1,547
Computer equipment and software	672	2,113
Leasehold improvements	115	350
Manufacturing equipment	—	124
	1,608	4,134
Less accumulated depreciation and amortization	(586)	(1,355)
Total property and equipment, net	$ 1,022	$ 2,779

Total depreciation expense amounted to $179,000, $349,000 and $769,000 for the years ended December 31, 2013, 2014 and 2015, respectively.

6. Accrued Expenses

The following table presents the components of accrued expenses (in thousands):

	December 31,	
	2014	2015
Research and development	$ 11,433	$ 23,048
Salaries, bonuses and other compensation	4,012	9,634
Sales and marketing	294	1,747
Professional services	529	1,021
Other accrued expenses	482	1,178

Total accrued expenses	$ 16,750	$ 36,628

7. 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 Convertible Notes. The Company received net proceeds of $194.7 million from the sale of the Convertible Notes, after deducting discounts, commissions and other expenses of $6.6 million. 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, as described below.

The Convertible Notes are governed by the terms of a Senior Debt Securities Indenture, as supplemented by the First Supplemental Indenture relating to the Convertible Notes, collectively the Indenture, between the Company and U.S. Bank National Association, as trustee. 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, which represents a premium of approximately 35% over the last reported sale price of the Company's common stock on September 23, 2014.

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

Table of Contents

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, 2015 (and only during such calendar quarter), if the closing sale price of the Company's common stock for at least 20 trading 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.

On or after April 1, 2021 until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert all or any portion of their Convertible Notes, in multiples of $1,000 principal amount, at the option of the holder regardless of the foregoing circumstances.

If a make-whole adjustment event, as described in the Indenture, occurs and a holder elects to convert its Convertible Notes in connection with such make-whole adjustment event, such holder may be entitled to an increase in the conversion rate as described in the Indenture.

The Company may not redeem the Convertible Notes prior to the maturity date and no "sinking fund" is provided for the Convertible Notes, which means that the Company is not required to periodically redeem or retire the Convertible Notes. Upon the occurrence of certain fundamental changes involving the Company, holders of the Convertible Notes may require the Company to repurchase for cash all or part of their Convertible Notes at a repurchase price equal to 100% of the principal amount of the Convertible Notes to be repurchased, plus accrued and unpaid interest.

The Indenture does not contain any financial covenants or restrictions on the payments of dividends, the incurrence of indebtedness or the issuance or repurchase of securities by the Company or any of its subsidiaries.

The terms of the Indenture provide the Company with the option to settle the Convertible Notes in cash, common stock, or a combination of cash and common stock. As a result, in accordance with Accounting Standards Codification, or ASC, 470-20, Debt with Conversion and Other Options, the Company separately accounts for the

liability and equity components of the Convertible Notes by allocating the principal between the liability component and the embedded conversion option, or equity component. Based on market data available for publicly traded, senior, unsecured corporate bonds issued by companies in the same industry and with similar maturity, the Company estimated the implied interest rate, assuming no conversion option. Assumptions used in the estimate represent what market participants would use in pricing the liability component, including market interest rates, credit standing, and yield curves, all of which are defined as Level 2 observable inputs. The estimated implied interest rate was applied to the Convertible Notes, which resulted in a fair value of the liability component of $113.4 million upon issuance, calculated as the present value of implied future payments based on the $201.3 million aggregate principal amount. The equity component of the Convertible Notes was recognized as a debt discount, recorded in additional paid-in capital, and represents the difference between the aggregate principal of the Convertible Notes and the fair value of the Convertible Notes without conversion option on their issuance date. The debt discount is amortized to interest expense using the effective interest method over seven years, or the life of the Convertible Notes. The equity component is not remeasured as long as it continues to meet the conditions for equity classification.

Table of Contents

The Company's outstanding convertible note balances at December 31, 2015 consisted of the following (in thousands):

	December 31, 2015
Liability component	
Principal	$ 201,250
Less: debt discount and issuance costs, net	(79,925)
Net carrying amount	$ 121,325
Equity component	$ 87,843

In connection with the issuance of the Convertible Notes, the Company incurred issuance costs, primarily consisting of underwriting, legal and other professional fees, which the Company allocated to the liability and equity components in a manner consistent with the allocation of the principal, as described above. Of the total $6.6 million of debt issuance costs, $2.9 million were allocated to the equity component and recorded as a reduction to additional paid-in capital and $3.7 million were allocated to the liability component and recorded as a reduction in the carrying amount of the convertible note. The portion allocated to the liability component is amortized to interest expense over the expected life of the Convertible Notes using the effective interest method.

The Company determined the expected life of the debt was equal to the seven year contractual term of the Convertible Notes. As of December 31, 2015, the carrying value of the Convertible Notes was $121.3 million and the fair value of the Convertible Notes approximated $338.8 million. The effective interest rate on the liability component is 12.9%. The following table sets forth total interest expense recognized related to the Convertible Notes during the year ended December 31, 2015 (in thousands):

	Year Ended December 31, 2015
Contractual interest expense	$ 6,054
Amortization of debt discount	8,697
Amortization of debt issuance costs	663
Total interest expense	$ 15,414

The Company has evaluated the Indenture for derivatives pursuant to ASC 815, Derivatives and Hedging, and identified an embedded derivative that requires bifurcation as the feature is not clearly and closely related to the host instrument. The embedded derivative is a default provision, which could require additional interest payments. The Company has determined that the fair value of this embedded derivative was nominal as of December 31, 2015.

In conjunction with the offering of the Convertible Notes, the Company entered into privately-negotiated Capped Calls with certain counterparties. Each Capped Call is an integrated instrument consisting of a call option on the Company's common stock purchased by the Company from the counterparties with an exercise price equal to the conversion price of $35.13 per share for the underlying number of shares and a cap component that incorporates a cap price of $45.54 per share. The cap component is economically equivalent to a call option sold by the Company to the counterparties for the underlying number of shares with an exercise price of $45.54 per share. As an integrated instrument, the settlement of the Capped Calls coincides with the maturity date of the Convertible Notes. The aggregate cost of the Capped Calls was $20.8 million and was recorded in stockholders' equity and will not be remeasured.

8. Stockholders' Equity

As of December 31, 2015, the authorized capital stock of the Company consisted of 10,000,000 shares of preferred stock and 100,000,000 shares of common stock, both with a par value of $0.0001, of which no shares of preferred stock were issued or outstanding and 40,279,783 shares of common stock were issued and outstanding.

Preferred Stock

The Company's certificate of incorporation authorizes its board of directors to issue preferred stock from time to time in one or more series. The rights, preferences, restrictions, qualifications and limitations of such stock are determined by the board of directors.

Table of Contents

Common Stock

In March 2013, the Company sold 5,428,000 shares of common stock, in an underwritten public offering at a price to the public of $18.00 per share, resulting in gross proceeds of approximately $97.7 million. Net proceeds to the Company after deducting fees, commissions and other expenses related to the offering were approximately $91.3 million. The shares were issued pursuant to a registration statement on Form S-1.

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.

The holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders of the Company. Subject to the preferences that may be applicable to any outstanding shares of preferred stock, the holders of common stock are entitled to receive ratably such dividends, if any, as may be declared by the Company's board of directors.

9. Stock-Based Compensation

The following table presents stock-based compensation expense as reflected in the Company's consolidated statements of operations and comprehensive loss (in thousands):

	Years Ended December 31,		
	2013	2014	2015
Research and development	$ 2,034	$ 4,954	$ 11,082
General and administrative	5,725	6,729	14,832
Total stock-based compensation expense	$ 7,759	$ 11,683	$ 25,914

The Company maintains several equity compensation plans, including the TESARO, Inc. 2012 Omnibus Incentive Plan, or the 2012 Incentive Plan, the TESARO, Inc. 2010 Stock Incentive Plan, or the 2010 Incentive Plan, the TESARO, Inc. 2015 Non-Employee Director Stock Incentive Plan, or the 2015 Director Plan, and the TESARO, Inc. 2012 Employee Stock Purchase Plan, or the 2012 ESPP. Terms of stock award agreements, including vesting requirements, are determined by the board of directors, subject to the provisions of the individual plans. To date, awards granted to employees by the Company generally vest either monthly over four years, or 25% one year from the vesting start date and 75% in equal installments over the subsequent thirty-six (36) months, and are exercisable from the date of grant for a period of ten years.

2012 Omnibus Incentive Plan

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 (which is an additional 6,857 shares) plus that 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. Each year starting with 2014, the number of shares available for grants of awards under the 2012 Incentive Plan will be 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, 2015, and 2016, the number of shares authorized for issuance under the 2012 Incentive Plan was increased by 1,309,560 shares, 1,444,403 shares, and 1,611,191 shares, respectively. In addition, 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

Table of Contents

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. As of December 31, 2015, there were 1,437,159 shares available for grant under the 2012 Incentive Plan, prior to taking into account the additional shares authorized for issuance as of January 1, 2016, as described above.

2010 Stock Incentive Plan

In connection with the Company's formation, the Company adopted the 2010 Incentive Plan, under which it was authorized to grant stock-based awards to purchase up to 1,981,130 shares of common stock as of January 1, 2012. As of April 27, 2012, the Company ceased making awards under the 2010 Incentive Plan and the remaining 6,857 shares available for future grants were added to the total number of shares reserved for issuance under the 2012 Incentive Plan. For options granted under the 2010 Incentive Plan, the exercise price equaled the estimated fair value of the common stock as determined by the board of directors on the date of grant. As of December 31, 2015, there are no shares available for grant under the 2010 Incentive Plan.

2015 Director Plan

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. As of December 31, 2015, there were 411,571 shares available for grant under the 2015 Director Plan.

Restricted Common Stock

The Company records stock-based compensation expense for common stock subject to repurchase, or restricted common stock grants, based on the grant date intrinsic value for employees. The Company recorded stock-based compensation expense of $669,000, $116,000 and $1,000, respectively, for the years ended December 31, 2013, 2014 and 2015 associated with restricted common stock grants. The total for the years ended December 31, 2013 and 2014 includes $646,000 and $96,000, respectively, related to accounting for awards held by a non-employee consultant.

There were no grants of restricted stock during the years ended December 31, 2013, 2014 and 2015. The total grant date fair value of restricted stock that vested during the years ended December 31, 2013, 2014 and 2015 was $25,000, $21,000, and $2,000, respectively. At December 31, 2015, there was no unrecognized compensation cost related to unvested restricted stock.

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	Weighted-average remaining contractual term (years)	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2014	3,726,329	$ 18.82	8.1	$ 69,176
Granted	2,908,452	54.32		
Exercised	(382,580)	20.73		
Cancelled	(373,849)	38.62		
Outstanding at December 31, 2015	5,878,352	$ 35.00	8.1	$ 110,798
Vested at December 31, 2015	2,398,126	$ 16.65	6.7	$ 85,971
Vested and expected to vest at December 31, 2015 (a)	5,500,680	$ 33.87	8.0	$ 109,452

(a) This represents the number of vested options as of December 31, 2015, plus the number of unvested options expected to vest as of December 31, 2015, based on the unvested options at December 31, 2015, adjusted for the estimated forfeiture rate.

Table of Contents

The fair value of each stock option was estimated at the date of grant using a Black-Scholes option-pricing model with the following assumptions:

	Years Ended December 31,		
	2013	2014	2015
Dividend yield	—	—	—
Volatility	73% - 78%	69% - 76%	63% - 65%
Risk-free interest rate	1.07% - 2.05%	1.65% - 2.07%	1.35% - 1.95%
Expected term (years)	5.50 - 6.25	5.50 - 6.08	5.50 - 6.08

The Company uses the simplified method as prescribed by SEC Staff Accounting Bulletin No. 107, Share-Based Payment, to calculate the expected term, as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term for options granted. The expected term is applied to all stock option grants as a whole, as the Company does not expect substantially different exercise or post-vesting termination behavior among its population. The computation of expected volatility is based on a blend of the historical volatility of the company and the volatility of a representative group of public biotechnology and life sciences companies with similar characteristics to the Company, including substantial product development and therapeutic focus. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. Management assesses expected forfeitures based on the experience of the Company and recognizes compensation costs only for those equity awards expected to vest.

The Company recorded stock-based compensation expense associated with stock options of $6.8 million, $11.1 million, and $24.5 million for the years ended December 31, 2013, 2014 and 2015, respectively. The totals for the years ended December 31, 2013, 2014 and 2015 include $1.1 million, $0.3 million, and $0.3 million, respectively, related to accounting for awards held by non-employee consultants. The weighted-average grant date fair values of options granted in the years ended December 31, 2013, 2014 and 2015 were $18.48, $20.33 and $32.05 per share, respectively. The aggregate intrinsic value of options exercised during the years ended December 31, 2013, 2014 and 2015 was $4.8 million, $3.4 million and $11.8 million, respectively. The intrinsic value of a stock option is the amount by which the fair market value of the underlying stock on the exercise date exceeds the exercise price of the stock option.

At December 31, 2015, there was $79.7 million of total unrecognized compensation cost related to unvested stock options, which the Company expects to recognize over a remaining weighted-average period of 2.9 years.

In June 2013, June 2014, and June 2015 as provided for under the 2012 Incentive Plan, the Company issued 4,368, 10,411 and 3,429 shares of common stock, respectively, with aggregate values of $0.3 million for all three periods, to certain non-employee board members who elected to receive shares of common stock in lieu of cash, as payment of

fees owed them for services as members of the Company's board of directors.

During September 2013, the Company's former Executive Vice President, Chief Financial Officer, Treasurer and Secretary, or the former CFO, resigned from his employment with the Company effective August 31, 2013 and transitioned to serving the Company as a non-employee consultant through March 31, 2014. In accordance with the terms of the 2012 Incentive Plan and the 2010 Incentive Plan, stock awards previously granted to the former CFO under these plans continued to vest through March 31, 2014. As a result, beginning in September 2013, the Company accounted for unvested stock awards previously granted to the former CFO as non-employee awards. The Company recorded stock-based compensation expense based on the fair values of awards as measured on their vesting dates, and the fair values of any unvested awards were remeasured at each financial reporting date until they vested, with any increases or decreases in fair value recorded as stock-based compensation expense. Fair values of stock options were determined on each measurement date using the Black-Scholes option pricing model, and fair values of restricted stock awards were equal to the fair market value of the Company's common stock on the measurement date. During the years ended December 31, 2013 and 2014, the Company recorded incremental stock-based compensation expense of $1.8 million and $0.4 million, respectively, associated with these awards (options and restricted stock awards), as the result of the change in status of the former CFO.

In August 2014, the Company granted 2,750 stock options to certain non-employee consultants, of which 2,500 were outstanding as of December 31, 2015 with a weighted-average exercise price of $29.04 per share. The Company records stock-based compensation expense based on the fair values of awards as measured on their vesting dates. Fair values of stock options are determined on each measurement date using the Black-Scholes option pricing model. During the year ended December 31, 2014, 2,750 options with a weighted-average grant date fair value of $17.50 were granted, and no options were vested,

Table of Contents

exercised or forfeited. During the year ended December 31, 2015, all 2,750 options vested, resulting in the company recording incremental stock based compensation expense of $0.1 million. Of these shares, 250 were exercised during the year ended December 31, 2015. The fair value of the shares was estimated using the Black-Scholes option-pricing model using the fair value of the common stock and the following assumptions: zero dividend yield; volatility of 69%; risk-free interest rate of 1.87%; and expected term of 5.50 years. There were no stock option grants to non-employee consultants during the years ended December 31, 2013 or 2015.

Restricted Stock Units

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

	Shares	Weighted-average grant date fair value per share
Unvested restricted stock units at December 31, 2014	15,600	$ 29.04
Granted	60,000	56.00
Vested	(8,091)	29.04
Forfeited	(3,600)	29.04
Withheld for taxes (a)	(3,909)	29.04
Unvested restricted stock units at December 31, 2015	60,000	$ 56.00

(a) The Company elected to pay cash equal to the minimum amount required to be withheld for income tax purposes instead of issuing the shares of common stock. The cash is remitted to the appropriate taxing authority.

In August 2014, the Company issued 19,500 restricted stock units, or RSUs, to certain employees. These stock awards have performance conditions, pursuant to which vesting of the award is contingent on the occurrence of certain milestone events. As a result, the related compensation cost is recognized as an expense, starting when the milestone becomes probable of being met, through the remaining performance period. The expense recognized for these awards is based on the grant date fair value of the Company's common stock multiplied by the number of units granted, net of estimated forfeitures. None of the 60,000 RSUs granted during the year ended December 31, 2015 included performance conditions.

The weighted-average grant date fair values of RSUs granted during the years ended December 31, 2014 and 2015 were $29.04 and $56.00 per share, respectively. There were no grants of RSUs during the year ended December 31, 2013. The total grant date fair value of RSUs that vested during the years ended December 31, 2014 and 2015 was $113,000 and $453,000, respectively, based upon the number of RSUs vested multiplied by the closing stock price of the Company's common stock on the grant date. As of December 31, 2015, there was approximately $2.9 million of unrecognized compensation cost related to unvested RSUs that is expected to be recognized over a weighted-average period of approximately 3.5 years.

Employee Stock Purchase Plan

On June 6, 2012, the board of directors adopted the 2012 ESPP, and the stockholders approved it on June 18, 2012, to be effective in connection with the closing of the Company's initial public offering. A total of 275,000 shares of common stock were originally approved for future issuance under the 2012 ESPP pursuant to purchase rights granted to the Company's employees or to employees of the Company's designated subsidiaries. As of December 31, 2015, 236,723 shares remained available for issuance. The 2012 ESPP provides for consecutive six-month offering periods, during which participating employees may elect to have a portion of their compensation withheld and used for the purchase of common stock at the end of each offering period. The purchase price is equal to 85% of the lower of the fair market value of a share of common stock on the first trading date of each offering period or the fair market value of a share of common stock on the last trading day of the offering period, and is limited by participant to $25,000 in fair value of common stock per year. The 2012 ESPP will terminate on June 6, 2022, the tenth anniversary of the date of initial adoption of the plan. For the years ended December 31, 2013, 2014 and 2015, the Company issued a total of 7,831, 9,845 and 20,601 shares, respectively, of common stock under the 2012 ESPP and recognized $67,000, $99,000 and $310,000, respectively, in related stock-based compensation expense.

Due to its operating losses in all periods to date, the Company has not recorded any tax benefits associated with stock-based compensation expense and option exercises. Tax benefits will be recorded when realized.

Table of Contents

10. Income Taxes

The following table presents a reconciliation of income (loss) before the provision for (benefit from) income taxes during the years ended December 31, 2013, 2014, and 2015 (in thousands):

	Year Ended December 31,		
	2013	2014	2015
United States	$ (87,953)	$ (141,119)	$ (212,707)
Foreign	(4,409)	(29,893)	(38,701)
(Loss) income before provision for (benefit from) income taxes	$ (92,362)	$ (171,012)	$ (251,408)

The Company accounts for income taxes in accordance with ASC 740, Income Taxes, or ASC 740. Deferred income tax assets and liabilities are determined based upon 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.

For the years ended December 31, 2013, 2014 and 2015, the Company did not record any current or deferred income tax provisions or benefits.

As of December 31, 2015, the Company had federal net operating loss carryforwards of approximately $447.3 million and state net operating loss carryforwards of $338.3 million, which are available to reduce future taxable income. Approximately $13.1 million of the federal and state net operating loss carryforwards will result in an increase to additional paid-in capital if and when these carryforwards are used to reduce federal and state income taxes payable. The Company also had federal research and development tax credit carryforwards of $10.7 million and state research and development tax credit carryforwards of $2.5 million, which may be used to offset future tax liabilities.

The Company has gross unrecognized tax benefits related to research and development credits of $2.0 million and $1.1 million, respectively, as of December 31, 2015 and 2014. These benefits, if recognized, would be offset by an adjustment to the valuation allowance. The Company has not, as yet, conducted a study of its research and development credit carryforwards. Such a study could result in an adjustment to those carryforwards; however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against all of the Company’s tax credit carryforwards, including its research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the consolidated balance sheet position or statement of operations if an adjustment were required.

The Company's policy is to recognize both interest and penalties related to unrecognized tax benefits in income tax expense. Due to its historical net loss position, the Company has not recognized any interest or penalties related to unrecognized tax benefits.

The statute of limitations for assessment by the IRS and state and foreign tax authorities remains open for all tax years. The Company files a United States federal income tax return and a Commonwealth of Massachusetts state income tax return, and applicable foreign tax filings. There are currently no federal, state or foreign audits in process.

Table of Contents

The following table presents the principal components of the Company's deferred tax assets and liabilities (in thousands):

	December 31,	
	2014	2015
Deferred tax assets:		
Federal net operating loss carryforwards	$ 86,163	$ 147,611
State net operating loss carryforwards	13,270	17,361
Depreciation and amortization	14,647	13,594
Stock-based compensation	4,891	11,845
Tax credit carryforwards	5,780	10,573
Other	1,289	3,120
Total deferred tax assets	126,040	204,104
Less: valuation allowance	(101,399)	(183,421)
Net deferred tax assets	$ 24,641	$ 20,683
Deferred tax liability:		
Debt discount on convertible notes	(24,641)	(20,683)
Net deferred taxes	—	—

ASC 740 requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of available evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. After consideration of all the evidence, both positive and negative, the Company has recorded full valuation allowances against its deferred tax assets at both December 31, 2014 and 2015, because management has determined that is it more likely than not that these assets will not be realized. The valuation allowance increased by $82.0 million from December 31, 2014 to December 31, 2015, primarily due to an increase in operating losses.

The following table presents a reconciliation of income tax expense (benefit) at the statutory federal income tax rate to the effective income tax rate as reflected in the consolidated financial statements:

	Years Ended December 31,		
	2013	2014	2015
Federal income tax (benefit)/expense at statutory rate	(34.0)%	(34.0)%	(34.0)%
State income tax benefit	(5.1)	(4.4)	(2.3)
Permanent items	0.8	0.7	0.2
Foreign rate differential	1.6	5.9	5.1
Federal research and development credit	(2.5)	(1.4)	(1.6)
Change in valuation allowance	39.2	33.2	32.6
Effective income tax rate	0.0 %	0.0 %	0.0 %

11. Employee Benefit Plans

In 2010, the Company adopted a retirement plan, which is qualified under section 401(k) of the Internal Revenue Code, for its U.S. employees. The plan allows eligible employees to defer, at the employee's discretion, pre-tax or post-tax compensation up to the IRS annual limits. Company contributions may be made at the discretion of the board of directors.

Effective as of January 1, 2012, the Company amended its 401(k) plan to provide for employer matching contributions equal to (1) 100% of employee deferral contributions up to a deferral rate of 3% of compensation, plus (2) 50% of employee deferral contributions up to a deferral rate of an additional 2% of compensation. During the years ended December 31, 2013, 2014 and 2015, the Company made aggregate matching contributions of $0.3 million, $0.5 million and $1.0 million, respectively.

The Company maintains a pension plan covering employees of its wholly owned subsidiary in Switzerland. This plan is considered a defined benefit plan and is a government-mandated retirement fund that provides benefits to employees upon retirement, death, or disability. Employer and employee contributions are made based on various percentages of salaries and wages that vary based on employee age and other factors. As of December 31, 2015, the plan had an unfunded net pension

Table of Contents

obligation of approximately $0.1 million and plan assets of approximately $0.1 million. In 2015, the Company recognized expense of $0.1 million related to this plan.

12. 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. The following table presents future minimum rental commitments, by fiscal year and in the aggregate, as of December 31, 2015 (in thousands):

	Operating Leases
2016	$ 2,345
2017	1,151
Thereafter	—
Total minimum lease payments	$ 3,496

The Company recorded $647,000, $1,525,000 and $2,091,000 in rent expense for the years ended December 31, 2013, 2014 and 2015, respectively.

The Company has entered into agreements with certain vendors for the provision of services, including services related to data management clinical operation support services, 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.

Litigation

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 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.

13. License and Collaboration Agreements

Rolapitant In-License

In December 2010, the Company entered into a license agreement with OPKO Health, Inc., or OPKO, to obtain an exclusive, royalty-bearing, sublicensable worldwide license to research, develop, manufacture, market and sell rolapitant. The license agreement also extended to an additional, backup compound, SCH900978, to which the Company has the same rights and obligations as rolapitant, but which the Company is not currently advancing. Under the OPKO license the Company is obligated to use commercially reasonable efforts to conduct all preclinical, clinical, regulatory and other activities necessary to develop and commercialize rolapitant. Under the terms of the OPKO license, the Company paid OPKO $6.0 million upon signing the agreement and issued to OPKO shares of its convertible preferred stock, then valued at $0.6 million which shares have since been converted into common stock. The Company is also required to make development milestone payments to OPKO of up to an aggregate of $30.0 million if specified regulatory and initial commercial sales milestones are achieved. In addition, the Company is required to make additional milestone payments to OPKO of up to an aggregate of $85.0 million if specified levels of annual net sales of rolapitant are achieved. Upon the commencement of commercial sales of rolapitant, the Company is required to pay OPKO tiered royalties on the amount of annual net sales of rolapitant achieved in the United States and Europe at percentage rates that range from the low teens to the low twenties, which the Company expects 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. If the Company elects to develop and commercialize rolapitant in Japan through a third-party licensee the Company will share equally with OPKO all amounts received by it in connection with such activities under the Company’s agreement with such third party, subject to certain exceptions and deductions. The Company is responsible for all preclinical,

Table of Contents

clinical, regulatory and other activities necessary to develop and commercialize rolapitant. There were no ongoing clinical trials for rolapitant at the time of its acquisition. As of the date of acquisition, none of the assets acquired had alternative future uses, nor had they reached a stage of technological feasibility. As no processes or activities that would constitute a "business" were acquired along with the license, the transaction was accounted for as an asset acquisition by recording the entire purchase price as acquired in-process research and development expense of $6.6 million. As of December 31, 2015, the Company has made two milestone payments totaling $20.0 million under this license agreement, $15.0 million of which was paid in November of 2015 and has been capitalized as an intangible asset on the consolidated balance sheet.

Niraparib In-License

In May 2012, the Company entered into a license agreement with Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., or Merck, under which the Company 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. The Company is not currently advancing MK-2512. Under the Merck license, the Company is obligated to use diligent efforts to develop and commercialize a licensed product. Under the terms of the license agreement, the Company was required to make an up-front payment to Merck of $7.0 million in June 2012. The Company is also required to make milestone payments to Merck of up to $57.0 million in 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, the Company will pay Merck tiered royalties at a percentage rate in the low teens based on worldwide annual net sales. As of the date of acquisition, none of the assets acquired had alternative future uses, nor had they reached a stage of technological feasibility. As no processes or activities that would constitute a "business" were acquired along with the license, the transaction has been accounted for as an asset acquisition and the entire purchase price of $7.0 million has been recorded as acquired in-process research and development expense. The Company has made two milestone payments to Merck to date totaling $2.8 million.

Immuno-Oncology Platform License

In March 2014, the Company entered into a collaboration and exclusive license agreement with AnaptysBio, Inc., or AnaptysBio, a privately-held therapeutic antibody company. Under the terms of this agreement, the Company 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 certain specified immunotherapy antibodies. Specifically, the Company received exclusive rights to monospecific antibody product candidates targeting TIM-3, LAG-3 and PD-1 (TSR-042) and bi-specific antibody product candidates targeting PD-1/TIM-3, and PD-1/LAG-3. The Company executed an amendment in November 2014 to add an additional bi-specific combination. Under the agreement, AnaptysBio is responsible for performing initial discovery and development of therapeutic antibodies, with the goal of generating immunotherapy antibodies for use in the treatment of cancer. The Company is responsible for the performance and costs of all subsequent preclinical, clinical, regulatory, manufacturing and other activities necessary to develop and commercialize antibodies selected under each

of four development programs and is obligated to use commercially reasonable efforts to research, develop or commercialize at least one product under each development program.

Under the terms of the agreement, the Company made an up-front, non-creditable and non-refundable cash payment of $17.0 million to AnaptysBio in March 2014. Under the terms of the amendment, the Company made an up-front, non-creditable and non-refundable cash payment of $2.0 million in December 2014. The Company is also required to reimburse AnaptysBio on a quarterly basis for up to two years from the effective date of the agreement for specified costs incurred by AnaptysBio in its initial discovery and development activities covered by the agreement. Programs may be extended by mutual agreement of the parties, and the Company can terminate on a program-by-program basis by providing 90 days prior written notice, subject to a wind-down period during which the Company's obligation to reimburse AnaptysBio for specified costs would continue. For each of the four development programs, the Company will be required to make milestone payments to AnaptysBio of up to $18.0 million if certain research and development milestone events are achieved, 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. The Company will be required to pay AnaptysBio tiered single-digit 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.

As of the date of the license transaction, none of the assets acquired had alternative future uses, nor had they reached a stage of technological feasibility. As the processes or activities that were acquired along with the license do not constitute a

Table of Contents

"business", the transaction has been accounted for as an asset acquisition. In addition, the Company has concluded that it is reimbursing AnaptysBio at fair value for the research services called for under the agreement. As a result of these factors, the up-front payments totaling $19.0 million have been recorded as acquired in-process research and development expense, and no portion of the payments has been ascribed to the future services to be provided to the Company by AnaptysBio. For the years ended December 31, 2014 and 2015, the Company recorded approximately $4.6 million and $6.5 million, respectively, of research and development expense, associated with amounts due to AnaptysBio under the collaboration. The Company made milestone payments totaling $2.0 million during the year ended December 31, 2015.

TSR-011 In-License

In March 2011, the Company entered into a license agreement with Amgen, Inc., or Amgen, under which it received an exclusive, royalty bearing, sublicensable worldwide license under certain of Amgen's patent rights to research, develop, manufacture, market and sell licensed ALK inhibitor compounds, including TSR-011. In October 2015, the Company's Board of Directors determined to discontinue the development of TSR-011, and the Company notified Amgen of its intention to terminate the license agreement pursuant to the terms of the agreement. The license agreement with Amgen was terminated in January 2016. In connection with terminating the agreement, the Company expects the ongoing wind down of clinical and other activities related to TSR-011 to continue through 2016.

Technology Licenses

In October 2012, the Company entered into two license agreements with AstraZeneca UK Limited, having aggregate upfront payments of $0.4 million. These agreements provide the Company with the exclusive right to certain methods of treating patients with PARP inhibitors solely with respect to niraparib. Under certain circumstances, the Company may be required to make milestone and royalty payments to AstraZeneca UK Limited based on the achievement of certain development and regulatory milestone events with regard to niraparib, and on net sales of niraparib. The Company made milestone payments totaling $0.2 million and $0.1 million to AstraZeneca during the years ended December 31, 2013 and 2014, respectively, and no payments during the year ended December 31, 2015.

Merck Collaboration

In May 2015, the Company 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. 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 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 year ended December 31, 2015, the Company incurred

$1.2 million in external costs related to this study, of which $0.6 million is reimbursable by Merck. At December 31, 2015, $0.6 million of cost-sharing receivable from Merck has been recorded in accounts receivable on the consolidated balance sheet.

Table of Contents

14. Consolidated Quarterly Financial Data - Unaudited

The following table presents unaudited consolidated quarterly financial data for the years ended December 31, 2014 and 2015 (in thousands, except per share data):

	Three Months Ended							
	March 31, 2014	June 30, 2014	September 30, 2014	December 31, 2014	March 31, 2015	June 30, 2015	September 30, 2015	Decembe 2015
se revenue	$ —	$ —	$ —	$ —	$ —	$ —	$ 87	$ 230
nses:								
of sales - gible asset tization	—	—	—	—	—	—	—	268
arch and opment	28,117	$ 30,569	29,925	29,814	33,545	38,930	40,063	$ 42,852
g, general nistrative	4,688	5,587	6,263	7,397	11,242	16,783	22,766	27,910
ired ocess rch and opment	17,000 (a)	900 (b)	—	7,000 (c)	—	1,000 (d)	—	1,000
expenses	49,805	37,056	36,188	44,211	44,787	56,713	62,829	72,030
from tions	(49,805)	(37,056)	(36,188)	(44,211)	(44,787)	(56,713)	(62,742)	(71,800
est expense	—	—	(42)	(3,734)	(3,726)	(3,853)	(3,853)	(3,982)
est income	5	5	4	10	7	9	9	23
oss	$ (49,800)	$ (37,051)	$ (36,226)	$ (47,935)	$ (48,506)	$ (60,557)	$ (66,586)	$ (75,759
oss per share c and ed	$ (1.43)	$ (1.03)	$ (1.01)	$ (1.33)	$ (1.30)	$ (1.51)	$ (1.66)	$ (1.89)
hted-average s - basic and ed	34,856	35,982	36,029	36,071	37,312	40,008	40,038	40,151

(a) In the quarter ended March 31, 2014, the Company paid an up front fee of $17.0 million to AnaptysBio related to the immuno-oncology platform.

(b)

In the quarter ended June 30, 2014, the Company made a milestone payment to Merck for niraparib as a result of the first patient dosing in the BRAVO trial, which occurred in April 2014.

(c) In the quarter ended December 31, 2014, the Company made a $5.0 million milestone payment to OPKO related to the acceptance of the oral rolapitant NDA for review by the FDA, as well as an up front payment of $2.0 million to AnaptysBio related to the immuno-oncology platform amendment.

(d) In the quarter ended June 30, 2015, the Company incurred a $1.0 million milestone obligation to AnaptysBio related to the immuno-oncology platform.

(e) In the quarter ended December 31, 2015, the Company made a $1.0 million milestone payment to AnaptysBio related to the immuno-oncology platform.

15. Subsequent Event

On February 24, 2016, the Company entered into a Stock Purchase Agreement with certain accredited investors, including funds affiliated with three of its directors, pursuant to which the Company agreed to issue an aggregate of 4,404,658 shares of its common stock, at a price per share of $35.19 (calculated at the volume weighted average price for the 10-day period ending on February 22, 2016), in a private placement transaction exempt from registration under the Securities Act of 1933, for an aggregate purchase price of $155.0 million, subject to the satisfaction of certain closing conditions. The closing of

Table of Contents

the offering is subject to customary closing conditions and expiration or early termination of any applicable waiting periods under the Hart-Scott-Rodino Act, and is expected to occur prior to the end of April 2016, but no earlier than March 18, 2016.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of December 31, 2015, management, with the participation of our Principal Executive Officer and Principal Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including the Principal Executive Officer and the Principal Financial Officer, to allow timely decisions regarding required disclosures. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective. Based on this evaluation, our Principal Executive Officer and Principal Financial Officer concluded that, as of December 31, 2015, the design and operation of our disclosure controls and procedures were effective.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, our principal executive officer and principal financial officer and effected by our board of directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in conformity with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision of and with the participation of our principal executive officer and principal financial officer, our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2015 based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control—Integrated Framework (2013). Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2015.

Ernst & Young LLP, independent registered public accounting firm, who audited and reported on the TESARO, Inc. Consolidated Financial Statements included in this annual report, has also audited the effectiveness of our internal control over financial reporting as of December 31, 2015, as stated in its report appearing in Item 8, “Financial Statements and Supplementary Data”, of this Annual Report on Form 10-K.

Table of Contents

Changes in Internal Control Over Financial Reporting

In November 2015, we began shipping, and recording inventory related to, our newly approved product, VARUBI. In addition, we are using a third party logistics provider for shipping, inventory, customer service, and certain other logistical and financial services related to these shipments of VARUBI. As a result, we are relying on their systems and processes for the above functions. We have performed a variety of reconciliations and have implemented certain internal controls processes in various functional areas of the Company to ensure that financial data related to VARUBI shipments and inventory activity has been correctly reflected in our financial statements. We are not aware of any material adverse impacts on our internal controls over financial reporting as a result of the implementation of these new controls. There were no other reportable changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2015 that materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders

TESARO, Inc.

We have audited TESARO, Inc.'s internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). TESARO, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, TESARO, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of TESARO, Inc. as of December 31, 2014 and December 31, 2015, and the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2015 of TESARO, Inc. and our report dated February 26, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

February 26, 2016

Table of Contents

ITEM 9B. OTHER INFORMATION

None.

Table of Contents

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K and is incorporated herein by reference from our definitive proxy statement relating to our 2016 annual meeting of stockholders, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, also referred to in this Form 10-K as our 2016 Proxy Statement, which we expect to file with the SEC no later than April 30, 2016.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item will be set forth in our 2016 Proxy Statement to be filed with the SEC within 120 days of December 31, 2015, and is incorporated into this Annual Report on Form 10-K by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item will be set forth in our 2016 Proxy Statement to be filed with the SEC within 120 days of December 31, 2015, and is incorporated into this Annual Report on Form 10-K by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item will be set forth in our 2016 Proxy Statement to be filed with the SEC within 120 days of December 31, 2015, and is incorporated into this Annual Report on Form 10-K by reference.

Securities Authorized for Issuance Under Equity Compensation Plans

Equity Compensation Plan Information as of December 31, 2015

Number of securities

Plan Category	Number of securities to be issued upon exercise of outstanding options and rights (a)	Weighted-average exercise price of outstanding options and rights (b)	remaining available for issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders (1) (2) (3)	5,863,352	$ 34.04	2,085,453
Equity compensation plans not approved by security holders (4)	75,000	57.66	—
Total	5,938,352	$ 34.34	2,085,453

(1) As of December 31, 2015, 1,437,159 shares remained available for issuance under our 2012 Omnibus Incentive Plan, or the 2012 Incentive Plan, which became effective in April 2012, including 6,857 remaining shares that were then available for future issuance under the 2010 Stock Incentive Plan, or the 2010 Incentive Plan, which were transferred to the 2012 Incentive Plan. The number of shares of our common stock reserved for issuance under the 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 the 2010 Incentive Plan and (ii) on January 1 of each year, starting in 2014, 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 December 31, 2015, 151,075 shares of our common stock had been cancelled under the 2010 Incentive Plan and transferred to the 2012 Incentive Plan. Effective January 1, 2016, the number of shares authorized for issuance under the 2012 Incentive Plan was increased by 1,611,191 shares.

(2) As of December 31, 2015, 236,723 shares were reserved for issuance under our 2012 Employee Stock Purchase Plan, or ESPP, which became effective in June 2012.

(3) As of December 31, 2015, 411,571 shares were reserved for issuance under our 2015 Non-Employee Director Stock Incentive Plan, or the 2015 Director Plan, which became effective in May 2015.

Table of Contents

(4) On March 30, 2015, 75,000 shares were granted as part of an inducement award outside of the 2012 Omnibus Incentive Plan.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item will be set forth in our 2016 Proxy Statement to be filed with the SEC within 120 days of December 31, 2015, and is incorporated into this Annual Report on Form 10-K by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item will be set forth in our 2016 Proxy Statement to be filed with the SEC within 120 days of December 31, 2015, and is incorporated into this Annual Report on Form 10-K by reference.

Table of Contents

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) See Item 8 for the Financial Statements required to be included in this Annual Report on Form 10-K.

(2)All financial statement schedules have been omitted because they are not applicable or not required or because the information is included elsewhere in the Financial Statements or the Notes thereto.

(3)See the accompanying Index to Exhibits filed as a part of this Annual Report on Form 10-K, which list is incorporated by reference in this Item.

(b)See the accompanying Index to Exhibits filed as a part of this Annual Report on Form 10-K.

(c)Other schedules are not applicable.

Table of Contents

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.

Date: February 26, 2016 By: /s/ Leon O. Moulder, Jr.
Leon O. Moulder, Jr.
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Leon O. Moulder, Jr. Leon O. Moulder, Jr.	Chief Executive Officer, Director (Principal Executive Officer)	February 26, 2016
/s/ Mary Lynne Hedley, Ph.D. Mary Lynne Hedley, Ph.D.	President, Chief Operating Officer and Director	February 26, 2016
/s/ Timothy R. Pearson Timothy R. Pearson	Executive Vice President and Chief Financial Officer (Principal Financial Officer)	February 26, 2016
/s/ Edward C. English Edward C. English	Vice President of Finance and Administration (Principal Accounting Officer)	February 26, 2016
/s/ David M. Mott David M. Mott	Chairman of the Board of Directors	February 26, 2016
/s/ Lawrence M. Alleva Lawrence M. Alleva	Director	February 26, 2016
/s/ James O. Armitage, M.D. James O. Armitage, M.D.	Director	February 26, 2016
/s/ Earl M. (Duke) Collier, Jr. Earl M. (Duke) Collier, Jr.	Director	February 26, 2016
/s/ Garry A. Nicholson Garry A. Nicholson	Director	February 26, 2016

/s/ Arnold L. Oronsky, Ph.D. Arnold L. Oronsky, Ph.D.	Director	February 26, 2016
/s/ Beth Seidenberg, M.D. Beth Seidenberg, M.D.	Director	February 26, 2016

Table of Contents

INDEX TO EXHIBITS

Exhibit Number		Exhibit Description
3.1		Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on July 3, 2012 (File No. 001-35587)).
3.2		Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on July 3, 2012 (File No. 001-35587)).
4.1		Form of Certificate of Common Stock (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1/A filed on June 19, 2012 (File No. 333-180309)).
4.2		Second Amended and Restated Investors' Rights Agreement, dated June 6, 2011, by and between the Company and certain investors named therein (incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1/A filed on May 17, 2012 (File No. 333-180309)).
4.3		Amendment No. 1 to the Second Amended and Restated Investors' Rights Agreement (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-1/A filed on May 17, 2012 (File No. 333-180309)).
4.4		Senior Debt Securities Indenture, dated September 29, 2014, by and between the Company and U.S. Bank National Association, as trustee (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on September 29, 2014 (File No. 001-35587)).
4.5		First Supplemental Indenture, dated September 29, 2014, by and between the Company and U.S. Bank National Association, as trustee (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on September 29, 2014 (File No. 001-35587)).
10.1	+	TESARO, Inc. 2010 Stock Incentive Plan, as amended, and forms of agreement thereunder (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 filed on March 23, 2012 (File No. 333-180309)).
10.2	+	TESARO, Inc. 2012 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1/A filed on June 19, 2012 (File No. 333-180309)).
10.3	+	Amendment to the TESARO, Inc. 2012 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 14, 2015 (File No. 001-35587)).
10.4	+	Form of Incentive Stock Option Agreement under 2012 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1/A filed on June 27, 2012 (File No. 333-180309)).
10.5	+	Form of Nonstatutory Stock Option Agreement under 2012 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 1, 2015 (File No. 001-35587)).

10.6	+	Form of Restricted Stock Unit Agreement under 2012 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 7, 2015 (File No. 001-35587)).
10.7	+	TESARO, Inc. 2012 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1/A filed on June 19, 2012 (File No. 333-180309)).
10.8	+	TESARO, Inc. 2015 Non-Employee Director Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on August 7, 2015 (File No. 001-35587)).

Table of Contents

10.9	+	Form of Nonstatutory Stock Option Agreement under 2015 Non-Employee Director Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 7, 2015 (File No. 001-35587)).
10.10	+	Non-Qualified Stock Option Inducement Award Agreement, dated March 30, 2015, by and between the Company and Joseph L. Farmer (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on August 7, 2015 (File No. 001-35587)).
10.11	+	Form of Indemnification Agreement by and between the Company and each of its directors and executive officers (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 filed on March 23, 2012 (File No. 333-180309)).
10.12	+	Indemnification Agreement by and between the Company and David M. Mott (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1 filed on March 23, 2012 (File No. 333-180309)).
10.13	+	Indemnification Agreement by and between the Company and Arnold L. Oronsky (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1 filed on March 23, 2012 (File No. 333-180309)).
10.14	+	Indemnification Agreement by and between the Company and Beth Seidenberg, M.D. (incorporated by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1 filed on March 23, 2012 (File No. 333-180309)).
10.15	+	Amended and Restated Offer Letter Agreement, dated June 18, 2012, by and between the Company and Leon O. Moulder, Jr. (incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1/A filed on June 19, 2012 (File No. 333-180309)).
10.16	+	Amended and Restated Offer Letter Agreement, dated June 18, 2012, by and between the Company and Mary Lynne Hedley, Ph.D. (incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1/A filed on June 19, 2012 (File No. 333-180309)).
10.17	+	Offer Letter Agreement, dated May 27, 2014, by and between the Company and Timothy R. Pearson (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 27, 2014 (File No. 001-35587)).
10.18	+	Offer Letter Agreement, dated June 2, 2015, by and between the Company and Jeffrey H. Hanke.
10.19	+	Offer Letter Agreement, dated April 14, 2015, by and between the Company and Grant C. Bogle.
10.20	*	Exclusive License Agreement, dated December 10, 2010, by and between the Company and OPKO Health, Inc. (incorporated by reference to Exhibit 10.17 to the Company's Registration Statement on Form S-1/A filed on June 22, 2012 (File No. 333-180309)).
10.21	*	Process Development and Manufacturing Services Agreement, dated March 31, 2012, by and between the Company and Hovione Inter Limited (incorporated by reference to Exhibit 10.19 to the Company's Registration Statement on Form S-1/A filed on June 22, 2012 (File No. 333-180309)).
10.22	*	

License Agreement, dated May 22, 2012, by and between the Company and Merck Sharpe & Dohme Corp. (incorporated by reference to Exhibit 10.20 to the Company's Registration Statement on Form S-1/A filed on June 22, 2012 (File No. 333-180309)).

10.23 * Collaboration and Exclusive License Agreement, dated March 10, 2014, by and among the Company, TESARO Development, Ltd. and AnaptysBio, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 2, 2014 (File No. 001-35587)).

Table of Contents

10.24	*	Amendment No. 1 to Collaboration and Exclusive License Agreement, dated November 28, 2014, by and among the Company, TESARO Development, Ltd. and AnaptysBio, Inc. (incorporated by reference to Exhibit 10.21 to the Company's Annual Report on Form 10-K filed on February 25, 2015 (File No. 001-35587)).
10.25	*	Master Manufacturing Services Agreement, dated October 13, 2015, by and between the Company and Patheon Inc.
10.26	*	Product Agreement, dated October 13, 2015, by and between the Company and Patheon Inc.
10.27		Base Capped Call Confirmation, dated September 25, 2014, by and between the Company and Citibank, N.A. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 29, 2014 (File No. 001-35587)).
10.28		Base Capped Call Confirmation, dated September 25, 2014, by and among the Company, Deutsche Bank AG, London Branch, and Deutsche Bank Securities Inc., acting solely as agent (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on September 29, 2014 (File No. 001-35587)).
10.29		Additional Capped Call Confirmation, dated September 25, 2014, by and between the Company and Citibank, N.A. (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on September 29, 2014 (File No. 001-35587)).
10.30		Additional Capped Call Confirmation, dated September 25, 2014, by and among the Company, Deutsche Bank AG, London Branch, and Deutsche Bank Securities Inc., acting solely as agent (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed on September 29, 2014 (File No. 001-35587)).
12.1		Computation of Ratio of Earnings to Fixed Charges.
21.1		Subsidiaries of the Company.
23.1		Consent of Ernst & Young LLP.
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

+ Indicates management contract or compensatory plan.

* Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.