TESARO, Inc.
Form 10-K
February 25, 2015
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended December 31, 2014

or

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

For the transition period from to

Commission file number 001-35587

TESARO, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

(339) 970-0900

(Registrant s Telephone Number, Including Area Code)

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 x No o

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 o No x

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

Indicate by check mark 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 x

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

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

The aggregate market value of the registrant s voting stock held by non-affiliates as of June 30, 2014 was approximately $631,362,000 based on the closing price of $31.11 of the Common Stock of the registrant as reported on the NASDAQ Global Select Market on such date. As of February 19, 2015, there were 36,110,407 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 2015 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, 2014, 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, 2014

TABLE OF CONTENTS

Table of Contents

PART I

This Annual Report filed on Form 10-K and the information incorporated herein by reference includes statements that are, or may be deemed, forward-looking statements. In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms believes, estimates, anticipates, expects, plans, intends, may, could, might, will, should, approximately or, in each case, their negative or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this Annual Report on Form 10-K and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned preclinical studies and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, the degree of clinical utility of our products, particularly in specific patient populations, expectations regarding clinical trial data, our results of operations, financial condition, liquidity, prospects, growth and strategies, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and industry change and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and events in the industry in which we operate may differ materially from the forward-looking statements contained herein.

Any forward-looking statements that we make in this Annual Report on Form 10-K speak only as of the date of this Annual Report on Form 10-K, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Annual Report on Form 10-K or to reflect the occurrence of unanticipated events.

You should also read carefully the factors described in the Risk Factors section of this Annual Report on Form 10-K to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. You are advised, however, 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.

The TESARO logo is a trademark 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 acquire, in-license and develop oncology product candidates. We have in-licensed and are currently developing three clinical-stage product candidates, rolapitant,

niraparib and TSR-011. We submitted a new drug application, or NDA, for an oral formulation of rolapitant, to the U.S. Food and Drug Administration, or the FDA, in September 2014. If the NDA is approved by the FDA, oral rolapitant will become our first marketed product. In March 2014, we added immuno-oncology programs by entering into a collaboration and exclusive license agreement with AnaptysBio, Inc., or AnaptysBio, for the discovery and development of antibodies for several specified immuno-oncology targets.

- *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. We are developing both oral and intravenous, or IV, formulations of rolapitant. In December 2013, we announced top-line results for two Phase 3 trials of oral rolapitant and in May 2014, we announced top-line results for a third Phase 3 trial of oral rolapitant. The primary endpoint in each of these three trials was successfully achieved. In September 2014, we submitted to the FDA an NDA for oral rolapitant, which was accepted for review by the FDA in November 2014. We are currently preparing to begin marketing of oral rolapitant in the fourth quarter of 2015, assuming the NDA is approved on or about the Prescription Drug User Fee Act, or PDUFA, action date of September 5, 2015. The IV formulation of rolapitant is currently in various Phase 1 clinical trials. As part of a registration program for IV rolapitant, we have initiated a clinical study comparing the plasma exposure and bioequivalence of IV rolapitant and oral rolapitant. In January 2014, in a single ascending dose study we identified a dose of our IV

Table of Contents

formulation of rolapitant, 185mg, that we believe is likely to achieve bioequivalence to a 200mg dose of oral rolapitant, and we commenced a study to compare the plasma pharmacokinetic profile of IV rolapitant to the oral formulation in the third quarter of 2014. In the first quarter of 2015 we plan to initiate clinical studies to evaluate the safety of IV rolapitant to support an NDA submission, which we expect to submit in the fourth quarter of 2015.

- *Niraparib* is an orally active and potent poly (ADP-ribose) polymerase, or PARP, inhibitor. In July 2013, we dosed the first patient in a Phase 3 clinical trial, which we refer to as the NOVA trial, evaluating niraparib for the treatment of patients with high grade serous, platinum sensitive, relapsed ovarian cancer. In April 2014, we dosed the first patient in a Phase 3 clinical trial, which we refer to as the BRAVO trial, evaluating niraparib in breast cancer patients with germline breast cancer susceptibility gene, or BRCA, mutations. Based on research related to PARP inhibitors generally, we believe that niraparib may be effective in several additional oncology settings. Therefore, 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. Additionally, we intend to evaluate niraparib as a first-line maintenance therapy in ovarian cancer patients, as a therapy for patients with ovarian cancer who previously have been treated with three or more regimens of therapy, and in advanced metastatic small cell lung cancer, or SCLC, patients. We may also evaluate niraparib for the treatment of gastric and prostate cancer.

- *TSR-011* is an orally available targeted anti-cancer agent that is a potent inhibitor of both anaplastic lymphoma kinase, or ALK, and tropomyosin-related kinase, or TRK, currently in a Phase 1/2a dose escalation clinical trial in cancer patients. We have identified the maximum tolerated dose of TSR-011 and are now evaluating fractionated 60 and 120 milligram (mg) doses of TSR-011 in patients with ALK or TRK expression, including those with ALK-positive, or ALK+, and TRK-positive, or TRK+, non-small cell lung cancer, or NSCLC, who have not been previously treated with ALK inhibitors, those with ALK+ NSCLC who have progressed during treatment with other ALK inhibitors, and in those patients with other tumor types driven by ALK or TRK. A controlled release formulation is now available and is being evaluated in the ongoing study.

- *Immuno-Oncology Platform*: PD-1, or programmed cell death protein 1, is a key immune checkpoint molecule that can limit T-cell-mediated immune responses. The presence of the PD-1 ligand, or PD-L1, has been identified on many tumor types, and expression of PD-L1 has been linked to poor clinical outcomes in a variety of cancers. Anti-PD-1 antibodies have demonstrated in vivo efficacy in tumor models, have shown promising results in several clinical studies, and in September 2014, the FDA approved KEYTRUDA®, the first approved anti-PD-1 antibody, for the treatment of certain melanomas. As part of our collaboration with AnaptysBio, we received exclusive rights to monospecific antibody product candidates targeting TIM-3, LAG-3 and PD-1 and dual-reactive antibody product candidates targeting PD-1/TIM-3, PD-1/LAG-3 and an additional dual-reactive combination. We expect to file an investigational new drug application, or IND, for our first immuno-oncology antibody, TSR-042, which targets PD-1, by the end of 2015. We anticipate beginning clinical trials using TSR-042, the lead anti-PD-1 antibody product candidate that we have in-licensed as part of the agreement with AnaptysBio, in early 2016. With respect to the TIM-3 and LAG-3 targets, we have either identified or are working toward identifying lead and backup compounds. We intend to select lead and backup compounds for the dual-reactive PD-1/TIM-3 and PD-1/LAG-3 targets during the first half of 2015. In addition, we plan to evaluate our immuno-oncology anti-tumor agents, such as TSR-042, in combination preclinical pharmacology studies with niraparib, TSR-011 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 and oncology supportive care products, 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 conjunction with established companies in Europe and China. In addition to developing commercial capabilities within these three geographic areas, we intend to establish a network of licensees and distributors for our products in other geographic areas.

Table of Contents

Since our founding, we have relied on private and public financing sources to fund our operations. As of December 31, 2014, our principal source of liquidity was cash and cash equivalents, which totaled $256.9 million. From inception through December 31, 2014, including through our 2012 initial public offering, we have raised a total of $383.9 million in net cash proceeds from private placements of convertible preferred stock and public offerings of common stock. This total includes the sale in February 2014 of 3,200,000 shares of common stock in an underwritten public offering pursuant to a 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 estimated offering expenses.

On September 29, 2014, we completed the issuance of $201.3 million aggregate principal amount of senior convertible notes, generating proceeds, net of underwriting discounts, commissions and offering expenses, of $194.7 million. In conjunction with the sale of the Convertible Notes, we used approximately $20.8 million of the net proceeds to enter into capped 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 we are required to make in excess of the principal amount, upon conversion of the Convertible Notes.

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

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 and oncology supportive care products that are potentially safer and more effective than existing treatments.

The key components of our strategy are:

- ***Rapidly Develop and Successfully Commercialize Rolapitant for the Prevention of CINV.*** In early 2012 we enrolled the first patient in our global Phase 3 clinical program for rolapitant, approximately one year after in-licensing this product candidate. In December 2013 we reported top-line results for two of our three Phase 3 clinical trials of oral rolapitant. In May 2014, we announced top-line results for the third Phase 3 trial of oral rolapitant. Our Phase 3 clinical program for oral rolapitant included investigative sites in over 25 countries. In September 2014, we submitted to the FDA an NDA for oral rolapitant, which was accepted for review by the FDA in November 2014. We are currently preparing to begin marketing oral rolapitant in the fourth quarter of 2015, assuming the NDA is approved on or about the PDUFA date of September 5, 2015. Our rolapitant program also includes the development of an IV formulation. 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, if approved, 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, which we commenced in July 2013. 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. We also are collaborating with SARC to evaluate niraparib in combination with temozolomide for the treatment of Ewing s sarcoma. We intend to initiate during the first quarter of 2015 a potential registration trial of niraparib as a therapy for patients with ovarian cancer who have previously been treated with three or more regimens of therapy, and additional trials in the SCLC and first-line ovarian cancer maintenance settings during the second half of 2015. We may also evaluate niraparib for the treatment of gastric and prostate cancer, and we plan to evaluate niraparib in combination preclinical pharmacology studies with our immuno-oncology anti-tumor agents.

Table of Contents

- ***Advance TSR-011 Through Clinical Trials for the Treatment of NSCLC and Other Tumor Types Associated with ALK and TRK Mutations.*** We are pursuing a development pathway that we believe, if successful, will enable us to reduce the time to receive regulatory approval for this product candidate. In September 2012, we filed an investigational new drug application, or IND, for TSR-011 with the FDA that became effective in October 2012, and in November 2012, we announced that we had dosed the first patient in a Phase 1/2a dose escalation clinical trial of TSR-011 in cancer patients. We have identified the maximum tolerated dose of TSR-011 and are now evaluating fractionated 60mg and 120mg doses of TSR-011 in patients with ALK or TRK expression, including those with ALK+ and TRK+ NSCLC who have not been previously treated with ALK inhibitors, those with ALK+ NSCLC who have progressed during treatment with other ALK inhibitors, and those patients with other tumor types driven by ALK or TRK. A controlled release formulation of TSR-011 is now available and is being evaluated in the ongoing study. ALK is a key driver of multiple types of cancers, including subsets of NSCLC, neuroblastoma and lymphoma. TRK may drive tumor growth in patients with TRK+ NSCLC, colorectal cancer and thyroid cancer. In order to maximize the commercial potential of TSR-011, we are studying TSR-011 in multiple tumor types and treatment settings. We believe that TSR-011 may be differentiated from crizotinib and ceritinib, currently the only two marketed ALK inhibitors, as well as other ALK inhibitors in development, due to its potency, specificity and activity on specific mutant ALK proteins and by its tolerance profile to date, which could attract clinical investigators and patients to our clinical trials. We also plan to evaluate TSR-011 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.*** In March 2014, we entered into a collaboration and exclusive license agreement with AnaptysBio for the discovery and development of immunotherapy antibodies against certain validated immuno-oncology targets, and we amended that agreement in November 2014. Under the agreement, 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 dual-reactive antibody product candidates targeting PD-1/TIM-3, PD-1/LAG-3 and an additional dual-reactive combination candidate. We have selected a lead monospecific antibody product candidate for the PD-1 program, TSR-042, and we intend to select other lead candidates and carry out preclinical, clinical, regulatory and other activities necessary to develop and commercialize antibodies selected under each of the development programs. 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 we either in-license or access through collaborative transactions with others. We expect that TSR-042 will begin clinical trials in early 2016.

- ***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 oncology supportive care products 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 our three current product candidates, 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 and oncology supportive care products that is balanced by stage of development, resource requirements and development risk. We categorize acquisition or in-licensing targets as follows:

Table of Contents

- *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 the sales and marketing and medical affairs organizations we intend to build 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 when we acquired rights to niraparib in May 2012, it was representative of this type of asset.

- *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 TSR-011 is representative of this type of asset.

- *Currently marketed products and soon to be marketed products around which we could develop a commercial operation.* We continue to seek, and may 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 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 currently have exclusive worldwide rights to all of our current product candidates (rolapitant, niraparib, TSR-011, 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, niraparib, and TSR-011 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 currently 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

Table of Contents

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.

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. The American Cancer Society estimated that in the United States in 2014, approximately 1.7 million new cases of cancer would be diagnosed and more than 585,000 people would die from the disease. Current treatments for cancer include surgery, radiation therapy, chemotherapy, hormone therapy and targeted therapy. The IMS Institute for Healthcare Informatics estimated in a 2012 report that global oncology spending will exceed $90 billion by 2017, representing the largest class of drug spending globally. The National Institutes of Health estimated in a 2011 analysis that direct medical costs (i.e., a total of all health expenditures) associated with cancer will reach $158 billion by 2020.

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 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 Candidates

Our first three 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.

Table of Contents

Rolapitant Neurokinin-1 (NK-1) Receptor Antagonist

Overview

Rolapitant is a potent and long-acting NK-1 receptor antagonist that is being developed as a supportive care product for the prevention of CINV. We demonstrated in three phase 3 trials that a single dose of rolapitant, when administered along with the current standard of care for CINV (a 5-HT3 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 & Co, Inc., or 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.

Chemotherapy Induced Nausea and Vomiting

According to CINV prevention and treatment guidelines developed and published by respected oncology organizations such as the National Cancer Care Network, or NCCN, Multinational Association for Supportive Care in Cancer, or MASCC, and American Society of Clinical Oncology, or ASCO, if not prevented by prophylaxis, CINV has the potential to afflict up to 90% or more of cancer patients undergoing chemotherapy, depending upon the type of chemotherapy administered, the dosing schedule of the chemotherapy and the patients gender, among other predisposing factors. Prolonged nausea and vomiting may result in unwanted weight loss, dehydration and malnutrition as well as hospitalization. If not prevented, CINV may result in a delay or discontinuation of chemotherapy treatment. Based on our analysis of market data provided by IMS Health Incorporated and patient treatment data collected by Ipsos Healthcare, a market research firm, we estimate that the annual NK-1 receptor antagonist market in the United States consists of approximately 5 million potential treatments administered on the first day of chemotherapy in combination with the current standard of care for the prevention of CINV. We estimate that approximately 85-90% of these potential 5 million treatments would be for patients receiving the combination of anthracycline and cyclophosphamide, or AC, based chemotherapy, for the treatment of breast cancer, or for certain patients receiving moderately emetogenic chemotherapy, or MEC, for other types of cancer. The

Table of Contents

remaining potential treatments are for patients receiving highly emetogenic chemotherapy, or HEC, regimens that contain cisplatin. Current treatment guidelines recommend that all cancer patients receiving AC based chemotherapy for breast cancer and cisplatin containing regimens should be treated with an NK-1 receptor antagonist in addition to the current standard of care for CINV, while cancer patients receiving MEC regimens could in appropriate circumstances be treated with an NK-1 receptor antagonist in addition to the current standard of care for the prevention of CINV. The NCCN guidelines clarify that it is appropriate to treat cancer patients receiving a MEC regimen that utilizes carboplatin with an NK-1 receptor antagonist in addition to the current standard of care for CINV.

The Journal of Supportive Oncology has reported that the perception of healthcare professionals as to whether their patients experience delayed nausea and vomiting due to chemotherapy differs significantly from actual patient experience. Specifically, this journal reported in 2004 that healthcare professionals perceived that 76% of their patients did not experience delayed nausea and 91% of their patients did not experience delayed vomiting when actual patient experience indicated that only 43% of patients did not experience delayed nausea and 59% of patients did not experience delayed vomiting.

The current standard of care for CINV consists of a 5-HT3 receptor antagonist (usually one of ondansetron, granisetron, dolasetron or palonosetron) plus a corticosteroid (usually dexamethasone). 5-HT3, or serotonin sub-type 3, receptor antagonists block the binding of serotonin to the 5-HT3 receptor in specific nerve endings in the body and the brain, resulting in a reduction in nausea and vomiting in patients at risk for CINV. Additional protection against CINV is provided to certain patients when an NK-1 receptor antagonist is administered together with a 5-HT3 receptor antagonist. NK-1 receptor antagonists block substance P from binding to NK-1 receptors. Substance P is a natural substance in the brain that binds to the NK-1 receptor and represents a second mechanism that induces nausea and vomiting. Currently there are only two 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 on October 10, 2014 the FDA approved a combination of netupitant and palonosetron, which is known by the brand name AKYNZEO® and marketed by Helsinn Healthcare, or Helsinn, and Eisai Inc., or Eisai, as a combined 5-HT3 and NK-1 receptor antagonist. Based on Merck s announcement of its financial results for the year ended December 31, 2014, EMEND generated $553 million (unaudited) in global revenues in 2014. We believe there is a significant need for an NK-1 receptor antagonist with what we expect to be the approved safety and efficacy profile of rolapitant.

The following chart summarizes rankings of chemotherapy treatment side effects from a study of patients diagnosed with ovarian, primary peritoneal or fallopian tube cancer who received at least three cycles of platinum-based chemotherapy. Using a visual analog score, where patients rank different side effects on a scale from zero to 1.0, with zero being the least favorable and 1.0 being the most favorable, patients evaluated different side effects related to cancer and chemotherapy treatment, including CINV 1-6, representing different scenarios of CINV. According to the study, the most favorable side effects included perfect health and clinical remission, followed closely by CINV 1, or complete-to-almost-complete control of CINV. By contrast, all of the least favorable side effects, other than death, included nausea and vomiting. This study, the results of which are summarized in the figure below, shows that patients view CINV as one of the least favorable side effects of chemotherapy treatment.

Table of Contents

Patient Rankings of Chemotherapy Treatment Side Effects

Source: Adapted from Charlotte C. Sun et al., *Rankings and symptom assessments of side effects from chemotherapy: insights from experienced patients with ovarian cancer,* Support Care Cancer (2005).

There are two phases associated with CINV: acute and delayed. The acute phase occurs within the first 24 hours following chemotherapy treatment. It is believed that this phase is caused largely by chemotherapy-induced increases in serotonin release and activation of 5-HT3 receptors on vagal afferent neurons in the gut.

There are currently four 5-HT3 receptor antagonists on the market in the United States (ondansetron, palonosetron, granisetron and dolasetron) and one additional agent is available in several international markets (tropisetron), all of which are clinically effective in preventing acute CINV, particularly when given in combination with a corticosteroid, such as dexamethasone. Despite the success of the 5-HT3 receptor antagonists, protection of patients from acute CINV is not complete because other neurotransmitters are also involved in the onset of CINV. Furthermore, there remains a strong need to develop potent therapies effective to prevent or treat delayed CINV.

Delayed CINV is described as occurring after 24 hours and up to five days following emetogenic chemotherapy and is believed to be primarily driven by a different etiology than acute CINV. Combination therapy with a corticosteroid and 5-HT3 receptor antagonist, particularly with the first generation 5-HT3 receptor antagonists, is less effective during the delayed phase than it is in the acute phase of CINV. This is because the primary etiology of delayed CINV appears to involve substance P. Substance P binds to NK-1 receptors, which are highly concentrated in the brain. Activation of NK-1 receptors in the brain plays a central role in nausea and vomiting induced by emetogenic stimuli, including certain cancer chemotherapies. An NK-1 receptor antagonist works by blocking the binding of substance P with NK-1 receptors. A clinical study that employed positron emission tomography, a medical technique utilized for imaging biochemical activity within the body, demonstrated that

rolapitant, provided in single oral doses ranging from 5mg to 200mg, binds to brain NK-1 receptors. At a time point of five days following administration of a single 200mg dose, over 90% of NK-1 receptors remained occupied by rolapitant. The addition of an NK-1 receptor antagonist to the standard of care (a 5-HT3 receptor antagonist plus a corticosteroid) has been demonstrated to improve the management of both acute and delayed CINV experienced by cancer patients undergoing chemotherapy.

Despite the importance of the NK-1 receptor in the etiology of both acute and delayed emesis, there are only three approved products that target this receptor: oral aprepitant and its IV pro-drug fosaprepitant, which are both known by the brand name EMEND, and AKYNZEO. In multiple clinical trials, EMEND provided significantly better protection against both acute and delayed emesis when it was added to a 5-HT3 receptor antagonist and corticosteroid as compared to the 5-HT3 receptor antagonist and corticosteroid alone. Similar results were observed in clinical trials of AKYNZEO when added to a corticosteroid. EMEND was initially introduced as an oral formulation in 2003. In 2010, Merck introduced a single-

Table of Contents

dose IV formulation of EMEND, which we believe currently accounts for approximately 80% of all EMEND usage. AKYNZEO was introduced in capsule form in October 2014.

We believe that the product profile of rolapitant, if approved, will provide a long-lasting clinical benefit to patients with a better drug interaction profile than the other NK-1 receptor antagonists on the market or in development. Pharmacokinetic and pharmacodynamic studies demonstrate that rolapitant has a half-life of approximately 180 hours and has high affinity for the human NK-1 receptor (Ki =0.7nM). Positron emission tomography, or PET, scans of patients five days after a single oral 200mg dose of rolapitant demonstrate greater than 90% NK-1 receptor occupancy. Further, data from clinical studies demonstrate that rolapitant is not an inhibitor or inducer of cytochrome P450 3A4 isoenzyme, or CYP3A4. When a drug inhibits or induces CYP3A4, it can lead to an adverse effect on the ability to metabolize other drugs. The data indicates that rolapitant does not alter the pharmacokinetics of midazolam or other tested CYP3A4 substrates, and consequently is unlikely to have an effect on the pharmacokinetics of drugs metabolized by CYP3A4. Based upon this data, and in contrast with the current oral and IV NK-1 receptor antagonists on the market, we believe that administration of rolapitant is unlikely to cause a clinically significant pharmacokinetic interaction with many commonly used drugs intended for cancer patients undergoing chemotherapy.

Clinical Guidelines for the Usage of 5-HT3 and NK-1 Receptor Antagonists

Most patients who receive preventative therapy for CINV receive chemotherapy regimens that are defined as having either high or moderate risk of causing nausea or vomiting. HEC regimens include those containing cisplatin, and for regulatory approval of drugs to prevent CINV in patients receiving HEC, this is an important patient population to study. CINV prevention and treatment guidelines developed and published by respected oncology organizations such as NCCN, MASCC, and ASCO also define anthracycline-cyclophosphamide containing treatment regimens as HEC. Such regimens are frequently utilized to treat certain types of breast cancer. MEC is categorized by ASCO, NCCN and other treatment guidelines, and includes chemotherapy agents such as carboplatin, irinotecan, ifosfamide and cisplatin when administered in doses of less than 50mg/m2.

Emetogenic Potential (ASCO, MASCC, NCCN Guidelines)	**Proportion of Patients Who Will Experience Emesis in the Absence of Effective Antiemetic Prophylaxis**
High	≥90% of patients
Moderate	30 - 90% of patients
Low	10 - 30% of patients
Minimal	<10% of patients

According to current treatment guidelines, the risk of vomiting for patients receiving HEC regimens, including anthracycline-cyclophosphamide, is equal to or greater than 90%. The current treatment guidelines also suggest that MEC regimens are associated with a risk of vomiting in the range of 30% to 90%. Based on our analysis of the market data and patient treatment data described above, we estimate that patients receiving HEC regimens, including for these purposes AC based chemotherapy, make up approximately 70% of the potential NK-1 receptor antagonist treatment market and patients receiving MEC regimens make up approximately 30% of the market.

We estimate that the U.S. NK-1 market was approximately $312 million in 2014, which is based on the sales of oral and IV formulations of EMEND. Our analysis of data from IMS Health indicates that following the 2011 launch of a single dose, IV-only regimen (versus the pre-existing three-day oral regimen), for the aprepitant IV pro-drug, fosaprepitant, the number of EMEND patient treatments grew over 20% for two consecutive years. In addition to sales of EMEND, in October 2014 Helsinn and Eisai introduced AKYNZEO to the market. We believe

the market will expand further based upon the combined 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

Key Characteristics of Rolapitant

Rolapitant is a highly potent, long acting NK-1 receptor antagonist that, if approved, may provide control of CINV over the five-day period of risk for cancer patients receiving emetogenic chemotherapy, including HEC and MEC. The safety and pharmacokinetic profile observed in Phase 1 clinical trials, combined with the clinical activity and safety profile observed in a randomized Phase 2 clinical trial described below, suggest that rolapitant represents a potential advance in the prevention of CINV. We believe that rolapitant has several important characteristics, including:

- *Long Half-Life.* Pharmacokinetic and pharmacodynamic studies demonstrate that rolapitant has a half-life of approximately 180 hours and has high affinity for the human NK-1 receptor (Ki =0.7nM). PET scans of patients five days after a single oral 200mg dose of rolapitant demonstrate greater than 90% NK-1 receptor occupancy.

- *Reduced Risk of CYP3A4 Drug Interactions.* Data from clinical studies demonstrate that rolapitant is not an inhibitor or inducer of cytochrome P450 3A4 isoenzyme, or CYP3A4. CYP3A4 is a liver enzyme that is responsible for the metabolism of a number of drugs. When a drug inhibits or induces CYP3A4, it can lead to an adverse effect on the ability to metabolize other drugs. The data indicates that rolapitant does not alter the pharmacokinetics of midazolam or other tested CYP3A4 substrates, and consequently is unlikely to have an effect on the pharmacokinetics of drugs metabolized by CYP3A4. Based upon this data, and in contrast with the current oral and IV NK-1 receptor antagonists on the market, we believe that administration of rolapitant is unlikely to cause a clinically significant pharmacokinetic interaction with many commonly used drugs intended for cancer patients undergoing chemotherapy.

Rolapitant Clinical Development

In 2008, Schering-Plough completed three Phase 2 clinical trials in which rolapitant was evaluated for the prevention of CINV, PONV and the treatment of chronic cough. One of these trials was designed to assess the efficacy and safety of rolapitant for the prevention of CINV for up to six cycles of chemotherapy, and to determine a Phase 3 dose. This was a multicenter, randomized, double-blind clinical trial in which 454 cancer patients receiving HEC were administered a 5-HT3 receptor antagonist and a corticosteroid (ondansetron and dexamethasone), and randomized in equal fashion to groups receiving either placebo or 10mg, 25mg, 100mg or 200mg of a single dose oral formulation of rolapitant. Subjects recorded episodes of emesis, severity of nausea, and use of rescue medications daily in a subject diary from days one through six of cycle 1.

The rolapitant 200mg group, compared to the control group, had significantly greater complete response rates, meaning no emesis and no use of rescue medication, in the overall phase, meaning zero to 120 hours after receipt of HEC, the acute phase, meaning zero to 24 hours after receipt of HEC, and the delayed phase, meaning greater than 24 hours to 120 hours after receipt of HEC. The tables below present the comparisons of complete response rates in the rolapitant 200mg group and the control group for the overall, acute and delayed phases.

	Complete Response Rate		
	200mg Rolapitant	**Control**	**P-Value**
Overall (0 to 120 hours)	62.5%	46.7%	0.032
Acute (0 to ≤24 hours)	87.6%	66.7%	0.001

Delayed (>24 to 120 hours)	63.6%	48.9%	0.045

In clinical trials, the p-value is a measure of how strongly the data support a real difference between the effects of treatment and control. The smaller the p-value, the stronger the evidence. Conventionally, if the p-value is less than 0.05, the presumption is that there is a real difference between the treatment and control groups, and the results are deemed statistically significant.

Table of Contents

Treatment-related adverse events were mild and included constipation, headache, fatigue and dizziness. Overall, serious adverse events occurred with similar incidences across all treatment groups (9% to 14%). The most common serious adverse events were neutropenia (a disorder characterized by an abnormally low number of certain types of white blood cells), febrile neutropenia (the development of fever, often with signs of infection, in a patient with neutropenia), vomiting, dehydration, nausea and pneumonia. These events, however, were considered by investigators to be related to chemotherapy or the underlying cancer and not to rolapitant. Data from this clinical study demonstrated that a dose of 200mg rolapitant administered with a 5-HT3 receptor antagonist and dexamethasone achieved statistically significant improvement in preventing CINV than 5-HT3 receptor antagonist and dexamethasone alone, and this dose was selected for advancement into Phase 3 clinical trials.

Results from the Phase 2 clinical trial discussed above demonstrated what we believe is a promising level of activity for CINV prevention for the five-day period following administration of chemotherapy, the period during which patients are at highest risk for CINV. We presented data from the Phase 2 clinical trial of rolapitant for the prevention of CINV at the ASCO annual meeting in June 2012.

Rolapitant Phase 3 Clinical Program

Based on the results of the Phase 2 clinical trial, in early 2012, we enrolled the first patient in our Phase 3 clinical program for oral rolapitant. The Phase 3 clinical program consisted of 2,456 patients each participating in one of three Phase 3 clinical trials focused on evaluating rolapitant plus the standard of care compared with control plus the standard of care. This global program consisted of two randomized, double-blind, active-controlled clinical trials evaluating the efficacy of a single 200mg oral dose of rolapitant in patients receiving HEC, and one clinical trial evaluating the efficacy of a single 200mg oral dose of rolapitant in patients receiving MEC. In each of the Phase 3 clinical trials the standard of care consisted of the 5-HT3 receptor antagonist granisetron in combination with the corticosteroid dexamethasone. The patients in these clinical trials were evaluated for evidence of an improvement in control of nausea and vomiting during the acute, delayed and overall periods between zero and 120 hours post administration of chemotherapy. The primary outcome of each trial was based on complete response (defined as no emesis and no use of rescue medication) in the delayed phase (24 hours to 120 hours). Additional outcome measures included complete response for other time points, the incidence and intensity of nausea, and safety and tolerability.

In December 2013, we announced top-line results for two of the three completed Phase 3 trials of rolapitant. The first completed Phase 3 study of rolapitant was an international, multicenter, randomized, double-blind, active-controlled study that enrolled 1,369 cancer patients receiving MEC, approximately half of whom were receiving anthracycline-based treatment for breast cancer. Patients were randomized to receive either control, which consisted of a 5-HT3 receptor antagonist plus dexamethasone, or 200mg of oral rolapitant plus control. The rolapitant arm successfully achieved statistical significance over the control arm for the primary endpoint of complete response in the delayed phase. Secondary endpoints were tested in a hierarchical manner and multiplicity was controlled using the Bonferroni-Holm method. A greater proportion of patients treated with rolapitant in this trial achieved a complete response in the acute and overall phases and experienced no significant nausea compared to the control arm, although statistical significance was not met for these secondary endpoints when tested in this manner.

The second completed Phase 3 study of rolapitant was an international, multicenter, randomized, double-blind, active-controlled study that enrolled 555 patients receiving HEC, defined as regimens that contain cisplatin at a dose equal to or greater than 60mg/m2. Patients were randomized to receive either control, which consisted of 5-HT3 receptor antagonist plus dexamethasone, or 200mg of oral rolapitant plus control. Similar to the MEC study, the rolapitant arm in the HEC study successfully achieved statistical significance over the control arm for the primary endpoint of complete response in the delayed phase of CINV. Again, secondary endpoints were tested in a hierarchical manner and multiplicity was controlled using the Bonferroni-Holm method. A greater proportion of patients treated with rolapitant in this trial achieved a

complete

Table of Contents

response in the acute and overall phases and experienced no significant nausea compared to the control arm, although statistical significance was not met for these secondary endpoints.

In May 2014, we announced top-line results of the third and final completed Phase 3 trial of oral rolapitant. This trial was an international, multicenter, randomized, double-blind, active-controlled study that enrolled 532 cancer patients receiving HEC, defined as cisplatin-based regimens at a dose equal to or greater than 60mg/m2. Patients were randomized to receive either control, which consisted of a 5-HT3 receptor antagonist plus dexamethasone, or 200mg of oral rolapitant plus control. The rolapitant arm in this study successfully achieved statistical significance over the control arm for the primary endpoint of complete response in the delayed phase of CINV. In addition, the rolapitant arm also successfully achieved statistical significance over the control arm for the key secondary endpoints of complete response in the acute (0 to 24 hour) and overall (0 to 120 hour) phases of CINV, and for the secondary endpoints of no significant nausea (overall phase), and time to first event. In addition, tertiary endpoints of no significant nausea (acute and delayed phases), no nausea (delayed and overall phases), and complete protection, meaning no emesis, no use of rescue medication and no significant nausea (acute, delayed and overall phases) were achieved. Treatment emergent adverse events were similar between the rolapitant and control arms, and were consistent with earlier clinical studies.

During June 2014, we presented data from all three of our Phase 3 trials of rolapitant for the prevention of CINV at the annual meeting of the American Society of Clinical Oncology in Chicago, and at the MASCC/ISOO International Symposium on Supportive Care in Cancer annual meeting in Miami. These data included a retrospective subset analysis on U.S. patients in our trial of rolapitant in patients receiving MEC. This subset represented approximately 33% of the evaluable subjects in the MEC trial. In the U.S. subset analysis, patients treated with rolapitant achieved a higher complete response rate in the delayed, acute and overall phases and experienced higher rates of no emesis, no significant nausea, and complete protection in the overall phase, compared to the control arm.

In September 2014, we presented data from two of the three Phase 3 trials at the annual meeting of the European Society of Medical Oncology, including a retrospective subset analysis on outcomes by geographic regions and an analysis of the impact of CINV on daily life in the two trials that enrolled patients receiving HEC. In the regional subset analysis, patients treated with rolapitant achieved a higher complete response rate in the delayed, acute and overall phases across all geographic regions. Patients treated with rolapitant also achieved higher mean scores compared to the control group on the Functional Living Index-Emesis questionnaire, a patient reported outcome measure used to assess quality of life.

In each Phase 3 study, safety and tolerability data for patients who received rolapitant were similar to the results for those who received control, and were consistent with earlier clinical studies. The most frequently observed treatment-related adverse events were balanced across treatment arms and included fatigue, headache and dizziness.

In September 2014, we submitted to the FDA an NDA, for oral rolapitant, which was accepted for review by the FDA in November 2014. We are currently preparing to be able to launch oral rolapitant in the fourth quarter of 2015, assuming the NDA is approved on or about the PDUFA date of September 5, 2015.

Intravenous Formulation of Rolapitant

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. In January 2014, in a single ascending dose study we identified a dose of our IV formulation of rolapitant that we believe is likely to achieve bioequivalence to a 200mg dose of oral rolapitant. We plan to conduct a bridging safety study in patients to support regulatory approval of the IV formulation. Current plans for the development of the IV formulation are dependent on the success of the oral formulation. 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 commenced a study to compare the plasma exposure of IV rolapitant to the oral formulation in the third quarter of 2014. In the first quarter of 2015 we plan to initiate clinical studies to evaluate the safety of IV rolapitant to support an NDA submission, which we expect to submit in the fourth quarter of 2015. We expect to launch an IV formulation of rolapitant, if approved, approximately one year following the launch of the oral formulation.

Table of Contents

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. In July 2013, we dosed the first patient in our NOVA trial. During the second quarter of 2014, we dosed the first patient in our BRAVO trial. Based on research related to PARP inhibitors generally, we believe that niraparib may be effective in several additional oncology settings. Therefore, we are collaborating with SARC to evaluate niraparib in combination with temozolomide for the treatment of Ewing s sarcoma. Additionally, we intend to initiate during the first quarter of 2015 a potential registration trial of niraparib as a therapy for patients with ovarian cancer who have previously been treated with three or more prior regimens of therapy, and additional trials in the SCLC and first-line ovarian cancer maintenance settings during the second half of 2015. We may also evaluate niraparib for the treatment of gastric and prostate cancer, and we plan to evaluate niraparib in combination preclinical pharmacology studies with our immuno-oncology anti-tumor agents.

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 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. PARP inhibitors have shown preclinical efficacy as monotherapy against tumors with existing defects, such as BRCA1 and BRCA2, that compromise their ability to repair DNA, and as a combination therapy when administered together with anti-cancer agents that induce DNA damage.

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 show that niraparib may have advantages as a treatment for certain cancers, including:

- potent inhibition of PARP and demonstrated tumor growth inhibition in tumor models;

Table of Contents

- 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, including a RECIST response rate of 75% in a cohort of heavily pretreated ovarian cancer patients using the dose that has been selected for Phase 3 studies; 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 solid tumors, including ovarian, breast, gastric, lung, Ewing s sarcoma and prostate cancers.

Niraparib Preclinical Development

In vitro, niraparib increased the radiosensitivity of 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. Oral treatment with niraparib at doses ranging from 30mg to 400mg given once daily was evaluated in 60 patients with advanced solid tumors. The first part of the clinical study was a dose escalation to establish a maximum tolerated dose. The second part of the clinical study was a dose expansion study that included patients with platinum resistant ovarian cancer and prostate cancer. The maximum tolerated dose of oral niraparib was established as 300mg daily on a continuous schedule. A mean plasma half-life of 40 hours (range 37 to 42 hours) and dose-proportional pharmacokinetics were observed. PARP inhibition of 50% or more was observed following administration of niraparib doses equal to or greater than 80mg when measured at times when plasma contained the lowest levels of the drug. Evidence of anti-tumor activity was observed in patients with BRCA1 and BRCA2 mutations and in patients with sporadic cancers. In total, there were 12 patients with responses under the Response Evaluation Criteria in Solid Tumors, or

RECIST, published rules. Ten of the 12 patients had ovarian cancer (seven BRCA-mutation carriers, three sporadic), and two of the 12 were patients with breast cancer. In addition, stable disease, or SD, occurred in eight other patients. Four of those eight patients had ovarian cancer (two BRCA-mutation carriers), and two of the eight patients had NSCLC. Overall, 46% of ovarian cancer patients (n=47) had a clinical benefit, defined as SD for greater than 12 weeks (21%) or partial response (26%), or PR. Sixty-three percent of ovarian cancer patients with a BRCA mutation (n=21) had clinical benefit, defined as SD for greater than 12 weeks (21%) or PR (37%). In June 2013, we presented updated Phase 1 data at the ASCO annual meeting that demonstrated RECIST response rates as presented in the table below.

	Response Rate
High grade serous, platinum-sensitive ovarian cancer	
At recommended Phase 3 dose (300mg)	75%
Across all doses	46%
Germline BRCA mutation across all doses	50%
BRCA-positive breast cancer	
Across all doses	50%

Dose-limiting toxicities included grade 3 fatigue in one patient with clinical progression, and grade 3 pneumonitis and grade 4 thrombocytopenia, all of which resolved. Grade 1-2 toxicities included fatigue, anorexia, nausea and

Table of Contents

myelosuppression. 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.

In 2013, we met with the FDA and European Medicines Agency, or EMA, regarding our clinical development plans for niraparib in ovarian cancer patients. Based on the results of these meetings, we initiated our 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. In this ongoing trial, patients are enrolling 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. The basis for this pivotal clinical study includes results from Phase 1 and Phase 2 studies with PARP inhibitor compounds, including a Phase 1 study of niraparib, that show a substantial RECIST response rate (up to 75%) in patients with ovarian cancer, together with the results of a clinical study in ovarian cancer in which another then-investigational PARP inhibitor, LYNPARZATM (olaparib), demonstrated a PFS benefit when compared to placebo in the maintenance setting. We began enrolling patients in this global trial in July 2013. We expect to report initial data from NOVA during 2015.

In 2014 we entered into a collaboration with Myriad Genetics, Inc., or Myriad, for the use and development of a homologous recombination deficiency (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 TESARO s 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.

We intend to initiate during the first quarter of 2015 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. This trial is planned to be a single arm, open label study, targeted to enroll 225 patients. Endpoints include objective response rate and duration of response across platinum sensitive, platinum resistant, gBRCAmut and HRD patient subsets. We further intend to initiate a clinical trial of niraparib in the first-line ovarian cancer maintenance setting during the second half of 2015. The first-line ovarian cancer study will include patients who have responded to first-line platinum chemotherapy. Patients will likely be randomized 2:1 to receive niraparib or placebo. The endpoints for this study include progression free survival, progression free survival in subsequent therapy, or PFS2, overall survival and safety.

In 2013, we met with FDA and EMA regarding our clinical development plans for niraparib in breast cancer patients. Based on the results of these meetings, we initiated our BRAVO trial in the fourth quarter of 2013, and we began dosing the first patient in the second quarter of 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. The BRAVO trial is based upon the clinical activity of niraparib observed in a Phase 1 study of niraparib and the results of clinical studies of other PARP inhibitors including LYNPARZA (olaparib), which was recently approved, and BMN-673 (talazoparib).

We also intend to evaluate niraparib as a first-line, maintenance therapy in advanced metastatic SCLC patients. The SCLC study is currently planned to enroll patients with advanced metastatic SCLC who have received platinum-based chemotherapy and experienced a partial or complete response. Endpoints will include PFS, overall survival, safety and quality of life. Based on our analysis of third-party market research, we believe there are approximately 30,000 new cases of SCLC diagnosed in the U.S. annually, representing 13% of all lung cancers. We plan to begin enrollment of patients in the trial in the second half of 2015.

19

Table of Contents

TSR-011 Anaplastic Lymphoma Kinase (ALK) and Tropomyosin-Related Kinase (TRK) Inhibitor

Overview

TSR-011 is an investigational, orally available, small molecule inhibitor of ALK and TRK for the treatment of NSCLC and potentially other cancer indications. The TSR-011 program represents a molecularly targeted approach to treating certain cancer sub-populations of NSCLC that express ALK gene fusions or mutations that result in pathological constitutive activation of ALK, thereby enabling tumor cells to grow. Abnormal ALK and TRK proteins, or ALK and TRK expression, are also associated with sub-populations of other cancers including lymphoma, neuroblastoma, colorectal and thyroid cancer. TSR-011 was specifically designed to be selective for, bind tightly to, and inhibit the activity of the ALK protein to lead to or cause the death of cancer cells and the shrinking of tumors. In August 2011, the FDA approved the first ALK inhibitor, developed by Pfizer Inc., or Pfizer, Xalkori® (crizotinib), for the treatment of patients with locally advanced or metastatic NSCLC who are ALK+. In April 2014, the FDA approved the second ALK inhibitor, developed by Novartis AG, or Novartis, Zykadia TM (ceritinib), for the treatment of patients with locally advanced or metastatic NSCLC who are ALK+ and who have progressed on or are intolerant to crizotinib. To date, no TRK inhibitor has been approved for commercial use in any indication.

Although the ALK gene is not widely expressed in adults, ALK is known to be involved in certain types of cancers, including subsets of NSCLC, neuroblastoma and lymphoma. For patients in these subsets, the ALK gene is fused to an activating partner or contains point mutations, which results in constitutive activation of ALK and the growth of cancer cells and tumor development. Inhibition of ALK in these cancer cells results in cell death and tumor growth inhibition or regression. The limited tissue distribution and expression of ALK in adult subjects means that ALK may be a good molecular target for a cancer therapeutic because an ALK inhibitor would primarily affect cancer cells and tumors. TRK receptors include a family of three receptors with associated ligands, including nerve growth factor that binds to TRK-A. TRK gene rearrangements have been found in several tumor types, including NSCLC, papillary thyroid cancer, colorectal cancer and salivary cancer. In patients with these tumors, the TRK gene is fused to an activating partner or contains point mutations, which results in constitutive activation of TRK, the growth of cancer cells and tumor development. Inhibition of TRK in these cancer cells results in cell death and tumor growth inhibition. TRK expression in tumors is involved with tumor aggressiveness, metastatic potential, perineural invasion and pain.

We believe that existing commercially available diagnostic tests for the identification of ALK gene fusions will facilitate rapid and efficient development of our lead ALK/TRK inhibitor product candidate, TSR-011, for ALK-associated indications. In September 2012, we filed an IND for TSR-011 with the FDA that became effective in October 2012, and in November 2012, we announced that we had dosed the first patient in a Phase 1/2a dose escalation clinical trial of TSR-011 in cancer patients. Data from this trial will be used to select a dose and schedule of TSR-011. In the second half of 2013, we identified 60mg as a dose to move forward in clinical development. We also began a Phase 1 expansion study to explore fractionated doses of 60mg daily and 120mg daily of TSR-011 in patients with ALK or TRK expression, including those with ALK+ and TRK+ NSCLC who have not been previously treated with ALK inhibitors, those with ALK+ NSCLC who have progressed during treatment with other ALK inhibitors, and those patients with other tumor types driven by ALK or TRK. A controlled release formulation of TSR-011 is now available and is being evaluated in the ongoing study. The expansion stage of the Phase 1 clinical trial will evaluate the activity of TSR-011 in cancer patients with ALK mutations or gene fusions. Data from this study will inform us of the activity of TSR-011 in a relevant patient population, including ALK inhibitor naïve and resistant ALK+ NSCLC patients and TRK+ patients, and will be used to design clinical trials that will be used to support future regulatory submissions. We also plan to evaluate TSR-011 in combination preclinical pharmacology studies with our immuno-oncology anti-tumor agents.

Non-Small Cell Lung Cancer (NSCLC)

According to the American Cancer Society, over 1.6 million new lung cancer cases are identified worldwide annually, including 200,000 new lung cancer cases in the United States. Lung cancer is the leading cause of cancer death in men and the second leading cause of cancer death in women. Lung cancer is typically divided into two groups based upon the histologic appearance of the tumor cells, small cell and non-small cell lung cancer, each of which is treated with distinct chemotherapeutic approaches. According to the American Cancer Society, NSCLC accounts for approximately 85% of lung cancer cases, with approximately 75% of these patients being diagnosed with metastatic or advanced disease. Despite the introduction of new therapies, such as Avastin® (bevacizumab) solution for IV infusion and Alimta® (pemetrexed for injection), patients with locally advanced or metastatic NSCLC have five-year survival rates of just 24% and 4%, respectively, according to the Surveillance Epidemiology and End Results program of the National Cancer Institute. ALK is believed to be a key driver of tumor development in approximately 5% of all NSCLC patients. TRK may also drive tumor growth in patients with TRK+ NSCLC.

Table of Contents

Background on ALK and TRK Inhibitors

There are currently two ALK inhibitors being marketed. In 2011, Pfizer launched Xalkori (crizotinib), a dual MET/ALK inhibitor that acts as an inhibitor for mesenchymal epithelial transition tyrosine kinase, or MET, a driver of certain types of cancers, and ALK. In April 2014, the FDA approved the second ALK inhibitor, developed by Novartis, Zykadia (ceritinib), for the treatment of patients with locally advanced or metastatic NSCLC who are ALK+ who have progressed on or are intolerant to crizotinib. Clinical studies have demonstrated efficacy of crizotinib in a NSCLC sub-population expressing an ALK fusion protein. Treatment with crizotinib results in rapid tumor shrinkage in the majority of ALK patients. However, resistance mechanisms to crizotinib treatment occur within a median time frame of ten months. In addition, the FDA issued a Dear Doctor letter in December 2011 related to drug-induced hepatotoxicity, which now requires monitoring of elevated liver enzymes. Currently, crizotinib is dosed near its maximum tolerated dose, and side effects include severe or fatal pneumonitis, corrected QT interval prolongation and visual effects.

We believe there is a well-defined development and regulatory approval path for an ALK inhibitor, and that TSR-011 can be developed in a rapid and efficient manner, because appropriate patients for study can be identified with commercially available and other diagnostic tests, and testing for ALK at diagnosis is becoming more common. Based upon the data set forth below, we believe TSR-011 has the potential to be effective in patients who have not been treated with ALK inhibitors as well as those patients who have progressed after prior treatment with other ALK inhibitors. To date, no TRK inhibitor has been approved for commercial use in any indication.

TSR-011 Preclinical Development

TSR-011 has demonstrated promising results in preclinical studies, and was found to be more active against the ALK protein than what is reported in other studies for crizotinib. Also in these studies, it was observed that the IC50 of TSR-011 for recombinant ALK L1196M was 0.1nM, which is 200 times less than the IC50 of crizotinib for this ALK mutant protein. IC50 is the concentration of inhibitor at which 50% of the target protein activity is inhibited. The ALK L1196M mutation has been detected in patients whose tumors progress while they are being treated with crizotinib, and is currently the most commonly identified ALK mutation observed in patients treated with crizotinib.

The *in vivo* activity of our ALK inhibitors has been examined in several ALK models, including an anaplastic large cell lymphoma xenograft model. Daily oral dosing resulted in statistically significant tumor growth inhibition ($p < 0.0001$) without weight loss. The activity of ALK was evaluated in these tumors post dosing and complete inhibition of phosphorylated ALK, a marker of ALK activation, was observed.

TSR-011 Clinical Development

We plan to develop TSR-011 for oncology indications, including the treatment of patients with NSCLC whose tumors have altered ALK or TRK proteins and expression patterns. In September 2012, we filed an IND for TSR-011 with the FDA that became effective in October 2012, and in November 2012, we announced that we had dosed the first patient in a Phase 1/2a dose escalation clinical trial of TSR-011 in cancer patients. One goal of the Phase 1 clinical trial is to determine the maximum tolerated dose of TSR-011 and to define an optimal dosing schedule. During the dose escalation phase of this trial we identified a 60mg dose for further clinical study. This total daily dose is being studied in a 60mg and 120mg expansion cohort as a fractionated dose, administered as 30mg every 12 hours and 20mg every eight hours for the 60mg fractionated dose and 40 mg every eight hours for the 120mg fractionated dose in patients with ALK+ and TRK+ cancers. A controlled release formulation

of TSR-011 is now available and is being evaluated in the ongoing study. In September 2013 at the European Cancer Conference, we reported that we had observed preliminary clinical activity in this study in one papillary thyroid carcinoma patient and one pancreatic cancer patient without ALK expression, and in three patients with ALK+ NSCLC who progressed following prior treatment with crizotinib. Of the three ALK+ NSCLC patients who progressed on prior crizotinib treatment, one achieved a RECIST partial response after four weeks of treatment with TSR-011; one, with disease not evaluable by RECIST criteria, achieved an investigator-assessed partial response; and one has stable disease. In addition, one patient with papillary thyroid carcinoma and one patient with pancreatic cancer each had long-term stable disease following several cycles of TSR-011 treatment. Preliminary results after eight weeks of treatment with TSR-011 demonstrated disease control (partial responses plus stable disease) in 11 of 17 (65%) evaluable patients treated with TSR-011.

Table of Contents

We plan to evaluate TSR-011 in three parallel cohorts of patients: those with ALK+ NSCLC who have not been previously treated with ALK inhibitors; those with NSCLC who have progressed during treatment with other ALK inhibitors; and those with other tumor types expressing ALK or TRK. We have expanded the Phase 1/2a clinical trial of TSR-011 to multiple clinical trial sites in the United States, Europe and Asia. During cohort expansion and prior to initiating a registration study, we intend to replace the Phase 1 formulation with an extended release formulation that is intended to provide convenience for patients. Information from this study may also be used to optimize future clinical trial designs that will be used to support future regulatory submissions.

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 over the next 12 to 18 months.

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 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 expect to begin clinical trials using TSR-042 in early 2016. In addition, we plan to evaluate our immuno-oncology anti-tumor agents, such as TSR-042, in combination preclinical pharmacology studies with TSR-011, niraparib and potentially other anti-tumor agents.

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

have progressed on YERVOY® (ipilimumab). We are aware of several companies that have anti-PDL-1 and/or anti-PD-1 modulators in development for various indications, including Bristol-Myers Squibb, Merck, Pfizer, Genentech, MedImmune (AstraZeneca), Medivation and EMD Serono (Merck KGaA).

Anti-TIM-3 and Dual-Reactive 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

Table of Contents

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 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 a lead anti-TIM-3 candidate for clinical development. In addition, several dual-reactive antibodies to PD-1 and TIM-3 have been isolated and are in the process of being advanced into functional activity testing.

There are currently no anti-TIM-3 antibody products being marketed. We are not aware of any companies that have anti-TIML-3 and/or anti-TIM-3 modulators in clinical development for any indications.

Anti-LAG-3 and Dual-Reactive 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, a lead clinical candidate has been identified, and additional backup candidates continue to be generated. In addition, AnaptysBio is progressing toward screening and isolation of dual-reactive antibodies to PD-1 and LAG-3.

There are currently no anti-LAG-3 antibody products being marketed. We are aware of several companies that have anti-LAGL-3 and/or anti-LAG-3 modulators in development for various indications, including Bristol-Myers Squibb and Merck.

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, we paid OPKO $6.0 million upon signing the agreement and issued 1,500,000 shares of our Series O convertible preferred 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 $5.0 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. If commercial sales of rolapitant commence, we are required to pay OPKO tiered royalties on the amount of annual net sales achieved in the United States and Europe at percentage rates that range from the low teens to the low twenties, which we expect will result in an effective royalty rate in the low teens. The royalty rate on annual net sales outside of the United States and Europe is slightly above the single digits. We will pay royalties on rolapitant until the later of 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

Table of Contents

the product, in each case, on a country-by-country and product-by-product basis. If we elect to develop and commercialize rolapitant in Japan through a third-party licensee, we will share equally with OPKO all amounts received by us in connection with such activities under our agreement with such third party, subject to certain exceptions and deductions. OPKO also retains an option to become the exclusive distributor of such products in Latin America, provided that OPKO exercises that option within a defined period following specified regulatory approvals in the United States.

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 Sharp & Dohme Corp., a subsidiary of 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, one in the amount of $1.9 million upon dosing of the first patient in our NOVA trial in July 2013 and one in the amount of $0.9 million upon dosing of the first patient in our BRAVO trial in April 2014. We are required to make total milestone payments to Merck of up to $57.0 million in 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 TSR-011

In March 2011, we entered into a license agreement with Amgen, under which we 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. We are also responsible for using commercially reasonable efforts to conduct all preclinical, clinical, regulatory and other activities necessary to develop and commercialize an ALK product. In the event that we wish to sublicense any of the development and commercialization rights to any third party, we are required to grant Amgen a right of first negotiation with respect to the rights we propose to sublicense.

Under the terms of the license agreement, we made an up-front payment to Amgen of $0.5 million, and upon dosing of the first patient in our Phase 1/2a clinical trial in October 2012, we made a milestone payment of $1.0 million. We are required to make total milestone payments to Amgen of up to an aggregate of $138.0 million if specified clinical development, regulatory, initial commercialization and annual net product sales milestones are achieved. If commercial sales of a product commence, we will pay Amgen royalties at percentage rates ranging from the mid-single digits to slightly above the single digits based on cumulative worldwide net sales until the later of the last patent licensed from Amgen covering the product, the loss of regulatory exclusivity for the product, or the tenth anniversary of the first commercial sale of the product, in all cases, on a country-by-country and product-by-product basis.

Table of Contents

The license with Amgen will remain in force until the expiration of the royalty term in each country, unless Amgen has cause to terminate the license earlier for our material breach of the license or bankruptcy, or in the event that we or any sublicensee bring a challenge against Amgen in relation to the licensed patents. We have the right to terminate the license with Amgen on Amgen s bankruptcy, or at any time during the term on ninety days written notice if our board of directors concludes that due to scientific, technical, regulatory or commercial reasons, the further commercialization of licensed products is no longer feasible.

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 dual-reactive 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 TIM-3, LAG-3 and PD-1 (TSR-042) and three dual-reactive antibody product candidates targeting PD-1/TIM-3, PD-1/LAG-3 and an additional dual-reactive 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 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.

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.

Table of Contents

Rolapitant Competition

Oral aprepitant, its IV formulation fosaprepitant, and netupitant are currently the only commercially available NK-1 receptor antagonists. Oral aprepitant and IV fosaprepitant are both known by the brand name EMEND and are marketed by Merck. Eisai and Helsinn market an oral combination NK-1 receptor antagonist and 5-HT3 receptor antagonist product (netupitant plus ALOXI (palonosetron HCl) that is known by the brand name AKYNZEO.

Niraparib Competition

There is currently one PARP inhibitor that is commercially available, AstraZeneca Plc s LYNPARZA (olaparib), which was approved in December 2014 by the FDA for use by ovarian cancer patients who have been treated with three or more prior lines of chemotherapy in the maintenance setting and also by the EMA for use by ovarian cancer patients who have been treated with one or more prior lines of chemotherapy. We believe the products in development targeting the PARP pathway consist of BioMarin Pharmaceutical Inc. s BMN-673 (talazoparib), 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, currently in Phase 2 clinical trials, and Teva Pharmaceutical Industries, Ltd. s CEP-9722, currently in a Phase 1 clinical trial.

TSR-011 Competition

There are currently two ALK inhibitors that are commercially available, Xalkori (crizotinib), a dual MET/ALK inhibitor marketed by Pfizer, and Zykadia (ceritinib), an ALK inhibitor marketed by Novartis. Zykadia was approved in December 2014 for those who have progressed on or are intolerant to crizotinib.

In addition, we are aware of several oral ALK inhibitors in clinical development, including Chugai Pharmaceutical Co., Ltd. s CH5424802 (alectinib), approved in Japan and currently in Phase 3 clinical trials in the United States and Europe, ARIAD Pharmaceuticals, Inc. s AP26113, currently in a Phase 2 clinical trial, and Xcovery s X-396 as well as Pfizer s P-06463922, currently in Phase 1 clinical trials.

There are currently no commercially available TRK inhibitors. We are aware of TRK inhibitors in clinical and preclinical development, including Ignyta s RXDX-101 (entrectinib), which is in the Phase 1 portion of a potential Phase 1/2 clinical trial, and Loxo Oncology s LOXO-101, also in a Phase 1 study.

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. These include: Bristol-Myers Squibb, which has an approved

anti-PD-1 antibody, OPDIVO (nivolumab), and an anti-LAG-3 antibody in development; Merck, which has an approved anti-PD-1 antibody that is commercially available by the trade name KEYTRUDA (pembrolizumab), formerly called MK-3475; and Pfizer, Genentech, Medimmune (AstraZeneca), Medivation and EMD Serono (Merck KGaA), which have anti-PDL-1 and/or anti-PD-1 modulators in development. We are also aware of several other companies with immuno-oncology antibodies or programs in the preclinical or research phase.

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 Candidates Rolapitant Neurokinin-1 (NK-1) Receptor Antagonist Chemotherapy Induced Nausea and Vomiting, Our Product Candidates Niraparib Poly (ADP-ribose) Polymerase (PARP) Inhibitor and Our Product Candidates TSR-011 Anaplastic Lymphoma Kinase (ALK) and Tropomyosin-Related Kinase (TRK) Inhibitor Background on ALK and TRK Inhibitors.

Commercial Operations

We intend to build the commercial infrastructure in North America, and alone or in conjunction with other established companies in Europe and China necessary to effectively support the commercialization of rolapitant, niraparib, and TSR-011, TSR-042, and our other immuno-oncology candidates, together with future product candidates, if and when we believe a regulatory approval of the first of such product candidates in a particular geographic market appears likely in the

Table of Contents

near term. The commercial infrastructure is expected to include a targeted, oncology sales force to establish relationships with a focused group of oncologists, oncology nurses and pharmacists. The sales force will be supported by sales management, internal sales support, an internal marketing group and distribution support. Additionally, the sales and marketing teams will manage relationships with key accounts such as managed care organizations, group-purchasing organizations, hospital systems, oncology group networks, and government accounts. To develop the appropriate commercial infrastructure, we will have to invest significant amounts of financial and management resources, some of which will be committed prior to any confirmation that rolapitant, niraparib, TSR-011, or any other 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 pharmaceutical 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 its 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. 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 Europe are addressed in a centralized way through the European Medicines Agency, but country-specific regulation remains essential in many respects.

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 Public Health Service Act, 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.

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.

Table of Contents

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.

We have completed a Phase 3 clinical program for rolapitant. In 2013 and 2014 respectively, we initiated separate NOVA and BRAVO trials for niraparib. We also intend to evaluate niraparib as a first-line maintenance therapy in ovarian cancer patients, as a therapy for patients with ovarian cancer who have previously been treated with three or more regimens of therapy, and in SCLC patients. We are also collaborating with SARC to evaluate niraparib in combination with temozolomide for the treatment of Ewing s sarcoma. We may also evaluate niraparib for the treatment of gastric and prostate cancer. With regard to our ALK/TRK program, we are conducting a Phase 1/2a dose escalation clinical trial of TSR-011 in cancer patients.

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.

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

Table of Contents

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. In September 2014, we submitted to the FDA an NDA for oral rolapitant, which was accepted for review by the FDA in November 2014 and has a PDUFA date of September 5, 2015.

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 of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, 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 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.

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

Table of Contents

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 drug 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.

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.

Table of Contents

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, niraparib and TSR-011, if approved, 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, niraparib and TSR-011, if approved, will qualify for patent term restoration.

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.

In February 2012, the FDA released three draft guidance documents as part of the implementation of the abbreviated approval pathway for biosimilars. In March 2013, the FDA released a draft guidance document regarding formal meetings between FDA and biosimilar product sponsors or applicants. Although no biosimilar applications have yet been licensed by the FDA, the agency accepted the first such application in 2014, and an advisory committee recommended its approval in January 2015. The FDA has indicated that it expects to release additional guidance documents regarding biosimilars in 2015, including guidance documents relating to interchangeability, statistical issues in demonstrating similarity and biosimilars labeling. 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, proposed regulations, and decisions in the course of considering specific applications. Such evolution may significantly affect the impact of the BPCI Act on both reference product and biosimilar sponsors.

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 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

Table of Contents

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 Europe, for example, a CTA must be submitted to each country s national health authority and an independent ethics committee, much like the FDA and 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, 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 country). 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. Based on the opinion of the EMA, the European Commission takes 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 approach; and anticipation of high therapeutic benefit. In these circumstances, the EMA ensures that the opinion of the CHMP is given within 150 days.

Table of Contents

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.

In the EU, 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. An EU Member State may approve a specific price or level of reimbursement for the medicinal product, or alternatively adopt a system of direct or indirect controls on the profitability of the company responsible for placing the medicinal product on the market, including volume-based arrangements and reference pricing mechanisms.

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 and Sweden. The HTA process in the European Economic Area, or EEA, Member States 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-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.

Table of Contents

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. It also provides for the establishment of a voluntary network of national authorities or bodies responsible for HTA in the individual EU Member States. The purpose of the network is to facilitate and support the exchange of scientific information concerning HTAs. This could lead to harmonization between EU Member States of the criteria taken into account in the conduct of HTA and their impact on pricing and reimbursement decisions.

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 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.

Payments made to physicians in certain EU Member States must be publically disclosed. Moreover, 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 European Union, 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 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

Table of Contents

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 may obtain regulatory approval. Sales of any of our product candidates, if approved, 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 any 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, the federal agency that administers the Medicare and Medicaid programs, has made draft National Average Drug Acquisition Cost, or NADAC, and draft National Average Retail Price, or NARP, data publicly available on at least a monthly basis. In July 2013, CMS suspended the publication of draft NARP data, pending funding decisions. In November 2013, CMS moved to publishing final rather than draft NADAC data and has since made updated NADAC data publicly available on a weekly basis. As a result of this continuous evolution, 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.

If we participate in the Medicaid drug rebate program, we will have certain price reporting obligations to the Medicaid drug rebate program, and we may have obligations to report ASP figures to the Medicare program. Under the Medicaid drug rebate program, we would be required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to CMS. These data include AMP and, in the case of innovator products, the best price for each drug which, in general, represents the lowest price available from the manufacturer to any entity in the United States in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions.

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.

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

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

Table of Contents

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 the product candidates that we are developing and could adversely affect our net revenues and operating results.

The marketability of 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 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, 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,

Table of Contents

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 2015, 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 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 one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Federal law requires that any company that participates in the Medicaid rebate program also participate in the Public Health Service s 340B drug pricing program in order for federal funds to be available for the manufacturer s drugs under Medicaid and Medicare Part B. The 340B drug pricing 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 no higher than the statutory federal ceiling price. The requirements under the 340B and FSS programs could reduce the revenue we may generate from 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 remuneration to those who prescribe, purchase, or recommend pharmaceutical and biological products, including certain discounts, or engaging consultants for 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

Table of Contents

product. Other companies have faced enforcement actions for causing false claims to be submitted because of the company s marketing the product for unapproved, and thus non-reimbursable, uses. In addition, 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.

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 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 four patent portfolios, one each for our rolapitant, niraparib, ALK/TRK 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

Table of Contents

consists of 14 issued United States patents and 126 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 68 issued non-United States patents.

Our PARP inhibitor portfolio includes three 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 five of the patent families are being prosecuted or maintained by Merck in consultation with us. The three patent families relating to niraparib include applications and patents directed to compositions of matter, methods of treatment (including treatment of cancer and other diseases), and particular salts of niraparib. Of these three 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 64 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, Russia, New Zealand and South Africa.

Our anaplastic lymphoma kinase portfolio consists of three patent families directed to both compositions of matter and methods of treating certain cancer sub-populations whose tumors express mutant ALK protein. These three patent families are at early stages of prosecution. One U.S. patent has issued. Other pending applications in the portfolio include two patent applications in the United States and 32 patent applications outside of the United States.

Our immunotherapeutic antibodies portfolio presently includes a United States patent application covering particular lead antibodies to one identified target of interest. Additional filings are contemplated with respect 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 currently 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 licenses from OPKO for rolapitant and from Amgen for TSR-011 grant 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 currently 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 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 currently 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

Table of Contents

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 Europe 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.

In addition, we intend to seek orphan drug status in jurisdictions in which it is available. An orphan drug designation may be granted where a drug or biological product is developed specifically to treat a rare or uncommon medical condition. If a product which has an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, meaning that the applicable regulatory authority may not approve any other applications to market the same drug or biologic for the same indication, except in certain very limited circumstances, for a period of seven years in the United States and ten years in the European Union. Orphan drug designation does not prevent competitors from developing or marketing different drugs or biologics for an indication, or the same drug or biologic for different indications.

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. A sister patent, 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.

Patent applications directed towards IV formulations of rolapitant (including in the form of a micelle formulation) are pending in the United States and multiple foreign jurisdictions.

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 three patent families that relate to niraparib include one issued United States patent: United States Patent 8,071,623. This patent has a term of until March 2030. We have filed corresponding applications and have been issued 64 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 patent family corresponding to United States Application No. 13/091,427 discloses and claims a broad genus of compounds that encompasses niraparib. This family includes applications pending in multiple jurisdictions and one patent issued in 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.

Table of Contents

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, New Zealand and South Africa. 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.

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.

Anaplastic Lymphoma Kinase (ALK) Inhibitor

We have an exclusive, worldwide license from Amgen to a portfolio of patents related to inhibitors of anaplastic lymphoma kinase, including TSR-011. Our ALK portfolio consists of three patent families. The first patent family, corresponding to International Patent Application number PCT/US2011/035186 and directed toward novel compositions of matter and methods of treating certain cancer sub-populations whose tumors express an ALK fusion protein, is pending in multiple jurisdictions. U.S. Patent US 8,716,281 claims composition of matter of these inhibitors. The second family, corresponding to International Patent Application number PCT/US2011/045703 and directed toward the genus of compounds that includes TSR-011 is pending in multiple jurisdictions. These applications, if issued, would expire in 2031. The third family, directed to methods of treating ALK resistance, is pending in multiple jurisdictions.

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 (including in bispecific and other formats), as well as their production and use; additional filings are in progress.

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

In March 2012, we entered into a process development and manufacturing services agreement with Hovione Inter Limited, or Hovione, under which Hovione will provide certain process development and manufacturing services in connection with the manufacture of rolapitant. 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. Under the agreement, we will pay Hovione for services in accordance with the terms of work plans, which we will 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 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.

We currently contract with third parties for the manufacture of our product candidates for preclinical studies and clinical trials and intend to do so in the future. We currently work with Hovione as a contract manufacturer, or CMO, for the production of rolapitant drug substance, and with another CMO for the production of oral rolapitant drug product, and another CMO for the production of IV rolapitant drug product. We utilized CMOs for the manufacture of TSR-011 for use in preclinical and Phase 1/2a clinical trials. 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 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. Although we rely on CMOs, we have personnel with pharmaceutical development and manufacturing experience who are responsible for the relationships with our CMOs.

Table of Contents

Employees

As of December 31, 2014, we had 108 full-time employees, 27 of whom hold Ph.D. or M.D. degrees. Of these full-time employees, 77 were directly engaged in development activities, with the remainder serving in primarily general and administrative 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. We incurred research and development expenses, including acquired in-process research and development, of $55.2 million, $77.7 million, and $143.3 million during the years ended December 31, 2012, 2013 and 2014, respectively. We anticipate that a significant portion of our operating expenses will continue to be related to research and development in 2015 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 our financial statements and the related notes. We cannot assure you that any of the events discussed in the risk factors below will not occur. These risks, or other events that we do not currently anticipate or that we currently deem immaterial, may have a material adverse effect on our business, prospects, financial condition and results of operations.

Risks Related to Our Financial Position and Capital Needs

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

We are a biopharmaceutical company with a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. We have not generated any revenue from product sales to date, and we continue to incur significant development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception in 2010. For the year ended December 31, 2014, we reported a net loss of $171.0 million and had an accumulated deficit of $350.5 million as of December 31, 2014.

We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. 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 and the timing and amount of milestones and other required payments to third parties. If any of our product candidates fail in clinical trials or do not gain regulatory approval, or if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our stockholders equity and working capital.

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

We were incorporated in March 2010. Our operations to date have been limited to organizing and staffing our company, acquiring product and technology rights, and conducting product development activities for our three current product candidates. We have not yet obtained regulatory approval for, or demonstrated an ability to commercialize, any of our 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 on the market, or both.

We currently have no source of revenue and may never become profitable.

To date, we have not generated any revenues from the three clinical-stage product candidates that we have in-licensed, rolapitant, niraparib and TSR-011. We also have not generated any revenues from the other product candidates that we have in-licensed, including TSR-042, our monospecific antibody product candidates targeting TIM-3 and LAG-3, and our dual-reactive antibody product candidates targeting PD-1/TIM-3, PD-1/LAG-3 and an additional dual-reactive combination, which are in preclinical development. Our ability to generate revenue and become profitable depends upon our ability to successfully commercialize products, including any of our three clinical-stage product candidates, or the 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 rolapitant, niraparib, TSR-011 or TSR-042, we do not know when any of these products will generate revenue for us, if at all. Our ability to generate revenue from 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 rolapitant, niraparib and TSR-011;

Table of Contents

- complete and submit new drug applications, or NDAs, or biologic license applications, or BLAs, to the U.S. Food and Drug Administration, or FDA, and obtain regulatory approval for indications for which there is a commercial market;

- complete and submit NDAs 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 rolapitant, niraparib, TSR-011 and any of our other product candidates at acceptable cost levels;

- develop a commercial organization capable of sales, marketing and distribution;

- find suitable partners to help us market, sell and distribute our approved products; and

- obtain adequate reimbursement from third-party payors, including government payors.

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

Even if we are able to generate revenues from the sale of our products, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

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

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to advance the clinical development of our product candidates and launch and commercialize any product candidates for which we receive regulatory approval, including building our own commercial organizations to address certain markets. We believe that our existing cash and cash equivalents will be sufficient to fund our projected operating requirements through at least December 31, 2015. However, we expect to require additional capital for the further development and commercialization of our product candidates and may also need to raise additional funds to pursue our strategy of in-licensing or acquiring additional product candidates.

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

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of

Table of Contents

factors, including the factors discussed elsewhere in this Risk Factors section. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements, both short and long-term, will depend on many factors, including:

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

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

- the initiation, progress, timing, costs and results of clinical trials for our current product candidates and any future product candidates we may in-license, including our Phase 3 clinical trials for niraparib, our various Phase 1 clinical trials of IV rolapitant and our Phase 1/2a clinical trial for TSR-011;

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

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

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

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

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

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

- the effect of competing technological and market developments.

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

Risks Related to Our Business and Industry

Our future success is dependent primarily on the regulatory approval and commercialization of our product candidates, including oral rolapitant, which is the subject of an NDA currently pending before the FDA.

Although the oral rolapitant NDA is currently pending before the FDA, we currently do not have any products that have gained regulatory approval. The success of our business is dependent upon our ability to develop and commercialize our product candidates, particularly rolapitant, niraparib and TSR-011, which are currently our only clinical-stage product candidates. We are particularly dependent on the future success of rolapitant, because it is our most advanced product candidate. Our other product candidates are at earlier stages of development. Niraparib is currently in Phase 3 clinical trials in ovarian and breast cancer patients that commenced during 2013 and 2014, respectively, and TSR-011 is still early in clinical development. Our monospecific antibody product candidates targeting PD-1 (TSR-042), TIM-3 and LAG-3 and our dual-reactive antibody product candidates targeting PD-1/TIM-3, PD-1/LAG-3 and an additional dual-reactive combination, are in preclinical development.

As a result, our business is substantially dependent on our ability to complete the development of, obtain regulatory approval for, and successfully commercialize rolapitant (and to a lesser degree, our other product candidates) in a timely manner. 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

Table of Contents

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 rolapitant 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. If we are unable to obtain regulatory approval for rolapitant in one or more jurisdictions, or if any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of our existing product candidates or any other product candidate that we may in-license or acquire in the future. Furthermore, even if we obtain approval for rolapitant from the FDA and comparable foreign regulatory authorities, we will still need to develop a commercial organization, establish commercially viable pricing and obtain adequate reimbursement from third-party and government payors. If we are unable to successfully commercialize rolapitant, we may not be able to earn sufficient revenues to continue our business.

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

Success in preclinical testing and early clinical studies does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of an investigational drug, or the safety, purity, and potency of an investigational biological product. A number of companies in the pharmaceutical and biotechnology industries, including many with greater resources and experience than us, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier clinical trials. Despite the results reported in earlier clinical trials for niraparib and in preclinical studies for TSR-011, we do not know whether the clinical trials we may conduct will demonstrate adequate efficacy and safety, or safety, purity, and potency, to result in regulatory approval to market any of our product candidates in any particular jurisdiction or jurisdictions. If later-stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates may be adversely impacted.

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 rolapitant, niraparib and TSR-011. We may experience delays in our ongoing or future clinical trials and we do not know whether planned clinical trials will begin or enroll subjects on time, need to be redesigned, or be completed on schedule, if at all. Clinical trials may be delayed, suspended or prematurely terminated for a variety of reasons, such as:

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

- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical study;

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

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

- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;

Table of Contents

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

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

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

- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication;

- failure of our third-party clinical trial managers to satisfy their contractual duties or meet expected deadlines;

- delay or failure in adding new clinical trial sites;

- ambiguous or negative interim results, or results that are inconsistent with earlier results;

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

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

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

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

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

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

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

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

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

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous

Table of Contents

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. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we may in-license or acquire and seek to develop in the future will ever obtain regulatory approval.

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

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

The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data, to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that

is not desirable for the successful commercialization of that product candidate. In addition, if our product candidate produces undesirable side effects or safety issues, the FDA may require the establishment of Risk Evaluation Mitigation Strategies, or REMS, or a comparable foreign regulatory authority may require the establishment of similar strategies, that may, for instance, restrict distribution of our products and impose burdensome implementation requirements on us. Any of the foregoing scenarios could materially harm the commercial prospects of our product candidates.

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

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority. Drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete a clinical trial, and could result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally if one or more of our product candidates receives marketing approval, 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;

Table of Contents

- regulatory authorities may withdraw approvals of such product;

- regulatory authorities may require additional warnings on the label;

- we may be required to develop a REMS for such product or, if a REMS is already in place, to incorporate additional requirements under the REMS, or to develop a similar strategy as required by a comparable foreign regulatory authority;

- we may be required to conduct post-market studies;

- we could be sued and held liable for harm caused to subjects or patients; and

- our reputation may suffer.

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

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

Even if we obtain regulatory approval for a product candidate, it would be 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 after approval of any of our product candidates, those authorities may require labeling changes or establishment of a REMS or similar strategy, impose restrictions on a product s indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

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

Table of Contents

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

In the United States, engaging in impermissible promotion of our products for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. These false claims statutes include the federal civil False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment of government funds, and the individual could share in any judgment or settlement funds. Since 2004, False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements based on certain sales practices promoting off-label drug uses. For instance, in 2012, GlaxoSmithKline LLC agreed to plead guilty and to pay a total of $3 billion to settle civil and criminal allegations that the company promoted certain prescription drugs off-label, provided unlawful kickbacks, failed to report drug safety data, and falsely reported drug prices. 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. If we do not lawfully promote our approved products, 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.

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

Although our clinical development efforts have been focused primarily on an oral formulation of rolapitant, we have initiated a Phase 1 clinical trial of an intravenous, or IV, formulation of rolapitant. If we are successful in obtaining regulatory approval of the oral formulation, we would expect the FDA to require an NDA for approval of an IV formulation. Even if the oral formulation gains regulatory approval, there can be no assurance that we would be able to obtain regulatory approval of the IV formulation. To support an NDA for the IV formulation, we will have to provide clinical data specific to the IV formulation. If the clinical results of the IV formulation are positive, we estimate that it would take approximately one year following the submission of the oral form NDA for the FDA to approve the IV formulation, although our submission or FDA review could take significantly longer. The FDA may not accept our bioequivalence strategy and may require efficacy studies to support the NDA. We expect the IV formulation of rolapitant to serve what we believe is a larger portion of the market for NK-1 receptor antagonists and generate more revenue than the oral formulation. If we do not obtain regulatory approval for the IV formulation, it would negatively affect our revenue and growth prospects.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

We do not currently have an organization for the sales, marketing and distribution of pharmaceutical products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved by the FDA and comparable foreign regulatory authorities, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable. We will be competing with

Table of Contents

many companies that currently have extensive and well-funded sales and marketing operations. Without an internal commercial organization or the support of third parties to perform sales and marketing functions, we may be unable to compete successfully against these more established companies.

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

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

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current clinical-stage product candidates, rolapitant, niraparib and TSR-011, as well as our monospecific antibody product candidates targeting PD-1 (TSR-042), TIM-3 and LAG-3 and our dual-reactive antibody product candidates targeting PD-1/TIM-3, PD-1/LAG-3 and an additional dual-reactive combination, which are in preclinical development. We will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide.

There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing our clinical-stage product candidates. If rolapitant is successfully commercialized, we expect it to compete with EMEND, an NK-1 receptor antagonist marketed by Merck as well as AKYNZEO, an oral combination NK-1 receptor antagonist and 5-HT3 receptor antagonist (netupitant plus ALOXI (palonosetron HCl)) that is marketed by Helsinn and Eisai. Rolapitant would face additional competition if other products were developed for the treatment and prevention of CINV, or an IV formulation of AKYNZEO is developed. If niraparib is successfully commercialized, it may face competition from other PARP inhibitors if they are successfully developed and receive regulatory approval in the same market. We are aware of several PARP inhibitors in clinical development, including AbbVie s ABT-888 (veliparib), Eisai, Inc. s E-7016, Teva Pharmaceutical Industries, Ltd. s CEP-9722, Clovis Oncology, Inc. s CO-338 (rucaparib) and BioMarin Pharmaceutical Inc. s BMN-673 (talazoparib). If TSR-011 is successfully commercialized, we expect it to compete with Xalkori (crizotinib), a dual MET/anaplastic lymphoma kinase, or ALK, inhibitor marketed by Pfizer and Zykadia (ceritinib), an ALK inhibitor marketed by Novartis. Zykadia was approved in December 2014 for those with ALK+ NSCLC who have progressed on or are intolerant to crizotinib. We are also aware of several oral ALK inhibitors in clinical development with which TSR-011 could compete if they are approved in the same market, including: Chugai Pharmaceutical Co., Ltd. s CH5424802 (alectinib), ARIAD Pharmaceuticals, Inc. s AP26113, Astellas Pharma US, Inc. s ASP-3026, and Xcovery s X-396. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches.

There are also a number of pharmaceutical and biotechnology companies pursuing the development of cancer immunotherapies that may compete with our immunotherapy product candidates, which are in preclinical development. We are aware of several companies that have antibody-based products on the market or in clinical development that are directed at the same biological targets as some of our collaboration programs with AnaptysBio. These include: Bristol-Myers Squibb, which has an approved anti-PD-1 antibody, OPDIVO (nivolumab), and an anti-LAG-3 antibody in development; Merck, which has an approved anti-PD-1 antibody that is commercially available by the trade name KEYTRUDA (pembrolizumab),

Table of Contents

formerly called MK-3475; Pfizer, Genentech, Medimmune (AstraZeneca), Medivation and EMD Serono (Merck KGaA), which have anti-PDL-1 and/or anti-PD-1 modulators in development. We are also aware of several other companies with immuno-oncology antibodies or programs in the preclinical or research phase.

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

In addition to pharmaceutical and biotechnology companies, our potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. More established companies, as well as institutions, agencies and organizations, may have a competitive advantage over us due to their greater size, cash flows and institutional experience. Compared to us, many of our competitors may have significantly greater financial, technical and human resources.

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

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

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

The regulations that govern marketing approvals, pricing and reimbursement for new drug and biological products vary widely from country to country. 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. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial 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. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates even if our product candidates obtain marketing approval.

Our ability to commercialize any products successfully will also 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. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third-party payors also may seek additional clinical evidence, beyond the data required to obtain marketing approval, demonstrating clinical benefits and value in specific patient populations, before covering our products for those patients. We cannot be sure that coverage and reimbursement will

Table of Contents

be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

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. For drugs furnished by hospital outpatient departments, separate payment is not made by Medicare for products that do not exceed a cost per day threshold, which is the case for many existing oral anti-emetic products. It is possible that our products also would not be paid separately by Medicare in this setting. 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. CMS, the federal agency that administers the Medicare and Medicaid programs, has made draft National Average Drug Acquisition Cost, or NADAC, and draft National Average Retail Price, or NARP, data publicly available on at least a monthly basis. In July 2013, CMS suspended the publication of draft NARP data, pending funding decisions. In November 2013, CMS moved to publishing final rather than draft NADAC data and has since made updated NADAC data publicly available on a weekly basis. As a result of this continuous evolution, 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.

There may be significant delays in obtaining coverage and reimbursement for 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. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

If we participate in the Medicaid drug rebate program and fail to comply with our reporting and payment obligations under that or other governmental pricing 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.

If we participate in the Medicaid drug rebate program, we will have certain price reporting obligations to the Medicaid drug rebate program, and we may have obligations to report ASP figures to the Medicare program. Under the Medicaid drug rebate program, we would be required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to the CMS. These data include AMP and, in the case of innovator products, the best price for each drug which, in general, represents the lowest price available from the manufacturer to any entity in the United States in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions.

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.

Federal law requires that any company that participates in the Medicaid rebate program also participate in the Public Health Service s 340B drug pricing program in order for federal funds to be available for the manufacturer s drugs under

Table of Contents

Medicaid and Medicare Part B. The 340B drug pricing 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.

Federal law requires that for a company to be eligible to have its 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 grantees, it also must participate in the Department of Veterans Affairs, or the VA, Federal Supply Schedule, or FSS, pricing program. To participate, we will be required to enter into an FSS contract with the VA, under which we must make our innovator covered drugs available to four federal agencies, the VA, Department of Defense, Public Health Service and Coast Guard, or collectively the Big Four, at pricing that is capped pursuant to a statutory federal ceiling price, or FCP, formula set forth in Section 603 of the Veterans Health Care Act of 1992, or VHCA. The FCP is based on a weighted average wholesaler price known as the non-federal average manufacturer price, or Non-FAMP, which manufacturers are required to report on a quarterly and annual basis to the VA. If a company misstates Non-FAMPs or FCPs it must restate these figures. Pursuant to the VHCA, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to penalties of $100,000 for each item of false information.

FSS contracts are federal procurement contracts that include standard government terms and conditions, separate pricing for each product, and extensive disclosure and certification requirements. All items on FSS contracts are subject to a standard FSS contract clause that requires FSS contract price reductions under certain circumstances where pricing is reduced to an agreed tracking customer. Further, in addition to the Big Four, all other federal agencies and some non-federal entities are authorized to access FSS contracts. FSS contractors are permitted to charge FSS purchasers other than the Big Four agencies negotiated pricing for covered drugs that is not capped by the FCP; instead, such pricing is negotiated based on a mandatory disclosure of the contractor s commercial most favored customer pricing. We cannot anticipate the pricing structure we will enter into with respect to our products. The FSS contract price may have a material adverse effect on future revenues from sales of our products. The requirements under the 340B and FSS programs could reduce the revenue we may generate from any products that are commercialized in the future and could adversely affect our business and operating results.

To the extent our products become available in the retail pharmacy setting when they are commercialized, we would be subject to Section 703 of the National Defense Authorization Act for Fiscal Year 2008. Pursant to that statute, DoD has established a program under which manufacturers are required to pay FCP-based rebates on TRICARE retail utilization of covered drugs. Rebates are computed by subtracting the applicable FCP from the corresponding annual Non-FAMP. Additionally, companies that want their covered drugs to be eligible for DoD formulary inclusion must enter into a Section 703 Agreement with TMA under which the company agrees to pay the quarterly rebates.

If we overcharge the government in connection with our FSS contract or underpay rebates under the Tricare retail rebate program, whether due to a misstated FCP or otherwise, we will be required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges could result in allegations against us under the Federal 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.

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. The Medicaid rebate amount for each manufacturer is computed each quarter based on the manufacturer s submission to CMS of its current AMP and, in the case of innovator products, BP figures, for the quarter. If we participate in the Medicaid drug rebate program and become aware that our reporting for a prior quarter was incorrect, or has changed, we will be obligated to resubmit the corrected data for a period not to exceed twelve quarters from the quarter in which the data originally were due. Such restatements and recalculations would increase our costs for complying with the laws and regulations governing the Medicaid drug rebate program. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. Price recalculations also may affect the ceiling price at which we would be required to offer our products to certain covered entities, such as safety-net providers, under the 340B drug discount program.

If we participate in the Medicaid drug rebate program or our products are covered under Medicare Part B, we will be liable for errors associated with our submission of ASP pricing data. In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted false AMP, ASP, or best price information to the

Table of Contents

government, we may be liable for civil monetary penalties in the amount of $100,000 per item of false information. If we are found to have made a misrepresentation in the reporting of our ASP, the Medicare statute provides for civil monetary penalties of up to $10,000 for each misrepresentation for each day in which the misrepresentation was applied. Our failure to submit monthly/quarterly AMP, ASP, and best price data on a timely basis could result in a civil monetary penalty of $10,000 per day for each day the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we would participate in the Medicaid program. In the event that CMS terminates our rebate agreement, federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs that we are able to successfully commercialize.

In September 2010, CMS and the OIG indicated that they intend to pursue more aggressively those companies who fail to report these data to the government in a timely manner. 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. If we participate in, or a product we successfully commercialize receives coverage under, one of these governmental programs, we cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect.

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

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

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

In March 2010, the President signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, together the Affordable Care Act. This law substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Affordable Care Act is intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms. The Affordable Care Act expanded manufacturers rebate liability under the Medicaid program from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well; increased the minimum Medicaid rebate due for most innovator drugs in general from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP; and capped the total rebate amount for innovator drugs at 100% of AMP. The Affordable Care Act and subsequent legislation also changed the definition of AMP. The Affordable Care Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government. Each such manufacturer pays a prorated share of the branded prescription drug fee of $3.0 billion in 2015, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners. The Affordable Care Act also expanded the 340B program to include additional types of covered entities.

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

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. Beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologics, were reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. The Bipartisan Budget Act of 2013 extended the 2% reduction to 2023, and the

Table of Contents

Protecting Access to Medicare Act of 2014 extended the 2% reduction, on average, to 2024. If Congress does not take action in the future to modify these sequestrations, Medicare Part D plans could seek to reduce their negotiated prices for drugs. Other legislative or regulatory cost containment provisions, as described below, could have a similar effect.

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

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

In December 2010, we entered into a license agreement with OPKO to obtain exclusive worldwide rights to research, develop, manufacture, market and sell rolapitant. The license agreement also extended to an additional, backup compound, SCH900978, to which we have the same rights and obligations as rolapitant, but which we are not currently advancing. In May 2012, we entered into a license agreement with Merck, under which we obtained exclusive, worldwide rights to certain patents and non-exclusive rights to certain Merck know-how, to research, develop, manufacture, market and sell niraparib and a backup compound, MK-2512, for all therapeutic and prophylactic uses in humans. We are not currently advancing MK-2512. In March 2011, we entered into a license agreement with Amgen to obtain exclusive worldwide rights to research, develop, manufacture, market and sell an ALK/TRK inhibitor product. In March 2014, we entered into a collaboration and exclusive license agreement with AnaptysBio, under which we obtained exclusive, worldwide rights to certain patents and intellectual property of AnaptysBio to research, develop, manufacture, market and sell antibody product candidates targeting PD-1, TIM-3 and LAG-3 and non-exclusive rights to certain other patents and intellectual property of AnaptysBio necessary to utilize the intellectual property exclusively licensed to us.

Our agreements with OPKO, Merck and Amgen require us to use commercially reasonable efforts, in the case of rolapitant and TSR-011, and diligent efforts, in the case of niraparib, to develop and commercialize such products in accordance with such agreements, and to make timely milestone, royalty and other payments, provide certain information regarding our activities with respect to such products, maintain the confidentiality of information we receive from OPKO, Merck and Amgen and indemnify OPKO, Merck and Amgen with respect to our development and commercialization activities under the terms of the agreements. Our agreement with AnaptysBio requires us to use commercially reasonable efforts to fund the initial discovery and development of each of the antibody product candidates targeting PD-1, TIM-3 and LAG-3 during the time period set forth in the agreement and then to use such efforts to further develop and commercialize those candidates.

If we fail to meet these obligations, our licensors have the right to terminate our exclusive licenses and upon the effective date of such termination, have the right to re-obtain the licensed technology as well as aspects of any intellectual property controlled by us and developed during the period the agreements were in force that relate to the licensed technology. This means that our licensors could effectively take control of the development and commercialization of our product candidates after an uncured, material breach of our license agreements by us. This would also be the case if we voluntarily terminate the agreements. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve our rights under the patents licensed to us, we may not be able to do so in a timely manner, at an acceptable cost or at all. Any uncured, material breach under the licenses could result in our loss of exclusive rights and may lead to a complete termination of our product development and any commercialization efforts for the applicable product 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

Table of Contents

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 if we commercially sell any products that we may develop. 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.

We currently hold $10 million in product liability insurance coverage in the aggregate, which may not be adequate to cover all liabilities that we may incur. We expect to increase our insurance coverage when we begin to commercialize our product candidates, if ever. 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. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. 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 products, 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:

Table of Contents

- 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.

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

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our 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 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. 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 remuneration to those who prescribe, purchase, or recommend pharmaceutical and biological products, including certain discounts, including certain discounts, or engaging consultants for 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 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 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

Table of Contents

companies have faced enforcement actions for causing false claims to be submitted because of the company s marketing the product for unapproved, and thus non-reimbursable, uses. In addition, violation of the federal anti-kickback statute may be actionable under 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 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, 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 to publicly report 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; and

- 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.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards, comply with federal and state healthcare fraud and abuse laws and

regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our

Table of Contents

reputation. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

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

As of December 31, 2014, we had 108 full-time employees. 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 need additional managerial, operational, sales, marketing, financial and other resources. Our management, personnel and systems currently in place may not be adequate to support this future growth. Future growth would impose significant added responsibilities on members of management, including:

- managing our clinical trials effectively;
- 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 our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

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

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

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

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

We are highly dependent on Leon O. Moulder, Jr., our Chief Executive Officer, and Mary Lynne Hedley, Ph.D., our President and Chief Operating Officer. Although we have offer letter agreements with Mr. Moulder and Dr. Hedley, these agreements are at-will and do not prevent them from terminating their employment with us at any time. We do not maintain key person insurance for any of our executives or other employees. The loss of the services of any 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
- incur amortization expenses related to intangible assets or incur large and immediate write-offs.

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

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

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

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

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

We are relying on the commercial availability of diagnostic tests to identify patients who may benefit from TSR-011.

We believe that having a commercially available diagnostic test for the identification of ALK fusions will facilitate rapid and efficient development of our lead ALK inhibitor product candidate, TSR-011. While other diagnostic tests are in development (such as tests based on immunohistochemistry and DNA sequencing), the Abbott Vysis Break Apart FISH Probe test, or Vysis diagnostic test, is currently the only commercially available diagnostic test for the identification of ALK fusions in the United States. The Vysis diagnostic test is provided by a third party who has no contractual obligation to us to continue to manufacture the test or make it available commercially or to us. We expect that manufacturers of any future diagnostic tests that may become available would similarly have no contractual obligation to us to continue to manufacture tests or to make them available commercially to us. In addition, many diagnostic tests are subject to regulation by the FDA and comparable foreign regulatory authorities and the FDA or another regulatory authority could limit their use. Furthermore, the providers of diagnostic tests may encounter production difficulties that could constrain the supply of the tests or they could otherwise decide to discontinue selling or manufacturing the diagnostic tests. If diagnostic tests are not commercially available, development or commercialization of TSR-011 could be adversely affected.

Table of Contents

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

For certain of our cancer therapeutic product candidates (currently niraparib and TSR-011), we believe we have acquired product candidates for which diagnostic tests or specific clinical criteria will allow us to identify cancer patients who will be more likely to respond. We plan to rely on diagnostic tests to help us more accurately identify patients with those criteria both during our clinical trials and in connection with the commercialization of our product candidates. Diagnostic tests, including companion diagnostics, are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and require separate regulatory approval prior to commercialization. We do not develop diagnostic tests internally. We are therefore dependent on the sustained cooperation and effort of third-party collaborators in developing and obtaining approval for these tests. For example, our niraparib product candidate will use a test owned and administered by a third party to identify breast cancer patients with a BRCA gene mutation during clinical testing. We are also evaluating niraparib in patients with certain homologous recombinant deficiency, or HRD, scores. The test to determine this HRD score is owned and administered by the same third party that administers the BRCA gene mutation test. Therefore, it is possible that niraparib will be approved for these indications only in combination with one of these diagnostic tests. This third party may encounter difficulties in developing and obtaining approval for its test, or may fail to support the clinical development of niraparib for breast cancer as we expect, or may fail to keep the test on the market even if it is approved. Any such delay or failure could delay or prevent approval of niraparib for breast cancer, or products we may later acquire with similar characteristics.

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

Despite the implementation of security measures, our internal computer systems, and those of AnaptysBio, 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.

Risks Related to Our Dependence on Third Parties

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 GLP and Animal Welfare Act requirements. We and our collaborators and CROs are required to comply with GCP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the EEA, and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our collaborators or CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure that upon inspection by a given

Table of Contents

regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP requirements. Failure to comply with these regulations may require us to repeat preclinical and clinical trials, which would delay the regulatory approval process.

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

Because we have relied and rely on third parties for these functions, our internal capacity to perform these functions is limited. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results in a timely manner, or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. Although we carefully manage our relationships with AnaptysBio and our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

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

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

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

We do not own or operate facilities for the manufacture of our product candidates. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. We currently work with one contract manufacturer, or CMO, Hovione, for the production of rolapitant drug substance, and one other CMO for the production of oral rolapitant drug product for clinical trials and anticipated commercial needs if the product is approved. To meet our projected needs for clinical supplies to support our activities through regulatory approval and for

commercial manufacturing, the CMOs with whom we currently work will need to increase scale of production. We also currently work with a CMO for the production of IV rolapitant drug product for clinical use. We utilized CMOs for the manufacture of TSR-011 for use in preclinical and Phase 1/2a clinical trials. To meet our needs with respect to further clinical development, we plan to contract with additional CMOs for the manufacture of clinical supplies. 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 monospecific antibody product candidates targeting PD-1 (TSR-042), TIM-3 and LAG-3 and our dual-reactive antibody product candidates targeting PD-1/TIM-3, PD-1/LAG-3 and an additional dual-reactive combination, we currently work with one CMO for the production of biologics. For each of our product candidates, we may elect to pursue arrangements with

Table of Contents

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 otherwise we experience any problems with them. If we are unable to arrange for alternative third-party manufacturing sources, or to do so on commercially reasonable terms or in a timely manner, we may not be able to complete development of our product candidates, or market or distribute them.

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

Any significant disruption in our supplier relationships could harm our business. We source key materials from third parties, either directly through agreements with suppliers or indirectly through our manufacturers who have agreements with suppliers. There are a small number of suppliers for certain capital equipment and key materials that are used to manufacture our drugs. Such suppliers may not sell these key materials to our manufacturers at the times we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of these key materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these key materials. Any significant delay in the supply of a product candidate or its key materials for an ongoing clinical study could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these key materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

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. If we successfully commercialize any of our drugs, we may be required to establish large-scale commercial manufacturing capabilities. In addition, as our drug development pipeline increases and matures, we will have a greater need for clinical study and commercial manufacturing capacity. We have no experience manufacturing pharmaceutical products on a commercial scale and some of these suppliers will need to increase their scale of production to meet our projected needs for commercial manufacturing, the satisfaction of which on a timely basis may not be met.

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.

Table of Contents

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

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

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

66

Table of Contents

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.

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 each member of our senior management, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee s former

Table of Contents

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 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 $51.95 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;

Table of Contents

- 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 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.

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 able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors and their or our respective affiliates beneficially owned approximately 41.9% of our voting stock as of February 19, 2015. This group of stockholders has the ability to control us through their ownership position. These stockholders may be able to determine the outcomes of all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

Table of Contents

We are an emerging growth company and we intend to take advantage of reduced disclosure and governance requirements applicable to emerging growth companies, which could result in our common stock being less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, which we refer to as the JOBS Act, and we have taken or intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we have relied or will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company, which in certain circumstances could be for up to five years from the date of the closing of our initial public offering.

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

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. Commencing with this Annual Report on Form 10-K, we are required, under Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment must include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a control deficiency, or combination of control deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 of the Sarbanes-Oxley Act also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. However, for as long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the independent registered public accounting firm attestation requirement.

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. Once we become subject to the attestation requirement, if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the NASDAQ, the U.S. Securities and Exchange Commission, or the SEC, or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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

As a public company, we are incurring significant legal, accounting and other expenses that we did not incur as a private company, and these expenses may increase even more after we are no longer an emerging growth company. 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 will need to devote a substantial amount of

Table of Contents

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.

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 February 19, 2015, we have 36,110,407 shares of common stock outstanding. Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Of these outstanding shares, 15,147,953 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 and the lock-up agreements.

Furthermore, certain persons who were stockholders prior to our initial public offering are entitled to registration rights under the Securities Act with respect to shares they hold, which includes 14,018,620 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.

Table of Contents

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). The number of shares of our common stock reserved for issuance under our 2012 Incentive Plan will be increased (i) from time to time by the number of shares of our common stock forfeited upon the expiration, cancellation, forfeiture, cash settlement or other termination of awards under our 2010 Incentive Plan following the effective date of the 2012 Incentive Plan, and (ii) on January 1 of each year, 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. Effective January 1, 2014, the number of shares of our common stock authorized for issuance under the 2012 Incentive Plan was increased by 1,309,560 shares. Effective January 1, 2015, the number of shares of our common stock authorized for issuance under the 2012 Incentive Plan was increased by 1,444,403 shares. Future stock option grants and issuances of common stock under our 2012 Incentive Plan 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.

Table of Contents

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.

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

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

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

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

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

Convertible Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

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

Pursuant to Accounting Standards Codification Subtopic 470-20, *Debt with Conversion and Other Options*, which we refer to as ASC 470-20, an entity must separately account for the liability and equity components of the convertible debt instruments (such as the Convertible Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer s economic interest cost. The effect of ASC 470-20 on the accounting for the Convertible Notes is that the equity component is required to be included in the additional paid-in capital caption of stockholders equity on our consolidated balance sheet and the value of the equity component would be treated as original issue discount for purposes of accounting for the debt component of the Convertible Notes. As a result, we will be required to record a greater amount of non-cash interest expense in current periods presented as a result of the amortization of the discounted carrying value of the

Table of Contents

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.

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, 2014, we leased office space totaling 53,200 square feet in a facility in Waltham, Massachusetts, which we use primarily for corporate functions. The term of the lease continues until June 30, 2017. We believe our facility is 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, 2013:		
First quarter	$ 25.13	$ 16.52
Second quarter	$ 51.95	$ 20.98
Third quarter	$ 47.89	$ 30.68
Fourth quarter	$ 41.25	$ 27.50
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

On February 19, 2015, the last reported sale price of our common stock was $41.31 per share. As of the close of business on February 19, 2015, there were approximately 32 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.

Performance Graph (1)

The following graph presents a comparison from June 28, 2012 through December 31, 2014 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.

Table of Contents

(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, 2012, 2013 and 2014, and the historical balance sheet data as of December 31, 2013 and 2014, 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 period from March 26, 2010 (inception) to December 31, 2010 and for the year ended December 31, 2011and the historical balance sheet data as of December 31, 2010, 2011and 2012 has been derived from financial statements not included in this Annual Report on Form 10-K.

The financial information presented from March 26, 2010 (inception) to December 31, 2010 is based solely on the accounts of TESARO, Inc. Effective December 22, 2011, November 30, 2012 and December 27, 2012, respectively, TESARO UK Limited, TESARO Securities Corporation and TESARO Development, Ltd., our wholly-owned subsidiaries, were incorporated. All financial information presented after December 31, 2010 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.

	March 26, 2010 (Inception) to December 31, 2010	Years Ended December 31, 2011	2012	2013	2014
Statement of Operations Data:					
Expenses:					
Research and development	$ 46	$ 11,768	$ 47,200	$ 75,725	$ 118,425
General and administrative	1,668	3,158	6,715	14,780	23,935
Acquired in-process research and development	6,630	500	8,000	1,940	24,900
Total expenses	8,344	15,426	61,915	92,445	167,260
Loss from operations	(8,344)	(15,426)	(61,915)	(92,445)	(167,260)
Interest expense					(3,776)
Interest income	20	38	152	83	24
Other income (expense), net	(651)	(1,010)			
Net loss	$ (8,975)	$ (16,398)	$ (61,763)	$ (92,362)	$ (171,012)
Net loss per share applicable to common stockholders - basic and diluted	$ (26.65)	$ (31.90)	$ (4.51)	$ (2.93)	$ (4.79)
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	337	514	13,696	31,559	35,739

Balance Sheet Data:					
Cash and cash equivalents	$ 2,533	$ 39,825	$ 125,445	$ 130,310	$ 256,861
Working capital	(748)	38,835	114,902	121,916	234,231
Total assets	2,715	42,879	127,380	135,578	263,902
Convertible notes					115,481
Convertible preferred stock	8,388	64,348			
Common stock and additional paid-in capital		305	202,798	302,650	474,566
Total stockholders (deficit) equity	(8,975)	(25,068)	115,662	123,152	124,056

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 were founded in March 2010 by former executives of MGI PHARMA, Inc., an oncology and acute-care focused biopharmaceutical company. We have in-licensed and are currently developing three oncology-related product candidates, rolapitant, niraparib and TSR-011. We submitted a new drug application, or NDA, for oral rolapitant, to the United States Food and Drug Administration, or FDA, in September 2014. If the NDA is approved by the FDA, oral rolapitant will become our first marketed product. In March 2014, we added immuno-oncology programs by entering into a collaboration and exclusive license agreement with AnaptysBio, Inc., or AnaptysBio, for the discovery and development of antibodies for several immuno-oncology targets. We expect to file an investigational new drug application, or IND, for our first immuno-oncology antibody, TSR-042, which targets PD-1, by the end of 2015.

- *Rolapitant* is a potent and long-acting neurokinin-1, or NK-1, receptor antagonist for the prevention of chemotherapy induced nausea and vomiting, or CINV. We are developing both oral and intravenous formulations of rolapitant. In December 2013, we announced top-line results for two Phase 3 trials of oral rolapitant and in May 2014, we announced top-line results for a third Phase 3 trial of oral rolapitant. The primary endpoint was successfully achieved in each of these three trials. In September 2014, we submitted to the U.S. Food and Drug Administration, or FDA, a new drug application, or NDA, for oral rolapitant, which was accepted for review by the FDA in November 2014. We are currently preparing to begin marketing oral rolapitant in the fourth quarter of 2015, assuming the NDA is approved on or about the PDUFA date of September 5, 2015. The intravenous, or IV, formulation of rolapitant is currently in various Phase 1 clinical trials. As part of a registration program for IV rolapitant, we have initiated a clinical study comparing the exposure of IV rolapitant and oral rolapitant. In the first quarter of 2015 we plan to initiate clinical studies to evaluate the safety of IV rolapitant to support an NDA submission, which we expect to submit in the fourth quarter of 2015.

- *Niraparib* is an orally active and potent poly (ADP-ribose) polymerase, or PARP, inhibitor. In July 2013, we dosed the first patient in a Phase 3 clinical trial evaluating niraparib for the treatment of patients with high grade serous, platinum sensitive, relapsed ovarian cancer. We refer to this phase 3 trial as our NOVA trial. In April 2014, we dosed the first patient in a Phase 3 clinical trial evaluating niraparib in breast cancer patients with germline BRCA mutations. We refer to this phase 3 trial as our BRAVO trial. Based on research related to PARP inhibitors generally, we believe that niraparib may be effective in several additional oncology settings. Therefore, 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. Additionally, we intend to evaluate niraparib as a first-line maintenance therapy in ovarian cancer patients as a therapy for patients with ovarian cancer who have been treated with three or more prior regimens of therapy, and in advanced metastatic small cell lung cancer, or SCLC, patients. We may also evaluate niraparib for the treatment of gastric and prostate cancer.

- *TSR-011* is an orally available targeted anti-cancer agent that is a potent inhibitor of both anaplastic lymphoma kinase, or ALK, and tropomyosin-related kinase, or TRK, currently in a Phase 1/2a dose escalation clinical trial in cancer patients. We have identified the maximum tolerated dose of TSR-011 and are now evaluating fractionated 60 and 120mg doses of TSR-011 in patients with ALK or TRK expression, including those with ALK-positive, or ALK+, and TRK-positive, or TRK+, non-small cell lung cancer, or NSCLC, who have not been previously treated with ALK inhibitors, those with ALK+ NSCLC who have progressed during treatment with other ALK inhibitors, and in those patients with other tumor types driven by ALK or TRK. A controlled release formulation is now available and is being evaluated in the ongoing Phase 1 study.

- *Immuno-Oncology Platform*: PD-1, or programmed cell death protein 1, is a key immune checkpoint molecule that can limit T-cell-mediated immune responses. The presence of the PD-1 ligand, or PD-L1, has been identified on many tumor types, and expression of PD-L1 has been linked to poor clinical outcomes in a variety of cancers. Anti-PD-1 antibodies have demonstrated in vivo efficacy in tumor models and have shown promising results in several clinical studies, and in September 2014, the FDA approved KEYTRUDA®, the

Table of Contents

first approved anti-PD-1 antibody, for the treatment of certain melanomas. As part of our collaboration with AnaptysBio, we received exclusive rights to monospecific antibody product candidates targeting TIM-3, LAG-3 and PD-1 and dual-reactive antibody product candidates targeting PD-1/TIM-3, PD-1/LAG-3 and an additional dual-reactive combination. We anticipate beginning clinical trials using TSR-042, the lead anti-PD-1 antibody product candidate that we have in-licensed as part of the agreement with AnaptysBio, in early 2016. With respect to the TIM-3 and LAG-3 targets, we have either identified or are working toward identifying lead and backup compounds. We intend to select lead and backup compounds for the dual-reactive PD-1/TIM-3 and PD-1/LAG-3 targets during the first half of 2015. In addition, we plan to evaluate our immuno-oncology anti-tumor agents, such as TSR-042, in combination preclinical pharmacology studies with niraparib, TSR-011 and other anti-tumor agents.

We commenced business operations in May 2010. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring and developing product candidates, identifying potential product candidates and undertaking preclinical studies, clinical trials and manufacturing activities related to our product candidates. To date, we have not generated any revenues and 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, 2014, we had an accumulated deficit of $350.5 million. Our net losses were $171.0 million, $92.4 million, and $61.8 million for the years ended December 31, 2014, 2013 and 2012, respectively. We expect to incur significant expenses and operating losses for the foreseeable future. Overall, we expect 2015 operating expenses to increase over current levels as we incur increased costs related to the advancement of our ongoing commercialization activities, including hiring our own sales force, developing our marketing infrastructure, executing related marketing and promotional programs, hiring consultants and establishing systems in preparation for the potential commercialization of oral rolapitant, costs related to the advancement of clinical trial and other development activities under our current development programs, such as IV rolapitant, niraparib and TSR-011, costs related to the immuno-oncology development activities under our collaboration with AnaptysBio, and costs related to potential future in-licensed development programs. In addition, future license payments or milestone payments could cause our total operating expenses to fluctuate. For example, if our NDA submission for oral rolapitant is approved by the FDA, upon our first commercial sale we would be obligated to make a $15.0 million milestone payment to OPKO Health, or OPKO. If we obtain regulatory approval for any of our product candidates, or in anticipation of obtaining regulatory approval, such as with respect to oral rolapitant, we expect that we will continue to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Furthermore, we expect to incur increasing general and administrative costs associated with our anticipated growth and continuing operation as a public company and we will incur substantial interest expense going forward as a result of the issuance of convertible debt in September 2014. 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 the regulatory approval of oral rolapitant and our development, sales and marketing efforts. Accordingly, we will seek to fund our operations 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. In consideration for this license, we paid OPKO $6.0 million upon signing the agreement and issued 1,500,000 shares of our Series O convertible preferred stock. At the time of this transaction, the fair value of the Series O convertible preferred stock was determined to be $0.6 million. 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 $5.0 million to date, if specified regulatory and initial commercial sales milestones are achieved in the U.S. and Europe. 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. If commercial sales of rolapitant commence, we are required to pay OPKO tiered royalties on the amount of annual net sales achieved in the United States and Europe at percentage rates that range from the low teens to the low twenties, which we expect will result in an effective royalty rate in the low teens. The royalty rate on annual net sales outside of the United States and Europe is slightly above the single digits. We will pay royalties on rolapitant until the later of: (i) the date that all of the patent rights licensed from OPKO and covering rolapitant expire, are invalidated or are not enforceable, and (ii) 12 years from the first commercial sale of the product, in each case, on a country-by-country and product-by-product basis. If

Table of Contents

we elect to develop and commercialize rolapitant in Japan through a third-party licensee, we will share equally with OPKO all amounts received by us in connection with such activities under our agreement with such third party, subject to certain exceptions and deductions. OPKO also retains an option to become the exclusive distributor of such products in Latin America, provided that OPKO exercises that option within a defined period following specified regulatory approvals in the United States.

We are responsible for all preclinical, clinical, regulatory and other activities necessary to develop and commercialize rolapitant. There were no ongoing clinical trials for rolapitant or SCH900978 at the time of our acquisition of these rights. As of the date of acquisition, none of the assets acquired had alternative future uses, nor had they reached a stage of technological feasibility. We accounted for this transaction as an asset acquisition because we did not acquire any processes or activities that would constitute a business in addition to the license. Accordingly, we recorded the entire purchase price of $6.6 million as acquired in-process research and development expense in 2010.

Rolapitant Intravenous Formulation. We are also developing a single dose intravenous rolapitant formulation with respect to which we have selected a dose of 185mg for further development. We have also completed a multiple ascending dose study of intravenous 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 initiated a clinical study comparing the exposure of the IV and oral formulations of rolapitant and we plan to initiate clinical studies in the first quarter of 2015 to evaluate the safety of IV rolapitant to support an NDA submission, which we expect to submit in the fourth quarter of 2015.

Niraparib. In May 2012, we entered into a license agreement with Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., or 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 made an up-front payment to Merck of $7.0 million in June 2012. We have made two milestone payments to Merck, one in the amount of $1.9 million upon dosing of the first patient in our NOVA trial in July 2013 and one in the amount of $0.9 million upon dosing of the first patient in our BRAVO trial in April 2014. We are required to make total milestone payments to Merck of up to $57.0 million in U.S. and European development and regulatory milestones for the first indication, up to $29.5 million in development and regulatory milestones for each successive indication, and up to $87.5 million in one-time sales milestones based on the achievement of annual sales objectives. If commercial sales of niraparib commence, we will pay Merck tiered royalties at percentage rates in the low teens based on worldwide annual net sales, until the later of the expiration of the last patent licensed from Merck covering or claiming niraparib, or the tenth anniversary of the first commercial sale of niraparib, in either case, on a country-by-country basis.

None of the assets to which we acquired rights have alternative future uses, nor have they reached a stage of technological feasibility. We accounted for this transaction as an asset acquisition because we did not acquire any processes or activities that would constitute a business in addition to the license. Accordingly, we recorded the entire purchase price of $7.0 million as acquired in-process research and development expense in 2012.

We are responsible for all clinical, regulatory and other activities necessary to develop and commercialize niraparib. At the time of the license transaction, niraparib had completed a Phase 1 clinical trial in cancer patients as a monotherapy. We are evaluating niraparib for the treatment of patients with high grade serous, platinum sensitive, relapsed ovarian cancer in our NOVA trial, which we initiated in July 2013. We are also evaluating niraparib in breast cancer patients with germline BRCA mutations in our BRAVO trial, which we initiated in April 2014. Based on our analysis of third-party market research, we believe there will be approximately 10,000 eligible ovarian cancer patients in both the U.S. and in Europe, and approximately 10,000 eligible breast cancer patients in both the U.S. and in Europe at the time of potential launch.

We also intend to initiate during the first quarter of 2015 a potential registration trial of niraparib for the treatment of patients with ovarian cancer who have been treated with three or more prior regimens of therapy. This trial is planned to be a single arm, open label study, targeted to enroll 225 patients who have received three or more prior lines of chemotherapy. Endpoints include objective response rate and duration of response across platinum sensitive, platinum resistant, gBRCA$_{mut}$ and HRD patient subsets. We further intend to initiate a clinical trial of niraparib in the first-line ovarian cancer maintenance setting during the second half of 2015. The first-line ovarian cancer study will include patients who have responded to first-line platinum chemotherapy. Patients will likely be randomized 2:1 to receive niraparib or placebo. The endpoints for this study include progression free survival, PFS2, overall survival and safety.

Table of Contents

We also intend to evaluate niraparib as a first-line, maintenance therapy in advanced metastatic SCLC patients. The SCLC study is currently planned to enroll patients with advanced metastatic SCLC who have received platinum-based chemotherapy and experienced a partial or complete response. Endpoints will include progression free survival, overall survival, safety and quality of life. Based on our analysis of third-party market research, we believe there are approximately 30,000 new cases of SCLC diagnosed in the U.S. annually, representing 13% of all lung cancers. We plan to begin enrollment of patients in the trial in the second half of 2015.

We also sponsor certain investigator sponsored trials investigating the use of niraparib in various other settings. We may also evaluate niraparib for the treatment of gastric and prostate cancer.

TSR-011. In March 2011, we entered into a license agreement with Amgen, Inc., or Amgen, to obtain exclusive worldwide rights to research, develop, manufacture, market and sell certain licensed ALK inhibitor compounds, including TSR-011. Under the terms of the license agreement, we made an up-front payment to Amgen of $0.5 million, and upon dosing of the first patient in our Phase 1/2a clinical trial of TSR-011 in October 2012, we made a milestone payment of $1.0 million. We are required to make total milestone payments to Amgen of up to an aggregate of $138.0 million if specified clinical development, regulatory, initial commercialization and annual net product sales milestones are achieved. If commercial sales of a product commence, we will pay Amgen tiered royalties at percentage rates ranging from the mid-single digits to slightly above the single digits based on cumulative worldwide net sales until the later of the last patent licensed from Amgen covering the product, the loss of regulatory exclusivity for the product, or the tenth anniversary of the first commercial sale of the product, in all cases, on a country-by-country and product-by-product basis.

We are responsible for all preclinical, clinical, regulatory and other activities necessary to develop and commercialize the licensed product candidates. At the time of the license transaction, TSR-011 was a preclinical compound. We are currently conducting a Phase 1/2a dose escalation clinical trial in cancer patients. We accounted for this transaction as an asset acquisition because we did not acquire any processes or activities that would constitute a business in addition to the license. Accordingly, we recorded the entire purchase price of $0.5 million as acquired in-process research and development expense in 2011.

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

Under the terms of the amended agreement, in 2014 we made up-front, non-creditable and non-refundable cash payments of $19.0 million to AnaptysBio. We are also 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, 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. At the time of the license transaction, the specified antibodies were in preclinical development. We accounted for this transaction as an asset acquisition

because the processes or activities that were acquired along with the license do not constitute a business . We recorded the total up-front payments of $19.0 million as acquired in-process research and development expense in the year ended December 31, 2014.

Public Offerings of Common Stock, Private Placements of Securities and Issuance of Convertible Notes. As of December 31, 2014, our principal source of liquidity was cash and cash equivalents, which totaled $256.9 million. Since our inception on March 26, 2010, we have funded our operations primarily through public offerings of our common stock, the

Table of Contents

private placement of our equity securities and issuance of convertible notes. From inception through December 31, 2013, we received $289.7 million in proceeds, net of underwriting discounts and commissions and offering expenses, from public offerings of common stock and private placements of convertible preferred stock. In February 2014, we completed a public offering of our common stock whereby we sold an additional 3,200,000 shares of our common stock at a price to the public of $31.50 per share and received approximately $94.2 million in proceeds, net of underwriting discounts and commissions and offering expenses. On September 29, 2014, we issued $201.3 million aggregate principal amount of Convertible Notes, with estimated net proceeds of $194.7 million, and we used $20.8 million of the proceeds from this transaction to enter into capped call option transactions, or Capped Calls, associated with the Convertible Notes.

Financial Operations Overview

Revenue

To date, we have not generated any revenues. 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, TSR-011, 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 incur increased costs as we establish our commercial infrastructure and otherwise advance our ongoing commercialization activities, continue our development of, and seek regulatory approvals for, our product candidates, incur additional costs under our collaboration with AnaptysBio and incur costs associated with our anticipated growth and 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 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:

- license fees and milestone payments related to the acquisition of in-licensed products, 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, clinical trial materials and other research and development materials;

- fees and costs related to regulatory filings and operations;

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

- other costs associated with clinical and preclinical activities.

Research and development costs are expensed as incurred. License fees and development milestone payments related to in-licensed products and technology are expensed as acquired IPR&D if it is determined that they have no alternative future use. Costs for certain development activities, such as clinical trials, are recognized based on an evaluation

Table of Contents

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 research and development costs will increase from current levels, depending on the progress of our clinical development programs as well as increasing costs associated with our collaboration with AnaptysBio, manufacturing related costs, and potential development milestone payments. More specifically, we expect costs to increase as we: continue our currently ongoing phase 3 trials for, and initiate additional investigative studies related to, niraparib; continue clinical and other development activities for the IV formulation of rolapitant as well as TSR-011; 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 product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including the uncertainties of future clinical and preclinical studies, uncertainties in clinical trial enrollment rates and significant and changing government regulation. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate s commercial potential.

The following table presents research and development expenses and acquired in-process research and development expenses on a program-specific basis for our in-licensed product candidates for the years ended December 31, 2012, 2013 and 2014, respectively (in thousands). 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 below.

Table of Contents

	Years Ended December 31,		
	2012	2013	2014
Rolapitant Expenses			
Acquired in-process research and development	$	$	$ 5,000
Research and development	36,524	42,685	33,017
Rolapitant total	36,524	42,685	38,017
Niraparib Expenses			
Acquired in-process research and development	7,000	1,940	900
Research and development	679	15,742	46,694
Niraparib total	7,679	17,682	47,594
TSR-011 Expenses			
Acquired in-process research and development	1,000		
Research and development	3,066	3,524	6,014
TSR-011 total	4,066	3,524	6,014
Immuno-Oncology Platform Expenses			
Acquired in-process research and development			19,000
Research and development			5,726
Immuno-Oncology Platform total			24,726
Personnel and Other Expenses	6,931	13,774	26,974
Total	**$ 55,200**	**$ 77,665**	**$ 143,325**

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs, including stock-based compensation and travel expenses, for personnel in executive and other administrative or non-research and development functions. Other general and administrative expenses include certain facility-related costs, communication expenses, pre-commercialization activities and professional fees for legal, patent review, consulting and accounting services.

We anticipate that our general and administrative expenses will increase in the future in support of both our preparation for the potential commercialization of our product candidates 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, including the hiring of our own sales force, continuing the development of our marketing infrastructure, executing related marketing and promotional programs, hiring consultants, establishing information technology systems, and payments to lawyers and other professionals, among other expenses. Additionally, if we obtain regulatory approval of a product candidate, we anticipate that we will continue to incur significant increases in payroll and expense relating to the sales and marketing of our products.

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.

84

Table of Contents

Results of Operations

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

	Years Ended December 31, 2013	2014	Increase/ (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, primarily 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.

Table of Contents

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.

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.

Comparison of the Year Ended December 31, 2013 to the Year Ended December 31, 2012

	Years Ended December 31,		Increase/
	2012	2013	(Decrease)
	(in thousands)		
Expenses:			
Research and development	$ 47,200	$ 75,725	$ 28,525
General and administrative	6,715	14,780	8,065
Acquired in-process research and development	8,000	1,940	(6,060)
Total expenses	61,915	92,445	30,530
Loss from operations	(61,915)	(92,445)	(30,530)
Other income (expense), net	152	83	(69)
Net loss	$ (61,763)	$ (92,362)	$ (30,599)

Revenues. We did not recognize any revenue for the years ended December 31, 2012 or 2013.

Research and Development Expenses. Research and development expenses were $75.7 million for the year ended December 31, 2013, compared to $47.2 million for the year ended December 31, 2012, an increase of $28.5 million. The increase was primarily due to higher expenses related to the development of niraparib and rolapitant, higher personnel and other expenses in support of our development activities, and to a lesser extent, higher expenses associated with the development of TSR-011. Significant changes resulting in this increase included:

- an increase of $15.0 million in costs associated with niraparib development activities, primarily related to the NOVA trial, which was initiated in July 2013, start-up activities for the BRAVO trial, which we initiated in April 2014, and costs relating to drug substance and drug product development, clinical supply manufacturing and distribution;

- an increase of $6.2 million in costs associated with rolapitant development activities, primarily the Phase 3 and other ongoing clinical trials, offset somewhat by reduced costs related to drug substance and drug product development activities;

- an increase of $0.5 million in costs associated with TSR-011 development activities, which primarily resulted from higher clinical costs associated with the ongoing Phase 1/2a study that began in the fourth quarter of 2012; and

- an increase of $6.8 million in salaries, benefits and other personnel costs (including stock-based compensation) related to increased research and development headcount supporting the growth of our development activities.

General and Administrative Expenses. General and administrative expenses were $14.8 million for the year ended December 31, 2013, compared to $6.7 million for the year ended December 31, 2012, an increase of $8.1 million. The increase was due primarily to increases of $4.5 million in stock-based compensation expense, of which $1.8 million was

Table of Contents

related to accounting for awards held by a non-employee consultant, with the remainder related to increased awards of stock options to both new and existing employees and higher grant-date fair values of those awards, $2.1 million in salaries, benefits and other personnel related costs, and $1.5 million in professional and consulting fees and other expenses to support corporate operational activities, such as insurance and certain other costs associated with public company operations.

Acquired In-Process Research and Development Expenses. 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 the result of the first patient dosing in the NOVA trial, which occurred in July 2013. During the year ended December 31, 2012, acquired in-process research and development expenses totaled $8.0 million, consisting of a $7.0 million up-front cash payment associated with the May 2012 acquisition of licensing rights for our niraparib program, and a $1.0 million milestone payment in November 2012 relating to our TSR-011 program.

Other Income (Expense), Net. Other income for the years ended December 31, 2012 and 2013 consisted solely of interest income earned on cash and cash equivalents.

Liquidity and Capital Resources

Sources of Liquidity

To date, we have not generated any revenue. As of December 31, 2014, our principal source of liquidity was cash and cash equivalents, which totaled $256.9 million. Since our inception on March 26, 2010, we have funded our operations primarily through public offerings of our common stock, the private placement of our equity securities and the issuance of convertible notes. Prior to July 2012, we had received $120.4 million in net proceeds from the private placement of our convertible preferred stock. In July 2012, we completed an initial public offering of our common stock (including partial exercise of the underwriters over-allotment option) whereby we sold 6,430,183 shares of our common stock at a price to the public of $13.50 per share and received approximately $78.0 million in proceeds, net of underwriting discounts and commissions and offering expenses. In March 2013, we completed a public offering of our common stock whereby we sold an additional 5,428,000 shares of our common stock at a price to the public of $18.00 per share and received approximately $91.3 million in proceeds, net of underwriting discounts and commissions and offering expenses. In February 2014, we completed a public offering of our common stock whereby we sold an additional 3,200,000 shares of our common stock at a price to the public of $31.50 per share and received approximately $94.2 million in proceeds, net of underwriting discounts and commissions and offering expenses. On September 29, 2014, we completed the issuance of $201.3 million aggregate principal amount of senior convertible notes, generating proceeds, net of underwriting discounts, commissions and offering expenses, of $194.7 million. In conjunction with the sale of the Convertible Notes, we used approximately $20.8 million of the net proceeds to enter into Capped Calls with certain counterparties. The Capped Calls are expected generally to reduce the potential dilution, and/or offset to an extent the cash payments we are required to make in excess of the principal amount, upon conversion of the Convertible Notes.

Cash Flows

The following table presents a summary of the primary sources and uses of cash for the years ended December 31, 2012, 2013 and 2014 (in thousands):

	Years Ended December 31,		
	2012	2013	2014
Net cash provided by (used in):			
Operating activities	$ (42,757)	$ (84,888)	$ (117,485)
Investing activities	(7,965)	(2,340)	(25,911)
Financing activities	136,342	92,093	269,947
Increase in cash and cash equivalents	$ 85,620	$ 4,865	$ 126,551

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, 2013 and 2014 were primarily due to increases in research and development expenses as we

Table of Contents

continued to develop our product candidates and pursue our immuno-oncology platform strategy. These increases in research and development expenses were primarily caused by increases in external research and development costs and in headcount.

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, all of which were recorded as acquired in-process research and development expense as incurred:

- for the year ended December 31, 2012, a $7.0 million up-front payment for the niraparib program license and a $1.0 million development milestone payment related to the TSR-011 program;

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

- 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.

Cash used in investing activities for the years ended December 31, 2012, 2013 and 2014 also included the use of $0.2 million, $0.4 million, and $1.0 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, 2012, net cash proceeds of $58.3 million from the issuance of Series B convertible preferred stock, and $78.0 million (net of underwriting discounts and commissions and offering expenses) from our initial public offering of common stock and the related partial exercise by the underwriters of the over-allotment option granted to them in connection with the initial public offering;

- 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; and

- 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.

Cash provided by financing activities during the years ended December 31, 2013 and 2014 also included $0.8 million and $1.9 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. The cash provided by these equity plans during the year ended December 31, 2012 was not significant.

Operating Capital Requirements

We expect to incur significant expenses and operating losses for the foreseeable future. Overall, we expect 2015 operating expenses to increase over current levels as we incur increased costs related to the advancement of our ongoing commercialization activities, including hiring our own sales force, developing our marketing infrastructure, executing related marketing and promotional programs, hiring consultants and establishing systems in preparation for the potential commercialization of oral rolapitant, costs related to the advancement of clinical trial and other development activities under our current development programs, such as IV rolapitant, niraparib and TSR-011, costs related to the immuno-oncology development activities under our collaboration with AnaptysBio, and costs related to potential future in-licensed development

Table of Contents

programs. We are subject to all of 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 believe that our existing cash and cash equivalents will be sufficient to fund our cash flow requirements, including any milestone obligations that may arise, required costs relating to our March 2014 collaboration and exclusive license agreement with AnaptysBio, and cash interest obligations related to our Convertible Notes, through at least December 31, 2015. However, we expect to require additional capital for the further development and potential commercialization of our product candidates and may also need to raise additional funds to pursue our strategy of in-licensing or acquiring additional product candidates and to meet our obligation to repay the Convertible Notes at maturity or, at our election, upon conversion.

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

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements, both short and long-term, will depend on many factors, including:

- the cost of establishing sales, marketing and distribution capabilities for rolapitant 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 3 clinical trials for niraparib;

- the clinical development plans we establish for TSR-011;

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

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

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

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

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

Table of Contents

- 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, 2014 (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)	$ 243,513	$ 6,038	$ 12,075	$ 12,075	$ 213,325
Purchase commitments	16,131	7,178	8,953		
Operating lease obligations	4,243	1,697	2,546		
Totals	$ 263,887	$ 14,913	$ 23,574	$ 12,075	$ 213,325

(a) See Note 5, 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. Amount includes both principal and interest.

Purchase Commitments

Purchase commitments in the table above relate to agreements with certain vendors for the provision of services, including services related to data management, clinical operation support and companion diagnostic development that we are not contractually able to terminate for convenience and avoid any and all future obligations to the vendors. Under such agreements, we are contractually obligated to make certain minimum payments to the vendors, with exact amounts in the event of termination based on the timing of termination and the exact terms of the relevant agreement. In the table above, we have included our estimated commitments under such agreements as of December 31, 2014, assuming we do not terminate these agreements. 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.

As of December 31, 2014, 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. As a result of cancellation rights included in our contractual agreements with our CROs (other than those described in the preceding paragraph), we have not included any amounts related to our CRO contracts in the contractual

obligations table above.

Operating and Facility Lease Obligations

Operating lease obligations in the table above relate to an operating lease for an office facility. We lease approximately 53,200 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 $5.0 million has been paid as of December 31, 2014. 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

Table of Contents

sales milestones based on the achievement of annual sales objectives. Pursuant to our license agreement with Amgen for the development and commercialization of TSR-011, we have made one milestone payment of $1.0 million to date, and we are required to make total milestone payments to Amgen of up to an aggregate of $138.0 million if specified clinical development, regulatory, initial commercialization and annual net product sales milestones are achieved. 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.

Off-Balance Sheet Arrangements

As of December 31, 2014, 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 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:

Table of Contents

- CROs in connection with clinical studies;
- investigative sites in connection with clinical studies;
- collaborator entities in connection with our collaboration agreements;
- vendors in connection with preclinical development activities; and
- vendors related to product manufacturing, development and distribution of clinical supplies.

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.

Net Operating Loss and Research and Development Carryforwards

As of December 31, 2014, we had federal net operating loss carryforwards of $264.5 million to potentially offset future federal income taxes. We also had federal research and development tax credit carryforwards of $4.8 million to potentially offset future federal income taxes. The federal net operating loss carryforwards and research and development tax credit carryforwards expire at various times through 2034. Net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. These carryforwards may be or become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the United States Internal Revenue Code of 1986, as amended, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of our company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. As of December 31, 2014, we recorded a full valuation allowance against our net operating loss and research and development tax credit carryforwards, as we believe it is more likely than not that the tax benefits will not be realized. In the future, if we determine that a portion or all of the tax benefits associated with our tax carryforwards will be realized, net income would increase in the period of determination, due to the reversal of a portion or all of the related valuation allowance.

92

Table of Contents

Stock-Based Compensation

We recognize compensation costs related to stock options, restricted stock units and restricted stock awards granted to employees, including those with performance conditions, 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 highly 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 data from a representative peer group 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, 2012, 2013 and 2014:

	Years Ended December 31,		
	2012	**2013**	**2014**
Dividend yield			
Volatility	66% - 71%	73% - 78%	69% - 76%
Risk-free interest rate	0.89% - 1.56%	1.07% - 2.05%	1.65% - 2.07%
Expected term (years)	6.25	5.50 - 6.25	5.50 - 6.08

Stock-based compensation expense totaled $1.8 million, $7.8 million, and $11.7 million, respectively, for the years ended December 31, 2012, 2013 and 2014. As of December 31, 2014, we had $31.1 million of total unrecognized stock-based compensation expense, which is expected to be recognized over a weighted-average remaining vesting period of approximately 2.5 years. We expect stock-based compensation expense to increase in future periods due to the potential of increases in the market value of our common stock, and expected increases in headcount and stock option grants.

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

Table of Contents

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 milestone payments, are immediately expensed as acquired in-process research and development in the period in which they are incurred. Royalties owed on future sales of licensed products pursuant to such licenses are expensed in the period the related revenues are recognized.

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, 2013 and December 31, 2014, we had cash and cash equivalents of $130.3 million and $256.9 million, respectively, consisting primarily of money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of United States interest rates, particularly because our investments are in short-term securities. Our securities are subject to interest rate risk and 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, 2013 and 2014, and the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders (deficit) equity, and cash flows for each of the three years in the period ended December 31, 2014. 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. We were not engaged to perform an audit of the Company s internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and 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, 2013 and 2014, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

/s/ ERNST & YOUNG LLP

Boston, Massachusetts
February 25, 2015

Table of Contents

TESARO, Inc.

Consolidated Balance Sheets

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

	December 31, 2013	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 130,310	$ 256,861
Other current assets	4,029	1,735
Total current assets	134,339	258,596
Property and equipment, net	440	1,022
Other assets	799	4,284
Total assets	$ 135,578	$ 263,902
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 1,869	$ 6,089
Accrued expenses	10,541	16,750
Other current liabilities	13	1,526
Total current liabilities	12,423	24,365
Convertible notes, net		115,481
Other non-current liabilities	3	
Total liabilities	12,426	139,846
Commitments and contingencies *(Note 5 and 10)*		
Stockholders equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at both December 31, 2013 and December 31, 2014; no shares issued or outstanding at both December 31, 2013 and December 31, 2014		
Common stock, $0.0001 par value; 100,000,000 shares authorized at both December 31, 2013 and December 31, 2014; 32,739,008 and 36,110,082 shares issued and outstanding at December 31, 2013 and December 31, 2014, respectively	3	4
Additional paid-in capital	302,647	474,562
Accumulated deficit	(179,498)	(350,510)
Total stockholders equity	123,152	124,056
Total liabilities and stockholders equity	$ 135,578	$ 263,902

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,		
	2012	**2013**	**2014**
Expenses:			
Research and development	$ 47,200	$ 75,725	$ 118,425
General and administrative	6,715	14,780	23,935
Acquired in-process research and development	8,000	1,940	24,900
Total expenses	61,915	92,445	167,260
Loss from operations	(61,915)	(92,445)	(167,260)
Interest expense			(3,776)
Interest income	152	83	24
Net loss	$ (61,763)	$ (92,362)	$ (171,012)
Net loss per share applicable to common stockholders - basic and diluted	$ (4.51)	$ (2.93)	$ (4.79)
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	13,696	31,559	35,739
Comprehensive loss	$ (61,763)	$ (92,362)	$ (171,012)

See accompanying notes to consolidated financial statements.

Table of Contents

TESARO, Inc.

Consolidated Statements of Convertible Preferred Stock and Stockholders (Deficit) Equity

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

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders
	Shares	Amount	Shares	Amount	Capital	Deficit	(Deficit) Equity
Balance at December 31, 2011	**41,052,319**	**$ 64,348**	**1,259,996**	**$**	**$ 305**	**$ (25,373)**	**$ (25,068)**
Issuance of Series B convertible preferred stock; $2.175 per share, net of offering costs of $110	26,884,442	58,349					
Conversion of convertible preferred stock into common stock	(67,936,761)	(122,697)	19,410,490	2	122,695		122,697
Issuance of common stock, net of issuance costs of $8,847			6,430,183	1	77,959		77,960
Issuance of common stock resulting from exercise of stock options			19,016		33		33
Issuance of common stock as payment of Board of Directors fees in lieu of cash			16,644		253		253
Stock-based compensation expense					1,550		1,550
Net loss						(61,763)	(61,763)
Balance at December 31, 2012		**$**	**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**

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,		
	2012	**2013**	**2014**
Operating activities			
Net loss	$ (61,763)	$ (92,362)	$ (171,012)
Adjustments to reconcile net loss to net cash used in operating activities:			
Acquired in-process research and development	8,000	1,940	24,900
Depreciation expense	64	179	349
Stock-based compensation expense	1,803	7,759	11,683
Non-cash interest expense			2,249
Loss on disposal of property and equipment			80
Changes in operating assets and liabilities:			
Other assets	1,020	(3,112)	2,327
Accounts payable	2,565	(1,301)	4,220
Accrued expenses	5,565	1,996	6,209
Other liabilities	(11)	13	1,510
Net cash used in operating activities	(42,757)	(84,888)	(117,485)
Investing activities			
Acquisition of product candidate and technology licenses and milestone payments	(8,000)	(1,940)	(24,900)
Purchase of property and equipment	(165)	(400)	(1,011)
Change in restricted cash	200		
Net cash used in investing activities	(7,965)	(2,340)	(25,911)
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	77,960	91,312	94,199
Proceeds from exercise of stock options	33	634	1,663
Proceeds from issuance of common stock under Employee Stock Purchase Plan		147	249
Payment of minimum tax withholdings on share-based awards			(33)
Proceeds from sale of convertible preferred stock, net of issuance costs	58,349		
Net cash provided by financing activities	136,342	92,093	269,947
Increase in cash and cash equivalents	85,620	4,865	126,551
Cash and cash equivalents at beginning of period	39,825	125,445	130,310
Cash and cash equivalents at end of period	$ 125,445	$ 130,310	$ 256,861
Non-cash investing and financing activities			
Conversion of convertible preferred stock to common stock	$ 122,697	$	$
Supplemental disclosure of cash flow information:			
Cash paid for interest	$	$	$

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, intends to commercialize these products. Since incorporation, primary activities have consisted of acquiring product candidates, advancing development of these product candidates, developing intellectual property, recruiting personnel and raising capital. The Company intends to in-license or acquire additional product candidates across various stages of development, operates in one segment and has never earned revenue from its activities. 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 whom 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.

Public Offerings of Common Stock

On June 27, 2012, the Company priced its initial public offering whereby it sold 6,000,000 shares of common stock at a price of $13.50 per share. The shares began trading on the NASDAQ Global Select Market on June 28, 2012, and the transaction closed on July 3, 2012. Immediately prior to the closing of the offering, all outstanding shares of convertible preferred stock converted into 19,410,490 shares of common stock. On July 23, 2012, the underwriters purchased an additional 430,183 shares by exercising a portion of the over-allotment option granted to them in connection with the initial public offering. As a result of the closing of the initial public offering and subsequent exercise of the over-allotment option, the Company received aggregate net proceeds of approximately $78.0 million, which is net of underwriting discounts and commissions and offering expenses.

In connection with the completion of its initial public offering, on July 3, 2012, the Company filed an amended and restated certificate of incorporation, which, among other things, changed the number of authorized shares of common stock to 100,000,000 shares and preferred stock to 10,000,000 shares, both with a par value of $0.0001 per share.

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.

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 product candidates and the achievement of a level of revenues adequate to support its cost structure. The Company may never achieve profitability, and unless and until it does, the Company will continue to need to raise additional capital. Management intends to fund future operations through additional public or private equity or debt offerings and may seek additional capital through arrangements with strategic partners or from other sources.

Table of Contents

Reverse Stock Split

On June 19, 2012, the Company effected a 1 for 3.50 reverse stock split of its common stock. The Company s historical share and per share information has been retroactively adjusted to give effect to this reverse stock split.

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: TESARO UK Limited, TESARO Securities Corporation and TESARO Development, Ltd. 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.

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 and stock-based compensation expense. Significant estimates in these consolidated financial statements include estimates made in connection with accrued research and development expenses, stock-based compensation expense and valuation of convertible notes. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

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.

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 certificate of deposits, commercial paper and U.S. government and U.S. government agency obligations. Cash equivalents are reported at fair value.

Fair Value of Financial Instruments

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

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

Table of Contents

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, 2013 and 2014 and indicates the fair value hierarchy of the valuation inputs utilized to determine such fair value (in thousands):

		December 31, 2013			
Description	**Balance Sheet Classification**	**Total**	**Level 1**	**Level 2**	**Level 3**
Assets:					
Money market funds	Cash and cash equivalents	$ 128,801	$ 128,801	$	$
Total assets		$ 128,801	$ 128,801	$	$

		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	$	$

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, 2014, the carrying value of the Convertible Notes was $115.5 million, net of unamortized discount, and the fair value of the principal amount was $251.1 million. The Convertible Notes are discussed in more detail in Note 5, 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
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 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, 2014.

Table of Contents

Research and Development Expenses

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

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

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

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

- the cost of acquiring, developing and manufacturing active pharmaceutical ingredients, clinical trial materials and other research and development materials;

- fees and costs related to regulatory filings and activities;

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

- other costs associated with clinical and preclinical activities.

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

Acquired In-Process Research and Development Expense

The Company has acquired the rights to develop and commercialize new product candidates. Up-front payments that relate to the acquisition of a new drug compound, as well as milestone payments, are immediately expensed as acquired in-process research and development in the period in which they are incurred, provided that the 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. Royalties owed on future 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 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.

Table of Contents

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 equity-based award at its grant date using the Black-Scholes option pricing model. 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.

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.

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,		
	2012	2013	2014
Outstanding stock awards	2,134	2,853	3,742
Unvested restricted stock	349	102	4
	2,483	2,955	3,746

In September 2014, 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 is required to make in excess of the principal amount, upon conversion of the Convertible Notes in the event that the market price of the Company s common stock is greater than the floor price of the Capped Calls. See Note 5, Convertible Notes , for additional information. 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. During the period between issuance and December 31, 2014, the requisite criteria for conversion had not been met, and thus there would be no shares issuable under the conversion premium. As such, no shares have been presented in the table above.

New Accounting Pronouncements - Recently Adopted

In June 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-10, which eliminates the concept of a development stage entity, or DSE, in its entirety from GAAP. Under prior guidance, DSEs are required to report incremental information, including inception-to-date financial information, in their financial statements. A DSE is an entity devoting substantially all of its efforts to establishing a new business and for which either planned principal operations have not yet commenced or have commenced but there has been no significant revenues generated from that business. Entities classified as DSEs will no longer be subject to these incremental reporting requirements after adopting ASU No. 2014-10. ASU No. 2014-10 is effective for fiscal years beginning after December 15, 2014, with early adoption permitted. Retrospective application is required for the elimination of incremental DSE disclosures. Prior to the issuance of ASU No. 2014-10, the Company had met the definition of a DSE since its inception. The Company elected to adopt this ASU early, and therefore it has eliminated the incremental disclosures previously required of DSEs.

New Accounting Pronouncements - Recently Issued

In April 2014, the FASB issued ASU No. 2014-08, which amends guidance for reporting discontinued operations and disposals of components of an entity. The amended guidance requires that a disposal representing a strategic shift that

Table of Contents

has (or will have) a major effect on an entity s operations and financial results or a business activity classified as held for sale should be reported as discontinued operations. The amendments also expand the disclosure requirements for discontinued operations and add new disclosure requirements for individually significant dispositions that do not qualify as discontinued operations. This guidance is effective prospectively for fiscal years beginning after December 15, 2014 (early adoption is permitted only for disposals that have not been previously reported). The Company does not expect the adoption of this guidance to have a material effect on its consolidated financial statements.

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*. This guidance is effective for fiscal years beginning after December 15, 2016, with early adoption not permitted. 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. 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. The Company is currently in the process of evaluating the impact of adoption of this guidance on its consolidated financial statements and related disclosures.

3. Property and Equipment

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

	December 31,	
	2013	**2014**
Furniture and fixtures	$ 244	$ 821

Computer equipment and software		404		672
Leasehold improvements		67		115
		715		1,608
Less accumulated depreciation and amortization		(275)		(586)
Total property and equipment, net	$	440	$	1,022

Total depreciation expense amounted to $64,000, $179,000 and $349,000 for the years ended December 31, 2012, 2013 and 2014, respectively.

Table of Contents

4. Accrued Expenses

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

	December 31,	
	2013	2014
Research and development	$ 7,422	$ 11,433
Salaries, bonuses and other compensation	2,462	4,012
Professional services	389	529
Other accrued expenses	268	776
Total accrued expenses	$ 10,541	$ 16,750

5. 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, which includes $26.3 million principal amount of Convertible Notes issued pursuant to the full exercise of an over-allotment option granted to the underwriters in the offering. 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, or the Base Indenture, as supplemented by the First Supplemental Indenture relating to the Convertible Notes, or the Supplemental Indenture, and together with the Base Indenture, 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 business day immediately preceding April 1, 2021, holders may convert their Convertible Notes at their option only under the following circumstances:

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

Table of Contents

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 Indenture contains customary terms and covenants and events of default. If an event of default (other than certain events of bankruptcy, insolvency or reorganization involving the Company) occurs and is continuing, the Trustee by notice to the Company, or the holders of at least 25% in principal amount of the outstanding Convertible Notes by written notice to the Company and the Trustee, may declare 100% of the principal and accrued and unpaid interest, if any, on all of the Convertible Notes to be due and payable immediately. Upon the occurrence of certain events of bankruptcy, insolvency or reorganization involving the Company, 100% of the principal and accrued and unpaid interest, if any, on all of the Convertible Notes will become due and payable automatically. Notwithstanding the foregoing, the Indenture provides that, to the extent the Company elects and for up to 180 days after the occurrence of an event of default relating to certain failures by the Company to comply with certain reporting covenants, the remedy for such an event of default consists exclusively of the right to receive additional interest on the Convertible Notes.

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. As of December 31, 2014 it continues to meet the conditions for equity classification. In addition, third-party transaction costs are required to be allocated to the liability and equity components based on their relative values.

The Company s outstanding convertible note balances at December 31, 2014 consisted of the following (in thousands):

		December 31, 2014
Liability component:		
Principal	$	201,250
Less: debt discount, net		(85,769)
Net carrying amount	$	115,481
Equity component	$	87,843

Table of Contents

In connection with the issuance of the Convertible Notes, the Company incurred approximately $6.6 million of debt issuance costs, which primarily consisted 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 non-current assets on the balance sheet. 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, 2014, the carrying value of the Convertible Notes was $115.5 million and the fair value of the Convertible Notes approximated $251.1 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, 2014 (in thousands):

		Year Ended December 31, 2014
Contractual interest expense	$	1,526
Amortization of debt discount		2,074
Amortization of debt issuance costs		176
Total interest expense	$	3,776

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, 2014.

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 of $20.8 million was recorded in stockholders equity and will not be remeasured.

6. Convertible Preferred Stock and Stockholders Equity

As of December 31, 2014, 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 36,110,082 shares of common stock were issued and outstanding.

Convertible Preferred Stock

On March 21, 2012, the Company sold 26,884,442 shares of Series B convertible preferred stock to existing investors pursuant to the Series B Purchase Agreement at a price of $2.175 per share, resulting in net proceeds to the Company of approximately $58.3 million. The Company evaluated the terms of the Series B convertible preferred stock and concluded that an investor s right to acquire additional shares of Series B convertible preferred stock was not legally detachable and therefore was embedded and not required to be separated from Series B convertible preferred stock.

The Company accounts for potentially beneficial conversion features in accordance with Accounting Standards Codification, or ASC, 470-20, *Debt with Conversion and Other Options*. At the time of each of the issuances of convertible preferred stock, the common stock into which the Series A and B convertible preferred stock is convertible had a fair value less than the effective conversion price of the convertible preferred stock and, as such, there was no intrinsic value on the respective commitment dates.

Table of Contents

On July 3, 2012, immediately prior to the closing of the Company s initial public offering, all 67,936,761 shares outstanding of all series of the Company s convertible preferred stock were converted into 19,410,490 shares of its common stock. As of December 31, 2014, the Company did not have any convertible preferred stock authorized, issued or 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.

Common Stock

On June 27, 2012, the Company priced its initial public offering whereby the Company sold 6,000,000 shares of common stock at a price of $13.50 per share. The shares began trading on the NASDAQ Global Select Market on June 28, 2012, and the transaction closed on July 3, 2012. Immediately prior to the closing of the offering, all outstanding shares of convertible preferred stock converted into 19,410,490 shares of common stock. On July 23, 2012, the underwriters purchased an additional 430,183 shares of common stock by exercising a portion of the over-allotment option granted to them in connection with the initial public offering. As a result of the closing of the initial public offering and subsequent exercise of the over-allotment option, the Company received aggregate net proceeds of approximately $78.0 million, which is net of underwriting discounts and commissions and offering expenses.

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.

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.

7. 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,		
	2012	2013	2014
Research and development	$ 544	$ 2,034	$ 4,954
General and administrative	1,259	5,725	6,729
Total stock-based compensation expense	$ 1,803	$ 7,759	$ 11,683

The Company maintains several equity compensation plans, including the TESARO, Inc. 2012 Omnibus Incentive Plan, or the 2012 Incentive Plan, the 2010 Stock Incentive Plan, or the 2010 Incentive Plan, and the 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, options granted to employees by the Company generally vest 25% one year from the vesting start date and 75% in equal installments over the subsequent 36 months and are exercisable from the date of grant for a period of ten years.

Table of Contents

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 and 2015, the number of shares authorized for issuance under the 2012 Incentive Plan was increased by 1,309,560 shares and 1,444,403 shares, respectively. Awards under the 2012 Incentive Plan may include the following award types: stock options, which may be either incentive stock options or nonqualified stock options; stock appreciation rights; restricted stock; restricted stock units; dividend equivalent rights; performance shares; performance units; cash-based awards; other stock-based awards, including unrestricted shares; or any combination of the foregoing. The exercise price of stock options granted under the 2012 Incentive Plan is equal to the closing price of a share of the Company s common stock on the grant date. As of December 31, 2014, there were 423,759 shares available for grant under the 2012 Incentive Plan, prior to taking into account the additional shares authorized for issuance as of January 1, 2015, as described above.

2010 Stock Incentive Plan

In connection with the Company s formation, the Company adopted the TESARO, Inc. 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, 2014, there are no shares available for grant under the 2010 Incentive Plan.

Restricted Common Stock

In connection with the Company s formation, the founders purchased an aggregate of 1,071 shares of common stock at a nominal per share purchase price. On May 10, 2010, in connection with the Company s sale of Series A-1 convertible preferred stock, each such share was reclassified into 1,000 shares of common stock, or an aggregate of 1,071,426 shares of common stock, or the Founder Common. The shares of Founder Common were issued subject to restricted stock agreements between the Company and each founder. The Founder Common shares vested in full as of March 26, 2014.

On February 7, 2011, the Company granted to the founders and one employee an aggregate of 188,570 shares of common stock as compensation for services provided, or the 2011 Awards. The 2011 Awards are subject to the 2010 Incentive Plan and various restrictions pursuant to restricted stock agreements between the Company and each recipient, including restrictions on transfer and a Company right of repurchase. The 2011 Awards vested in full as of January 6, 2015.

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 $24,000, $669,000 and $116,000, respectively, for the years ended December 31, 2012, 2013 and 2014 associated with restricted common stock grants. The totals for the years ended December 31, 2013 and 2014 include $646,000 and $96,000, respectively, related to accounting for awards held by a non-employee consultant.

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

Table of Contents

	Shares	Weighted-average grant date fair value per share
Unvested restricted stock at December 31, 2013	102,412	$ 0.76
Granted		
Vested	(89,332)	0.23
Forfeited	(8,929)	0.53
Unvested restricted stock at December 31, 2014	4,151	$ 12.79

The weighted-average grant date fair value of restricted stock granted during the year ended December 31, 2013 was $46.22 per share. There were no grants of restricted stock during the years ended December 31, 2012 or 2014. The total grant date fair value of restricted stock that vested during the years ended December 31, 2012, 2013 and 2014 was $47,000, $25,000, and $21,000, respectively. At December 31, 2014, the total unrecognized compensation cost related to unvested restricted stock was insignificant.

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, 2013	2,852,793	$ 12.77	8.4	$ 46,708
Granted	1,320,573	30.65		
Exercised	(157,113)	10.59		
Cancelled	(289,924)	17.75		
Outstanding at December 31, 2014	3,726,329	$ 18.82	8.1	$ 69,176
Vested at December 31, 2014	1,552,249	$ 10.16	7.2	$ 42,428
Vested and expected to vest at December 31, 2014 (a)	3,646,747	$ 18.56	8.0	$ 68,628

(a) This represents the number of vested options as of December 31, 2014, plus the number of unvested options expected to vest as of December 31, 2014, based on the unvested options at December 31, 2014, adjusted for the estimated forfeiture rate.

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,		
	2012	2013	2014
Dividend yield			
Volatility	66% - 71%	73% - 78%	69% - 76%
Risk-free interest rate	0.89% - 1.56%	1.07% - 2.05%	1.65% - 2.07%

Expected term (years)	6.25	5.50 - 6.25	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 the historical volatility of a representative group of public biotechnology and life sciences companies with similar characteristics to the Company, including early stage of 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 $1,526,000, $6,770,000, and $11,081,000 for the years ended December 31, 2012, 2013 and 2014, respectively. The totals for the years ended

Table of Contents

December 31, 2013 and 2014 include $1,132,000 and $297,000, respectively, related to accounting for awards held by a non-employee consultant. The weighted-average grant date fair values of options granted in the years ended December 31, 2012, 2013 and 2014 were $5.29, $18.48 and $20.33 per share, respectively. The aggregate intrinsic value of options exercised during the years ended December 31, 2012, 2013 and 2014 was $0.2 million, $4.8 million and $3.4 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, 2014, there was $30.7 million of total unrecognized compensation cost related to unvested stock options, which the Company expects to recognize over a remaining weighted-average period of 2.5 years.

In October 2012, June 2013 and June 2014, as provided for under the 2012 Incentive Plan, the Company issued 16,644, 4,368 and 10,411 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, all of which were outstanding as of December 31, 2014 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 stock options were granted to certain non-employee consultants, with a weighted-average grant date fair value of $17.50, and no options were vested, exercised or forfeited. 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 option grants to non-employee consultants during the years ended December 31, 2012 or 2013.

Restricted Stock Units

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.

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

Table of Contents

	Shares	Weighted-average grant date fair value per share
Unvested restricted stock units at December 31, 2013		$
Granted	19,500	29.04
Vested	(2,634)	29.04
Forfeited		
Withheld for taxes (a)	(1,266)	29.04
Unvested restricted stock units at December 31, 2014	15,600	$ 29.04

(a) The Company has 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.

The weighted-average grant date fair values of RSUs granted during the year ended December 31, 2014 was $29.04 per share. There were no grants of RSUs during the years ended December 31, 2012 or 2013. The total grant date fair value of RSUs that vested during the years ended December 31, 2012, 2013 and 2014 was $0, $0, and $113,000, 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, 2014, there was approximately $453,000 of unrecognized compensation cost related to the RSU grants that is expected to be recognized over a weighted-average period of approximately 0.75 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, 2014, 257,324 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 day 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 and 2014, the Company issued a total of 7,831 and 9,845 shares, respectively, of common stock under the 2012 ESPP and recognized $67,000 and $99,000, 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.

8. 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, 2012, 2013 and 2014 (in thousands):

	Years Ended December 31,		
United States	$ (61,763)	$ (87,953)	$ (141,119)
Foreign		(4,409)	(29,893)
(Loss) income before provision for (benefit from) income taxes	$ (61,763)	$ (92,362)	$ (171,012)

For the years ended December 31, 2012, 2013 and 2014, the Company did not record any current or deferred income tax provisions or benefits.

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:

Table of Contents

	Years Ended December 31,		
	2012	2013	2014
Federal income tax (benefit)/expense at statutory rate	(34.0)%	(34.0)%	(34.0)%
State income tax benefit	(5.4)	(5.1)	(4.4)
Permanent items	0.4	0.8	0.7
Foreign rate differential	0.0	1.6	5.9
Federal research and development credit	0.0	(2.5)	(1.4)
Change in valuation allowance	39.0	39.2	33.2
Effective income tax rate	0.0%	0.0%	0.0%

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.

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

	December 31,	
	2013	2014
Deferred tax assets:		
Federal net operating loss carryforwards	$ 50,265	$ 86,163
State net operating loss carryforwards	7,762	13,270
Depreciation and amortization	5,793	14,647
Tax credit carryforwards	2,984	5,780
Stock-based compensation	2,248	4,891
Other	779	1,289
Total deferred tax assets	69,831	126,040
Less: valuation allowance	(69,831)	(101,399)
Net deferred tax assets	$	$ 24,641
Deferred tax liability:		
Debt discount on convertible notes		(24,641)
Net deferred taxes	$	$

As of December 31, 2014, the Company had federal net operating loss carryforwards of approximately $259.2 million and state net operating loss carryforwards of $257.6 million, which are available to reduce future taxable income. Approximately $5.8 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 $5.9 million and state research and development tax credit carryforwards of $1.4 million, which may be used to offset future tax liabilities.

These federal and state operating loss carryforwards, or NOL, and tax credit carryforwards will expire at various dates through 2034. The NOL and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service, or the IRS, and state tax authorities. These carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years.

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 continues to maintain a valuation allowance for the full amount of the 2014 deferred tax asset because it is more likely than not that the deferred tax asset will not be realized. The valuation allowance increased by $31.6 million from December 31, 2013 to December 31, 2014, primarily due to an increase in net operating losses.

Table of Contents

The Company has gross unrecognized tax benefits related to research and development credits of $1.0 million and $0.5 million, respectively, as of December 31, 2014 and 2013. At December 31, 2014, $1.0 million represented the amount of unrecognized tax benefits that, 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 tax authorities remains open for all tax years. Since the Company is in a loss carryforward position, the Company is generally subject to examination by the U.S. federal, state and local income tax authorities for all tax years in which a loss carryforward is available. The Company files a United States federal income tax return and a Commonwealth of Massachusetts state income tax return. There are currently no federal or state audits in process.

9. Employee Benefit Plan

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, 2012, 2013 and 2014, the Company made aggregate matching contributions of $137,000, $277,000 and $484,000, respectively.

10. Commitments and Contingencies

The Company leases approximately 53,200 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. The lease agreement provides for one month of free rent with respect to a portion of the leased premises. The Company recognizes rental expense on a straight-line basis over the respective lease term including any free rent periods. The following table presents future minimum rental commitments, by fiscal year and in the aggregate, as of December 31, 2014 (in thousands):

	Operating Leases
2015	$ 1,697
2016	1,697
2017	849
Thereafter	
Total minimum lease payments	$ 4,243

The Company recorded $166,000, $647,000 and $1,525,000 in rent expense for the years ended December 31, 2012, 2013 and 2014, respectively.

The Company has entered into agreements with certain vendors for the provision of services, including services related to data management, clinical operation support and companion diagnostic development, that the Company is not contractually able to terminate for convenience and avoid any and all future obligations to the vendors. Under such agreements, the Company is contractually

Table of Contents

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.

11. License 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 1,500,000 shares of its Series O convertible Preferred Stock. At the time of the license transaction, the fair value of Series O convertible Preferred Stock was determined to be $630,000. 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. If commercial sales of rolapitant commence, the Company is 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 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. OPKO also retains an option to become the exclusive distributor of such products in Latin America, provided that OPKO exercises that option within a defined period following specified regulatory approvals in the United States. The Company is responsible for all preclinical, 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, 2014, the Company has made one milestone payment of $5.0 million under this license agreement, in connection with the acceptance of the oral rolapitant NDA for review by the FDA in November 2014.

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. The Company is also responsible for using commercially reasonable efforts to conduct all preclinical, clinical, regulatory and other activities necessary to develop and commercialize an ALK product. In the event that the Company wishes to sublicense any of the development and commercialization rights to any third party, it is required to grant to Amgen a right of first negotiation with respect to the rights it proposes to sublicense. Under the terms of the license agreement, in 2011 the Company made an up-front payment to Amgen of $0.5 million. In November 2012, in connection with the initiation of its Phase 1/2a clinical trial for TSR-011, the Company made a milestone payment to Amgen of $1.0 million. The Company is required to make total milestone payments to Amgen of up to an aggregate of $138.0 million if specified clinical development, regulatory, initial commercialization and annual net product sales milestones are achieved. If commercial sales of a product commence, the Company will pay Amgen royalties at percentage rates ranging from the mid-single digits to slightly above the single digits

Table of Contents

based on cumulative worldwide net sales. At the time of the license transaction, TSR-011 was a preclinical compound. 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 and the entire purchase price of $0.5 million was recorded as acquired in-process research and development expense. Milestone payments are also recorded as acquired in-process research and development and expensed as achieved.

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, one in the amount of $1.9 million upon dosing of the first patient in the Phase 3 ovarian cancer clinical trial in July 2013, which the Company refers to as its NOVA trial, and one in the amount of $0.9 million upon dosing of the first patient in the Phase 3 breast cancer clinical trial in April 2014, which the Company refers to as its BRAVO trial.

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.

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 dual-reactive 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 dual-reactive 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

Table of Contents

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 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 year ended December 31, 2014, the Company recorded approximately $4.6 million of research and development expense, associated with amounts due to AnaptysBio under the collaboration. As of December 31, 2014, the Company has not made any additional milestone payments under this agreement.

Table of Contents

12. Consolidated Quarterly Financial Data - Unaudited

The following table presents unaudited consolidated quarterly financial data for the years ended December 31, 2013 and 2014 (in thousands, except per share data):

	Three Months Ended							
	March 31, 2013	June 30, 2013	Sept. 30, 2013	Dec. 31, 2013	March 31, 2014	June 30, 2014	Sept. 30, 2014	Dec. 31, 2014
Expenses:								
Research and development	$ 16,503	$ 18,177	$ 22,163	$ 18,882	$ 28,117	$ 30,569	$ 29,925	$ 29,814
General and administrative	2,400	3,412	4,503	4,465	4,688	5,587	6,263	7,397
Acquired in-process research and development			1,940(a)		17,000(b)	900(c)		7,000(d)
Total expenses	18,903	21,589	28,606	23,347	49,805	37,056	36,188	44,211
Loss from operations	(18,903)	(21,589)	(28,606)	(23,347)	(49,805)	(37,056)	(36,188)	(44,211)
Interest expense							(42)	(3,734)
Interest income	34	25	17	7	5	5	4	10
Net loss	$ (18,869)	$ (21,564)	$ (28,589)	$ (23,340)	$ (49,800)	$ (37,051)	$ (36,226)	$ (47,935)
Net loss per share - basic and diluted	$ (0.66)	$ (0.67)	$ (0.88)	$ (0.72)	$ (1.43)	$ (1.03)	$ (1.01)	$ (1.33)
Weighted-average shares - basic and diluted	28,798	32,336	32,453	32,597	34,856	35,982	36,029	36,071

(a) In the quarter ended September 30, 2013, the Company made a milestone payment to Merck for niraparib as a result of the first patient dosing in the NOVA trial, which occurred in July 2013.

(b) 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.

(c) 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.

(d) 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.

Table of Contents

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, 2014, 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, 2014, 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, 2014 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, 2014.

Changes in Internal Control Over Financial Reporting

During the quarter ended December 31, 2014, there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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 2015 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 2015 Proxy Statement, which we expect to file with the SEC no later than April 30, 2015.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item is set forth in our 2015 Proxy Statement to be filed with the SEC within 120 days of December 31, 2014, and is incorporated into this Annual Report on Form 10-K by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is set forth in our 2015 Proxy Statement to be filed with the SEC within 120 days of December 31, 2014, 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 is set forth in our 2015 Proxy Statement to be filed with the SEC within 120 days of December 31, 2014, 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, 2014

	Number of securities to be issued upon exercise of outstanding options and rights (a)	Weighted-average exercise price of outstanding options and rights (b)	Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a))

				(c)
Plan Category				
Equity compensation plans approved by security holders				
(1) (2)	3,741,929	$	18.86	681,083
Equity compensation plans not approved by security holders		$		
Total	3,741,929	$	18.86	681,083

(1) As of December 31, 2014, 423,759 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, 2014, 146,282 shares of our common stock had been cancelled under the 2010 Incentive Plan and transferred to the 2012 Incentive Plan. Effective January 1, 2015, the number of shares authorized for issuance under the 2012 Incentive Plan was increased by 1,444,403 shares.

(2) As of December 31, 2014, 257,324 shares were reserved for issuance under our 2012 Employee Stock Purchase Plan, or ESPP, which became effective in June 2012.

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

The information required by this Item is set forth in our 2015 Proxy Statement to be filed with the SEC within 120 days of December 31, 2014, and is incorporated into this Annual Report on Form 10-K by reference.

Table of Contents

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item is set forth in our 2015 Proxy Statement to be filed with the SEC within 120 days of December 31, 2014, 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 25, 2015

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 25, 2015
/s/ Mary Lynne Hedley, Ph.D. Mary Lynne Hedley, Ph.D.	President, Chief Operating Officer and Director	February 25, 2015
/s/ Timothy R. Pearson Timothy R. Pearson	Executive Vice President and Chief Financial Officer (Principal Financial Officer)	February 25, 2015
/s/ Edward C. English Edward C. English	Vice President of Finance and Administration (Principal Accounting Officer)	February 25, 2015
/s/ David M. Mott David M. Mott	Chairman of the Board of Directors	February 25, 2015
/s/ Lawrence M. Alleva Lawrence M. Alleva	Director	February 25, 2015
/s/ James O. Armitage, M.D. James O. Armitage, M.D.	Director	February 25, 2015
/s/ Earl M. (Duke) Collier, Jr. Earl M. (Duke) Collier, Jr.	Director	February 25, 2015
/s/ Arnold L. Oronsky, Ph.D. Arnold L. Oronsky, Ph.D.	Director	February 25, 2015
/s/ Beth Seidenberg, M.D. Beth Seidenberg, M.D.	Director	February 25, 2015

126

Table of Contents

INDEX TO EXHIBITS

Exhibit Number	Exhibit Description
3.1(A)	Amended and Restated Certificate of Incorporation of the Company.
3.2(A)	Amended and Restated Bylaws of the Company.
4.1(B)	Form of Certificate of Common Stock.
4.2(C)	Second Amended and Restated Investors Rights Agreement, dated as of June 6, 2011, as amended, between the Company and certain investors named therein.
4.3(C)	Amendment No. 1 to the Second Amended and Restated Investors Rights Agreement.
4.4(D)	Senior Debt Securities Indenture, dated September 29, 2014, between the Company and U.S. Bank National Association, as trustee
4.5(D)	First Supplemental Indenture, dated September 29, 2014, between the Company and U.S. Bank National Association, as trustee
10.1+(E)	TESARO, Inc. 2010 Stock Incentive Plan, as amended, and forms of agreement thereunder.
10.2+(B)	TESARO, Inc. 2012 Omnibus Incentive Plan.
10.3+(B)	TESARO, Inc. 2012 Employee Stock Purchase Plan.
10.4(F)	Form of Option Agreement under 2012 Omnibus Incentive Plan.
10.5+(E)	Form of Indemnification Agreement between the Company and each of Leon O. Moulder, Jr., Mary Lynne Hedley, Ph.D. and Lawrence M. Alleva.
10.6+(E)	Indemnification Agreement between the Company and David M. Mott.
10.7+(E)	Indemnification Agreement between the Company and Arnold L. Oronsky.
10.8+(E)	Indemnification Agreement between the Company and Beth Seidenberg, M.D.
10.9+(B)	Amended and Restated Offer Letter Agreement by and between the Company and Leon O. Moulder, Jr., dated June 18, 2012.
10.10+(B)	Amended and Restated Offer Letter Agreement by and between the Company and Mary Lynne Hedley, dated June 18, 2012.
10.11+(E)	Restricted Stock Agreement by and between the Company and Leon O. Moulder, Jr., dated May 10, 2010.
10.12+(E)	Restricted Stock Agreement by and between the Company and Mary Lynne Hedley, dated May 10, 2010.
10.13+(E)	Form of Non-Disclosure and Inventions Assignment Agreement by and between the Company and each of Messrs. Moulder and Dr. Hedley.
10.14*(G)	Exclusive License Agreement by and between the Company and OPKO Health, Inc., dated December 10, 2010.
10.15*(G)	Exclusive License Agreement by and between the Company and Amgen, Inc., dated as of March 18, 2011.

Table of Contents

10.16*(G)	Process Development and Manufacturing Services Agreement by and between the Company and Hovione Inter Limited, dated March 31, 2012.
10.17*(G)	License Agreement by and between the Company and Merck Sharpe & Dohme Corp., dated May 22, 2012.
10.18(H)	Consulting Agreement, dated as of August 31, 2013, by and between the Company and Richard J. Rodgers.
10.19(H)	Separation and Release Agreement, dated as of August 31, 2013, by and between the Company and Richard J. Rodgers.
10.20*(I)	Collaboration and Exclusive License Agreement by and among TESARO, Inc., TESARO Development, Ltd. and AnaptysBio, Inc., dated as of March 10, 2014.
10.21*	Amendment No. 1 to Collaboration and Exclusive License Agreement by and among TESARO, Inc., TESARO Development, Ltd. and AnaptysBio, Inc., dated as of November 28, 2014
10.22+(J)	Offer Letter Agreement by and between TESARO, Inc. and Timothy R. Pearson, dated May 27, 2014.
10.23(D)	Base Capped Call Confirmation, dated September 23, 2014, between the Company and Citibank, N.A.
10.22(D)	Base Capped Call Confirmation, dated September 23, 2014, among the Company, Deutsche Bank AG, London Branch, and Deutsche Bank Securities Inc., acting solely as agent
10.24(D)	Additional Capped Call Confirmation, dated September 25, 2014, between the Company and Citibank, N.A.
10.25(D)	Additional Capped Call Confirmation, dated September 25, 2014, among the Company, Deutsche Bank AG, London Branch, and Deutsche Bank Securities Inc., acting solely as agent
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

(A) Filed as an exhibit to the Registrant s Form 8-K filed on July 3, 2012 (File No. 001-35587)

128

Table of Contents

(B) Filed as an exhibit to the Registrant s Form S-1/A filed on June 19, 2012 (File No. 333-180309)

(C) Filed as an exhibit to the Registrant s Form S-1/A filed on May 17, 2012 (File No. 333-180309)

(D) Filed as an exhibit to the Registrant s Current Report on Form 8-K filed on September 29, 2014 (File No. 001-35587)

(E) Filed as an exhibit to the Registrant s Form S-1 filed on March 23, 2012 (File No. 333-180309)

(F) Filed as an exhibit to the Registrant s Form S-1/A filed on June 27, 2012 (File No. 333-180309)

(G) Filed as an exhibit to the Registrant s Form S-1/A filed on June 22, 2012 (File No. 333-180309)

(H) Filed as an exhibit to the Registrant s Form 8-K filed on August 30, 2013 (File No. 001-35587)

(I) Filed as an exhibit to the Registrant s Form 10-Q filed on May 2, 2014 (File No. 001-35587)

(J) Filed as an exhibit to the Registrant s Form 8-K filed on May 27, 2014 (File No. 001-35587)

+ 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.