TESARO, Inc.
Form 10-K
February 20, 2013
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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, 2012

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 o

No x

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 o
Non-accelerated filer x (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, 2012 was approximately $57,000,000 based on the closing price of $13.99 of the Common Stock of the registrant as reported on the NASDAQ Global Select Market on such date (assuming the closing of the registrant s initial public offering and the conversion of all outstanding shares of the registrant s convertible preferred stock to shares of common stock immediately prior to the closing of the offering). As of February 1, 2013, there were 27,136,329 shares of the registrant s Common Stock, par value $0.0001 per share, outstanding.

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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 such statement, 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 were founded in March 2010 by former executives of MGI PHARMA, Inc., or MGI PHARMA, 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:

- *Rolapitant* a potent and long-acting neurokinin-1, or NK-1, receptor antagonist currently in Phase 3 clinical trials for the prevention of chemotherapy induced nausea and vomiting, or CINV.

- *Niraparib* formerly known as MK-4827, an orally active and potent poly (ADP-ribose) polymerase, or PARP, inhibitor that has undergone a Phase 1 clinical trial in cancer patients as a monotherapy. We intend to evaluate niraparib for the treatment of patients with platinum sensitive ovarian cancer in a Phase 3 clinical study, which we expect to commence during 2013. Additionally, we may evaluate niraparib for the treatment of breast, gastric, lung, sarcoma and prostate cancer.

- *TSR-011* an orally available anaplastic lymphoma kinase, or ALK, inhibitor (targeted anti-cancer agent) currently in a Phase 1/2 clinical trial.

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 that are safer and more effective than existing treatments.

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In December 2010, we in-licensed the exclusive worldwide rights to our first product candidate, rolapitant, a long-acting NK-1 receptor antagonist that is being developed for the prevention of CINV. 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 even discontinuation of chemotherapy treatment. Based on our analysis of market data provided by IMS Health Incorporated and patient treatment data collected from approximately 475 cancer treatment sites in the United States by Ipsos Healthcare, a market research firm, we estimate that in 2011 there were approximately 6.6 million treatments administered on the first day of chemotherapy of the current standard of care for the prevention of CINV. The same patient treatment data indicates that in 2011 approximately 60% of cancer patients receiving the current standard of care for the prevention of CINV were treated with highly emetogenic chemotherapy, or HEC, regimens, and approximately 24% of cancer patients receiving the current standard of care for the prevention of CINV were treated with carboplatin, a commonly utilized chemotherapy agent that qualifies as a moderately emetogenic chemotherapy, or MEC, regimen. Current treatment guidelines recommend that all cancer patients receiving HEC 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 on a MEC regimen that utilizes carboplatin with an NK-1 receptor antagonist in addition to the current standard of care for CINV. Based on this data, we estimate that 70% to 80% of cancer patients to whom the current standard of care for the prevention of CINV is administered on the first day of treatment should also receive treatment with an NK-1 receptor antagonist.

The current standard of care for CINV consists of a 5-HT3 receptor antagonist (usually any 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. Optimal 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, aprepitant and its pro-drug fosaprepitant, which are both known by the brand name EMEND and marketed by Merck & Co., Inc., or Merck, are the only commercially available NK-1 receptor antagonists. Based upon Merck s announcement of its financial results for the year ended December 31, 2012, EMEND generated $489 million (unaudited) in global revenues in 2012. We believe there is a significant need for another NK-1 receptor antagonist with improved properties over EMEND.

We believe that rolapitant has several important characteristics, including rapid onset (meaning within approximately three hours of completing chemotherapy treatment) and long duration of action, low potential for drug-drug interactions, and meaningful impact on reducing nausea. We are investigating whether a single dose of rolapitant will, when administered along with the current standard of care for CINV, significantly increase the control of both nausea and vomiting over the 5-day period of risk for cancer patients receiving emetogenic chemotherapy as compared to the current standard of care alone. We presented data from a 454-patient, randomized, placebo controlled Phase 2 clinical trial that evaluated rolapitant in patients at high risk for CINV at the ASCO conference in June 2012, which included data discussed below under Our Product Candidates Rolapitant Neurokinin (NK-1) Receptor Antagonist Rolapitant Clinical Development. We expect to report top line results for our ongoing Phase 3 clinical program for rolapitant during the second half of 2013.

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We in-licensed the exclusive worldwide rights to rolapitant from OPKO Health, Inc., or OPKO. OPKO had acquired certain NK-1 receptor related assets, including rolapitant, in 2010 from Schering-Plough Corporation, or Schering-Plough, as part of a United States Federal Trade Commission, or FTC, requirement to divest certain assets in connection with Schering-Plough s combination with Merck. Prior to its divestiture of rolapitant, Schering-Plough evaluated rolapitant in over 1,000 subjects, including studies for the prevention of post-operative nausea and vomiting, or PONV, and chronic cough, and completed a Phase 2 clinical trial in patients at high risk for CINV.

In May 2012, we in-licensed niraparib from Merck Sharp & Dohme Corp., a subsidiary of Merck, receiving the exclusive worldwide rights for all therapeutic and prophylactic uses in humans and non-exclusive rights to certain Merck know-how.

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 have been linked to certain types of cancers, including breast, ovarian and lung. We intend to evaluate niraparib for the treatment of patients with platinum sensitive ovarian cancer in a Phase 3 clinical study, which we expect to commence during 2013. Additionally, we may evaluate niraparib for the treatment of breast, gastric, lung, sarcoma and prostate cancer.

In March 2011, we in-licensed the exclusive worldwide rights to TSR-011, from Amgen, Inc., or Amgen. TSR-011 is a small molecule inhibitor of ALK, for the treatment of NSCLC and potentially other cancer indications. The ALK 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 proteins, or ALK expression, is also associated with sub-populations of other cancers including lymphoma and neuroblastoma. TSR-011 was specifically designed to be selective for, bind tightly to and inhibit the activity of the ALK protein to result in the death of cancer cells and the shrinking of tumors. In August 2011, the United States Food and Drug Administration, or 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 positive.

We plan to develop TSR-011 for oncology indications, including, but not limited to, the treatment of patients with NSCLC whose tumors express an altered ALK protein. During 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 1/2 dose escalation clinical trial of TSR-011 in cancer patients.

Upon successful development and regulatory approval of any of our product candidates we intend to make them available to cancer patients in North America, Europe and China through our own commercialization efforts. At this time, we believe that if we commercialize our products directly in these geographic areas, we will receive a greater return on our investment than if we license these products to third parties for sale. We believe this because our management team has experience commercializing products in these geographic areas, including an understanding of the relevant sales, marketing and reimbursement frameworks unique to these areas. In addition to developing internal commercial capabilities within these three geographic areas, we intend to establish a network of licensees and distributors for our products in other geographic areas.

We were founded in March 2010 by former executives of MGI PHARMA, which was acquired by Eisai Co., Ltd. in 2008. While at MGI PHARMA, our senior management team collaborated in the clinical development and commercialization of several cancer therapeutics and oncology supportive care drugs, including Aloxi (palonosetron HCl). In marketing rolapitant, we believe we will be able to leverage our senior management team s long-standing experience with key opinion leaders, patient groups, payors, oncology networks, cancer centers, oncologists, oncology nurses, and pharmacists. Given this experience, we believe we can successfully develop and, if approved, commercialize rolapitant, and grow the market for NK-1 receptor antagonists.

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Our senior management team includes our Chief Executive Officer and co-founder, Leon (Lonnie) Moulder, Jr., our President and Chief Scientific Officer and co-founder, Mary Lynne Hedley, Ph.D., and our Executive Vice President and Chief Financial Officer and co-founder, Richard Rodgers. Mr. Moulder has been involved in a number of biopharmaceutical companies, including as vice-chairman of the board of directors and president and chief executive officer of Abraxis BioScience, Inc., vice chairman of Eisai Corporation of North America and president and chief executive officer of MGI PHARMA. Dr. Hedley has served as the executive vice president and chief scientific officer of Abraxis BioScience, Inc., executive vice president of Eisai Corporation of North America and executive vice president and chief scientific officer of MGI PHARMA. Dr. Hedley also co-founded and served as chief executive officer and president of a biotechnology company, ZYCOS, Inc., which was acquired by MGI PHARMA. Mr. Rodgers has previously served as the senior vice president of finance and administration and chief financial officer for Abraxis BioScience, Inc. and senior vice president, controller and chief accounting officer of MGI PHARMA.

On June 28, 2012, we completed our initial public offering through which we 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 29, 2012, and the transaction closed on July 3, 2012. Immediately prior to the closing of the offering, all outstanding shares of our convertible preferred stock converted into 19,410,490 shares of common stock. On July 23, 2012, the underwriters of our initial public offering 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, we received aggregate net proceeds of approximately $78.0 million, which is net of underwriting discounts and commissions and offering expenses.

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 senior management team to identify, acquire and develop promising drug candidates and to commercialize cancer therapeutics and oncology supportive care products that are safer and more effective than existing treatments. This strategy is based upon our belief that it is efficient and effective to focus our efforts on both cancer therapeutics and oncology supportive care because the same treatment centers and healthcare professionals can be covered by a single sales and marketing organization.

The key components of our strategy are:

- ***Rapidly Develop and Successfully Commercialize Rolapitant for the Prevention of CINV.*** During 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. We expect to report top line Phase 3 clinical trial data for rolapitant in the second half of 2013. We believe that our senior management team s experience in the development of oncology products will allow us to rapidly identify and accrue patients in our Phase 3 clinical program for rolapitant, which will include investigative sites in over 25 countries. We believe that we are well positioned to maximize the commercial potential of rolapitant. At MGI PHARMA, in 2003 our senior management team successfully launched and commercialized Aloxi, 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. This success was despite the fact that Aloxi was the fourth 5-HT3 receptor antagonist to market in the United States and competed with products sold by GlaxoSmithKline plc, Roche Holding Ltd. and Sanofi S.A. We intend to leverage the experience that our senior management team gained at MGI PHARMA to establish rolapitant as part of the standard of care for prevention of CINV in patients who, per established treatment

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guidelines, could benefit from an NK-1 receptor antagonist, in addition to the current treatment with a 5-HT3 receptor antagonist.

- ***Continue the clinical development and successfully commercialize niraparib for the treatment of cancers that are susceptible to PARP inhibition.*** 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 was also observed. We intend to evaluate niraparib for the treatment of patients with platinum sensitive ovarian cancer in a Phase 3 clinical study, which we expect to commence during 2013. Additionally, we may evaluate niraparib for the treatment of breast, gastric, lung, sarcoma and prostate cancer.

- ***Advance TSR-011 Through Clinical Trials for the Treatment of NSCLC and Other Tumor Types Associated with ALK Mutations.*** We intend to pursue a development pathway that, if successful, will enable us to reduce the time to receive regulatory approval for this product candidate. During 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 1/2 dose escalation clinical trial of TSR-011 in cancer patients. We are seeking to identify the maximum tolerated dose of TSR-011 and subsequently evaluate TSR-011 in select patient populations, including those with ALK-positive, or ALK+, 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. ALK is a key driver of multiple types of cancers, including subsets of NSCLC, neuroblastoma and lymphoma. In order to maximize the commercial potential of TSR-011, we plan to study TSR-011 in multiple tumor types and treatment settings. We believe that TSR-011 is differentiated from crizotinib, the only marketed ALK inhibitor, as well as other ALK inhibitors in development due to its potency, specificity and activity on specific mutant ALK proteins and by its pharmacological properties, which could attract clinical investigators and patients to our clinical trials.

- ***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 includes 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 have these characteristics. We believe that our ability to execute on this strategy is due to our senior management team s previous experience with in-licensing and acquiring cancer therapeutics and oncology supportive care products on mutually advantageous terms while at MGI PHARMA, developing and obtaining regulatory approval for these compounds and their prior success in 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:

- *Lower risk, later-stage assets that serve as a foundation for building a commercial business.* We will continue to seek to in-license or acquire late-stage product candidates such as rolapitant, with 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 seek to acquire mid-stage product candidates and advance these to final clinical testing, regulatory approval and commercialization. In identifying mid-stage assets, we will focus on assets that we believe demonstrate activity and adequate safety based on early

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clinical testing (i.e., Phase 1 or 2 clinical trials). Assets at this mid-stage generally will have more risk of eventual success than later-stage assets we acquire. 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 seek to 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 seek to 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. Having multiple marketed products can lead to efficiencies of scale in sales and marketing and medical affairs, as well as driving faster market penetration for future products.

- ***Build Global Capabilities to Maximize the Value of Our Product Candidates.*** We currently retain the exclusive worldwide rights to all of our product candidates, rolapitant, niraparib and TSR-011, and we intend to utilize this to develop and commercialize our product candidates globally. We seek to acquire global rights for product candidates we may acquire or in-license in the future.

- *Develop Our Products Globally.* We are developing rolapitant, and intend to develop niraparib, TSR-011 and any future product candidates, on a global basis in order to more rapidly accrue patients and support regulatory submission to health authorities outside of the United States. We believe that this will result in shortened development timelines, earlier submission of marketing authorization and, if the clinical results warrant, regulatory approval earlier than would be expected if we were to run clinical development programs entirely within the United States.

- *Commercial Operations in Key Markets.* We currently plan to commercialize our portfolio of cancer therapeutics and oncology supportive care products by deploying fully integrated sales and marketing organizations in core strategic markets specifically North America, key European markets and China and establishing distributor networks or licensee arrangements in non-core markets around the world. We believe that building our own commercial operations function in our core strategic markets is an important component of our strategy because by doing so we expect to receive a greater return on our product investment than if we license these products to third parties for sale. We believe this is because our management team has experience commercializing products in these core strategic markets, and understands the relevant sales, marketing and reimbursement frameworks. We, therefore, expect that we will be able to generate higher revenue than if we sell exclusively through licensees or distributors.

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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 2012 approximately 1.6 million new cases of cancer would be diagnosed and more than 577,000 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 estimates in a 2012 report that global oncology spending will reach $83 billion to $88 billion by 2016, representing the largest class of drug spending globally. The National Institutes of Health estimates 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. Certain 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. For our 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 cancer therapeutics that can be developed in a targeted patient population enriched for those who will respond to the drug candidate. We expect that the characteristics of these compounds will permit us to design clinical trials that, if successful 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 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 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.

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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 are investigating whether a single dose of rolapitant will, when administered along with the current standard of care for CINV (a 5-HT3 receptor antagonist plus a corticosteroid), significantly increase the control of both nausea and vomiting over the 5-day 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 assets, including rolapitant, in 2010 from Schering-Plough as part of an FTC requirement to divest certain assets in connection with Schering-Plough s combination with Merck. 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.

Chemotherapy Induced Nausea and Vomiting

According to CINV prevention and treatment guidelines developed and published by respected oncology organizations such as NCCN, MASCC, and 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 age and 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 even discontinuation of chemotherapy treatment. Based on our analysis of market data provided by IMS Health Incorporated and patient treatment data collected from approximately 475 cancer treatment sites in the

United States by Ipsos Healthcare, a market research firm, we estimate that in 2011 there were approximately 6.6 million treatments administered on the first day of chemotherapy consisting of the current standard of care for the prevention of CINV (a 5-HT3 receptor antagonist (usually one of ondansetron, granisetron, dolasetron or palonosetron) plus a corticosteroid (usually dexamethasone)). The same patient treatment data indicates that in 2011 approximately 60% of cancer patients receiving the current standard of care for the prevention of CINV were treated with highly emetogenic chemotherapy, or HEC, regimens, and approximately 24% of cancer patients receiving the current standard of

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care for the prevention of CINV were treated with carboplatin, a commonly utilized chemotherapy agent that qualifies as a moderately emetogenic chemotherapy, or MEC, regimen. Current treatment guidelines recommend that all cancer patients receiving HEC 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 on a MEC regimen that utilizes carboplatin with an NK-1 receptor antagonist in addition to the current standard of care for CINV. Based on this data, we estimate that 70% to 80% of cancer patients to whom the current standard of care for the prevention of CINV is administered on the first day of treatment should also receive treatment with an NK-1 receptor antagonist.

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 100, with zero being the least favorable and 100 being the most favorable, patients evaluated different side effects related to cancer and chemotherapy treatment, including CINV 1-6, representing different scenarios of CINV. For all subjects in this study, the most favorable side effects included perfect health and clinical remission. CINV 1 or complete-to-almost complete control of CINV followed, while almost all of the least favorable side effects included nausea and vomiting. This figure shows that patients view CINV as one of the least favorable side effects of chemotherapy treatment.

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.

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There are currently four 5-HT3 receptor antagonists on the market in the US (ondansetron, palonosetron, granisetron and dolasetron) and one additional agent that 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 that is 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 two approved products that target this receptor, aprepitant and its pro-drug fosaprepitant, which are both known by the brand name EMEND and marketed by Merck. 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. EMEND was initially introduced as an oral formulation in 2003. In 2010, Merck introduced a single-dose intravenous, or IV, formulation of EMEND, which we believe currently accounts for approximately 80% of all EMEND usage.

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. Highly emetogenic chemotherapy, or 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. Moderately emetogenic chemotherapy, or 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

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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 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.

While the United States NK-1 market was approximately $270 million in 2011 (represented by oral and IV formulations of EMEND), we believe there is a larger market opportunity for the class. 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 pro-drug, fosaprepitant, the patient treatment market grew over 25% compared to the prior year. We believe the market will expand further based upon the combined sales and marketing activities and enhanced educational initiatives associated with three companies competing within the NK-1 receptor antagonist market. In addition to our activities and initiatives and those of Merck, we expect that Helsinn Healthcare and Eisai Inc. will be introducing a combination NK-1 receptor antagonist and 5-HT3 receptor antagonist product, netupitant plus Aloxi (palonosetron HCl). 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.

The Need for a Second Generation NK-1 Receptor Antagonist

Rolapitant is a highly potent, long acting NK-1 receptor antagonist that may provide control of both nausea and vomiting over the 5-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 clinical activity and safety profile observed in a randomized Phase 2 clinical trial described below, indicate that rolapitant represents a potential advance in the prevention of CINV. Among its advantages are:

- *Long Half Life.* Data from a Phase 1 clinical trial showed that, after oral administration, rolapitant is rapidly absorbed and slowly cleared. The half-life is greater than 120 hours, a finding that suggests that a single dose may be sufficient to block CINV during both the acute (zero to 24 hour) and delayed (from 24 to 120 hours) phases. In comparison, the currently marketed oral NK-1 receptor antagonist therapy requires three doses per chemotherapy cycle.

- *Reduced Risk of 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 antagonist on the market, we believe that administration of rolapitant is unlikely to cause a clinically significant pharmacokinetic interaction with many commonly used drugs metabolized by CYP3A4 and intended for cancer patients undergoing chemotherapy.

- *Rapid Onset of Activity.* In a Phase 2 clinical trial, time to first emesis or use of rescue medication for rolapitant versus the control group showed rapid onset of activity within approximately three hours of completing chemotherapy treatment, which represents a quicker onset of action than has been observed in other agents in its class.

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- *Potential for Reduction in Significant Nausea.* In a Phase 2 clinical trial, the rolapitant 200mg dose group had significantly greater rates of no significant nausea in the overall, acute, and delayed phases than the control group, potentially representing an improvement over current anti-emetic therapies.

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 200 mg 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 comparisons of the rolapitant 200mg group to control group for the overall, acute and delayed phase were 62.5% versus 46.7% (p = 0.032), 87.6% versus 66.7% (p= 0.001) and 63.6% versus 48.9% (p= 0.045), respectively. The comparisons of the rolapitant 100mg group to control group for the overall, acute and delayed phase were 53.8% versus 46.7% (p = 0.315), 74.7% versus 66.7% (p = 0.209) and 58.2% versus 48.9% (p = 0.191), respectively. The comparisons of the rolapitant 25mg group to control group for the overall, acute and delayed phase were 53.4% versus 46.7% (p = 0.342), 70.8% versus 66.7% (p = 0.504) and 54.5% versus 48.9% (p = 0.417), respectively. The comparisons of the rolapitant 10mg group to control group for the overall, acute and delayed phase were 48.4% versus 46.7% (p = 0.791), 66.7% versus 66.7% (p = 0.954) and 50.5% versus 48.9% (p = 0.788), respectively. 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. Rates for no significant nausea for the 200mg rolapitant dose group also demonstrated a superior treatment effect versus the control group in the overall, acute, and delayed phases of CINV. The comparisons of the rolapitant 200mg group to control group for the overall, acute and delayed phases for the secondary endpoint of no significant nausea were 63% versus 42% (p = 0.005), 87% versus 73% (p = 0.029) and 64% versus 48% (p = 0.026), respectively. A validated questionnaire was used to assess patient quality of life and these data also demonstrated statistically significant better quality of life scores for the treatment group versus the control group.

	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

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

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antagonist and dexamethasone achieved statistically significant improvement in preventing CINV than did 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 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. The safety and tolerability of single and repeat doses of rolapitant has been assessed in over 1,000 subjects, including each of the Phase 2 clinical trials completed by Schering-Plough. Although we will continue electrocardiogram, or ECG, monitoring in our Phase 3 clinical trials, no significant QTc prolongation effect (a type of heart rhythm abnormality) was detected in a thorough QT study utilizing doses of up to 800mg of rolapitant. 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 rolapitant. The Phase 3 clinical program consists of approximately 2,400 patients participating in one of three Phase 3 clinical trials. This global program consists of two randomized, double blind and placebo 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. Each of the HEC clinical trials consist of approximately 530 patients and are focused on evaluating rolapitant plus the standard of care compared with control plus the standard of care. The MEC clinical trial consists of approximately 1,350 patients and is focused on evaluating rolapitant plus the standard of care compared with placebo plus the standard of care. In each of the Phase 3 clinical trials the standard of care consists of the 5-HT3 receptor antagonist granisetron in combination with the corticosteroid dexamethasone. Results from each of these clinical trials are anticipated in the second half of 2013. The patients in these clinical trials are being 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 will be based on complete response (defined as no emetic episodes and no rescue medication) in the delayed phase (24 hours to 120 hours). Additional outcome measures include complete response for other time points, the incidence and intensity of nausea, and safety and tolerability.

Intravenous Formulation of Rolapitant

We are developing a single dose rolapitant IV formulation to address what we believe is the market need for this dosage form. We believe this formulation will provide physicians with an additional route of administering rolapitant, while also alleviating certain concerns associated with payor pre-approval, logistics and pharmacy availability that are sometimes associated with oral formulations of drugs utilized by cancer patients. We expect to identify a single dose of the IV formulation that is bioequivalent to the single dose of the oral formulation through a standard bioequivalence clinical study. Following identification of a single dose of the IV formulation that is bioequivalent to the oral formulation, we anticipate conducting a bridging safety study to support regulatory approval. Current plans for the development of the IV formulation are dependent on the success of the oral formulation. We expect that the new drug application, or NDA, that we submit to the FDA for the IV formulation of rolapitant will rely heavily on, and reference data in, the NDA submission for oral rolapitant. We plan to discuss this approach with the FDA prior to conducting a bridging safety study. We expect to launch an IV formulation of rolapitant approximately one year following the launch of the oral formulation.

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

Overview

Niraparib, formerly known as MK-4827, is an orally active and potent poly (ADP-ribose) polymerase, or PARP, inhibitor that has completed a Phase 1 clinical trial in cancer patients as a monotherapy treatment of solid tumors. We intend to evaluate niraparib for the treatment of patients with platinum sensitive ovarian cancer. Additionally, we may evaluate niraparib for the treatment of breast, gastric, lung, sarcoma and prostate cancer.

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 was observed. We intend to continue clinical development of niraparib for the treatment of patients with solid tumors.

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 germ-line BRCA mutations.

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.

During October 2012, we entered into two license agreements with AstraZeneca UK Limited, having aggregate upfront payments of approximately $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.

Background on PARP Inhibitors

As mentioned above, PARP is a family of proteins involved in many functions in a cell. 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.

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Key Characteristics of Niraparib

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

- potent inhibition of PARP and demonstrated tumor growth inhibition in tumor models;
- dose responsive pharmacokinetics in humans;
- demonstrated reduction of PARP activity in human subjects;
- amenable dosage formulation for further clinical and commercial development;
- clinical activity with once daily oral administration as a monotherapy, including a disease control rate of 63% in a selected patient population in a Phase 1 clinical trial that enrolled patients with advanced cancers; 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, 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, or MTD. The second part of the clinical study was a dose expansion study that included patients with platinum resistant ovarian cancer and prostate cancer. The MTD of oral niraparib was established as 300mg daily on a continuous schedule. A mean plasma half-life of 40 hours (range 37 42 hours) and dose-proportional pharmacokinetics were observed. PARP inhibition of 50% of more was observed following administration of niraparib doses equal to or greater than 80 mg 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 partial responses. 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%). Dose limiting toxicities included grade 3

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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 myelosuppression. Overall conclusions from this trial were that niraparib dosing was well tolerated, demonstrated linear pharmacokinetics, provided evidence of target modulation and promising anti-tumor activity in patients with either BRCA mutated or non-BRCA mutated cancers.

In February 2013, we met with the FDA regarding our clinical development plans for niraparib. Based on the results of this meeting, we plan to initiate a registration study for niraparib in patients with platinum sensitive ovarian cancer. We expect this Phase 3 trial to be a randomized, double-blind, multi-center trial that assesses the effectiveness of niraparib compared with placebo to delay progression following a platinum containing chemotherapy regimen. The basis for this pivotal clinical study includes results from Phase 1 and Phase 2 studies with PARP inhibitor compounds, including Phase 1 studies of niraparib, that show response rates of approximately 20% to 40% in patients with ovarian cancer, together with the results of a clinical study in ovarian cancer in which another investigational PARP inhibitor, olaparib, demonstrated a progression free survival benefit when compared to placebo in the maintenance setting. We expect to begin enrolling patients in this trial in 2013.

TSR-011 Anaplastic Lymphoma Kinase (ALK) Inhibitor

Overview

TSR-011 is an orally available ALK inhibitor currently in a Phase 1/2 clinical trial. We are currently testing TSR-011 as a treatment for NSCLC and potentially other cancer indications. 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. In August 2011, the first ALK inhibitor was approved for the treatment of NSCLC.

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 inhibitor product candidate, TSR-011. During 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 1/2 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. 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 and will be used to design clinical trials that will be used to support future regulatory submissions.

In March 2011, we entered into a license agreement with Amgen to obtain exclusive worldwide rights to research, develop, manufacture, market and sell licensed ALK inhibitor compounds and in October 2012 we dosed the first patient in a Phase 1/2 dose escalation clinical trial of TSR-011 in cancer patients.

Non-Small Cell Lung Cancer (NSCLC)

According to the American Cancer Society, over 1.6 million new lung cancer cases are identified worldwide annually, of which over 200,000 of these new lung cancer cases are 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) and Alimta (pemetrexed), 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.

Background on ALK Inhibitors

There is currently one ALK inhibitor that is 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

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driver of certain types of cancers, and ALK. Clinical studies demonstrated impressive efficacy 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 10 months. In addition, there was a Dear Doctor letter issued by the FDA 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 as side effects include severe or fatal pneumonitis, QTc prolongation and visual effects.

While crizotinib is a dual MET/ALK inhibitor, the compounds we in-licensed from Amgen, including TSR-011, were specifically designed based on the crystal structure of ALK to be selective for, and to bind to, ALK (as opposed to dual MET/ALK). 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. Based upon the data set forth below, we believe TSR-011 has the potential to be effective in patients progressing on crizotinib because it has activity against ALK mutations that arise in patients following treatment with crizotinib.

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 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 proteins and expression patterns. During 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 1/2 dose escalation clinical trial of TSR-011 in cancer patients. One goal of the Phase 1 clinical trial will be to determine the maximum tolerated dose of TSR-011 and to define an optimal dosing schedule. Following identification of the maximum tolerated dose of TSR-011 in patients with advanced cancer during the dose escalation phase of this trial, we plan to evaluate TSR-011 in three parallel cohorts of patients in the phase 2 portion: 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. We plan to expand the Phase 1/2 clinical trial of TSR-011 to multiple clinical trial sites in the U.S., Asia and Europe. Information from this study may also be used to optimize future clinical trial designs that will be used to support future regulatory submissions.

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

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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 preferred stock. We are 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, 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 twelve years from the first commercial sale of the product, in each case, on a country-by-country and product-by-product basis. If we elect to develop and commercialize rolapitant in Japan through a third-party licensee we will share equally with OPKO all amounts received by us in connection with such activities under our agreement with such third party, subject to certain exceptions and deductions. OPKO also retains an option to become the exclusive distributor of such products in Latin America, provided that OPKO exercises that option within a defined period following 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 million in June 2012. We are also required to make milestone payments to Merck of up to $57 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.

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License for ALK Program

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 to 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 subsequently, upon dosing of the first patient in our Phase 1/2 clinical trial, made an additional payment of $1.0 million. We are required to make additional milestone payments to Amgen of up to an aggregate of $137 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.

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.

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.

Many of our competitors may have significantly greater financial, technical and human resources than we have. 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.

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Rolapitant Competition

Aprepitant and its pro-drug fosaprepitant, which are both known by the brand name EMEND and marketed by Merck, are currently the only commercially available NK-1 receptor antagonists. Helsinn Healthcare has an active clinical program for an oral combination NK-1 receptor antagonist and 5-HT3 receptor antagonist product (netupitant plus Aloxi (palonosetron HCl)) that would be marketed by Helsinn Healthcare and Eisai, Inc.

Niraparib Competition

We believe the products in development targeting the PARP pathway consist of AbbVie s ABT-888 (veliparib) and AstraZeneca Plc s AZD-2281 (olaparib), each currently in Phase 2 clinical trials, Clovis Oncology, Inc. s CO-338 (rucaparib) and Biomarin Pharmaceutical Inc. s BMN-673, each currently in Phase 1/2 clinical trials, and Eisai, Inc. s E-7016 and Teva Pharmaceutical Industries, Ltd. s CEP-9722, each currently in Phase 1 clinical trials.

TSR-011 Competition

There is currently one ALK inhibitor that is marketed, Xalkori (crizotinib), a dual MET/ALK inhibitor marketed by Pfizer. In addition, we are aware of four oral ALK inhibitors in clinical development. These products are Chugai Pharmaceutical Co., Ltd. s CH5424802 and ARIAD Pharmaceuticals, Inc. s AP26113, currently in Phase 1/2 clinical trials, Astellas Pharma US, Inc. s ASP-3026, currently in Phase 1 clinical trials, and Novartis AG s LDK378, currently in a Phase 2 clinical trial.

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 Market for Cancer Therapeutics and Oncology Supportive Care Products, Our Product Candidates Rolapitant Neurokinin-1 (NK-1) Receptor Antagonist Chemotherapy Induced Nausea and Vomiting (CINV), Our Product Candidates Niraparib Poly (ADP-ribose) Polymerase (PAPR) Inhibitor and Our Product Candidates TSR-011 Anaplastic Lymphoma Kinase (ALK) Inhibitor Background of ALK Inhibitors.

Commercial Operations

We intend to build the commercial infrastructure in North America, Europe and China necessary to effectively support the commercialization of rolapitant, niraparib and TSR-011, 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 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

or TSR-011 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 FDC 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

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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 FDC Act, FDA approval is required before any new drug, including a generic equivalent of a previously approved drug, can be marketed in the United States. As a general matter, the FDA must approve an NDA before a new drug product (other than a generic drug) may be marketed in the United States. NDAs 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 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 if the study was conducted in accordance with GCP and the FDA is able to validate the data.

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

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

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- 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.

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 initiated a Phase 3 clinical program for rolapitant. Our PARP inhibitor, niraparib, has undergone a Phase 1 clinical trial in cancer patients as a monotherapy. We intend to evaluate niraparib for the treatment of patients with platinum sensitive ovarian cancer in a Phase 3 clinical study, which we expect to commence during 2013. Additionally, we may evaluate niraparib for the treatment of breast, gastric, lung, sarcoma and prostate cancer. With regard to our ALK program, we are conducting a Phase 1/2 dose escalation clinical trial of TSR-011 in cancer patients.

NDA Submission and Review. After completing clinical testing of an investigational drug, a sponsor must prepare and submit an NDA 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. When an NDA 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.

Although the FDC Act states that the FDA must review and act on an NDA within 180 days, in practice the process typically takes longer than that. In fact, FDA performance goals generally provide for action on an NDA within 12 months of submission, but even 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 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 8 months from submission.

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

FDA, we anticipate that the FDA will allow us to defer a pediatric assessment of rolapitant until after approval.

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If it concludes that an NDA does not meet the regulatory standards for approval, the FDA typically issues a Complete Response letter communicating the agency s decision not to approve the application and 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 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, 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 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), 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 through, among other things, standards and regulations for direct-to-consumer advertising, 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 for off-label uses that is, uses not approved by the FDA and therefore not described in the drug 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 for off-label use, but may engage in non-promotional, balanced communication regarding off-label use under certain conditions. Failure to comply with applicable FDA requirements and restrictions in this

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area may subject a company to adverse publicity and enforcement action by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products.

Other Requirements. In addition, companies that manufacture or distribute drug products or that hold approved NDAs 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.

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

Once the FDA accepts for filing an ANDA or 505(b)(2) application containing a Paragraph IV certification, the applicant must within 20 days provide notice to the RLD NDA holder and patent owner that the application with patent challenge has been submitted, and provide the factual and legal basis for the applicant s assertion that the patent is invalid or not infringed. If the NDA holder or patent owner file 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 rolapitant, niraparib and TSR-011, if approved, to qualify for five-year NCE exclusivity.

Patent Term Restoration. Under the Hatch-Waxman Act, a portion of the patent term lost during product development and FDA review of an NDA or 505(b)(2) application 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, plus the time between the date of submission of the NDA 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 United States 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 rolapitant, niraparib and TSR-011, if approved, to qualify for patent term restoration.

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 cover the drug are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve an ANDA or 505(b)(2) application owing to regulatory exclusivity or listed patents. 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 intended to treat rare diseases or conditions, which generally are diseases or conditions affecting less than 200,000 individuals annually in the United States. If a sponsor demonstrates that a drug 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 that is approved for the orphan drug designated indication is granted seven years of orphan drug exclusivity. During that period,

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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 regulations in the United States, we will be subject to a variety of 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 approvals 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 much like IND prior to the commencement of clinical trials. In Europe, for example, a clinical trial application, or 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 are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug under European Union regulatory systems, we must submit a marketing authorization application. The application used to file the NDA in the United States is similar to that required in Europe, with the exception of, among other things, country-specific document requirements.

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 and the applicable regulatory requirements and the 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 or criminal penalties or monetary fines, suspension or withdrawal of regulatory approvals, suspension of ongoing clinical studies, refusal to approve pending applications or supplements to applications filed by us, suspension or the imposition of restrictions on operations, product recalls, the refusal to permit the import or export of our products or the seizure or detention of products.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we 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.

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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.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. Government healthcare programs and other third-party payors are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. If these payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit. The United States government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. Adoption of such controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for products such as the product candidates that we are developing and could adversely affect our net revenue and 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 particular, the Affordable Care Act contains provisions that may reduce the profitability of drug products, including, for example, increased rebates for covered outpatient drugs sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries, and annual fees based on pharmaceutical companies share of sales to federal healthcare programs. 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.

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 to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable 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 intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement

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to get a false claim paid. In recent years, several pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly submitting false or misleading pricing information to government health care programs and providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted 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 false claims laws.

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.

Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer s products from reimbursement under government programs, criminal fines and imprisonment.

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.

Patents and Proprietary Rights

We have in-licensed three patent portfolios, one each for rolapitant, niraparib and our ALK program.

Our NK-1 receptor antagonist portfolio, which relates to rolapitant, consists of eight patent families currently being prosecuted or maintained, which include applications and patents directed to compositions of matter, formulations (including oral and IV), solid forms, methods of treatment (including both delayed and acute onset nausea and/or vomiting and timing of administration in relation to chemotherapy) and methods of preparing rolapitant. Rolapitant is a NK-1 receptor antagonist being developed for the prevention of chemotherapy induced nausea and/or vomiting. The portfolio licensed for rolapitant consists of eight issued United States patents and 87 issued non-United States patents across the eight families. In the patent family covering the composition of matter, we have three issued United States patents and 66 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 in and outside the United States. This first family consists of applications pending in and outside the

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United States and a patent issued in Japan. The second family, which claims niraparib, presently comprises 64 issued patents world-wide, including a patent in the United States as well as patents in several European countries. This second family also has applications pending world-wide. The third patent family relating to niraparib is directed to particular salts of niraparib. This third family is being prosecuted in the United States and worldwide, and a patent has issued in 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. No patents are currently issued, but we have submitted 2 patent applications in the United States and 17 patent applications outside of the United States. These are currently at a very early stage of prosecution and a number of the applications have not yet been published. The three families consist of three Patent Cooperation Treaty applications, two of which have been nationalized. A third Patent Cooperation Treaty application is pending but has yet to publish. The national phase deadlines for conversion of the pending PCT applications expires in June 2014.

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. This potential issue is exacerbated by the fact that currently, in the United States, the first to make the claimed invention is entitled to the patent. In March 2013, the United States will transition to a first to file system in which the first inventor to file a patent application will be 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 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.

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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 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 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. 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 pharmaceutical 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 very 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 is developed specifically to treat a rare or uncommon medical treatment. 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 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 for an indication.

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

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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.

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. 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. 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.

A patent application directed to a tablet formulation of rolapitant is allowed in the United States. 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 world-wide. 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 on approximately January 2028.

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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 (including the United States) 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.

The third patent family relating to niraparib discloses and claims particular salts of niraparib. This family includes applications pending in multiple jurisdictions (including the United States) and patents issued in 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)

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 (including the United States). 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 not yet published.

Manufacturing

During 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 may terminate the agreement at the end of each phase of the initial work plan and may terminate any work plan executed after the initial work plan upon at least thirty (30) days prior written notice to Hovione.

Additionally, we currently contract with other 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 one contract manufacturer, or CMO, Hovione, for the production of rolapitant drug substance, and one other CMO for the production of a rolapitant oral drug product for Phase 3 clinical trials. We utilized CMOs for the manufacture of TSR-011 for use in preclinical and Phase 1/2 clinical trials. To meet our needs with respect to further clinical

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development, we plan to contract with additional CMOs for the manufacture of clinical supplies. We do not currently have agreements with any CMOs for the production of niraparib but expect to contract with appropriate CMOs for the production of drug substance and drug product in the near future. Existing inventory for niraparib drug substance and drug product from Merck provides the initial clinical trial material needed for our niraparib clinical program. For each of our product candidates, we may elect to pursue 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.

Employees

As of December 31, 2012, we had 37 full-time employees, 11 of whom hold Ph.D. or M.D. degrees. Of these full time employees, 30 were engaged in development activities and seven were engaged in support administration, including business development and finance. 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 $6.7 million, $12.3 million and $55.2 million during the period March 26, 2010 through December 31, 2010 and the years ended December 31, 2011 and 2012, respectively. We anticipate that a significant portion of our operating expenses will continue to be related to research and development in 2013 as we continue to advance our product candidates through clinical development.

Code of Ethics

Our Board of Directors, or the Board, has adopted a code of business conduct and ethics that applies to our officers, directors and employees. We have posted the text of our code of business conduct and ethics on our website at http://www.tesarobio.com in the Investors section. In addition, subject to NASDAQ regulations, we intend to promptly disclose (1) the nature of any amendment to our code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer, or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of business conduct and ethics that is granted to one of these specified officers, the name of such person who is granted the waiver, and the date of the waiver on our website (or in any other medium required by law or the NASDAQ) in the future.

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 material is electronically filed with, or furnished to, the U.S. Securities and Exchange Commission, or the SEC. These SEC reports 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,

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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 the Notes to Financial Statements included in Part II, Item 8 Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

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 development stage 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, 2012, we reported a net loss of $61.8 million and have a deficit accumulated during the development stage of $87.1 million as of December 31, 2012.

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 and our ability to generate revenues. 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 two of our three 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 and/or approved products on the market.

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

To date, we have not generated any revenues from the three product candidates that we have in-licensed, rolapitant, niraparib and TSR-011. Our ability to generate revenue and become profitable depends upon our ability to successfully commercialize products, including any of our product candidates, or other product candidates that we may in-license or acquire in the future. Even if we are able to successfully achieve regulatory approval for rolapitant, niraparib or TSR-011, 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;
- complete and submit new drug applications, or NDAs, to the United States Food and Drug Administration, or 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 and TSR-011 at acceptable cost levels;
- develop a commercial organization capable of sales, marketing and distribution in our core strategic markets;
- find suitable distribution partners to help us market, sell and distribute our approved products in non-core markets; and
- obtain adequate reimbursement from third-party, including government, payors.

In addition, because of the numerous risks and uncertainties associated with product development, including 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 and interest thereon will be sufficient to fund our projected operating requirements through at least January 1, 2014. However, we expect to require additional capital for the further development and commercialization of our

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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 public or private equity or debt offerings. 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. If we raise additional funds through the issuance of additional debt or equity securities that could result in dilution to our existing stockholders, and/or increased fixed payment obligations. Furthermore, these securities may have rights senior to those of our common stock and could contain covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

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

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

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

- the attainment of milestones and our need to make royalty payments to OPKO Health, Inc., or OPKO, Merck Sharpe & Dohme Corp., a subsidiary of Merck & Co., Inc., or Merck, or Amgen, Inc., or Amgen, or 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 outcome, timing and cost of regulatory approvals by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than those that we currently expect;

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

- the effect of competing technological and market developments;

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

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

If a lack of available capital means that we are unable to expand our operations or otherwise capitalize on our business opportunities, our business, financial condition and results of operations could be materially adversely affected.

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Risks Related to Our Business and Industry

Our future success is dependent primarily on the regulatory approval and commercialization of our product candidates, including rolapitant, which is currently undergoing Phase 3 clinical trials.

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 rolapitant, niraparib and TSR-011, which are currently our only 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 an earlier stage of development. Niraparib has undergone a Phase 1 clinical trial in cancer patients and TSR-011 is still early in clinical 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, niraparib and TSR-011 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 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 related to use restrictions for certain age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for rolapitant in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of niraparib or TSR-011 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 approval for 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, rolapitant, 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. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience, 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 rolapitant and 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 to result in regulatory approval to market in any particular jurisdiction or jurisdictions any of our product candidates. If later-stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates may be adversely impacted.

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Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

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. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our future clinical trial results may not be successful.

We have ongoing clinical trials for rolapitant and TSR-011, and we are planning to initiate a Phase 3 clinical trial for niraparib beginning in 2013. 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 regulatory authorities, to conduct a clinical trial at each site;

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

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

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

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

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

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

- delay or failure in adding new clinical trial sites;

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

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

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

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

- failure to demonstrate a benefit from using a drug;

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

- 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, inability to obtain and maintain patient consents, risk that enrolled subjects will 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 committed activities, we have limited influence over their actual performance.

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

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

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate s clinical development and may vary among jurisdictions. 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 for its proposed indication;
- failure of clinical trials 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 or other submission or to obtain regulatory approval;

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- disapproval of the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; or

- changes in the 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 does not include the labeling claims necessary or 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 a similar strategy, 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 for 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 an 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. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. In one Phase 2 clinical trial for rolapitant, 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. In a Phase 1 clinical trial for niraparib, treatment-related adverse events were generally mild to moderate and included fatigue, anorexia, nausea and myelosuppression (a condition in which bone marrow activity is decreased, resulting in fewer red and white blood cells and platelets). The most common serious adverse events were thrombocytopenia (a decrease in platelets), severe fatigue and pneumonitis (the inflammation of the lungs), all of which were resolved. For both rolapitant and niraparib, additional or more severe side effects may be identified through further clinical trials.

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;

- regulatory authorities may withdraw approvals of such product;

- regulatory authorities may require additional warnings on the label;

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- we may be required to develop a REMS for each 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 by the FDA and comparable foreign regulatory authorities governing the manufacture, 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, regulatory authorities, may require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product s indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. For example, the label ultimately approved for rolapitant, if any, may include restrictions on use.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or cGMP, regulations. 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;

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

- 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, 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. Additionally, 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 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 by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual will share in any fines or settlement funds. Since 2004, these 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 settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded 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.

Our clinical development efforts are currently focused on an oral formulation of rolapitant. However, we are also developing an intravenous, or IV, formulation. 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. 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 compared to the oral formulation. If we do not obtain regulatory approval for the IV formulation, that would negatively affect our revenue and growth prospects.

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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 many companies that currently have extensive and well-funded sales and marketing operations. Without an internal commercial organization or the support of a third party 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 many 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 another country, 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 product candidates, rolapitant, niraparib and TSR-011, and 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 product candidates. If rolapitant is successfully commercialized, we expect it to compete with EMEND, an NK-1 receptor antagonist marketed by Merck. Additionally, we are aware that Helsinn Healthcare has an active clinical program for the development of an oral combination NK-1 receptor antagonist and 5-HT3 receptor antagonist (netupitant plus Aloxi (palonosetron HCI) that will be marketed by Helsinn Healthcare and Eisai, Inc. and with which rolapitant would compete. 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 AstraZeneca Plc s AZD-2281 (olaparib), 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. 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. We are also

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aware of at least four oral ALK inhibitors in clinical development with which TSR-011 could compete if they are approved in the same market: Chugai Pharmaceutical Co., Ltd. s CH5424802 and ARIAD Pharmaceuticals, Inc. s AP26113, currently in Phase 1/2 clinical trials, Astellas Pharma US, Inc. s ASP-3026, currently in Phase 1 clinical trials, and Novartis AG s LDK378, currently in a Phase 2 clinical trial. 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. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Our 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.

More established companies 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 products vary widely from country to country. In the United States, recently passed legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or 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.

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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 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.

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, manufacture, sale and distribution. 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.

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 some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that 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 the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician administered drugs. In recent years, Congress has considered further reductions in Medicare reimbursements for drugs administered by physicians. The Centers for Medicare and Medicaid Services, the agency that runs the Medicare program, 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 the Medicare Modernization Act and 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, President Obama signed into law the Affordable Care Act, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries,

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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 to include the utilization of Medicaid managed care organizations, effective upon enactment, March 23, 2010; increased the minimum rebate due for innovator drugs from 15.1% of average manufacturer price (AMP) to 23.1% of AMP, effective the first quarter of 2010; 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, effective the fourth quarter of 2010. Further, the new law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. 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. Although it is too early to determine the effect of the Affordable Care Act, it appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, 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. Most recently, on August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, creates the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. The American Taxpayer Relief Act of 2012 delayed implementation of these reductions by two months, and if Congress does not act to prevent these cuts, they will take effect on April 1, 2013. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the 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 inhibitor product. These agreements 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.

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.

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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, including because we are focusing on a specific area of care and we may be unable to identify product candidates that we believe are an appropriate strategic fit for our company.

The in-licensing and acquisition of product candidates is a competitive area, and a number of more established companies are also pursuing strategies to in-license or acquire product candidates that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash 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 make 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 to 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

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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 decrease 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:

- 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 United States 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, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;

- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or HIPAA, imposes criminal and

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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 created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

- the federal physician sunshine requirements under the Affordable Care Act requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; 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, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures.

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 we have established, 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 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.

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

As of December 31, 2012, we had 37 full-time employees. As our development and commercialization plans and strategies develop, or as a result of any in-licenses or acquisitions, 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 a 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 pharmaceutical 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 executive officers and to attract, retain and motivate qualified personnel.

We are highly dependent on Leon O. Moulder, Jr., our Chief Executive Officer, Mary Lynne Hedley, our President and Chief Scientific Officer, and Richard J. Rodgers, our Executive Vice President and Chief Financial Officer. Although we have offer letter agreements with Mr. Moulder, Dr. Hedley and Mr. Rodgers, 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.

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

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

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

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

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

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

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

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

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 Abbot 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

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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.

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

Despite the implementation of security measures, our internal computer systems, and those of our 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 liability 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 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 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 the CROs does not relieve us of our regulatory responsibilities. We also rely on third parties to assist in conducting our preclinical studies in accordance with Good Laboratory Practices, or GLP, and the Animal Welfare Act requirements. We and our CROs are required to comply with current GCP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or the EEA, and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials 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.

Our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going clinical, nonclinical and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements 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.

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Because we have relied on third parties, 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. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar 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 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 terminate, 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 a rolapitant oral drug product for Phase 3 clinical trials. 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. We utilized CMOs for the manufacture of TSR-011 for use in preclinical and Phase 1/2 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. We do not currently have agreements with any CMOs for the production of niraparib but expect to contract with appropriate CMOs for the production of drug substance and drug product in the near future. Existing inventory for niraparib drug substance and drug product from Merck provides the initial clinical trial material needed for our niraparib clinical program. For each of our product candidates, we may elect to pursue 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

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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 or product, refusal to permit the import or export of products, injunction, or imposing 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 a cost or in 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.

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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.

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, 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, 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 these 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 are typically 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

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first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

Currently, in the United States, assuming the other requirements for patentability are met, the first to make the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. In March 2013, the United States will transition 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 current system or new one, 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.

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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 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 and/or management personnel 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.

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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 $20.26 per share. In addition to the factors discussed in this Risk Factors section and elsewhere in this Annual Report on Form 10-K, these factors include:

- the success of competitive products or technologies;
- regulatory actions with respect to our products or our competitors products;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- results of clinical trials of our product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to in-license or acquire additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;

- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors; and
- general economic, industry and market conditions.

In addition, the stock market in general, and the NASDAQ Global Select Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the 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 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.

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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 69.2% of our voting stock. This group of stockholders has the ability to control us through their ownership position. These stockholders may be able to determine 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.

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 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, but not limited to, 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 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 our annual report on Form 10-K for the year ending December 31, 2013, we will be 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 will need to 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, but not limited to, not being required to comply with the independent registered public accounting firm attestation requirement.

Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting

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knowledge, and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if 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. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begin its Section 404 reviews, 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 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 will be 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 time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. The increased costs will 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 the 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 1, 2013, we have 27,136,329 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, 19,132,835 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 the 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.

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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 15,564,413 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 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 significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell substantial amounts of common stock or securities convertible into or exchangeable for common stock. These future issuances of common stock or common stock-related securities, together with the exercise of outstanding 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 Plan, which became effective in April 2012, is 1,428,571 plus the number of shares of our common stock reserved for issuance under our 2010 Stock Incentive Plan, or the 2010 Plan, as of the effective date of the 2012 Plan (which is an additional 6,857 shares). The number of shares of our common stock reserved for issuance under our 2012 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 Plan following the effective date of the 2012 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. Future option grants and issuances of common stock under our 2012 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

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of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These provisions include:

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

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

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

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

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

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

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not Applicable

ITEM 2. PROPERTIES

Our offices are located at a 23,814 square foot facility in Waltham, Massachusetts used primarily for corporate functions. The agreements for this space expire at various times from March 2013 through March 2015. We believe that our existing facility is sufficient for our needs for the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS

We are not currently party to any material proceedings

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ITEM 4. MINE SAFETY DISCLOSURES

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

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 sales prices for our common stock as reported on the NASDAQ Global Select Market.

Year ended December 31, 2012	HIGH	LOW
Second quarter (beginning June 29, 2012)	$ 14.15	$ 12.82
Third quarter	$ 15.05	$ 11.05
Fourth quarter	$ 20.00	$ 13.83

On February 1, 2013, there were approximately 26 holders of record of our common stock.

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.

Recent Sales of Unregistered Securities

Set forth below is information regarding certain shares of common stock, preferred stock and stock options issued by us within the past three years that were not registered under the Securities Act of 1933, as amended, which we refer to as the Securities Act. Also included is the consideration, if any, received by us for such shares and information relating to the section of the Securities Act, or rule of the SEC, under which exemption from registration was claimed.

(a) Issuances of Capital Stock:

(1) On March 26, 2010, we issued an aggregate of 1,071,426 shares of our common stock to our founders at a price per share of $0.00004 for an aggregate purchase price of $37.50, which, in addition to reflecting a 1 for 3.50 reverse stock split of our common stock in connection with our initial public offering, reflects a 1,000 for 1 stock split of our common stock on May 10, 2010.

(2) On May 10, 2010, we issued an aggregate of 10,000,000 shares of our Series A-1 preferred stock at a price per share of $1.00 for an aggregate purchase price of $10,000,000.

(3) On December 10, 2010, we issued an aggregate of 1,500,000 shares of our Series O preferred stock. The shares were issued as part of the consideration for the exclusive worldwide rights to research, develop, manufacture and sell rolapitant under a licensing agreement between the Company and

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OPKO Health, Inc.

(4) On February 7, 2011, we issued 188,570 shares of our common stock to our named executive officers and an employee pursuant to restricted stock awards.

(5) On February 11, 2011, we issued an aggregate of 10,000,000 shares of our Series A-2 preferred stock at a price per share of $1.00 for an aggregate purchase price of $10,000,000.

(6) On June 6, 2011, we issued an aggregate of 18,390,796 shares of our Series B preferred stock at a price per share of $2.175 for an aggregate purchase price of $39,999,993.

(7) On July 7, 2011, we issued an aggregate of 1,161,523 shares of our Series B preferred stock at a price per share of $2.175 for an aggregate purchase price of $2,526,313.

(8) On March 21, 2012, we issued an aggregate of 26,884,442 shares of our Series B preferred stock at a price per share of $2.175 for an aggregate purchase price of $58,473,678.

(b) Grants of Stock Options:

(1) From September 21, 2010 through May 16, 2012, we granted stock options to purchase an aggregate of 1,844,985 shares of our common stock with exercise prices ranging from $0.04 to $6.62 per share, to certain of our employees and directors in connection with services provided by such parties to us.

We deemed the issuances of the securities described in paragraph (a)(1) above to be exempt from registration under the Securities Act, in reliance on Section 4(2) of the Securities Act, relative to transactions by an issuer not involving a public offering in that the shares were issued to our founders, who are also our executive officers. We deemed the offers, sales and issuances of the securities described in paragraphs (a)(2) and (a)(3) and paragraph (a)(5) through (a)(7) above to be exempt from registration under the Securities Act, in reliance on Section 4(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, relative to transactions by an issuer not involving a public offering.

We deemed the grant of restricted stock awards and stock options described in paragraphs (a)(1), (a)(4) and (b)(1) to be exempt from registration under the Securities Act in reliance on Rule 701 pursuant to the Securities Act as offers and sales of securities under compensatory benefit plans and contracts relating to compensation in compliance with Rule 701. The grant of restricted stock awards described in paragraph (a)(4) was deemed to be exempt from registration under the Securities Act, in reliance on Section 4(2) of the Securities Act relative to transactions by an issuer not involving a public offering in that the shares were issued to our founders, who are also our executive officers. Each of the recipients of securities in any transaction exempt from registration either received or had adequate access, through employment, business or other relationships, to information about us.

All purchasers of securities in transactions exempt from registration pursuant to Regulation D represented to us that they were accredited investors and were acquiring the shares for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration

statement or an available exemption from the registration requirements of the Securities Act.

All of the foregoing securities are deemed restricted securities for purposes of the Securities Act. The book entries representing the issued shares of common stock described above include appropriate notations setting forth that the applicable securities have not been registered and the applicable restrictions on transfer. There were no underwriters employed in connection with any of the transactions set forth above.

Use of Proceeds from Sales of Registered Securities

Our initial public offering of common stock was effected through a Registration Statement on Form S-1

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(File No. 333-180309) that was declared effective by the Securities and Exchange Commission on June 29, 2012, which registered an aggregate of 6,000,000 shares of our common stock. On June 29, 2012, 6,000,000 shares of common stock were sold on our behalf at an initial public offering price of $13.50 per share, for aggregate gross proceeds of $81.0 million, managed by Citigroup and Morgan Stanley. On July 23, 2012, in connection with the exercise by the underwriters of our initial public offering of a portion of the over-allotment option granted to them in connection with the initial public offering, 430,183 additional shares of common stock were sold on our behalf at the initial public offering price of $13.50 per share, for aggregate gross proceeds of approximately $5.8 million.

We paid to the underwriters underwriting discounts and commissions of approximately $6.1 million in connection with the offering. In addition, we incurred expenses of approximately $2.8 million in connection with the offering, which when added to the underwriting discounts and commissions paid by us, amounts to total expenses of approximately $8.9 million. Thus, the net offering proceeds to us, after deducting underwriting discounts and commissions and offering expenses, were approximately $78.0 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

As of December 31, 2012, we had used approximately $23.1 million of the net proceeds from our initial public offering to fund operations, capital expenditures, working capital and other general corporate purposes. The remainder of the proceeds have been invested into money market funds.

ITEM 6. SELECTED FINANCIAL DATA

The following table 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 period from March 26, 2010 (inception) to December 31, 2010, the years ended December 31, 2011 and 2012, the period from March 26, 2010 (inception) to December 31, 2012 and the historical balance sheet data as of December 31, 2011 and 2012 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 balance sheet data presented below as of December 31, 2010, 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, TESARO UK Limited, TESARO Securities Corporation and TESARO Development, Ltd., our wholly owned subsidiaries, were incorporated, respectively. All financial information presented after December 31, 2010 has been consolidated and includes the accounts of our wholly owned subsidiaries. Our historical results are not necessarily indicative of results expected in any future period.

The selected historical financial data presented below should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and our 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 financial statements and the related notes thereto.

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Statement of Operations Data:

	March 26, 2010 (Inception) to December 31, 2010	Years Ended December 31, 2011	2012	The Period from March 26, 2010 (Inception) to December 31, 2012
		(in thousands, except per share amounts)		
Expenses:				
Research and development	$ 46	$ 11,768	$ 47,200	$ 59,014
General and administrative	1,668	3,158	6,715	11,541
Acquired in-process research and development	6,630	500	8,000	15,130
Total expenses	8,344	15,426	61,915	85,685
Loss from operations	(8,344)	(15,426)	(61,915)	(85,685)
Interest income	20	38	152	210
Other income(expense)	(651)	(1,010)		(1,661)
Net loss	$ (8,975)	$ (16,398)	$ (61,763)	$ (87,136)
Net loss per share applicable to common stockholders - basic and diluted	$ (26.65)	$ (31.90)	$ (4.51)	$ (16.64)
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	337	514	13,696	5,237

	2010	As of December 31, 2011	2012
		(in thousands)	
Balance Sheet Data:			
Cash and cash equivalents	$ 2,533	$ 39,825	$ 125,445
Working capital	(748)	38,835	114,902
Total assets	2,715	42,879	127,380
Preferred stock	8,388	64,348	
Common stock and additional paid-in capital		305	202,798
Total stockholders (deficit) equity	(8,975)	(25,068)	115,662

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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., or MGI PHARMA, 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:

- *Rolapitant* a potent and long-acting neurokinin-1, or NK-1, receptor antagonist currently in Phase 3 clinical trials for the prevention of chemotherapy induced nausea and vomiting, or CINV.

- *Niraparib* formerly known as MK-4827, an orally active and potent poly (ADP-ribose) polymerase, or PARP, inhibitor that has undergone a Phase 1 clinical trial in cancer patients as a monotherapy. We intend to evaluate niraparib for the treatment of patients with platinum sensitive ovarian cancer in a Phase 3 clinical study, which we expect to commence during 2013. Additionally, we may evaluate niraparib for the treatment of breast, gastric, lung, sarcoma and prostate cancer.

- TSR-011 an orally available anaplastic lymphoma kinase, or ALK, inhibitor (targeted anti-cancer agent) currently in a Phase 1/2 clinical trial.

Development Stage Operations. 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 and clinical trials of our product candidates. To date, we have not generated any revenues and have financed our operations with net proceeds from private placements of our preferred stock and an initial public offering of our common stock. On June 19, 2012, we effectuated a 1 for 3.50 reverse stock split of our common stock. Our historical share and per share information has been retroactively adjusted to give effect to this reverse stock split.

As of December 31, 2012, we had a deficit accumulated during the development stage of $87.1 million. Our net losses were $61.8 million, $16.4 million and $9.0 million for the year ended December 31, 2012, the year ended December 31, 2011 and for the period from March 26, 2010 (inception) to December 31, 2010, respectively. We expect to incur significant expenses and increasing operating losses for the foreseeable future. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the development and clinical trials of, and seek regulatory approval for, our product candidates. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will seek to fund our operations through public equity or debt financings or 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 expect that research and development expenses will increase as we continue the development of our product candidates and general and administrative costs will increase as we grow and operate as a public company. 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 Health, Inc., or 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 consideration for this license, we paid OPKO $6.0 million upon signing the agreement and issued 1,500,000 shares of our Series O preferred stock. At the time of this transaction, the fair value of our Series O preferred stock was determined to be approximately $0.6 million. We are also required to make 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, 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

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

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 terms of the license agreement, we made an up-front payment to Merck of $7.0 million in June 2012. We are 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, we will pay Merck tiered royalties at percentage rates in the low teens based on worldwide annual net sales, until the later of the expiration of the last patent licensed from Merck covering or claiming niraparib, or the tenth anniversary of the first commercial sale of niraparib, in either case, on a country-by-country basis.

We are responsible for all clinical, regulatory and other activities necessary to develop and commercialize niraparib. At the time of the license transaction, niraparib had completed a Phase 1 clinical trial in cancer patients as a monotherapy. We intend to evaluate niraparib for the treatment of patients with platinum sensitive ovarian cancer in a Phase 3 clinical study, which we expect to commence during 2013. Additionally, we may evaluate niraparib for the treatment of breast, gastric, lung, sarcoma and prostate cancer. None of the assets to which we acquired rights have alternative future uses, nor have they reached a stage of technological feasibility. We have accounted for this transaction as an asset acquisition because we did not acquire any processes or activities in addition to the license. Accordingly, we recorded the entire purchase price of $7.0 million to acquired in-process research and development expense.

ALK Program. 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. Under the terms of the license agreement, we made an up-front payment to Amgen of $0.5 million, and we recently paid to Amgen an additional $1.0 million in connection with the initiation of our Phase 1 clinical trial of our ALK product candidate, TSR-011. We are also required to make additional milestone payments to Amgen of up to an aggregate of $137.0 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 ALK product candidates. At the time of the license transaction, ALK was a preclinical

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compound. We accounted for this transaction as an asset acquisition because we did not acquire any processes or activities in addition to the license. We recorded the entire purchase price to acquired in process research and development expense of $0.5 million. During the fourth quarter of 2012, we announced that our IND application for TSR-011 has become effective and that we have dosed the first patient in a Phase 1/2 clinical study.

Private Placements of Securities and Initial Public Offering. As of December 31, 2012, our principal source of liquidity was cash and cash equivalents, which totaled $125.4 million. Since our inception on March 26, 2010, we have funded our operations primarily through the private placement of our equity securities and an initial public offering of our common stock. As of December 31, 2012, we had received $120.4 million in net proceeds from the issuance of preferred stock. On June 28, 2012, we completed our initial public offering through which we 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 29, 2012, and the transaction closed on July 3, 2012. Immediately prior to the closing of the offering, all outstanding shares of our convertible preferred stock converted into 19,410,490 shares of common stock. On July 23, 2012, the underwriters of our initial public offering 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, we received aggregate net proceeds of approximately $78.0 million, which is net of underwriting discounts and commissions and offering expenses.

Financial Operations Overview

The information reported within our financial statements from March 26, 2010 to December 31, 2010 was based solely on the accounts of TESARO, Inc. Effective December 22, 2011 and November 30, 2012 and December 27, 2012, TESARO UK Limited, TESARO Securities Corporation and TESARO Development, Ltd., our wholly owned subsidiaries, were incorporated, respectively. All financial information presented after December 31, 2010 has been consolidated and includes the accounts of our wholly owned subsidiaries. All intercompany transactions and balances are eliminated in consolidation.

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 and TSR-011, or other products or product candidates that we may in-license or acquire in the future. We expect to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. 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 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;

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• expenses incurred under agreements with contract research organizations, or CROs, and investigative sites that conduct our clinical trials and preclinical studies;

• the cost of acquiring, developing and manufacturing active pharmaceutical ingredients and clinical trial materials;

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

• costs associated with other preclinical activities and regulatory operations.

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

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. We plan to increase our research and development expenses for the foreseeable future. Our costs associated with rolapitant will increase as we continue to enroll our Phase 3 clinical trials and continue the development of both the oral and intravenous formulations. While we have not had significant costs to date associated with niraparib, we will incur increasing costs and expenses associated with the product as it is further developed. We expect costs associated with TSR-011 to increase as we continue clinical development activities for this program.

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 rate 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 identifies research and development expenses and acquired in-process research and development expenses on a program-specific basis for our product candidates in-licensed through December 31, 2012. Personnel-related costs, depreciation and stock-based compensation are not allocated to a program, as they are deployed across multiple projects under development and, as such, are separately classified as personnel and other expenses in the table below (in thousands).

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	Year Ended December 31,		The Period from March 26, 2010 (Inception) to December 31, 2012
	2011	2012	
Rolapitant Expenses			
Acquired in-process research and development	$	$	$ 6,630
Research and development	9,041	36,524	45,579
Rolapitant total	9,041	36,524	52,209
Niraparib Expenses			
Acquired in-process research and development		7,000	7,000
Research and development		679	679
Niraparib total		7,679	7,679
TSR-011 Expenses			
Acquired in-process research and development	500	1,000	1,500
Research and development	688	3,066	3,754
TSR-011 total	1,188	4,066	5,254
Personnel and Other Expenses	2,039	6,931	9,002
Total	**$ 12,268**	**$ 55,200**	**$ 74,144**

General and Administrative Expenses

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

We anticipate that our general and administrative expenses will increase in the future with continued research and development activities, potential commercialization of our product candidates and continued costs of operating as a public company. These increases will likely include increased costs related to the hiring of additional personnel and payments to outside consultants, lawyers and accountants, among other expenses. Additionally, if and when we believe a regulatory approval of the first product candidate appears likely, we anticipate an increase in payroll and expense as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidates.

Other Income and Loss

Other income and expense consists of interest income earned on cash and cash equivalents and expense related to the issuance of certain rights to Series A-1 preferred stock investors to purchase shares of Series A-2 preferred stock, or the Series A-2 Purchase Rights. The Series A-2 Purchase Rights provided for the purchase of preferred stock and were deemed to be legally detachable and separately exercisable, and therefore represented free-standing financial instruments that were accounted for as a liability. We recorded the fair value of the Series A-2 Purchase Rights at the date of issuance of the Series A-1 preferred stock and adjusted the carrying value of such rights to their estimated fair value at each reporting date. The estimated fair value was determined using a valuation model which considers the probability of achieving defined milestones, our cost of capital, the

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estimated period the Series A-2 Purchase Rights would be outstanding, consideration received for the instrument with such rights, the number of shares to be issued to satisfy such rights and at what price and any changes in the fair value of the underlying instrument to such rights. From the date of issuance to December 31, 2010 the estimated change in fair value of the Series A-2 Purchase Rights was $0.7 million. On February 10, 2011, the holders of the Series A-2 Purchase Rights exercised such rights. From January 1, 2011 to February 10, 2011, the estimated change in the fair value of the Series A-2 Purchase Rights resulted in other expense of $1.0 million.

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 expenses and stock-based compensation. 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.

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

Accrued Research and Development Expenses

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

- CROs in connection with clinical studies;
- investigative sites in connection with clinical studies;
- vendors in connection with preclinical development activities; and

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

We base our expenses related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple CROs that conduct and manage clinical studies 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 clinical 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 accrual or prepaid

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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 differs 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 amount actually incurred.

Net Operating Loss Carryforwards

As of December 31, 2012, we have federal net operating loss carryforwards of $69.5 million to offset future federal income taxes. We also have federal research and development tax credit carryforwards of $0.3 million to offset future federal income taxes. The federal net operating loss carryforwards and research and development tax credit carryforwards expire at various times through 2032. Net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities and may 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. At December 31, 2012, we recorded a 100% 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 fully 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.

On January 2, 2013, the President signed into law The American Taxpayer Relief Act of 2012. Under prior law, a taxpayer was entitled to a research tax credit for qualifying amounts paid or incurred on or before December 31, 2011. The 2012 Taxpayer Relief Act extends the research credit for two years to December 31, 2013. The extension of the research credit is retroactive and includes amounts paid or incurred after December 31, 2011. As a result of the retroactive extension, we expect to record a deferred tax asset before valuation allowance of approximately $0.8 million for qualifying amounts incurred in 2012. The deferred tax asset and corresponding valuation allowance will be recorded in the period of enactment, which is the first quarter of 2013.

Stock-Based Compensation

We recognize compensation costs related to stock options and shares of restricted stock granted to employees based on the estimated fair value of the awards on the date of grant, net of estimated forfeitures. Described below is the methodology we have utilized in measuring stock-based compensation expense. Following the consummation of our initial public offering, stock option and restricted stock values are determined based on 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 Accounting Standards Codification Topic 718, *Compensation-Stock Compensation*, which we refer to as ASC 718. Determining the amount of stock-based compensation to be recorded requires us to develop estimates of the fair value of stock-based awards as of their 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. Calculating the fair value of stock-based awards requires that we make highly subjective assumptions. We use the Black-Scholes option pricing model to value our stock option awards. Use of this valuation methodology requires that we make assumptions as to the volatility of our common stock, the expected term of our stock options, the risk free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield. Prior to June 2012, we were a privately-held company with a limited operating history and accordingly we utilize 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, number of

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employees and therapeutic focus. We use the simplified method as prescribed by the Securities and Exchange Commission 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 grant is based on the U.S. Treasury yield curve in effect at the time of grant for instruments with a similar expected life.

The fair value of stock options was estimated at the grant date using the following assumptions:

	The Period from March 26, 2010 (Inception) to December 31, 2010	Year Ended December 31, 2011	2012
Dividend yield			
Volatility	82%	67% - 68%	66% - 71%
Risk-free interest rate	2.06%	1.07% - 2.03%	0.89% - 1.56%
Expected term (years)	6.25	6.25	6.25

Stock-based compensation expense was insignificant for the period March 26, 2010 (inception) through December 31, 2010 and totaled $305,000 for the year ended December 31, 2011, and $1,803,000 for the year ended December 31, 2012. As of December 31, 2012, we had $7.2 million of total unrecognized compensation expense, which is expected to be recognized over a weighted-average remaining vesting period of approximately 3.0 years. We expect the impact of stock compensation to grow in future periods due to the potential increases in the value of our common stock, increased headcount and additional stock option grants.

Under ASC 718, we are required to estimate the level of forfeitures expected to occur and record compensation expense only for those awards that we ultimately expect will vest. Due to the lack of historical forfeiture activity of our plan, we expect to estimate our forfeiture rate based on peer company data with characteristics similar to our company. For the period from March 26, 2010 (inception) through December 31, 2012, we used a forfeiture rate of zero. There have been an insignificant number of forfeitures through December 31, 2012.

Results of Operations

The information reported within our financial statements from March 26, 2010 to December 31, 2010 was based solely on the accounts of TESARO, Inc. Effective December 22, 2011 and November 30, 2012 and December 27, 2012, TESARO UK Limited, TESARO Securities Corporation and TESARO Development, Ltd., our wholly owned subsidiaries, were incorporated, respectively. All financial information presented after December 31, 2010 has been consolidated and includes the accounts of our wholly owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

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Comparison of the Year Ended December 31, 2012 to the Year Ended December 31, 2011

	Years Ended December 31,		Increase/ (Decrease)
	2011	2012	
	(in thousands)		
Expenses:			
Research and development	$ 11,768	$ 47,200	$ 35,432
General and administrative	3,158	6,715	3,557
Acquired in-process research and development	500	8,000	7,500
Total expenses	15,426	61,915	46,489
Loss from operations	(15,426)	(61,915)	(46,489)
Other income (expense), net	(972)	152	1,124
Net loss	$ (16,398)	$ (61,763)	$ (45,365)

Revenues. We did not recognize any revenue for the years ended December 31, 2011 or 2012.

Research and Development Expenses. Research and development expenses were $47.2 million for the year ended December 31, 2012, compared to $11.8 million for the year ended December 31, 2011, an increase of $35.4 million. The increase was primarily due to expenses related to the development of our in-licensed product candidates, rolapitant and TSR-011, as well as increases in the personnel and related costs necessary to support the progress of our clinical development activities. Significant 2012 activities causing the increase in expense included:

- an increase of $27.5 million in costs associated with rolapitant clinical trials and the Phase 3 clinical program, including drug product development, clinical supply manufacturing and distribution;

- an increase of $2.4 million associated with TSR-011 product development and IND enabling studies, which was not acquired until March 2011;

- an increase of $0.7 million in niraparib product research and development activities, which was acquired in May 2012; and

- an increase of $4.8 million primarily for salaries, benefits and other personnel costs to support the growth of our development activities.

General and Administrative Expenses. General and administrative expenses for the year ended December 31, 2012 were $6.7 million compared to $3.2 million for the year ended December 31, 2011, an increase of $3.5 million. The increase was due primarily to an increase of $1.8 million in salaries, benefits and other personnel related costs and $1.7 million in professional and consulting fees and other expenses to support corporate operational activities including certain additional costs associated with public company operations.

Acquired In-Process Research and Development Expenses. We had acquired in-process research and development expenses of $8.0 million for the year ended December 31, 2012, compared to $0.5 million for the year ended December 31, 2011. The increase was due to the difference in up-front acquisition costs and milestone payments associated with our obtaining and maintaining licensing rights for different products during these time periods. We paid $7.0 million in cash and recognized the entire amount as acquired in-process research and development expense to acquire the licensing rights to our niraparib program, and we paid a $1.0 million milestone to Amgen related to our ALK program during the year ended December 31, 2012. We paid $0.5 million which was

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recognized as acquired in-process research and development expense to acquire the licensing rights to our ALK program in the year ended December 31, 2011.

Other Income (expense), Net. Other income (expense), net was $0.2 million for the year ended December 31, 2012, compared to a loss of $(1.0) million for the year ended December 31, 2011, an increase of approximately $1.2 million. The increase was primarily due to the change in value of the Series A-2 Purchase Rights issued in connection with the issuance of 10,000,000 shares of Series A-1 preferred stock on May 10, 2010. The Company recorded the fair value of the Series A-2 Purchase Rights at the date of issuance of the Series A-1 preferred stock and adjusted the carrying value of such rights to their estimated fair value at each reporting date as well as upon settlement. On February 10, 2011, the holders of the Series A-2 Purchase Rights exercised such rights. From January 1, 2011 to February 10, 2011, the estimated increase in fair value of the Series A-2 Purchase Rights was $1.0 million.

Comparison of the Year Ended December 31, 2011 to the Period from March 26, 2010 (Inception) to December 31, 2010:

	Period from March 26, 2010 (inception) to December 31, 2010	Year Ended December 31, 2011 (In thousands)	Increase (Decrease)
Expenses:			
Research and development	$ 46	$ 11,768	$ 11,722
General and administrative	1,668	3,158	1,490
Acquired in-process research and development	6,630	500	(6,130)
Total expenses	8,344	15,426	7,082
Loss from operations	(8,344)	(15,426)	(7,082)
Other income (expense), net	(631)	(972)	(341)
Net loss	$ (8,975)	$ (16,398)	$ (7,423)

Revenues. We did not recognize any revenue for the year ended December 31, 2011 or the period from March 26, 2010 (inception) to December 31, 2010.

Research and Development Expenses. Research and development expenses were $11.8 million for the year ended December 31, 2011, compared to $46,000 for the period from March 26, 2010 (inception) to December 31, 2010, an increase of $11.7 million. The increase was primarily due to the development expenses related to the development of our in-licensed product candidates, rolapitant and TSR-011. Significant 2011 activities causing the increase in expense included:

- an increase of $9.0 million for rolapitant related to the costs for clinical trials and preparations for the Phase 3 clinical program including drug product development, clinical supply manufacturing and distribution;

- an increase of $0.7 million associated with TSR-011 product development and IND enabling studies; and

- an increase of $2.0 million to salaries, benefits and other personnel costs to support the growth in our 2011 development activities.

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General and Administrative Expenses. General and administrative expenses for the year ended December 31, 2011 were $3.2 million compared to $1.7 million for the period from March 26, 2010 (inception) to December 31, 2010, an increase of $1.5 million. The increase was due primarily to an increase of $1.0 million in professional and consulting fees and $0.5 million in personnel related expenses to support corporate operational activities.

Acquired In-Process Research and Development Expenses. Acquired in-process research and development expenses were $0.5 million for the year ended December 31, 2011, compared to $6.6 million for the period from March 26, 2010 (inception) to December 31, 2010, a decrease of approximately $6.1 million. The decrease was primarily due to the difference in up-front acquisition costs associated with the acquisition of licensing rights for our ALK program in March 2011 compared with the acquisition costs for the licensing rights to rolapitant in December 2010. We paid $0.5 million in cash and recognized $0.5 million as acquired in-process research and development expense to acquire the licensing rights to our ALK program for the year ended December 31, 2011. For the period from March 26, 2010 (inception) to December 31, 2010, we paid $6.0 million in cash and issued 1,500,000 shares of our Series O preferred stock to acquire the licensing rights to rolapitant. At the time of the acquisition of the licensing rights to rolapitant, the fair value of our Series O preferred stock was determined to be $0.6 million. As a result, we recognized $6.6 million as acquired in-process research and development expense for the period from March 26, 2010 (inception) to December 31, 2010.

Other Income (Expense), Net. Other income (expense), net was $(1.0) million for the year ended December 31, 2011, compared to $(0.6) million for the period from March 26, 2010 (inception) to December 31, 2010, an increase of approximately $0.4 million. The increase was primarily due to change in value of the Series A-2 Purchase Rights issued in connection with the issuance of 10,000,000 shares of Series A-1 preferred stock on May 10, 2010. The Company recorded the fair value of the Series A-2 Purchase Rights at the date of issuance of the Series A-1 preferred stock and adjusted the carrying value of such rights to their estimated fair value at each reporting date. From the date of issuance to December 31, 2010 the estimated change in fair value of the Series A-2 Purchase Rights was $0.7 million. On February 10, 2011, the holders of the Series A-2 Purchase Rights exercised such rights. From January 1, 2011 to February 10, 2011, the estimated change in fair value of the Series A-2 Purchase Rights was $1.0 million.

Liquidity and Capital Resources

Sources of Liquidity

To date, we have not generated any revenue. As of December 31, 2012, our principal source of liquidity was cash and cash equivalents, which totaled $125.4 million. Since our inception on March 26, 2010, we have funded our operations primarily through the private placement of our equity securities and our initial public offering. On July 3, 2012, we closed our initial public offering through which we sold 6,000,000 shares of common stock at a price of $13.50 per share. On July 23, 2012, the underwriters of our initial public offering 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, we received aggregate net proceeds of approximately $78.0 million, which is net of underwriting discounts and commissions and offering expenses.

Prior to our initial public offering, we had received $120.4 million in net proceeds from the private placement of our preferred stock. This amount includes net proceeds of approximately $58.3 million that we received in March 2012 upon the issuance of 26,884,442 shares of our Series B preferred stock to certain existing investors in connection with the Series B Purchase Agreement.

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Cash Flows

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

	The Period from March 26, 2010 (Inception) to December 31, 2010	Years Ended December 31, 2011	2012
		(in thousands)	
Net cash provided by (used in):			
Operating activities	$ (1,231)	$ (14,141)	$ (42,757)
Investing activities	(6,162)	(698)	(7,965)
Financing activities	9,926	52,131	136,342
Net increase in cash and cash equivalents	2,533	37,292	85,620

Operating Activities. The use of cash in all periods resulted primarily from our net losses adjusted for non-cash charges and favorable changes in components of working capital. The significant increase in cash used in operating activities for the year ended December 31, 2011 compared to the period from March 26, 2010 (inception) to December 31, 2010 is primarily due to an increase in research and development expenses as we continued to develop rolapitant and TSR-011, including an increase in development personnel, increased spending on external research and development costs offset by increases in the balance of accounts payable and accrued expenses. In addition, we commenced operations in May 2010 and, as such, the period ended December 31, 2010 reflects only a partial year of activity. The increase of $28.6 million in cash used in operating activities for the year ended December 31, 2012 compared to the year ended December 31, 2011 was primarily due to an increase in research and development expenses as we continued to develop rolapitant, niraparib and TSR-011, including an increase in development personnel, an increase in spending on external research and development costs offset by a decrease in working capital.

Investing Activities. The cash used in investing activities for the year ended December 31, 2011 and the period from March 26, 2010 (inception) to December 31, 2010 is primarily due to a $0.5 million up front cash payment for the ALK program license and a $6.0 million up front cash payment for the rolapitant license agreement, respectively. The increase of $7.3 million in cash used in investing activities for the year ended December 31, 2012 compared to the year ended December 31, 2011 was due primarily to cash payments made during 2012 of $7.0 million for the niraparib program license and $1.0 million for a milestone due in connection with the ALK program.

Financing Activities. The cash provided by financing activities for the period from March 26, 2010 (inception) to December 31, 2010 is the result of the sale and issuance of 10,000,000 shares of our Series A-1 preferred stock for net proceeds of $9.9 million. The cash provided by financing activities for the year ended December 31, 2011 is the result of the sale and issuance of 10,000,000 shares of our Series A-2 preferred stock for net proceeds of $10.0 million, and the sale and issuance of 19,552,319 shares of our Series B preferred stock for net proceeds of $42.1 million. The increase of $84.2 million in cash provided by financing activities for the year ended December 31, 2012 compared to the year ended December 31, 2011 was due primarily to the aggregate net proceeds of $78.0 million, which is net of underwriting discounts and commissions, from the closing of our July 2012 initial public offering and the related partial exercise by the underwriters of our initial public offering of the over-allotment option granted to them in connection with the initial public offering, as well as net proceeds of $58.3 million from the issuance of 26,884,442 shares of Series B preferred stock in March of 2012. The cash provided by financing

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activities for the year ended December 31, 2011 was the result of the sale and issuance of 10,000,000 shares of our Series A-2 preferred stock for net proceeds of $10.0 million, and the sale and issuance of 19,552,319 shares of our Series B preferred stock for net proceeds of $42.1 million.

Operating Capital Requirements

We do not anticipate commercializing any of our product candidates for several years. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. 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.

We believe that our existing cash and cash equivalents and interest thereon will be sufficient to fund our projected operating requirements through at least January 1, 2014. 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 public or private equity or debt offerings. 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. If we raise additional funds through the issuance of debt or equity securities it could result in dilution to our existing stockholders, increased fixed payment obligations and these securities may have rights senior to those of our common stock and could contain covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors. 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 near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of clinical trials for our product candidates and future product candidates we may in-license, including our Phase 3 clinical trials for rolapitant and niraparib and the further development of TSR-011;

- the attainment of milestones and our need to make milestone and royalty payments to OPKO, Merck or Amgen, 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 outcome, timing and cost of regulatory approvals by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than those that we currently expect;

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

• the effect of competing technological and market developments;

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

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

If a lack of available capital results in an inability 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 at December 31, 2012 (in thousands):

		Minimum Lease Payments			
	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years
Operating lease obligations	$ 1,580	$ 636	$ 944		

Operating and Facility Lease Obligations

The Company leases office space in Waltham, Massachusetts under two non-cancelable operating lease agreements. The term of the original lease for the existing premises commenced December 1, 2011 and expires on March 31, 2013. The term of the second lease, covering both the existing premises as well as additional office space within the same facility, commences April 1, 2013 (for the existing premises) and February 1, 2013 (for the additional office space) and will continue until March 31, 2015. Both lease agreements provide for free rent for the first month.

In addition to base rent, we may also be required to pay a proportionate share of certain of the landlord s annual operating costs above certain base amounts. In connection with our lease agreements, we have delivered to the landlord a security deposit of approximately $0.2 million.

Purchase Commitments

In addition to the amounts set forth in the table above, we have certain obligations under licensing agreements with third parties contingent upon achieving various development, regulatory and commercial milestones. Pursuant to our license agreement with OPKO, we may be required to

pay OPKO up to an aggregate of $30.0 million if certain regulatory approvals and initial commercial sales of rolapitant are made. Further, we are required to pay OPKO up to an aggregate of $85.0 million in commercial milestone payments 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 are required to make milestone payments to Merck of up to $57 million in development and regulatory milestones for the first indication, up to $29.5 million in development and regulatory milestones for each successive indication, and up to $87.5 million in one-time sales milestones based on the achievement of annual sales objectives. Pursuant to our license agreement with Amgen for the development and commercialization of TSR-011, we are also required to pay Amgen an aggregate of up to an additional $137 million if specified clinical development, regulatory, initial commercialization and annual net product sales milestones are achieved. Finally, pursuant to 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.

Other Funding Commitments

As of December 31, 2012, we had several ongoing clinical studies in various clinical trial stages. Our most significant clinical trial expenditures were to clinical research organizations, or CROs. As a result of our cancellation rights, we have not included these CRO contracts in a contractual obligations table.

Technology Licenses

During October 2012, we entered into two license agreements with AstraZeneca UK Limited, having aggregate upfront payments of approximately $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.

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Off-Balance Sheet Arrangements

As of December 31, 2012, we did not have any off-balance sheet arrangements as defined in Regulation S-K, Item 303(a)(4)(ii).

Recently Adopted Accounting Standards

In May 2011, the Financial Accounting Standards Board issued Accounting Standards Update (ASU) No. 2011-04, Fair Value Measurement (Topic 82) Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs (ASU 2011-04). The amendments in this update will ensure that fair value has the same meaning in U.S. GAAP and in International Financial Reporting Standards and that their respective fair value measurement and disclosure requirements are the same. ASU 2011-05 was effective for us in the first quarter of fiscal year 2012. The adoption of this standard has not had a material impact on our financial position or results of operations.

In June 2011, the Financial Accounting Standards Board issued ASU No. 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income (ASU 2011-05), which requires an entity to present total comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. ASU 2011-05 does not change any of the components of comprehensive income, but it eliminates the option to present the components of other comprehensive income as part of the statement of stockholders equity. ASU 2011-05 was effective for us in the first quarter of fiscal year 2012. The adoption of this standard has impacted our financial statement presentation, but has not had a material impact on our financial position or results of operations.

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, 2011 and December 31, 2012, we had cash and cash equivalents of $39.8 million and $125.4 million, respectively, consisting primarily of money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of United States interest rates, particularly because our investments are in short-term securities. Our securities are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

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Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

TESARO, Inc.

(A Development Stage Company)

Consolidated Financial Statements

Period from March 26, 2010 (Inception) to December 31, 2010, the years ended December 31, 2011 and 2012,

and the period from March 26, 2010 (Inception) to December 31, 2012

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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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. (a development stage enterprise) (the Company) as of December 31, 2011 and 2012, and the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders (deficit) equity, and cash flows for the period from March 26, 2010 (inception) to December 31, 2010, the years ended December 31, 2011 and 2012, and for the period from March 26, 2010 (inception) to December 31, 2012. 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, 2011 and 2012, and the consolidated results of its operations and its cash flows for the period from March 26, 2010 (inception) to December 31, 2010, the years ended December 31, 2011 and 2012, and for the period from March 26, 2010 (inception) to December 31, 2012, in conformity with U.S. generally accepted accounting principles.

/s/ ERNST & YOUNG LLP

Boston, Massachusetts
February 20, 2013

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TESARO, Inc.

(A Development Stage Company)

Consolidated Balance Sheets

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

	December 31, 2011	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 39,825	$ 125,445
Other current assets	2,606	1,175
Total current assets	42,431	126,620
Property and equipment, net	118	219
Restricted cash	200	
Other assets	130	541
Total assets	$ 42,879	$ 127,380
Liabilities, convertible preferred stock and stockholders (deficit) equity		
Current liabilities:		
Accounts payable	$ 605	$ 3,170
Accrued expenses	2,980	8,545
Other current liabilities	11	3
Total current liabilities	3,596	11,718
Other non-current liabilities	3	
Commitments and contingencies *(Note 9 and 10)*		
Convertible preferred stock, $0.0001 par value; 67,936,782 shares and no shares authorized at December 31, 2011 and December 31, 2012, respectively; 41,052,319 shares and no shares issued and outstanding at December 31, 2011 and December 31, 2012	64,348	
Stockholders (deficit) equity:		
Preferred stock, $0.0001 par value; no shares and 10,000,000 shares authorized at December 31, 2011 and December 31, 2012, respectively; no shares issued and outstanding at December 31, 2011 and December 31, 2012, respectively		
Common stock, $0.0001 par value; 85,459,770 and 100,000,000 shares authorized at December 31, 2011 and December 31, 2012, respectively; 1,259,996 and 27,136,329 shares issued and outstanding at December 31, 2011 and December 31, 2012, respectively		3
Additional paid-in capital	305	202,795
Deficit accumulated during the development stage	(25,373)	(87,136)
Total stockholders (deficit) equity	(25,068)	115,662

Total liabilities, convertible preferred stock and stockholders (deficit) equity	$ 42,879	$ 127,380

See accompanying notes to financial statements.

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TESARO, Inc.

(A Development Stage Company)

Consolidated Statements of Operations and Comprehensive Loss

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

	The Period from March 26, 2010 (Inception) to December 31, 2010	Years Ended December 31, 2011	2012	The Period from March 26, 2010 (Inception) to December 31, 2012
Expenses:				
Research and development	$ 46	$ 11,768	$ 47,200	$ 59,014
General and administrative	1,668	3,158	6,715	11,541
Acquired in-process research and development	6,630	500	8,000	15,130
Total expenses	8,344	15,426	61,915	85,685
Loss from operations	(8,344)	(15,426)	(61,915)	(85,685)
Interest income	20	38	152	210
Other income(expense)	(651)	(1,010)		(1,661)
Net loss	$ (8,975)	$ (16,398)	$ (61,763)	$ (87,136)
Net loss per share applicable to common stockholders - basic and diluted	$ (26.65)	$ (31.90)	$ (4.51)	$ (16.64)
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	337	514	13,696	5,237
Comprehensive Loss	$ (8,975)	$ (16,398)	$ (61,763)	$ (87,136)

See accompanying notes to financial statements.

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TESARO, Inc.

(A Development Stage Company)

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

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

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total Stockholders (Deficit) Equity
	Shares	Amount	Shares	Amount			
Balance at March 26, 2010 (Inception)		$		$	$	$	$
Issuance of common stock to founders			1,071,426				
Issuance of Series A-1 convertible preferred stock; $1.00 per share, net of offering costs of $74 and investor rights obligation	10,000,000	7,758					
Issuance of Series O convertible preferred stock	1,500,000	630					
Net loss						(8,975)	(8,975)
Balance at December 31, 2010	**11,500,000**	**$ 8,388**	**1,071,426**	**$**	**$**	**$ (8,975)**	**$ (8,975)**
Issuance of Series A-1 convertible preferred stock; $1.00 per share, net of offering costs of $17 and investor rights obligation	10,000,000	13,812					
Issuance of Series B convertible preferred stock; $2.175 per share, net of offering costs of $378	19,552,319	42,148					
Issuance of restricted common stock			188,570				
Stock-based compensation expense					305		305
Net loss						(16,398)	(16,398)
Balance at December 31, 2011	**41,052,319**	**$ 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 to members of Board of Directors in			16,644		253		253

lieu of fees						
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**

See accompanying notes to financial statements.

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TESARO, Inc.

(A Development Stage Company)

Consolidated Statements of Cash Flows

(all amounts in 000 s)

	The Period from March 26, 2010 (Inception) to December 31, 2010	Years Ended December 31, 2011	2012	The Period from March 26, 2010 (Inception) to December 31, 2012
Operating activities				
Net loss	$ (8,975)	$ (16,398)	$ (61,763)	$ (87,136)
Adjustments to reconcile net loss to net cash used in operating activities:				
Acquired in-process research and development	6,630	500	8,000	15,130
Depreciation	7	35	64	106
Increase in fair value of investor rights obligation	651	1,010		1,661
Share based compensation expense		305	1,803	2,108
Changes in operating assets and liabilities:				
Other assets	(27)	(2,709)	1,020	(1,716)
Accounts payable	109	496	2,565	3,170
Accrued expenses	368	2,612	5,565	8,545
Other liabilities	6	8	(11)	3
Net cash used in operating activities	(1,231)	(14,141)	(42,757)	(58,129)
Investing activities				
Acquisition of product candidate licenses and milestone payments	(6,000)	(500)	(8,000)	(14,500)
Restricted cash	(100)	(100)	200	
Purchase of property and equipment	(62)	(98)	(165)	(325)
Net cash used in investing activities	(6,162)	(698)	(7,965)	(14,825)
Financing activities				
Proceeds from initial public offering, net of issuance costs			77,960	77,960
Proceeds from exercise of stock options			33	33
Proceeds from sale of convertible preferred and common stock and related investor rights, net of issuance costs	9,926	52,131	58,349	120,406
Net cash provided by financing activities	9,926	52,131	136,342	198,399
Increase in cash and cash equivalents	2,533	37,292	85,620	125,445
Cash and cash equivalents at beginning of period		2,533	39,825	
Cash and cash equivalents at end of period	$ 2,533	$ 39,825	$ 125,445	$ 125,445

Non-cash investing and financing activities						
Issuance of Series O convertible preferred stock	$	630			$	630
Settlement of investor rights obligation			$	3,829	$	3,829
Conversion of convertible preferred stock to common stock				$ 122,697	$	122,697

See accompanying notes to financial statements.

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TESARO, Inc.

(A Development Stage Company)

Notes to Consolidated Financial Statements

1. Nature of Business

The Company

TESARO, Inc. (the Company or TESARO), is a development stage company that was incorporated in Delaware on March 26, 2010 and commenced operations in May 2010. TESARO is headquartered in Waltham, Massachusetts.

TESARO is an oncology-focused biopharmaceutical company dedicated to improving the lives of cancer patients by identifying, acquiring, developing and commercializing cancer therapeutics and oncology supportive care products in the United States, Europe and other international markets. Since incorporation, primary activities have consisted of acquiring product candidates, advancing development of its 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. The Company currently operates in one segment. The Company has never earned revenue from these activities and, accordingly, the Company is considered to be in the development stage as of December 31, 2012. The Company is subject to a number of risks similar to those of other development stage companies, 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 of its product candidates and further its in-licensing and acquisition activities.

The Company has one business activity, which is the identification, acquisition, development and commercialization of oncology therapeutics and supportive care product candidates, and a single reporting and operating unit structure.

Initial Public Offering

On June 28, 2012, the Company completed 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 29, 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.

Liquidity

The Company has incurred significant operating losses since inception and has relied on its ability to fund

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its operations through private and public equity financings, and management expects operating losses and negative 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 achieving a level of revenues adequate to support the Company s 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 public equity or debt financing or other sources. The Company expects that its existing cash and cash equivalents as of December 31, 2012 will be sufficient to fund its current operating plan through at least January 1, 2014.

Reverse Stock Split

On June 19, 2012, the Company effectuated 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 information reported within the Company s financial statements from March 26, 2010 to December 31, 2010 was based solely on the accounts of TESARO, Inc. Effective December 22, 2011, November 30, 2012 and December 27, 2012, TESARO UK Limited, TESARO Securities Corporation and TESARO Development, Ltd., wholly owned subsidiaries of the Company, were incorporated, respectively. All financial information presented after December 31, 2010 has been consolidated and includes the accounts of the Company and its wholly owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation. The financial statements are prepared in conformity with accounting principles generally accepted in the United States (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 estimates and assumptions that affect the reported amounts of assets, liabilities, expenses, other comprehensive income and related disclosures. On an ongoing basis, management

evaluates its estimates, including estimates related to clinical trial accruals and stock-based compensation expense. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions 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, cash equivalents and restricted cash. The Company maintains its cash and cash equivalent balances in the

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form of money market 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 the investment credit quality. The hierarchy defines three levels of valuation inputs:

Level 1 inputs	Quoted prices in active markets for identical assets or liabilities
Level 2 inputs	Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly
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, 2011 and 2012 and indicates the fair value hierarchy of the valuation inputs utilized to determine such fair value (in thousands).

Description	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
December 31, 2011				
Money market funds	$ 39,337	$ 39,337	$	$
	$ 39,337	$ 39,337	$	$
December 31, 2012				
Money market funds	$ 123,888	$ 123,888	$	$
	$ 123,888	$ 123,888	$	$

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

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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 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 life of the original lease

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 recognized.

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 the assets book value to future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceed their fair value, which is measured based on the projected discounted future net cash flows arising from the assets. No impairment losses have been recorded through December 31, 2012.

Research and Development Expenses

Research and development costs are charged to expense as incurred and include, but are not limited to:

- license fees 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, benefits, travel and stock-based compensation expense;

- expenses incurred under agreements with contract research organizations and investigative sites that conduct clinical trials and preclinical studies;

- the cost of acquiring, developing and manufacturing clinical trial materials;

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

- costs associated with preclinical activities and regulatory operations.

Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to us by our vendors on their actual costs incurred. 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 financial statements as prepaid or accrued research and development.

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Acquired In-Process Research and Development Expense

The Company has acquired the rights to develop and commercialize new product candidates. The up-front payments to acquire a new drug compound, as well as future milestone payments, are immediately expensed as acquired in-process research and development in the period in which they are incurred provided that no processes or activities have been obtained along with the license, the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, no alternative future use exists. Royalties owed on future sales of the products licensed pursuant to the agreements are expensed in the period the related sales 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.

Stock-Based Compensation Expense

Stock-based compensation is recognized as expense for all stock-based awards based on estimated fair values. The Company determines equity-based compensation at the 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. Any changes to the estimated forfeiture rates are accounted for prospectively.

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 for common stock equivalents. The Company s potentially dilutive shares, which include the Preferred Stock, outstanding stock options and unvested restricted stock 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 amounts in the table below were excluded from the calculation of diluted net loss per share, prior to the use of the treasury stock method, due to their anti-dilutive effect (in thousands):

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	The Period from March 26, 2010 (Inception) to December 31, 2010	Year Ended December 31, 2011	2012	The Period from March 26, 2010 (Inception) to December 31, 2012
Preferred stock	3,286	11,729		
Outstanding stock options	14	894	2,134	2,134
Unvested restricted stock	653	641	349	349
	3,953	13,264	2,483	2,483

3. Property and Equipment

Property and equipment and related accumulated depreciation are as follows (in thousands):

	December 31, 2011	2012
Furniture and fixtures	$	$ 31
Computer equipment and software	150	266
Leasehold improvements		18
	150	315
Less accumulated depreciation and amortization	(32)	(96)
	$ 118	$ 219

Total depreciation expense amounted to $7,000, $35,000 and $64,000 for the period from March 26, 2010 (inception) to December 31, 2010, the year ended December 31, 2011 and the year ended December 31, 2012, respectively.

4. Accrued Expenses

Accrued expenses are as follows (in thousands):

	As of December 31, 2011	2012
Research and development	$ 1,995	$ 6,635
Salaries, bonuses and other compensation	688	1,316
Professional services	155	237
Other	142	357
	$ 2,980	$ 8,545

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5. Convertible Preferred Stock and Stockholders Equity

As of December 31, 2012, 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 27,136,329 shares of common stock were issued and outstanding.

Convertible Preferred Stock

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

Prior to the closing of the initial public offering, the Company s Convertible Preferred Stock consisted of the following (in thousands, except share and per share amounts):

	As of December 31,	
	2011	2012
Series A Convertible Preferred Stock, $0.0001 par value: 20,000,000 shares authorized, issued and outstanding at December 31, 2011	$ 21,570	$
Series O Convertible Preferred Stock, $0.0001 par value: 1,500,000 shares authorized, issued and outstanding at December 31, 2011	630	
Series B Convertible Preferred Stock, $0.0001 par value: 46,436,782 shares authorized at December 31, 2011; 19,552,319 shares issued and outstanding at December 31, 2011	42,148	

In connection with the issuance of 10,000,000 shares of Series A-1 Preferred Stock on May 10, 2010, the Company issued certain rights to Series A-1 Preferred Stock investors to purchase shares of Series A-2 Preferred Stock (the Series A-2 Purchase Rights). The Series A-2 Purchase Rights were deemed to be legally detachable and separately exercisable and therefore represent free-standing financial instruments that are accounted for as liabilities. The Company recorded the fair value of the Series A-2 Purchase Rights at the date of issuance of the Series A-1 Preferred Stock and adjusted the carrying value of such rights to their estimated fair value at each reporting date. Increases or decreases in the fair value of the Series A-2 Purchase Rights were recorded as other expense or income in the statement of operations. The estimated fair value was determined using a valuation model that includes various significant unobservable inputs including the probability of achieving defined milestones, the Company s cost of capital, the estimated period the Series A-2 Purchase Rights would be outstanding, consideration received for the instrument with such rights, the number of shares to be issued to satisfy such rights and at what price and any changes in the fair value of the underlying instrument to such rights. At the date of issuance of the Series A-1 Preferred Stock, May 10, 2010, the Series A-2 Purchase Rights were recorded at their fair value of $2.2 million.

In February 2011, the holders of the Series A-2 Purchase Rights exercised such rights. In connection with the closing of the Series A-2 Preferred Stock purchase, the Company issued 10,000,000 shares of Series A-2 Preferred Stock at a purchase price of $1.00 per share, resulting in net proceeds to the Company of $10.0 million. The Series A-2 Purchase Right was also settled in connection with the closing of the Series A-2

Preferred Stock. The Company estimated the fair value of the Series A-2 Purchase Right, resulting in other expense of

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$1.0 million. Upon the closing of the purchase of Series A-1 Preferred Stock, the fair value of the Series A-2 Purchase Right was recorded in additional paid-in capital.

The Series O Junior Preferred Stock (Junior Preferred Stock) was issued on December 10, 2010 in connection with the in-licensing of rolapitant (see Note 10, License Agreements).

In June 2011, the Company entered into the Series B Preferred Stock Purchase Agreement with various investors, as amended in July 2011 and March 2012 (the Series B Purchase Agreement). The Series B Purchase Agreement provided for the issuance of up to $101 million of Series B Preferred Stock, subject to various terms and conditions. On June 6, 2011 and July 7, 2011, the Company sold 18,390,796 shares and 1,161,523 shares, respectively, of Series B Preferred Stock pursuant to the Series B Purchase Agreement at a price of $2.175 per share, resulting in aggregate net proceeds to the Company of $42.1 million. Subject to the terms of the Series B Purchase Agreement, the Company was required to sell, and certain existing investors were required to purchase, up to an additional $58.5 million of Series B Preferred Stock upon the occurrence of, or in connection with, certain milestone events. Pursuant to the March 2012 amendment to the Series B Purchase Agreement, the Company and the existing investors agreed to accelerate the purchase and sale of the remaining shares of Series B Preferred Stock available for issuance under the Series B Purchase Agreement, notwithstanding the original milestones. On March 21, 2012, the Company sold an additional 26,884,442 shares of Series B 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 Preferred Stock and concluded that an investor s right to acquire additional shares of Series B Preferred Stock was not legally detachable and therefore was embedded and not required to be separated from Series B Preferred Stock.

The Company accounts for potentially beneficial conversion features under 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.

Preferred Stock

Our certificate of incorporation authorizes our 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 our board.

Common Stock

On June 28, 2012, the Company completed 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 29, 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.

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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.

6. Stock-Based Compensation

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

	The Period from March 26, 2010 (Inception) to December 31, 2010	Year Ended December 31, 2011	2012	The Period from March 26, 2010 (Inception) to December 31, 2012
Research and development	$	$ 46	$ 544	$ 590
General and administrative		259	1,259	1,518
Total stock-based compensation expense	$	$ 305	$ 1,803	$ 2,108

The Company maintains several equity compensation plans, including the 2012 Omnibus Incentive Plan (the 2012 Incentive Plan), the 2010 Stock Incentive Plan (the 2010 Incentive Plan), and the 2012 Employee Stock Purchase Plan (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 by the Company vest twenty five percent (25%) one year from vesting start date and seventy-five percent (75%) in equal installments over the subsequent thirty-six (36) months (subject to acceleration of vesting in the event of certain change of control transactions) and are exercisable from the date of grant for a period of ten years.

2012 Omnibus Incentive Plan

On April 27, 2012, the stockholders of the Company approved the TESARO, Inc. 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 which 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. 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. As of December 31, 2012, the Company has granted 16,644 unrestricted shares and stock options covering 375,354 shares of common stock, of which 7,856 have been forfeited, under the 2012 Incentive Plan. The exercise price of each option has been equal

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to the closing price of a share of our common stock on the grant date or the fair value as determined by the board of directors on the grant date.

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 357 shares of Common Stock to eligible employees, officers, directors and consultants. On May 10, 2010, in connection with the Company s sale of Series A-1 Preferred Stock, each such share was reclassified for 1,000 shares of Common Stock, or an aggregate of 357,142 shares available under the 2010 Incentive Plan. On June 6, 2011, in connection with the Company s sale of Series B Preferred Stock, the 2010 Incentive Plan was amended to increase the aggregate number of shares of Common Stock available to be issued under the 2010 Incentive Plan to 1,981,130 shares of Common Stock. As of December 31, 2012, a total of 1,785,703 options and 188,570 restricted stock awards have been granted, and 19,016 options have been exercised, under the 2010 Incentive Plan. 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.

Restricted Common Stock

In connection with the Company s formation, the founders purchased an aggregate of 1,071 shares of Company Common Stock at a nominal per share purchase price. On May 10, 2010, in connection with the Company s sale of Series A-1 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 (the Founder Common). The shares of Founder Common were issued subject to restricted stock agreements between the Company and each founder. Under these agreements, the founders shares vest as follows: twenty five percent (25%) of such stock vested effective as of March 26, 2010, and seventy-five percent (75%) of such stock vests in equal installments over the subsequent forty-eight (48) months (subject to acceleration of vesting in the event of certain terminations of employment and in connection with certain change of control transactions).

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 (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. Under these agreements, the recipients shares of Common Stock vest as follows: twenty five percent (25%) of such stock vests effective as of January 6, 2012, and seventy-five percent (75%) of such stock vests in equal installments over the subsequent thirty-six (36) months (subject to acceleration of vesting in the event of certain change of control transactions).

The Company records stock-based compensation expense for the Common Stock subject to repurchase, or restricted Common Stock grants, based on the grant date intrinsic value for employees. For the period from March 26, 2010 (inception) to December 31, 2010 the Company did not recognize any stock-based compensation for restricted Common Stock grants. The Company recorded stock-based compensation expense of approximately $24,000 for each of the years ended December 31, 2011 and 2012 associated with restricted Common Stock grants.

A summary of the Company s restricted stock activity and related information is as follows:

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	Shares	Weighted-average fair value per share
Unvested at December 31, 2011	640,578	$ 0.14
Granted		
Vested	(291,244)	0.16
Forfeited		
Unvested at December 31, 2012	349,334	$ 0.15

The weighted-average grant date fair value of restricted stock granted during the period from March 26, 2010 (inception) to December 31, 2010 and the year ended December 31, 2011 was $0.00 and $0.53 per share, respectively. The total grant date fair value of restricted stock that vested during the period from March 26, 2010 (inception) to December 31, 2010, the year ended December 31, 2011, the year ended December 31, 2012 was $0, $0, and $47,000, respectively. At December 31, 2010, December 31, 2011 and December 31, 2012 there was $0, $75,000 and $51,000 of total unrecognized compensation cost related to restricted stock, respectively. As of December 31, 2012, the Company expects to recognize this cost over a remaining weighted-average period of 2.0 years.

Stock Options

A summary of the Company s stock option activity and related information follows:

	Shares	Weighted-average exercise price per share	Weighted-average remaining contractual term (years)	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2011	893,564	$ 1.31		
Granted	1,267,493	8.44		
Exercised	(19,016)	1.74		
Cancelled	(7,856)	6.62		
Outstanding at December 31, 2012	2,134,185	5.52	9.0	$ 24,444
Vested at December 31, 2012	302,057	1.32	8.6	$ 4,722
Vested and expected to vest at December 31, 2012 (1)	2,134,185	$ 5.52	9.0	$ 24,444

(1) This represents the number of vested options as of December 31, 2012, plus the number of unvested options expected to vest as of December 31, 2012, based on the unvested options at December 31, 2012, adjusted for the estimated forfeiture rate of 0%.

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

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	The Period from March 26, 2010 (Inception) to December 31, 2010	Year Ended December 31, 2011	2012
Dividend yield			
Volatility	82%	67% - 68%	66% - 71%
Risk-free interest rate	2.06%	1.07% - 2.03%	0.89% - 1.56%
Expected term (years)	6.25	6.25	6.25

The Company uses the simplified method as prescribed by the Securities and Exchange Commission 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 to employees. The expected term is applied to the stock option grant group as a whole, as the Company does not expect substantially different exercise or post-vesting termination behavior among its employee 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 life of the stock options. Management assesses expected forfeitures based on the experience of the Company coupled with comparison to data from the representative group of company peers and recognizes compensation costs only for those equity awards expected to vest.

For the period from March 26, 2010 (inception) to December 31, 2010 the Company did not recognize any stock-based compensation for employee stock option grants. The Company recorded stock-based compensation expense of $281,000 for the year ended December 31, 2011, and $1,526,000 for the year ended December 31, 2012, associated with employee stock options. The weighted-average grant date fair value of options granted in the period from March 26, 2010 (inception) to December 31, 2010, the year ended December 31, 2011, and the year ended December 31, 2012 was $0.03, $2.63, and $5.29 per share, respectively. The aggregate intrinsic value of options exercised during the period from March 26, 2010 (inception) to December 31, 2010, the year ended December 31, 2011, the year ended December 31, 2012 was $0, $0, and $0.2 million, respectively. The intrinsic value of a stock option is the amount by which the fair market value of the underlying stock exceeds the exercise price of the common stock option.

At December 31, 2010, December 31, 2011 and December 31, 2012, there was $0, $2.2 million and $7.2 million of total unrecognized compensation cost related to unvested stock options, respectively. As of December 31, 2012, the Company expects to recognize this cost over a remaining weighted-average period of 3.0 years.

In October 2012 and as provided for under the 2012 Incentive Plan, the Company issued 16,644 shares of common stock with an aggregate value of approximately $253,000 to certain non-employee board members who elected to have shares of stock issued to them in lieu of fees owed them for services as members of the Company s board of directors.

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

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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 have been reserved 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. The 2012 ESPP provides for consecutive 6-month offering periods, during which participating employees may elect to have their compensation withheld and applied to the purchase of common stock at the end of each offering period. The purchase price of the common stock will be 85% of the lower of the fair market value of a share of common stock on the first trading date of each offering period or the fair market value of a share of common stock on the last trading day of the offering period and is limited by participant to $25,000 in fair value of common stock per year. The 2012 ESPP will terminate on June 6, 2022, the tenth anniversary of the date of initial adoption of the plan. As of December 31, 2012, the Company had not begun any offering periods under the 2012 ESPP.

7. Income Taxes

The Company accounts for income taxes under FASB Accounting Standards Codification 740 (ASC 740). Deferred income tax assets and liabilities are determined based upon differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse.

For the period from March 26, 2010 (inception) to December 31, 2010, and the years ended December 31, 2011 and 2012, the Company did not have a current or deferred income tax expense or benefit.

As of December 31, 2012 the Company had federal net operating loss carryforwards of approximately $69.5 million and state net operating loss carryforwards of $69.0 million, which are available to reduce future taxable income. The Company also had federal tax credits of $0.3 million, which may be used to offset future tax liabilities. The net operating loss (NOL) and tax credit carryforwards will expire at various dates through 2032. The NOL and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating loss and tax credit 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.

The Company s reserves related to taxes are based on a determination of whether and how much of a tax benefit taken by the Company in its tax filings or positions is more likely than not to be realized following resolution of any potential contingencies present related to the tax benefit. As of December 31, 2012, the Company has recorded $0.1 million of gross unrecognized tax benefits related to research and development credits which if recognized, would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the consolidated balance sheet or statement of operations if the benefit was recognized.

The Company s policy is to recognize both interest and penalties related to unrecognized tax benefits in income tax expense. Due to the 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 Internal Revenue Service, or the IRS, and state tax authorities remains open for all tax years. The Company files income tax returns in the U.S. federal and Massachusetts jurisdictions. There are currently no federal or state audits in process.

On January 2, 2013, the President signed into law The American Taxpayer Relief Act of 2012. Under prior law, a taxpayer was entitled to a research tax credit for qualifying amounts paid or incurred on or before December 31, 2011. The 2012 Taxpayer Relief Act extends the research credit for two years to December 31, 2013. The extension of the research credit is retroactive and includes amounts paid or incurred after December

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31, 2011. As a result of the retroactive extension, the Company expects to record a deferred tax asset before valuation allowance of approximately $0.8 million for those qualifying amounts which were incurred in 2012. The deferred tax asset and corresponding valuation allowance will be recorded in the period of enactment, which is the first quarter of 2013.

The principal components of the Company s deferred tax assets are as follows (in thousands):

	As of December 31,	
	2011	2012
Deferred tax assets:		
Federal net operating loss carryforwards	$ 5,622	$ 23,634
Depreciation and amortization	2,599	5,428
State net operating loss carryforwards	864	3,644
Tax credit carryforwards	295	443
Stock-based compensation	29	357
Other	101	99
Total deferred tax assets	9,510	33,605
Less valuation allowance	(9,510)	(33,605)
Net deferred tax assets	$	$

ASC 740 requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of available evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. After consideration of all the evidence, both positive and negative, the Company has recorded a valuation allowance against its deferred tax assets at December 31, 2011 and 2012, respectively because the Company s management has determined that is it more likely than not that these assets will not be fully realized. The increase in the valuation allowance in 2012 primarily relates to the net loss incurred by the Company.

As of December 31, 2012, the Company had federal and state net operating losses of approximately $0.1 million related to excess tax deductions that have been excluded from the above table. The benefit of these net operating losses will be recognized as an increase in additional paid in capital when it results in a reduction in taxable income

A reconciliation of income tax expense (benefit) at the statutory federal income tax rate and income taxes as reflected in the financial statements is as follows:

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	March 26, 2010 (Inception) to December 31, 2010	Year Ended December 31, 2011	2012
Federal income tax (benefit)/expense at statutory rate	(34.0)%	(34.0)%	(34.0)%
State income tax benefit	(5.3)%	(4.8)%	(5.4)%
Permanent items	2.9%	2.6%	0.4%
Federal research and development credit	0.0%	(1.8)%	0.0%
Change in valuation allowance	36.4%	38.0%	39.0%
Effective income tax rate	0.0%	0.0%	0.0%

8. 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 2012, the Company made aggregate matching contributions of approximately $137,000 to the 401(k) plan.

9. Commitments and Contingencies

The Company leases office space in Waltham, Massachusetts under two non-cancelable operating lease agreements. The term of the original lease for the existing premises commenced December 1, 2011 and expires on March 31, 2013. The term of the second lease, covering both the existing premises as well as additional office space within the same facility, commences April 1, 2013 (for the existing premises) and February 1, 2013 (for the additional office space) and will continue until March 31, 2015. Both lease agreements provide for free rent for the first month. The Company recognizes rental expense on a straight-line basis over the respective lease terms including any free rent periods. Future minimum rental commitments, by fiscal year and in the aggregate, is provided below (in thousands):

	December 31, 2012
2013	$ 636
2014	755
2015	189
Thereafter	
Total minimum lease payments	$ 1,580

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The Company recorded approximately $28,700, $76,800 and $166,100 in rent expense for the period from March 26, 2010 (inception) to December 31, 2010 and the years ended December 31, 2011 and 2012, respectively.

Litigation

The Company may periodically become subject to legal proceedings and claims arising in connection with on-going 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.

10. License Agreements

Rolapitant In-License

In December 2010, the Company entered into a license agreement with OPKO Health, Inc. (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 our Junior Preferred Stock. At the time of the license transaction, the fair value of Junior 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 process or activities were acquired along with the license, the transaction was accounted for as an asset acquisition by recording the entire purchase price to acquired in-process research and development expense of $6.6 million. As of December 31, 2012, the Company has not made any additional milestone payments under this license agreement.

ALK 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

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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 1/2 clinical trial for TSR-011, the Company made an additional milestone payment to Amgen of $1.0 million. The Company is required to make aggregate milestone payments to Amgen of up to an additional $137 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 based on cumulative worldwide net sales. At the time of the license transaction, ALK 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 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, including the $1.0 million milestone payment made during 2012, 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. (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 process or activities 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. As of December 31, 2012, the Company has not made any additional milestone payments under this license agreement.

Technology Licenses

During October 2012, the Company entered into two license agreements with AstraZeneca UK Limited, having aggregate upfront payments of approximately $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.

11. Consolidated Quarterly Financial Data - Unaudited

The following tables provide unaudited consolidated quarterly financial data for the years ended December 31, 2011 and 2012 (in thousands, except per share data):

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	March 31, 2011	June 30, 2011	Sept. 30, 2011	Dec. 31, 2011	March 31, 2012	June 30, 2012	Sept. 30, 2012	Dec. 31, 2012
Expenses:								
Research and development	$ 384	$ 1,462	$ 1,921	$ 8,001(a)	$ 8,150	$ 11,532	$ 11,876	$ 15,642
General and administrative	623	552	893	1,090	1,199	1,685	1,736	2,095
Acquired in-process research and development	500					7,000(b)		1,000
Total expenses	1,507	2,014	2,814	9,091	9,349	20,217	13,612	18,737
Loss from operations	(1,507)	(2,014)	(2,814)	(9,091)	(9,349)	(20,217)	(13,612)	(18,737)
Interest income	4	7	14	13	20	39	53	40
Other income(expense)	(1,010)							
Net loss	$ (2,513)	$ (2,007)	$ (2,800)	$ (9,078)	$ (9,329)	$ (20,178)	$ (13,559)	$ (18,697)
Net loss per share: basic and diluted	$ (5.74)	$ (4.11)	$ (5.20)	$ (15.41)	$ (13.59)	$ (21.31)	$ (0.52)(c)	$ (0.70)
Weighted-average shares: basic and diluted	438	488	539	589	687	947	26,130(c)	26,740

(a) In the quarter ended December 31, 2011, the Company began to incur expenses related to rolapitant Phase 3 clinical trials.

(b) In the quarter ended June 30, 2012, the Company paid a license fee to Merck for niraparib.

(c) In July 2012, the Company completed its initial public offering, which resulted in net proceeds of approximately $78.0 million from the issuance of 6,430,183 shares of common stock, which includes the sale of 430,183 shares under the underwriters over-allotment option. In connection with the initial public offering, all of the outstanding shares of the Company s convertible preferred stock were converted into 19,410,490 shares of common stock.

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

None.

Item 9A. CONTROLS AND PROCEDURES

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

As of December 31, 2012, management, with the participation of our Chief Executive Officer and Chief 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 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 Chief Executive Officer and the Chief 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

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evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2012, the design and operation of our disclosure controls and procedures were effective.

Management s Report on and Changes in Internal Control Over Financial Reporting

This Annual Report on Form 10-K does not include a report of management s assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to the transition period established by rules of the SEC for newly public companies.

Item 9B. OTHER INFORMATION

None.

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 2013 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 2013 Proxy Statement, which we expect to file with the SEC no later than April 30, 2013.

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Executive Officers and Directors

The following table sets forth information about our current directors and executive officers, including their ages, as of December 31, 2012.

Name	Age	Position
Leon O. Moulder, Jr.	55	Chief Executive Officer, Director
Mary Lynne Hedley, Ph.D.	50	President and Chief Scientific Officer, Director
Richard J. Rodgers	46	Executive Vice President, Chief Financial Officer, Secretary and Treasurer
David M. Mott(2)(3)	47	Chairman of the Board of Directors

Lawrence M. Alleva(1)	63	Director
Arnold L. Oronsky, Ph.D.(1)(2)	73	Director
Beth Seidenberg, M.D.(3)	55	Director
Paul Walker(1)	38	Director

(1) Audit Committee member

(2) Governance and Nominating Committee member

(3) Compensation Committee member

Leon (Lonnie) O. Moulder, Jr. has served as Chief Executive Officer and as a member of our board of directors since co-founding the Company in March 2010. From April 2009 to January 2010, Mr. Moulder served as vice chairman of the board of directors and president and chief executive officer of Abraxis BioScience, Inc., a

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biotechnology company, and as president and chief executive officer of its wholly owned operating subsidiary, Abraxis BioScience, LLC, and the Abraxis Oncology division. Before that, Mr. Moulder served as vice chairman of Eisai Corporation of North America, from January 2008 until January 2009, following Eisai Co. Ltd. s acquisition of MGI PHARMA, Inc., a pharmaceutical company, in January 2008. Mr. Moulder served as president and chief executive officer and as member of the board of directors of MGI PHARMA, Inc. from May 2003 through January 2008. Mr. Moulder joined MGI PHARMA, Inc. in September 1999 as executive vice president and was promoted to president and chief operating officer in May 2002. Mr. Moulder earned a bachelor of science degree in pharmacy from Temple University and master of business administration degree from the University of Chicago. Mr. Moulder currently serves as a director of Cubist Pharmaceuticals, Inc. (NASDAQ:CBST), a publicly held biopharmaceutical company, and Trevena, Inc. Our board of directors believes Mr. Moulder s perspective and experience as our co-founder and Chief Executive Officer, as well as his depth of operating and senior management experience in our industry and his experience serving on the boards of directors of public and private companies in the life sciences industry, provides him with the qualifications and skills to serve as a director.

Mary Lynne Hedley, Ph.D. has served as our President and Chief Scientific Officer and as a member of our board of directors since co-founding the Company in March 2010. From July 2009 to February, Dr. Hedley served as executive vice president of operations and chief scientific officer of Abraxis BioScience, Inc., a biotechnology company. Dr. Hedley served as executive vice president of Eisai Corporation of North America from January 2008 until July 2009, following Eisai Co. Ltd. s acquisition of MGI PHARMA, Inc. in January 2008. Dr. Hedley served in various positions at MGI PHARMA, Inc. from 2004 through its acquisition in January 2008, most recently as executive vice president and chief scientific officer. Prior to that, Dr. Hedley co-founded and served as the president and chief executive officer of ZYCOS, Inc., a biotechnology company, which was acquired by MGI PHARMA, Inc. in 2004. Prior to co-founding Zycos, Dr. Hedley completed two consecutive postdoctoral fellowships at Harvard University. Dr. Hedley earned her bachelor of science degree in microbiology from Purdue University and her doctoral degree in Immunology from the University of Texas, Southwestern Medical Center. Our board of directors believes Dr. Hedley s perspective and experience as our co-founder and President, as well as her educational background and operating and management experience in the life sciences industry, provides her with the qualifications and skills to serve as a director.

Richard J. Rodgers has served as our Executive Vice President, Chief Financial Officer, Secretary and Treasurer since co-founding the Company in March 2010. Mr. Rodgers previously served as the senior vice president of finance and administration of Abraxis BioScience, Inc., a biotechnology company, from June 2009 to February 2010 and as its chief financial officer from July 2009 to February 2010. Prior to that, Mr. Rodgers served as senior vice president, controller and chief accounting officer of MGI PHARMA, Inc. from 2004 until it acquisition by Eisai Co. Ltd. in January 2008. Mr. Rodgers has held finance and accounting positions at several private and public companies, including Arthur Anderson & Co. Mr. Rodgers earned his bachelor of science degree in financial accounting from St. Cloud State University and his master of business administration degree in Finance from the University of Minnesota, Carlson School of Business. Mr. Rodgers is a Certified Public Accountant (inactive).

David M. Mott has served on our board of directors since May 2010 and as the Chairman of the board of directors since July 2011. Mr. Mott has served as a general partner of New Enterprise Associates, an investment firm focused on venture capital and growth equity investments, since September 2008, where he leads the healthcare investing practice. From 1992 until 2008, Mr. Mott worked at MedImmune Limited, a biotechnology company and subsidiary of AstraZeneca Plc (NYSE:AZN), and served in numerous roles during his tenure including chief financial officer, president and chief operating officer, and most recently as chief executive officer from October 2000 to July 2008. During that time, Mr. Mott also served as executive vice president of

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AstraZeneca Plc from June 2007 to July 2008 following AstraZeneca Plc s acquisition of MedImmune Limited in June 2007. Prior to joining MedImmune Limited, Mr. Mott was a vice president in the healthcare investment banking group at Smith Barney, Harris Upham & Co. Inc. Mr. Mott received a bachelor of arts degree from Dartmouth College. Mr. Mott also serves as the chairman of the boards of directors for 3-V Biosciences, Inc., Mersana Therapeutics, Inc., and Zyngenia, Inc., and serves on the board of directors of Ardelyx, Inc., Epizyme, Inc., Omthera Pharmaceuticals, Inc. and Prosensa. Our board of directors believes Mr. Mott s experience in the life sciences industry as a senior executive and venture capitalist, as well as his service on the boards of directors of other life sciences companies, provides him with the qualifications and skills to serve as a director.

Lawrence (Larry) M. Alleva was appointed to our board of directors in March 2012. Mr. Alleva is currently retired. Prior to his retirement in June 2010, Mr. Alleva was employed by PricewaterhouseCoopers LLP, or PwC, for 39 years, 28 of which as a partner with the firm. Mr. Alleva served clients primarily in the technology sector, including pharmaceutical and biotechnology companies. Additionally, he served in a variety of office and regional practice leadership roles, most recently as ethics and compliance leader (assurance) for PwC from 2006 until his retirement. Mr. Alleva is a Certified Public Accountant (inactive). Mr. Alleva received a bachelor of science degree in accounting from Ithaca College and attended Columbia University s Executive MBA Program. Mr. Alleva also serves as a director for GlobalLogic, Inc. and Bright Horizons Family Solutions, Inc. Our board of directors believes Mr. Alleva s extensive experience and expertise working with public companies on corporate finance and accounting matters as a Certified Public Accountant (inactive), as well as his experience in a senior leadership role at PwC, provides him with the qualifications and skills to serve as a director.

Arnold L. Oronsky, Ph.D. has served on our board of directors since June 2011. Dr. Oronsky has been a general partner with InterWest Partners, a venture capital firm, since 1994, focusing primarily on life science companies. Dr. Oronsky also serves as a senior lecturer at Johns Hopkins Medical School. Prior to joining InterWest Partners, Dr. Oronsky served as the vice president for discovery research at the Lederle Laboratories division of American Cyanamid Company. Dr. Oronsky holds a Ph.D. in immunology from Columbia University and an A.B. degree from New York University. Dr. Oronsky serves as chairman of the board of directors for Dynavax Technologies (NASDAQ: DVAX), a publicly held biotechnology company, as well as several privately held life science companies. Our board of directors believes Dr. Oronsky s experience in the life sciences industry as a venture capitalist, his educational background and his service on the boards of directors of other public and private life sciences companies, provides him with the qualifications and skills to serve as a director.

Beth Seidenberg, M.D. has served on our board of directors since June 2011. Dr. Seidenberg has been a partner at Kleiner Perkins Caufield & Byers, a venture capital firm, since May 2005, where she has primarily focused on life science investing. Dr. Seidenberg was previously the senior vice president, head of global development and chief medical officer at Amgen, Inc. (NASDAQ: AMGN), a biotechnology company. In addition, Dr. Seidenberg was a senior executive in research and development at Bristol Myers Squibb Company (NYSE: BMY), a biopharmaceutical company, and Merck & Co., Inc. (NYSE: MRK), a healthcare company. Dr. Seidenberg received her bachelor of science degree from Barnard College and her medical degree from the University of Miami School of Medicine and completed her post-graduate training at Johns Hopkins University and the National Institutes of Health. Dr. Seidenberg serves on the board of directors of: Auxogyn, Inc., 3-V Biosciences, Inc., Breathe Technologies, Inc., Epizyme, Inc., iPierian Inc. and Redbrick Health Corporation. Our board of directors believes Dr. Seidenberg s training as a physician, as well as her experience in the life sciences industry as a senior executive and venture capitalist, provides her with the qualifications and skills to serve as a director.

Paul Walker has served on our board of directors since May 2010. Mr. Walker has served as a partner of New Enterprise Associates, an investment firm focused on venture capital and growth equity investments, since

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May 2008, where he has primarily focused on later-stage biotechnology and life sciences investments. From January 2001 to March 2008, Mr. Walker worked at MPM Capital, a life science venture capital firm, as a general partner with the MPM BioEquities Fund. From July 1996 to December 2000, Mr. Walker served as portfolio manager at Franklin Templeton Investments. Mr. Walker received a bachelor of science degree in biochemistry and cell biology from the University of California at San Diego. Mr. Walker is Chartered Financial Analyst. Our board of directors believes Mr. Walker s experience in the life sciences industry as an investor and venture capitalist, as well as his educational background, provides him with the qualifications and skills to serve as a director.

Audit Committee

The board of directors has a standing audit committee. The members of the audit committee are Dr. Oronsky, Mr. Alleva and Mr. Walker. Our board of directors has determined that Mr. Alleva qualifies as an audit committee financial expert as such term is currently defined in Item 407(d)(5) of Regulation S-K. Each member of the audit committee is able to read and understand fundamental financial statements, including our balance sheet, income statement and cash flows statements. The audit committee has adopted a charter that is posted on our website.

Audit Committee Report

THE FOLLOWING REPORT OF THE AUDIT COMMITTEE DOES NOT CONSTITUTE SOLICITING MATERIAL AND SHOULD NOT BE DEEMED FILED OR INCORPORATED BY REFERENCE INTO ANY OTHER FILING BY US UNDER THE SECURITIES ACT OF 1933 OR THE SECURITIES EXCHANGE ACT OF 1934, EXCEPT TO THE EXTENT WE SPECIFICALLY INCORPORATE THIS REPORT.

The audit committee operates under a written charter adopted by the board of directors, which is available in the Investors section of our corporate website, which is www.tesarobio.com. The audit committee reviews the charter and proposes necessary changes to the board on an annual basis.

During the fiscal year ended December 31, 2012, the audit committee fulfilled its duties and responsibilities generally as outlined in its charter. The audit committee has:

- reviewed and discussed with management the audited financial statements for the fiscal year ended December 31, 2012;
- discussed with Ernst & Young, LLP, or Ernst & Young, the independent auditors for fiscal year 2012, the matters required to be discussed by Statement on Auditing Standards No. 61, Communication with Audit Committees, as amended, as adopted by the Public Company Accounting Oversight Board in Rule 3200T; and
- received the written disclosures and the letter from the independent auditors required by applicable requirements of the Public Company Accounting Oversight Board regarding the independent auditors communications with the audit committee concerning independence, and has discussed with the independent auditors their independence.

On the basis of the reviews and discussions referenced above, the audit committee recommended to the board of directors that the audited financial statements be included in TESARO s Annual Report on Form 10-K for the fiscal year ended December 31, 2012 for filing with the Securities and Exchange Commission.

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AUDIT COMMITTEE (FEBRUARY 12, 2013)

Lawrence M. Alleva, Chair
Arnold L. Oronsky, Ph.D.
Paul Walker

Corporate Governance Policies and Procedures

We have adopted several policies to govern the activities of our Company, including a corporate governance policy and a Code of Business Conduct and Ethics.

The corporate governance policy addresses the following topics:

- the duties and responsibilities of each director;
- the composition, responsibilities and operation of the board of directors;
- the establishment and operation of board committees;
- succession planning for our Chief Executive Officer;
- convening executive sessions of independent directors;
- the board of directors interaction with management and third parties; and
- the evaluation of the performance of the board of directors and the Chief Executive Officer.

The Code of Business Conduct and Ethics is designed to promote the highest standards of ethical conduct by our directors, executive officers and employees. The Code of Business Conduct and Ethics requires that our directors, executive officers and employees avoid conflicts of interest, comply with all laws and other legal requirements, conduct business in an honest and ethical manner and otherwise act with integrity and in our best interest. Under the terms of the Code of Business Conduct and Ethics, directors, executive officers and employees are required to report any conduct that they believe in good faith to be an actual or apparent violation of the Code of Business Conduct and Ethics.

Further, we have established procedures to receive, retain and treat complaints regarding accounting, internal accounting controls and auditing matters. These procedures ensure that individuals may submit concerns regarding questionable accounting or auditing matters in a confidential and anonymous manner. The Code of Business Conduct and Ethics also prohibits the Company from retaliating against any director, executive officer or employee who reports actual or apparent violations of the Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics is available on our website. We intend to disclose future amendments to the Code of Business Conduct and Ethics, or any waivers of its requirements, on our website or in filings under the Exchange Act to the extent required by the applicable rules and exchange requirements.

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Item 11. EXECUTIVE COMPENSATION

EXECUTIVE AND DIRECTOR COMPENSATION

Compensation Review

This Compensation Review addresses the principles underlying our policies and decisions with respect to the compensation of our executive officers who are named in the Summary Compensation Table below, or our named executive officers, and material factors relevant to these policies and decisions. It should be read together with the related tables and disclosures that follow. Our named executive officers for the fiscal year ended December 31, 2012 were:

- Leon O. Moulder, Jr., our Chief Executive Officer;
- Mary Lynne Hedley, Ph.D., our President and Chief Scientific Officer; and
- Richard J. Rodgers, our Executive Vice President and Chief Financial Officer.

In reviewing this Compensation Review, please note that we are an emerging growth company and under the JOBS Act are not required to provide a Compensation Discussion and Analysis of the type required by Item 402 of Regulation S-K. This Compensation Review is intended to supplement the SEC-required disclosure, which is included below this section, and it is not a Compensation Discussion and Analysis.

Compensation Philosophy and Objectives

Our primary objectives with respect to compensation of our named executive officers are to retain and motivate them, because we believe they have experience and competencies that are critical to achievement of our business goals. This is consistent with the overall approach of our compensation system generally, which is to attract, retain and motivate employees (including our officers), who have relevant, critical skills and experience, and can make important contributions to the achievement of our business goals. We seek to achieve these objectives by establishing the components of our compensation packages at competitive levels. For our named executive officers, this means implementing annual variable incentive compensation that is tied to specific corporate goals, and by using equity awards that vest over time, in order to align our named executive officers interests with the interest of our stockholders in increasing long-term stockholder value. The Compensation Committee of our Board of Directors, or the Compensation Committee, acting under authority delegated to it by our Board of Directors, makes compensation decisions regarding our named executive officers, other than our Chief Executive Officer. For our Chief Executive Officer, the Compensation Committee makes formal recommendations to the Board of Directors, with our non-management directors making the final compensation decisions for our Chief Executive Officer.

Determination of Compensation. Our named executive officers are also our founders. The framework for each of their respective compensation packages was initially established and memorialized in offer letters in May 2010 when our named executive officers and New Enterprise Associates, or NEA, and its affiliates completed our Series A preferred stock financing. In addition to being our only employees at the time, all of our named executive officers personally invested in the Company as part of the Series A financing. NEA, a sophisticated life sciences investor, determined, on an arm s-length basis in connection with this financing, that the compensation packages for our named executive officers were appropriate. We believe that these arrangements reflected both market standards for venture capital-backed companies with a business plan similar to ours and the experience of our named executive officers.

For 2011, we continued to use the framework for our named executive officers compensation that was established in May 2010. Consistent with this framework, our Compensation Committee and our Board of Directors modestly increased our named executive officers base salaries, adopted new corporate objectives under our short-term incentive, or STI, program, and determined the timing, size and form of equity awards. For 2011 compensation decisions, our Compensation Committee and Board of Directors considered our financial condition and the contributions that the named executive officers had made to our business, relying on its members

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collective industry experience and business judgment. The Compensation Committee also considered information from Mr. Moulder, who as our Chief Executive Officer regularly discussed compensation issues with the Chairman of the Compensation Committee and met with the Compensation Committee to discuss these matters. Mr. Moulder also provided the Compensation Committee and Board of Directors his evaluation of the performance of the named executive officers other than himself.

For 2012, our Compensation Committee and the non-management members of our Board of Directors again used the framework used in prior years for our named executive officers compensation. Consistent with its determinations in 2011, the Compensation Committee and the non-management members of our Board of Directors made adjustments to the base salaries of our executive officers and the corporate objectives under our STI program for 2012.

Components of our Compensation Program

The compensation program for our named executive officers consists of base salary, STI opportunities and equity awards. Our named executive officers are also entitled to certain compensation upon termination of their employment. We believe these different forms of compensation provide appropriate incentives to achieve our business goals within the context of our overall philosophy for compensation.

Base Salary. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive s skill set, experience, roles and responsibilities. Base salary amounts for each named executive officer were initially set in May 2010 at $350,000, $300,000 and $275,000 for Mr. Moulder, Dr. Hedley and Mr. Rodgers, respectively. The Compensation Committee reviewed the base salaries for 2011 and 2012, and determined that an increase was appropriate for each year given the individual performance of each of our named executive officers and our overall performance. For 2012, the Compensation Committee and Board of Directors approved increasing the base salary for each of our named executive officers to $375,000, $350,000 and $300,000 for Mr. Moulder, Dr. Hedley and Mr. Rodgers, respectively. This represented an increase to the base salary for each of our named executive officers of approximately 5%, 14% and 7%, respectively.

Short-term Incentive Payouts.

General. Our STI program is intended to provide a cash incentive to our named executive officers for achieving both company-wide and individual goals approved at the beginning of each year by our Compensation Committee and Board of Directors. We believe that having an annual STI program is a customary practice necessary to retain executives, and that it motivates our executives to achieve the specific goals that are a part of the program. For 2011, the STI program for our named executive officers was based entirely on company-wide goals and did not include individual goals. This decision to use exclusively company-wide goals in 2011 was based in part on our named executive officers having recently founded the company and that the early-stage nature of the business made rewards for personal performance less important than overall company success. For 2012, our STI program was modified to permit us to pay a cash incentive for the achievement of company-wide and individual goals.

Relative Weighting Between Company-wide and Individual Goals. For 2012, the company-wide goals and individual goals for our named executive officers were established by the Compensation Committee and approved by our Board of Directors. The Compensation Committee and the Board of Directors determined that

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for 2012 the STI program would weight company-wide goals and individual goals in accordance with the chart set forth below for each of our named executive officers:

	Weighting of Company-Wide Goals	Weighting of Individual Goals
Leon O. Moulder, Jr., Chief Executive Officer	90%	10%
Mary Lynne Hedley, Ph.D. President and Chief Scientific Officer	90%	10%
Richard J. Rodgers, Executive Vice President, Chief Financial Officer, Treasurer and Secretary	80%	20%

The relative weighting between the company-wide goals and the individual goals reflects our belief that if the primary focus of our named executive officers is the achievement of company-wide goals then we will increase the likelihood of achieving our strategic plan.

Target Payout. The STI Program is structured so that achievement of the company-wide goals and the individual goals at a level of 100% would result in the named executive officer receiving an STI target payment in an amount equal to a specified percentage of his or her base salary. For Mr. Moulder and Dr. Hedley, a 100% achievement under the STI program would result in a target payment equal to 30% of each of their base salaries (or $112,500 for Mr. Moulder, and $105,000 for Dr. Hedley). For Mr. Rodgers, a 100% achievement under the STI program would result in a target payment equal to 25% of his base salary, or $75,000. The STI program for 2012 was also structured so that each named executive officer could achieve between zero and 150% of the target award with respect to the achievement of the company-wide goals. In other words, the maximum payment that Mr. Moulder and Dr. Hedley could receive under the STI program would be 145% of their target award, or $163,125 and $152,250, respectively. Mr. Rodgers could receive up to 140% of his target award under the STI program, or $105,000.

Company-wide Goals. For 2012, the Compensation Committee and the Board of Directors selected five company-wide goals based on our operating plan and long-term strategy. The Compensation Committee and the Board of Directors weighted each of the five company-wide goals equally based on their subjective judgment regarding the importance of each of those goals. If each of the company-wide goals was achieved at the 100% level, then each of the named executive officers would receive 100% of his or her target award under the STI program with respect to the company-wide goals. Likewise, if none of the company-wide goals are achieved then our named executive officers would not receive their target awards under the STI program with respect to the company-wide goals. Put differently, our STI program does not assure our named executive officers of any payment under the STI program. Because the STI program is not based entirely on the achievement of company-wide goals, the achievement of 100% of the company-wide goals only accounts for a portion of the STI program payment for each of our named executive officers. Specifically, achievement of 100% of the company-wide goals would account for 90% of the target payout for Mr. Moulder and Dr. Hedley, and 80% of the target payout for Mr. Rodgers.

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For 2012, the five company-wide goals related to (1) the enrollment for the rolapitant oral Phase 3 clinical trial, (2) the advancement of the rolapitant *intravenous* development program, (3) the status of the clinical development program of TSR-011, our novel ALK inhibitor, (4) the expansion of our product pipeline, and (5) completing activities for our initial public offering. As mentioned above, the Compensation Committee and the Board of Directors agreed that each of our company-wide goals should be equally weighted, i.e., assigned a value of 20% of the company-wide goals portion of the STI program. Achievement of our target goals involved future performance and, therefore, was subject to uncertainty at the time the goals were set. The Compensation Committee believes it established target goals that were achievable with an appropriate amount of dedication and hard work and, therefore, it was more likely than not that each executive officer would earn a payment under the STI program, but not necessarily the target award under the STI program, which is consistent with our compensation philosophy. However, our Compensation Committee believes that at the time the objectives were set, there would be a substantial degree of difficulty in achieving the objectives at the target 100% level and a much greater degree of difficulty in achieving them at the stretch 150% level.

In early 2013, our Compensation Committee reviewed our progress on these company-wide goals for 2012 and concluded that the Company-wide goals had been achieved at a 90% percent level. For Mr. Moulder and Dr. Hedley, this means that they have earned 90% of the company-wide goals portion of their STI target payment, or 81% of the total STI target payment or approximately 24% of their base salaries. For Mr. Rodgers, this means that he has earned 72% of the total STI target payment or approximately 18% of his base salary.

Individual Goals. Also at the beginning of 2012, the Compensation Committee established individual goals for each of our named executive officers. The rationale behind assigning individual goals to each of our named executive officers is that each of them is responsible for activities within their respective job functions that support achieving company-wide goals and the Company s strategic plan. We believe that it is important that these individual goals be achieved and incentivized. Nevertheless, as demonstrated by the relative weighting between the company-wide goals and the individual goals for each of our named executive officers, we believe that individual goals are secondary to the company-wide goals.

We assigned each of our named executive officers a total of three individual goals. Each of those individual goals was then weighted to reflect the decision of our Compensation Committee or our Board of Directors as to the relative importance of each goal to the officer s job function and the contribution that successfully performing the goal would make to our company-wide goals and strategic plan. If the officer accomplished all of his or her individual goals at his or her expected performance level, then the officer would receive 100% of the target STI payment in respect of the officer s individual goals. For Mr. Moulder and Dr. Hedley, this would equate to 10% of each of their STI target payment , or three percent of their base salaries. For Mr. Rodgers, performing his individual goals at target would equate to an STI payment to Mr. Rodgers equal to 20% of his STI target payment, or five percent of his base salary.

Our Compensation Committee determines the level of achievement for Dr. Hedley and Mr. Rodgers of their individual goals. This determination is made following consultation with Mr. Moulder and is based partially on his recommendation. The degree to which Mr. Moulder has achieved his individual goals is determined by our Board of Directors and is based partially on the recommendation of the Compensation Committee.

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The following paragraphs describe for each of our named executive officers their individual goals, the relative weighting of each of those individual goals, the level of achievement by the executive officer for each individual goal, and the percentage STI payment arising from the achievement of the individual goal. We note that each named executive officer had as an individual goal the accomplishment of the Company s initial public offering, or IPO. We also note that this was a company-wide goal. As an individual goal, the IPO was intended as a reference to each named executive officer s functional role for the IPO, as opposed to the company-wide effort of the IPO generally. The completion of our IPO represented 25%, 25% and 35%, respectively, of the individual goal portion of the STI program for Mr. Moulder, Dr. Hedley and Mr. Rodgers.

Leon O. Moulder, Jr., Chief Executive Officer. In addition to the goal related to our IPO referred to above, Mr. Moulder was assigned goals related to governance of and leadership for our Board of Directors and providing company-wide leadership through the development of our management team and creating organizational and operational structure. The goal related to governance and leadership for our Board of Directors was assigned a weighting of 25% and the goal related to Company leadership was assigned a weighting of 50%, in each case, for the individual goal portion of the STI program. Our Compensation Committee recommended and our Board of Directors approved Mr. Moulder s performance of his individual goals at the 82.5% level. Accordingly, for 2012, Mr. Moulder earned 82.5% of the 10% portion of the STI target payment that was attributed to the achievement of his individual performance goals, or approximately 2.5% of his base salary.

Mary Lynne Hedley, Ph.D., President and Chief Scientific Officer. Dr. Hedley was assigned goals related to (1) the development and implementation of our product candidate program strategy and (2) developing and implementing portions of our corporate organizational structure, formalizing and providing structure and accountability for the operations of the medical and scientific functions of the Company and contributing to the development of leadership and management of the Company. These two goals were assigned a weighting of 25% and 50% respectively, for the personal performance portion of Dr. Hedley s STI program payment. As referred to above, 25% of Dr. Hedley s personal performance portion of the STI program was attributed to IPO activities. Based on the achievement of her individual goals, the Compensation Committee determined that Dr. Hedley performed her individual goals at the 85% level. Accordingly, for 2012, Dr. Hedley earned 85% of the 10% portion of the STI target payment that was attributed to the achievement of her individual performance goals or approximately 2.6% of her base salary.

Richard J. Rodgers, Executive Vice President, Chief Financial Officer, Treasurer and Corporate Secretary. In addition to his goal related to the IPO, Mr. Rodgers was assigned goals related to (1) hiring experienced and qualified personnel for the Company s financial analysis and accounting function, and (2) scaling the finance and accounting function to support a publicly-traded company following our IPO. Our Compensation Committee determined that Mr. Rodgers performed his individual goals at the 100% level for 2012. Therefore, Mr. Rodgers earned 100% of the 20% portion of the STI target payment that was attributed to the performance of his individual goals or 5% of his base salary.

Overall STI Program Payments for 2012. The following chart sets forth for each of our named executive officers their target STI payment, the percentages of the STI payment attributable to company-wide and individual goals, the level of performance achieved by each named executive officer with respect to both the company-wide and individual goals and then the total STI payment to each named executive officer as a result of his or her

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participation in the STI program for 2012. Where appropriate, we have included this information both as a percentage and as a dollar amount.

Named Executive Officer	Target Award ($)	Target Award (%)	Company-wide Goal Achievement (%)	Company-wide Goal achievement ($)	Individual goal Achievement (%)	Individual goal Achievement ($)	STI Payout (%)	STI Payout ($)
Leon O. Moulder, Jr.	112,500	30%	90%	91,125	82.5%	9,275	89%	100,400
Mary Lynne Hedley, Ph.D.	105,000	30%	90%	85,050	85%	8,950	90%	94,000
Richard J. Rodgers	75,000	25%	90%	54,000	100%	15,000	92%	69,000

Equity Awards. Our use of equity awards is intended to align our named executive officers interests with the interest of our stockholders by providing an incentive to our named executive officers to increase long-term stockholder value. Furthermore, we believe that in the biopharmaceutical industry, equity awards are a primary motivator to retain executives. We have determined the size and frequency of awards based on numerous factors, including the executive s skills and experience, the executive s responsibilities, internal equity and the approach to setting compensation described under Determination of Compensation above.

In February 2011, our Board of Directors, at the recommendation of our Compensation Committee, granted a restricted stock award to each of our named executive officers. The Compensation Committee viewed this award as an annual equity award consistent with the objectives and purposes described in this Compensation Review. The Compensation Committee used restricted stock instead of stock options because the fair market value of our common stock at the time was nominal, which meant that the exercise price of stock options would be immaterial to us and to the executive, and did not outweigh the potential for favorable tax treatment for the award recipients of restricted stock.

In July 2011, in connection with the closing of our Series B financing, the Compensation Committee and Board of Directors granted stock options to each of our named executive officers. This award helped, in part, to counterbalance the proportionate reduction in stock ownership experienced by each of our named executive officers, as our founders, as a result of the size of the Series B financing.

In March 2012, the Compensation Committee and the Board of Directors granted additional stock options to each of our named executive officers. This award was also intended to partially offset the proportionate reduction in stock ownership experienced by our named executive officers, as a result of our Series B investors acquiring additional Series B Preferred Stock. This award was also intended to motivate our named executive officers to increase our long-term shareholder value over the values of our company at the time of our then-anticipated initial public offering. We selected stock options rather than restricted stock for these equity grant because we believe that stock options are better tools for increasing long-term shareholder value than restricted

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stock. We believe restricted stock (and similar equity compensation instruments) are better devices to create an ownership stake in the company. While we believe both goals are important, for the equity grants to our named executive officers in connection with our Series B financing, we believe that stock options better served our goals at that time.

The following table summarizes the stock options awarded to the named executive officers in 2012:

	Options Awarded		Grant Date Fair Value
Leon O. Moulder, Chief Executive Officer	371,428	$	1,585,998
Mary Lynne Hedley, Ph.D., President and Chief Scientific Officer	342,857	$	1,463,999
Richard J. Rodgers, Executive Vice President, Chief Financial Officer, Treasurer and Secretary	121,428	$	518,498

These stock options vest 25% on the one-year anniversary of the grant date and, thereafter, 1/36th of the remaining options vest on each monthly anniversary of the grant date.

Offer Letters

In May 2010, in connection with our Series A preferred stock financing, we entered into offer letters with our named executive officers that reflect the framework for executive compensation discussed above. The offer letters were negotiated between our named executive officers and NEA, and the terms of the letters were an important part of our named executive officers , who are also our founders, willingness to agree to the financing. In June 2012, these agreements were amended and restated in anticipation of our initial public offering. These amended agreements were designed to be a part of a competitive compensation package for a publicly-traded company and to keep our named executive officers focused on our business goals and objectives.

Payments on Termination

Pursuant to their offer letters, each of our named executive officers is entitled to specified benefits in the event of the termination of their employment under specified circumstances, including termination following a change of control of our Company. The terms of these arrangements are more fully described below under Offer Letter Agreements and Potential Payments Upon a Termination or Change in Control. We believe these protections are appropriate for the founders of a development-stage biopharmaceutical company. We believe that providing benefits in the event of a change of control of our Company allows our named executive officers to focus their attention on building our business rather than on the personal implications of a transaction.

Compensation Consultant

Prior to 2012, our Compensation Committee did not engage the services of outside consultants or advisors to review and provide advice with respect to the compensation of our executive officers. However, as a part of determining compensation for 2013 for our named executive officers, the Compensation Committee engaged Radford, an AON Hewitt Consulting Company, as an independent compensation consultant. Radford provides analysis and recommendations to the Compensation Committee regarding:

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- trends and emerging topics with respect to Executive Compensation;
- peer group selection for executive compensation benchmarking;
- compensation practices for our peer group;
- compensation programs for executives and all of our associates; and
- stock utilization and related metrics.

When requested, Radford consultants attend meetings of the Compensation Committee, including executive sessions in which executive compensation issues are discussed. Radford reports to the Compensation Committee and not to management, although Radford meets with management for purposes of gathering information for their analyses and recommendations.

Peer Group

During 2012, as part of its consideration of executive officer compensation for 2013, the Compensation Committee established a peer group against which it could compare the Company s executive compensation to determine competitiveness and market trends. In developing this peer group of companies, the Compensation Committee, with assistance from Radford, considered the market capitalization and other key business metrics of biotechnology and biopharmaceutical companies. The peer group consists of the following companies:

Achillion	Aegerion Pharmaceuticals	AVEO Pharmaceuticals
Cell Therapeutics	ChemoCentryx	Clovis Oncology
Corcept Therapeutics	Curis	Endocyte
Infinity Pharmaceuticals	Keryx Biopharmaceuticals	MAP Pharmaceuticals
Merrimack Pharmaceuticals	Neurocrine Biosciences	New Link Genetics
Oncothyreon	Raptor Pharma	Rigel Pharmaceuticals
Supernus Pharmaceuticals	Threshold Pharmaceuticals	ZIOPHARM Oncology

At the time this peer group was established, our market capitalization was at approximately the 62% percentile of these peer companies. We did not consider this peer group in connection with our named executive officer compensation for 2012.

Federal Tax Considerations under Sections 162(m)

Section 162(m) of the Internal Revenue Code of 1986, as amended, disallows a federal income tax deduction to any publicly traded corporation for any remuneration in excess of $1.0 million of compensation paid to specified executive officers in a calendar year. Compensation in excess of $1.0 million may be deducted if, among other things, it qualifies as performance-based compensation within the meaning of Section 162(m). We expect that our Compensation Committee will periodically consider the potential consequences of Section 162(m) on the various elements of our executive compensation program and where in its judgment determines it is reasonably practicable and consistent with our overall compensation program objectives, it will seek to structure the equity incentives component of our executive compensation program to comply with exemptions in Section 162(m). Our 2012 Omnibus Incentive Plan has been structured to facilitate this process. However, our

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Board of Directors or Compensation Committee may, in their judgment, authorize compensation payments that do not comply with the exemptions in Section 162(m) in situations where they believe that such payments are appropriate.

The regulations under Section 162(m) include a grandfather provision to protect existing compensation arrangements of privately held companies that go public. The Section 162(m) limitation does not apply to any compensation plan or agreement, including our 2012 Omnibus Incentive Plan, that existed before a corporation becomes publicly held to the extent that the plan or agreement was disclosed in the prospectus accompanying the initial public offering. This exception may be relied on until the earliest of: (i) the expiration of the plan or agreement, (ii) the material modification of the plan or agreement, (iii) the issuance of all stock and other compensation that has been allocated under the plan, or (iv) the first shareholder meeting at which directors will be elected that occurs after the close of the third calendar year following the calendar year in which the initial public offering occurs.

Executive Compensation

The following table presents summary information regarding the total compensation awarded to, earned by, or paid to our Chief Executive Officer, our President and Chief Scientific Officer and our Executive Vice President and Chief Financial Officer for services rendered to us for the years ended December 31, 2011 and 2012. We refer to these individuals as our named executive officers.

Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Stock Awards ($) (1)	Option Awards ($) (2)	Non-Equity Incentive Plans ($) (3)	All Other Compensation ($) (4)	Total
Leon O. Moulder, Jr.	2012	376,442		1,585,998	100,400		2,062,840
Chief Executive Officer	2011	356,731	35,625	784,969	101,668		1,278,993
Mary Lynne Hedley, Ph.D.	2012	351,346		1,463,999	94,000	11,935	1,921,280
President, Chief Scientific Officer	2011	305,769	33,375	713,608	87,144		1,139,896
Richard J. Rodgers	2012	301,154		518,498	69,000	12,110	900,762
Executive Vice President and Chief Financial Officer	2011	280,289	22,500	267,603	66,569		636,961

(1) The amounts reflect the aggregate grant date fair value of restricted stock granted during the year computed in accordance with the provisions of ASC 718. For information regarding assumptions underlying the value of stock awards, see Note 6 to our financial statements and the discussion under Part II, Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies Stock-Based Compensation, of this Annual Report on Form 10-K.

(2) The amounts reflect the aggregate grant date fair value of option awards granted during the year computed in accordance with the provisions of ASC 718. For information regarding assumptions underlying the value of stock awards, see Note 6 to our financial statements and

the discussion under Part II, Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies Stock-Based Compensation, of this Annual Report on Form 10-K.

(3) The figures shown for non-equity incentive plan compensation represents amounts earned for the fiscal years ended December 31, 2011 and 2012, that were paid during 2012 and 2013, respectively. See Compensation Review Short-term Incentive Payouts for more information.

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(4) The amounts shown represent the sum of Company 401(k) contributions and the dollar value of life insurance premiums we paid for the applicable named executive officer.

Narrative Disclosure Relating to Summary Compensation Table

For an explanation of the amount of salary, bonus, stock and option awards and other compensation paid to our named executive officers, please see Compensation Review Components of our Compensation Program, and the disclosure provided in the Summary Compensation Table, above.

Grants of Plan-Based Awards

The following table provides information concerning grants of plan-based awards to each of our named executive officers during 2012.

Name	Grant Date	Estimated Possible Payouts Under Non-Equity Incentive Plan Awards			All Other Option Awards: Number of Securities Underlying Options (#)	Exercise or Base Price of Option Awards ($/Sh) (2)	Grant Date Fair Value of Stock and Option Awards ($) (3)
		Threshold ($)	Target ($) (1)	Maximum ($)			
Leon O. Moulder, Jr.	3/16/2012	$	$ 112,500	$ 163,125	371,428	$ 6.615	$ 1,585,998
Mary Lynne Hedley, Ph.D.	3/16/2012	$	$ 105,000	$ 152,250	342,857	$ 6.615	$ 1,463,999
Richard J. Rodgers	3/16/2012	$	$ 75,000	$ 105,000	121,428	$ 6.615	$ 518,498

(1) Amounts shown as estimated possible payouts under non-equity incentive plan awards are the target and maximum cash incentive each executive was eligible to receive pursuant to the terms of our STI program. For actual amounts paid, see Summary Compensation Table. For more information regarding these payments, see Compensation Review Components of our Compensation Program Short-term Incentive Payouts.

(2) Amounts represent the fair value of our common stock as determined in good faith by our board of directors on the date of grant. For a description of the terms of stock options granted, please see Compensation Review Components of our Compensation Program Equity Awards.

(3) Reflects the grant date fair value of each award computed in accordance with ASC 718. These amounts do not correspond to the actual value that will be recognized by the named executive officers. The assumptions used in the valuation of these awards are consistent with the valuation methodologies specified in Note 6 of the Notes to Financial Statements included in Part II, Item 8 Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

Outstanding Equity Awards at Fiscal Year-End

The following table provides information regarding equity awards held by each of our named executive officers that were outstanding as of December 31, 2012.

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	Option Awards					Stock Awards	
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised, Unearned Options	Option Exercise Price ($) ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($) (5)
Leon O. Moulder, Jr.		371,428(1)		$ 6.615	3/16/2022		
	111,311	202,974(2)		$ 1.33	7/19/2021		
						35,343(3)	599,064
						117,188(4)	1,986,337
Mary Lynne Hedley, Ph.D.		342,857(1)		$ 6.615	3/16/2022		
	101,189	184,525(2)		$ 1.33	7/19/2021		
						33,111(3)	561,231
						100,447(4)	1,702,577
Richard J. Rodgers		121,428(1)		$ 6.615	3/16/2022		
	37,945	69,197(2)		$ 1.33	7/19/2021		
						22,322(3)	378,358
						33,482(4)	567,520

(1) The options held by the named executive officers were granted on March 16, 2012. On the one-year anniversary of the grant date, 25% of these options vest and, thereafter, 1/36th of the remaining options vest on each monthly anniversary of the grant date.

(2) The options held by the named executive officers were granted on July 19, 2011. On the one-year anniversary of the grant date, 25% of these options vested and, thereafter, 1/36th of the remaining options have vested or will vest on each monthly anniversary of the grant date.

(3) The restricted stock held by the named executive officer was awarded on February 7, 2011. The amount shown as having not vested as of December 31, 2012 vests in equal monthly portions through January 2016.

(4) The restricted stock held by the named executive officer was purchased on March 26, 2010 in connection with the founding of the Company. The amount shown as having not vested as of December 31, 2012 vests in equal monthly portions through March 2014.

(5) Represents the market value of the shares based on a closing price on December 31, 2012 of $16.95 per share.

Option Exercises and Stock Vested

The following table sets forth information regarding the number of shares of stock awards acquired on vesting by our named executive officers during the fiscal year ended December 31, 2012. No options were exercised during the fiscal year ended December 31, 2012.

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Name	Stock Awards: Number of Shares Acquired on Vesting (#)	Stock Awards: Value Realized on Vesting ($) (1)
Leon O. Moulder, Jr.	126,264	$ 1,287,293
Mary Lynne Hedley, Ph.D.	110,816	1,137,264
Richard J. Rodgers	47,321	459,939

(1) The value realized upon vesting is the fair value of our common stock on the vesting date multiplied by the number of shares acquired on vesting.

Pension Benefits and Deferred Compensation

We maintain a defined contribution employee retirement plan for our employees. Our 401(k) plan is intended to qualify as a tax-qualified plan under Section 401 of the Code so that contributions to our 401(k) plan, and income earned on such contributions, are not taxable to participants until withdrawn or distributed from the 401(k) plan. Effective as of January 1, 2012, we amended our 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. We did not maintain any deferred compensation plans for any named executive officer for the year ended December 31, 2012.

Amended and Restated Offer Letter Agreements

We have amended and restated offer letter agreements with all of our named executive officers. The agreements were originally entered into on May 10, 2010, and amended and restated on June 18, 2012 in anticipation of our initial public offering, and are at-will arrangements. These agreements were designed to be a part of a competitive compensation package and keep our executive officers focused on our business goals and objectives. The agreements provide for base salaries, incentive compensation benefits and, in certain circumstances, severance benefits.

The amended and restated offer letter agreements with each of Mr. Moulder, Dr. Hedley and Mr. Rodgers provided for an initial base salary of $375,000, $350,000 and $300,000, respectively. Mr. Moulder, Dr. Hedley and Mr. Rodgers are also eligible for a bonus target of 30%, 30% and 25% of their respective annual base salary, payable upon attainment of objectives as determined by our board of directors. In addition to base salary and bonus, the amended and restated offer letter agreements provide for vacation benefits and the ability to participate in our employee benefit plans on the same terms as other similarly situated executive officers.

The amended and restated offer letter agreements also provide the named executive officer with certain payments and benefits upon certain terminations of employment. Pursuant to the amended and restated offer letter

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agreements, in order to receive certain severance benefits each named executive officer is required to execute a general release in favor of the Company, which includes, among other things, non-solicitation and non-disparagement provisions.

Under the terms of the amended and restated offer letter agreements, in the event that the named executive officer resigns without Good Reason, as defined below, or their employment terminates due to death or disability (as such term is defined in the amended and restated offer letter agreements), such executive is entitled to receive the following: (i) unpaid annual base salary for services rendered prior to the date of termination or resignation, (ii) any earned but unpaid annual bonus for any year prior to the year in which termination of employment occurs, (iii) reimbursement of any un-reimbursed business expenses, (iv) accrued but unused vacation pay and (v) any other payments, benefits or fringe benefits to which the executive is entitled to under the terms of any applicable compensation arrangement or benefit, equity or fringe benefit plan or program or grant (items (i) through (v) collectively referred to herein as accrued benefits). In the event that the Company terminates the executive for Cause, as defined below, the executive will be entitled to receive all of their accrued benefits, with the exception of any earned but unpaid bonus.

In the event the named executive officer s employment is terminated for any reason other than for Cause, death, or disability, or if the named executive officer resigns for Good Reason, and such termination is not in connection with or within 12 months following an Offer Letter Change of Control, as defined below, the named executive officer is entitled, provided he or she executes a release in favor of the Company and any revocation period in connection with such release has lapsed, to receive the following payments and compensation (in accordance with our regular pay policies and commencing 60 days following termination):

- their accrued benefits;

- in the case of Mr. Moulder, 18 months base salary, and in the case of Dr. Hedley and Mr. Rodgers, 12 months base salary;

- payment of a monthly COBRA coverage premium for the earlier of (i) in the case of Mr. Moulder, 18 months, and in the case of Dr. Hedley and Mr. Rodgers, 12 months, or (ii) the date upon which the executive commences full-time employment or employment that provides such executive with eligibility for healthcare benefits substantially comparable to those provided by the Company; and

- the vesting of such executive s restricted stock, purchased on March 26, 2010, pursuant to the terms of their restricted stock agreement with the Company, or the Restricted Stock Agreement. All other equity awards will be governed by the terms of the applicable award agreement.

If, in connection with or within 12 months following an Offer Letter Change of Control, as defined below, the named executive officer s employment is terminated for any reason other than for Cause or if the named executive officer resigns for Good Reason, the named executive officer is entitled, provided he or she executes a release in favor of the Company and any revocation period in connection with such release has lapsed to receive the following payments and compensation:

- their accrued benefits;

- in the case of Mr. Moulder, 18 months base salary, and in the case of Dr. Hedley and Mr. Rodgers, 12 months base salary, payable in a lump sum 60 days after termination;

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- in the case of Mr. Moulder, 150% of his target bonus for the year his employment terminates, and in the case of Dr. Hedley and Mr. Rodgers, 100% of their target bonus for the year their employment terminates, payable in a lump sum 60 days after termination of employment;

- payment of a monthly COBRA coverage premium for the earlier of (i) in the case of Mr. Moulder, 18 months following termination of employment, and in the case of Dr. Hedley and Mr. Rodgers, 12 months following termination of employment, or (ii) the date upon which the executive commences full-time employment or employment that provides such executive with eligibility for healthcare benefits substantially comparable to those provided by the Company; and

- the immediate vesting of all of such executive s restricted stock and stock options.

If any of the payments or benefits received by the executive in connection with an Offer Letter Change of Control or termination of employment, whether received pursuant to the amended and restated offer letter agreements or otherwise, referred to as 280G payments, constitute parachute payments within the meaning of Section 280G of the Code and would be subject to the excise tax imposed by Section 4999 of the Code, then, pursuant to the terms of the amended and restated offer letter agreements, such 280G payments shall be reduced by us so that the executive will not be considered to have received a parachute payment, unless the executive would receive a greater after-tax amount by receiving all such 280G payments without reduction pursuant to the terms of the amended and restated offer letter agreements.

For purposes of the amended and restated offer letter agreements, termination for Cause shall mean termination for such named executive officer s: (i) willful misconduct or gross negligence as to a material matter in connection with their duties; (ii) act constituting material dishonesty or fraud with respect to the Company; (iii) indictment for, conviction of, or a plea of guilty or *nolo contendere* to, a felony under applicable law; (iv) material violation of a material term of any written Company policy made available to the executive; (v) failure to attempt in good faith to perform their duties in all material respects or follow a clear, lawful and reasonable directive of the board of directors; or (vi) material breach of fiduciary duty owed to the Company that has caused or could reasonably be expected to cause a material injury to the Company s business; provided, however, that the Company has provided the executive with written notice of the existence of such event or circumstance and, with respect to the circumstances in clauses (iv) and (v) only, the executive fails to substantially cure the event or circumstance identified within 30 days of receipt of such notice. A resignation by the named executive officer shall be deemed a resignation for Good Reason if the executive provides written notice to the Company of the specific circumstances alleged to constitute Good Reason within 90 days after any one or more of the following events: (i) the executive is required to report to another person other than the board of directors, in the case of Mr. Moulder, and the Chief Executive Officer, in the case of Dr. Hedley and Mr. Rodgers, or the assignment to the executive of any duties or responsibilities which result in the material diminution of the executive s position as, in the case of Mr. Moulder, the Chief Executive Officer of the Company, in the case of Dr. Hedley, the President and Chief Scientific Officer of the Company, and in the case of Mr. Rodgers, the Executive Vice President and Chief Financial Officer of the Company, subject to certain exceptions; (ii) a reduction by the Company in the executive s annual base salary or target bonus percentage; (iii) the relocation of the executive s primary office at the Company s headquarters in the Boston, Massachusetts metropolitan area to another location by more than 50 miles or relocation of the executive s primary office at the Company s headquarters to another location that is not the Company s headquarters; or (iv) a breach by the Company of the terms of the executive s amended and restated offer letter agreement or the executive s Restricted Stock Agreement, including, without limitation, the diminution of such executive s job title. In each case, the Company shall have 30 days to cure such circumstances in all material respects upon the receipt of notice from

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the executive of such circumstances. In no event shall termination for Good Reason occur after the 180th day following the first occurrence of any Good Reason event.

For purposes of the amended and restated offer letter agreements, the term Offer Letter Change of Control shall mean the occurrence of any of the following: (i) subject to certain exceptions, a Person (as defined in the amended and restated offer letter agreement) or group (within the meaning of Sections 13(d) and 14(d)(2) of the Exchange Act) becomes the beneficial owner (as defined in Rule 13d-3 under the Exchange Act) of more than 50% of the total voting power of the voting stock of the Company, on a fully diluted basis; (ii) individuals who on the effective date of the 2012 Plan constitute the board of directors (together with any new directors whose election by such board or whose nomination by such board for election by the stockholders of the Company was approved by a vote of at least a majority of the members of such board then in office who either were members of such board on the effective date of the 2012 Plan or whose election or nomination for election was previously so approved) cease for any reason to constitute a majority of the members of such board then in office; (iii) the Company consolidates with, or merges with or into, any Person, or any Person consolidates with, or merges with or into, the Company, other than any such transaction in which the holders of securities that represented 100% of the voting stock of the Company immediately prior to such transaction (or other securities into which such securities are converted as part of such merger or consolidation transaction) own directly or indirectly at least a majority of the voting power of the voting stock of the surviving Person in such merger or consolidation transaction immediately after such transaction; (iv) there is consummated any direct or indirect sale, lease, transfer, conveyance or other disposition (other than by way of merger or consolidation), in one transaction or a series of related transactions, of all or substantially all of the assets of the Company and its subsidiaries, taken as a whole, to any Person or group (within the meaning of Sections 13(d) and 14(d)(2) of the Exchange Act); or (v) the stockholders of the Company adopt a plan or proposal for the liquidation, winding up or dissolution of the Company.

Non-Disclosure and Inventions Assignment Agreement

Each of our named executive officers has also entered into a standard form agreement with respect to the non-disclosure of information and assignment of inventions. Among other things, this agreement obligates each named executive officer to refrain from disclosing any of our proprietary and confidential information received during the course of employment and to assign to us any inventions conceived or developed during the course of their employment.

Potential Payments Upon a Termination or Change in Control

As discussed under the caption Amended and Restated Offer Letter Agreements above, we have agreements with our named executive officers pursuant to which they will receive severance payments upon certain termination events. The information below describes and quantifies certain compensation that would be available under our existing plans and arrangements if (i) the named executive officer was terminated as of December 31, 2012 or (ii) if an Offer Letter Change of Control, Change of Control or Acquisition, as the case may be and each as defined herein, occurred on December 31, 2012 and the named executive officer had been subsequently terminated on the same date.

Acceleration of Restricted Stock and Equity Awards.

Pursuant to the terms of each named executive officer s Restricted Stock Agreement, in the event of a Change of Control that occurs during any time such named executive officer s Business Relationship (as such term is defined in the Restricted Stock Agreements) with the Company or

any parent corporation or subsidiary, all

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shares of restricted stock awards granted pursuant to such Restricted Stock Agreement shall fully vest. In the event of a termination by the Company for Cause or if the executive resigns for Good Reason, in addition to any shares of common stock such executive receives pursuant to the normal vesting schedule of their Restricted Stock Agreement, an additional 18.75% of the shares subject to such executive s agreement shall vest. For purposes of these shares of restricted stock, a Change of Control shall mean (A) the Company merges with or into or consolidates with any other corporation or sells, leases or otherwise disposes of all or substantially all of its assets or properties, unless the stockholders of the Company, before giving effect to such merger, consolidation or sale, lease or other disposition of assets, beneficially own at least 50% of the outstanding shares of capital stock of, or other equity interests in, the surviving or acquiring corporation or entity (calculated on a fully diluted basis) or (B) any person (other than persons who were stockholders of the Company prior to such transactions or any venture capital or private equity investor making a portfolio investment), together with its associates, acquires beneficial ownership of 50% or more of the outstanding shares of the Company s common stock.

In addition, in the event of an Acquisition or a Offer Letter Change of Control of the Company, as defined herein, all equity awards granted under the Company s 2010 Stock Incentive Plan or any other applicable equity plan that are outstanding immediately prior to the Acquisition or Offer Letter Change of Control shall become fully vested and exercisable.

Termination Other than for Cause, Death or Disability; Resignation for Good Reason. Assuming a December 31, 2012 termination event, the aggregate value of the payment and benefits to which each named executive officer would be entitled to in the event that the named executive officer s employment is terminated for any reason other than for Cause, death, or Disability, or if the named executive officer resigns for Good Reason, would be as follows:

Name	Cash Severance ($) (1)	Benefits and Health Programs ($) (2)	Value of Accelerated Awards Under Restricted Stock Agreements ($) (3)	Total ($)
Leon O. Moulder, Jr.	562,500	30,280	1,589,063	2,181,843
Mary Lynne Hedley, Ph.D.	350,000	20,186	1,362,034	1,732,220
Richard J. Rodgers	300,000	20,186	454,006	774,192

(1) This amount represents, in the case of Mr. Moulder, 18 months base salary, and in the case of Dr. Hedley and Mr. Rodgers, 12 months of the executive s base salary, each at the rate in effect immediately prior to the executive s termination of employment.

(2) This amount represents, in the case of Mr. Moulder, 18 months, and in the case of Dr. Hedley and Mr. Rodgers, 12 months, of continued Company-paid benefits and health coverage.

(3) The value of the restricted stock vesting acceleration is calculated based on a closing price on December 31, 2012 of $16.95 per share with respect to unvested restricted stock subject to acceleration.

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Termination Following a Change of Control or Acquisition. Assuming a December 31, 2012 Offer Letter Change of Control, Change of Control or Acquisition, as the case may be, and subsequent termination event on that same date for any reason other than Cause, death or disability, or if the named executive officer resigns for Good Reason, the aggregate value of the payment and benefits to which each named executive officer would be entitled to would be as follows:

Name	Cash Severance ($) (1)	Bonus ($) (2)	Benefits and Health Programs ($) (3)	Value of Accelerated Awards Under Restricted Stock Agreements ($) (4)	Value of All Other Accelerated Equity ($) (5)	Total ($)
Leon O. Moulder, Jr.	562,500	168,750	30,280	1,986,377	7,608,226	10,356,133
Mary Lynne Hedley, Ph.D.	350,000	105,000	20,186	1,702,577	6,986,939	9,164,702
Richard J. Rodgers	300,000	75,000	20,186	567,520	2,714,713	3,677,419

(1) This amount represents, in the case of Mr. Moulder, 18 months base salary, and in the case of Dr. Hedley and Mr. Rodgers, 12 months of the executive s base salary, each at the rate in effect immediately prior to the executive s termination of employment.

(2) This amount represents, in the case of Mr. Moulder, 150% of his target bonus for the year his employment terminates, and in the case of Dr. Hedley and Mr. Rodgers, 100% of their target bonus for the year their employment terminates, payable if an executive is terminated without Cause or resigns for Good Reason upon an Offer Letter Change of Control.

(3) This amount represents, in the case of Mr. Moulder, 18 months, and in the case of Dr. Hedley and Mr. Rodgers, 12 months, of continued Company-paid benefits and health coverage.

(4) The value of the restricted stock vesting acceleration is calculated based on a closing price on December 31, 2012 of $16.95 per share with respect to unvested restricted stock subject to acceleration.

(5) Assuming a December 31, 2012 Offer Letter Change of Control or Acquisition, the value of all equity awards issued pursuant to the applicable equity plan that would vest and become exercisable for each named executive officer would be as follows:

Name	Value of Stock Options ($)	Value of Restricted Shares ($)
Leon O. Moulder, Jr.	7,009,162	599,064

Mary Lynne Hedley, Ph.D.	6,425,708	561,231
Richard J. Rodgers	2,335,815	378,358

The value of stock option vesting acceleration is calculated based on a closing price on December 31, 2012 of $16.95 per share with respect to unvested restricted stock subject to acceleration, less the exercise price of these unvested options shares. The actual value will vary depending on the date the options are exercised. The

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value of the restricted stock vesting acceleration is calculated based on a closing price on December 31, 2012 of $16.95 per share with respect to unvested restricted stock subject to acceleration.

Non-Employee Director Compensation

In May 2012, our board of directors approved a non-employee director compensation policy, which became effective for all non-employee directors upon the effective date of the registration statement for our initial public offering on June 29, 2012. Each non-employee director receives an annual base retainer of $40,000. In addition, our non-employee directors receive the following cash compensation for board services, as applicable:

- the non-executive chairman of the board of directors receives an additional annual retainer of $10,000;
- each member of our audit, compensation and governance and nominating committees receives an additional retainer of $5,000, $5,000 and $2,500, respectively;
- each chairperson of our audit, compensation and governance and nominating committees receives an additional annual retainer of $10,000, $7,500 and $5,000, respectively;
- for each board meeting attended in excess of 10 per year, such non-employee director receives $1,500; and
- for each committee meeting attended in excess of six per year, such non-employee director receives $1,000.

All amounts shall be paid in quarterly installments.

In addition, newly appointed non-employee directors will receive a one-time initial award of options to purchase 28,571 shares of our common stock, which will vest annually over a three-year period subject to the director s continued service on the board of directors. Thereafter, each non-employee director will receive an annual award of options to purchase 10,714 shares of our common stock, which will vest on the earlier of the one-year anniversary of the date of grant and the next annual meeting of stockholders, subject to the director s continued service on the board of directors.

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Director Compensation

The following table summarizes the compensation paid to or earned by our non-employee directors during the year ended December 31, 2012.

Name	Fees Earned or Paid in Cash (1)	Stock Awards	Option Awards (2)	Non-Equity Incentive Plans	All Other Compensation	Total
Lawrence M. Alleva(3)	$ 50,634	$	$ 113,994	$	$	**$ 164,628**
David M. Mott	63,289					**63,289**
Arnold L. Oronsky, Ph.D.	48,094					**48,094**
Beth Seidenberg, M.D.	45,569					**45,569**
Paul Walker	45,569					**45,569**

(1) Includes annual fees, committee chairmanship fees and meeting fees, including fees paid at the election of a director in Company stock pursuant to the 2012 Omnibus Incentive Plan. Each of the directors elected to receive his or her entire 2012 annual retainer in fully-vested shares of common stock. The number of shares issued in lieu of the retainer fees and committee fees were: Mr. Alleva: 3,329 shares; Mr. Mott: 4,161 shares; Dr. Oronsky 3,162 shares; Dr. Seidenberg 2,996 shares; and Mr. Walker 2,996 shares, in each case having a fair market value of $15.21 per share on the date of issuance.

(2) Amounts shown do not reflect compensation actually received by the director but represent the aggregate full grant date fair value of stock option awards granted to the director and calculated in accordance with ASC 718, disregarding adjustments for forfeiture assumptions. The assumptions used to value the stock option awards are set forth in Note 6 of the Notes to Financial Statements included in Part II, Item 8 Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

(3) Mr. Alleva was appointed to the Board in March 2012 and was granted options to purchase 21,428 and 7,142 shares of our common stock on April 27, 2012 and May 2, 2012, respectively, at an exercise price of $6.615 per share.

The following table sets forth as of December 31, 2012, the aggregate number of exercisable and unexercisable option awards outstanding held by our current non-employee directors:

	Option Awards	
Name	Exercisable	Unexercisable (#)
David M. Mott		

Lawrence M. Alleva	28,570
Arnold L. Oronsky, Ph.D.	
Beth Seidenberg, M.D.	
Paul Walker	

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There were no unvested restricted stock awards outstanding at December 31, 2012.

Non-employee directors are provided an election to receive their retainer and fees in cash or common stock and to defer the receipt of the stock to a date elected by the director or to termination of their service as a director.

Equity Benefit Plans

	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 holder (1) (2)	2,134,185	$	5.52	1,326,286
Equity compensation plans not approved by security holders				
Total	2,134,185	$	5.52	1,326,286

(1) As of December 31, 2012, 1,051,286 shares were authorized 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.

(2) As of December 31, 2012, 275,000 shares were reserved for issuance under our 2012 Employee Stock Purchase Plan, or ESPP, which became effective in June 2012.

401(k) Retirement Plan

We maintain a defined contribution employee retirement plan for our employees. Our 401(k) plan is intended to qualify as a tax-qualified plan under Section 401 of the Code so that contributions to our 401(k) plan, and income earned on such contributions, are not taxable to participants until withdrawn or distributed from the 401(k) plan. Our 401(k) plan provides that each participant may contribute up to 100% of his or her pre-tax compensation, up to a statutory limit of $17,500 for 2013. Participants who are at least 50 years old can also make catch-up contributions, which in 2013 may be up to an additional $5,500 above the statutory limit. Under our 401(k) plan, each employee is fully vested in his or her deferred salary contributions. Employee contributions are

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held and invested by the plan s trustee. Our 401(k) plan also permits us to make discretionary and matching contributions, subject to certain limits. Effective as of January 1, 2012, we amended our 401(k) plan to provide for employer matching contributions equal to (1) 100% of employee deferral contributions up to a deferral rate of 3% compensation plus (2) 50% of employee deferral contributions up to a deferral rate of an additional 2% compensation.

Compensation Committee

Compensation Committee Interlocks and Insider Participation

The board of directors has a standing compensation committee, which met six (6) times during 2012. The members of the compensation committee are Mr. Mott and Dr. Seidenberg. None of the members of our compensation committee has ever been an officer or employee of the Company. None of our executive officers serves, or has served during the last fiscal year, as a member of the board of directors, compensation committee or other board committee performing equivalent functions of any entity that has one or more executive officers serving as one of our directors or on our compensation committee.

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

Securities Authorized for Issuance Under Equity Compensation Plans

Equity Compensation Plan Information

As of December 31, 2012

	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)	2,134,185	$ 5.52	1,326,286
Equity compensation plans not approved by security holders			
Total	2,134,185	$ 5.52	1,326,286

(1) As of December 31, 2012, 1,051,286 shares were authorized 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

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of common stock outstanding at such time or (y) the number of shares determined by our board of directors.

(2) As of December 31, 2012, 275,000 shares were reserved for issuance under our 2012 Employee Stock Purchase Plan, or ESPP, which became effective in June 2012.

Performance Graph(1)

The following graph shows a comparison from June 29, 2012 through December 31, 2012 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.

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(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 and 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.

Beneficial Ownership of Common Stock

The following table sets forth certain information as of February 1, 2013 (unless otherwise specified), with respect to the beneficial ownership of our common stock by each person who is known to own beneficially more than 5% of the outstanding shares of common stock, each person currently serving as a director, each nominee for director, each named executive officer (as set forth in the Summary Compensation Table above), and all directors and executive officers as a group:

Name of Beneficial Owner	Shares of Common Stock Beneficially Owned(1)	Percentage of Class
5% Stockholders		
Entities affiliated with New Enterprise Associates (1)	11,499,255	42.4%
Entity affiliated with InterWest Partners (2)	3,074,863	11.3%
Entities affiliated with Kleiner Perkins Caufield & Byers (3)	2,192,665	8.1%
T. Rowe Price Associates, Inc. (4)	1,448,791	5.3%
Wellington Management Company, LLP (5)	1,395,720	5.1%
Directors and Named Executive Officers		
Leon O. Moulder, Jr.(6)	1,230,238	4.5%
Mary Lynne Hedley, Ph.D.(7)	768,329	2.8%
Richard J. Rodgers (8)	332,140	1.2%
David M. Mott (9)	11,503,416	42.4%
Lawrence M. Alleva	18,050	*
Arnold L. Oronsky, Ph.D.(2)	3,074,863	11.3%
Beth Seidenberg, M.D.(10)	2,195,661	8.1%
Paul Walker(11)	2,996	*
All of our directors and executive officers as a group (8 persons)	19,125,693	69.2%

* Represents beneficial ownership of less than 1%.

(1) Includes 11,499,255 shares of common stock held of record by New Enterprise Associates 13, L.P. (NEA 13). The shares directly held by NEA 13 are indirectly held by NEA Partners 13, L.P. (NEA Partners 13), the sole general partner of NEA 13, NEA 13 GP, LTD (NEA 13 LTD), the sole general partner of NEA Partners 13 and each of the individual directors of NEA 13 GP, LTD. The individual directors of NEA 13 LTD (collectively, the NEA 13 Directors) are M. James Barrett, Peter J. Barris, Forest Baskett, Ryan D. Drant, Patrick J. Kerins, Krishna Kittu Kolluri, C. Richard Kramlich, David M. Mott (a member of our board of directors), Scott D. Sandell, Ravi Viswanathan and Harry R. Weller. NEA 13, NEA Partners 13 and NEA 13 LTD and the NEA 13 Directors share voting and dispositive power with regard to the Company s securities directly held by NEA 13. The principal business address for New Enterprise Associates is 1954 Greenspring Drive, Suite 600, Timonium, Maryland 21093.

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(2) Includes 3,071,701 shares of common stock held of record by InterWest Partners X, LP (IW10). InterWest Management Partners X, LLC (IMP10) is the general partner of IW10 and has sole voting and dispositive power over the shares directly held by IW10. Harvey B. Cash, Bruce A. Cleveland, Christopher B. Ehrlich, Philip T. Gianos, W. Stephen Holmes, Nina S. Kjellson, Gilbert H. Kliman, Arnold L. Oronsky, Douglas A. Pepper and Thomas L. Rosch are managing directors of IMP10. Keval Desai and Khaled A. Nasr are venture members of IMP10. Each managing director and venture member of IMP10 shares voting and dispositive power over the shares directly held by IW10 and disclaims beneficial ownership of such shares, except to the extent of his or her pecuniary interest therein. The address for IW10 and IMP10 is 2710 Sand Hill Road, Suite 200, Menlo Park, California 94025.

(3) Includes (i) 2,021,637 shares held by Kleiner Perkins Caufield & Byers XIV, LLC (KPCB XIV) and (ii) 171,028 shares held by KPCB XIV Founders Fund, LLC (KPCB XIV Founders). The shares held by KPCB XIV and KPCB XIV Founders are held for convenience in the name of KPCB Holdings, Inc., as nominee. KPCB Holdings, Inc. has no voting, dispositive or pecuniary interest in any such shares. The managing member of KPCB XIV and KPCB XIV Founders is KPCB XIV Associates, LLC (KPCB XIV Associates). Brook Byers, L. John Doerr, Raymond Lane, Theodore Schlein, William Joy, William B. Gordon, the managing members, and Beth Seidenberg, M.D., a member, of KPCB XIV Associates, exercise shared voting and dispositive control over the shares directly held by KPCB XIV and KPCB XIV Founders. Dr. Seidenberg disclaims beneficial ownership of all shares held by KPCB XIV and KPCB XIV Founders except to the extent of her pecuniary interest therein. The address for all entities and individuals affiliated with Kleiner Perkins Caufield & Byers is 2750 Sand Hill Road, Menlo Park, California 94025.

(4) Based solely on a Schedule 13G filed by T. Rowe Price Associates, Inc. on February 13, 2013. The principal business address for T. Rowe Price Associates, Inc. is 100 E. Pratt Street, Baltimore, Maryland 21202.

(5) Based solely on a Schedule 13G filed by Wellington Management Company, LLP on February 14, 2013. The principal business address for Wellington Management Company, LLP is 280 Congress Street, Boston, Massachusetts 02210.

(6) Includes 105,952 shares of common stock subject to outstanding options that are exercisable within 60 days of February 1, 2013.

(7) Includes 97,619 shares of common stock subject to outstanding options that are exercisable within 60 days of February 1, 2013.

(8) Includes 34,822 shares of common stock subject to outstanding options that are exercisable within 60 days of February 1, 2013.

(9) Includes 4,161 shares of common stock held of record by David M. Mott and the shares held directly by NEA 13. Mr. Mott, a general partner at New Enterprise Associates, disclaims beneficial ownership of all of the shares held directly by NEA 13 except to the extent of his pecuniary interest therein, if any.

(10) Includes 2,996 shares held of record by Beth Seidenberg, M.D. and the shares held directly by KPCB XIV and KPCB XIV Founders, whose beneficial ownership Dr. Seidenberg disclaims except to the extent of her pecuniary interest therein.

(11) Includes 2,996 shares held of record by Paul Walker. Mr. Walker, a partner at New Enterprise Associates, has no voting or dispositive power with regard to any of the shares held directly by NEA 13 and disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein, if any.

We are not aware of any arrangements the operation of which may at a subsequent date result in a change in our control.

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

Certain Relationships and Related Person Transactions

Policies and Procedures for Related Person Transactions

Under our Policy for Related Person Transactions entered into in connection with our initial public offering, all related person transactions are reviewed and approved by our audit committee (or any other committee of the board of directors consisting of independent directors) or our full board of directors. This review will cover any material transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, the amount involved exceeds $120,000, and a related person had or will have a direct or indirect material interest, including, but not limited to, purchases of goods or services by or from a related person or entities in which the related person has a material interest, and indebtedness, guarantees of indebtedness and employment by us of a related person. A related person, as determined since the beginning of our last fiscal year, is any executive officer, director or nominee to

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become director, a holder of more than 5% of our common stock, including any immediate family members of such persons or any entity which is owned or controlled by such a person.

Related Person Transactions

The following is a description of transactions, since January 1, 2012, to which we have been a party, in which the amount involved exceeded or will exceed $120,000, and in which any of our executive officers, directors or holders of more than 5% of any class of our voting securities, or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest, other than compensation, termination and change in control arrangements, which are described above under Executive and Director Compensation. We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable, in arm s-length transactions with unrelated third parties. The following transactions were entered into before the adoption of our Policy for Related Person Transactions described above and were approved by our full board of directors.

Issuance of Series B Preferred Stock

In June 2011, July 2011 and March 2012, we issued and sold an aggregate of 46,436,761 shares of our Series B preferred stock at a price per share of $2.175, for aggregate consideration of approximately $101 million. In connection with the sale of the Series B preferred stock, we paid approximately $77,000 in legal fees for the benefit of the investors, including the stockholders identified in the table below.

The table below sets forth the number of shares of Series B preferred stock purchased by our stockholders who held more than 5% of any class of our voting securities or their affiliates in June 2011 and March 2012. No shares were purchased by these stockholders and their affiliates in July 2011. In connection with the closing of our initial public offering, every 3.5 shares of preferred stock set forth in the table below were converted into one share of our common stock.

	June 2011 Purchase of Series B Preferred Stock (#)	Aggregate Purchase Price of June 2011 Purchase of Series B Preferred Stock ($)	March 2012 Purchase of Series B Preferred Stock (#)	Aggregate Purchase Price of March 2012 Purchase of Series B Preferred Stock ($)	Shares of Common Stock Issued Upon Conversion of Series B Preferred Stock (#)
Stockholders					
Entities affiliated with New Enterprise Associates(1)	7,741,199	16,837,108	10,647,306	23,157,892	5,253,859
Entity affiliated with InterWest Partners(2)	3,871,748	8,421,052	5,323,654	11,578,948	2,627,257
Entities affiliated with Kleiner Perkins Caufield & Byers(3)	2,903,811	6,315,789	3,992,740	8,684,211	1,970,443

(1) David M. Mott and Paul Walker, each of whom is one of our directors, are a general partner and partner, respectively, of New Enterprise Associates.

(2) Arnold L. Oronsky, Ph.D., one of our directors, is a general partner of InterWest Partners.

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(3) Shares are held for convenience in the name of KPCB Holdings, Inc., as nominee. Beth Seidenberg, M.D., one of our directors, is a partner of Kleiner Perkins Caufield & Byers.

Participation in our Initial Public Offering

At our request, the underwriters in our initial public offering allocated an aggregate of 1,863,332 shares of our common stock in our initial public offering to certain of our directors and existing stockholders, or certain of their affiliates, including New Enterprise Associates, InterWest Partners, and Kleiner Perkins Caufield & Byers, or funds affiliated with them, and Lawrence M. Alleva, a member of our board of directors. The shares were offered and sold on the same terms as the other shares that were offered and sold in our initial public offering. The table below sets forth the number of shares of Series B preferred stock purchased by these entities and Mr. Alleva.

	Shares Purchased in the Offering
Offering Participant	
Entities affiliated with New Enterprise Associates(1)	1,111,111
Entity affiliated with InterWest Partners(2)	444,444
Entities affiliated with Kleiner Perkins Caufield & Byers(3)	222,222
Lawrence M. Alleva	11,481

(1) David M. Mott and Paul Walker, each of whom is one of our directors, are a general partner and partner, respectively, of New Enterprise Associates.

(2) Arnold L. Oronsky, Ph.D., one of our directors, is a general partner of InterWest Partners.

(3) Shares are held for convenience in the name of KPCB Holdings, Inc., as nominee. Beth Seidenberg, M.D., one of our directors, is a partner of Kleiner Perkins Caufield & Byers.

Second Amended and Restated Investors Rights Agreement

In connection with the sale of our Series B preferred stock, in June 2011 we entered into an investors rights agreement with the then holders of our outstanding preferred stock, including our named executive officers and entities with which certain of our directors are affiliated. The agreement provides that with respect to the common stock issued upon conversion of our preferred stock, these holders have the right to demand that we file a registration statement or request that the shares of common stock be covered by a registration statement that we are otherwise filing. These registration rights were validly waived for our initial public offering. In addition to the registration rights, the investors rights agreement provided for certain information rights, board observer rights and rights of first refusal that terminated upon completion of our initial public offering.

Director Independence

Our board of directors believes, and NASDAQ Marketplace rules require, that a majority of its members should be independent directors. In addition, the respective charters of the audit, compensation and governance and nominating committees, currently require that each member of such committees be independent directors. Consistent with NASDAQ s independence criteria, the board of directors has affirmatively determined that each of our directors other than Mr. Moulder, who is our Chief Executive Officer, and Dr. Hedley, who is our President and Chief Scientific Officer, is independent of TESARO and our management. NASDAQ s independence criteria includes a series of objective tests, such as that the director is not an employee of TESARO and has not engaged in various types of business dealings with us. In addition, as further required by NASDAQ rules, the board of

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directors has subjectively determined as to each independent director that no relationship exists that, in the opinion of the board of directors, would interfere with each such director s exercising independent judgment in carrying out his or her responsibilities as a director. In making these determinations on the independence of our directors, the board of directors considered the relationships that each such director has with the Company and all other facts and circumstances the board deemed relevant in determining independence, including the beneficial ownership of our capital stock by each such director.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Principal Accountant Fees and Services

We regularly review the services and fees of our independent registered public accounting firm. These services and fees are also reviewed by the audit committee on an annual basis. The aggregate fees incurred for the fiscal years ended December 31, 2012 and 2011 for each of the following categories of services are as follows:

	2011	2012
Fee Category		
Audit Fees	$ 96,200	$ 777,500
Audit-Related Fees		
Tax Fees	$ 6,500	$ 16,500
All Other Fees	$ 1,900	$ 1,900
Total Fees	$ 104,600	$ 795,900

Audit Fees. Consist of fees incurred for professional services rendered for the audit of our annual financial statements, review of our interim financial statements and services provided in connection with our securities offerings and registration statements.

Audit-Related Fees. Consist of fees incurred for assurance and related services that are reasonably related to the performance of the audit or review of our financial statements and are not reported under Audit Fees.

Tax Fees. Consist of fees incurred for tax compliance, tax advice and tax planning and includes fees for tax return preparation and tax consulting.

All Other Fees. Consist of fees incurred for products and services, other than those described above under Audit Fees, Audit-Related Fees and Tax Fees.

During the fiscal years ended December 31, 2012 and 2011, Ernst &Young has provided various services, in addition to auditing our financial statements. The audit committee has determined that the provision of such services is compatible with maintaining Ernst &Young s

independence. In 2012 and 2011, all fees paid to Ernst &Young were pre-approved pursuant to the policy described below.

Audit Committee s Pre-Approval Policies and Procedures

The audit committee reviews with Ernst &Young and management the plan and scope of Ernst & Young s proposed annual financial audit and quarterly reviews, including the procedures to be utilized and Ernst &Young s compensation. The audit committee also pre-approves all auditing services, internal control related services and permitted non-audit services (including the fees and terms thereof) to be performed for us by Ernst &Young, subject to the de minimis exception for non-audit services that are approved by the audit committee prior to the completion of an audit. The audit committee may delegate pre-approval authority to one or more

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members of the audit committee consistent with applicable law and listing standards, provided that the decisions of such audit committee member or members must be presented to the full audit committee at its next scheduled meeting.

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.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TESARO, Inc.

Date: February 20, 2013 By: /s/ Leon O. Moulder, Jr.
Leon O. Moulder, Jr.
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed 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 20, 2013
/s/ Mary Lynne Hedley, Ph.D. Mary Lynne Hedley, Ph.D.	President, Chief Scientific Officer and Director	February 20, 2013
/s/ Richard J. Rodgers Richard J. Rodgers	Executive Vice President, Chief Financial Officer, Secretary and Treasurer (Principal Financial Officer)	February 20, 2013
/s/ Edward C. English Edward C. English	Vice President, Controller and Principal Accounting Officer	February 20, 2013
/s/ David M. Mott David M. Mott	Chairman of the Board of Directors	February 20, 2013
/s/ Lawrence M. Alleva Lawrence M. Alleva	Director	February 20, 2013
/s/ Arnold L. Oronsky, Ph.D. Arnold L. Oronsky, Ph.D.	Director	February 20, 2013
/s/ Paul Walker	Director	February 20, 2013

Paul Walker

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/s/ Beth Seidenberg, M.D. Beth Seidenberg, M.D.	Director	February 20, 2013

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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.
10.1+(D)	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(E)	Form of Option Agreement under 2012 Omnibus Incentive Plan.
10.5+(D)	Form of Indemnification Agreement between the Company and each of Leon O. Moulder, Jr., Mary Lynne Hedley, Ph.D., Richard J. Rodgers and Lawrence M. Alleva.
10.6+(D)	Indemnification Agreement between the Company and David M. Mott.
10.7+(D)	Indemnification Agreement between the Company and Arnold L. Oronsky.
10.8+(D)	Indemnification Agreement between the Company and Paul Walker.
10.9+(D)	Indemnification Agreement between the Company and Beth Seidenberg, M.D.
10.10+(B)	Amended and Restated Offer Letter Agreement by and between the Company and Leon O. Moulder, Jr., dated June 18, 2012.
10.11+(B)	Amended and Restated Offer Letter Agreement by and between the Company and Mary Lynne Hedley, dated June 18, 2012.
10.12+(B)	Amended and Restated Offer Letter Agreement by and between the Company and Richard J. Rodgers, dated June 18, 2012.
10.13+(D)	Restricted Stock Agreement by and between the Company and Leon O. Moulder, Jr., dated May 10, 2010.
10.14+(D)	Restricted Stock Agreement by and between the Company and Mary Lynne Hedley, dated May 10, 2010.
10.15+(D)	Restricted Stock Agreement by and between the Company and Richard J. Rodgers, dated May 10, 2010.
10.16+(D)	Form of Non-Disclosure and Inventions Assignment Agreement by and between the Company and each of Messrs. Moulder and Rodgers and Dr. Hedley.
10.17*(F)	Exclusive License Agreement by and between the Company and OPKO Health, Inc., dated December 10, 2010.

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10.18*(F)	Exclusive License Agreement by and between the Company and Amgen, Inc., dated as of March 18, 2011.
10.19*(F)	Process Development and Manufacturing Services Agreement by and between the Company and Hovione Inter Limited, dated March 31, 2012.
10.20*(F)	License Agreement by and between the Company and Merck Sharpe & Dohme Corp., dated May 22, 2012.
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

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

(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 Form S-1 filed on March 23, 2012 (File No. 333-180309)

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

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

+ 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.