Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

☒ **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

☐ **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Commission file number: 000-51967

TRANSCEPT PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**33-0960223**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

1003 W. Cutting Blvd., Suite #110
Point Richmond, California 94804
(510) 215-3500
(Address, including zip code, and telephone number, including area code, of registrant's principal executive office)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of exchange on which registered
Common Stock, par value $0.001 per share	**NASDAQ Global Market**

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

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

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

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

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

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

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

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

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

The aggregate market value of the common stock of the registrant held by non-affiliates of the registrant on June 30, 2012, the last business day of the registrant's second fiscal quarter was: $85,270,634.

As of March 8, 2013 there were 18,745,146 shares of the registrant's common stock outstanding.

Documents incorporated by reference: Items 10, 11, 12, 13, and 14 of Part III incorporate information by reference from the Proxy Statement to be filed with the Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) to Form 10-K.

TABLE OF CONTENTS

Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements that are based upon current expectations within the meaning of the Private Securities Litigation Reform Act of 1995. Transcept Pharmaceuticals, Inc., or Transcept, intends that such statements be protected by the safe harbor created thereby. Forward-looking statements involve risks and uncertainties and actual Transcept results and the timing of events may differ significantly from those results discussed in the forward-looking statements. Examples of such forward-looking statements include, but are not limited to, statements about or relating to:

- expected activities and responsibilities of us and Purdue Pharmaceuticals L.P., or Purdue Pharma, under our United States License and Collaboration Agreement, or the Collaboration Agreement;
- the future satisfaction of conditions required for continued commercialization of Intermezzo under the Collaboration Agreement, and the fulfillment of Purdue Pharma's obligations under the Collaboration Agreement;
- our potential receipt of revenue under the Collaboration Agreement, including milestone and royalty revenue;
- expectations for the commercial potential of Intermezzo and Purdue Pharma's continued commitment to collaborate with us;
- our expectations regarding suits that Purdue Pharma or we have filed or may file in regards to Abbreviated New Drug Application, or ANDA, proceedings, and the timing, costs and results of such actions and ANDA proceedings;
- expectations regarding reimbursement for Intermezzo in the United States;
- expectations with respect to our intent and ability to successfully and profitably carry out plans to co-promote Intermezzo to psychiatrists in the United States through our co-promotion option under the Collaboration Agreement;
- the potential benefits of, and markets for, Intermezzo and any future products or product candidates;
- potential competitors and competitive products, including generic manufacturers;
- expectations with respect to our intent and ability to successfully enter into other collaboration or co-promotion arrangements;
- expectations regarding our ability to obtain regulatory approval of Intermezzo outside of the United States;
- the adequacy of our current cash, cash equivalents and marketable securities to fund our operations for at least the next twelve months;
- capital requirements and our need for additional financing;
- expectations regarding future losses, costs, expenses, expenditures and cash flows;
- the ability and degree to which we may obtain and maintain market exclusivity from the U.S. Food and Drug Administration, or FDA, for Intermezzo and any future product candidates under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or FFDCA;
- our ability to maintain and obtain additional patent protection for Intermezzo without violating the intellectual property rights of others;
- the period over which we expect to offset against revenue the $10.0 million contribution related to the direct-to-consumer advertising campaign led by Purdue Pharma;
- our expectations regarding issuances of patents from any currently pending or future patent applications;
- expected future sources of revenue and capital; and
- our expectations regarding the use of proceeds from our recent public offering of common stock.

Forward-looking statements do not reflect the potential impact of any future in-licensing, collaborations, acquisitions, mergers, dispositions, joint ventures, or investments we may enter into or make. Except as required by law, we undertake no obligation to, and expressly disclaim any obligation to, revise or update the forward-looking statements made herein or the risk factors whether as a result of new information, future events or otherwise. Forward-looking statements involve risks and uncertainties, which are more fully discussed in the “Risk Factors” section and elsewhere in this Annual Report on Form 10-K, including, but not limited to, those risks and uncertainties relating to:

- potential termination of the Collaboration Agreement by Purdue Pharma ;

- physician or patient reluctance to use Intermezzo;
- our ability to identify and finance additional products for in-licensing or acquisition, and the ability of those products to be accretive to our earnings;
- the potential for delays in or the inability to complete commercial partnership relationships, including additional marketing alliances for Intermezzo outside the United States;
- unexpected results from and/or additional costs related to ANDA proceedings;
- changing standards of care and the introduction of products by competitors that could reduce our royalty rates under the Collaboration Agreement, or alternative therapies for the treatment of indications we target;
- generic equivalents to Intermezzo whose introduction would reduce royalty rates under the Collaboration Agreement;
- our inability to obtain additional financing, if available, under favorable terms, if necessary;
- difficulties or delays in building a sales and marketing organization in connection with any exercise of our co-promote option to psychiatrists under the Collaboration Agreement;
- our inability to operate any sales and marketing organization profitably in connection with any exercise of our co-promote option to psychiatrists under the Collaboration Agreement;
- unexpected adverse side effects or inadequate therapeutic efficacy of our product candidates that could slow or prevent product approval or approval for particular indications;
- other difficulties or delays in development, testing, obtaining regulatory approvals for, and undertaking production and marketing of Intermezzo and our other product candidates;
- the uncertainty of protection for our intellectual property, through patents, trade secrets or otherwise; and
- potential infringement of the intellectual property rights or trade secrets of third parties.

Transcept Pharmaceuticals, Inc.™ is a registered and unregistered trademark of ours in the United States and other jurisdictions. Intermezzo® is a registered and unregistered trademark of Purdue Pharma and associated companies in the United States and other jurisdictions and is a registered and unregistered trademark of ours in certain other jurisdictions. Other trademarks and trade names referred to in this Annual Report on Form 10-K are the property of their respective owners.

PART I

Item 1. Business

Overview

We are a specialty pharmaceutical company focused on the development and commercialization of proprietary products that address important therapeutic needs in the field of neuroscience. In November 2011, the U.S. Food and Drug Administration, or FDA, approved our New Drug Application, or NDA, for Intermezzo® (zolpidem tartrate) sublingual tablet C-IV for use as needed for the treatment of insomnia when a middle-of-the-night awakening is followed by difficulty returning to sleep. Intermezzo, a prescription product, was made commercially available in the United States in April 2012.

In July 2009, we entered into a United States License and Collaboration Agreement, or the Collaboration Agreement, with Purdue Pharmaceutical Products L.P., or Purdue Pharma, which provides Purdue Pharma with an exclusive license to commercialize Intermezzo in the United States. We granted Purdue Pharma and an associated company the right to negotiate for the commercialization of Intermezzo in Mexico and Canada, and retained rights to commercialize Intermezzo in the rest of the world. The Collaboration Agreement also provides us an option to begin co-promoting Intermezzo to psychiatrists in the United States as late as 55 months after commercial launch, or November 2016. We retain full rights to Intermezzo outside North America and plan to develop and market Intermezzo in major markets outside the United States through alliances with one or more development and marketing partners.

Purdue Pharma is obligated to pay us tiered base royalties on net sales of Intermezzo in the United States ranging from the mid-teens up to the mid-twenty-percent level, and we are eligible to receive up to an additional $70 million in net sales based milestone payments. The Collaboration Agreement also provides us the option to co-promote Intermezzo to psychiatrists in the United States. If we exercise this option and begin marketing to psychiatrists, Purdue Pharma will be obligated to pay us an additional royalty on sales of Intermezzo to psychiatrists. The rate of this additional co-promote royalty ranges from 40% to 22% and would be fixed at the time we begin our specialty marketing effort.

In November 2012, we announced that Purdue Pharma plans to broaden its Intermezzo commercialization efforts. As part of this effort, Purdue initiated a direct-to-consumer (DTC) advertising campaign to which it contributed approximately $19 million and we committed approximately $10 million. This $29 million program began with print and digital advertisements in November 2012 and television advertisements in January 2013, and will be executed primarily during the first six months of 2013. In addition, in January 2013 Purdue Pharma began utilizing its analgesic sales force as part of the overall Intermezzo commercialization effort. The total sales force currently consists of approximately 615 sales representatives, including approximately 525 analgesic sales representatives joined by an additional approximately 90 contract sales representatives that are dedicated exclusively to the promotion of Intermezzo.

In December 2012, we announced that a Phase 2 clinical trial of TO-2061, an investigational product for adjunctive therapy in patients with obsessive compulsive disorder and our only product candidate in active clinical development, did not meet its primary endpoint. Based on this result, we have discontinued the clinical development of TO-2061.

As we evaluate the impact of DTC advertising on physician and patient awareness of Intermezzo, our key business objectives will be to continue to support the launch of Intermezzo in the United States, build a pipeline of proprietary products through internal development efforts and through business and corporate development activities, and continue to position Transcept to address unmet medical needs in the field of neuroscience.

Intermezzo® (zolpidem tartrate) sublingual tablet C-IV

Our first approved product, Intermezzo (zolpidem tartrate) sublingual tablet, is a sublingual formulation of zolpidem approved for use as needed for the treatment of insomnia when a middle-of-the-night awakening is followed by difficulty returning to sleep. Intermezzo is the first and only sleep aid approved by the FDA for this indication.

Intermezzo is formulated as a sublingual tablet containing a bicarbonate-carbonate buffer and is rapidly absorbed in both women and men. The recommended and maximum dose of Intermezzo is 1.75 mg for women and 3.5 mg for men, taken once per night. The recommended doses for women and men are different because women clear zolpidem from the body at a slower rate than men. Intermezzo is to be taken in bed when a patient wakes in the middle of the night and has difficulty returning to sleep. Intermezzo should only be taken if the patient has at least 4 hours of bedtime remaining before the planned time of waking.

Intermezzo was studied in two Phase 3 clinical trials involving more than 370 patients. In these studies, patients taking Intermezzo required less time to fall back to sleep after waking compared to people taking placebo. Intermezzo was also

studied in a highway driving safety study to evaluate the effects of middle-of-the-night administration of Intermezzo on next-morning driving performance.

Intermezzo is the first and only sleep aid approved specifically for use in the middle of the night at the time that patients awaken and have difficulty returning to sleep. Intermezzo has been uniquely designed for this indication and employs the following product features:

- *Known active agent.* The active pharmaceutical ingredient in Intermezzo is zolpidem tartrate, cited by IMS Health as the most commonly prescribed agent for the treatment of insomnia in the United States, with over 1.39 billion zolpidem tablets prescribed in the United States for the twelve months ended December 31, 2012. Approved in 1992 as the active ingredient in Ambien ®, a branded prescription sleep aid, zolpidem has a well established record of safety and efficacy.
- *Rapid absorption.* Intermezzo disintegrates in the sublingual cavity after administration. On average, Intermezzo is rapidly absorbed in both genders, with a mean Tmax across studies of about 35 minutes to about 75 minutes. We believe that rapid absorption, the delivery of the active pharmaceutical ingredient into systemic circulation, is a key product feature **.**
- *Dose.* The recommended dose of Intermezzo in women and in elderly patients is 1.75 mg, and the recommended dose in men is 3.5 mg . Intermezzo is indicated for use as needed for the treatment of insomnia when a middle-of-the-night awakening is followed by difficulty returning to sleep. Intermezzo should only be taken if the patient has at least 4 hours of bedtime remaining before the planned time of waking.

  Ambien® and its generic equivalents are available in doses of 5 mg and 10 mg. Ambien CR ® and its generic equivalents are available in doses of 6.25 mg and 12.5 mg. Each of these products is intended to be taken only at the beginning of the night in order to fall and stay asleep throughout the night, and is not appropriate to be taken in the middle of the night when a patient has only 4 hours of bedtime remaining. In January 2013, the FDA issued a new safety warning that may result in a change in the recommended doses for women of these and other bedtime zolpidem products. This FDA safety warning specifically states that the dose recommendations for Intermezzo were not affected.

Our financial performance and profitability

We have incurred net losses since inception as we have devoted substantially all of our resources to research and development, including contract manufacturing and clinical trials, and the administrative functions needed to support these efforts. As of December 31, 2012, we had cash, cash equivalents and marketable securities of approximately $85.3 million, working capital of approximately $92.3 million, and an accumulated deficit of approximately $112.1 million.

Our ability to generate near term revenue is dependent upon the receipt of milestone and royalty payments under our Collaboration Agreement with Purdue Pharma. Please see “Risk Factors” below for a discussion of risks related to our dependence on Purdue Pharma and the uncertainty of future revenue.

Our business strategy

Our goal is to become a leading developer and marketer of pharmaceutical products that fill important therapeutic needs in the field of neuroscience. Our efforts to achieve this goal are driven by the following key strategies:

- *Support Purdue Pharma to create Intermezzo awareness among physicians and patients.* Our U.S. marketing partner, Purdue Pharma, launched Intermezzo in April 2012. In November 2012, we and Purdue Pharma announced a broadened Intermezzo commercialization plan which utilizes the Purdue Pharma analgesic sales force of approximately 525 sales representatives and an Intermezzo-only contract sales force of approximately 90 sales representatives. This selling effort is supported by a $29 million direct to consumer (DTC) advertising campaign to be executed primarily during the first six months of 2013. We contributed $10.0 million to this DTC advertising campaign.
- *Evaluate Intermezzo prescription trends and assess whether we should exercise our option to co-promote Intermezzo to psychiatrists.* Under the terms of the Collaboration Agreement, Purdue Pharma will pay us a tiered base royalty on U.S. net sales of Intermezzo that ranges from the mid-teens to the mid-20% level. The base royalty is tiered according to the achievement of certain fixed net sales thresholds by Purdue Pharma, which net sales levels reset each year for the purpose of calculating the royalty. If we elect to exercise our co-promote option, we are entitled to receive an additional co-promote royalty from Purdue Pharma on net revenue that is generated by psychiatrist prescriptions.

- *Maximize the market opportunity for Intermezzo through marketing alliances.* We have retained rights to commercialize Intermezzo in the rest of the world and have an effort underway to enter into one or more development and marketing alliances with established pharmaceutical companies in major markets outside the United States.
- *Develop an internal product pipeline to address unmet needs in the field of neuroscience.* We are evaluating the development of internally generated product concepts that fulfill unmet needs in the field of neuroscience.
- *Identify and evaluate strategic product licensing opportunities.* We are seeking additional development stage and marketed pharmaceutical product licensing opportunities to leverage the specialty marketing infrastructure that we plan to build in support of Intermezzo . The identification and licensing of such a product could be an important factor in our decision to exercise the psychiatry co-promote option with Purdue Pharma.

The *Intermezzo* Opportunity

Overview of the insomnia market

According to IMS Health, an independent market research firm, the number of prescriptions filled in the United States to treat insomnia grew to approximately 83 million for the twelve months ended December 31, 2012.

Middle-of-the-night awakening: the most common insomnia symptom

The 2003 National Sleep Foundation, or NSF, "Sleep in America" poll of the United States population between the ages of 55 and 84 described waking up during the night as the most prevalent insomnia symptom, affecting 33% of respondents. Based on the 2005 NSF poll data, we estimate that middle-of-the-night awakening is 50% more common than difficulty going to sleep at bedtime among the general population. The 2009 NSF poll found that 46% of respondents described being "awake a lot during the night."

Based on a study published in 2009 of nearly 9,000 individuals, the Stanford Sleep Epidemiology Research Center has estimated that about one-third of adults in the United States experience middle-of-the-night awakenings at least three times each week. The study concluded that more than 90% of those subjects who reported middle-of-the-night awakenings reported that this insomnia symptom persisted for at least six months. In the Stanford study, fewer than 25% of this middle-of-the-night awakening group reported difficulty going to sleep at bedtime.

Data from a study published in *Population Health Management* in 2010, based on information from the United States National Health and Wellness Survey to evaluate the economic and humanistic burden of chronic insomnia characterized by nighttime awakenings, indicate that this condition was associated with a significant negative impact in health care utilization, health-related quality of life and work productivity.

Commonly prescribed sleep aids

The most commonly prescribed sleep aids are recommended for bedtime use only. These sleep aids are formulated with doses of an active pharmaceutical ingredient such that they require patients to remain in bed for seven to eight hours to avoid the risks associated with next day residual effects. The prolonged duration of seven to eight hour sleep aids makes them unsuitable for administration in the middle of the night when an awakening occurs, as this would increase the risk of residual sedative effects the following day.

Middle-of-the-night awakenings typically do not occur every night, thus bedtime use of a high dose sleep aid to prevent an awakening requires that the patient either predict which night an awakening might occur, or take a seven to eight hour product every night. The result is that patients may use their sleep aid more often than necessary, and at a higher dose than necessary, as compared to a rapidly absorbed, low dose sleep aid that is designed to be used only on the nights and at the time that an awakening actually occurs.

Commercialization

Intermezzo collaboration with Purdue Pharma in the United States

In July 2009, we entered into the Collaboration Agreement with Purdue Pharma that grants an exclusive license to Purdue Pharma to commercialize Intermezzo in the United States and pursuant to which:

- Purdue Pharma paid us a $25.0 million non-refundable license fee in August 2009;

- Purdue Pharma paid us a $10.0 million non-refundable intellectual property milestone in December 2011 when the first of two issued formulation patents was listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or Orange Book;
- Purdue Pharma paid us a $10.0 million non-refundable intellectual property milestone in August 2012 when the first of two issued patents with claims directed to methods of treating middle-of-the-night insomnia with low doses of zolpidem was listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or Orange Book;
- We have transferred the Intermezzo NDA to Purdue Pharma, and Purdue Pharma is obligated to assume the expense associated with maintaining the NDA and further development of Intermezzo in the United States, including any expense associated with post-approval studies;
- Purdue Pharma is obligated to commercialize Intermezzo in the United States at its expense using commercially reasonable efforts;
- Purdue Pharma is obligated to pay us tiered base royalties on net sales of Intermezzo in the United States ranging from the mid-teens up to the mid-20% level. The base royalty is tiered depending upon the achievement of certain fixed net sales thresholds by Purdue Pharma, which net sales levels reset each year for the purpose of calculating the royalty;
- Purdue Pharma is obligated to pay us up to an additional $70.0 million upon the achievement of certain net sales targets for Intermezzo in the United States.

We have retained an option to co-promote Intermezzo to psychiatrists in the United States. The option can be exercised as late as August 2015. We may begin promotion to psychiatrists 8 to 15 months after option exercise. The exact timing of when we begin promoting to psychiatrists is determined by the calendar month in which the option exercise notice is delivered to Purdue Pharma. If we exercise the co-promote option and enter the marketplace, we are entitled to receive an additional co-promote royalty from Purdue Pharma on net sales that are generated by psychiatrist prescriptions. Had we chosen to exercise the option as soon as we were eligible, we could have begun promoting to psychiatrists in May 2013 and received a co-promote royalty of 40%. The co-promote royalty rate declines on a straight-line basis to approximately 22% if we do not begin promoting to psychiatrists until November 2016, at which time the right to co-promote expires. Net sales qualifying for this additional co-promote royalty are limited by an annual cap of 15% of total Intermezzo annual net sales in the United States. The co-promote option cannot be transferred to a third party, except under a limited circumstance at the discretion of Purdue Pharma.

Under the Collaboration Agreement, Purdue Pharma shall be responsible for the manufacture of Intermezzo for commercialization in the United States. We and Purdue Pharma share responsibility for the cost of defending against product liability and related claims, and have agreed to allocate any losses for such claims on a comparative fault basis but, in the absence of such determination, have agreed to split such losses equally. We and Purdue Pharma are also responsible for 40% and 60%, respectively, of costs relating to enforcement of our intellectual property initiated by Purdue Pharma under the Collaboration Agreement, with an aggregate cap on our expenses of $1 million per calendar year and $4 million for the term of the agreement.

Purdue Pharma has the right to terminate the Collaboration Agreement at any time upon advance notice of 180 days. Our co-promote option may also be terminated by Purdue Pharma upon our acquisition by a third party or in the event of entry of generic competition to Intermezzo. The royalty payments discussed above are subject to reduction in connection with, among other things, the entry of generic competition to Intermezzo. The Collaboration Agreement expires on the later of 15 years from the date of first commercial sale in the United States or the expiration of patent claims related to Intermezzo. The Collaboration Agreement is also subject to termination by Purdue Pharma in the event of FDA or governmental action that materially impairs Purdue Pharma's ability to commercialize Intermezzo or the occurrence of a serious event with respect to the safety of Intermezzo. The Collaboration Agreement may also be terminated by us upon Purdue Pharma commencing an action that challenges the validity of Intermezzo related patents. We also have the right to terminate the Collaboration Agreement immediately if Purdue Pharma is excluded from participation in federal healthcare programs. The Collaboration Agreement may also be terminated by either party in the event of a material breach by or insolvency of the other party.

Sales and marketing

Purdue Pharma launched Intermezzo in the United States in April 2012. In November 2012, we announced that Purdue Pharma plans to broaden its Intermezzo commercialization efforts. As part of this effort, Purdue initiated a DTC advertising campaign to which it contributed approximately $19 million and we committed approximately $10 million. This $29 million program began with print and digital advertisements in November 2012 and television advertisements in January 2013, and will be executed primarily during the first six months of 2013. In addition, in January 2013 Purdue Pharma began utilizing its

analgesic sales force as part of the overall Intermezzo commercialization effort. This sales force consists of approximately 525 sales representatives and will be joined by an additional approximately 90 contract sales representatives that are dedicated exclusively to the promotion of Intermezzo.

Intermezzo commercialization outside the United States

Pursuant to the Collaboration Agreement, we granted Purdue Pharma and an associated company the right to negotiate for the commercialization of Intermezzo in Mexico and Canada, respectively, and retained rights to commercialize Intermezzo in the rest of the world. We plan to enter into one or more development and marketing alliances to develop and commercialize Intermezzo with established pharmaceutical companies in major markets outside the United States.

We have not yet applied for regulatory approval to sell Intermezzo in any country other than the United States, and believe we may need to conduct successful additional clinical trials in certain jurisdictions before we could obtain such approval. We currently plan to market and sell our products that receive regulatory approval outside the United States through pharmaceutical companies that are established in their respective markets.

In-Licensing and Exploratory Product Development

We are also seeking, through internal product development and external business development activities, additional product opportunities that can be of importance in the field of neuroscience. We have an in-licensing effort underway to identify and secure licenses to patents and development rights relating to the use of existing drugs in the field of neuroscience.

Competition

Intermezzo competes against well-established products currently used in the treatment of insomnia, both branded and generic. Competitive products include generic formulations of zolpidem available from multiple manufacturers, branded formulations of zolpidem, such as Ambien ® and Ambien CR® marketed by sanofi-aventis, Lunesta® marketed by Sunovion Pharmaceuticals Inc., a subsidiary of Dainippon-Sumitomo Pharma Co., Ltd., Rozerem ® marketed by Takeda Pharmaceuticals Company Limited, Sonata® marketed by King Pharmaceuticals, Inc. and generic forms of this product, Silenor ®, a product developed by Somaxon Pharmaceuticals, Inc. which is being acquired by Pernix Therapeutics Holdings, Inc., and a number of other pharmaceutical agents, including antidepressants and antipsychotics, that are prescribed off-label. None of the currently marketed sleep aids that have FDA approval are specifically approved for use as needed for the treatment of insomnia when a middle-of-the-night awakening is followed by difficulty returning to sleep. However, many of these products can be used to prevent middle-of-the-night awakenings by prophylactic use at bedtime.

The market for prescription sleep products has evolved significantly over the last 30 years. Until about 30 years ago, the market was dominated by barbiturate sedative-hypnotics such as Seconal® and Nembutal®. These were superseded by the benzodiazepine class of sedative-hypnotics including Dalmane®, Restoril™ and Halcion®. Zolpidem, which is a selective modulator of $GABA_A$ receptor and is a member of the non-benzodiazepine class of sleep aids, was introduced in the United States in 1993 under the Ambien® brand for the treatment of sleep onset insomnia at 10 mg for non-elderly adult use and 5 mg for elderly use, and, according to Wolters Kluwer, rapidly achieved the dominant position in the prescription sleep aid market. An extended release version of zolpidem was launched successfully as Ambien CR® in 2005. The patent for Ambien® expired in April 2007, and shortly thereafter the FDA approved the generic manufacture of zolpidem by multiple pharmaceutical companies. The FDA approved the generic manufacture of zolpidem extended release 6.25 mg in October 2010 and zolpidem extended release 12.5 mg in June 2011. In January 2013, the FDA reduced the recommended dose of zolpidem at bedtime for women from 10 mg to 5 mg for immediate-release products such as Ambien and its generic equivalents, and from 12.5 mg to 6.25 mg for extended-release products such as Ambien CR and its generic equivalents. The FDA also informed manufacturers of zolpidem-based bedtime prescription sleep aids that, for men, the labeling should recommend that health care professionals consider prescribing the lower doses 5 mg for immediate-release products and 6.25 mg for extended-release products. This FDA safety warning did not affect Intermezzo.

According to IMS Health, an independent market research firm, the number of generic zolpidem prescriptions filled in the United States to treat insomnia accounted for approximately 43% of the U.S. prescription market for sleep aids during the twelve months ended September 2011. Over 1.2 billion branded and generic zolpidem tablets were prescribed in the United States during this period. The pricing of generically manufactured zolpidem is significantly lower than branded formulations of zolpidem and other non-generic sleep aids.

Other branded prescription sleep aids include Lunesta® (eszopiclone), which was approved in December 2004 by the FDA and launched in the first quarter of 2005, and Rozerem® (ramelteon). According to IMS Health, in October 2011, Lunesta® held a 5.5% U.S. prescription market share and Rozerem® held a 0.5% U.S. prescription market share. Edluar™, a sublingual tablet containing zolpidem for which Orexo AB received marketing approval in March 2009, was launched in the U.S. market by Meda Pharmaceuticals, Inc. in September 2009. Zolpimist ™, an orally administered spray containing zolpidem,

received marketing approval from the FDA in December 2008, and was launched by ECR Pharmaceuticals Company, Inc., a wholly-owned subsidiary of Hi-Tech Pharmacal Co., Inc., in February 2011. Edluar™ and Zolpimist™ employ the same 10 mg and 5 mg zolpidem doses as generic Ambien ® and are designed to be used in the same manner at bedtime to promote sleep onset. In March 2010, Somaxon Pharmaceuticals, Inc. which is in the process of being acquired by Pernix Therapeutics Holdings, Inc. announced FDA approval of Silenor ®, a low dose doxepin formulation intended for use at bedtime for the treatment of both transient (short term) and chronic (long term) insomnia characterized by difficulty with sleep maintenance in both adults and elderly patients. In September 2010, Somaxon announced that Silenor ® was commercially available in the United States.

A number of other agents are used to treat insomnia. These include Sonata ®, a short-acting sleep aid, which lost patent protection in June 2008. Although not approved or promoted for the treatment of middle-of-the-night awakenings, some physicians prescribe Sonata ® off-label for this purpose. There are also a number of other pharmaceutical agents including antidepressants and antipsychotics that are not approved for the treatment of insomnia but are frequently prescribed off-label owing to their ancillary sedative effects. For example, the antidepressant generic trazodone is widely prescribed off-label for the treatment of insomnia.

In addition to current products for the treatment of insomnia, a number of new prescription products may enter the insomnia market over the next several years. These may include the following:

- Suvorexant, an orexin receptor antagonist, is being developed by Merck & Co., Inc. for the treatment of insomnia. Merck announced in November 2012 that the New Drug Application for MK-4305 was accepted for standard review by the U.S. Food and Drug Administration.
- Tasimelteon (VEC-162), a melatonin agonist being developed by Vanda Pharmaceuticals Inc., received an orphan designation from the FDA in January 2010 for treatment of non-24 hour sleep/wake disorder in blind individuals without light perception. In December 2012, Vanda announced that it plans to submit an NDA for tasimelteon to the FDA in mid-2013.
- NovaDel Pharma, Inc. states on its company website that a low-dose version of Zolpimist™ for the treatment of middle-of-the-night awakenings is in development.
- SKP-1041, a controlled-release zaleplon formulation, is being developed by Somnus Therapeutics Inc. targeting treatment of middle-of-the-night awakenings with a formulation that is administered at bed time. According to a notice posted on www.clinicaltrials.gov, a Phase 2 study of SKP-1041 was completed in December 2010.
- AZ-007, Staccato zaleplon, an inhaled version of zaleplon, is being developed by Alexza Pharmaceuticals, Inc. for the treatment of insomnia. Alexza completed a Phase 1 trial of AZ-007 in 2008 and has commented publicly that they are evaluating AZ-007 for its suitability to treat middle-of-the-night awakenings. AZ-007 incorporates a vaporization technology developed by Alexza.

There are a variety of other drugs intended as sleep aids under earlier stages of development. With the exceptions of a possible new formulation of Zolpimist™ and AZ-007, as noted above, we believe that all of these product candidates are intended to be taken at bedtime, and are not being developed for the as-needed treatment of middle-of-the-night awakenings at the time they occur.

Manufacturing

We do not have or intend to develop internal clinical supply or commercial manufacturing capabilities for Intermezzo, or other product candidates. In connection with entering into the Collaboration Agreement with Purdue Pharma, we amended our existing supply agreements for Intermezzo to be effective upon notice to suppliers that the NDA for Intermezzo has been transferred from us to Purdue Pharma. These amendments, which became effective in December 2011, allowed Purdue Pharma to enter into direct supply agreements with such manufacturers for Intermezzo supplied and sold in the United States. Accordingly, Purdue Pharma has entered into agreements with respect to the U.S. territory with certain manufacturers and suppliers. We also have retained our agreements with several of the same manufacturers and suppliers; however, following the effectiveness of the amendments to these agreements, our supply agreements are limited to the manufacture and supply of Intermezzo outside of the U.S. territory. While our goal is to commercialize Intermezzo outside the U.S. territory with the assistance of one or more marketing partners, we have no plans to make use of such manufacturing and supply arrangements in the near future. In connection with a termination of the Collaboration Agreement, the amendments to supply agreements implementing the territory changes will also terminate, and all supply arrangements for the U.S. territory return to us.

We have a primary manufacturing and supply agreement with Patheon, Inc., or Patheon, to manufacture a supply of Intermezzo for use outside the United States, and Purdue Pharma has entered into an agreement with Patheon to manufacture and supply Intermezzo for use in the United States. We and Purdue Pharma currently have arrangements to use Sharp

Corporation as a primary packager of Intermezzo. Purdue Pharma relies upon SPI Pharma, Inc., or SPI Pharma, as a supplier for certain key excipients contained within Intermezzo and as the sole supplier for one such excipient, Pharmaburst ®. If we obtain approval to sell Intermezzo outside the U.S. territory, we would likely also rely on SPI Pharma as a supplier for the same excipients. In addition, Purdue Pharma relies upon Teva Pharmaceutical Industries Ltd., API Division (formerly Plantex USA, Inc.), or Teva API, as the sole source for a special form of zolpidem tartrate, which is the active pharmaceutical ingredient of Intermezzo. Purdue Pharma is dependent upon these manufacturers for the commercial supply of Intermezzo in the United States. Should any of these key suppliers fail to perform under the terms of their respective agreements, it could have a significant impact on Purdue Pharma's commercialization efforts for Intermezzo and our ability to generate revenue under the Collaboration Agreement. In the event we commercialize Intermezzo outside the U.S. territory, we would likely also rely on many of the same key manufacturers and suppliers as Purdue Pharma intends to use to commercialize Intermezzo in the U.S. territory.

All of these supply and manufacturing agreements contain customary commercial terms for pharmaceutical companies regarding forecasting, payment, pricing, ordering, current good manufacturing practices, or cGMP, compliance and quality. All such agreements provide for payment for supplies within 30 days of being invoiced upon their shipment. Other than the agreements with Sharp and Patheon, all agreements set forth four quarters of forecasting, with the first such quarter's forecast being a binding firm order. The agreements with Sharp and Patheon contain similar forecasting provisions, except that the Sharp agreement sets forth a 12-month rolling forecast, with the first three months of such forecast being a binding firm order, and the Patheon agreement sets forth 18-month, non-binding forecasting, but with a requirement that firm orders be separately placed three months prior to expected delivery. There are no alternate manufacturers qualified at this time with respect to the commercial supply of Intermezzo, nor are there alternate manufacturers identified or qualified with respect to the commercial supply of several of the key ingredients and packaging materials used in Intermezzo. If manufacturers are required to be changed, prior approval by the FDA and comparable foreign regulators would be required and Purdue Pharma would likely incur significant costs and expend significant efforts to educate the new manufacturer with respect to, or to help the new manufacturer independently develop, the processes necessary for production. If we exercise our right to co-promote Intermezzo to psychiatrists, we may also incur such costs and expend such efforts to ensure commercial supply of Intermezzo. Manufacturing and supply switching costs in the pharmaceutical industry can be very high, and switching manufacturers or key suppliers can frequently take 12 to 18 months to complete, although in certain circumstances such a switch may be significantly delayed or prevented by regulatory and other factors. Please see “Risk Factors” below for a discussion of our supply and manufacturing risks related to Intermezzo.

Manufacturers and suppliers of Intermezzo are subject to current cGMP requirements, U.S. Drug Enforcement Administration, or DEA, regulations and other rules and regulations prescribed by foreign regulatory authorities. Purdue Pharma, and we through our collaboration with Purdue Pharma, depend on third party suppliers and manufacturers for continued compliance with cGMP requirements and applicable foreign standards.

Government Regulation

Prescription drug products are subject to extensive regulation by the FDA, including regulations that govern the testing, manufacturing, safety, efficacy, labeling, storage, record keeping, distribution, import, export, advertising and promotion of such products under the Federal Food Drug and Cosmetic Act, or FFDCA, and its implementing regulations, and by comparable agencies and laws in foreign countries. Failure to comply with applicable FDA or other regulatory requirements may result in a variety of administrative or judicially imposed sanctions, including FDA refusal to approve pending applications, suspension or termination of clinical trials, warning letters, civil or criminal penalties, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market.

New drug approval

FDA approval is required before any new drug, including a new use or new dosage form of a previously approved drug, can be marketed in the United States. Applications for FDA approval of a new, brand name drug product must contain, among other things, information relating to safety and effectiveness, pharmaceutical formulation, stability, manufacturing, processing, packaging and labeling.

An NDA for a brand name drug product generally requires, among other things:

- completion of extensive preclinical laboratory and animal testing in compliance with FDA good laboratory practice, or GLP, regulations;
- submission to the FDA of an Investigational New Drug, or IND, application to conduct human clinical testing, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug product for each indication;

- satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is produced to assess compliance with FDA's cGMP regulations; and
- submission to and approval by the FDA of an NDA.

The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates or any indications will be granted on a timely basis, if at all.

Preclinical tests include laboratory evaluation of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animals. The results of preclinical tests, together with manufacturing information and analytical data, are submitted as part of an IND to the FDA. The IND automatically becomes effective 30 days after acceptance by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The submission of an IND may not result in FDA authorization to commence a clinical trial. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the study until completed. The FDA, the IRB, or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

For purposes of an NDA submission and approval, human clinical trials are typically conducted in the following four sequential phases, which may overlap:

- *Phase 1:* Studies are initially conducted in a limited population to test the product candidate for initial safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, on occasion, in patients.
- *Phase 2:* Studies are generally conducted in a limited patient population to identify adverse effects and safety risks, to determine initial efficacy of the product for specific targeted indications and to determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain additional information prior to beginning larger, more expensive and time consuming Phase 3 clinical trials. In limited situations, a Phase 2 trial may be accepted by the FDA and serve as one of the pivotal trials in the approval of a product candidate if the study is positive.
- *Phase 3:* These are commonly referred to as pivotal studies. When Phase 2 evaluations demonstrate that a dose range of the product is effective and has an acceptable safety profile, Phase 3 trials are undertaken in larger patient populations in the target indication to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population, often at multiple, geographically dispersed clinical trial sites.
- *Phase 4:* In many cases, the FDA incorporates into the approval of an NDA the sponsor's agreement to conduct additional studies or clinical trials within a specified time period after NDA approval to further assess a drug's safety and effectiveness. The FDA may also exercise its authority to mandate such studies or clinical trials as post-marketing requirements. Such post approval trials are typically referred to as Phase 4 studies.

Controlled clinical trials conducted for our drug candidates must be included in a clinical trials registry and results database that is available and accessible to the public through the internet. Failure to properly satisfy the clinical trial registry and results reporting requirement could result in significant civil monetary penalties.

The submission of an NDA is no guarantee that the FDA will find it complete and accept it for filing. The FDA reviews all NDAs submitted before it accepts them for filing. It may refuse to file the application and instead request additional information, in which case, the application must be resubmitted with the supplemental information. After the application is deemed filed by the FDA, FDA staff will review an NDA to determine, among other things, whether a product is safe and efficacious for its intended use.

In 1992, under the Prescription Drug User Fee Act, or PDUFA, the FDA agreed to specific goals for improving the drug review time and created a two-tiered system of review times-Standard Review and Priority Review. Standard Review is applied to a drug that offers at most, only minor improvement over existing marketed therapies. The 2012 amendments to PDUFA set a goal that for 90% of the NDAs receiving a Standard Review of an NDA, the review be accomplished within a ten month time frame. A Priority Review designation is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. The goal of the FDA for Priority Reviews is to complete 90% of such reviews within six months. The FDA strives to meet these review goals, but is not legally required to do so, and in individual cases may extend the goal date under certain circumstances. The FDA has substantial discretion in the approval process and may disagree with an applicant's interpretation of the data submitted in its NDA. As part of this review, the FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved, but is not bound by

the recommendation of such advisory committee. The FDA may deny approval of an NDA if the applicable regulatory criteria are not satisfied, or it may require additional clinical data or additional pivotal Phase 3 clinical trials.

Under legislation enacted in 2007 that granted significant new powers to the FDA, many of which are aimed at improving the safety of drug products before and after approval, 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. If required, a REMS may include various elements, such as publication of a medication guide, patient package insert, a communication plan to educate healthcare providers of the drug's risks, limitations on who may prescribe or dispense the drug, or other measures that the FDA deems necessary to assure the safe use of the drug.

Once the NDA is approved, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase 4 studies or clinical trials, and surveillance programs to monitor the effect of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are to be any material modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, we will likely be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional and extensive preclinical studies and clinical trials.

Section 505(b)(2) New Drug Applications

As an alternate path to FDA approval for modifications of products previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FFDCA. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act. This statutory provision permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant, and for which the applicant has not obtained a right of reference from the owner of the data. The Hatch-Waxman Act permits the applicant to rely upon the FDA's prior findings of safety and effectiveness of a drug that has obtained FDA approval. In addition to relying on prior FDA findings of safety and effectiveness for a referenced drug product, the FDA may require companies to perform additional preclinical or clinical studies to support approval of the modification to the referenced product. We submitted the NDA for Intermezzo under Section 505(b)(2).

To the extent that a Section 505(b)(2) application relies on a prior FDA finding of safety and effectiveness of a previously approved product, the FDA's ability to give final approval to the 505(b)(2) application may be delayed by any non-patent exclusivity that has been awarded to the referenced drug product. In addition, a 505(b)(2) applicant is required to certify to the FDA concerning any patents listed for the referenced product in the FDA publication titled “Approved Drug Products with Therapeutic Equivalence Evaluations,” or the Orange Book. Specifically, the applicant must certify in the application that, for each patent that claims the drug or a use of the drug for which the applicant is seeking approval:

- there is no patent information listed for the reference drug (known as a Paragraph I certification);
- the listed patent has expired for the reference drug (known as a Paragraph II certification);
- the listed patent for the reference drug has not expired, but will expire on a particular date and approval is sought after patent expiration (known as a Paragraph III certification); or
- the listed patent for the reference drug is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of the product for which the 505(b)(2) NDA is submitted (known as a Paragraph IV certification).

A paragraph III certification, stating that a listed patent has not expired, but will expire on a particular date, may delay the approval of an application submitted under 505(b)(2) until the expiration of the patent. A paragraph IV certification, stating that a listed patent is invalid, unenforceable, or not infringed may require us to notify the patent owner and the holder of the NDA for the referenced product, and may result in patent litigation against us and the entry of a 30 month stay on FDA's ability to issue final approval to our 505(b)(2) NDA.

Under Hatch-Waxman exclusivity, the FDA is precluded from approving an abbreviated new drug application for a generic version of a drug for a period of three years from its date of approval and is precluded from approving a 505(b)(2) application that seeks to reference the FDA's findings of safety and effectiveness for such drug, or otherwise seeks approval of a similar drug product for the same basic conditions of use, for a period of three years from the date of approval. This form of exclusivity may not prevent the FDA from approving an NDA that relies only on its own data.

Manufacturing and other regulatory requirements

With respect to post-market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals, which include, among others, standards for direct-to-consumer advertising, industry-sponsored scientific and educational activities, and promotional activities involving the internet, as well as a

prohibition on off-label promotion. The FDA has very broad enforcement authority under the FFDCA, and failure to abide by these regulations can result in penalties, including the issuance of a warning letter directing entities to correct deviations from FDA standards, a requirement that future advertising and promotional materials must be pre-cleared by the FDA, and state and federal civil and criminal investigations and prosecutions. Numerous other laws, not administered by the FDA, also apply to the promotion of pharmaceuticals, alleged violations of which may also result in state and federal civil and criminal investigation and prosecutions.

We and our contract manufacturers are required to comply with applicable FDA manufacturing requirements contained in the FDA cGMP regulations, which require, among other things, quality control and assurance and maintenance of records and documentation. Manufacturing facilities must meet cGMP requirements to the satisfaction of the FDA and pass a pre-approval inspection before we can use them to manufacture our products. We and our third party manufacturers are also subject to periodic inspections of facilities by the FDA and other authorities, including inspection of the procedures and operations used in the testing and manufacture of our products to assess continued compliance with applicable regulations. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action and civil and criminal penalties. Adverse patient experiences and failure to maintain regulatory compliance could result in additional sanctions, including withdrawal of product approvals.

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our activities. In each of these areas, as above, the FDA and other agencies have broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect on us.

DEA regulation

Zolpidem, the active pharmaceutical ingredient in Intermezzo, is classified as a schedule IV controlled substance by the DEA. As a result, manufacturing of zolpidem is subject to regulation by the DEA. Controlled substances are those drugs that appear on one of five schedules promulgated and administered by the DEA under the Controlled Substances Act, or CSA. Drug substances are scheduled under the CSA when, because of their effects on the central nervous system, they have the potential to be abused and their use may lead to physical or psychological dependence. The CSA governs, among other things, the distribution, record keeping, handling, security, and disposal of controlled substances. We, Purdue Pharma, and our respective key third party suppliers who handle zolpidem must be registered by the DEA in order to engage in these activities, and are subject to periodic and ongoing inspections by the DEA and similar state drug enforcement authorities to assess ongoing compliance with DEA regulations. Any failure by us, Purdue Pharma, or our third party suppliers to comply with these regulations could lead to a variety of sanctions, including the revocation, or a denial of renewal, of DEA registration, injunctions, or civil or criminal penalties and loss of supply.

Third party reimbursement and pricing controls

In the United States and elsewhere, sales of pharmaceutical products depend in significant part on the availability of coverage and reimbursement to providers and the consumer from third party payors, such as government and private insurance plans. Third party payors are increasingly challenging the prices charged for medical products and services. Our products may not be considered cost effective, and coverage and reimbursement may not be available or sufficient to allow sales of our products on a competitive and profitable basis.

In the United States, there have been a number of federal and state proposals to implement governmental pricing control, including the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010, together known as the Affordable Care Act, which are expected to impact our business and operations in ways we cannot currently predict. These changes could significantly influence the purchase of pharmaceutical products, resulting in lower prices and a reduction in product demand.

The number and complexity of both federal and state laws continues to increase, and additional governmental resources are being added to enforce these laws and to prosecute companies and individuals who are believed to be violating them. While it is too early to predict what effect these changes will have on our business, we anticipate that government scrutiny of pharmaceutical sales and marketing practices will continue for the foreseeable future and subject us to the risk of government investigations and enforcement actions.

Medicare

We expect that in the United States many patients who are treated with Intermezzo will be Medicare beneficiaries. The Centers for Medicare and Medicaid Services, or CMS, is the agency that administers Medicare and, at the federal level, administers Medicaid.

Effective January 1, 2006, Congress enacted a prescription drug benefit known as Medicare Part D. CMS contracts with numerous managed care plans and drug benefit plans to deliver this drug benefit. These plans develop formularies that determine which products are covered and what co-pay will apply to covered drugs. Coverage for Intermezzo will be under the Medicare Part D benefits. The plans have considerable discretion in establishing formularies and tiered co-pay structures, negotiating rebates with manufacturers and placing prior authorization and other restrictions on the utilization of specific products, subject to CMS review for discriminatory practices. Additionally, the Affordable Care Act will reduce patient responsibility for the Part D funding gap from 100% in 2010 to 25% in 2020, and requires manufacturers to pay a 50% discount on the negotiated price of branded drugs dispensed to Medicare Part D patients in the coverage gap.

Medicaid

Medicaid is a federal and state entitlement program jointly funded by the federal and state governments that pays for medical assistance for certain individuals and families with low incomes and resources and who meet other eligibility requirements. Medicaid is the largest source of funding for medical and health-related services for the indigent population of the United States.

Pharmaceutical manufacturers, as a condition of having federal funds being made available to pay for the manufacturer's products under Medicaid, must enter into an agreement with the Secretary of the Department of Health and Human Services to participate in the Medicaid Drug Rebate Program. We expect that Purdue Pharma will sign a Medicaid agreement, such that Intermezzo will be eligible for reimbursement under Medicaid and subject to rebates under the Medicaid Drug Rebate Program. Under the Medicaid Drug Rebate Program, as amended through the Affordable Care Act, we are required to pay a rebate based on our Average Manufacturer Price, or AMP, for Intermezzo to each participating state Medicaid program for each unit of product dispensed to Medicaid beneficiaries and reimbursed by Medicaid. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to CMS, the federal agency that administers the Medicaid Drug Rebate Program. Effective March 23, 2010, rebates are also due on the utilization of Medicaid managed care organization.

Several state Medicaid programs have implemented Preferred Drug Lists, or PDLs, for drugs paid for under fee-for-service arrangements and more states may adopt this practice. Products placed on a state Medicaid program's PDL are subject to fewer restrictions on their utilization by Medicaid fee-for-service patients. In states that have adopted PDLs, Purdue Pharma or we may be required to provide substantial supplemental rebates to state Medicaid authorities for fee-for service utilization and potentially for capitated utilization as well in order for Intermezzo to be included on the PDL.

Pharmaceutical manufacturers, as a condition of having federal funds being made available to pay for the manufacturer's products under Medicaid and Medicare Part B, also must enter into an agreement with the Secretary of the Department of Health and Human Services to participate in the 340B Drug Pricing Program, enacted by the Public Health Service, or PHS, Act. Under the 340B program, participating pharmaceutical manufacturers agree to charge statutorily-defined covered entities, such as certain hospitals serving a disproportionate share of low income patients, no more than the 340B “ceiling price” for the manufacturer's covered outpatient drugs.

Federal Supply Schedule pricing program

Federal law requires that for a company to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs, and purchased by PHS 340B eligible entities and certain federal agencies, it also must participate in the Department of Veterans Affairs (VA) Federal Supply Schedule, or FSS, pricing program. Section 603 of the Veteran's Health Care Act of 1992, or VHCA, requires the manufacturer to execute a Master Agreement and Pharmaceutical Pricing Agreement, with the VA under which the manufacturer agrees to make its covered drugs available for federal procurement on a VA Federal Supply Schedule, or FSS, contract to the ” Big Four” federal agencies-the VA; the Department of Defense, or DoD; the Public Health Service, or PHS; and the Coast Guard-at pricing that is capped pursuant to a statutory Federal ceiling price, or FCP, formula. The FCP is based on a weighted-average wholesaler price known as the “non-federal average manufacturer price,” or Non-FAMP.

State Pharmaceutical Assistance Programs

Another source of reimbursement for drug products is state Pharmaceutical Assistance Programs, or SPAPs. Many of these programs were created by states to aid low-income elderly or persons with disabilities who do not qualify for Medicaid. Payment of rebates to these programs is typically a condition of the program's coverage of a manufacturer's product. The manufacturer of a drug would pay rebates to SPAPs to gain coverage as appropriate. If the programs are not considered

qualified programs by CMS, the rebates we provide these entities would not be excluded from our Medicaid best price calculation, potentially increasing our rebate liability under the Medicaid Drug Rebate and PHS 340B programs.

Private insurance reimbursement

Commercial insurers usually offer pharmacy benefits and tend to adopt reimbursement methodologies for a product similar to those adopted by Medicare. If private insurers decide to cover Intermezzo, they will reimburse for the drug in a variety of ways, depending on the insurance plan's policies, employer and benefit manager input and contracts with their physician network.

The continuing efforts of government and third party payors to contain or reduce the costs of health care could decrease the price that we receive for products we may sell, including Intermezzo. In addition, third party insurance coverage may not be available to patients for our products at all, especially in light of the availability of low-cost generic zolpidem therapeutics, regardless of the fact that such products are not designed or approved to treat middle-of-the-night awakenings at the time a patient awakens and has difficulty returning to sleep. Third party payors could also impose conditions that must be met by patients prior to providing coverage for use of our products, such as a prior authorization procedure or “step-edit” system that requires a patient to first utilize a lower price alternative product prior to a higher price product

Intellectual Property and Proprietary Technology

Our success will depend in part on our ability to protect Intermezzo and future products and product candidates by obtaining and maintaining a strong proprietary position both in the United States and in other countries. To develop and maintain our proprietary position, we will rely on patent protection, regulatory protection, trade secrets, know-how, continuing technological innovations and licensing opportunities.

The active pharmaceutical ingredient in Intermezzo, zolpidem, and many of the inactive ingredients, have been known and used for many years. The zolpidem composition of matter is no longer subject to patent protection. Accordingly, our patents and applications are directed to the particular formulations and methods of use of zolpidem. There can be no assurance that our issued patents that cover the compositions and methods of using the buffered formulation of Intermezzo will prevent others from marketing formulations using the same active and inactive ingredients in similar but different formulations for the same indication statement. Issued patents and currently pending patent applications that cover Intermezzo have claims that are directed to both formulation and methods of use and are summarized below:

- *Buffered formulations of zolpidem*. We have two issued U.S. patents that expire no sooner than 2025, one pending U.S. patent application and 14 corresponding foreign patents or applications. Foreign patents have been granted in Australia, China, Japan, Mexico, New Zealand, Singapore, and South Africa.
- *Middle of the night use of zolpidem*. We have two issued U.S. patents that expire no sooner than 2025, one pending U.S. patent application and 15 foreign patents or applications. Patents have been granted in South Africa, New Zealand and Singapore.
- *Applications co-owned with SPI*. We have one pending U.S. patent application, which is co-owned with SPI pursuant to the Supply Agreement between us and SPI, covering the compositions containing a key Intermezzo excipient. Under the Supply Agreement, we have a royalty-free, fully paid-up exclusive license with respect to this patent application, with a right to grant sublicenses, for products incorporating both this key excipient and zolpidem. This license survives the termination of the Supply Agreement.

The patent positions of pharmaceutical companies 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. Consequently, we do not know whether any of our patent applications will result in the issuance of patents or, if any of our issued patents will provide significant proprietary protection or will be circumvented or challenged and found to be unenforceable or invalid. In limited instances, patent applications in the United States and certain other jurisdictions are maintained in secrecy until patents issue, 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. Moreover, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention or in opposition proceedings in a foreign patent office, any of which could result in substantial cost to us, even if the eventual outcome is favorable. There can be no assurance that a court of competent jurisdiction would hold the patents, if issued, valid. 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 such technology. To the extent we determine it to be prudent, we intend to bring litigation against third parties that we believe are infringing our patents.

The Hatch-Waxman Act permits the FDA to approve ANDAs for generic versions of brand name drugs like Intermezzo. Following the commercial launch of Intermezzo in April 2012, we received notifications in July 2012 from three companies, Actavis Elizabeth LLC (Actavis), Watson Laboratories, Inc. - Florida (Watson), and Novel Laboratories, Inc. (Novel), in

September 2012, from each of Par Pharmaceutical, Inc. and Par Formulations Private Ltd. (together, the Par Entities), and in February 2013 from Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (together, Dr. Reddy's) stating that each has filed with the FDA an abbreviated new drug application, or ANDA, that references Intermezzo.

- Actavis & Watson: In the July 2012 notifications, Actavis and Watson indicated that each company's ANDA includes Paragraph IV patent certifications to our U.S. Patent Nos. 7,658,945 (expiring April 15, 2027) and 7,682,628 (expiring February 16, 2025) (together, the "'945 and '628 Patents"). On November 28, 2012, Watson withdrew its ANDA, and, as a result of such withdrawal, on December 18, 2012 Transcept and Purdue agreed to voluntarily dismiss the Action without prejudice and on December 20, 2012 a court order was entered to such effect. The dismissal of Watson's ANDA had no effect on the ANDA filed by Actavis, a wholly owned subsidiary of Watson Pharmaceuticals, Inc. On January 24, 2013, Actavis notified Transcept that it has included Paragraph IV patent certifications to our U.S. Patent Nos. 8,242,131 (expiring August 20, 2029) and 8,252,809 (expiring February 16, 2025) (together, the "'131 and '809 Patents").
- Novel: In the July 2012 notifications, Novel indicated that its ANDA includes Paragraph IV patent certifications to the '945 and '628 Patents. On December 10, 2012, Novel notified Transcept that it has included Paragraph IV patent certifications to the '131 and '809 Patents.
- Par Entities: The ANDAs submitted by the Par Entities each include Paragraph IV patent certifications to the '945, '628, '131 and '809 Patents.
- Dr. Reddy's: The ANDA submitted by Dr Reddy's includes Paragraph IV patent certifications to the '945, '628, '131 and '809 Patents.

In August 2012, September 2012, and October 2012, respectively, we joined Purdue Pharma in filing actions against Actavis, Watson, Novel, the Par Entities, and certain of their affiliates, alleging patent infringement and seeking injunctive and other relief. In December 2012, we and Purdue Pharma agreed to voluntary dismiss the action against Watson following its withdrawal of its ANDA application. After receiving the supplemental notifications referenced above, we and Purdue Pharma amended our pending complaints against Actavis and Novel to also allege infringement of the '131 and '809 patents. We have not filed an action against Dr. Reddy's, and there is no guarantee that we or Purdue Pharma will do so within 45 days of our receipt of Dr. Reddy's notification.

We also rely on trade secret protection for our confidential and proprietary information. 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. However, we believe that the substantial costs and resources required to develop technological innovations will help us protect our products.

We require our employees, consultants and members of our scientific advisory board to execute confidentiality agreements upon the commencement of employment, consulting or collaborative relationships with us. These agreements provide that all confidential information developed or made known during the course of the relationship with us be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions resulting from work performed for us, utilizing the property or relating to our business and conceived or completed by the individual during employment shall be our exclusive property to the extent permitted by applicable law. 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.

Employees

As of March 8, 2013, we had 15 employees, 3 of whom hold Ph.D., Pharm.D., or equivalent degrees. A total of 6 employees were engaged in research and development and 9 were in administration and finance. None of our employees are represented by a labor union or subject to a collective bargaining agreement. We have not experienced any work stoppages and we consider our relations with our employees to be satisfactory.

Merger of Novacea, Inc. and Transcept Pharmaceuticals, Inc.

Transcept Pharmaceuticals, Inc., or Transcept, was incorporated in Delaware in 2001 as Novacea, Inc., or Novacea. Novacea previously traded on The NASDAQ Global Market under the ticker symbol "NOVC." On January 30, 2009, Novacea completed a business combination, or merger, with a privately held company, Transcept Pharmaceuticals, Inc., or TPI, pursuant to which TPI became a wholly-owned subsidiary of Novacea and the corporate name of Novacea was changed to "Transcept Pharmaceuticals, Inc."

Trading of Transcept Pharmaceuticals, Inc. securities on The NASDAQ Global Market under the ticker symbol "TSPT" commenced on February 2, 2009.

In this Annual Report, "Transcept," "the Company," "we," "our" and "us" refer to the public company formerly known as Novacea and now known as Transcept Pharmaceuticals, Inc., and, as successor to the business of TPI, includes activities taking place with respect to the business of TPI prior to the merger of TPI and Novacea, as applicable.

Available Information

Availability of Reports. We are a reporting company under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and file reports, proxy statements and other information with the Securities and Exchange Commission, or SEC. The public may read and copy any of our filings at the SEC's Public Reference Room at 100 F Street N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Because we make filings with the SEC electronically, you may access this information at the SEC's Internet site: www.sec.gov. This site contains reports, proxies and information statements and other information regarding issuers that file electronically with the SEC.

Web Site Access. Our internet web site address is www.transcept.com. We make available, free of charge at the "Investors" portion of our web site, annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Reports of beneficial ownership filed pursuant to Section 16(a) of the Exchange Act are also available on our web site. Information in, or that can be accessed through, this web site is not part 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 risks and uncertainties described below and all information contained in this report before you decide to purchase our common stock. If any of the possible adverse events described below actually occurs, we may be unable to conduct our business as currently planned and our financial condition and operating results could be harmed. In addition, the trading price of our common stock could decline due to the occurrence of any of the events described below, and you may lose all or part of your investment.

We have had a limited operating history that may make it difficult for you to evaluate the potential success of our business and we have a history of incurring losses.

We were founded in January 2001 under our former name, Novacea, Inc., and in January 2009 underwent a merger with Transcept Pharmaceuticals, Inc., a privately held company, or TPI, founded in 2002, which is the primary business we currently conduct. Our operations to date have been limited to organizing and staffing, acquiring, developing and securing technology and undertaking preclinical studies and clinical trials. Furthermore, our business is not profitable and has incurred losses in each year since the inception of TPI in 2002. Our net loss for the years ended December 31, 2012, 2011 and 2010 was $12.0 million, $3.9 million and $9.3 million, respectively. We had an accumulated deficit at December 31, 2012 of $112.1 million.

In November 2011, we obtained regulatory approval for the commercial sale of our lead product candidate, Intermezzo, from the FDA. In April 2012, our U.S. marketing partner, Purdue Pharma, launched Intermezzo. We have not demonstrated over a substantial period of time the ability to meet and adhere to other regulatory standards applicable to an FDA approved product, to conduct sales and marketing activities or to co-promote a product with a collaboration partner, including Purdue Pharma. Consequently, any predictions you make about our future success or viability may not be as accurate as they would be if we had a longer operating history.

We expect to continue to incur losses for the foreseeable future until such time, if ever, that Intermezzo is successfully commercialized by Purdue Pharma and we receive milestone and royalty revenue from our collaboration that exceeds our expenses. For the foreseeable future, we expect our accumulated deficit to increase as we continue our research, development, regulatory, and collaboration efforts with respect to Intermezzo both in support of Purdue Pharma and potential collaboration partners outside North America. If Purdue Pharma does not successfully commercialize Intermezzo, or future product candidates, if any, do not gain regulatory approval and are not commercialized or do not achieve market acceptance, we may not be able to generate any revenue. We cannot assure you that we will ever be profitable or that we can sustain profitability, even if achieved. If we fail to achieve and maintain profitability, or if we are unable to fund our continuing losses, you could lose all or part of your investment.

We are dependent on the commercial success of Intermezzo in the United States for the treatment of middle-of-the-night awakening, which recently became commercially available.

In November 2011, the FDA granted marketing approval for the commercial sale of Intermezzo in the United States for use as-needed for the treatment of insomnia when a middle-of-the-night awakening is followed by difficulty returning to sleep.

In July 2009, we entered into a Collaboration Agreement with Purdue Pharma, which provided Purdue Pharma with the option to commercialize Intermezzo in the United States at its expense. On November 30, 2011, Purdue Pharma notified us that it exercised its option to commercialize Intermezzo and subsequently launched commercial sales of Intermezzo in the United States in April 2012.

In December 2012, we announced that a Phase 2 clinical trial of TO-2061, an investigational product for adjunctive therapy in patients with obsessive compulsive order and our only product candidate in active clinical development did not meet its primary endpoint. Based on these negative results, we have discontinued the clinical development of TO-2061.

Because we do not have another product candidate that has advanced into a pivotal trial or received regulatory approval for commercial sale, our future success is currently dependent on the successful commercialization of Intermezzo in the United States by Purdue Pharma. If Purdue Pharma does not successfully commercialize Intermezzo in the United States, our ability to generate revenue will be jeopardized and, consequently, our business will be seriously harmed.

We are substantially dependent upon the efforts of Purdue Pharma to commercialize Intermezzo in the United States and will be dependent on the efforts of other collaboration partners if we enter into future strategic collaborations.

The success of sales of Intermezzo in the United States is dependent on the ability of Purdue Pharma to successfully commercialize Intermezzo pursuant to the Collaboration Agreement. The terms of the Collaboration Agreement provide that Purdue Pharma can terminate the agreement for any reason at any time upon advance notice of 180 days. For example, Purdue Pharma may find that the commercial potential of Intermezzo is not sufficient to continue pursuing. If the Collaboration Agreement is terminated, our business and our ability to generate revenue from sales of Intermezzo will be substantially harmed and we will be required to develop our own sales and marketing organization or enter into another strategic collaboration in order to commercialize Intermezzo in the United States. We do not currently have the infrastructure in place or adequate resources to launch a commercial product and implementing such infrastructure would require substantial time and resources and such efforts may not be successful.

The manner in which Purdue Pharma commercializes Intermezzo, including the amount and timing of Purdue Pharma's investment in commercial activities and pricing of Intermezzo, will have a significant impact on the ultimate success of Intermezzo in the United States, and the success of the overall commercial arrangement with Purdue Pharma. If the launch and resulting sales of Intermezzo are not deemed successful, our stock price may decline. The outcome of Purdue Pharma's commercialization efforts could also have an effect on investors' perception of potential sales of Intermezzo outside the United States, which could also cause a decline in our stock price and may make it more difficult for us to enter into strategic collaborations outside the United States.

Under the Collaboration Agreement, Purdue Pharma is responsible for conducting post-approval studies of Intermezzo and bears the cost associated with such studies. The planning and execution of these studies, if any, will be primarily the responsibility of Purdue Pharma, and may not be carried out in accordance with our preferences, or could yield results that are detrimental to Purdue Pharma's sales of Intermezzo in the United States or detrimental to our efforts to develop or commercialize Intermezzo outside the United States.

While we plan to enter into one or more additional strategic collaborations for the development and commercialization of Intermezzo outside the United States, we may not be able to enter into these collaborations on acceptable terms, if at all. Our collaboration with Purdue Pharma as our commercial partner for Intermezzo in the United States could also limit the potential collaboration options we have outside the United States or could render potential collaborators less inclined to enter into an agreement with us because of such relationship. Further, we have granted Purdue Pharma and an associated company an option to negotiate with us for a license to commercialize Intermezzo in Mexico and Canada. While these options and subsequent negotiation periods continue, we are prevented from negotiating with and being able to enter into commercialization agreements with other potential strategic partners for the development or commercialization of Intermezzo in such countries.

If we decide to enter into a strategic collaboration covering future product candidates, our ability to receive any significant revenue under such arrangements will be dependent on the efforts of the collaboration partner and may result in lower levels of income than if we marketed or developed our product candidates entirely on our own. Our collaboration partner may not fulfill its obligations or carry out marketing activities for the product candidates as diligently as we would like. We could also become involved in disputes with our collaboration partner, which could lead to delays in or termination of commercialization programs and time-consuming and expensive litigation or arbitration. If a collaboration partner terminates or breaches its agreement, or otherwise fails to complete its obligations in a timely manner, the chances of successfully developing or marketing our product candidates would be materially and adversely affected.

Intermezzo, despite obtaining FDA approval, may never achieve market acceptance, nor may future product candidates, if any, even if regulatory approval for such product candidates is obtained.

Despite obtaining FDA regulatory approval for the commercial sale of Intermezzo, the commercial success of Intermezzo and/or future product candidates, if any, even if regulatory approval is obtained for such candidates, will depend upon, among other things, acceptance by physicians and patients. Market acceptance of, and demand for, any products that we develop and that are commercialized by us or our collaboration partner will depend on many factors, including:

- the effectiveness of our or a collaboration partner's sales, marketing and distribution strategies, including the direct-to-consumer campaign;
- the availability, relative cost and relative efficacy and safety of alternative and competing treatments including the existence of generic or branded competition;
- further expanding managed care access for Intermezzo;
- motivating physicians to identify middle-of-the-night awakenings as an important manifestation of insomnia;
- building awareness among physicians and patients of Intermezzo as the right treatment option;
- the ability to obtain adequate pricing and sufficient insurance coverage and reimbursement;
- building awareness among patients of Intermezzo as a treatment option;
- the ability to provide acceptable evidence of safety and efficacy of Intermezzo or future products for their respective indications;
- the ease of use of Intermezzo; and
- the ability to produce commercial quantities sufficient to meet demand.

If Intermezzo and/or future product candidates fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business.

Intermezzo faces substantial competition from companies with established products.

Intermezzo has been approved for use as-needed for the treatment of insomnia when a middle-of-the-night awakening is followed by difficulty returning to sleep, an indication that we believe represents an opportunity within the broader insomnia therapeutic market. The insomnia market is large, deeply commercialized and characterized by intense competition among generic products and large, established pharmaceutical companies with well-funded, well-staffed and experienced sales and marketing organizations, as well as far greater name recognition than we or Purdue Pharma have.

Intermezzo competes in this large market against well-established branded products with a history of deep market penetration and significant advertising support, as well as with new market entrants and generic competitors selling zolpidem and other sleep aids at a fraction of the price at which Purdue Pharma sells Intermezzo.

Intermezzo is the first sleep aid approved by the FDA specifically for use as needed for the treatment of insomnia when a middle-of-the-night awakening is followed by difficulty returning to sleep. We are not aware of any product candidate that has successfully completed the clinical trials required for approval for such indication. However, currently approved and marketed seven- to eight-hour therapeutics may be prescribed by doctors and used by patients to treat this condition when used to deliver a prophylactic dose of a sleep aid at the beginning of the night.

In 2010, we sponsored an epidemiology study conducted by Dr. Ronald Kessler that sought to quantify the extent of the off-label middle-of-the-night use of seven- to eight-hour sleep aids. The study suggested that approximately 11% of all hypnotic users sometimes take their sleep aid in the middle of the night in order to return to sleep, and that approximately 50% of those hypnotic users who reported middle-of-the-night awakening as their most bothersome insomnia symptom sometimes take their bedtime sleep aid in the middle of the night. Despite the fact that currently available sleep aids are not approved to be taken in the middle of the night, these findings suggest the possibility that some patients may use, or continue to use, these products, or their low cost generic versions, rather than Intermezzo. In addition, anecdotal evidence suggests that some patients currently split low cost generic tablets for off-label use in the middle of the night, despite the fact that these patients have no instruction as to the proper dose or how long they should stay in bed and refrain from driving.

The most widely prescribed prescription sleep aids in the United States are generic forms of Ambien ® and Ambien CR ®, which were originally developed by sanofi-aventis, and are available from multiple generic manufacturers. Edluar ™, a sublingual tablet containing zolpidem, was launched in the U.S. market by Meda Pharmaceuticals, Inc. in September 2009. Zolpimist ™, an orally administered spray containing zolpidem, was launched by ECR Pharmaceuticals Company, Inc., a

wholly-owned subsidiary of Hi-Tech Pharmacal Co., Inc., in February 2011. Edluar™ and Zolpimist™ employ the same 10 mg and 5 mg zolpidem doses as generic Ambien® and are designed to be used in the same manner at bedtime to promote sleep onset.

Lunesta® (eszopiclone), marketed by Sunovion Pharmaceuticals Inc., a subsidiary of Dainippon-Sumitomo Pharma Co. Ltd., and Rozerem ® (ramelteon), marketed by Takeda Pharmaceuticals Company Limited, can similarly treat middle-of-the-night awakenings by providing a prophylactic dose at bedtime in order to avoid a middle-of-the-night awakening. Also, short duration products such as Sonata ®, which uses the active ingredient zaleplon and is marketed by Pfizer, Inc., have been used off-label for the as-needed treatment of middle-of-the-night awakenings. In September 2010, Silenor ® became commercially available in the United States. Silenor® is a low dose version of doxepin intended for use at bedtime for the treatment of both transient (short term) and chronic (long term) insomnia characterized by difficulty with sleep maintenance in both adults and elderly patients. Silenor ® is marketed by Pernix Therapeutics, Inc. Other drugs, such as the antidepressant generic trazodone, are also widely prescribed off-label for the treatment of insomnia.

If Purdue Pharma is unsuccessful in achieving market acceptance for Intermezzo with physicians and patients due to competing products, it would likely have a material adverse effect on our business, results of operations, financial condition and prospects.

We may need to engage in costly, and potentially unsuccessful, litigation to protect our intellectual property from potential generic manufacturers of Intermezzo.

The Hatch-Waxman Act permits the FDA to approve ANDAs for generic versions of brand name drugs like Intermezzo. We refer to this process as the "ANDA process." In brief, the ANDA process permits competitor companies to obtain marketing approval for a drug product with the same active ingredient, dosage form, strength, route of administration, and labeling as the approved brand name drug, but without having to conduct and submit clinical studies to establish the safety and efficacy of the proposed generic product. In place of such clinical studies, an ANDA applicant usually needs only to submit data demonstrating that its product is bioequivalent to the brand name product, usually based on pharmacokinetic studies. Following the commercial launch of Intermezzo in April 2012, companies are able to submit an ANDA application for a generic version of Intermezzo at any time pursuant to the Hatch-Waxman Act.

The Hatch-Waxman Act requires an applicant for a drug product that relies, in whole or in part, on the FDA's prior approval of Intermezzo, to notify us of its application if the applicant is seeking to market its product prior to the expiration of the patents that claim Intermezzo. This notice is required to contain a detailed factual and legal statement explaining the basis for the applicant's opinion that the proposed product does not infringe our patents, that our patents are invalid, or both. Pursuant to the Collaboration Agreement, Purdue Pharma then has the option of bringing a patent infringement suit in federal district court against each company seeking approval for its product within 45 days from the date of receipt of each notice. Pursuant to the Collaboration Agreement, if Purdue Pharma chooses to file a patent infringement suit, we may decide whether to join Purdue Pharma as a named party in such lawsuit, or if Purdue Pharma chooses not to file patent infringement claims within the required 45 days, we may choose to do so on our own behalf. If such a suit is commenced within this 45 day period, we will be entitled to receive a 30 month stay on FDA's ability to give final approval to any of the proposed products that reference Intermezzo. The stay may be shortened or lengthened if either party fails to cooperate in the litigation and it may be terminated if the court decides the case in less than 30 months. If the litigation is resolved in favor of the applicant before the expiration of the 30 month period, the stay will be immediately lifted and the FDA's review of the application may be completed. Such litigation is often time-consuming and costly, and may result in generic competition if such patent(s) are not upheld or if the generic competitor is found not to infringe such patent(s).

In July 2012, we received notifications from three companies, Actavis Elizabeth LLC (Actavis), Watson Laboratories, Inc. - Florida (Watson), and Novel Laboratories, Inc. (Novel), in September 2012 from each of Par Pharmaceutical, Inc. and Par Formulations Private Ltd. (together, the Par Entities), and in February 2013 from Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (together, Dr. Reddy's) stating that each has filed with the FDA an abbreviated new drug application, or ANDA, that references Intermezzo.

- Actavis & Watson: In the July 2012 notifications, Actavis and Watson indicated that each company's ANDA includes Paragraph IV patent certifications to our U.S. Patent Nos. 7,658,945 (expiring April 15, 2027) and 7,682,628 (expiring February 16, 2025) (together, the "'945 and '628 Patents"). On November 28, 2012, Watson withdrew its ANDA, and, as a result of such withdrawal, on December 18, 2012 we and Purdue agreed to voluntarily dismiss the action without prejudice and on December 20, 2012 a court order was entered to such effect. The dismissal of Watson's ANDA had no effect on the ANDA filed by Actavis, a wholly owned subsidiary of Watson Pharmaceuticals, Inc. On January 24, 2013, Actavis notified us that it has included Paragraph IV patent certifications to our U.S. Patent Nos. 8,242,131 (expiring August 20, 2029) and 8,252,809 (expiring February 16, 2025)(together, the "'131 and '809 Patents").

- Novel: In the July 2012 notifications, Novel indicated that its ANDA includes Paragraph IV patent certifications to the '945 and '628 Patents. On December 10, 2012, Novel notified us that it has included Paragraph IV patent certifications to the '131 and '809 Patents.
- Par Entities: The ANDAs submitted by the Par Entities each include Paragraph IV patent certifications to the '945, '628, '131 and '809 Patents.
- Dr. Reddy's: The ANDA submitted by Dr Reddy's includes Paragraph IV patent certifications to the '945, '628, '131 and '809 Patents.

In August 2012, September 2012, and October 2012, respectively, we joined Purdue Pharma in filing actions against Actavis, Watson, Novel, the Par Entities, and certain of their affiliates, alleging patent infringement and seeking injunctive and other relief. After receiving the supplemental notifications referenced above, we and Purdue Pharma amended our pending complaints against Actavis and Novel to also allege infringement of the '131 and '809 patents.

In December 2012, we and Purdue Pharma agreed to voluntary dismiss the action against Watson without prejudice following its withdrawal of its ANDA application on November 28, 2012. On December 20, 2012, a court order was entered to such effect. The dismissal of Watson's ANDA had no effect on the ANDA filed by Actavis, a wholly owned subsidiary of Watson Pharmaceuticals, Inc.

We have not filed an action against Dr. Reddy's, and there is no guarantee that we or Purdue Pharma will do so within 45 days of our receipt of Dr. Reddy's notification.

The filing of the Actavis, Novel, each of the Par Entities', Dr. Reddy's and any future ANDA applications referencing Intermezzo could have an adverse impact on our stock price, and litigation, if any, to enforce our patents is likely to require significant management attention and may require substantial capital resources. If the patents covering Intermezzo are not upheld in litigation or if the generic competitor is found to not infringe these patents, the resulting generic competition for Intermezzo would have a material adverse effect on our revenue and results of operations.

Other companies may develop new products to compete with Intermezzo.

We are aware of several companies that have stated that they intend to develop new products for the treatment of middle-of-the-night awakenings. NovaDel Pharma, Inc. has indicated that it has commenced development of a low-dose version of Zolpimist™ for the treatment of middle-of-the-night awakenings with the intent to enter such product candidate into clinical trials, and Somnus Therapeutics Inc. has indicated that it is similarly targeting treatment of middle-of-the-night awakenings with development of its controlled-release zaleplon formulation that would be dosed at bedtime, SKP-1041. Additionally, Alexza Pharmaceuticals, Inc. is developing AZ-007, immediate release zaleplon, for its ability to treat middle-of-the-night awakenings.

There are many other companies working to develop new products and other therapies to treat insomnia. Several of these products are in late stage clinical trials. In June 2012, Merck and Co., Inc. announced positive Phase 3 data from two pivotal trials of an investigational new drug. Merck filed an NDA with the U.S. Food and Drug Administration in 2012. In January 2010, Vanda Pharmaceuticals Inc. received an orphan drug designation from the FDA for VEC-162 (tasimelteon), a melatonin agonist similar to ramelteon, for treatment of non-24 hour sleep/wake disorder in blind individuals without light perception. Vanda may seek approval for additional, broader insomnia indications for this product candidate. In December 2012, Vanda announced that it plans to submit an NDA for tasimelteon to the FDA in mid-2013.

Furthermore, new developments, including the development of other drug technologies and methods of treating conditions, occur in the biopharmaceutical industry at a rapid pace, and may negatively affect the commercial prospects of Intermezzo.

Many potential competitors, either alone or together with their partners, have substantially greater financial resources, research and development programs, clinical trial and regulatory experience, expertise in prosecution of intellectual property rights, and manufacturing, distribution and sales and marketing capabilities than us and our collaboration partner. As a result of such factors, our competitors may:

- develop product candidates and market products that are less expensive, safer, more effective or easier to use than Intermezzo;
- commercialize competing products, including generic versions of Intermezzo;
- initiate or withstand substantial price competition more successfully than we can;
- have greater success in recruiting skilled scientific workers and experienced sales and marketing personnel from the limited pool of available talent;

- more effectively negotiate third party licenses and strategic collaborations; and
- take advantage of acquisition or other opportunities more readily than us or our collaboration partner.

We may require substantial additional funding and may need to curtail operations if we are unable to raise capital when needed.

We had cash, cash equivalents and marketable securities of $85.3 million at December 31, 2012. We expect our negative cash flows from operations to continue for the foreseeable future as Purdue Pharma attempts to establish Intermezzo as a successful brand in the insomnia category, as we work to establish one or more development and marketing alliances with pharmaceutical companies in major markets outside the United States, and as we seek additional products and product candidates through business development efforts. We will need to generate significant revenue to achieve profitability. We do not know whether or when we will become profitable because of the significant uncertainties with respect to Purdue Pharma's ability to successfully commercialize Intermezzo and, as a result, our ability to generate revenue from sales of Intermezzo and from our existing and potential future collaborations, if any.

If our Collaboration Agreement with Purdue Pharma is terminated or other factors arise, our cash, cash equivalents and marketable securities may prove insufficient to fund our operations through the successful commercialization of Intermezzo. Also, the development and potential regulatory approval of any additional product candidates will likely require additional funding, which may not be available at the time needed on commercially reasonable terms, if at all.

We currently believe that our available cash, cash equivalents and marketable securities and interest income will be sufficient to fund our anticipated levels of operations for at least the next twelve months. However, our future capital requirements will depend on many factors, including:

- the ability of Purdue Pharma to successfully commercialize Intermezzo in the United States;
- whether we choose to share the cost of future advertising or other marketing efforts with Purdue Pharma related to the commercialization of Intermezzo in the United States;
- the cost of establishing or contracting for sales and marketing capabilities if we exercise our option to co-promote Intermezzo to psychiatrists in the United States, and potential costs of being required to engage in contracting to replace Purdue Pharma's primary care sales and marketing capabilities if our existing Collaboration Agreement with Purdue Pharma is terminated;
- the extent to which we develop internally, acquire or in-license new products, technologies or businesses;
- the cost of conducting pre-clinical and clinical trials and other development activities;
- the receipt of milestone and other payments, if any, from Purdue Pharma under the Collaboration Agreement;
- the prospect, cost and timing for the development of Intermezzo to obtain regulatory approval for Intermezzo outside the United States;
- the ability to license Intermezzo outside the United States and the terms and timing of any such licensing arrangements;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, including in connection with ANDA proceedings relating to Intermezzo; and
- the effect of competing technological and market developments.

In addition, we may seek to raise additional funds to:

- develop internally, acquire or in-license new products, technologies or businesses or to otherwise fund our operations;
- establish or contract for sales and marketing capabilities if we exercise our option to co-promote Intermezzo, or to build our own sales force if Purdue Pharma does not continue with our collaboration to commercialize Intermezzo in the United States; and
- support the ongoing promotion of Intermezzo by Purdue Pharma.

There can be no assurance that additional funding, if needed, will be available on attractive terms, or at all. Our failure to raise capital as and when needed may require us to significantly curtail one or more of our development, licensing or acquisition programs, which could have a negative impact on our financial condition and our ability to successfully pursue our business strategy.

If we choose to exercise our co-promotion option and are unable to establish an effective and profitable sales and marketing infrastructure in the United States, our financial performance could be substantially harmed.

In order to commercialize Intermezzo or any other product candidates successfully, we must enter into and maintain strategic collaborations to perform, and/or acquire or internally develop a sales and marketing infrastructure. We have entered into a strategic collaboration for commercialization of Intermezzo in the United States with Purdue Pharma and may develop our own sales force and marketing infrastructure to co-promote Intermezzo to psychiatrists in the United States. If we exercise our co-promotion option and are unable to develop a sales and marketing infrastructure to effectively commercialize Intermezzo, our ability to generate additional revenue from potential sales of Intermezzo to psychiatrists would be substantially harmed. Even if we develop an effective sales and marketing organization, we may not be able to generate sufficient revenue from our additional co-promotion royalties from Purdue Pharma to make that operation profitable during the first several years of operation, or at all.

The development of sales and marketing infrastructure is difficult and time consuming, and requires substantial financial and other resources. Factors that may hinder our efforts to develop an internal sales and marketing infrastructure include:

- the inability to recruit, retain and effectively manage adequate numbers of effective sales and marketing personnel;
- the inability of sales representatives to obtain access to or convince adequate numbers of physicians to prescribe Intermezzo or future products, if approved;
- the lack of complementary products to be offered by sales representatives, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- the abundance of well branded, competing products sold and distributed by large established organizations; and
- unforeseen delays, costs and expenses associated with creating a sales and marketing organization.

We cannot transfer or assign to a third party our option to co-promote Intermezzo to psychiatrists in the United States, except in a limited circumstance at the discretion of Purdue Pharma.

The Collaboration Agreement prohibits the transfer or assignment of our co-promotion option to third parties, except in a limited circumstance at the discretion of Purdue Pharma. The Collaboration Agreement provides that if we have not exercised the co-promote option prior to an acquisition of us or a change in control, the co-promote option will terminate. In the event that we have exercised our co-promote option and have met certain sales criteria, Purdue Pharma maintains full discretion over our ability to transfer or assign the co-promote option to a third party in the event of an acquisition of us or change in control. The Collaboration Agreement also prohibits any transfer or assignment of our co-promote option to a third party, except in the limited circumstance described in the foregoing sentence. The inability to transfer or assign our co-promote option to a third party reduces our flexibility in monetizing the option and may decrease the value of Transcept to potential acquirors.

If we delay exercising our co-promotion option for Intermezzo or commencing co-promotion activities after exercise, the royalties for net sales of Intermezzo that we may receive under the co-promotion option are reduced.

The Collaboration Agreement provides that we can exercise our co-promotion option at any point before or on the last day of the fortieth calendar month (e.g. on or before August 31, 2015) after commercial launch of Intermezzo in the United States, which occurred in early April 2012. The Collaboration Agreement also provides that we cannot begin co-promoting Intermezzo until at least 12 months following the commercial launch of Intermezzo in the United States. In the event that we exercise our co-promotion option in the first four months of a calendar year, we cannot commence co-promotion activities until the first month of the next calendar year. In the event that we exercise our option after the fourth calendar month of the year, we cannot commence co-promotion activities until 15 months from the date we exercise our option. Had we chosen to exercise the option as soon as we were eligible, we could have begun promoting to psychiatrists in May 2013 and received a co-promote royalty of 40%. The co-promote royalty rate declines on a straight-line basis to approximately 22% if we do not begin promoting to psychiatrists until November 2016, at which point our right to co-promote expires. A delay in the exercise of our co-promote option or the commencement of co-promotion activities following exercise of our option will adversely affect the revenue we can generate pursuant to our co-promotion right.

If we fail to acquire, develop and commercialize additional product candidates or approved products, we may be unable to grow our business.

As part of our growth strategy we intend to seek to expand our product pipeline by exploring the in-licensing, acquisition, development and commercialization of product candidates and approved products in the field of neuroscience. As a result of

the failure of TO-2061 to meet the primary endpoint in our Phase 2 study, we do not currently have a product candidate in clinical development. Further, because our internal research and development capabilities are limited, and because new product approvals can take many years, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify and select promising product candidates and approved products, negotiate licensing or acquisition agreements with their current owners and finance these arrangements, including via collaboration and development arrangements with third parties.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. We compete for acquisition and license agreements with pharmaceutical and biotechnology companies and academic research institutions, including those with substantially greater financial, marketing, sales and other resources. We have limited resources to identify and execute the acquisition or in-licensing of third party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates or approved products on terms that we find acceptable, or at all. In addition, even if we generate interest in an acquisition or in-license of a product candidate or approved product, other companies may have stronger relationships with third parties with whom we are interested in collaborating and/or may have more established histories of developing and commercializing products. As a result, they may have a competitive advantage in entering into collaboration and development arrangements with such third parties.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including pre-clinical or clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any products that we develop or approved products that we acquire will be manufactured or sold profitably or achieve market acceptance.

If we are unable to acquire or in-license additional product candidates or approved products and successfully develop and commercialize them, it would likely have a material adverse effect on our business, results of operations, financial condition and prospects.

Governmental and third party payors may impose restrictions on reimbursement or pricing controls that could limit product revenue.

The continuing efforts of government and third party payors to contain or reduce the costs of health care through various means may reduce potential revenue we may receive from sales of Intermezzo. In particular, third party insurance coverage may not be available to patients for Intermezzo or other future products, if any, especially in light of the availability of low-cost generic zolpidem therapeutics, regardless of the fact that such products are not specifically designed or indicated to specifically treat middle-of-the-night awakening. Government and third party payors could also impose conditions on reimbursement, price controls and other conditions that must be met by patients prior to providing coverage for use of our products. For example, insurers may establish a "step-edit" system that requires a patient to utilize a lower price alternative product prior to becoming eligible for reimbursement of a higher price product. If government and third party payors do not provide adequate coverage and reimbursement levels for our products, or if price controls, prior authorization or step-edit systems are enacted, our royalties and/or product revenue will suffer. Also, potential revenue based on sales to Federal government customers, including the Departments of Veterans Affairs and Defense, will be limited given that Intermezzo will be subject to statutory price constraints that apply to innovator products (those approved by the FDA under NDAs). In addition, we are subject to the requirements of the Medicaid Drug Rebate Program, the Public Health Service's 340B drug pricing discount program, the Medicare Part D Coverage Gap Discount Program, and other regulatory requirements including an Affordable Care Act requirement that manufacturers of branded prescription drugs pay an annual fee to the Federal government. Each manufacturer's fee is calculated based on the dollar value of its sales to certain federal programs and the aggregate dollar value of all branded prescription drug sales by covered manufacturers. A manufacturer's fee will be its prorated share of the industry's total fee obligation (approximately $2.8 billion in 2013 and set to increase in following years), based on the ratio of its sales to the total sales by manufacturers to these same programs. We cannot predict our share of this fee because it will be determined in part on other entities' sales to the relevant programs.

Negative publicity and documented side effects concerning products used to treat patients in the insomnia market may harm commercialization of Intermezzo.

Products containing zolpidem, the active ingredient in Intermezzo, are widely marketed. Zolpidem use has been linked to negative effects, such as sleepwalking and amnesia, and has the potential to cause physical or psychological dependence. Furthermore, zolpidem is classified as a Schedule IV controlled substance under the Controlled Substances Act, and is subject

to certain packaging, prescription and purchase volume limitations. There can be no assurance that additional negative publicity or increased governmental controls on the use of zolpidem or other compounds used in products for the insomnia market would not inhibit or prevent commercialization of Intermezzo. Furthermore, negative information arising out of clinical trials, post-market adverse event reporting or publicity concerning zolpidem and other hypnotic pharmaceuticals could cause the FDA to make approval or marketing of new products for the insomnia market more difficult by requiring additional pre- or post-market studies or different non-clinical or clinical studies or taking other actions, out of safety or other concerns, or could lead to reduced consumer usage of sleep aids, including zolpidem products and Intermezzo. For example, in January 2013, the FDA took steps to ensure that patients are warned that the use of zolpidem products intended to be taken at bedtime may negatively affect patient driving ability the morning after dosing.

Intermezzo, and any other future product candidate for which we may receive regulatory approval from the FDA, will be subject to ongoing regulatory requirements and may face regulatory or enforcement action.

Intermezzo, as well as any other product candidate for which we receive regulatory approval, together with related third party manufacturing facilities and processes, post-approval clinical data, and advertising and promotional activities for the product, will be subject to significant review, oversight and ongoing and changing regulation by the FDA. Failure to comply with regulatory requirements may subject us, or Purdue Pharma, to administrative and judicially-imposed sanctions. These may include warning letters, adverse publicity, civil and criminal penalties, injunctions, product seizures or detention, product recalls, total or partial suspension of production, refusal to approve pending product marketing applications, import alerts placing a hold on the importation of drug products and drug substances, and withdrawal of product approvals. Even if we receive regulatory approval to market a particular product candidate, the approval could be conditioned on our conducting additional costly post-approval studies or could limit the indicated uses included in our labeling. The FDA has the authority to require certain post-market studies, including post-market studies to further evaluate the safety of the drug and the use of the drug in certain patient populations, including pediatric and geriatric populations. For example, as part of the approval of Intermezzo, the FDA required us to conduct a post-market study of the ability of patients to comply with our dosing instructions in an actual-use setting. Moreover, the product may later be found to cause adverse effects that limit or prevent its widespread use, force us or our marketing partner to withdraw it from the market or impede or delay the ability to obtain regulatory approvals in additional countries. The FDA also requested that all manufacturers of sedative-hypnotic pharmaceutical products modify their product labeling to include strong language concerning potential risks. These risks include severe allergic reactions and complex sleep-related behaviors, which include sleep-driving. The FDA also recommended that pharmaceutical manufacturers of sedative-hypnotics conduct clinical studies to investigate the frequency with which sleep-driving and other complex behaviors occur in association with individual drug products, and to deliver to the FDA information related to the effect, if any, their drug products may have on next day driving safety. Our ongoing regulatory requirements may also change from time to time, potentially harming or making costlier our commercialization efforts. For example, in January 2013, the FDA required the manufacturers of certain zolpidem-based prescription sleep aids other than Intermezzo to reduce the recommended dose for such products. Although we were not subject to such mandatory dose reduction, we cannot guarantee that our existing regulatory requirements will not change and consequently harm our business.

If manufacturers supplying Intermezzo or any other product candidate fail to produce in the volumes and quality that are required on a timely basis, or to comply with stringent regulations applicable to pharmaceutical manufacturers, there may be delays in the commercialization of or an inability to meet demand for Intermezzo or delays in the development of future product candidates, if any, and we may lose potential revenue.

Neither we nor Purdue Pharma manufacture Intermezzo and we do not currently have plans to develop the capacity to manufacture any product or product candidates. We have a primary manufacturing and supply agreement with Patheon, Inc. to manufacture a supply of Intermezzo for use outside the United States, and Purdue Pharma has entered into an agreement with Patheon to manufacture and supply Intermezzo for use in the United States. We and Purdue Pharma currently have arrangements to use Sharp Corporation as a primary packager of Intermezzo. Purdue Pharma relies upon SPI Pharma, Inc. as a supplier for certain key excipients contained within Intermezzo and as the sole supplier for one such excipient, Pharmaburst ®. If we obtain approval to sell Intermezzo outside the U.S. territory, we would likely also rely on SPI Pharma as a supplier for the same excipients. In addition, Purdue Pharma relies upon Teva Pharmaceutical Industries Ltd., API Division (formerly Plantex USA, Inc.) as the sole source for a special form of zolpidem tartrate, which is the active pharmaceutical ingredient of Intermezzo.

Purdue Pharma is dependent upon these manufacturers for the commercial supply of Intermezzo in the United States. The realization of any of the risks described here would have a significant impact on Purdue Pharma's commercialization efforts for Intermezzo and our ability to generate revenue under the Collaboration Agreement. In the event we commercialize Intermezzo outside the U.S. territory, we would likely also rely on the same key manufacturers and suppliers as Purdue Pharma intends to use to commercialize Intermezzo in the U.S. territory.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel, and compliance with strictly enforced federal, state and foreign regulations. Third-party manufacturers and key suppliers may not perform as agreed, may terminate their agreements, or may experience manufacturing difficulties due to resource constraints or as a result of labor disputes, unstable political environments at foreign facilities or financial difficulties. For example, Purdue Pharma's supplier of zolpidem tartrate with its manufacturing facility in Israel may face geopolitical risk that could prevent it from providing supplies from such facility. Additionally, third-party manufacturers and key suppliers may become subject to claims of infringement of intellectual property rights of others, which could cause them to incur substantial expenses, and, if such claims were successful, could cause them to incur substantial damages or cease production of our products or product components. In addition, several of the suppliers of Intermezzo have only one facility qualified to supply key components of Intermezzo, and transferring such supply to an alternate site could take substantial time and resources. Any interruption of supply from such facilities could materially impair the ability to manufacture Intermezzo, which may harm Purdue Pharma's ability to commercialize Intermezzo in the United States and impair our ability to generate revenue from Intermezzo through our collaboration with Purdue Pharma. Furthermore, as noted above, in the event we commercialize Intermezzo outside the U.S. territory, we would likely also rely on the same key manufacturers and suppliers as Purdue Pharma intends to use to commercialize Intermezzo in the U.S. territory. These manufacturers and suppliers may also choose, or be required, to seek licenses from the claimant, which may not be available on acceptable terms or at all. If these manufacturers or key suppliers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to launch Intermezzo in the United States through our collaboration with Purdue Pharma or, if we choose to commercialize Intermezzo accordingly, outside of the United States, or any other product candidate, if approved, would be jeopardized. Even if we were able to launch a product, these difficulties could cause increases in the prices we or our collaborators pay for supply of such product and its components which could substantially hinder or prevent commercialization efforts.

In addition, all manufacturers and suppliers of pharmaceutical products must comply with current good manufacturing practice, or cGMP, requirements enforced by the FDA through its facilities inspection program. The FDA is likely to conduct inspections of third-party manufacturer and key supplier facilities as part of its review of any of our NDAs. If third-party manufacturers and key suppliers are not in compliance with cGMP requirements, it may result in a delay of approval, particularly if these sites are supplying single source ingredients required for the manufacture of Intermezzo. These cGMP requirements include quality control, quality assurance and the maintenance of records and documentation. Furthermore, regulatory qualifications of manufacturing facilities are applied on the basis of the specific facility being used to produce supplies. As a result, if one of these manufacturers shifts production from one facility to another, the new facility must go through a complete regulatory qualification process and be approved by regulatory authorities prior to being used for commercial supply. Manufacturers may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any quantities supplied is compromised due to a third-party manufacturer or key supplier failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for our product candidates and, even if such approval is obtained, any resulting products may not be successfully commercialized.

There are no alternate manufacturers qualified at this time with respect to the commercial supply of Intermezzo, nor are there alternate manufacturers identified or qualified with respect to the commercial supply of several of the key ingredients and packaging materials used in Intermezzo. If manufacturers are required to be changed, prior approval by the FDA and comparable foreign regulators would be required and Purdue Pharma would likely incur significant costs and expend significant efforts to educate the new manufacturer with respect to, or to help the new manufacturer independently develop, the processes necessary for production. If we exercise our right to co-promote Intermezzo to psychiatrists, we may also incur such costs and expend such efforts to ensure commercial supply of Intermezzo. Manufacturing and supply switching costs in the pharmaceutical industry can be very high, and switching manufacturers or key suppliers can frequently take 12 to 18 months to complete, although in certain circumstances such a switch may be significantly delayed or prevented by regulatory and other factors.

Any of these factors could cause the delay or suspension of commercialization of Intermezzo or any other product candidate that we may develop, hinder or delay future regulatory submissions and/or required regulatory approvals, or entail higher costs or result in an inability to effectively commercialize our products. Furthermore, if manufacturers fail to deliver the required commercial quantities of raw materials, including the active pharmaceutical ingredient, key excipients or finished product on a timely basis and at commercially reasonable prices, we or our strategic partners, including Purdue Pharma, would be unable to meet demand for our products and we would lose potential revenue.

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.

Before obtaining regulatory approvals for the commercial sale of future product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that the product candidate is both safe and effective for use in each target indication. Clinical trial results may be negatively affected by factors that had not been fully anticipated prior to commencement of the trial. Such trials may fail to demonstrate efficacy in the treatment of the intended disorder or may fail to demonstrate that a product candidate is safe when used as directed or even when misused. The results obtained in completed clinical trials and non-clinical studies may not be predictive of results from ongoing or future trials. Actual results of any future studies may differ materially from past studies due to various risks and uncertainties, including, but not limited to, the following:

- identical study designs evaluating identical endpoints may produce different study results;
- different study designs intended to measure the same or similar endpoints may produce different results;
- different studies in different or progressively larger patient populations could reveal more frequent, more severe or additional side effects that were not seen in earlier studies; and
- the unpredictable nature of clinical trials generally.

Although we seek to design our clinical trial protocols to address known factors that may negatively affect results, there can be no assurance that protocol designs will be adequate or that factors that we may or may not be aware of or anticipate will not have a negative effect on the results of our clinical trials. Once a study has commenced, we may voluntarily suspend or terminate the study if at any time we believe that there is an unacceptable safety risk to patients.

Further, side effects could interrupt, delay or halt clinical trials of our product candidates and could result in the FDA or other regulatory authorities stopping further development of or denying approval of our product candidates. Based on results at any stage of clinical trials, we may decide to repeat or redesign a trial, modify our regulatory strategy or even discontinue development of one or more of our product candidates. In addition, from time to time the FDA will review the safety of an approved product, molecule or therapeutic class. These types of safety reviews by the FDA, or new clinical findings generated by the scientific community, could cause us to modify our clinical study plans, or abandon such programs altogether.

If our product candidates are not shown to be both safe and effective in clinical trials, the resulting delays in developing other compounds and conducting associated non-clinical testing and clinical trials, as well as the potential need for additional financing, would have a material adverse effect on our business, financial condition and results of operations.

Delays in the commencement or completion of clinical testing could result in increased costs to us and delay our ability to generate revenue.

We do not know whether future clinical trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be disrupted for a variety of reasons, including difficulties in:

- recruiting and enrolling patients to participate in a clinical trial,
- addressing issues raised by the FDA or other regulatory authorities regarding safety, design, scope and objectives of clinical studies;
- obtaining regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective clinical research organizations and trial sites;
- manufacturing sufficient quantities of a product candidate; and
- obtaining institutional review board approval to conduct a clinical trial at a prospective site.

A clinical trial may also be suspended or terminated by us or the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or in accordance with our clinical protocols;
- inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues; and
- inadequate patient enrollment or lack of adequate funding to continue the clinical trial.

In addition, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes, which could impact the cost, timing or successful completion of a clinical trial. Further, conducting clinical trials in foreign countries, as we have historically done, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries. If we experience delays in the commencement or completion of our clinical trials, the commercial prospects for our product candidates and our ability to generate product revenue will be harmed. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also lead to the denial of regulatory approval of a product candidate.

The commercial success of Intermezzo depends, in part, on meeting the conditions for market exclusivity under Section 505 of the Federal Food, Drug and Cosmetic Act, or FFDCA.

We have been granted approval of a NDA for Intermezzo submitted under Section 505(b)(2) of the FFDCA, enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. Section 505(b)(2) permits applicants to rely in part on clinical and non-clinical studies conducted by third parties. Specifically, with respect to Intermezzo, we relied in part on third party data concerning zolpidem, which is the active ingredient in Intermezzo and in the previously approved insomnia products Ambien ® and Ambien CR®.

In connection with the approval of the Intermezzo NDA, the FDA has granted three years of Hatch-Waxman marketing exclusivity for Intermezzo. Under this form of exclusivity, the FDA is precluded from approving an abbreviated new drug application (ANDA) for a generic of Intermezzo, i.e., a product candidate that the FDA views as a therapeutically equivalent drug product having the same conditions of use as Intermezzo (for example, the same labeling, the same dosage form and route of administration, the same strength and the same bioavailability as Intermezzo). Marketing exclusivity for Intermezzo also precludes the FDA from approving 505(b)(2) applications for proposed drug products having the same or similar conditions of use as Intermezzo, including applications that rely on Intermezzo as the reference product. The exclusivity lasts for a period of three years from the date of Intermezzo approval, or until November 2014, though the FDA may accept and commence review of ANDAs and 505(b)(2) NDAs during the three-year period. However, the three-year exclusivity period may not prevent FDA from approving an original NDA that relies only on its own data to support the approval. In addition, we received notifications in July 2012, September 2012, December 2012, January 2013 and February 2013 that Actavis, Watson, Novel, each of the Par Entities and Dr. Reddy's has filed with the FDA one or more ANDAs, including Paragraph IV certifications, for generic versions of Intermezzo. An ANDA with a Paragraph IV certification indicates that the ANDA applicant is seeking approval for a generic version of Intermezzo and is challenging the enforceability of one or more of the drug product or method of use patents that claim Intermezzo.

If Intermezzo does not maintain market exclusivity under the FFDCA, including due to existing or future ANDAs, it would likely have a material adverse effect on our business, results of operations, financial condition and prospects.

We rely on third parties to conduct our non-clinical and clinical trials. If these third parties do not perform as contractually required or as otherwise expected, we may not be able to obtain regulatory approval for our current and future product candidates, if any.

We do not currently conduct non-clinical and clinical trials on our own and instead rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories, to assist us with our non-clinical and clinical trials. We, and our third parties, are also required to comply with regulations and standards, commonly referred to as Good Clinical Practice, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. If these third parties do not successfully carry out their duties with regard to our products in development or fail to successfully carry out their duties to us as they relate to meeting future regulatory obligations or expected deadlines, if the third parties need to be replaced, or if the quality or accuracy of the data these third parties obtained during the development of a product candidate is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our non-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for a product candidate.

We or any future partners may never receive regulatory approval to market or commercialize Intermezzo outside of the United States.

In order to market and commercialize Intermezzo outside of the United States, we and any future partners must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional pre-clinical studies and clinical trials and additional administrative review periods. For example, European regulatory authorities generally require clinical testing comparing the efficacy of the

new drug to an existing drug prior to granting approval. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed in this "Risk Factor" section regarding FDA approval in the United States, as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries.

We may face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for a product candidate and may have to limit such candidate's commercialization.

The use of a product candidate in clinical trials and the sale of any products for which we obtain marketing approval, including Intermezzo, exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or others selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. We are also obligated under certain circumstances to indemnify suppliers and others with whom we have contractual relationships for product liability claims such entities might incur with respect to our products and product candidates. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for Intermezzo or future products, if any;
- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- loss of revenue; and
- the inability to commercialize future product candidates.

Under our Collaboration Agreement with Purdue Pharma, we remain liable for 50% of the cost of defending against any product liability or personal or economic injury claims. In addition, we and Purdue Pharma have agreed to allocate any losses for such claims on a comparative fault basis but in the absence of such determination have agreed to split such losses equally. Although we currently have product liability insurance coverage for our clinical trials with limits that we believe are customary and adequate to provide us with coverage for foreseeable risks associated with our development efforts, this insurance coverage may not reimburse us or may be insufficient to reimburse us for the actual expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We have product liability insurance covering the sale of Intermezzo in the United States.

We depend on key personnel and if we are not able to retain them, our business will suffer.

We are highly dependent on the principal members of our management and scientific staff, including but not limited to Glenn A. Oclassen, our President and Chief Executive Officer, Thomas P. Soloway, our Executive Vice President and Chief Operating Officer and Nikhilesh N. Singh, Ph.D., our Senior Vice President and Chief Scientific Officer. The competition for skilled personnel among biopharmaceutical companies in the San Francisco Bay Area is intense and the employment services of our scientific, management and other executive officers may be terminated at-will. If we lose one or more of these key employees, our ability to implement and execute our business strategy successfully could be seriously harmed. Replacing key employees may be difficult and may take an extended period of time because of the limited number of individuals in the biopharmaceutical industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. We do not carry key man life insurance on any of our key personnel other than Dr. Singh.

The commercial success, if any, of Intermezzo depends, in part, on certain patent rights and rights we are seeking through certain patent applications.

The potential commercial success of Intermezzo depends in part on patents that have been issued to us from the U.S. Patent and Trademark Office, or USPTO, covering the formulation and use of Intermezzo that expire no earlier than February 2025. In addition, we have pending certain foreign equivalent patent applications.

The active, and many of the inactive, ingredients in Intermezzo, including generically manufactured zolpidem, has been known and used for many years. The zolpidem composition of matter is no longer subject to patent protection. Accordingly, certain of our patents for Intermezzo are directed to the particular formulations of its ingredients. Although we believe our formulation and the use of Intermezzo are patentable, and such patents have the potential to provide a competitive advantage,

these patents may not prevent others from marketing formulations using the same active and inactive ingredients in similar but different formulations. Moreover, if our patents are successfully challenged and ruled to be invalid and/or unenforceable, we would be exposed to direct competition from low-priced generic products.

There can be no assurance that our pending patent applications and applications we may file in the future, or those applications we may license from third parties, will result in patents being issued in a timely manner, or at all. Even if patents issue, the claims in such patents may not issue in a form that will be advantageous to us, may not cover Intermezzo and its unique features, and may not provide us with proprietary protection or competitive advantages. For instance, with Intermezzo, competitors may be able to engineer around our formulation patents and applications with alternate formulations that deliver therapeutic effects sufficiently similar to Intermezzo to warrant approval under existing FDA standards for generic product approvals. Accordingly, other drug companies may be able to develop generic versions of our products even if we are able to maintain our current proprietary rights.

Alternatively, other drug companies can challenge the validity of our patents and seek to gain marketing approval for generic versions of our products. For example, drug makers may attempt to introduce low-dose zolpidem products similar to Intermezzo immediately after the expiration of Hatch-Waxman marketing exclusivity and prior to the expiration of patents that may be issued relating to our respective products by challenging the validity of our patents or certifying that their competitive products do not infringe our patents.

Generic drug manufacturers routinely initiate challenges during the Hatch-Waxman marketing exclusivity period. We received notifications in July 2012, September 2012, December 2012, January 2013 and February 2013 that Actavis, Watson, Novel, each of the Par Entities and Dr. Reddy's has filed with the FDA one or more ANDAs, including Paragraph IV certifications, for generic versions of Intermezzo. If we or Purdue Pharma initiate timely patent litigation against a generic or 505(b)(2) sponsor who seeks to challenge one or more of the patents that claim Intermezzo, we would be entitled to a regulatory stay that prohibits final approval of the generic or 505(b)(2) product for 30 months from the date we receive notice of the challenge to our patents. That stay may be terminated if we or Purdue Pharma do not succeed in maintaining litigation against the generic or 505(b)(2) applicant. In addition, if a generic or 505(b)(2) applicant formulates around our patents, we may not be able to initiate Hatch-Waxman patent litigation and, as a result, there would be no 30 month regulatory stay on FDA's ability to give final approval to the generic or 505(b)(2) application. In August 2012, September 2012, and October 2012, we joined Purdue Pharma in filing actions against Actavis, Watson, Novel, the Par Entities, and certain of their affiliates, alleging patent infringement and seeking injunctive and other relief. In December 2012, we and Purdue Pharma agreed to voluntary dismiss the action against Watson following its withdrawal of its ANDA application. We have not filed an action against Dr. Reddy's, and there is no guarantee that we or Purdue Pharma will do so within 45 days of our receipt of Dr. Reddy's notification.

In addition, among other limitations, certain of our patents that protect Intermezzo are limited in scope to certain uses and formulations of zolpidem, so potential competitors could develop similar products using active pharmaceutical ingredients other than zolpidem. Any patents that have been allowed, we have obtained or do obtain may be challenged by re-examination, opposition, or other administrative proceeding, or may be challenged in litigation, and such challenges could result in a determination that the patent is invalid and/or unenforceable.

Failure to obtain effective patent protection for Intermezzo or future product candidates, if any, would allow for products to be marketed by competitors that would undermine sales, marketing and collaboration efforts for our product candidates, and reduce or eliminate our revenue. In addition, both the patent application process and the process of managing patent disputes can be time consuming and expensive.

If we are unable to maintain and enforce our proprietary rights, we may not be able to compete effectively or operate profitably.

Our commercial success will depend, in part, on obtaining and maintaining patent protection, trade secret protection and regulatory protection of our proprietary technology and information as well as successfully defending against third party challenges to our proprietary technology and information. We will be able to protect our proprietary technology and information from use by third parties only to the extent that we have valid and enforceable patents, trade secrets or regulatory protection to cover them and we have exclusive rights to utilize them.

Our commercial success will continue to depend in part on the patent rights we own, the patent rights we have licensed, the patent rights of our suppliers and the patent rights we plan to obtain related to future products we may market. Our success also depends on our and our licensors' and suppliers' ability to maintain these patent rights against third party challenges to their validity, scope or enforceability. Further, if we were to in-license intellectual property, we may not fully control the patent prosecution of the patents and patent applications we have licensed. There is a risk that licensors to us will not devote the same resources or attention to the prosecution of the licensed patent applications as we would if we controlled the prosecution of the patent applications, and the resulting patent protection, if any, may not be as strong or comprehensive as if we had prosecuted

the applications ourselves. The patent positions of biopharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies' patents has emerged to date in the United States. The patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third party patents. For example:

- we or our licensors might not have been the first to make the inventions covered by pending patent applications and issued patents;
- we or our licensors might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that none of our pending patent applications or any pending patent applications of our licensors will result in issued patents;
- our patents, if issued, and the issued patents of our licensors may not provide a basis for commercially viable products, or may not provide us with any competitive advantages, or may be challenged and invalidated by third parties;
- we may not develop additional proprietary technologies or product candidates that are patentable; or
- the patents of others may have an adverse effect on our business.

We also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. While we seek to protect confidential information, in part, by confidentiality agreements with our employees, consultants, contractors, or scientific and other advisors, they may unintentionally or willfully disclose our information to competitors. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

If we are not able to defend the patent or trade secret protection position of our technologies and product candidates, then we will not be able to exclude competitors from developing or marketing competing products, and we may not generate enough revenue from product sales, if any, to justify the cost of development of our product candidates and to achieve or maintain profitability.

If we are sued for infringing intellectual property rights of other parties, such litigation will be costly and time consuming, and an unfavorable outcome would have a significant adverse effect on our business.

Although we believe that we would have valid defenses to allegations that our current product and product candidates, production methods and other activities infringe the valid and enforceable intellectual property rights of any third parties of which we are aware, we cannot be certain that a third party will not challenge our position in the future. Other parties may own patent rights that might be infringed by our products or other activities, or other parties may claim that their patent rights are infringed by excipients manufactured by others and contained in our products. There has been, and we believe that there will continue to be, significant litigation and demands for licenses in the life sciences industry regarding patent and other intellectual property rights. Competitors or other patent holders may assert that our products and the methods we employ are covered by their patents. These parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages or possibly prevent us from commercializing our product candidates. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

As a result of patent infringement claims, or in order to avoid potential claims, we may choose to seek, or be required to seek, a license from the third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be non-exclusive, which would give competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly.

These risks of intellectual property infringement are similarly faced by our suppliers and collaborators, which could hinder or prevent them from manufacturing or commercializing our products.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

In the event a competitor infringes upon one of our patents or other intellectual property rights, litigation to enforce our intellectual property rights or to defend our patents against challenge, even if successful, could be expensive and time consuming and could require significant time and attention from management. Under the Collaboration Agreement, Purdue Pharma has the right, but not the obligation, to bring action against a party engaged in infringement of our patents covering Intermezzo, and we are required to share 40% of the costs related to all such actions up to an aggregate cap of $1.0 million per calendar year and $4.0 million over the term of the agreement. Additionally, in August 2012, September 2012 and October 2012, we joined Purdue Pharma in filing actions against Actavis, Watson, Novel, the Par Entities, and certain of their affiliates, alleging patent infringement and seeking injunctive and other relief. In December 2012, we and Purdue Pharma agreed to voluntary dismiss the action against Watson following its withdrawal of its ANDA application. . We have not filed an action against Dr. Reddy's, and there is no guarantee that we or Purdue Pharma will do so within 45 days of our receipt of Dr. Reddy's notification. We may not have sufficient resources to enforce our intellectual property rights or to defend our patents against challenges from others.

The pharmaceutical industry is characterized by extensive litigation and administrative proceedings over patent and other intellectual property rights. We could therefore become subject to litigation that could be costly, result in the diversion of management's time and efforts, and require us to pay damages. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Our competitors may assert that they own U.S. or foreign patents containing claims that cover our products, components of our products, or the methods we employ in making or using our products. In addition, we may become a party to an interference proceeding declared by the USPTO to determine the priority of inventions. Because patent applications can take many years to issue, there may be applications now pending of which we are unaware, which may later result in issued patents that contain claims that cover our products. There could also be existing patents, of which we are unaware, that contain claims that cover one or more components of our products. As the number of participants in our industry increases, the possibility of patent infringement claims against us also increases.

Any interference proceeding, litigation, or other assertion of claims against us may cause us to incur substantial costs, place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. If the relevant patents were upheld as valid and enforceable and we were found to infringe, we could be required to pay substantial damages and/or royalties and could be prevented from selling our products unless we could obtain a license or were able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may be unable to make, use, sell, or otherwise commercialize one or more of our products. In addition, if we were found to willfully infringe, we could be required to pay treble damages, among other penalties.

If we fail to comply with our obligations in the agreements under which we license rights to products or technology from third parties, we could lose license rights that are important to our business.

We are a party to a number of agreements that include technology licenses that are important to our business and expect to enter into additional licenses in the future. For example, we hold licenses from SPI relating to key excipients used in the manufacture of Intermezzo. If we fail to comply with these agreements, the licensor may have the right to terminate the license, in which event we and our collaboration partners would not be able to market products covered by the license, including Intermezzo.

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

Certain of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we ourselves have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper or prevent our or a collaboration partner's ability to develop or commercialize certain potential products, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

If our agreements with employees, consultants, advisors and corporate partners fail to protect our intellectual property, proprietary information or trade secrets, it could have a significant adverse effect on us.

We have taken steps to protect our intellectual property and proprietary technology by entering into confidentiality agreements and intellectual property assignment agreements with our employees, consultants, advisors and corporate partners. However, such agreements may not be enforceable or may not provide meaningful protection for all of our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure. Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. Furthermore, the laws of some foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States.

Our operations involve hazardous materials, which could subject us to significant liabilities.

Our research and development processes involve the controlled use of hazardous materials, including chemicals. Our operations produce hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge or injury from these materials. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of these materials. We could be subject to civil damages in the event of an improper or unauthorized release of, or exposure of individuals, including employees, to hazardous materials. In addition, claimants may sue us for injury or contamination that results from our use of these materials and our liability may exceed our total assets. We maintain limited insurance for the use of hazardous materials which may not be adequate to cover any claims. Compliance with environmental and other laws and regulations may be expensive and current or future regulations may impair our research, development or production efforts.

Risks Related to Our Common Stock

We may fail to meet publicly announced financial guidance or other expectations about our business, which would cause our stock to decline in value.

There are a number of reasons why we might fail to meet financial guidance or other expectations about our business, including, but not limited to, the following:

- unexpected difficulties in Purdue Pharma's efforts to commercialize Intermezzo in the United States;
- delays or unexpected changes in Purdue Pharma's plan to invest in and support the sales and marketing of Intermezzo;
- the effectiveness of the sales, marketing and distribution efforts by Purdue Pharma in the United States and overall success of Purdue Pharma's commercialization efforts in the United States;
- whether we choose to share the cost of future advertising or other marketing efforts with Purdue Pharma related to the commercialization of Intermezzo in the United States;
- lower than expected pricing and reimbursement levels, or no reimbursement at all, for Intermezzo in the United States;
- the use of currently available sleep aids that are not approved to be taken in the middle of the night;
- negative developments or setbacks in our efforts to seek marketing approval for Intermezzo outside of the United States;
- FDA approval of generic versions of Intermezzo or negative developments in any ongoing ANDA proceedings;
- current and future competitive products that have or obtain greater acceptance in the market than Intermezzo;
- if only a subset of or no affected patients respond to therapy with Intermezzo or future products, if any;
- negative publicity about the results of our clinical studies, or those of others with similar or related products may reduce demand for Intermezzo or future products, if any;
- the inability to sell a product at the price we expect; or
- the inability to supply enough product to meet demand.

If we fail to meet our revenue and/or expense projections and/or other financial guidance for any reason, our stock could decline in value.

Our stock price is volatile.

The market price of our common stock is subject to significant fluctuations. During the 12-month period ended December 31, 2012, the sales price of our common stock on The NASDAQ Global Market ranged from a high of $12.99 in

April 2012 to a low of $4.10 in November 2012. Market prices for securities of early-stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. The volatility of the market price of our common stock is exacerbated by the low trading volume of our common stock and the high proportion of our shares held by insiders. Some of the factors that may cause the market price of our common stock to fluctuate include:

- the perception of our prospects for successful commercialization of Intermezzo by Purdue Pharma, including the costs associated with the launch;
- announcements by us or Purdue Pharma regarding the commercialization and/or marketing efforts of Intermezzo;
- the termination by Purdue Pharma of the Collaboration Agreement, or the termination of other future collaboration or partnering agreements;
- the failure of any product candidates, if approved, to achieve commercial success, including due to competition from generic versions of Intermezzo, or the perception by investors that commercial success may not be achieved;
- issues in manufacturing Intermezzo, or other approved products, if any, or product candidates;
- the entry into any in-licensing agreements securing licenses, patents or development rights;
- the results of any future clinical trials of our product candidates;
- the entry into, or termination of, key agreements, including additional commercial partner agreements;
- the initiation of, material developments in, or conclusion of litigation to enforce or defend our intellectual property rights or defend against the intellectual property rights of others;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to the insomnia market, including with respect to other products and potential products in such market;
- the introduction of technological innovations or new therapies that compete with our potential products;
- the loss of key employees;
- changes in estimates or recommendations by securities analysts, if any, who cover our common stock;
- future sales of our common stock;
- general and industry-specific economic conditions that may affect our research and development expenditures;
- changes in the structure of health care payment systems, including changes to prescription drug reimbursement levels; and
- period-to-period fluctuations in financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

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

The trading market for our common stock is influenced by the research and reports that securities or industry analysts publish about us, our business and our stock. As of December 31, 2012, we had research coverage by six securities analysts. If any of the analysts who cover us downgrades our stock or publishes inaccurate or unfavorable research regarding us or our business model, technology or stock performance, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Moreover, the unpredictability of our financial results likely reduces the certainty, and therefore reliability, of the forecasts by securities or industry analysts of our future financial results, adding to the potential volatility of our stock price.

Future sales of our common stock may cause our stock price to decline and impede our ability to raise capital.

Our common stock is closely held. Our executive officers and directors beneficially own or control approximately 20.8% of our approximately 18.7 million outstanding shares of common stock as of December 31, 2012 and an additional 11.2% is beneficially owned by a venture capital firm in which one of our directors is a partner. Significant portions of these shares are held by a small number of stockholders. In addition, other investors not otherwise affiliated with us beneficially own a significant number of shares of our common stock based on filings made with the SEC.

All of our outstanding shares of common stock are freely tradable without restriction or further registration under the federal securities laws, unless held or purchased by our "affiliates" as that term is defined in Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. Also, some stockholders affiliated with our directors maintain rights with respect to the registration of the sale of their shares of common stock with the SEC. The shares authorized for issuance under our stock option plans and employee stock purchase plan are registered under the Securities Act and can be freely sold in the public market upon issuance, subject to restrictions imposed on our affiliates under Rule 144.

Sales into the public market by our officers, directors and their affiliates, or other major stockholders, of a substantial number of shares, or the expectation that such sales may occur, could significantly reduce the market price of our common stock.

In addition, certain of our executive officers may establish predetermined selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934, or the Exchange Act, for the purpose of effecting sales of common stock.

If any such sales occur, are expected to occur or a large number of our shares are sold in the public market, the trading price of our common stock could decline. Further, any such decline or expectation could impede our ability to raise capital in the future through the sale of equity securities under terms that are favorable to us.

Raising additional funds by issuing securities or through licensing arrangements may cause dilution to existing stockholders, restrict our operations or require us to relinquish proprietary rights.

Additional financing may not be available to us when we need it or may not be available on favorable terms. To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership will be diluted and the terms of any new equity securities may have preferences over our common stock. Any debt financing we enter into may involve covenants that restrict our operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. In addition, if we raise additional funds through licensing arrangements, it may be necessary to relinquish potentially valuable rights to potential products or proprietary technologies, or grant licenses on terms that are not favorable to us.

Failure to maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 could have a material adverse effect on our stock price.

Section 404 of the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC require an annual management assessment of the effectiveness of our internal control over financial reporting and, based on our public float, a report by our independent registered public accounting firm attesting to the effectiveness of our internal control over financial reporting at the end of the fiscal year. If we fail to maintain the adequacy of our internal control over financial reporting, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC. If we cannot in the future favorably assess, or, if required, our independent registered public accounting firm is unable to provide an unqualified attestation report on, the

effectiveness of our internal control over financial reporting, investor confidence in the reliability of our financial reports may be adversely affected, which could have a material adverse effect on our stock price.

Anti-takeover provisions in the Collaboration Agreement with Purdue Pharma, in our charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by stockholders to replace or remove management.

Provisions in the Collaboration Agreement with Purdue Pharma, our certificate of incorporation and our bylaws may delay or prevent an acquisition or a change in management. The provisions in the Collaboration Agreement include an agreement with Purdue Pharma that prevents Purdue Pharma from acquiring above a certain percentage of our stock and engaging in certain other activities for a limited period of time following the commercial launch of Intermezzo that may lead to an acquisition of our company without our consent. In addition, our co-promote option pursuant to the Collaboration Agreement cannot be transferred to a third party, except under a limited circumstance at the discretion of Purdue Pharma, which may significantly reduce the value of our shares to a potential acquirer. Such provisions in our charter documents include a classified board of directors, a prohibition on actions by written consent of stockholders and the ability of our board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us unless certain conditions are met. Although we believe most of these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by stockholders to replace or remove the then-current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

We have never paid dividends on our capital stock, and do not anticipate that we will pay any cash dividends in the foreseeable future.

We have not paid cash dividends on any of our classes of capital stock to date, and our current expectation is that we will retain our future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain, if any, as a result of holding shares of our common stock, for the foreseeable future.

The highly concentrated ownership of our common stock may prevent stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause our stock price to decline.

Our executive officers and directors beneficially own or control approximately 20.8% of the outstanding shares of our common stock as of December 31, 2012 and an additional 11.2% is beneficially owned by a venture capital firm in which one of our directors is a partner. Accordingly, these executive officers, directors and their affiliates, acting as a group, will have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of us, even if such a change of control would benefit our other stockholders. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our operational headquarters is located in Point Richmond, California, where we lease approximately 14,600 square feet of space under a lease that expires in May 2013. Approximately 3,000 square feet of the Point Richmond space is product development laboratory space and the remainder is general office space.

On March 6, 2013 we extended our lease agreement for 11,600 square feet of space in our current facility in Point Richmond, California by one year.

We believe our current facilities are suitable and adequate for our current needs.

Item 3. Legal Proceedings

In July 2012, we received notifications from three companies, Actavis Elizabeth LLC (Actavis), Watson Laboratories, Inc. - Florida (Watson), and Novel Laboratories, Inc. (Novel), in September 2012 from each of Par Pharmaceutical, Inc. and Par Formulations Private Ltd. (together, the Par Entities), and in February 2013 from Dr. Reddy's Laboratories, Inc. and Dr.

Reddy's Laboratories, Ltd. (together, Dr. Reddy's) stating that each has filed with the FDA an abbreviated new drug application, or ANDA, that references Intermezzo.

- Actavis & Watson: In the July 2012 notifications, Actavis and Watson indicated that each company's ANDA includes Paragraph IV patent certifications to our U.S. Patent Nos. 7,658,945 (expiring April 15, 2027) and 7,682,628 (expiring February 16, 2025) (together, the "'945 and '628 Patents"). On November 28, 2012, Watson withdrew its ANDA, and, as a result of such withdrawal, on December 18, 2012, we and Purdue agreed to voluntarily dismiss the action without prejudice and on December 20, 2012 a court order was entered to such effect. The dismissal of Watson's ANDA had no effect on the ANDA filed by Actavis, a wholly owned subsidiary of Watson Pharmaceuticals, Inc. On January 24, 2013, Actavis notified us that it has included Paragraph IV patent certifications to our U.S. Patent Nos. 8,242,131 (expiring August 20, 2029) and 8,252,809 (expiring February 16, 2025) (together, the "'131 and '809 Patents").

- Novel: In the July 2012 notifications, Novel indicated that its ANDA includes Paragraph IV patent certifications to the '945 and '628 Patents. On December 10, 2012, Novel notified us that it has included Paragraph IV patent certifications to the '131 and '809 Patents.

- Par Entities: The ANDAs submitted by the Par Entities each include Paragraph IV patent certifications to the '945, '628, '131 and '809 Patents.

- Dr. Reddy's: The ANDA submitted by Dr Reddy's includes Paragraph IV patent certifications to the '945, '628, '131 and '809 Patents.

In August 2012, September 2012, and October 2012, we joined Purdue Pharma in filing actions against Actavis, Watson, Novel, the Par Entities, and certain of their affiliates, in the U.S. District Court for the District of New Jersey alleging patent infringement and seeking injunctive and other relief. In December 2012, we and Purdue Pharma agreed to voluntary dismiss the action against Watson following its withdrawal of its ANDA application. After receiving the supplemental notifications referenced above, we and Purdue Pharma amended our pending complaints against Actavis and Novel to also allege infringement of the '131 and '809 patents.

In order to maintain patent-based exclusivity under the Hatch-Waxman Act, Purdue Pharma may choose to file patent infringement claims against Dr. Reddy's and its affiliates in federal district court within 45 days of Purdue Pharma's receipt of Dr. Reddy's Paragraph IV certification. If Purdue Pharma chooses to file claims, we will need to decide whether to join Purdue Pharma as a named party in any such resulting lawsuit. If Purdue Pharma chooses not to file patent infringement claims against Dr. Reddy's within the required 45 days, it is possible that we may choose to do so on our own behalf.

In January 2013, we and Purdue Pharma filed suit in the Eastern District of Virginia against the USPTO in connection with certain changes to the Leahy-Smith America Invents Act. We and Purdue Pharma are seeking recalculation of the patent term adjustment of the '131 Patent. Purdue Pharma has agreed to bear the costs and expenses associated with this litigation.

From time to time we are involved in legal proceedings arising in the ordinary course of business. We believe there is no other litigation pending that could have, individually or in the aggregate, a material adverse effect on our results of operations or financial condition.

Item 4. Mine Safety Disclosures

None.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock is currently traded on The NASDAQ Global Market under the symbol "TSPT." Prior to February 2, 2009, our common stock was traded under the symbol "NOVC." On January 30, 2009, in connection with the merger of Novacea and TPI, we completed a reverse stock split pursuant to which each five shares of our common stock was converted into one share of our common stock. The share-related information presented in this Annual Report on Form 10-K has been adjusted to reflect the reverse stock split.

The following table sets forth the range of high and low sales prices of our common stock for the quarterly periods indicated as reported by The NASDAQ Global Market.

	Sales Price	
	High	Low
Year ended December 31, 2011		
First quarter	$ 9.57	$ 7.42
Second quarter	$ 11.88	$ 8.13
Third quarter	$ 11.06	$ 2.58
Fourth quarter	$ 9.37	$ 5.91
Year ended December 31, 2012		
First quarter	$ 10.59	$ 7.77
Second quarter	$ 12.99	$ 5.81
Third quarter	$ 6.81	$ 5.09
Fourth quarter	$ 5.56	$ 4.10

On January 30, 2009, Novacea completed a business combination with TPI. Novacea securities listed on The NASDAQ Global Market, trading under the ticker symbol "NOVC," were suspended for trading as of the close of business on Friday, January 30, 2009 and trading of Transcept securities on The NASDAQ Global Market under the ticker symbol "TSPT" commenced on Monday, February 2, 2009.

The closing price of our common stock as reported by The NASDAQ Global Market on March 8, 2013 was $5.35 per share. As of March 8, 2013, there were approximately 49 holders of record of our common stock.

Dividend Policy

No dividends have been declared or paid on our common stock. We do not anticipate that we will pay any cash dividends on our common stock in the foreseeable future.

Recent Sales of Unregistered Securities

We did not sell any unregistered securities during the fourth quarter of fiscal 2012.

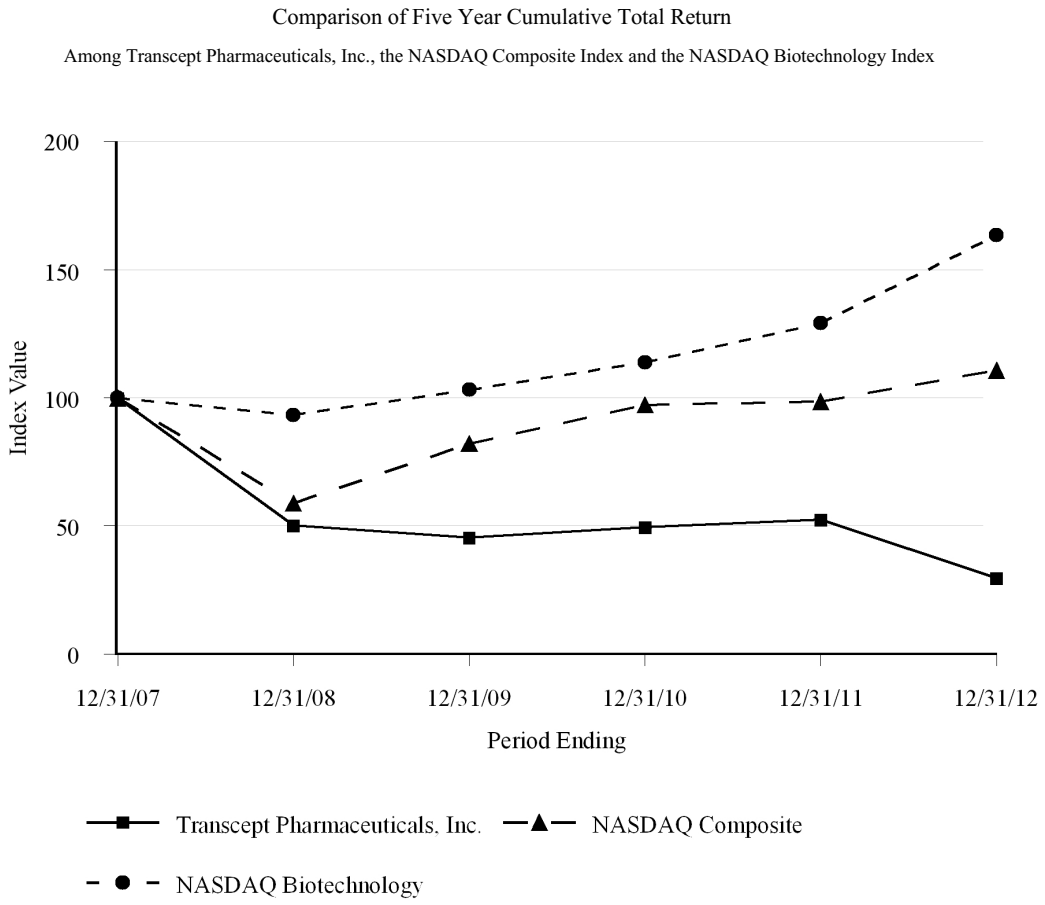
Issuer Purchases of Equity Securities

There were no repurchases of our common stock during the fourth quarter of fiscal 2012.

Performance Graph

Presented below is a line graph comparing the yearly percentage change in the cumulative total return on the Company's Common Stock to the cumulative total return of the NASDAQ Composite Index and the NASDAQ Biotech Index for the period commencing on December 31, 2007 and ending on December 31, 2012.

The graph assumes that $100 was invested in the Company's Common Stock, the NASDAQ Composite Index and the NASDAQ Biotech Index on December 31, 2007 and that all dividends were reinvested the date of payment without payment of any commissions. We have not declared or paid any dividends on our common stock. The performance of our common stock shown in the graph below represents past performance and should not be considered an indication of future performance.



Item 6. Selected Financial Data

The following selected financial data has been derived from our audited financial statements. The information below is not necessarily indicative of the results of future operations and should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," and Item 1A, "Risk Factors," of this Annual Report on Form 10-K, and the financial statements and related notes thereto included in Item 8 of this Annual Report on Form 10-K, in order to fully understand factors that may affect the comparability of the information presented below. All per share amounts reflect the conversion of TPI common stock to our common stock on January 30, 2009 at the rate of 0.14134 shares of common stock, after giving effect to the 1-for-5 reverse stock split, for each share of TPI common stock outstanding on January 30, 2009.

	For the year ended December 31,				
	2012	2011	2010	2009	2008
	(in thousands, except per share data)				
Statements of operations data					
Net revenue	$ 9,597	$ 19,694	$ 12,500	$ 5,208	$ —
Operating expenses:					
Research and development	11,191	11,273	10,684	9,005	10,381
General and administrative	10,263	12,185	11,038	16,050	7,924
Merger related transaction costs	—	—	—	2,224	1,967
Total operating expenses	21,454	23,458	21,722	27,279	20,272
Loss from operations	(11,857)	(3,764)	(9,222)	(22,071)	(20,272)
Interest and other income (expense), net	(159)	(116)	(81)	271	313
Net loss	$ (12,016)	$ (3,880)	$ (9,303)	$ (21,800)	$ (19,959)
Basic and diluted net loss per share attributable to common stockholders	$ (0.70)	$ (0.29)	$ (0.69)	$ (1.79)	$ (49.77)
Weighted average common shares outstanding	17,052	13,534	13,416	12,166	401

	As of December 31,				
	2012	2011	2010	2009	2008
	(in thousands)				
Selected Balance Sheet Data					
Cash, cash equivalents, marketable securities and restricted cash	$ 85,475	$ 62,562	$ 68,171	$ 89,102	$ 11,883
Total assets	98,056	69,151	73,807	95,218	13,781
Working capital	92,303	62,498	59,775	74,293	6,875
Convertible preferred stock	—	—	—	—	71,037
Common stock and additional paid-in capital	207,496	165,817	160,023	157,943	1,504
Accumulated deficit	(112,110)	(100,094)	(96,214)	(86,911)	(65,111)
Total stockholders' equity (net capital deficiency)	95,393	65,752	63,811	71,071	(63,581)

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following Management's Discussion and Analysis of Financial Condition and Results of Operations contains certain statements that are not strictly historical and are "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995 and involve a high degree of risk and uncertainty. Actual results may differ materially from those projected in the forward-looking statements due to other risks and uncertainties. All forward-looking statements included in this section are based on information available to us as of the date hereof, and we assume no obligation to update any such forward-looking statement, except as required by law.

Company Overview

We are a specialty pharmaceutical company focused on the development and commercialization of proprietary products that address important therapeutic needs in the field of neuroscience.

Intermezzo® (zolpidem tartrate) sublingual tablet C-IV

Our first approved product, Intermezzo (zolpidem tartrate) sublingual tablet, is a sublingual formulation of zolpidem approved for use as needed for the treatment of insomnia when a middle-of-the-night awakening is followed by difficulty returning to sleep. Intermezzo is the first and only sleep aid approved by the FDA for this indication.

According to IMS Health, an independent market research firm, the number of prescriptions filled in the United States to treat insomnia grew to approximately 83 million for the twelve months ended December 31, 2012. Data from a major study conducted by the Stanford Sleep Epidemiology Center and published in 2009 indicate that middle-of-the-night awakening is the most common form of insomnia in the United States and affects approximately one-third of the population at least three times each week. Data from a study published in *Population Health Management* in 2010, based on information from the United States National Health and Wellness Survey to evaluate the economic and humanistic burden of chronic insomnia characterized by nighttime awakenings, indicate that this condition was associated with a significant negative impact in health care utilization, health-related quality of life and work productivity.

In July 2009, we entered into the Collaboration Agreement with Purdue Pharma that grants an exclusive license to Purdue Pharma to commercialize Intermezzo in the United States and pursuant to which:

- Purdue Pharma paid us a $25.0 million non-refundable license fee in August 2009;
- Purdue Pharma paid us a $10.0 million non-refundable intellectual property milestone in December 2011 when the first of two issued formulation patents was listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or Orange Book;
- Purdue Pharma paid us a $10.0 million non-refundable intellectual property milestone in August 2012 when the first of two issued method-of-use patents was listed in the FDA's Orange Book;
- We transferred the Intermezzo New Drug Application ("NDA") to Purdue Pharma, and Purdue Pharma is obligated to assume the expense associated with maintaining the NDA and further development of Intermezzo in the United States, including any expense associated with post-approval studies;
- Purdue Pharma is obligated to commercialize Intermezzo in the United States at its expense using commercially reasonable efforts;
- Purdue Pharma is obligated to pay us tiered base royalties on net sales of Intermezzo in the United States ranging from the mid-teens up to the mid-20% level. The base royalty is tiered depending upon the achievement of certain fixed net sales thresholds by Purdue Pharma, which net sales levels reset each year for the purpose of calculating the royalty ; and
- Purdue Pharma is obligated to pay us up to an additional $70.0 million upon the achievement of certain net sales targets for Intermezzo in the United States.

We have retained an option to co-promote Intermezzo to psychiatrists in the United States. The option can be exercised as late as August 2015 . We may begin promotion to psychiatrists 8 to 15 months after option exercise. The exact timing of when we begin promoting to psychiatrists is determined by the calendar month in which the option exercise notice is delivered to Purdue Pharma. If we exercise the co-promote option and enter the marketplace, we are entitled to receive an additional co-promote royalty from Purdue Pharma on net sales that are generated by psychiatrist prescriptions. Had we chosen to exercise the option as soon as we were eligible, we could have begun promoting to psychiatrists in May 2013 and received a co-promote royalty of 40%. The co-

promote royalty rate declines on a straight-line basis to approximately 22% if we do not begin promoting to psychiatrists until November 2016, at which time the right to co-promote expires. Net sales qualifying for this additional co-promote royalty are limited by an annual cap of 15% of total Intermezzo annual net sales in the United States. The co-promote option cannot be transferred to a third party, except under a limited circumstance at the discretion of Purdue Pharma.

Purdue Pharma has the right to terminate the Collaboration Agreement at any time upon advance notice of 180 days. Our co-promote option may also be terminated by Purdue Pharma upon our acquisition by a third party or in the event of entry of generic competition to Intermezzo. The royalty payments discussed above are subject to reduction in connection with, among other things, the entry of generic competition to Intermezzo. The Collaboration Agreement expires on the later of 15 years from the date of first commercial sale in the United States or the expiration of patent claims related to Intermezzo. The Collaboration Agreement is also subject to termination by Purdue Pharma in the event of FDA or governmental action that materially impairs Purdue Pharma's ability to commercialize Intermezzo or the occurrence of a serious event with respect to the safety of Intermezzo. The Collaboration Agreement may also be terminated by us upon Purdue Pharma commencing an action that challenges the validity of Intermezzo related patents. We also have the right to terminate the Collaboration Agreement immediately if Purdue Pharma is excluded from participation in federal healthcare programs. The Collaboration Agreement may also be terminated by either party in the event of a material breach by or insolvency of the other party.

We began earning royalty revenue during 2012, upon commercial launch of Intermezzo in April 2012. Royalty revenue earned during the year ended December 31, 2012 was $0.8 million.

We recorded as revenue $10.0 million milestone payments received in August 2012 and December 2011, respectively. The patent-related milestones were substantive and at-risk given the inherent uncertainty and risks associated with obtaining patent approval from the U.S. Patent and Trademark Office and subsequent listing in the FDA's Orange Book in addition to the inherent uncertainty and risks associated with obtaining FDA approval for Intermezzo and the opportunity for Purdue Pharma to terminate the Collaboration Agreement after its review of the terms of the FDA approval. We have no additional performance obligations under the Collaboration Agreement related to these milestone payments.

We also granted Purdue Pharma and an associated company the right to negotiate for the commercialization of Intermezzo in Mexico and Canada, respectively, and retained rights to commercialize Intermezzo in the rest of the world. We recorded revenue of $0.2 million and $0.7 million in Gross other revenue for the years ended December 31, 2012 and 2011, respectively, associated with these rights.

Through June 30, 2011, we recognized revenue from the $25 million non-refundable license fee ratably over an estimated 24-month period beginning in August 2009 and ending in July 2011 as this represented the estimated period during which we had significant participatory obligations under the Collaboration Agreement. During the quarter ended September 30, 2011, we re-assessed the time period over which the remaining $1.04 million of deferred revenue at June 30, 2011 was recognized, and we recorded the remaining revenue through November 30, 2011 based on FDA approval of Intermezzo and the completion of our participatory obligations under the Collaboration Agreement. Revenue recognized in connection with the license fee during the years ended December 31, 2011, and 2010 was $7.3 million, and $12.5 million, respectively.

On November 21, 2012, we agreed to contribute $10.0 million to Purdue Pharma's $29.0 million national direct-to-consumer ("DTC") advertising campaign (“Program”), including digital, print and television advertising to support Intermezzo commercialization. We initially recorded the $10.0 million payment to Purdue as a prepaid expense. We plan to recognize this payment as an offset against revenue over an estimated seven month period beginning December 1, 2012 and ending on June 30, 2013, as the advertising costs are incurred.

For the three-months and year ended December 31, 2012, this revenue offset totaled $1.4 million. Prepaid advertising costs were $8.6 million at December 31, 2012. There were no similar advertising costs in the prior periods.

TO-2061: an investigational product for adjunctive therapy in patients with obsessive compulsive disorder

In March 2011, we announced that we had started a Phase 2 clinical trial of TO-2061, an investigational product for adjunctive therapy in patients with obsessive compulsive disorder and our only product candidate in active clinical development. In December 2012, we announced that this trial did not meet its primary endpoint. Based on this result, we have discontinued the clinical development of TO-2061.

Net Loss and Profitability

We have incurred net losses since inception as we have devoted substantially all of our resources to research and development, including contract manufacturing and clinical trials. As of December 31, 2012, we had an accumulated deficit of $112.1 million. Our net loss for the years ended December 31, 2012, 2011, and 2010 was $12.0 million, $3.9 million, and $9.3 million, respectively.

As of December 31, 2012, we had cash, cash equivalents, and marketable securities of $85.3 million and working capital of $92.3 million.

Prior to the fourth quarter of 2011, our only source of revenue has been the receipt in August 2009 of a $25.0 million non-refundable license fee received pursuant to our Collaboration Agreement with Purdue Pharma. Through June 30, 2011, we recognized revenue from the license fee ratably over an estimated 24-month period beginning in August 2009 and ending in July 2011 as this represented the estimated period during which we had significant participatory obligations under the Collaboration Agreement. During the quarter ended September 30, 2011, we re-assessed the time period over which the remaining $1.04 million of deferred revenue at June 30, 2011 was recognized, and we recorded the remaining revenue through November 30, 2011, based on FDA approval of Intermezzo and the completion of our participatory obligations under the Collaboration Agreement. During each of 2011 and 2012, we received $10.0 million in intellectual property milestones payments and during 2012, we began receiving royalty revenue pursuant to our Collaboration Agreement with Purdue Pharma.

Our ability to generate additional near term revenue is dependent upon our ability to license the development and commercialization of Intermezzo outside the United States and the receipt of milestone and royalty payments under our Collaboration Agreement with Purdue Pharma.

Intermezzo and our other product candidates, if approved for commercial use, may never achieve market acceptance and may face competition from both generic and branded pharmaceutical products.

Financial Operations Overview

Net revenue

In December 2012, we contributed $10.0 million to Purdue Pharma's Intermezzo direct-to-consumer advertising campaign. We are recognizing this contribution as an offset against revenue over an estimated seven month period beginning December 1, 2012 and ending on June 30, 2013, as the advertising costs are incurred. This treatment resulted in a $1.4 million offset to revenue during 2012.

Revenue during 2012 included a $10.0 million milestone payment under our Collaboration Agreement with Purdue Pharma for the listing of our method-of-use patents in the FDA's Orange Book. Revenue during 2012 also included Intermezzo royalty revenues of $0.8 million, a non-refundable payment of $0.2 million from Purdue Pharma and an associated company for the right to negotiate for the commercialization of Intermezzo in Mexico and Canada, and the $1.4 million revenue offset related to the direct-to-consumer advertising campaign.

Through June 30, 2011, we recognized revenue from the $25 million non-refundable license fee ratably over an estimated 24-month period beginning in August 2009 and ending in July 2011 as this represented the estimated period during which we had significant participatory obligations under the Collaboration Agreement. During the quarter ended September 30, 2011, we re-assessed the time period over which the remaining $1.04 million of deferred revenue at June 30, 2011 was recognized, and we recorded the remaining revenue through November 30, 2011, based on FDA approval of Intermezzo and the completion of our participatory obligations under the Collaboration Agreement. The revenue recognized in connection with the license fee during the years ended December 31, 2011 and 2010 was $7.3 million and $12.5 million, respectively. There was no similar license fee during 2012. During the fourth quarter of 2011, we received a $10 million milestone payment under our Collaboration Agreement with Purdue Pharma for the listing of our formulation patents in the FDA's Orange Book. Revenue during 2011 also included:

- a non-refundable payment from Purdue Pharma and an associated company for the right to negotiate for the commercialization of Intermezzo in Mexico and Canada of $0.7 million; and
- $1.7 million for reimbursement of certain manufacturing-related costs.

Research and Development Expense

Research and development expense represented approximately 52%, 48% and 49% of total operating expenses for the years ended December 31, 2012, 2011, and 2010, respectively. Research and development costs are expensed as incurred. Research and development expense consists of expenses incurred in identifying, researching, developing and testing product candidates. These expenses primarily consist of the following:

- salaries, benefits, travel and related expense for personnel associated with research and development activities;
- fees paid to professional service providers for services related to the conduct and analysis of clinical trials;

- contract manufacturing costs for formulations used in clinical trials and pre-commercial manufacturing and packaging costs;
- fees paid to consultants related to continued development of Intermezzo and TO-2061;
- laboratory supplies and materials;
- depreciation of equipment; and
- allocated costs of facilities and infrastructure.

General and Administrative Expense

General and administrative expense consists primarily of salaries and related expense for personnel in executive, marketing, finance and accounting, information technology and human resource functions. Other costs include facility costs not otherwise included in research and development expense and professional fees for legal and accounting services.

Interest and other income (expense), net

Interest and other income (expense), net consists of interest income received from cash, cash equivalents, restricted cash and marketable securities held with certain financial institutions, and is offset by interest expense incurred on a $0.3 million loan for tenant improvements, payable to the landlord of our corporate facility in Point Richmond, California, and other income (expense), net, primarily relating to Delaware franchise tax.

Comparison of the Years Ended December 31, 2012 and 2011

Results of Operations

The following table summarizes results of operations with respect to the items set forth below for the years ended December 31, 2012 and 2011, in thousands, together with the percentage change in those items.

	Year ended December 31,			
	2012	2011	Favorable (Unfavorable)	% Change
Net revenue	$ 9,597	$ 19,694	$ (10,097)	(51)%
Research and development expense	11,191	11,273	82	1 %
General and administrative expense	10,263	12,185	1,922	16 %

Net revenue

Net revenue decreased 51% to $9.6 million for the year ended December 31, 2012 from $19.7 million for the comparable period in 2011 and consisted of the following:

- $10.0 million of milestone payments received in August 2012 and December 2011, respectively. The patent-related milestones were substantive and at-risk given the inherent uncertainty and risks associated with obtaining patent approval from the U.S. Patent and Trademark Office and subsequent listing in the FDA's Orange Book in addition to the inherent uncertainty and risks associated with obtaining FDA approval for Intermezzo and the opportunity for Purdue Pharma to terminate the Collaboration Agreement after its review of the terms of the FDA approval. We have no additional performance obligations under the Collaboration Agreement related to these milestone payments.
- a non-refundable payment from Purdue Pharma and an associated company for the right to negotiate for the commercialization of Intermezzo in Mexico and Canada of $0.2 million and $0.7 million in 2012 and 2011, respectively; and
- 2012 also included:
  - $0.8 million of royalty revenue recorded in connection with the April 2012 commercial launch of Intermezzo; and
  - $1.4 million of advertising costs paid to Purdue Pharma recorded as a revenue offset. In December 2012, we contributed $10.0 million to Purdue Pharma's Intermezzo direct-to-consumer advertising campaign. This

contribution is being recognized as an offset against revenue over an estimated seven month period beginning December 1, 2012 and ending on June 30, 2013, as the advertising costs are incurred.

- 2011 also included:
  - recognition of the remaining $7.3 million of license fee revenue related to a non-refundable license fee received from Purdue Pharma. There was no similar revenue during 2012; and
  - $1.7 million for the reimbursement of certain manufacturing-related costs.

Research and Development Expense

Research and development expense decreased 1% to $11.2 million for the year ended December 31, 2012 from $11.3 million for the comparable period in 2011. The decrease of approximately $0.1 million for the year ended December 31, 2012 is primarily attributable to:

- a decrease of $2.1 million in personnel costs, related expenses and other general expenses, including severance and benefit continuation expense of approximately $0.6 million incurred in 2011 in connection with the restructuring announced in July 2011, and a decrease of $0.3 million in stock-based compensation associated with performance-based options. We began recording compensation expense related to performance-based options upon FDA approval of Intermezzo on November 23, 2011, when the vesting was deemed to be probable; and
- a decrease of $0.7 million of costs related to the Intermezzo development program, principally due to the FDA approval of the Intermezzo NDA in November 2011.

These decreases were partially offset by an increase of $2.7 million of costs related to the TO-2061 development program for our Phase 2 clinical trial.

General and Administrative Expense

General and administrative expense decreased 16% to $10.3 million for the year ended December 31, 2012 from $12.2 million for the comparable period in 2011. The approximately $1.9 million decrease is primarily attributable to:

- a decrease of $2.4 million in personnel costs and related expenses, primarily due to 2011 severance and benefit continuation expense of approximately $0.7 million incurred in connection with the restructuring announced in July 2011, 2011 stock-based compensation expense of approximately $0.2 million to modify the terms of certain stock options previously granted to two members of our Board of Directors to align and extend the exercise period of the options after the directors' end of service to us in June 2011 and $0.8 million of stock-based compensation associated with performance-based options. We began recording compensation expense related to performance-based options upon FDA approval of Intermezzo on November 23, 2011, when the vesting was deemed to be probable; and
- a $0.1 million reduction in facilities and related costs due to the termination of one of our property leases and reductions in other general facilities costs.

These decreases are partially offset by a $0.6 million increase in professional fees, including market research, legal and third party consulting.

Comparison of the Years Ended December 31, 2011 and 2010

Results of Operations

The following table summarizes results of operations with respect to the items set forth below for the years ended December 31, 2011 and 2010, in thousands, together with the percentage change in those items.

	Year ended December 31,			
	2011	2010	Favorable (Unfavorable)	% Change
Net revenue	$ 19,694	$ 12,500	$ 7,194	58 %
Research and development expense	11,273	10,684	(589)	(6)%
General and administrative expense	12,185	11,038	(1,147)	(10)%

Net revenue

Net revenue increased 58% to $19.7 million for the year ended December 31, 2011 from $12.5 million for the comparable period in 2010. The increase of approximately $7.2 million is primarily attributable to:

- Revenue for both periods includes recognition of a portion of the $25.0 million non-refundable license fee we received from Purdue Pharma under our Collaboration Agreement. Through June 30, 2011, we recognized revenue over an estimated 24-month period beginning in August 2009 and ending in July 2011, as this represented the estimated period during which we had significant participatory obligations under the collaboration agreement. During the quarter ended September 30, 2011, we re-assessed the time period over which the remaining $1.04 million of deferred revenue at June 30, 2011 was recognized, and we recorded the remaining revenue through November 30, 2011, based on FDA approval of Intermezzo and the completion of our participatory obligations under the Collaboration Agreement. Thus the year ended December 31, 2011 included $7.3 million of license fee revenue as compared to $12.5 million for the year ended December 31, 2010.
- During the fourth quarter of 2011, we received and recorded a $10.0 million milestone payment under our Collaboration Agreement with Purdue Pharma for the listing of our formulation patents in the FDA's Orange Book. We achieved no similar milestones during 2010.
- 2011 also included:
    - a non-refundable payment from Purdue Pharma and an associated company for the right to negotiate for the commercialization of Intermezzo in Mexico and Canada of $0.7 million; and
    - $1.7 million for the reimbursement of certain manufacturing-related costs.

There was no similar revenue during 2010.

Research and Development Expense

Research and development expense increased 6% to $11.3 million for the year ended December 31, 2011 from $10.7 million for the comparable period in 2010. The increase of approximately $0.6 million for the year ended December 31, 2011 is primarily attributable to:

- an increase of $2.2 million in the TO-2061 development program, including an increase of $2.6 million for our Phase 2 clinical trial partially offset by a decrease associated with our two 12-week Phase 1 studies which were substantially complete during 2010; and
- an increase of $1.6 million in personnel costs, related expenses and other general expenses, including severance and benefit continuation expense of approximately $0.6 million incurred in connection with the restructuring announced in July 2011, and $0.7 million of stock-based compensation associated with performance-based options. We began recording compensation expense related to performance-based options upon FDA approval of Intermezzo on November 23, 2011, when the vesting was deemed to be probable.

These increases are partially offset by a decrease of $3.2 million in the Intermezzo development program, principally due to the substantial completion of clinical trials during 2010.

General and Administrative Expense

General and administrative expense increased 10% to $12.2 million for the year ended December 31, 2011 from $11.0 million for the comparable period in 2010. The approximately $1.2 million increase is primarily attributable to:

- An increase of $2.4 million in personnel costs and related expenses, primarily including severance and benefit continuation expense of approximately $0.7 million incurred in connection with the restructuring announced in July 2011, stock-based compensation expense of approximately $0.2 million to modify the terms of certain stock options previously granted to two members of our Board of Directors to align and extend the exercise period of the options after the directors' end of service to us in June 2011 and $1.2 million of stock-based compensation associated with performance-based options. We began recording compensation expense related to performance-based options upon FDA approval of Intermezzo on November 23, 2011, when the vesting was deemed to be probable.

These increases are partially offset by:

- a $0.9 million reduction in professional fees, including market research, legal and third party consulting and
- a $0.3 million reduction in facilities and related costs due to the termination of one of our property leases and reductions in other general facilities costs.

Liquidity and Capital Resources

At December 31, 2012, we had cash, cash equivalents and marketable securities of $85.3 million.

Sources of Liquidity

Prior to 2009, we financed our operations primarily through private placements of preferred stock (subsequently converted to common stock), debt financing and interest income. On August 4, 2009, we received a $25 million non-refundable license fee from Purdue Pharma in connection with our entry into the Collaboration Agreement. In December 2011, we received a $10 million milestone payment from Purdue Pharma in accordance with the Collaboration Agreement.

On May 1, 2012 we completed a public offering of 4.5 million shares of our common stock at a public offering price of $9.00 per share. Net proceeds to us from the public offering were approximately $37.7 million after deducting underwriting discounts and commissions and offering expenses.

In August 2012, we received an additional $10.0 million milestone payment from Purdue Pharma in connection with the Collaboration Agreement.

Purdue Pharma launched Intermezzo in April 2012 and we began recognizing royalty revenue during the second quarter of 2012.

The following table summarizes our cash provided by (used in) operating, investing and financing activities (in thousands):

	Year Ended December 31,		
	2012	2011	2010
Net cash used in operating activities	$ (15,205)	$ (5,707)	$ (19,548)
Net cash provided by investing activities	5,170	1,266	16,068
Net cash provided by financing activities	38,744	1,380	169

Net Cash Used in Operating Activities

Net cash used in operating activities for the years ended December 31, 2012, 2011 and 2010 was $15.2 million, $5.7 million and $19.5 million, respectively. Net cash used in operating activities during each of these years consisted primarily of our net loss adjusted for noncash items such as depreciation, amortization, stock-based compensation charges and noncash interest expense, as well as net changes in working capital. Net changes in working capital during 2011 and 2010 included $7.3 million and $12.5 million, respectively, of revenue recognition resulting in a decrease in deferred revenue. Net cash used in operating activities was partially offset during 2012 and 2011 by a $10 million milestone payment received in each year from Purdue Pharma in accordance with our Collaboration Agreement.

Net Cash Provided by Investing Activities

Net cash provided by investing activities was $5.2 million, $1.3 million and $16.1 million for the years ended December 31, 2012, 2011, and 2010, respectively. Net cash provided by investing activities during each of the years was primarily attributable to maturities of marketable securities, net of purchases. Uses of cash in investing activities in all periods included net purchases of property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities during the year ended December 31, 2012, 2011 and 2010 was $38.7 million, $1.4 million and $0.2 million, respectively. On May 1, 2012 we completed a public offering of 4.5 million shares of our common stock at a public offering price of $9.00 per share. Net proceeds to us from the public offering were approximately $37.7 million after deducting underwriting discounts and commissions and offering expenses. Net cash provided by financing activities during each of the years also included common stock issuances in connection with stock option exercises.

Capital Resources

We expect our cash, cash equivalents, and marketable securities of $85.3 million at December 31, 2012, will be sufficient to satisfy our liquidity requirements for at least the next twelve months. We believe our investments in cash equivalents and marketable securities are highly rated and highly liquid.

Our future capital requirements will depend on, and could increase significantly as a result of, numerous forward-looking factors, including:

- the ability of Purdue Pharma to successfully commercialize Intermezzo in the United States;
- whether we choose to share the cost of future advertising or other marketing efforts with Purdue Pharma, related to the commercialization of Intermezzo in the United States;

- the cost of establishing or contracting for sales and marketing capabilities if we exercise our option to co-promote Intermezzo to psychiatrists in the United States, and potential costs of being required to engage in contracting to replace Purdue Pharma's primary care sales and marketing capabilities if our existing Collaboration Agreement with Purdue Pharma is terminated;
- the extent to which we develop internally, acquire or in-license new products, technologies or businesses;
- the cost of conducting pre-clinical and clinical trials and other development activities;
- the receipt of milestone and other payments, if any, from Purdue Pharma under the Collaboration Agreement;
- the prospect, cost and timing for the development of Intermezzo to obtain regulatory approval for Intermezzo outside the United States;
- the ability to license Intermezzo outside the United States and the terms and timing of any such licensing arrangements;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, including in connection with ANDA proceedings relating to Intermezzo; and
- the effect of competing technological and market developments.

In addition, we may seek to raise additional funds to:

- develop internally, acquire or in-license new products, technologies or businesses or to otherwise fund our operations
- establish or contract for sales and marketing capabilities if we exercise our option to co-promote Intermezzo, or to build our own sales force if Purdue Pharma does not continue with our collaboration to commercialize Intermezzo in the United States; and
- support the ongoing promotion of Intermezzo by Purdue Pharma.

If our Collaboration Agreement with Purdue Pharma is terminated or other factors arise, our cash, cash equivalents and marketable securities may prove insufficient to fund our operations through the successful commercialization of Intermezzo. Also, the development and potential regulatory approval of any additional product candidates will likely require additional funding, which may not be available at the time needed on commercially reasonable terms, if at all.

Off-Balance Sheet Arrangements

Since inception, we have not engaged in any off-balance sheet financing activities, including the use of structured finance, special purpose entities or variable interest entities.

Contingencies

There are no legal proceedings or other matters as of December 31, 2012 that are expected to have a material adverse effect on our financial position, results of operations or cash flows.

Contractual Obligations and Commitments

Our contractual obligations and commitments as of December 31, 2012 include future minimum lease payments under operating leases, as shown in the following table:

Total Contractual Obligations
(in thousands)

Contractual Obligations	Payments due by period				
	Total	Less than one year	1 to 3 years	3 to 5 years	More than 5 years
Operating leases (1)	$ 131	$ 131	$ —	$ —	$ —
Loan payable (2)	24	24	—	—	—
Total contractual obligations	$ 155	$ 155	$ —	$ —	$ —

(1) Includes obligations under an operating lease for current corporate facilities of Transcept. In February 2006, we signed an operating lease for our corporate offices that include approximately 11,600 square feet of office and laboratory space in Point Richmond, California. The lease term is for seven years, commencing on June 1, 2006. In June 2007, we amended this operating lease to add approximately 3,000 square feet of additional office space. The lease term of this amendment coincides with the original lease agreement, with a separate commencement date of September 12, 2007. Both of these leases provide for periodic rent increases based upon previously negotiated or consumer price indexed adjustments.

On March 6, 2013, we extended our lease agreement for 11,600 square feet of space in our current facility in Point Richmond, California by one year.

(2) Loan payable represents a loan from the landlord of our corporate offices in Point Richmond, California for tenant improvements.

Recently Adopted Accounting Standards

Effective January 1, 2012, the Company adopted the Accounting Standards Update ("ASU") No. 2011-05, *Presentation of Comprehensive Income* on a retrospective basis. ASU No. 2011-05 was issued to enhance comparability between entities that report under U.S. GAAP and International Financial Reporting Standards ("IFRS"), and to provide a more consistent method of presenting non-owner transactions that affect an entity's equity. ASU 2011-05 eliminates the option to solely report other comprehensive income and its components in the statement of changes in stockholders' equity and requires an entity to present the total of comprehensive income, the components of net income and the components of other comprehensive income either in a single continuous statement or in two separate but consecutive statements. The adoption of this ASU did not have any impact on the Company's results of operations or financial position, but did require modifying the format of the former "Statements of Operations" to include total comprehensive income (loss) and changing the title of the statements to "Statements of Operations and Comprehensive Income (Loss)."

Effective January 1, 2012, the Company adopted ASU No. 2011-04, *Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and International Financial Reporting Standards ("IFRS")* on a prospective basis. This pronouncement was issued to provide a consistent definition of fair value and ensure that the fair value measurement and disclosure requirements are similar between U.S. GAAP and IFRS. ASU 2011-04 changes certain fair value measurement principles and enhances the disclosure requirements particularly for Level 3 fair value measurements. The adoption of ASU No. 2011-04 did not have a material impact on the Company's consolidated results of operations or financial condition.

Critical Accounting Policies

This discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as revenue and expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believed were reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Therefore, actual results could differ materially from those estimates under different assumptions or conditions.

Significant accounting policies are described in Note 1 to the Financial Statements included in Item 8 of this Annual Report on Form 10-K. Some of these accounting policies require us to make difficult and subjective judgments, often as a result of the need to make estimates on matters that are inherently uncertain. We believe that the following critical accounting policies reflect the more significant estimates and assumptions used in the preparation of our financial statements.

Revenue Recognition

We apply the revenue recognition criteria outlined in Staff Accounting Bulletin No. 104, *Revenue Recognition in Financial Statements*, and FASB ASC Topic 605 *Revenue Recognition,* sub-topic 25 *Multiple-Element Arrangements*.

Revenue arrangements with multiple components are divided into separate units of accounting if certain criteria are met, including whether the delivered component has stand-alone value to the customer. Consideration received is allocated among the separate units of accounting based on their respective fair values, or if fair value is not determinable, based on the Company's best estimate of selling price. Applicable revenue recognition criteria are then applied to each of the units.

Revenue is recognized when the four basic criteria of revenue recognition are met: (1) persuasive evidence of an arrangement exists; (2) transfer of technology has been completed or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured.

For each source of revenue, we comply with the above revenue recognition criteria in the following manner:

- Up-front license payments are assessed to determine whether or not the licensee is able to obtain any stand-alone value from the license. Where this is not the case, we do not consider the license deliverable to be a separate unit of accounting, and the revenue is deferred with revenue recognition for the license fee assessed in conjunction with the other deliverables that constitute the combined unit of accounting. When the period of deferral cannot be specifically identified from the related agreements, management estimates the period based upon provisions contained within the agreement and other relevant facts. We periodically review the estimated involvement period, which could impact the deferral period and, therefore, the timing and the amount of revenue recognized. It is possible that future adjustments will be made if actual conditions differ from our current plan and involvement assumptions;
- Payments received that are related to substantive, performance-based “at-risk” milestones are recognized as revenue upon achievement of the milestone or event specified in the underlying contracts, which represents the culmination of the earnings process. Amounts received in advance, if any, are recorded as deferred revenue until the milestone is reached; and
- Royalty revenue from sales of our licensed products, if and when approved for marketing by the appropriate regulatory agency, will be recognized as earned in accordance with the contract terms when royalties from licensees can be reasonably estimated and collectability is reasonably assured.

Clinical Trials

We accrue and expense costs for clinical trial activities performed by third parties, including clinical research organizations and clinical investigators, based upon estimates made of the work completed as of the reporting date, in accordance with agreements established with contract research organizations and clinical trial sites and the agreed upon fee to be paid for the services. We determine these estimates through discussion with internal personnel and outside service providers as to the progress or stage of completion of the trials or services. If the actual timing of performance of services or the level of effort varies from these estimates, the accrual will be adjusted accordingly. Costs of setting up clinical trial sites for participation in the trials are expensed as the activities are performed. Clinical trial site costs related to patient enrollment are accrued as patients are entered into the trial and reduced by any initial payment made to the clinical trial site when the first patient is enrolled. We adjust the estimates as actual costs become known. Through December 31, 2012, differences between actual and estimated activity levels for any particular study have not been material. However, if management does not receive complete and accurate information from vendors or underestimates activity levels associated with a study at a given point in time, we would have to record additional and potentially significant research and development expenses in future periods.

Stock-Based Compensation

We recognize stock based compensation in accordance with ASC Topic 718, *Compensation - Stock Compensation*, or ASC Topic 718. ASC Topic 718 requires an entity to measure the cost of employee services received in exchange for an award of equity instruments based on the fair value of the award on the date of grant and to recognize the cost over the period during which the employee is required to provide service in exchange for the award. Additionally, we are required to include an estimate of the number of awards that will be forfeited in calculating compensation costs, which are recognized over the requisite service period of the awards on a straight-line basis.

Measurement and recognition of share-based compensation under ASC Topic 718 involve significant estimates and subjective inputs. The grant date fair value of stock option awards is determined using an option valuation model, such as the Black-Scholes model that we used, and the amount of expense recognized during the period is affected by many complex and subjective assumptions. These assumptions include estimates of our future volatility, employee exercise behavior, the expected term of the stock options, the number of options expected to ultimately vest, and the probability of achieving performance conditions, as applicable. Until the merger with Novacea, our stock did not have a readily available market. Consequently, expected future volatility is derived from the weighted average of our historical volatility post-merger and the historical volatilities of several unrelated public companies within the specialty pharmaceutical industry. When making the selection of our industry peer companies to be used in the volatility calculation, consideration is given to the stage of development, size and financial leverage of potential comparable companies. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero coupon U.S. Treasury notes with maturities approximately equal to each grant's expected life. The assumed dividend yield was based on our expectations of not paying dividends in the foreseeable future. Given our limited history to accurately estimate the expected lives for the various employee groups, we used the "simplified" method as provided by Staff Accounting Bulletin No. 107, *Share Based Payment*. The "simplified" method is calculated as the average of the time-to-vesting and the contractual life of the options. Stock-based compensation recorded in our Statements of Operations is based on awards expected to ultimately vest and has been reduced for estimated forfeitures. Estimated forfeitures may differ from actual forfeiture rates which would affect the amount of expense recognized during the period. Share-based compensation is adjusted to reflect the value of options which ultimately vest as such amounts become known in future periods.

If in the future, our management determines that another method is more reasonable, or if another method for calculating these input assumptions is prescribed by authoritative guidance, and, therefore, should be used to estimate volatility or expected life, the fair value calculated for our stock options could change significantly. Higher volatility and longer expected lives result in an increase to stock-based compensation expense determined at the date of grant. Stock-based compensation expense affects both our research and development expense and general and administrative expense.

There is inherent uncertainty in these estimates and if we had made different assumptions than those described above, the amount of stock-based compensation expense, net loss and net loss per share amounts could have been significantly different.

No related tax benefits of stock-based compensation costs have been recognized since our inception.

Fair Value Measurements

On January 1, 2008, we adopted ASC Topic 820, *Fair Value Measurements and Disclosures* (formerly SFAS No. 157) as it applies to our financial assets and financial liabilities. ASC Topic 820 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. Fair value is defined as the estimated exit price received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date rather than on an entry price which represents the purchase price of an asset or liability. ASC Topic 820 establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

- Level 1 - Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.
- Level 2 - Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 - Unobservable inputs (i.e. inputs that reflect the reporting entity's own assumptions about the assumptions that market participants would use in estimating the fair value of an asset or liability) are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement. Where quoted prices are available in an active market, securities are classified as Level 1 of the valuation hierarchy. Level 1 securities include highly liquid money market funds. If quoted market prices are not available for the specific security, then we estimate fair value by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows. Level 2 instruments include commercial paper, U.S. corporate debt, and U.S. government sponsored enterprise issues. In certain cases where there is limited activity or less transparency around inputs to valuation, securities are classified as Level 3 within the valuation hierarchy.

During the year ended December 31, 2012, there were no significant changes to the valuation models used for purposes of determining the fair value of Level 2 assets.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Our exposure to market risk is confined to cash, cash equivalents and marketable securities which have contractual maturities of eighteen months or less, bear interest rates at fixed rates and are denominated in, and pay interest in, U.S. dollars. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs, maximization of investment performance and fiduciary control of cash and investments. Investments are classified as available-for-sale. We do not use derivative financial instruments in our investment portfolio. To achieve our goals, we invest excess cash in securities with different maturities to match projected cash needs and limit concentration of credit risk by diversifying investments among a variety of high credit-quality issuers, including U.S. government agencies, corporate debt obligations, taxable and tax-exempt pre-refunded municipal debt obligations and money market funds. There is no limit to the percentage of investments that may be maintained in U.S. Treasury debt obligations, U.S. agency debt obligations, or SEC-registered money market funds. The portfolio includes marketable securities with active secondary or resale markets to ensure portfolio liquidity, and we regularly review our portfolio against our policy. A hypothetical 100 basis point increase in interest rates would result in an approximate $193,000 decrease in the fair value of our marketable securities at December 31, 2012.

Item 8. Financial Statements and Supplementary Data

Index to Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of Transcept Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Transcept Pharmaceuticals, Inc. as of December 31, 2012 and 2011 and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Transcept Pharmaceuticals, Inc. at December 31, 2012 and 2011, and the consolidated results of its operations and comprehensive loss and its cash flows for each of the three years in the period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Transcept Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 12, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Redwood City, California
March 12, 2013

Transcept Pharmaceuticals, Inc.

Consolidated Balance Sheets
(in thousands, except for share and per share amounts)

	December 31,	
	2012	2011
Assets		
Current assets:		
Cash and cash equivalents	$ 39,368	$ 10,659
Marketable securities	45,907	51,703
Prepaid advertising	8,571	—
Prepaid and other current assets	920	3,275
Restricted cash	200	200
Total current assets	94,966	65,837
Property and equipment, net	128	314
Goodwill	2,962	2,962
Other assets	—	38
Total assets	$ 98,056	$ 69,151
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,001	$ 987
Accrued liabilities	1,639	2,108
Other liabilities, short-term portion	23	244
Total current liabilities	2,663	3,339
Other liabilities, long-term portion	—	60
Total liabilities	2,663	3,399
Commitments and contingencies		
Stockholders' equity:		
Preferred stock: $0.001 par value; 5,000,000 shares authorized; 0 shares issued and outstanding	—	—
Common stock: $0.001 par value; 100,000,000 shares authorized; 18,676,396 and 13,904,515 shares issued and outstanding at December 31, 2012 and 2011, respectively	19	14
Additional paid-in capital	207,477	165,803
Accumulated deficit	(112,110)	(100,094)
Accumulated other comprehensive income	7	29
Total stockholders' equity	95,393	65,752
Total liabilities and stockholders' equity	$ 98,056	$ 69,151

See accompanying notes.

Transcept Pharmaceuticals, Inc.

Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except per share amounts)

	Year Ended December 31,		
	2012	2011	2010
Revenue:			
Gross royalty revenue	$ 776	$ —	$ —
Gross license fee revenue	—	7,292	12,500
Gross milestone revenue	10,000	10,000	—
Gross other revenue	250	2,402	—
Advertising expense - Purdue Pharma	(1,429)	—	—
Net revenue	9,597	19,694	12,500
Operating expenses:			
Research and development	11,191	11,273	10,684
General and administrative	10,263	12,185	11,038
Total operating expenses	21,454	23,458	21,722
Loss from operations	(11,857)	(3,764)	(9,222)
Interest and other income (expense), net	(159)	(116)	(81)
Net loss	$ (12,016)	$ (3,880)	$ (9,303)
Basic and diluted net loss per share	$ (0.70)	$ (0.29)	$ (0.69)
Weighted average shares outstanding	17,052	13,534	13,416
Other comprehensive loss			
Changes in unrealized (loss) gain on marketable securities	(22)	27	(37)
Comprehensive loss	$ (12,038)	$ (3,853)	$ (9,340)

See accompanying notes.

Transcept Pharmaceuticals, Inc.
Consolidated Statement of Stockholders' Equity
(in thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2009	13,384	$ 13	$ 157,930	$ (86,911)	$ 39	$ 71,071
Exercise of options to purchase common stock	26	—	38	—	—	38
Employee stock purchase under Employee stock purchase plan	22	—	131	—	—	131
Stock-based compensation related to:						
Employee stock option grants	—	—	1,759	—	—	1,759
Non-employee stock option grants	—	—	31	—	—	31
Employee stock purchase plan	—	—	75	—	—	75
Stock option modifications	—	—	14	—	—	14
Vested restricted stock	18	—	32	—	—	32
Net loss	—	—	—	(9,303)	—	(9,303)
Unrealized gain on marketable securities	—	—	—	—	(37)	(37)
Total comprehensive loss						(9,340)
Balance at December 31, 2010	13,450	13	160,010	(96,214)	2	63,811
Exercise of options to purchase common stock	442	1	1,333	—	—	1,334
Employee stock purchases under Employee stock purchase plan	8	—	46	—	—	46
Stock-based compensation related to:						
Employee stock option grants	—	—	3,677	—	—	3,677
Non-employee stock option grants	—	—	355	—	—	355
Employee stock purchase plan	—	—	22	—	—	22
Stock option modifications	—	—	351	—	—	351
Vested restricted stock	5	—	9	—	—	9
Net loss	—	—	—	(3,880)	—	(3,880)
Unrealized loss on marketable securities	—	—	—	—	27	27
Total comprehensive loss						(3,853)
Balance at December 31, 2011	13,905	14	165,803	(100,094)	29	65,752
Exercise of options to purchase common stock	266	—	1,069	—	—	1,069
Employee stock purchases under Employee stock purchase plan	5	—	28	—	—	28
Stock-based compensation related to:						
Employee stock option grants	—	—	2,696	—	—	2,696
Non-employee stock option grants	—	—	187	—	—	187
Employee stock purchase plan	—	—	18	—	—	18
Stock option modifications	—	—	28	—	—	28
May 1, 2012 sale of common stock, net of offering costs of $2,848	4,500	5	37,648	—	—	37,653
Net loss	—	—	—	(12,016)	—	(12,016)
Unrealized gain on marketable securities	—	—	—	—	(22)	(22)
Total comprehensive loss						(12,038)
Balance at December 31, 2012	18,676	$ 19	$ 207,477	$ (112,110)	$ 7	$ 95,393

See accompanying notes.

Transcept Pharmaceuticals, Inc.

Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2012	2011	2010
Operating activities			
Net loss	$ (12,016)	$ (3,880)	$ (9,303)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	229	357	500
Stock-based compensation	2,929	4,405	1,879
Amortization of lease liability	(191)	(316)	(430)
Loss on disposals of fixed assets	—	2	2
Amortization of premium on available for sale securities	561	1,250	1,451
Changes in operating assets and liabilities:			
Prepaid and other current assets	(6,211)	(2,023)	24
Other assets	38	770	18
Accounts payable	14	389	(130)
Accrued and other liabilities	(558)	631	(1,059)
Deferred revenue	—	(7,292)	(12,500)
Net cash used in operating activities	(15,205)	(5,707)	(19,548)
Investing activities			
Purchases of property and equipment, net	(43)	(59)	(65)
Purchases of marketable securities	(41,037)	(52,175)	(106,618)
Maturities of marketable securities	46,250	53,500	122,751
Net cash provided by investing activities	5,170	1,266	16,068
Financing activities			
Proceeds from issuance of common stock, net	38,744	1,380	169
Net cash provided by financing activities	38,744	1,380	169
Net increase (decrease) in cash and cash equivalents	28,709	(3,061)	(3,311)
Cash and cash equivalents at beginning of period	10,659	13,720	17,031
Cash and cash equivalents at end of period	$ 39,368	$ 10,659	$ 13,720
Supplemental disclosure of cash flow information			
Cash paid during the year for interest	$ 5	$ 9	$ 13

See accompanying notes.

Transcept Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements

1. Organization and Summary of Significant Accounting Policies

Transcept Pharmaceuticals, Inc. (the "Company") is a specialty pharmaceutical company focused on the development and commercialization of proprietary products that address important therapeutic needs in the field of neuroscience. Intermezzo ® (zolpidem tartrate) sublingual tablet C-IV is the first FDA approved Transcept product. Purdue Pharmaceutical Products L.P. ("Purdue Pharma") holds commercialization and development rights for Intermezzo in the United States. The Company operates in one business segment.

The Company was incorporated in Delaware in 2001 as Novacea, Inc. ("Novacea"). Novacea previously traded on The NASDAQ Global Market under the ticker symbol "NOVC." On January 30, 2009, Novacea completed a business combination (the "Merger") with a privately held company, Transcept Pharmaceuticals, Inc. ("TPI"), pursuant to which TPI became a wholly-owned subsidiary of Novacea and the corporate name of Novacea was changed to "Transcept Pharmaceuticals, Inc." Prior to the Merger, Novacea substantially ended its business of developing novel therapies for the treatment of cancer. Following the closing of the Merger, the business conducted by TPI became the primary business of the combined entity and that business now operates through a wholly-owned subsidiary now known as Transcept Pharma, Inc.

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Management bases its estimates on historical experience and on assumptions believed to be reasonable under the circumstances. Actual results could differ materially from those estimates. Management makes estimates when preparing the financial statements including those relating to revenue recognition, clinical trials expense, advertising expense, and stock-based compensation.

Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements include the results of operations of Transcept Pharmaceuticals, Inc. and its wholly-owned subsidiary, Transcept Pharma, Inc. All significant intercompany accounts and transactions have been eliminated in consolidation.

Cash and Cash Equivalents

The Company invests its excess cash in bank deposits, money market accounts, and other marketable securities. The Company considers all highly liquid investments purchased with a maturity of three months or less from the date of purchase to be cash equivalents. Cash equivalents are carried at fair value. The Company invests in money market securities in a U.S. bank and is exposed to credit risk in the event of default by the financial institution to the extent of amounts recorded on the balance sheet.

Restricted cash consists of a Certificate of Deposit ("CD") which functions as security for the Company's credit cards with the domestic financial institution that issued the credit cards. The CD will remain as security concurrent with the continuation of the Company credit card program.

Marketable Securities

All marketable securities have been classified as "available-for-sale" and are carried at fair value as determined based upon quoted market prices. Management determines the appropriate classification of its investments in debt securities at the time of purchase and reevaluates such designation as of each balance sheet date. Management views its investment portfolio as available for use in current operations and, accordingly, has reflected all such investments as current assets although the stated maturity of individual investments may be one year or more beyond the balance sheet date. Unrealized gains and losses are included in accumulated other comprehensive loss and reported as a separate component of stockholders' equity. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other income (expense), net. The cost of securities sold is based on the specific identification method. Interest on marketable securities is included in interest income. The net carrying value of debt securities classified as available-for-sale is adjusted for amortization of premiums and accretion of discounts to maturity over the estimated life of the security. Such amortization is computed under the effective interest method and included in interest income.

Property and Equipment

Property and equipment is stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets, which range from two to five years. Leasehold improvements are amortized over the shorter of their estimated useful lives or the related lease term.

Long-Lived Assets

Long-lived assets include property and equipment. The carrying value of long-lived assets is reviewed for impairment whenever events or changes in circumstances indicate that the asset may not be recoverable. An impairment loss is recognized when the total of estimated future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount or appraised value, as appropriate. Through December 31, 2012, there have been no such impairments.

Goodwill

Goodwill is not subject to amortization, but is tested for impairment on an annual basis during the third quarter or whenever events or changes in circumstances indicate the carrying amount of these assets may not be recoverable. Goodwill impairment testing is a two-step process and performed on a reporting unit level. In the first step, the Company conducts an assessment of qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If the Company determines that it is more likely than not that the fair value of its reporting unit is less than its carrying amount, it then conducts the second step, a two-part test for impairment of goodwill. The Company first compares the fair value of its reporting units to their carrying values. If the fair values of the reporting units exceed the carrying value of the net assets, goodwill is not considered impaired and no further analysis is required. If the carrying values of the net assets exceed the fair values of the reporting units, then the second part of the impairment test must be performed in order to determine the implied fair value of the goodwill. If the carrying value of the goodwill exceeds the implied fair value, then an impairment loss equal to the difference would be recorded. For 2012, the Company performed its annual goodwill impairment analysis as of September 30, 2012 and concluded that goodwill is not impaired.

Revenue Recognition

The Company applies the revenue recognition criteria outlined in Staff Accounting Bulletin No. 104, *Revenue Recognition in Financial Statements*, and Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 605 *Revenue Recognition,* sub-topic 25 *Multiple-Element Arrangements.*

Revenue arrangements with multiple components are divided into separate units of accounting if certain criteria are met, including whether the delivered component has stand-alone value to the customer. Consideration received is allocated among the separate units of accounting based on their relative fair values or if fair value is not determinable, based on the Company's best estimate of selling price. Applicable revenue recognition criteria are then applied to each of the units.

Revenue is recognized when the four basic criteria of revenue recognition are met: (1) persuasive evidence of an arrangement exists; (2) transfer of technology has been completed or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured.

For each source of revenue, the Company complies with the above revenue recognition criteria in the following manner:

- Up-front license payments are assessed to determine whether or not the licensee is able to obtain any stand-alone value from the license. Where this is not the case, the Company does not consider the license deliverable to be a separate unit of accounting, and the revenue is deferred with revenue recognition for the license fee assessed in conjunction with the other deliverables that constitute the combined unit of accounting. When the period of deferral cannot be specifically identified from the agreement, management estimates the period based upon provisions contained within the related agreements and other relevant facts. The Company periodically reviews the estimated involvement period, which could impact the deferral period and, therefore, the timing and the amount of revenue recognized. It is possible that future adjustments will be made if actual conditions differ from the Company's current plan and involvement assumptions;
- Payments received that are related to substantive, performance-based "at-risk" milestones are recognized as revenue upon achievement of the milestone or event specified in the underlying contracts, which represents the culmination of the earnings process. Amounts received in advance, if any, are recorded as deferred revenue until the milestone is reached; and

- Royalty revenue from sales of the Company's licensed product is recognized as earned in accordance with the contract terms when royalties from licensees can be estimated and collectability is reasonably assured.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development costs consist of salaries and benefits, travel and related expenses, lab supplies and facility costs, as well as fees paid to other entities that conduct certain research and development activities on behalf of the Company.

Advertising

The Company expenses non-direct response advertising as incurred. Advertising expense consists of the Company's $10.0 million contribution to Purdue Pharma's national direct-to-consumer advertising campaign (the "Program"), including digital, print and television advertising to support Intermezzo commercialization. The Company initially recorded the $10.0 million payment to Purdue Pharma as a prepaid expense. This payment will be recognized over an estimated seven month period, beginning December 1, 2012, and ending on June 30, 2013, as the advertising costs are incurred. As this payment was made directly to Purdue Pharma, recognition of the expense is recorded as an offset to revenue.

For the year and three-months ended December 31, 2012, the offset to revenue totaled $1.4 million. Prepaid advertising costs were $8.6 million at December 31, 2012. There were no similar advertising costs in the prior periods.

Clinical Trials

The Company accrues and expenses costs for clinical trial activities performed by third parties, including clinical research organizations and clinical investigators, based upon estimates made of the work completed as of the reporting date, in accordance with agreements established with contract research organizations and clinical trial sites and the agreed upon fee to be paid for the services. The Company determines these estimates through discussion with internal personnel and outside service providers as to the progress or stage of completion of the trials or services. Costs of setting up clinical trial sites for participation in the trials are expensed immediately as research and development expenses. Clinical trial site costs related to patient enrollment are accrued as patients are entered into the trial and reduced by any initial payment made to the clinical trial site when the first patient is enrolled.

Stock-Based Compensation

The Company records stock-based compensation in accordance with ASC Topic 718 *Compensation – Stock Compensation* ("ASC Topic 718") (formerly Statement of Financial Accounting Standards ("SFAS") No. 123(R), *Share-Based Payment*). ASC Topic 718 requires an entity to measure the cost of employee services received in exchange for an award of equity instruments based on the fair value of the award on the date of grant and to recognize the cost over the period during which the employee is required to provide service in exchange for the award. Additionally, the Company is required to include an estimate of the number of awards that will be forfeited in calculating compensation costs, which are recognized over the requisite service period of the awards on a straight-line basis.

During the years ended December 31, 2012, 2011, and 2010, the Company recognized employee stock-based compensation costs of $2.7 million, $4.1 million, and $1.8 million, respectively, in accordance with the provisions of ASC Topic 718. No related tax benefits of stock-based compensation costs have been recognized since the Company's inception.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of ASC Topic 505, subtopic 50, *Equity-Based Payments to Non-Employees* (formerly Emerging Issues Task Force No. 96-18, *Accounting for Equity Instruments That are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services*), using a fair-value approach. The equity instruments, consisting of stock options and warrants granted to consultants, are valued using the Black-Scholes valuation model. The measurement of stock-based compensation is subject to periodic adjustments as the underlying equity instruments vest and is recognized as an expense over the period over which services are received. During the years ended 2012, 2011 and 2010, the Company recognized non-employee stock-based compensation costs of $0.2 million, $0.4 million, and $31,000.

Comprehensive Net Loss

The Company reports comprehensive net loss in accordance with FASB ASC Topic 220 *Comprehensive Income* ("ASC Topic 220"). Among other things, ASC Topic 220 requires unrealized gains or losses on the Company's available-for-sale

marketable securities to be included in other comprehensive loss and be reported as a separate component of stockholders' equity.

Income Taxes

The Company utilizes the liability method of accounting for income taxes as required by FASB ASC Topic 740 *Income Taxes*. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Uncertain tax positions are evaluated in accordance with this topic and if appropriate, the amount of unrecognized tax benefits are recorded within deferred tax assets. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized. Currently, there is no provision for income taxes as the Company has incurred operating losses to date. Tax-related interest and penalties, if any, are recorded as other expenses. To date, the Company has incurred no tax-related interest or penalties.

Warrants to Purchase Convertible Preferred Stock

Effective July 1, 2005, the Company adopted the provisions of ASC Topic 480 Distinguishing Liabilities from Equity ("ASC Topic 480") (formerly FASB Staff Position No. 150-5, Issuer's Accounting Under FASB Statement No. 150 for Freestanding Warrants and Other Similar Instruments with Characteristics of *Both Liabilities and Equity*, an interpretation of SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*). Under ASC Topic 480, freestanding warrants to purchase shares of convertible preferred stock were classified as liabilities on the balance sheets at fair value because the warrants may conditionally obligate the Company to transfer assets at some point in the future. The warrants were subject to remeasurement at each balance sheet date, and any change in fair value was recognized as a component of interest and other income (expense), net in the statements of operations and comprehensive loss.

The warrants to purchase convertible preferred stock converted into warrants to purchase shares of common stock on January 30, 2009, upon the closing of the Merger transaction, at which point the warrants were no longer subject to ASC Topic 480. During 2012, 94,556 of the outstanding warrants expired unexercised. The remaining 61,451 warrants have an exercise price of $8.136 per share and will, if not exercised, expire in 2016.

Concentration of Credit Risk

Financial instruments that are potentially subject to concentration of credit risk consist primarily of cash, cash equivalents, and marketable securities. The Company's investment policy restricts investments to high-quality investments and limits the amounts invested with any one issuer other than U.S. Treasury debt obligations, U.S. agency debt obligations, or Securities and Exchange Commission ("SEC") registered money market funds. The goals of the investment policy are as follows: preservation of capital, fulfillment of liquidity needs, maximization of investment performance and fiduciary control of cash and investments. The Company's exposure to market risk is limited primarily to interest income sensitivity, which is affected by changes in the general level of United States interest rates, particularly because the majority of the Company's investments are in short-term debt securities.

Concentration of Risk

The Company is dependent on Purdue Pharma to market and sell Intermezzo from which all of its royalty and milestone revenue to date has been derived.

Recently Adopted Accounting Standards

Effective January 1, 2012, the Company adopted the Accounting Standards Update ("ASU") No. 2011-05, *Presentation of Comprehensive Income* on a retrospective basis. ASU No. 2011-05 was issued to enhance comparability between entities that report under U.S. GAAP and International Financial Reporting Standards ("IFRS"), and to provide a more consistent method of presenting non-owner transactions that affect an entity's equity. ASU 2011-05 eliminates the option to solely report other comprehensive income and its components in the statement of changes in stockholders' equity and requires an entity to present the total of comprehensive income, the components of net income and the components of other comprehensive income either in a single continuous statement or in two separate but consecutive statements. The adoption of this ASU did not have any impact on the Company's results of operations or financial position, but did require modifying the format of the former "Statements of Operations" to include total comprehensive income (loss) and changing the title of the statements to "Statements of Operations and Comprehensive Income (Loss)."

Effective January 1, 2012, the Company adopted ASU No. 2011-04, *Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and International Financial Reporting Standards ("IFRS")* on a prospective basis. This pronouncement was issued to provide a consistent definition of fair value and ensure that the fair value measurement and disclosure requirements are similar between U.S. GAAP and IFRS. ASU 2011-04 changes certain fair value measurement principles and enhances the disclosure requirements particularly for Level 3 fair value measurements. The adoption of ASU No. 2011-04 did not have a material impact on the Company's consolidated results of operations or financial condition.

2. Results of Operations

Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of vested shares outstanding during the period. Diluted net loss per share is computed by giving effect to all potential dilutive common securities, including options, warrants and common stock subject to repurchase. For all periods presented in this report, stock options, warrants and common stock subject to repurchase were not included in the computation of diluted net loss per share because such inclusion would have had an antidilutive effect.

The following table presents the calculation of basic and diluted net loss per share (in thousands, except per share amounts):

	2012	2011	2010
Numerator:			
Net loss	$ (12,016)	$ (3,880)	$ (9,303)
Denominator:			
Weighted average common shares outstanding	17,052	13,535	13,430
Less: Weighted average common shares subject to repurchase	—	(1)	(14)
Denominator for basic and diluted net loss per share	17,052	13,534	13,416
Basic and diluted net loss per share	$ (0.70)	$ (0.29)	$ (0.69)

The following outstanding shares subject to options and warrants to purchase common stock and common stock subject to repurchase were antidilutive due to a net loss in the periods presented and, therefore, were excluded from the dilutive securities computation as of the dates indicated below (in thousands):

	December 31,		
	2012	2011	2010
Excluded potentially dilutive securities (1):			
Shares subject to options to purchase common stock	2,986	2,877	2,345
Shares subject to warrants to purchase common stock	61	156	156
Common stock subject to repurchase	—	—	5
Total	3,047	3,033	2,506

(1) The number of shares is based on the maximum number of shares issuable on exercise or conversion of the related securities as of the period end. Such amounts have not been adjusted for the treasury stock method or weighted average outstanding calculations as required if the securities were dilutive.

3. Available-for-sale Securities

The following is a summary of available-for-sale debt securities recognized as cash and cash equivalents, marketable securities, or restricted cash in the Company's consolidated balance sheets. Estimated fair values of available-for-sale securities are generally based on prices obtained from commercial pricing services (in thousands):

	December 31, 2012			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Certificates of deposit	$ 200	$ —	$ —	$ 200
Money market funds	27	—	—	27
Commercial paper	23,932	—	—	23,932
Corporate notes	6,294	—	—	6,294
Government sponsored enterprise issues	36,575	2	—	36,577
U.S. Treasury securities	17,308	5	—	17,313
	$ 84,336	$ 7	$ —	$ 84,343

	December 31, 2011			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Certificates of deposit	$ 200	$ —	$ —	$ 200
Money market funds	9,238	—	—	9,238
U.S. Treasury securities	51,674	29	—	51,703
	$ 61,112	$ 29	$ —	$ 61,141

The following table summarizes the classification of the available-for-sale securities on the Company's consolidated balance sheets (in thousands):

	December 31,	
	2012	2011
Cash and cash equivalents	$ 38,236	$ 9,238
Marketable securities	45,907	51,703
Restricted cash	200	200
	$ 84,343	$ 61,141

There were no sales of available-for-sale marketable securities during 2012 or 2011.

Based on the fair value of the Company's marketable securities at December 31, 2012, $2.3 million had a maturity of between one and two years, and the remaining $43.6 million had maturities of one year or less.

4. Fair Value

On January 1, 2008, the Company adopted ASC Topic 820 *Fair Value Measurements and Disclosures* (formerly SFAS No. 157) as it applies to the Company's financial assets and financial liabilities. ASC Topic 820 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. Fair value is defined as the estimated exit price received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date rather than on an entry price which represents the purchase price of an asset or liability. ASC Topic 820 establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

- Level 1—Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.
- Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3—Unobservable inputs (i.e. inputs that reflect the reporting entity's own assumptions about the assumptions that market participants would use in estimating the fair value of an asset or liability) are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement. Where quoted prices are available in an active market, securities are classified as Level 1 of the valuation hierarchy. Level 1 securities include highly liquid money market funds. If quoted market prices are not available for the specific security, then the Company estimates fair value by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows. Level 2 instruments include commercial paper, U.S. corporate debt, and U.S. government sponsored enterprise issues. There are no Level 3 liabilities in the periods presented.

In accordance with ASC Topic 820, the following table represents the Company's fair value hierarchy for its financial assets (cash equivalents and marketable securities) measured at fair value on a recurring basis as of December 31, 2012 (in thousands):

		Fair Value Measurements at Reporting Date Using		
	December 31, 2012	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Certificates of deposit	$ 200	$ 200	$ —	$ —
Money market funds	27	27	—	—
Commercial paper	23,932	—	23,932	—
Corporate notes	6,294	—	6,294	—
Government sponsored enterprise issues	36,577	—	36,577	—
U.S. Treasury securities	17,313	—	17,313	—
	$ 84,343	$ 227	$ 84,116	$ —

The following table represents the Company's fair value hierarchy for its financial assets (cash equivalents and marketable securities) measured at fair value on a recurring basis as of December 31, 2011 (in thousands):

		Fair Value Measurements at Reporting Date Using		
	December 31, 2011	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Certificates of deposit	$ 200	$ 200	$ —	$ —
Money market funds	9,238	9,238	—	—
U.S. Treasury securities	51,703	—	51,703	—
	$ 61,141	$ 9,438	$ 51,703	$ —

During the years ended December 31, 2012 and 2011, there were no significant changes to the valuation models used for purposes of determining the fair value of Level 2 assets. No other assets and liabilities were carried at fair value as of December 31, 2012.

Level 2 securities are priced using quoted market prices for similar instruments, nonbinding market prices that are corroborated by observable market data, or discounted cash flow techniques. There were no transfers of assets between different fair-value levels during the periods presented.

5. Prepaid and other current assets

Prepaid and other current assets consisted of the following (in thousands):

	December 31,	
	2012	2011
Receivable from Purdue Pharma	$ 92	$ 1,552
Prepaid expenses	563	610
Interest receivable	168	288
Other current assets	97	825
	$ 920	$ 3,275

The receivable from Purdue Pharma for the period ended December 31, 2012 consists of royalty revenue derived from Net Sales of Intermezzo generated by Purdue Pharma to wholesalers. The receivable from Purdue Pharma for the period ending December 31, 2011 consisted of reimbursement of certain Intermezzo manufacturing-related costs. These purchases and reimbursements were recorded as Gross other revenue during the fourth quarter of 2011. Payment was received in full in January 2012.

6. Property and Equipment, Net

Property and equipment consisted of the following (in thousands):

	December 31,	
	2012	2011
Computer equipment and software	$ 579	$ 593
Furniture and fixtures	577	569
Research equipment	797	797
Leasehold improvements	629	624
Construction in progress	5	—
	2,587	2,583
Less accumulated depreciation and amortization	(2,459)	(2,269)
Property and equipment, net	$ 128	$ 314

The Company recorded depreciation and amortization expense of $0.2 million, $0.4 million and $0.5 million for the years ended December 31, 2012, 2011 and 2010, respectively.

7. Commitments and Contingencies

Leases

In February 2006, the Company signed an operating lease for its corporate offices that included approximately 11,600 square feet of office and laboratory space in Point Richmond, California. The lease term is for seven years, commencing on June 1, 2006. In June 2007, the Company amended this operating lease to add approximately 3,000 square feet of additional office space. The lease term of this amendment coincides with the original lease agreement, with a separate commencement date of September 12, 2007. As part of this amendment, the landlord agreed to contribute $0.1 million toward the costs of tenant improvements for the additional space. This landlord contribution is being amortized on a straight-line basis over the term of the lease as a reduction to rent expense.

On February 20, 2009, the Company signed an operating lease for 12,257 square feet of general office space in Point Richmond, California. The lease term commenced in March 2009 and terminated on May 31, 2011. In conjunction with restructuring its operations upon signing the Collaboration Agreement discussed in Note 9, the Company vacated this property in August 2009 and recorded a charge to rent expense of $0.3 million related to the fair value of the remaining lease payments

reduced by estimated sublease income. This liability was amortized using the effective interest method over the remaining life of the lease, which terminated on May 31, 2011.

Future minimum payments under the remaining lease as of December 31, 2012 total $131,000 and will be due within one year.

Rent expense, net of sublease income as applicable, for the years ended December 31, 2012, 2011 and 2010 was $0.2 million, $0.3 million and $0.4 million, respectively. Sublease income for the years ended December 31, 2012, 2011 and 2010 was $0.3 million, $0.5 million and $0.4 million, respectively and was recorded as an offset against rent expense.

Indemnity Agreements

The Company indemnifies its officers and directors for certain events or occurrences, subject to certain limits. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recognized any liabilities relating to these agreements as of December 31, 2012.

Legal Proceedings

In July 2012, The Company received notifications from three companies, Actavis Elizabeth LLC (Actavis), Watson Laboratories, Inc. - Florida (Watson), and Novel Laboratories, Inc. (Novel), in September 2012, from each of Par Pharmaceutical, Inc. and Par Formulations Private Ltd. (together, the Par Entities), and in February 2013 from Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (together, Dr. Reddy's)

stating that each has filed with the FDA an abbreviated new drug application, or ANDA, that references Intermezzo.

- Actavis & Watson: In the July 2012 notifications, Actavis and Watson indicated that each company's ANDA includes Paragraph IV patent certifications to our U.S. Patent Nos. 7,658,945 (expiring April 15, 2027) and 7,682,628 (expiring February 16, 2025) (together, the "'945 and '628 Patents"). On November 28, 2012, Watson withdrew its ANDA, and, as a result of such withdrawal, on December 18, 2012, the Company and Purdue agreed to voluntarily dismiss the action without prejudice and on December 20, 2012 a court order was entered to such effect. The dismissal of Watson's ANDA had no effect on the ANDA filed by Actavis, a wholly owned subsidiary of Watson Pharmaceuticals, Inc. On January 24, 2013, Actavis notified the Company that it has included Paragraph IV patent certifications to Transcept's U.S. Patent Nos. 8,242,131 (expiring August 20, 2029) and 8,252,809 (expiring February 16, 2025) (together, the "'131 and '809 Patents").

- Novel: In the July 2012 notifications, Novel indicated that its ANDA includes Paragraph IV patent certifications to the '945 and '628 Patents. On December 10, 2012, Novel notified the Company that it has included Paragraph IV patent certifications to the '131 and '809 Patents.

- Par Entities: The ANDAs submitted by the Par Entities each include Paragraph IV patent certifications to the '945, '628, '131 and '809 Patents.

- Dr. Reddy's: The ANDA submitted by Dr Reddy's includes Paragraph IV patent certifications to the '945, '628, '131 and '809 Patents.

In August 2012, September 2012, and October 2012, the Company joined Purdue Pharma in filing actions against Actavis, Watson, Novel, the Par Entities, and certain of their affiliates, in the U.S. District Court for the District of New Jersey alleging patent infringement and seeking injunctive and other relief. In December 2012, the Company and Purdue Pharma agreed to voluntary dismiss the action against Watson following its withdrawal of its ANDA application. After receiving the supplemental notifications referenced above, the Company and Purdue Pharma amended their pending complaints against Actavis and Novel to also allege infringement of the '131 and '809 patents. The Company has not filed an action against Dr. Reddy's.

In January 2013, the Company and Purdue Pharma filed suit in the Eastern District of Virginia against the USPTO in connection with certain changes to the Leahy-Smith America Invents Act. The Company and Purdue Pharma are seeking a recalculation of the patent term adjustment of the '131 Patent. Purdue Pharma has agreed to bear the costs and expenses associated with this litigation.

From time to time the Company is involved in legal proceedings arising in the ordinary course of business. The Company believes there is no other litigation pending that could have, individually or in the aggregate, a material adverse effect on its results of operations or financial condition.

8. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2012	2011
Accrued payroll and related	$ 50	$ 825
Accrued vacation pay	138	144
Accrued professional fees	513	372
Accrued franchise taxes—Delaware	36	36
Accrued clinical trials	735	611
Other accrued liabilities	167	120
	$ 1,639	$ 2,108

9. Intermezzo Collaboration Agreement

In July 2009, the Company entered into the Collaboration Agreement with Purdue Pharma that grants an exclusive license to Purdue Pharma to commercialize Intermezzo in the United States and pursuant to which:

- Purdue Pharma paid a $25.0 million non-refundable license fee in August 2009;
- Purdue Pharma paid a $10.0 million non-refundable intellectual property milestone in December 2011 when the first of two issued formulation patents was listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or Orange Book;
- Purdue Pharma paid a $10.0 million non-refundable intellectual property milestone in August 2012 when the first of two issued method of use patents was listed in the FDA's Orange Book;
- The Company transferred the Intermezzo New Drug Application (“NDA”) to Purdue Pharma, and Purdue Pharma is obligated to assume the expense associated with maintaining the NDA and further development of Intermezzo in the United States, including any expense associated with post-approval studies;
- Purdue Pharma is obligated to commercialize Intermezzo in the United States at its expense using commercially reasonable efforts;
- Purdue Pharma is obligated to pay the Company tiered base royalties on net sales of Intermezzo in the United States ranging from the mid-teens up to the mid-20% level. The base royalty is tiered depending upon the achievement of certain fixed net sales thresholds by Purdue Pharma, which net sales levels reset each year for the purpose of calculating the royalty ; and
- Purdue Pharma is obligated to pay the Company up to an additional $70.0 million upon the achievement of certain net sales targets for Intermezzo in the United States.

The Company has retained an option to co-promote Intermezzo to psychiatrists in the United States. The option can be exercised as late as August 2015 . The Company may begin promotion to psychiatrists 8 to 15 months after option exercise. The exact timing of when the Company begins promoting to psychiatrists is determined by the calendar month in which the option exercise notice is delivered to Purdue Pharma. If the Company exercises the co-promote option and enters the marketplace, it is entitled to receive an additional co-promote royalty from Purdue Pharma on net sales that are generated by psychiatrist prescriptions. Had the Company chosen to exercise the option as soon as it was eligible, it could have begun promoting to psychiatrists in May 2013 and received a co-promote royalty of 40%. The co-promote royalty rate declines on a straight-line basis to approximately 22% if the Company does not begin promoting to psychiatrists until November 2016, at which time the right to co-promote expires. Net sales qualifying for this additional co-promote royalty are limited by an annual cap of 15% of total Intermezzo annual net sales in the United States. The co-promote option cannot be transferred to a third party, except under a limited circumstance at the discretion of Purdue Pharma.

Purdue Pharma has the right to terminate the Collaboration Agreement at any time upon advance notice of 180 days. The Company's co-promote option may also be terminated by Purdue Pharma upon the Company's acquisition by a third party or in the event of entry of generic competition to Intermezzo. The royalty payments discussed above are subject to reduction in connection with, among other things, the entry of generic competition to Intermezzo. The Collaboration Agreement expires on the later of 15 years from the date of first commercial sale in the United States or the expiration of patent claims related to Intermezzo. The Collaboration Agreement is also subject to termination by Purdue Pharma in the event of FDA or governmental action that materially impairs Purdue Pharma's ability to commercialize Intermezzo or the occurrence of a serious event with respect to the safety of Intermezzo. The Collaboration Agreement may also be terminated by the Company upon Purdue Pharma commencing an action that challenges the validity of Intermezzo related patents. The Company also has the right to terminate the Collaboration Agreement immediately if Purdue Pharma is excluded from participation in federal healthcare programs. The Collaboration Agreement may also be terminated by either party in the event of a material breach by or insolvency of the other party.

The Company began earning royalty revenue upon commercial launch of Intermezzo in April 2012. Royalty revenue earned during the year ended December 31, 2012 was $0.8 million.

The Company recorded as revenue $10.0 million of milestone payments that were received in August 2012 and December 2011, respectively. The patent-related milestones were substantive and at-risk given the inherent uncertainty and risks associated with obtaining patent approval from the U.S. Patent and Trademark Office and subsequent listing in the FDA's Orange Book in addition to the inherent uncertainty and risks associated obtaining FDA approval for Intermezzo and the opportunity for Purdue Pharma to terminate the Collaboration Agreement after its review of the terms of the FDA approval. The Company has no additional performance obligations under the Collaboration Agreement related to these milestone payments.

The Company also granted Purdue Pharma and an associated company the right to negotiate for the commercialization of Intermezzo in Mexico and Canada, respectively, and retained rights to commercialize Intermezzo in the rest of the world. The Company recognized revenue of $0.2 million and $0.7 million in Gross other revenue for the years ended December 31, 2012 and 2011, respectively, associated with these rights.

Through June 30, 2011, the Company recognized revenue from the $25 million non-refundable license fee ratably over an estimated 24-month period beginning in August 2009 and ending in July 2011 as this represented the estimated period during which the Company had significant participatory obligations under the Collaboration Agreement. During the quarter ended September 30, 2011, the Company re-assessed the time period over which the remaining $1.04 million of deferred revenue at June 30, 2011 was recognized, and the Company recorded the remaining revenue through November 30, 2011 based on FDA approval of Intermezzo and the completion of the Company's participatory obligations under the Collaboration Agreement. Revenue recognized in connection with the license fee during the years ended December 31, 2011, and 2010 was $7.3 million, and $12.5 million, respectively.

On November 21, 2012, the Company agreed to contribute $10.0 million to Purdue Pharma's $29.0 million national direct-to-consumer ("DTC") advertising campaign, including digital, print and television advertising to support Intermezzo commercialization. The Company initially recorded the $10.0 million payment to Purdue as a prepaid expense. The Company plans to recognize this payment as an offset to revenue over an estimated seven month period, beginning December 1, 2012, and ending on June 30, 2013, as the advertising costs are incurred.

For the year and three-months ended December 31, 2012, the offset to revenue totaled $1.4 million. Prepaid advertising costs were $8.6 million at December 31, 2012. There were no similar advertising costs in the prior periods.

10. Restructuring

On July 15, 2011, the Company implemented a reduction of approximately 45% of the Company's workforce. The reduction plan carried out a realignment of the Company's workforce and operations after receipt of the July 14, 2011 Intermezzo ® Complete Response Letter from the FDA. Employees subject to the workforce reduction plan were eligible for one-time severance benefits and option modifications that resulted in expense of approximately $1.2 million in total, the $1.0 million cash portion of which was paid out during the third quarter of 2011.

11. Stockholders' Equity

Capital Stock

The authorized capital stock of the Company consists of 100,000,000 shares of common stock, par value $0.001 per share and 5,000,000 shares of preferred stock, par value $0.001 per share. There are no shares of preferred stock issued or outstanding and the Company has no present plans to issue any shares of preferred stock.

Common Stock

On May 1, 2012, the Company completed a public offering of 4.5 million shares of its common stock at a public offering price of $9.00 per share. Net proceeds to the Company from the public offering were approximately $37.7 million after deducting underwriting discounts, commissions and offering expenses.

Stock Options

Various employees, directors and consultants have been granted options to purchase common shares under equity incentive plans adopted in 2001, 2002 and 2006 (the "2001 Plan", the "2002 Plan" and the "2006 Plan"). The 2001 Plan provided for the granting of incentive and non-statutory stock options to employees, officers, directors, and non-employees of the Company. The 2002 Plan provided for the granting of incentive and non-statutory stock options to employees, officers, directors, and consultants of the Company. Incentive stock options under all of these plans may be granted with exercise prices of not less than estimated fair value, and non-statutory stock options may be granted with an exercise price of not less than 85% of the estimated fair value of the common stock on the date of grant. Stock options granted to a stockholder owning more than 10% of voting stock of the Company must have an exercise price of not less than 110% of the estimated fair value of the common stock on the date of grant. The Company estimated the fair value of common stock until the Company became publicly traded. Stock options are generally granted with terms of up to ten years and vest over a period of four years. At December 31, 2012, there were no shares available for future grant under either the 2001 or the 2002 Plans.

The 2006 Plan became effective upon the completion of the Company's initial public offering in 2006, and was amended and restated on June 2, 2010 upon approval by the stockholders of the Company (the "Amended and Restated 2006 Plan"). The Amended and Restated 2006 Plan will terminate on June 2, 2020. The Amended and Restated 2006 Plan provides for the granting of incentive stock options, non-statutory stock options, restricted stock, performance share awards, performance stock units, dividend equivalents, restricted stock units, stock payments, deferred stock, performance-based awards and stock appreciation rights. The employee stock options generally vest over four years, are exercisable over a period not to exceed the contractual term of ten years from the date the stock options are issued and are granted at prices equal to the fair value of the Company's common stock on the grant date.

Stock option and restricted stock unit exercises are settled with newly issued common stock from the Amended and Restated 2006 Plan's previously authorized and available pool of shares. A total of 500,000 shares of common stock was originally authorized for issuance pursuant to the 2006 Plan, plus the number of shares of the Company's common stock available for issuance under the 2001 Plan that are not subject to outstanding options, as of the effective date of the 2006 Plan (including shares that are subject to stock options outstanding under the 2001 Plan that expire, are canceled or otherwise terminate unexercised, or shares that otherwise would have reverted to the share reserve of the 2001 Plan following the effective date of the 2006 Plan). An additional 750,000 shares of common stock were authorized for issuance under the Amended and Restated 2006 Plan and approved by the stockholders of the Company on June 2, 2010. The number of shares of common stock reserved for issuance under the 2006 Plan increased automatically on the first day of each fiscal year, beginning in 2007, by a number of shares equal to the least of: (i) 4.5% of shares of the Company's common stock outstanding on a fully diluted basis on such date; (ii) 400,000 shares; or (iii) a smaller number determined by the Company's board of directors. This provision resulted in an additional 400,000 shares of the Company's common stock becoming available for issuance on January 1, 2010 under the 2006 Plan. The number of shares of common stock reserved for issuance under the Amended and Restated 2006 Plan increases automatically on the first day of each fiscal year, beginning in 2011, by a number of shares equal to the least of: (i) 5.0% of shares of the Company's common stock outstanding on such date; (ii) 1,500,000 shares; or (iii) a smaller number determined by the Company's Board of Directors. This provision resulted in an additional 933,820, 695,225 and 672,488 of the Company's common stock becoming available for issuance on January 1, 2013, January 1, 2012, and January 1, 2011, respectively. The maximum aggregate number of shares that may be issued pursuant to incentive stock options under the Amended and Restated 2006 Plan is 25,000,000.

At December 31, 2012, stock options to purchase 2,046,981 shares of common stock were vested and exercisable and 841,858 shares remain available for future grant under the Amended and Restated 2006 Plan.

The following table summarizes the Company's stock option activity and related information through December 31, 2011:

		Options Outstanding	
	Number of Shares Available for Grant	Number of Shares	Weighted-Average Exercise Price Per Share
Balance at December 31, 2009	337,481	1,718,258	$ 7.494
Options authorized	1,150,000	—	
Options granted	(728,100)	728,100	$ 8.208
Options exercised	—	(25,973)	$ 1.467
Options forfeited	75,618	(75,618)	$ 16.811
2002 Plan shares expired	(2,313)	—	
Balance at December 31, 2010	832,686	2,344,767	$ 7.482
Options authorized	672,488	—	
Options granted	(1,502,750)	1,502,750	$ 5.253
Options exercised	—	(441,963)	$ 3.018
Options forfeited	529,044	(529,044)	$ 12.083
Balance at December 31, 2011	531,468	2,876,510	$ 6.157
Options authorized	695,225	—	
Options granted	(790,500)	790,500	$ 7.610
Options exercised	—	(266,522)	$ 4.010
Options forfeited	414,308	(414,308)	$ 13.042
2001 Plan shares expired	(8,643)	—	
Balance at December 31, 2012	841,858	2,986,180	$ 5.794

The total intrinsic value of options exercised during the years ended December 31, 2012, 2011 and 2010 was $1.0 million, $2.3 million and $0.2 million, respectively. The amount of cash received from exercise of stock options during the years ended December 31, 2012, 2011 and 2010 was $1.1 million, $1.3 million and $38,000, respectively.

Additional information related to the status of options at December 31, 2012 is as follows:

	Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding	2,986,180	$ 5.794	7.51	$ 2,166
Vested and exercisable	2,046,981	$ 4.932	6.96	$ 2,159

The intrinsic value of options is the fair value of the Company's stock at December 31, 2012 less the per share exercise price of the option multiplied by the number of shares.

As of December 31, 2010, there were 4,678 restricted common shares outstanding subject to repurchase rights held by the Company. In accordance with ASC Topic 718, *Compensation – Stock Compensation*, the Company recorded the $9,000 received for such shares as a liability in the balance sheet as of December 31, 2010, and did not show these shares as outstanding as of December 31, 2010. These shares were subject to repurchase upon termination of the stockholders' services to the Company and were subject to repurchase at the original issuance price. The Company's right to repurchase these shares lapsed at a rate of 2.08% per month and was completed during 2011. At December 31, 2012 and 2011, there were no restricted common shares outstanding subject to repurchase rights.

The following table summarizes information about stock options outstanding as of December 31, 2012:

	Options Outstanding		
Range of Exercise Prices	Number Outstanding	Number Exercisable	Weighted- Average Remaining Contractual Life (Years)
$0.8844 - $2.1225	360,143	360,143	3.97
$2.6800	560,250	560,250	8.65
$2.9600 - $6.0500	413,180	307,935	6.67
$6.1100 - $8.0700	124,207	28,957	8.83
$8.0900	529,000	111,140	9.09
$8.1800 - $8.2000	474,000	235,075	8.03
$8.2100 - $14.0000	525,400	443,481	6.92
	2,986,180	2,046,981	7.51

Stock Compensation Plans

The Company has recorded compensation expense for employee stock-based awards, excluding compensation expense for stock option modifications described below, of approximately $2.7 million, $3.7 million and $1.8 million during 2012, 2011 and 2010, respectively.

On January 14, 2010, the Company granted 225,500 options in the aggregate to select employees and one consultant that vested 50% upon approval by the U.S. Food and Drug Administration ("FDA") of Intermezzo and the remaining 50% vested on the first anniversary of any such approval; provided in each case, such approval occurred no later than January 14, 2012. The fair value of these options at grant date was $5.79 per share or approximately $1.3 million. On August 24, 2011, the Company granted 803,750 options in the aggregate to employees and one consultant that vested 50% upon approval by the U.S. Food and Drug Administration ("FDA") of Intermezzo and the remaining 50% vested on the first anniversary of any such approval; provided in each case, such approval occurred no later than August 24, 2013. These options automatically expire should the Board of Directors decide to cease development of Intermezzo or if Intermezzo approval is not received on or prior to August 24, 2013. The fair value of these options at grant date was $1.90 per share or approximately $1.5 million. The Company began recognizing compensation expense relating to both sets of performance-based options upon FDA approval of Intermezzo on November 23, 2011, when the vesting was deemed to be probable. Total expense related to employee performance-based options recognized during 2012 and 2011 was $0.6 million and $1.7 million, respectively, which is included in the above total employee-related stock option compensation.

The following table shows the range of assumptions used to compute the fair value of employee options granted during the years ended December 31, 2012, 2011 and 2010 using the Black-Scholes option pricing model:

	Year Ended December 31,		
	2012	2011	2010
Risk-free interest rate	0.79 - 1.00%	1.16 - 2.95%	2.73 - 2.95%
Expected life of the options	5.27 - 6.08 years	5.27 - 6.08 years	6.00 - 6.08 years
Dividend yield	None	None	None
Volatility	82.07 - 89.71%	80.99 - 95.70%	81.18 - 95.92%

The risk-free interest rate assumption was based on the United States Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued. The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. The weighted-average expected life of the options was calculated using the simplified method as prescribed by the Securities and Exchange Commission ("SEC") Staff Accounting Bulletin No. 107 and No. 110 ("SAB No. 107 and 110"). This decision was based on the lack of relevant historical data due to the Company's limited historical experience. In addition, due to the Company's limited historical data, the estimated volatility also reflects the application of SAB No. 107 and 110, using the weighted average of the Company's historical volatility post-Merger and the historical volatility of several unrelated public companies within the specialty pharmaceutical industry.

The weighted-average grant-date fair value of stock options granted to employees during the years ended December 31, 2012, 2011 and 2010 was $5.299, $3.718 and $5.798 per share, respectively. As of December 31, 2012, there is approximately $4.3 million of total unrecognized compensation cost related to the unvested share-based compensation arrangements granted under the Company's equity incentive plans. The remaining unrecognized compensation cost, will be recognized over a weighted-average period of 2.55 years.

As discussed in Note 1, the Company accounts for stock options granted to persons other than employees or directors at fair value using the Black-Scholes option-pricing model in accordance with ASC Topic 505, subtopic 50 *Equity-Based Payments to Non-Employees* (formerly EITF Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services).* Stock options granted to such persons and stock options that are modified and continue to vest when an employee has a change in employment status are subject to periodic revaluation over their vesting terms. The Company recognizes the resulting stock-based compensation expense during the service period over which the non-employee provides services to the Company. In connection with the issuance of options to purchase shares of common stock to non-employees, the Company recorded total stock-based compensation totaling approximately $0.2 million, including approximately $32,000 related to performance based options as described below, for the year ended December 31, 2012. Stock-based compensation for the year ended December 31, 2011 was approximately $0.4 million, including $0.2 million related to performance based options, and expense for the year ended December 31, 2010 was $31,000.

During 2012, the Company granted 70,000 options to purchase shares of common stock to two non-employees with an exercise price of $8.09 per share, vesting over 4 years. During 2011, the Company granted 25,000 options to purchase shares of common stock to one non-employee with an exercise price of $8.20 per share, vesting over 4 years and 38,750 options to purchase shares of common stock with an exercise price of $2.68 per share, of which 50% vested upon approval by the FDA of Intermezzo on November 23, 2011 and the remaining 50% vest on November 23, 2012. During 2010, the Company granted 35,800 options to purchase shares of common stock to one non-employee with an exercise price of $8.21 per share. Of these shares, 23,700 vest over 4 years. Of the remaining 12,100 options to purchase shares of common stock, 50% vested upon approval by the FDA of Intermezzo on November 23, 2011 and the remaining 50% vest on November 23, 2012. Total expense related to the performance-based options recognized during 2012 and 2011 was $32,000 and $0.2 million, respectively, and is included in the above total non-employee-related stock–based compensation. The following table shows the range of assumptions used to compute the stock-based compensation costs for stock options granted to non-employees during the years ended December 31, 2012, 2011, and 2010 using the Black-Scholes option pricing model:

	Year Ended December 31,		
	2012	2011	2010
Risk-free interest rate	0.95 - 2.23%	1.35 - 3.47%	2.12 - 3.84%
Expected life of the options	6.25 - 9.92 years	7.26 - 9.92 years	8.33 - 9.91 years
Dividend yield	None	None	None
Volatility	75.87 - 89.21%	76.68 - 93.19%	63.11 - 87.77%

Modification of Employee Stock-Based Awards

During the year ended December 31, 2009, the Company modified stock options of twelve of its employees in conjunction with their termination. The modifications included accelerated vesting on certain options and extension of the exercise period after termination on certain of the options. These modifications resulted in additional compensation expense of $14,000 which was recognized during 2010. The Company accounted for the modifications of stock option awards in accordance with ASC Topic 718.

During the year ended December 31, 2011, the Company modified the terms of stock options previously granted to thirteen of its employees in connection with a reduction in force. The modifications included accelerated vesting of certain options and extension of the exercise period after termination with respect to certain of the options. These modifications resulted in additional compensation expense of $0.2 million that was recognized during 2011. Additionally, during the year ended December 31, 2011, the Company modified the terms of certain stock options previously granted to two members of its Board of Directors to align and extend the exercise period of the options after the directors' end of service to the Company in June 2011. These modifications resulted in additional compensation expense of $0.2 million that was recognized during 2011. The Company accounted for the modifications of stock option awards in accordance with the provisions of ASC Topic 718.

During the year ended December 31, 2012, the Company modified the terms of stock options previously granted to an employee upon retirement to extend the exercise period of the options upon the end of service to the Company in May 2012.

Additionally, the Company modified the terms of stock options previously granted to a member of its Board of Directors to accelerate vesting of the option upon the director's anticipated end of service to the Company in April 2012. These modifications resulted in additional compensation expense of $28,000 that was recognized during 2012.

Employee Stock Purchase Plan

On June 3, 2009, at the annual meeting of stockholders, the stockholders of the Company approved the 2009 Employee Stock Purchase Plan ("ESPP"). The number of shares available for issuance over the term of the ESPP is limited to 500,000 shares. The ESPP is designed to allow eligible employees of the Company to purchase shares of common stock through periodic payroll deductions. The price of common stock purchased under the ESPP is equal to 85% of the lower of the fair market value of the common stock on the commencement date of each offering period or the specified purchase date.

The following table summarized the Company's ESPP activity through December 31, 2012:

	Number of Shares Available for Grant	Number of Shares Granted	Weighted-Average Grant Date Fair Value
Balance at December 31, 2009	477,940	22,060	
Purchases	(22,135)	22,135	$ 2.897
Balance at December 31, 2010	455,805	44,195	
Purchases	(8,119)	8,119	$ 3.245
Balance at December 31, 2011	447,686	52,314	
Purchases	(5,359)	5,359	$ 1.979
Balance at December 31, 2012	442,327	57,673	

The following table shows the range of assumptions used to compute the share-based compensation costs for the ESPP during the years ended December 31, 2012, 2011 and 2010 using the Black-Scholes option pricing model:

	Year Ended December 31,		
	2012	2011	2010
Risk-free interest rate	0.13 - 0.14%	0.05 - 0.11%	0.20 - 0.23%
Expected life of the options	0.50 years	0.50 years	0.50 years
Dividend yield	None	None	None
Volatility	49.64 - 61.94%	40.64 - 147.47%	33.68 - 93.20%

The risk-free interest rate assumption was based on the United States Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued. The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. The weighted-average expected life is based on the duration of time in the purchase period. In addition, due to the Company's limited historical data, the estimated volatility also reflects the application of SAB No. 107 and 110, using the weighted average of the Company's historical volatility post-Merger and the historical volatility of several unrelated public companies within the specialty pharmaceutical industry. The Company has recognized compensation expense for employee stock-based purchase plan awards of approximately $18,000, $22,000 and $75,000 during 2012, 2011 and 2010, respectively.

Reserved Shares

At December 31, 2012, the Company has reserved shares of common stock for future issuance as follows:

	Number of Shares
Employee stock purchase plan	442,327
Stock option plans:	
Subject to outstanding options	2,986,180
Available for future grants	841,858
Warrants	61,451
Total	4,331,816

12. Income taxes

There is no provision for income taxes because the Company has incurred operating losses since inception. Income tax expense (benefit) differed from the amounts computed by applying the U.S. federal income tax rate of 35% to pretax losses from operations as a result of the following (in thousands):

	For the year ended December 31,		
	2012	2011	2010
Computed tax benefit at federal statutory rate	$ (4,206)	$ (1,358)	$ (3,255)
State tax benefit, net of effect on Federal income taxes	(690)	(223)	(534)
State tax credits, net of Federal benefit	(105)	(121)	(116)
Federal tax credits	—	(365)	(313)
Permanent differences:			
Nondeductible stock option expense	467	180	324
State tax effect from permanent differences	79	17	56
Other	16	(79)	(66)
Change in valuation allowance	4,476	2,805	3,699
Other, net	(37)	(856)	205
Total tax expense	$ —	$ —	$ —

Deferred income taxes reflect the net tax effects of net operating loss and tax credit carryovers and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets are as follows (in thousands):

	December 31,	
	2012	2011
Current deferred tax assets	$ 185	$ 518
Valuation Allowance—current	185	518
Total current deferred assets	—	—
Non-current deferred tax assets:		
Net operating loss carryforwards	29,384	28,122
Depreciation	203	410
Research and development credits	2,750	2,590
Capitalized research and development expense	9,503	6,272
Stock-based compensation	2,252	1,815
Other	—	74
	44,092	39,283
Valuation allowance—non-current	44,092	39,283
Total non-current deferred tax assets	—	—
Total deferred tax assets	$ —	$ —

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by $4.5 million during 2012 and $2.8 million during 2011.

As of December 31, 2012, the Company had federal net operating loss carryforwards of approximately $73.4 million, which expire in the years 2022 through 2032 if not utilized. The Company had net operating loss carryforwards for state income tax purposes of $64.0 million, which expire in the years 2013 through 2032 if not utilized.

The Company has carryforwards from the federal Credit for Increasing Research Expenditures of approximately $1.7 million which expire in years 2023 through 2032. The Company also has state credit carryforwards of approximately $1.6 million that carry forward indefinitely.

As a result of certain realization requirements of ASC Topic 718, the table of deferred tax assets and liabilities shown above does not include certain deferred tax assets at December 31, 2012 that arose directly from tax deductions related to equity compensation in excess of compensation recognized for financial reporting purposes. Equity will be increased by approximately $0.8 million if and when such deferred tax assets are ultimately realized.

Utilization of the net operating loss and tax credit carryforwards may be subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization.

The Company adopted ASC Topic 740, subtopic 10-50-15, *Unrecognized Tax Benefit Related Disclosures* (formerly FASB Interpretation 48, *Accounting for Uncertainty in Income Taxes)* on January 1, 2007. There were no unrecognized income tax benefits at December 31, 2012 and December 31, 2011. There is no accrued interest or penalties associated with any unrecognized tax benefits.

The Company files U.S. and state income tax returns with varying statutes of limitations. The tax years from inception in 2002 forward remain open to examination due to the carryover of unused net operating losses and tax credits.

13. Subsequent Events

Workforce reduction

On January 2, 2013, the Company implemented a reduction of 29% of the Company's workforce. The reduction plan carries out a realignment of the Company's workforce and operations after Transcept announced that results from its Phase 2 clinical

trial evaluating TO-2061 in patients with obsessive compulsive disorder did not meet its primary endpoint. The Company expects to substantially complete the reduction plan during the first quarter of 2013. Employees subject to the workforce reduction plan are eligible for one-time severance benefits that include severance and benefits continuation expenses of approximately $0.3 million in total, which expenses are expected to be recorded in the first quarter of 2013. Further, the affected employees will receive one year accelerated vesting on outstanding options upon signing a separation and release agreement with the Company, and the affected employees will also be given the choice to extend the exercise period of their options to one year following termination. The Company currently cannot determine the total expense related to the modification of these stock option awards but expects to file an amendment to its Form 8-K announcing the workforce reduction within four business days of making such determination.

Lease agreement

On March 6, 2013, the Company extended its lease agreement for 11,600 square feet of space in its current facility in Point Richmond, California by one year.

14. Supplemental Financial Information

Quarterly Results of Operations (Unaudited)

The following table presents the unaudited statements of operations data for each of the eight quarters in the period ended December 31, 2012. The information has been presented on the same basis as the audited financial statements and all necessary adjustments, consisting only of normal recurring adjustments, have been included in the amounts below to present fairly the unaudited quarterly results when read in conjunction with the audited financial statements and related notes. The operating results for any quarter should not be relied upon as necessarily indicative of results for any future period.

Unaudited Quarterly Results of Operations
(in thousands, except per share amounts)

	Three months ended				
	March 31, 2012	June 30, 2012	September 30, 2012	December 31, 2012	Total for year 2012
Revenue:					
Gross royalty revenue	$ —	$ 493	$ 190	$ 93	$ 776
Gross milestone revenue	—	—	10,000	—	10,000
Gross other revenue	—	—	250	—	250
Advertising expense - Purdue Pharma	—	—	—	(1,429)	(1,429)
Net revenue	—	493	10,440	(1,336)	9,597
Operating expenses:					
Research and development	2,357	2,859	3,057	2,918	11,191
General and administrative	2,784	2,731	2,483	2,265	10,263
Total operating expenses	5,141	5,590	5,540	5,183	21,454
(Loss) income from operations	(5,141)	(5,097)	4,900	(6,519)	(11,857)
Interest and other income (expense), net	(36)	(43)	(45)	(35)	(159)
Net (loss) income	$ (5,177)	$ (5,140)	$ 4,855	$ (6,554)	$ (12,016)
Net (loss) income per share:					
Basic	$ (0.37)	$ (0.30)	$ 0.26	$ (0.35)	$ (0.70)
Diluted	$ (0.37)	$ (0.30)	$ 0.25	$ (0.35)	$ (0.70)
Weighted average common shares outstanding:					
Basic	13,925	17,053	18,568	18,628	17,052
Diluted	13,925	17,053	19,232	18,628	17,052
Comprehensive (loss) income	$ (5,206)	$ (5,142)	$ 4,862	$ (6,552)	$ (12,038)

Transcept Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (continued)

	Three months ended				
	March 31, 2011	**June 30, 2011**	**September 30, 2011**	**December 31, 2011**	**Total for year 2011**
Revenue:					
Gross license fee revenue	$ 3,125	$ 3,125	$ 625	$ 417	$ 7,292
Gross milestone revenue	—	—	—	10,000	10,000
Gross other revenue	—	—	—	2,402	2,402
Net revenue	3,125	3,125	625	12,819	19,694
Operating expenses:					
Research and development	2,491	2,763	2,668	3,351	11,273
General and administrative	2,544	2,582	2,919	4,140	12,185
Total operating expenses	5,035	5,345	5,587	7,491	23,458
(Loss) income from operations	(1,910)	(2,220)	(4,962)	5,328	(3,764)
Interest and other income (expense), net	(29)	(26)	(29)	(32)	(116)
Net (loss) income	$ (1,939)	$ (2,246)	$ (4,991)	$ 5,296	$ (3,880)
Net (loss) income per share:					
Basic	$ (0.14)	$ (0.17)	$ (0.37)	$ 0.39	$ (0.29)
Diluted	$ (0.14)	$ (0.17)	$ (0.37)	$ 0.37	$ (0.29)
Weighted average common shares outstanding:					
Basic	13,461	13,488	13,522	13,664	13,534
Diluted	13,461	13,488	13,522	14,397	13,534
Comprehensive (loss) income	$ (1,924)	$ (2,222)	$ (4,996)	$ 5,289	$ (3,853)

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

Not applicable.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Our management evaluated, with the participation and under the supervision of our Chief Executive Officer and our Chief Financial Officer, the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective at the reasonable assurance level to ensure that information we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission, or SEC, rules and forms, and that such information is accumulated and communicated to management as appropriate to allow timely decisions regarding required disclosures.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. We maintain a system of internal control that is designed to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Management assessed our internal control over financial reporting as of December 31, 2012, the end of our last fiscal year. Management based its assessment on criteria established in “Internal Control – Integrated Framework” issued by the Committee of Sponsoring Organizations of the Treadway Commission. Management’s assessment included evaluation of such elements as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies and our overall control environment.

Based on our assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2012 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with generally accepted accounting principles.

Our independent registered public accounting firm, Ernst & Young LLP, has audited our internal control over financial reporting as of December 31, 2012. Their attestation report on the audit of our internal control over financial reporting is included below.

Changes in Internal Control over Financial Reporting

There have not been any changes in our internal controls over financial reporting (as such item is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during our fiscal quarter ended December 31, 2012 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Inherent Limitations on the Effectiveness of Controls

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the controls are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Accordingly, our controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our control system are met.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of Transcept Pharmaceuticals, Inc.

We have audited Transcept Pharmaceutical, Inc.'s internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Transcept Pharmaceutical, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, Transcept Pharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Transcept Pharmaceuticals, Inc. as of December 31, 2012 and 2011 and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2012 of Transcept Pharmaceuticals, Inc. and our report dated March 12, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Redwood City, California
March 12, 2013

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Except as set forth below, the information required by this Item 10 is incorporated herein by reference to our Proxy Statement to be filed with the Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) to Form 10-K.

Section 16(a) Beneficial Ownership Reporting Compliance

The information regarding our Section 16 beneficial ownership reporting compliance is incorporated by reference from our definitive Proxy Statement described above, where it appears under the heading "Section 16(a) Beneficial Ownership Reporting Compliance."

Code of Business Conduct and Ethics

Our board of directors has adopted a code of business conduct and ethics. The code of business conduct applies to all of our employees, officers and directors. The full texts of our codes of business conduct and ethics are posted on our website at http://www.transcept.com under the Investors section. We intend to disclose future amendments to our codes of business conduct and ethics, or certain waivers of such provisions, at the same location on our website identified above and also in public filings. The inclusion of our website address in this report does not include or incorporate by reference the information on our website into this report.

Item 11. Executive Compensation

The information required by this Item 11 is incorporated by reference to our Proxy Statement to be filed with the Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) to Form 10-K.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Except as set forth below, the information required by this Item 12 is incorporated by reference to our Proxy Statement to be filed with the Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) to Form 10-K.

The following table provides certain information with respect to all of our equity compensation plans in effect as of December 31, 2012.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options and Warrants		Weighted-Average Exercise Price of Outstanding Options and Warrants		Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (1)	
Equity compensation plans approved by stockholders	2,986,180	(2)	$ 5.79	(3)	1,284,185	(4)
Equity compensation plans not approved by stockholders	61,451		$ 8.14		—	
Total	3,047,631		$ 5.84		1,284,185	

(1) The number of authorized shares under the Amended and Restated 2006 Equity Incentive Plan, or the Amended and Restated 2006 Plan, automatically increases on January 1 of each year by a number of shares equal to the lesser of (i) 1,500,000 shares, (ii) 5.0% of the outstanding shares on the last day of the immediately preceding fiscal year, or (iii) an amount determined by the Board of Directors.

(2) Includes 2,986,180 shares relating to outstanding options.

(3) Represents the weighted-average exercise price of outstanding options.

(4) Includes 442,327 shares available under the 2009 Employee Stock Purchase Plan and 841,858 shares available under the 2006 Plan.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item 13 is incorporated by reference to our Proxy Statement to be filed with the Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) to Form 10-K.

Item 14. Principal Accountant Fees and Services

The information required by this Item 14 is incorporated by reference to our Proxy Statement to be filed with the Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) to Form 10-K.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a)(1) Financial Statements

See Index to Financial Statements under Item 8.

(a)(2) Financial Statement Schedules

Financial statement schedules are omitted because they are not applicable or are not required or the information required to be set forth therein is included in the Financial Statements or notes thereto.

(a)(3) Exhibits

The exhibits listed in the Exhibit Index below are filed or incorporated by reference as part of this report.

Exhibit Index

Exhibit No.	Description of Exhibit
3.1(1)	Amended and Restated Certificate of Incorporation of Transcept Pharmaceuticals, Inc.
3.2(1)	Bylaws of Transcept Pharmaceuticals, Inc., as amended.
4.1(2)	Specimen Common Stock certificate of Transcept Pharmaceuticals, Inc.
4.2(2)	Form of Preferred Stock Purchase Warrant issued to certain TPI investors as of March 21, 2005.
4.3(2)	Preferred Stock Purchase Warrant issued by TPI to Hercules Technology Growth Capital, Inc., dated as of April 13, 2006.
4.4(3)	2005 Amended and Restated Investor Rights Agreement, dated as of December 21, 2005, by and between Novacea and purchasers of Novacea Series A, Series B and Series C Preferred Stock.
4.5(9)	Amended and Restated Investor Rights Agreement, dated as of February 27, 2007, by and between TPI and purchasers of TPI Series A, Series B, Series C and Series D Preferred Stock.
4.6(9)	Termination Agreement, dated as of January 26, 2009, by and between TPI and purchasers of TPI Series A, Series B, Series C and Series D Preferred Stock.
10.1(3)+	Novacea 2001 Stock Option Plan and forms of agreements relating thereto.
10.2(10)+	2006 Equity Incentive Plan, as amended and restated.
10.3(11)+	Form of Option Agreement under 2006 Incentive Award Plan.
10.4(2)+	TPI Amended and Restated 2002 Stock Option Plan and forms of agreements relating thereto.
10.5(7)+	Transcept Pharmaceuticals, Inc. 2009 Employee Stock Purchase Plan.
10.6(3)	Loan and Security Agreement, by and between Transcept Pharmaceuticals, Inc. and Hercules Technology Growth Capital, Inc. dated as of April 13, 2006.
10.7(3)	Secured Promissory Note issued to Hercules Technology Growth Capital, Inc., dated as of May 31, 2006.
10.8(2)	Lease, by and between TPI and Point Richmond R&D Associates, L.P., dated as of February 22, 2006.
10.9(2)	First Amendment to Lease, by and between TPI and Point Richmond R&D Associates, L.P., dated as of June 27, 2007.
10.10(4)	Second Amendment to Lease, by and between Transcept Pharmaceuticals, Inc. and Point Richmond R&D Associates, L.P., dated as of February 20, 2009.
10.11(4)	Lease, by and between Transcept and Point Richmond R&D Associates II, LLC, dated as of February 20, 2009.
10.12(13)+	Offer Letter dated May 29, 2012, by and between Transcept Pharmaceuticals, Inc. and John Kollins.

Exhibit No.	Description of Exhibit
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10.14+	Third Amended and Restated Director Compensation Policy.
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23.1	Consent of Independent Registered Public Accounting Firm.
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31.2	Certification of the Company's Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
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(15) Incorporated by reference from the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2012.

† Confidential treatment has been granted as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.

+ Indicates management contract or compensatory plan, contract or arrangement.

* The certification attached as Exhibit 32.1 that accompanies this Annual Report on Form 10-K is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Transcept Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-K, irrespective of any general incorporation language contained in such filing.

** XBRL information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

(b) Exhibits

See Exhibits listed under Item 15(a)(3) above.

(c) Financial Statement Schedules

Financial statement schedules are omitted because they are not applicable or are not required or the information required to be set forth therein is included in the Financial Statements or notes thereto.

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, in the City of Point Richmond, State of California, on the 12 th day of March, 2013.

Transcept Pharmaceuticals, Inc.

By: /s/ GLENN A. OCLASSEN

Glenn A. Oclassen
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Glenn A. Oclassen and Leone D. Patterson his true and lawful attorney-in-fact and agent, with full power of substitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this annual report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, each of the undersigned has executed this Power of Attorney as of the date indicated opposite his/her name.

Pursuant to the requirements of the Securities Exchange Act of 1934, 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/ GLENN A. OCLASSEN **Glenn A. Oclassen**	President, Chief Executive Officer, and Director *(Principal Executive Officer)*	March 12, 2013
/s/ LEONE D. PATTERSON **Leone D. Patterson**	Vice President, Finance and Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 12, 2013
/s/ CHRISTOPHER B. EHRLICH **Christopher B. Ehrlich**	Director	March 12, 2013
/s/ THOMAS D. KILEY **Thomas D. Kiley**	Director	March 12, 2013
/s/ JAKE R. NUNN **Jake R. Nunn**	Director	March 12, 2013
/s/ G. KIRK RAAB **G. Kirk Raab**	Chairman of the Board of Directors	March 12, 2013
/s/ FREDERICK J. RUEGSEGGER **Frederick J. Ruegsegger**	Director	March 12, 2013

Exhibit Index

Exhibit No.	Description of Exhibit
3.1(1)	Amended and Restated Certificate of Incorporation of Transcept Pharmaceuticals, Inc.
3.2(1)	Bylaws of Transcept Pharmaceuticals, Inc., as amended.
4.1(2)	Specimen Common Stock certificate of Transcept Pharmaceuticals, Inc.
4.2(2)	Form of Preferred Stock Purchase Warrant issued to certain TPI investors as of March 21, 2005.
4.3(2)	Preferred Stock Purchase Warrant issued by TPI to Hercules Technology Growth Capital, Inc., dated as of April 13, 2006.
4.4(3)	2005 Amended and Restated Investor Rights Agreement, dated as of December 21, 2005, by and between Novacea and purchasers of Novacea Series A, Series B and Series C Preferred Stock.
4.5(9)	Amended and Restated Investor Rights Agreement, dated as of February 27, 2007, by and between TPI and purchasers of TPI Series A, Series B, Series C and Series D Preferred Stock.
4.6(9)	Termination Agreement, dated as of January 26, 2009, by and between TPI and purchasers of TPI Series A, Series B, Series C and Series D Preferred Stock.
10.1(3)+	Novacea 2001 Stock Option Plan and forms of agreements relating thereto.
10.2(10)+	2006 Equity Incentive Plan, as amended and restated.
10.3(11)+	Form of Option Agreement under 2006 Incentive Award Plan.
10.4(2)+	TPI Amended and Restated 2002 Stock Option Plan and forms of agreements relating thereto.
10.5(7)+	Transcept Pharmaceuticals, Inc. 2009 Employee Stock Purchase Plan.
10.6(3)	Loan and Security Agreement, by and between Transcept Pharmaceuticals, Inc. and Hercules Technology Growth Capital, Inc. dated as of April 13, 2006.
10.7(3)	Secured Promissory Note issued to Hercules Technology Growth Capital, Inc., dated as of May 31, 2006.
10.8(2)	Lease, by and between TPI and Point Richmond R&D Associates, L.P., dated as of February 22, 2006.
10.9(2)	First Amendment to Lease, by and between TPI and Point Richmond R&D Associates, L.P., dated as of June 27, 2007.
10.10(4)	Second Amendment to Lease, by and between Transcept Pharmaceuticals, Inc. and Point Richmond R&D Associates, L.P., dated as of February 20, 2009.
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TRANSCEPT PHARMACEUTICALS, INC.

Third Amended and Restated Independent Director Equity Compensation Policy

Effective January 4, 2013

1. General. This Amended and Restated Independent Director Equity Compensation Policy (the "**Policy**") has been adopted by Transcept Pharmaceuticals, Inc., a Delaware corporation (the "**Company**"), in accordance with Section 10.1 of the Transcept Pharmaceuticals, Inc. 2006 Incentive Award Plan (the "**Equity Plan**"). Capitalized but undefined terms used herein shall have the meanings provided for in the Equity Plan.

2. Authority. Pursuant to Section 10.1 of the Equity Plan, this Policy sets forth the terms for the grant of awards under the Equity Plan to Independent Directors (as defined therein), which includes a written, non-discretionary formula, for the types of awards to be granted to Independent Directors and the number of shares of the Company's common stock, par value $0.001 per share (the "**Common Stock**"), subject to such awards, and also specifies, with respect to any such awards, the conditions on which such awards shall be granted, become exercisable, and expire, and such other terms as set forth below. Equity awards granted under the authority of the Equity Plan pursuant to the provisions of this Policy are hereinafter referred to as "**Awards**."

3. Option Awards. During the term of the Equity Plan, (i) a person who first becomes an Independent Director automatically shall be granted an Option to purchase 10,000 shares of Common Stock (an "**Initial Option**") on the date they begin to serve as an Independent Director, and (ii) an Independent Director who first becomes Chairman of the Board of Directors (the "**Chairman**") automatically shall be granted an Option to purchase such number of shares of Common Stock as the Board of Directors of the Company (the "**Board**") shall determine (an "**Initial Chairman Option**") on the date they begin to serve as Chairman of the Board. For the avoidance of doubt, a person who first becomes an Independent Director and, at the same time, becomes Chairman of the Board shall automatically be granted both an Initial Option and an Initial Chairman Option.

During the term of the Equity Plan, commencing on the date of the first meeting of the Board of Directors or the Compensation Committee (the "**Committee**") held in 2013, (i) Independent Directors automatically shall be granted an Option to purchase 13,500 shares of Common Stock effective as of the date of the first regularly scheduled Committee meeting in each fiscal year (a "**First Meeting**"), provided that the Independent Director has served as a member of the Board for at least six (6) months as of such date (the "**Annual Option**"), and (ii) an Independent Director that is the Chairman of the Board shall be granted an Option to purchase such number of shares of Common Stock as the Board shall determine effective as of the date of the First Meeting, provided that such individual has served as an Independent Director and Chairman of the Board for at least six (6) months as of such date (the "**Annual Chairman Option**"). Members of the Board who are employees of the Company who subsequently retire from the Company and remain on the Board will not be granted an Initial Option or Initial Chairman Option, as applicable, but to the extent they are otherwise eligible, will be granted, at each First Meeting after his or her retirement from employment with the Company an Annual Option and Annual Chairman Option grant, as applicable.

(a) Option Type; Exercise Price. Options granted to Independent Directors shall be Non-Qualified Stock Options. The exercise price per share of Common Stock subject to each Option granted to an Independent Director shall equal 100% of the Fair Market Value of a share of Common Stock on the date the Option is granted.

(b) Vesting; Term; Termination of Service Initial Options and Initial Chairman Options shall become vested and exercisable in substantially equal monthly installments over the three (3)-year period commencing on the date of grant. Annual Options shall become vested and exercisable in substantially equal monthly installments over the twelve (12)-month period commencing on the date of grant. Annual Chairman Options shall become vested and exercisable in substantially equal monthly installments over the forty-eight (48)-month period commencing on the date of grant. The term of each Option granted pursuant to this Policy shall be ten (10) years from the date the Option is granted. Upon an Independent Director's termination of membership on the Board for any reason other than for cause or a Qualified Retirement, his or her Options granted pursuant to this Policy shall remain exercisable for twelve (12) months following his or her termination of membership on the Board, and upon an Independent Director's termination of membership on the Board as a result of a Qualified Retirement, his or her Options granted pursuant to this Policy shall remain exercisable for eighteen (18) months following his or her termination of membership on the Board; provided, however, that no Option shall be exercisable after the expiration of the term of such Option. Unless otherwise determined by the Board on or after the date of grant of such Option, no portion of an Option granted pursuant to this Policy which is unexercisable at the time of an Independent Director's termination of membership on the Board shall thereafter become exercisable. A "Qualified Retirement" shall mean that the Independent Director resigns or elects not to stand for reelection to the board in connection with his or her retirement at any time after reaching the age of 62.

4. Automatic Acceleration. Anything to the contrary in the foregoing notwithstanding, Awards granted under this Policy shall automatically vest in full and become exercisable: (a) immediately prior to a Change in Control; or (b) in the case of an individual Independent Director participant, upon the Qualified Retirement of the director from service as a director of the Company.

5. Treatment of Awards Granted Prior to Policy. Equity awards granted to an Independent Director prior to April 3, 2009 effective date of this Policy pursuant to the terms of the Company's 2001 Stock Option Plan (the " **Prior Plan**") or otherwise shall automatically vest in full and become exercisable immediately prior to a Change in Control, notwithstanding anything to the contrary provided in the terms and conditions set forth in the Prior Plan or in any agreement evidencing the grant of the equity awards. Except as provided in this Section 5, equity awards granted prior to April 3, 2009 shall otherwise continue to be subject to the provisions in effect as of April 3, 2009 governing the terms and conditions of the awards that are set forth in the Prior Plan and/or in any agreement evidencing the grant of the awards.

6. Incorporation of Terms of Equity Plan. All applicable terms of the Equity Plan apply to this Policy as if fully set forth herein except to the extent such other provisions are inconsistent with this Policy, and all grants of Awards hereby are subject in all respect to the terms of the Equity Plan.

7. Written Grant Agreement. The grant of any Award under this Policy shall be made solely by and subject to the terms set forth in a written agreement in a form to be approved by the Board (or a Committee thereof in accordance with the terms of the Equity Plan) and duly executed by an executive officer of the Company.

8. Policy Subject to Amendment, Modification and Termination. This Policy may be amended, modified or terminated by the Board or a Committee, in either case in the sole discretion of the Board or Committee, as applicable, at any time. No Independent Director shall have any rights hereunder unless and until an Award is actually granted.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-145840) and related Prospectus of Novacea, Inc.;
(2) Registration Statement (Form S-3 No. 333-167598) and the related Prospectus of Transcept Pharmaceuticals, Inc.; and
(3) Registration Statements (Forms S-8 No. 333-135506, No. 333-150869, No. 333-157927, No. 333-157929, No. 333-160222, No. 333-164468, No. 333-172041, and No. 333-180517) pertaining to, the Novacea, Inc. 2006 Incentive Award Plan and the Amended 2001 Stock Option Plan of Novacea, Inc., the Novacea, Inc. 2006 Incentive Award Plan, the Transcept Pharmaceuticals, Inc. 2006 Incentive Award Plan, the Transcept Pharmaceuticals, Inc. Amended and Restated 2002 Stock Option Plan, the Transcept Pharmaceuticals, Inc. 2009 Employee Stock Purchase Plan, the Transcept Pharmaceuticals, Inc. 2006 Incentive Award Plan, and the Transcept Pharmaceuticals, Inc. Amended and Restated 2006 Incentive Award Plan;

of our reports dated March 12, 2013, with respect to the consolidated financial statements of Transcept Pharmaceuticals, Inc. and the effectiveness of internal control over financial reporting of Transcept Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2012.

/s/Ernst & Young LLP

Redwood City, California
March 12, 2013

Exhibit 31.1

Certification of Chief Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Glenn A. Oclassen, certify that:

1. I have reviewed this annual report on Form 10-K of Transcept Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: March 12, 2013

/s/ Glenn A. Oclassen

Glenn A. Oclassen
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Chief Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Leone D. Patterson, certify that:

1. I have reviewed this annual report on Form 10-K of Transcept Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: March 12, 2013

/s/ Leone D. Patterson

Leone D. Patterson
Vice President, Finance and Chief
Financial Officer
(Principal Financial Officer)

Exhibit 32.1

Certification of Chief Executive Officer and Chief Financial Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Transcept Pharmaceuticals, Inc. (the "Company") hereby certifies, to such officer's knowledge, that:

(i) the accompanying Annual Report on Form 10-K of the Company for the annual period ended December 31, 2012 (the " Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 12, 2013

/s/ Glenn A. Oclassen

Glenn A. Oclassen
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Leone D. Patterson

Leone D. Patterson
Vice President, Finance and
Chief Financial Officer
(Principal Financial Officer)

A signed original of this written statement required by Rule 13a-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350 has been provided to the Registrant and will be retained by the Registrant and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933 or the Securities Exchange Act of 1934 (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.