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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, 2011

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, 2011, the last business day of the registrant's second fiscal quarter was: $69,086,747.

As of March 26, 2012 there were 13,975,541 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.

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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:

- expectations regarding the timing of the commercial launch of Intermezzo in the United States by Purdue Pharmaceutical Products L.P., or Purdue Pharma;
- expectations regarding our TO-2061 development program;
- expected activities and responsibilities of us and Purdue Pharma under our United States License and Collaboration Agreement, or the Collaboration Agreement;
- our potential receipt of revenue under the Collaboration Agreement, including milestone and royalty revenue;
- the satisfaction of conditions under the Collaboration Agreement with Purdue Pharma required for continued commercialization of Intermezzo, and the payment of potential milestone payments, royalties and fulfillment of other Purdue Pharma obligations under the Collaboration Agreement;
- whether the commercial potential of Intermezzo will be sufficiently attractive for Purdue Pharma to continue with our collaboration;
- the potential benefits of, and markets for, Intermezzo and other product candidates;
- expectations regarding reimbursement for Intermezzo in the United States;
- plans for the manufacturing of Intermezzo and TO-2061;
- potential competitors and competitive products;
- 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;
- 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;
- losses, costs, expenses, expenditures and cash flows;
- the ability and degree to which we may obtain and maintain market exclusivity from the FDA for Intermezzo, TO-2061 and any future product candidates under Section 505(b)(2) of the FFDCA;
- our ability to maintain and obtain additional patent protection for Intermezzo and obtain patent protection for our TO-2061 development program without violating the intellectual property rights of others; and
- expected future sources of revenue and capital.

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;
- our ability to satisfy conditions under the Collaboration Agreement with Purdue Pharma required for Purdue Pharma to carry out its obligations under such agreement;
- the potential for delays in or the inability to complete commercial partnership relationships, including additional marketing alliances for Intermezzo outside the United States;
- physician or patient reluctance to use Intermezzo;
- changing standards of care and the introduction of products by competitors, including generic products whose introduction could reduce our royalty rates under the Collaboration Agreement, or alternative therapies for the treatment of indications we target;
- 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;
- 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;
- the ability to identify and finance additional products for in-licensing or acquisition, and the ability of those products to be accretive to our earnings;
- 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, TO-2061 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.

Intermezzo® and Transcept Pharmaceuticals, Inc.™ are registered and unregistered trademarks of ours in the United States and 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. We expect that Intermezzo, a prescription product, will be 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 early as 12 months after the commercial launch of Intermezzo in the United States and as late as 55 months after such commercial launch. We retain full rights to Intermezzo outside North America and plan to develop and market Intermezzo in major markets outside the United States through one or more development and marketing alliances.

On November 30, 2011, Purdue Pharma exercised its right to commercialize Intermezzo in the United States pursuant to the Collaboration Agreement. Purdue Pharma has notified us that it expects to launch Intermezzo in the United States in April of 2012 and plans to invest approximately $100 million to support the sales and marketing of Intermezzo during the first full year of commercialization. A portion of this investment will include the formation of a new 275 representative sales force devoted exclusively to the promotion of Intermezzo to those physicians who are the highest prescribers of insomnia products. 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 $80 million in intellectual property and 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 22% to 40% and would be fixed according to when we begin our specialty marketing effort.

We are also conducting a Phase 2 study of TO-2061, a low dose of ondansetron, to determine its effectiveness and safety when used as an adjunctive treatment for patients with obsessive compulsive disorder, or OCD, who have not adequately responded to standard first-line therapy with currently approved OCD medications.

As we transition from development to the commercialization of our first product, our key business objectives are to support the launch of Intermezzo in the United States, expand our pipeline of proprietary products, and position Transcept to become a sales and marketing organization that addresses 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 lower 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 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 1.24 billion zolpidem tablets prescribed in the United States for the twelve months ended September 30, 2011. 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 is not indicated for the treatment of middle-of-the-night insomnia when the patient has fewer than 4 hours of bedtime remaining before the 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.

TO-2061: investigational product in development as adjunctive therapy in patients with obsessive compulsive disorder

We are developing TO-2061, a low dose of ondansetron, to be used as adjunctive therapy in patients with obsessive compulsive disorder, or OCD, who have not adequately responded to first-line treatment with currently approved OCD medications, such as selective serotonin re-uptake inhibitors, or SSRIs. Our strategy is to augment the therapeutic effects of first-line pharmacotherapy in OCD patients with ondansetron to provide more effective treatments to control OCD in patients who do not respond adequately to conventional therapies. Ondansetron is currently marketed in higher doses as Zofran® by GlaxoSmithKline, and is available in generic form, for the prevention of nausea and vomiting caused by radiation therapy and chemotherapy and for the prevention of postsurgical nausea and vomiting. Typical daily doses of ondansetron for these indications are 16 mg to 24 mg. We are studying ondansetron at total daily doses of 1 mg to 1.5 mg.

In March 2011, we began a Phase 2 double-blind, multi-center, placebo-controlled study of TO-2061 to evaluate its effectiveness and safety when used as an adjunctive treatment for patients with OCD who have not adequately responded to standard first-line therapy with currently approved OCD medications, such as SSRIs.

The decision to conduct the Phase 2 study was based in part on two single-blind exploratory clinical studies that examined the use of a range of low doses of ondansetron in the treatment of OCD. These studies yielded initial results that we and our advisors believe to be encouraging.

OCD is characterized by a pattern of unwanted and intrusive thoughts that cause distress and consequent repetitive behaviors aimed at reducing this distress. OCD has been known to significantly impact everyday life activities of both patients and their families. It has been estimated by the U.S. Department of Health and Human Services that OCD affects 1% to 2% of the United States adult population, and the overall degree of impairment caused by OCD has been described as comparable to that experienced by patients who suffer with schizophrenia. Approximately 40% to 50% of OCD sufferers seek treatment from a physician and approximately 40% to 60% of OCD patients do not respond adequately to first-line pharmacotherapy. There is currently no FDA approved treatment for this group of patients. Atypical antipsychotics are often used off-label to augment first-line treatment of OCD, but approximately 68% of treatment resistant OCD patients do not respond adequately. Adverse events such as weight gain and metabolic disorders are associated with the use of atypical antipsychotics.

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, 2011, we had cash, cash equivalents and marketable securities of approximately $62.4 million, working capital of approximately $62.5 million, and an accumulated deficit of approximately $100.1 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, with an initial focus on psychiatry. Our efforts to achieve this goal are driven by the following key strategies:

- *Support Purdue Pharma with the transition in NDA ownership to ensure a successful commercial launch of Intermezzo in the United States.* Our U.S. marketing partner, Purdue Pharma, plans to launch Intermezzo in April 2012 and to invest approximately $100 million to support sales and marketing of Intermezzo during the first year of commercialization. We have been actively working with Purdue Pharma to ensure a smooth transition as it relates to manufacturing commercial product and medical affairs activities.
- *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 a product pipeline to address unmet needs in the field of neuroscience.* We are developing TO-2061, a low dose of ondansetron, to determine its safety and efficacy as an adjunctive therapy for patients with OCD who have not adequately responded to treatment with approved first-line pharmacotherapy. 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.
- *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 acquisition of such a product could be important factors in our decision to exercise the psychiatry co-promote option with Purdue Pharma.

- *Develop a specialty commercial organization focused on neuroscience*. The Collaboration Agreement provides us the option to co-promote Intermezzo to psychiatrists in the United States. This option allows us to begin co-promoting Intermezzo as early as 12 months after the commercial launch of Intermezzo and as late as 55 months after such commercial launch.
- *Plan for Intermezzo royalty and milestone payments.* 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 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. 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. This additional co-promote royalty ranges from 40% of net revenue, if we begin marketing to psychiatrists in the first month following the one year anniversary of commercial launch of Intermezzo in the United States, down to approximately 22% of net revenue, if we do not begin marketing to psychiatrists until 55 months after the commercial launch of Intermezzo. Net revenue qualifying for this additional co-promote royalty is limited by an annual cap of 15% of total Intermezzo annual net sales in the United States.

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 79 million for the twelve months ended September 30, 2011.

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 use 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;
- 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 and an additional $10.0 million upon meeting a second intellectual property milestone.

The Collaboration Agreement provides us with an option to co-promote Intermezzo to psychiatrists in the United States. This option may be exercised at any time before, or on, the last day of the 40th calendar month after commercial launch of Intermezzo in the United States, and allows us to begin co-promoting Intermezzo as early as 12 months after the commercial launch of Intermezzo and as late as 55 months after such launch. 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 revenue that is generated by psychiatrist prescriptions. This additional co-promote royalty ranges from 40%, if we begin marketing to psychiatrists in the first month following the one year anniversary of commercial launch of Intermezzo in the United States, down to approximately 22%, if we do not begin marketing to psychiatrists until 55 months after the commercial launch of Intermezzo. Net revenue qualifying for this additional co-promote royalty is limited by an annual cap of 15% of total Intermezzo annual net sales in the United States. Our co-promotion 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 $1.0 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

Our co-promote option with Purdue Pharma provides us with the potential to develop our own U.S. specialty sales and marketing capabilities focused on the promotion of Intermezzo to psychiatrists and other products that address unmet needs in the field of neuroscience. Our goal of developing our own sales and marketing infrastructure and starting commercial operations would be further supported by the successful development of TO-2061, the in-licensing of another product opportunity or obtaining approval for another product. To achieve commercial success in marketing and selling Intermezzo in the United States, we must work with our partner, Purdue Pharma, to integrate our sales and marketing infrastructure and implement our sales and marketing efforts.

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, and to identify and secure the rights to one or more approved products that can be effectively sold by the specialty sales and marketing team and support the sale of Intermezzo pursuant to our co-promote option in the event that we exercise our option under the Collaboration Agreement.

Competition

Once commercialized, Intermezzo will compete 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® marketed by Somaxon Pharmaceuticals, 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, several 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. 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. 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:

- 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.

- 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. Tasimelteon is currently being studied in two Phase 3 studies for this indication.
- Indiplon, another agent that belongs to the $GABA_A$ receptor modulator class of compounds, was being developed by Neurocrine Biosciences, Inc. for the treatment of sleep initiation insomnia and middle-of-the-night dosing. The FDA did not approve the indiplon New Drug Application that was submitted by Neurocrine Biosciences, Inc. in 2007. The future clinical development and regulatory path of this product are uncertain.
- 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.
- MK-4305, an orexin receptor antagonist, is being developed by Merck & Co., Inc. for the treatment of insomnia. According to notices posted on www.clinicaltrials.gov, Merck completed two Phase 3 trials of MK-4305, one in November 2011 and the other in January 2012.
- 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 indiplon, 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.

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.

New drug approval

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 30day 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. Clinical testing also must satisfy extensive Good Clinical Practice, or GCP, regulations, including regulations for obtaining informed consent by each patient.

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 clinical trials to further assess a drug's safety and effectiveness after NDA approval. 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.

If, after reviewing the NDA, the FDA determines that the application cannot be approved in its current form, the FDA sends the NDA sponsor a Complete Response Letter identifying all outstanding deficiencies that preclude final approval. The FDA then halts its review until the NDA sponsor resubmits the NDA with new information designed to address the deficiencies. The resubmission of an NDA after the receipt of a Complete Response Letter can be considered either a Class I resubmission in connection with which the goal of the FDA is to respond in two months after resubmission or a Class II resubmission in connection with which the goal of the FDA is to respond in six months after resubmission. A Class I resubmission is an application resubmitted after deficiencies in the final printed labeling, draft labeling, safety updates, stability updates, phase IV commitments, assay validation data, final release testing on the last 1-2 manufacturing lots (used to support approval), minor reanalysis of data previously submitted to the application and/or other minor clarifying information. A Class II resubmission is an application resubmitted after other deficiencies not under a Class I resubmission, including items that require an advisory committee meeting.

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 2007 amendments to PDUFA set a goal that a Standard Review of an NDA be accomplished within a ten month timeframe. 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 completing a Priority Review is six months. The FDA strives to, and usually does, meet these review goals, but is not legally required to do so in every case. For example, the review of the Intermezzo NDA was a Standard Review, and the original PDUFA date was extended by three months. The review process is often significantly extended by FDA requests for additional information or clarification. 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. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. 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. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials may be subject to different interpretation, and the FDA may interpret data from our clinical trials differently than we do. The 2007 amendments to PDUFA will expire in September 2012 and are expected to be immediately replaced by a new set of goals that will dictate the general timeframes followed by the FDA for the review and approval of NDAs.

Under new legislation 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, 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). If our development of TO-2061 is successful, our plan is to submit an NDA for TO-2061 under Section 505(b)(2). We would then face the same challenges under Section 505(b)(2) as described below for Intermezzo.

Our Intermezzo NDA relied on the prior approval and extensive information that has been collected for immediate release zolpidem products, which contain the approved active drug substance contained in Intermezzo. 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.

The FDA has granted three years of Hatch-Waxman exclusivity for Intermezzo. Under this form of exclusivity, the FDA is precluded from approving an abbreviated new drug application for a generic version of

Intermezzo for a period of three years from the date of approval of Intermezzo. In addition, under this form of exclusivity, FDA is precluded from approving a 505(b)(2) application that seeks to reference the Agency's findings of safety and effectiveness for Intermezzo, or otherwise seeks approval of a zolpidem-based drug product for the same basic conditions of use as Intermezzo, for a period of three years from the date of approval of Intermezzo. This form of exclusivity may not prevent the FDA from approving an NDA that relies only on its own data.

Manufacturing cGMP requirements

We and our contract manufacturers are required to comply with applicable FDA manufacturing requirements contained in the FDA cGMP regulations. cGMP regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. The manufacturing facilities for active pharmaceutical ingredients, or APIs, and finished drug products 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.

The API used to manufacture some of our product candidates originates outside the United States. The FDA could increase its diligence with regard to foreign sourced materials and manufacturing processes which may result in increased costs of maintaining foreign manufacturing and could lengthen or delay the regulatory review process required to gain approval for our product candidates.

Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including adverse publicity, warning letters, the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, and civil and criminal penalties. Adverse patient experiences with the product received by us must be reported to the FDA and could result in the imposition of market restriction through labeling changes or in product removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval.

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 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, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental pricing control. The implementation of the Patient Protection and Affordable Care Act of 2010 and the Health Care and Education Reconciliation Act of 2010, together known as the Affordable Care Act, could significantly influence the purchase of pharmaceutical products, resulting in lower prices and a reduction in product demand. While we cannot predict the full effect of implementation of this law, it could have a material adverse effect on our business, financial condition and profitability.

The Affordable Care Act also requires manufacturers of branded prescription drugs to pay an annual fee to the federal government beginning in 2011. Each manufacturer's fee will be 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 $2.5 billion in 2011 and set to increase in following years), based on the ratio of its sales to the total sales by covered entities. We cannot predict our share of this fee because it will be determined in part on other entities' sales to the relevant programs.

Medicare

Two principal payors in the United States are Medicaid and 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 within the Department of Health and Human Services that administers Medicare and, at the state 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 the drug benefit. These plans develop formularies that determine which products are covered and what co-pay will apply to covered drugs. If Medicare coverage for Intermezzo is available, CMS will reimburse through Part D. While CMS evaluates Part D plans' proposed formularies for potentially discriminatory practices, the plans have considerable discretion in establishing formularies, establishing tiered co-pay structures and placing prior authorization and other restrictions on the utilization of specific products. Moreover, Part D plan sponsors are permitted and

encouraged to negotiate rebates with manufacturers. Revenue for Intermezzo will be substantially affected by its formulary status on Part D plans and the rebates that Part D plan sponsors are able to negotiate.

The Affordable Care Act makes several changes to Medicare Part D to phase-out the patient coverage gap, known as the doughnut hole. Beginning in 2011, the Act reduces patient responsibility in the coverage gap from 100% in 2010 to 25% in 2020. Also beginning in 2011, drug manufacturers will be obligated to pay quarterly applicable discounts of 50% of the negotiated price of branded drugs issued to Medicare Part D patients in the coverage gap. Once our products are approved for marketing, rebates will likely be paid to the federal government under this Medicare Part D Coverage Gap Discount Program, which would reduce our revenue.

Medicaid

Medicaid is a federal and state entitlement program that pays for medical assistance for certain individuals and families with low incomes and resources and who meet other eligibility requirements. Medicaid became law in 1965 and is jointly funded by the federal and state governments (including the District of Columbia and the territories). 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. This program was established by the Omnibus Budget Reconciliation Act of 1990 and has been amended over time, most recently by the Affordable Care Act. Under the Medicaid Drug Rebate Program, a rebate would be paid to each participating state agency for each unit of product reimbursed by Medicaid, whether under a fee-for-service or capitated arrangement. The basic amount of the rebate for each product is the greater of 23.1% of the Average Manufacturer Price, or AMP, of that product, or the difference between AMP and the best price available from us to any non-excluded customer. The rebate amount also includes an added inflation adjustment if AMP increases faster than a specified inflation index, and in the case of certain drugs that are line extensions or new formulations of existing drugs, this inflation adjustment can be based on the AMP of the original version of the drug. The rebate amount is calculated quarterly based on our reports of its current AMP and best price for each of its products to CMS, and is capped at 100% of AMP. AMPs and best price may be recalculated after they are initially submitted based on the availability of additional data or because of additional analysis of prices that have been previously reported.

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 not subject to restrictions on their utilization by Medicaid fee-for-service patients, such as the need to obtain authorization prior to prescribing. If Intermezzo is not included on Medicaid PDLs, use of it in the Medicaid fee-for-service program may be adversely affected. In some 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, 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 are required to extend discounts based on the Medicaid rebate to a variety of health care entities referred to as covered entities. These covered entities include health care providers that receive health services grants from the PHS, as well as certain hospitals that serve a disproportionate share of Medicare and Medicaid beneficiaries.

Section 603 of the Veteran's Health Care Act of 1992, or VHCA, requires manufacturers of covered drugs to enter into a master agreement with the Secretary of the Department of Veteran Affairs, or VA, in order to have

their drugs covered under Medicaid and the Medicare Part B program. The VHCA also requires the manufacturer to execute a Pharmaceutical Pricing Agreement, or PPA, with the VA under which the manufacturer agrees to make its products available for federal procurement on a VA Federal Supply Schedule, or FSS, contract to the so called 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, which manufacturers are required to report to the VA on a quarterly and annual basis. FSS contracts are federal procurement contracts that include standard government terms and conditions and separate pricing for each product. In addition to the Big Four agencies, all other federal agencies and some non-federal entities are authorized to access FSS contracts. FSS contractors are permitted to charge FSS purchasers other than the Big Four agencies so called negotiated pricing for covered drugs that is not capped by the VHCA formula; instead, such pricing is negotiated based on a mandatory disclosure of the contractor's commercial so called most favored customer pricing. All items on FSS contracts are subject to a standard FSS contract clause that requires FSS contract price reductions under certain circumstances where pricing to an agreed so called tracking customer is reduced.

Pursuant to Section 703 of the National Defense Authorization Act for Fiscal Year 2008, DoD has established a program under which it seeks FCP-based rebates from drug manufacturers on TRICARE retail utilization. Under this authority, DoD asserts an entitlement to rebates on TRICARE Retail Pharmacy utilization from January 28, 2008 forward, unless TMA grants a waiver or compromise of amounts due from utilization in quarters that have passed prior to execution of a voluntary agreement with DoD. Rebates are computed by subtracting the applicable FCP from the corresponding annual Non-FAMP. DoD has asserted the right to apply offsets and/or proceed under the Debt Collection Act in the event that a company does not pay rebates or request a waiver of rebate liability in a timely fashion.

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 and, if they are considered qualified programs by CMS, the rebates we provide these entities would be excluded from our Medicaid best price calculation.

Private insurance reimbursement

Commercial insurers usually offer pharmacy benefits. 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. Private insurers tend to adopt reimbursement methodologies for a product similar to those adopted by Medicare. Revenue for Intermezzo may be materially and adversely affected if private payors make unfavorable reimbursement decisions or delay making favorable reimbursement decisions.

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, if approved. These payors' efforts could decrease the price that we receive for products it 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. For instance, insurers may establish a prior authorization procedure or "step-edit" system that requires a patient to utilize a lower price alternative product prior to becoming eligible to purchase a higher price product that may be better targeted to the condition being treated. There can be no assurance that third party payors will not similarly require a patient to first use generic zolpidem or other sleep aids prior to being eligible for insurance coverage of Intermezzo use.

If government and third party payors do not provide adequate coverage and reimbursement levels for our products, or if price controls or step-edit systems are enacted, our product royalties or revenue will suffer.

Intellectual Property and Proprietary Technology

Our success will depend in part on our ability to protect Intermezzo, TO-2061 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 February 2025, one pending U.S. patent application and 15 corresponding foreign patents or applications. Foreign patents have been granted in Australia, China, Mexico, New Zealand, Singapore, and South Africa.
- *Middle of the night use of zolpidem.* We have two pending U.S. patent applications and 13 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.

We do not currently have patent protection for TO-2061. The active pharmaceutical ingredient in TO-2061, ondansetron, has also been known and used for many years and, therefore, the ondansetron composition of matter is no longer subject to patent protection. Accordingly, we are seeking patent protection for methods of using ondansetron in combination with first-line pharmacotherapy, and optionally atypical antipsychotic drugs, in the treatment of OCD. There can be no assurance that we will be granted a patent that covers the intended use of TO-2061.

In addition to the applications directed to Intermezzo and TO-2061, we filed patent applications for various other formulations and methods of use of drugs including other uses of ondansetron. We are currently exploring the potential development of products relating to this ondansetron application, which relates to methods of treating a patient with formulations that deliver ondansetron across the oral mucosa for various conditions.

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.

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 15, 2012, we had 17 employees, 3 of whom hold Ph.D., Pharm.D., or equivalent degrees. A total of 6 employees were engaged in research and development and 11 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.” 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. After the merger, former TPI stockholders, option holders and warrant holders as of January 30, 2009 owned approximately 61% of Transcept common stock on a fully-diluted basis. After the merger, the stockholders, option holders and warrant holders of Novacea prior to the merger owned approximately 39% of the Transcept common stock on a fully-diluted basis. Under generally accepted accounting principles in the United States, the merger is treated as a “reverse merger” under the purchase method of accounting. For accounting purposes, TPI is considered to have acquired Novacea.

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, 2011, 2010 and 2009 was $3.9 million, $9.3 million and $21.8 million, respectively. We had an accumulated deficit at December 31, 2011 of $100.1 million.

We only recently obtained regulatory approval for the commercial sale of our lead product candidate, Intermezzo, from the FDA. We have not demonstrated 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.

In addition, 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, and with respect to our other product candidate, TO-2061. If Purdue Pharma does not successfully commercialize Intermezzo, or if TO-2061 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 only recently received FDA approval.

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. We currently have one other product candidate in clinical development, TO-2061, which is being evaluated as a potential adjunctive therapy for patients with OCD who have not adequately responded to standard first-line treatment with currently approved OCD medications and which is currently undergoing a Phase 2 clinical study.

In July 2009, we entered into a Collaboration Agreement with Purdue Pharma, which provides 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 informed us that it intends to launch commercial sales of Intermezzo in the United States in early April 2012. 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. Because we do not have another product candidate that has 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.

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 will be dependent on the ability of Purdue Pharma to successfully launch and 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 launches Intermezzo, including the timing of launch and potential pricing, 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 of commercial sales of Intermezzo in the United States by Purdue Pharma is delayed or prevented, our revenue will suffer and our stock price may decline. Further, if launch and resulting sales of Intermezzo are not deemed successful, our stock price may decline. The outcome of Purdue Pharma 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.

We may 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 additional 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.

Our ability to receive any significant revenue from TO-2061 or future product candidates, if any, covered by a strategic collaboration 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 TO-2061 or 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 TO-2061 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 ability to provide acceptable evidence of safety and efficacy of Intermezzo or future products for their respective indications;
- the ease of use of Intermezzo;
- the existence of generic or branded competition for Intermezzo;
- the ability to obtain adequate pricing and sufficient insurance coverage and reimbursement;
- the availability, relative cost and relative efficacy and safety of alternative and competing treatments;
- the effectiveness of our or a collaboration partner's sales, marketing and distribution strategies; and
- the ability to produce commercial quantities sufficient to meet demand.

If Intermezzo, TO-2061 and/or future product candidates fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business.

Intermezzo will face 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 our collaboration partner have.

Intermezzo will compete 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 we or our collaboration partner plan to sell Intermezzo.

We believe that Intermezzo is well positioned as 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 directly competitive approved products 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 King Pharmaceuticals, Inc., have been used off-label for the as-needed treatment of middle-of-the-night awakenings. In September 2010, Somaxon Pharmaceuticals, Inc. announced that its product, Silenor®, became commercially available in the United States. Silenor® is 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 clinical trials, Silenor® demonstrated maintenance of sleep into the seventh and eighth hours of the night, with no meaningful evidence of next-day residual effects. Other drugs, such as the antidepressant generic trazodone, are also widely prescribed off-label for the treatment of insomnia.

Other companies may develop new products to compete with Intermezzo.

We are aware of several new products currently in development that are seeking indication statements from the FDA for the treatment of middle-of-the-night awakenings. NovaDel Pharma, Inc. states on its web-site 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 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, or such product candidate, if approved by the FDA, may be prescribed and used off-label to treat other insomnia indications. In May 2010, Merck and Co., Inc. initiated two Phase 3 studies of MK-4305, an orexin receptor antagonist intended for the treatment of insomnia.

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 before Intermezzo can be launched;
- 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.

Until such time as Purdue Pharma can commercially launch Intermezzo, we have no source of product revenue. We have a limited operating history and have not yet commercialized any products. We had cash, cash equivalents and marketable securities of $62.4 million at December 31, 2011. We expect our negative cash flows from operations to continue for the foreseeable future as we undertake activities to pursue the commercialization of Intermezzo, develop TO-2061, seek regulatory approval for Intermezzo in other countries and seek additional products and product candidates through business development efforts. We do not know how long it will take to obtain regulatory approval of TO-2061 or any future product candidates, if any, or if such approval is obtainable. We also expect negative cash flows beyond the product launch of Intermezzo. As a result, we will need to generate significant revenue to pay these costs and 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 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 timing of the commercial launch of Intermezzo by Purdue Pharma;
- the ability of Purdue Pharma to successfully commercialize 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 rate of progress and cost of our ongoing TO-2061 clinical trial, the need to conduct additional 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 terms and timing of any licensing arrangements that we may establish for Intermezzo outside the United States;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the effect of competing technological and market developments.

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

- further develop Intermezzo to meet the requirements for regulatory approval of Intermezzo outside the United States;
- 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;
- continue to develop TO-2061 through clinical trials and other development activities; and
- develop internally, acquire or in-license new products, technologies or businesses or to otherwise fund our operations.

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 successful 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:

- inability to recruit, retain and effectively manage adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or convince adequate numbers of physicians to prescribe Intermezzo or future products, if approved;
- the abundance of well branded, competing products sold and distributed by large established organizations;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- 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 after commercial launch of Intermezzo in the United States. For example, if Intermezzo is launched in early April of 2012, we can exercise our co-promote option on or before August 31, 2015. 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 later of the one year anniversary following the commercial launch of Intermezzo in the United

States by Purdue Pharma or 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. If we choose to delay the exercise of our co-promote option or commencing co-promotion activities after exercising our option, our royalty percentage on sales of Intermezzo pursuant to the option decreases on a monthly basis from approximately 40%, if we begin co-promoting Intermezzo in the first month of the year following the commercial launch of Intermezzo in the United States, down to approximately 22%, if we begin co-promoting in the 55th month following the commercial launch. A delay in exercise of our co-promotion 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.

Governmental and third party payors may impose restrictions or 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 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. In addition, the Affordable Care Act requires manufacturers of branded prescription drugs to pay an annual fee to the Federal government beginning in 2011. Each manufacturer's fee will be 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 $2.5 billion in 2011 and set to increase in following years), based on the ratio of its sales to the total sales by covered entities. 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 or publicity concerning zolpidem and other hypnotic pharmaceuticals could cause the FDA to make approval of new products for the insomnia market more difficult, by requiring additional 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, based on our interactions with the FDA, it is possible that the FDA may take steps to warn patients that the use of other zolpidem products 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 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. Moreover, the product may later 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 has 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. It is unclear how and to what extent, if any, these requests and recommendations will affect Intermezzo.

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, nor do we manufacture TO-2061, and we do not currently have plans to develop the capacity to manufacture either product. 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, 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, TO-2061 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.

Our future clinical trials may fail to demonstrate adequately the safety and efficacy of TO-2061 or any future product candidates, which could prevent or delay regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of TO-2061 or 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. Our 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. For example, ondansetron is approved for episodic use. It has not been clinically determined what risks could be associated with the long term or chronic use of ondansetron in treatment resistant OCD. In addition, from time to time the FDA will review the safety of an approved product, molecule or therapeutic class. In a recent review of ondansetron the FDA revised the Important Safety Information related to ondansetron and cited a risk of QT prolongation, or irregular heart rhythm. These types of safety reviews by the FDA, or new clinical findings generated by the scientific community, could cause Transcept to modify its clinical study plans for ondansetron and other programs, 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, a problem we are currently experiencing with our TO-2061 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. 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, as well as TO-2061, depends 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 new drug application (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®. We also plan to seek approval of TO-2061, which is at an earlier stage of development, under a Section 505(b)(2) application.

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, although the FDA may accept and commence review of ANDAs and 505(b)(2) NDAs during the three-year period. This form of exclusivity may not prevent FDA from approving an original NDA that relies only on its own data to support the approval.

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 intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for Intermezzo, but we may be unable to obtain such product liability insurance on commercially reasonable terms.

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, 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 and TO-2061 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 two issued patents from the U.S. Patent and Trademark Office, or USPTO, covering the formulation and use of Intermezzo that expire no earlier than February 2025. The commercial success of Intermezzo may also depend upon a patent application that would cover middle-of-the-night use of zolpidem to treat insomnia at the time of awakening. In addition, we have pending certain foreign equivalent patent applications. We also have pending applications covering methods of treating OCD with TO-2061 in combination with first-line pharmacotherapy, and optionally atypical antipsychotic drugs.

The active, and many of the inactive, ingredients in Intermezzo and TO-2061, including generically manufactured zolpidem and ondansetron, respectively, have been known and used for many years. The zolpidem and ondansetron compositions of matter are no longer subject to patent protection. Accordingly, certain of our patents for Intermezzo and TO-2061 are directed to the particular formulations of its ingredients. Also, for both Intermezzo and TO-2061, we are seeking patent protection for new uses of such compounds. Although we believe our formulations and the use of Intermezzo and TO-2061 are patentable, and patents covering or arising from such product candidates have the potential to provide a competitive advantage, such 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, 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 or TO-2061 and their 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 or ondansetron products similar to our products 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. Furthermore, among other limitations, our patent applications 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 TO-2061, 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 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 any such action up to an aggregate cap of $1.0 million per calendar year and $4.0 million over the term of the agreement. 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 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. Because our internal research and development capabilities are limited, and because new product approvals can take several 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.

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 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:

- delays or unexpected difficulties in Purdue Pharma's efforts to commercially launch Intermezzo in the United States;
- delays or unexpected changes in Purdue Pharma's plan to invest approximately $100 million to support sales and marketing during the first year of Intermezzo commercialization;
- 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;
- 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;
- 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, 2011, the sales price of our common stock on The NASDAQ Global Market ranged from a high of $11.88 in June 2011 to a low of $2.58 in August 2011. 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 and the expected timing of the launch;
- announcements by Purdue Pharma regarding the commercialization 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, 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 results of current and any future clinical trials of our product candidates, such as our ongoing Phase 2 trial of TO-2061;
- 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, 2011, we had research

coverage by three 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 25.3% of our approximately 13.9 million outstanding shares of common stock as of December 31, 2011 and an additional 23.2% is beneficially owned by venture capital firms in which two of our directors are partners. 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 have established predetermined selling plans under Rule 10b5-1 of 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 25.3% of the outstanding shares of our common stock as of December 31, 2011 and an additional 23.2% is beneficially owned by venture capital firms in which two of our directors are partners. 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.

We also lease 25,288 square feet of general office space in South San Francisco, California, under a lease that expires in October 2012. All of the South San Francisco space was subleased to third parties in May and June 2009.

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

Item 3. Legal Proceedings

From time to time, we may be involved in litigation relating to claims arising out of our operations. We are not currently involved in any material legal proceedings.

SPI Pharmaceuticals, Inc., the sole supplier of Pharmaburst®, a key excipient used in Intermezzo, was the defendant in a lawsuit brought by Roquette Frères, or Roquette, in the Federal District Court of Delaware on August 31, 2006 that alleged that certain of SPI's products infringed one or more claims of a Roquette patent and sought monetary damages and injunctive relief. We were not named in, and were not a party to, the lawsuit. Although not specifically identified in the original complaint, press releases indicated that Pharmaburst® products were among the accused products. SPI has informed us that SPI and Roquette have concluded this lawsuit under terms that enable SPI to market its products globally without any restriction from Roquette.

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 (adjusted for the 1-for-5 reverse stock split which occurred on January 30, 2009).

	Sales Price	
	High	Low
Year ended December 31, 2010		
First quarter	$ 8.77	$6.33
Second quarter	$11.44	$7.91
Third quarter	$ 8.84	$6.75
Fourth quarter	$ 7.93	$5.84
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

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 26, 2012 was $9.81 per share. As of March 26, 2012, there were approximately 58 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.

Issuer Purchases of Equity Securities

There were no repurchases of our common stock during the fourth quarter of fiscal 2011.

Securities Authorized For Issuance Under Equity Compensation Plans

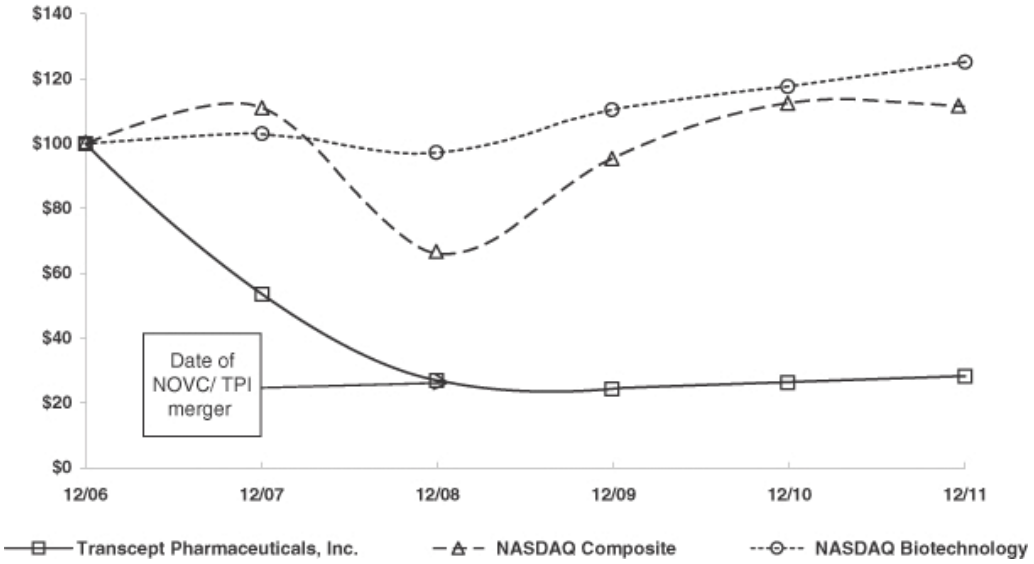
Information relating to compensation plans under which equity securities are authorized for issuance is set forth under Item 12. "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" of this Annual Report on Form 10-K.

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, 2006 and ending on December 30, 2011.

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, 2006 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.

Comparison of Five Year Cumulative Total Return
Among Transcept Pharmaceuticals, Inc., the NASDAQ Composite Index and the NASDAQ Biotechnology Index



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,				
	2011	2010	2009	2008	2007
	(in thousands, except per share data)				
Statements of operations data					
Total revenue	$ 19,694	$ 12,500	$ 5,208	$ —	$ —
Operating expenses:					
Research and development	11,273	10,684	9,005	10,381	15,885
General and administrative	12,185	11,038	16,050	7,924	5,300
Merger related transaction costs	—	—	2,224	1,967	—
Total operating expenses	23,458	21,722	27,279	20,272	21,185
Loss from operations	(3,764)	(9,222)	(22,071)	(20,272)	(21,185)
Interest and other income (expense), net	(116)	(81)	271	313	801
Net loss	$ (3,880)	$ (9,303)	$ (21,800)	$(19,959)	$(20,384)
Basic and diluted net loss per share attributable to common stockholders	$ (0.29)	$ (0.69)	$ (1.79)	$ (49.77)	$ (68.86)
Weighted average common shares outstanding	13,534	13,416	12,166	401	296

	As of December 31,				
	2011	2010	2009	2008	2007
	(in thousands)				
Selected Balance Sheet Data					
Cash, cash equivalents, marketable securities and restricted cash	$ 62,562	$ 68,171	$ 89,102	$ 11,883	$ 35,434
Total assets	69,151	73,807	95,218	13,781	37,769
Working capital	62,498	59,775	74,293	6,875	29,612
Convertible preferred stock	—	—	—	71,037	71,037
Common stock and additional paid-in capital	165,817	160,023	157,943	1,504	751
Accumulated deficit	(100,094)	(96,214)	(86,911)	(65,111)	(45,152)
Total stockholders' equity (net capital deficiency)	65,752	63,811	71,071	(63,581)	(44,316)

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 79 million for the twelve months ended September 30, 2011. 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;
- 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 and an additional $10.0 million upon meeting a second intellectual property milestone.

We have retained an option to co-promote Intermezzo to psychiatrists in the United States. This option allows us to begin co-promoting Intermezzo as early as 12 months after the commercial launch of Intermezzo and as late as 55 months after such launch. The option can be exercised as late as 40 months after such commercial launch. If we exercise the co-promote option and enter the market place, we are entitled to receive an additional co-promote royalty from Purdue Pharma on net revenue that is generated by psychiatrist prescriptions. This additional co-promote royalty ranges from 40%, if we begin marketing to psychiatrists in the first month following the one year anniversary of commercial launch of Intermezzo in the United States, down to approximately 22%, if we do not begin marketing to psychiatrists until 55 months after the commercial launch of Intermezzo. Net revenue qualifying for this additional co-promote royalty is limited by an annual cap of 15% of total Intermezzo annual net sales in the United States. Our co-promotion option cannot be transferred to a third party, except under a limited circumstance at the discretion of Purdue Pharma.

We recorded as revenue the $10.0 million milestone payment received in December 2011. The patent-related milestone was substantive and at-risk given 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 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. During the fourth quarter of 2011, the Company recorded revenue of $750,000 in Other Revenue associated with these rights.

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.

Through June 30, 2011, we recognized revenue from the $25.0 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, 2010 and 2009 was $7.3 million, $12.5 million and $5.2 million, respectively.

TO-2061: investigational product in development as adjunctive therapy in patients with obsessive compulsive disorder

We are developing TO-2061, a low dose of ondansetron, to be used as adjunctive therapy in patients with obsessive compulsive disorder, or OCD, who have not adequately responded to first-line treatment with currently approved OCD medications, such as selective serotonin re-uptake inhibitors, or SSRIs. Our strategy is to augment the therapeutic effects of first-line pharmacotherapy in OCD patients with ondansetron to provide more effective treatments to control OCD in patients who do not respond adequately to conventional therapies. Ondansetron is currently marketed in higher doses as Zofran® by GlaxoSmithKline, and is available in generic form, for the prevention of nausea and vomiting caused by radiation therapy and chemotherapy and for the prevention of postsurgical nausea and vomiting. Typical daily doses of ondansetron for these indications are 16 mg to 24 mg. We are studying ondansetron at total daily doses of 1 mg to 1.5 mg.

In March 2011, we began a Phase 2 double-blind, multi-center, placebo-controlled study of TO-2061 to evaluate its effectiveness and safety when used as an adjunctive treatment for patients with OCD who have not adequately responded to standard first-line therapy with currently approved OCD medications, such as SSRIs. The decision to conduct the Phase 2 study was based in part on two single-blind exploratory clinical studies that examined the use of a range of low doses of ondansetron in the treatment of OCD. These studies yielded initial results that we and our advisors believe to be encouraging.

OCD is characterized by a pattern of unwanted and intrusive thoughts that cause distress and consequent repetitive behaviors aimed at reducing this distress. OCD has been known to significantly impact everyday life activities of both patients and their families. It has been estimated by the U.S. Department of Health and Human Services that OCD affects 1% to 2% of the United States adult population, and the overall degree of impairment caused by OCD has been described as comparable to that experienced by patients who suffer with schizophrenia. Approximately 40% to 50% of OCD sufferers seek treatment from a physician and approximately 40% to 60% of OCD patients do not respond adequately to first-line pharmacotherapy. There is currently no FDA approved treatment for this group of patients. Atypical antipsychotics are often used off-label to augment first-line treatment of OCD, but approximately 68% of treatment resistant OCD patients do not respond adequately. Frequently reported adverse events associated with atypical antipsychotics include weight gain and metabolic disorders.

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, 2011, we had an accumulated deficit of $100.1 million. Our net loss for the years ended December 31, 2011, 2010, and 2009 was $3.9 million, $9.3 million, and $21.8 million, respectively. As of December 31, 2011, we had cash, cash equivalents, and marketable securities of $62.4 million and working capital of $62.5 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 the fourth quarter of 2011, we received a $10 million milestone payment from Purdue Pharma. We also recorded approximately $2.4 million from Purdue Pharma that included approximately $0.8 million for a non-refundable option to negotiate for the commercialization of Intermezzo in Mexico and Canada and approximately $1.6 million for reimbursement of certain manufacturing-related costs.

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

Revenue

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, 2010 and 2009 was $7.3 million, $12.5 million and $5.2 million, respectively. 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 $0.75 million; and
- $1.65 million for reimbursement of certain manufacturing-related costs.

Research and Development Expense

Research and development expense represented approximately 48%, 49%, and 33% of total operating expenses for the years ended December 31, 2011, 2010, and 2009, 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.

During the first half of 2009, we increased spending on our sales and marketing infrastructure, including increased headcount and marketing expense necessary to prepare for the commercialization of Intermezzo. Following our entry into the Collaboration Agreement with Purdue Pharma, the majority of our sales and marketing activities were transitioned to Purdue Pharma.

Interest Income

We receive interest income from cash, cash equivalents, restricted cash and marketable securities held with certain financial institutions.

Interest Expense

We incurred interest expense on the outstanding balance from our $10.0 million venture debt facility agreement, which was repaid in full during the first quarter of 2009. We also incur interest expense on a $0.3 million loan for tenant improvements, payable to the landlord of our corporate facility in Point Richmond, California.

Other Income (Expense), Net

Other income (expense), net relates to Delaware franchise tax, realized gains on the sales of marketable securities, and, through January 2009, the change in fair value of preferred stock warrants. In connection with our January 2009 merger (under our pre-merger name, Novacea, Inc.) with Transcept Pharmaceuticals, Inc., a privately-held Delaware corporation, or the Merger, the outstanding preferred stock warrants converted into outstanding common stock warrants and therefore are no longer treated as a liability requiring remeasurement to fair market value at each balance sheet date.

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
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%)
Interest income	79	127	(48)	(38%)
Interest expense	9	12	3	25%
Other income (expense), net	(186)	(196)	10	5%

Revenue

Revenue increased 58% to $19.69 million for the year ended December 31, 2011 from $12.50 million for the comparable period in 2010. The increase of approximately $7.19 million consists of the following:

- 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 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 $0.75 million; and
  - $1.65 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 $11.27 million for the year ended December 31, 2011 from $10.68 million for the comparable period in 2010. The increase of approximately $0.59 million for the year ended December 31, 2011 is primarily attributable to:

- an increase of $2.17 million in the TO-2061 development program, including an increase of $2.60 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 $1.61 million in personnel costs, related expenses and other general expenses, including severance and benefit continuation expense of approximately $0.58 million incurred in connection with the restructuring announced in July 2011, and $0.69 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 $3.19 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 $12.19 million for the year ended December 31, 2011 from $11.04 million for the comparable period in 2010. The approximately $1.15 million increase consists of the following:

- An increase of $2.38 million in personnel costs and related expenses, primarily including severance and benefit continuation expense of approximately $0.65 million incurred in connection with the restructuring announced in July 2011, stock-based compensation expense of approximately $0.15 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 $1.21 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 $0.85 million reduction in professional fees, including market research, legal and third party consulting and
- a $0.38 million reduction in facilities and related costs due to the termination of one of our property leases and reductions in other general facilities costs.

Interest Income

Interest income decreased 38% to $79,000 for the year ended December 31, 2011 from $127,000 for the comparable period in 2010. The decrease of approximately $48,000 for the year ended December 31, 2011 is attributable to lower yields on lower investment balances as compared to the year ended December 31, 2010.

Interest Expense

Interest expense is comparable between periods.

Other Income (Expense), Net

Other income (expense), net is comparable between periods and primarily consists of Delaware franchise tax.

Comparison of the Years Ended December 31, 2010 and 2009

The following table summarizes results of operations with respect to the items set forth below for the years ended December 31, 2010 and 2009, in thousands, together with the percentage change in those items.

	Year ended December 31,			
	2010	2009	Favorable (Unfavorable)	% Change
Revenue	$12,500	$ 5,208	$ 7,292	140%
Research and development expense	10,684	9,005	(1,679)	(19%)
General and administrative expense	11,038	16,050	5,012	31%
Merger related transaction costs	—	2,224	2,224	100%
Interest income	127	282	(155)	(55%)
Interest expense	12	179	167	93%
Other income (expense), net	(196)	168	(364)	(217%)

Revenue

Revenue for both periods relates to recognition of a portion of the $25.0 million non-refundable license fee we received from Purdue Pharma in connection with our entry into the Collaboration Agreement. We recognized revenue over an estimated 24-month period that commenced in August 2009 as we had continuing participatory obligations under the agreement for the commercialization of Intermezzo. Thus, the year ended December 31, 2010 includes twelve months of license fee revenue as compared to five months for the year ended December 31, 2009.

Research and Development Expense

Research and development expense increased 19% to $10.68 million for the year ended December 31, 2010 from $9.00 million for the comparable period in 2009. The approximately $1.68 million increase is primarily attributable to expenses associated with:

- the Intermezzo development program, including $1.29 million of clinical trial costs for the highway driving study; and
- the TO-2061 development program, including $1.34 million for two 12-week Phase 1 studies and preparations for a Phase 2 clinical trial.

These increases are partially offset by

- $0.95 million of payroll related savings from the reduction in force implemented in the third and fourth quarters of 2009 and other general cost reductions.

General and Administrative Expense

General and administrative expense decreased 31% to $11.04 million for the year ended December 31, 2010 from $16.05 million for the comparable period in 2009. The approximately $5.01 million decrease is attributable to the following:

- professional fees, including third party consulting and legal fees, decreased by $2.35 million and were primarily attributable to transitioning more of these functions in house in 2010;

- marketing related expense declined by $0.88 million as Purdue Pharma assumed these responsibilities in the second half of 2009 in accordance with the Collaboration Agreement;
- personnel costs and related expenses decreased by $0.56 million. A portion of the reduction is attributable to a reduction in headcount between periods. Personnel costs and related expenses for 2009 included severance expenses related to our 2009 reduction in force;
- facilities and related costs decreased by $0.63 million due to subleasing one facility and fully reserving the remaining rental payments on another facility during 2009; and
- other general and administrative expense decreased by $0.59 million.

Merger related transaction costs

Merger related transaction costs consisted primarily of $2.0 million in financial and advisory fees and $0.2 million in legal fees incurred in connection with the close of the Merger in January 2009. There were no comparable costs incurred during the year ended December 31, 2010.

Interest Income

Interest income decreased 55% to $127,000 for the year ended December 31, 2010 from $282,000 for the comparable period in 2009. The decrease of approximately $155,000 for the year ended December 31, 2010 is primarily attributable to reduced balances and changes in the mix of investments toward lower risk, lower yield investments.

Interest Expense

Interest expense decreased 93% to $12,000 for the year ended December 31, 2010 from $179,000 for the comparable period in 2009. The decrease of approximately $167,000 for the year ended December 31, 2010 was primarily attributable to lower average outstanding debt during 2010 as compared to the prior year due to the repayment in full of our debt under a Loan and Security Agreement with Hercules Technology Growth Capital, Inc., or Hercules, during the first quarter of 2009.

Other Income (Expense), Net

Other income (expense), net decreased to expense of $196,000 for the year ended December 31, 2010 from income of $168,000 for the comparable period in 2009. Other expense for the year ended December 31, 2010 consisted primarily of Delaware franchise tax. Other income for the year ended December 31, 2009 consisted of a decline in the fair value of warrants for preferred stock which resulted in recording other income as well as a realized gain on the sale of marketable securities.

Liquidity and Capital Resources

At December 31, 2011, we had cash, cash equivalents and marketable securities of $62.4 million.

Sources of Liquidity

From our inception through the completion of the Merger, we financed our operations primarily through private placements of preferred stock, debt financing and interest income. Through December 31, 2011, we received net proceeds of $71.0 million from the sale of preferred stock, all of which was converted to common stock upon completion of the Merger. In January 2009, through the Merger, we acquired an additional $80.9 million in cash, cash equivalents and marketable securities. 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.

In April 2006, we entered into a $10.0 million venture debt facility agreement with Hercules and drew down $4.0 million in May 2006 and $6.0 million in December 2006, against which interest accrued at rates of 10.69% and 10.94%, respectively. Outstanding principal, accrued interest, and unpaid interest under the loan and security agreement became due and payable on certain change-in-control transactions. In conjunction with the Merger and pursuant to an agreement with Hercules, on February 3, 2009 we repaid in full all amounts outstanding related to this loan.

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

	Year Ended December 31,		
	2011	2010	2009
Net cash (used in) provided by operating activities	$(5,707)	$(19,548)	$ 830
Net cash provided by investing activities	1,266	16,068	14,652
Net cash provided by (used in) financing activities	1,380	169	(2,883)

Net Cash (Used in) Provided by Operating Activities

Net cash used in operating activities for the years ended December 31, 2011 and December 31, 2010 was $5.71 million and $19.55 million, respectively. Net cash provided by operating activities was $0.83 million for the year ended December 31, 2009. Net cash used in operating activities during 2011 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, which included $7.29 million of revenue recognition resulting in a decrease in deferred revenue. Net cash used in operating activities during 2011 was partially offset by a $10 million milestone payment received from Purdue Pharma in accordance with our Collaboration Agreement. Net cash used in operating activities during 2010 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, which included $12.5 million of revenue recognition resulting in a decrease in deferred revenue. Net cash provided by operating activities during 2009 was primarily due to the receipt of the $25.0 million non-refundable license fee we received from Purdue Pharma in connection with our entry into the Collaboration Agreement partially offset by 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 Cash Provided by Investing Activities

Net cash provided by investing activities was $1.27 million, $16.07 million and $14.65 million for the years ended December 31, 2011, 2010, and 2009, respectively. Net cash provided by investing activities during the years ended December 31, 2011 and December 31, 2010 was primarily attributable to maturities of marketable securities, net of purchases. $47.99 million of net cash provided by investing activities during the year ended December 31, 2009 relates to the cash and cash equivalents that came from the Merger. This was partially offset by $33.02 million used in investing activities for the year ended December 31, 2009 due to purchases of marketable securities, net of sales and maturities. Uses of cash in investing activities in all periods included net purchases of property and equipment.

Net Cash Provided by (Used in) Financing Activities

Net cash provided by financing activities during the year ended December 31, 2011 and December 31, 2010 was $1.38 million and $0.17 million, respectively, and consisted of common stock issuances in connection with stock option exercises. Net cash used in financing activities for the year ended December 31, 2009 was $2.88 million and consisted of debt repayment. The outstanding debt with Hercules was fully repaid during the first quarter of 2009.

Capital Resources

We expect our cash, cash equivalents, and marketable securities of $62.4 million at December 31, 2011, 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 timing of the commercial launch of Intermezzo by Purdue Pharma;
- the ability of Purdue Pharma to successfully commercialize 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 rate of progress and cost of our ongoing TO-2061 clinical trial, the need to conduct additional 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 terms and timing of any licensing arrangements that we may establish for Intermezzo outside the United States;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the effect of competing technological and market developments.

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

- further develop Intermezzo to meet the requirements for regulatory approval of Intermezzo outside the United States;
- 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;
- continue to develop TO-2061 through clinical trials and other development activities; and
- develop internally, acquire or in-license new products, technologies or businesses or to otherwise fund our operations.

If our Collaboration Agreement with Purdue Pharma is terminated or other factors arise, we may decide to reduce operating expenses by limiting research and development efforts with respect to TO-2061 or other potential product candidates or otherwise reduce our expenses. Alternatively, we may decide to raise funds through public or private financings, collaboration relationships or other arrangements. There can be no assurance that funding, if needed, will be available on attractive terms, or at all. Furthermore, any additional equity financing may be dilutive to stockholders and debt financing, if available, may involve restrictive covenants. Similarly, financing obtained through future collaborations may require us to forego certain commercialization and other rights to our drug candidates. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to successfully pursue our business strategy.

Potential Impact of Global Market and Economic Conditions on Our Liquidity

In the United States and around the world, recent market and economic conditions have been unprecedented and challenging with tighter credit conditions and slower growth through 2011. During 2009, 2010 and into 2011, continued concerns about the systemic impact of the availability and cost of credit, energy costs, geopolitical issues, the U.S. mortgage market, a declining real estate market in the U.S. and added concerns fueled by the federal government interventions in the U.S. financial and credit markets have contributed to instability in both U.S. and international capital and credit markets and diminished expectations for the U.S. and global economy. These conditions, combined with volatile oil prices, declining business and consumer confidence and increased unemployment have contributed to volatility of unprecedented levels and an economic slowdown.

As a result of these market conditions, the cost and availability of capital and credit has been and may continue to be adversely affected by illiquid credit markets and wider credit spreads. If volatile and adverse market conditions continue, they may limit our ability to timely borrow or access the capital and credit markets to meet liquidity needs, resulting in an adverse effect on our financial condition and results of operations. In addition, the biopharmaceutical industry has fluctuated significantly in the past and has experienced significant downturns in connection with, or in anticipation of, deterioration in general economic conditions, and we cannot accurately predict the severity or duration of any downturn.

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, 2011 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, 2011 include future minimum lease payments under operating leases, as shown in the following table:

Total Contractual Obligations
(in thousands)

		Payments due by period			
Contractual Obligations	Total	Less than one year	1 to 3 years	3 to 5 years	More than 5 years
Operating leases(1)	$1,017	$ 886	$131	$—	$ —
Loan payable(2)	81	57	24	—	—
Total contractual obligations	$1,098	$ 943	$155	$—	$ —

(1) Includes obligations under an operating lease for current corporate facilities of Transcept, as well as obligations under an operating lease for the former Novacea corporate facilities. 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.

In June 2007, Novacea entered into an operating lease for its corporate facilities, located in South San Francisco, California. The Novacea lease for the corporate facilities is non-cancelable and has a five year term. The lease provides for periodic rent increases based upon previously negotiated or consumer price indexed adjustments. On March 25, 2009, we entered into a sublease agreement dated as of March 24, 2009 for 18,368 square feet of the 25,288 square feet located at our South San Francisco facilities. The term of the sublease commenced on June 1, 2009 and ends on October 31, 2012. On June 16, 2009, we entered into a sublease agreement dated for reference purposes as of June 11, 2009 for the remaining 6,920 square feet of the South San Francisco facility. The term of the sublease commenced on July 1, 2009 and ends on October 31, 2012. The above obligations do not include partially offsetting remaining sublease income of approximately $0.4 million.

(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, 2011, the Company adopted the Accounting Standards Update, ("ASU") No. 2009-13 *Multiple-Deliverable Revenue Arrangements* ("ASU No. 2009-13") on a prospective basis. ASU No. 2009-13 applies to multiple-deliverable revenue arrangements that are currently within the scope of the Accounting Standards Codification, or ASC, Topic 605-25. ASU No. 2009-13 provides principles and application guidance on whether multiple deliverables exist and how the arrangement should be separated and the consideration allocated. ASU No. 2009-13 requires an entity to allocate revenue in an arrangement using estimated selling prices of deliverables, if a vendor does not have vendor-specific objective evidence or third party evidence of selling price. The update eliminates the use of the residual method and requires an entity to allocate revenue using the relative selling price method and also significantly expands the disclosure requirements for multiple-deliverable revenue arrangements. The adoption of ASU No. 2009-13 did not have a material impact on the Company's results of operations and financial condition. However, the adoption may result in different accounting treatment for future collaboration arrangements than the accounting treatment applied to previous and existing collaboration arrangements.

In January 2010, the Financial Accounting Standards Board, or FASB, issued additional disclosure requirements for fair value measurements. The guidance requires previous fair value hierarchy disclosures to be further disaggregated by class of assets and liabilities. A class is often a subset of assets or liabilities within a line item in the statement of financial position. In addition, significant transfers between Levels 1 and 2 of the fair value hierarchy are required to be disclosed. These additional requirements became effective January 1, 2010 for quarterly and annual reporting. These amendments did not have an impact on the Company's consolidated financial results as this guidance relates only to additional disclosures. See Note 5, "Fair Value" for further information. In addition, the fair value disclosure amendments also require more detailed disclosures of the changes in Level 3 instruments. These changes were effective January 1, 2011 and did not have an impact on the Company's consolidated financial results as this guidance only relates to additional disclosures.

Effective January 1, 2011, the Company adopted ASU No. 2010-17, *Milestone Method of Revenue Recognition* on a prospective basis. Under the milestone method, contingent consideration received from the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity's performance or on the occurrence of a specific outcome resulting from the entity's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to the entity. A milestone does not include events for which the occurrence is contingent solely on the passage of time or solely on a collaboration partner's performance. A milestone is substantive if the consideration earned from the achievement of the milestone is consistent with our performance required to achieve the milestone or the increase in value to the collaboration resulting from our performance, relates solely to our past performance, and is reasonable relative to all of the other deliverables and payments within the arrangement. The adoption of ASU No. 2010-17 did not have a material impact on the Company's consolidated results of operations and 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, 2011, 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 (formerly Statement of Financial Accounting Standards, or 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, 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, 2011, 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, and fiduciary control of cash and investments. We also seek to achieve income from investments consistent with our investment policy. 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, commercial paper, corporate bonds and 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. Our policy also limits investments to U.S. Treasury debt or Securities and Exchange Commission, or SEC, registered money market funds. A hypothetical 100 basis point increase in interest rates would result in an approximate $305,000 decrease in the fair value of our marketable securities at December 31, 2011.

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, 2011 and 2010 and the related consolidated statements of operations, convertible preferred stock and stockholders' equity (net capital deficiency), and cash flows for each of the three years in the period ended December 31, 2011. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Transcept Pharmaceuticals, Inc. at December 31, 2011 and 2010, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Redwood City, California
March 30, 2012

Transcept Pharmaceuticals, Inc.

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

	December 31, 2011	December 31, 2010
Assets		
Current assets:		
Cash and cash equivalents	$ 10,659	$ 13,720
Marketable securities	51,703	54,251
Prepaid and other current assets	3,275	1,252
Restricted cash	200	200
Total current assets	65,837	69,423
Property and equipment, net	314	614
Goodwill	2,962	2,962
Other assets	38	808
Total assets	$ 69,151	$ 73,807
Liabilities, convertible preferred stock and stockholders' equity		
Current liabilities:		
Accounts payable	$ 987	$ 598
Accrued liabilities	2,108	1,393
Deferred revenue	—	7,292
Other liabilities, short-term portion	244	365
Total current liabilities	3,339	9,648
Other liabilities, long-term portion	60	348
Total liabilities	3,399	9,996
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; 13,904,515 and 13,449,755 shares issued and outstanding at December 31, 2011 and 2010, respectively	14	13
Additional paid-in capital	165,803	160,010
Accumulated deficit	(100,094)	(96,214)
Accumulated other comprehensive income	29	2
Total stockholders' equity	65,752	63,811
Total liabilities and stockholders' equity	$ 69,151	$ 73,807

See accompanying notes.

Transcept Pharmaceuticals, Inc.

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

	Year Ended December 31,		
	2011	2010	2009
Revenue:			
License fee revenue	$ 7,292	$12,500	$ 5,208
Milestone revenue	10,000	—	—
Other revenue	2,402	—	—
Total revenue	19,694	12,500	5,208
Operating expenses:			
Research and development	11,273	10,684	9,005
General and administrative	12,185	11,038	16,050
Merger related transaction costs	—	—	2,224
Total operating expenses	23,458	21,722	27,279
Loss from operations	(3,764)	(9,222)	(22,071)
Interest income	79	127	282
Interest expense	(9)	(12)	(179)
Other income (expense), net	(186)	(196)	168
Net loss	$ (3,880)	$ (9,303)	$(21,800)
Basic and diluted net loss per share	$ (0.29)	$ (0.69)	$ (1.79)
Weighted average shares outstanding	13,534	13,416	12,166

See accompanying notes.

Transcept Pharmaceuticals, Inc.

Consolidated Statement of Convertible Preferred Stock and Stockholders' Equity (Net Capital Deficiency)
(in thousands)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity (Net Capital Deficiency)
	Shares	Amount	Shares	Amount				
Balance at December 31, 2008	7,350	$ 71,037	455	$ —	$ 1,504	$ (65,111)	$ 26	$ (63,581)
Exercise of options to purchase common stock	—	—	293	1	384	—	—	385
Employee stock purchase under Employee stock purchase plan	—	—	22	—	85	—	—	85
Stock-based compensation related to:								
Employee stock option grants	—	—	—	—	1,057	—	—	1,057
Non-employee stock option grants	—	—	—	—	121	—	—	121
Employee stock purchase plan	—	—	—	—	62	—	—	62
Stock option modifications	—	—	—	—	127	—	—	127
Vested restricted stock	—	—	33	—	47	—	—	47
Conversion of preferred shares to common stock	(7,350)	(71,037)	7,350	7	71,030	—	—	71,037
Reclassification of warrant liability	—	—	—	—	400	—	—	400
Effect of the Merger (Note 2)	—	—	5,231	5	83,113	—	—	83,118
Net loss	—	—	—	—	—	(21,800)	—	(21,800)
Unrealized gain on marketable securities	—	—	—	—	—	—	13	13
Total comprehensive loss								(21,787)
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 purchases 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 loss 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 gain 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

See accompanying notes.

Transcept Pharmaceuticals, Inc.

Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2011	2010	2009
Operating activities			
Net loss	$ (3,880)	$ (9,303)	$ (21,800)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Depreciation and amortization	357	500	550
Stock-based compensation	4,405	1,879	1,367
Amortization of loan costs	—	—	28
Amortization of debt discount	—	—	47
Amortization of lease liability	(316)	(430)	(281)
Remeasurement of preferred stock warrants	—	—	(200)
Loss on disposals of fixed assets	2	2	157
Gain on sale of marketable securities	—	—	(111)
Amortization of premium on available for sale securities	1,250	1,451	1,395
Changes in operating assets and liabilities:			
Prepaid and other current assets	(2,023)	24	455
Other assets	770	18	(18)
Accounts payable	389	(130)	154
Accrued and other liabilities	631	(1,059)	(705)
Deferred revenue	(7,292)	(12,500)	19,792
Net cash (used in) provided by operating activities	(5,707)	(19,548)	830
Investing activities			
Purchases of property and equipment, net	(59)	(65)	(318)
Purchases of marketable securities	(52,175)	(106,618)	(128,324)
Maturities and sales of marketable securities	53,500	122,751	95,307
Cash and cash equivalents received from the Merger	—	—	47,987
Net cash provided by investing activities	1,266	16,068	14,652
Financing activities			
Payments on long-term debt	—	—	(3,353)
Proceeds from issuance of common stock, net	1,380	169	470
Net cash provided by (used in) financing activities	1,380	169	(2,883)
Net (decrease) increase in cash and cash equivalents	(3,061)	(3,311)	12,599
Cash and cash equivalents at beginning of period	13,720	17,031	4,432
Cash and cash equivalents at end of period	$ 10,659	$ 13,720	$ 17,031
Supplemental disclosure of cash flow information			
Cash paid during the year for interest	$ 9	$ 13	$ 136

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. Transcept is currently conducting a Phase 2 study of an investigational product, TO-2061, in patients with obsessive-compulsive disorder. 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. After the Merger, former TPI stockholders, option holders and warrant holders as of January 30, 2009 owned approximately 61% of Transcept common stock on a fully-diluted basis. After the Merger, the stockholders, option holders and warrant holders of Novacea prior to the Merger owned approximately 39% of the Transcept common stock on a fully-diluted basis. Under generally accepted accounting principles in the United States, the Merger was treated as a "reverse merger" under the purchase method of accounting. For accounting purposes, TPI was considered to have acquired Novacea. These financial statements reflect the historical results of TPI prior to the Merger and that of the combined company following the Merger, and do not include the historical results of Novacea prior to the completion of the Merger. All share and per share disclosures have been retroactively adjusted to reflect the exchange of shares in the Merger, and the 1-for-5 reverse stock split of the common stock on January 30, 2009.

Need to Raise Additional Capital

As of December 31, 2011, the Company had cash, cash equivalents and marketable securities of $62.4 million, working capital of $62.5 million, and an accumulated deficit of approximately $100.1 million. Management expects to continue to incur additional losses in the foreseeable future as the Company continues its research and development activities. Management believes that cash, cash equivalents and marketable securities balances on hand at December 31, 2011 will be sufficient to fund planned expenditures for at least the next twelve months. The Company may need substantial additional capital in the future to pursue the commercialization of Intermezzo, develop TO-2061, seek regulatory approval for Intermezzo in other countries and seek additional products and product candidates through business development efforts. Until the Company can generate a sufficient amount of product revenue, if ever, it expects to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. There can be no assurance that the Company will be successful in consummating any such financing transaction, or if the Company does consummate such a transaction, that the terms and conditions of such transaction will be favorable. Furthermore, any additional equity financing may be dilutive to stockholders and debt financing, if available, may involve restrictive covenants and warrants that are also dilutive. Similarly, financing obtained through future collaborations may require the Company to forego certain commercialization and other rights to its drug candidates. The Company's failure to raise capital as and when needed could have a negative impact on its financial condition and its ability to successfully pursue its business strategy.

Transcept Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (continued)

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, stock-based compensation, restructuring, and warrant liability valuation.

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 the 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 income and reported as a separate component of stockholders' equity (net capital deficiency). 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, ranging from two to five years. Leasehold improvements are amortized over the shorter of their estimated useful lives or the related lease term.

Transcept Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (continued)

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, 2011, there have been no such impairments.

Goodwill

Goodwill represents purchase consideration in excess of fair values assigned to the underlying net assets of acquired businesses. Goodwill is not amortized, but tested for impairment annually at September 30th, and at any time when events suggest impairment may have occurred. The Company's goodwill impairment test is performed by comparing the fair value of the reporting unit to the carrying value of the reporting unit. The Company has one reporting unit to which the goodwill is assigned and tested for impairment. In the event the carrying value of a reporting unit exceeds its fair value, an impairment loss would be recognized to the extent the carrying amount of the reporting unit's goodwill exceeds its implied fair value. Goodwill as of December 31, 2011 was approximately $3.0 million, and was recorded in connection with the Company's Merger with Novacea. Through December 31, 2011, there have been no impairments.

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;

Transcept Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (continued)

- 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 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.

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.

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, 2011, 2010, and 2009, the Company recognized employee stock-based compensation costs of $4,050,000, $1,848,000, and $1,246,000, 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*

Transcept Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (continued)

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.

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 (net capital deficiency).

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 other income (expense), net in the statements of operations.

The Company recorded $200,000 in other income (expense), net relating to changes in fair value of all preferred stock warrants during the year ended December 31, 2009. The Company continued to record adjustments to the fair value of the warrants until the closing of the Merger transaction on January 30, 2009, when they converted into warrants to purchase shares of common stock, at which point the warrants were no longer subject to ASC Topic 480. As of January 30, 2009, $400,000, the then-current aggregate fair value of these warrants, was reclassified from a liability to additional paid-in capital, a component of stockholders' equity (net capital deficiency). 94,556 of the outstanding warrants will, if not exercised, expire during 2012. The remaining 61,451 warrants 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. This policy also limits investments to U.S. Treasury debt or SEC registered money market funds. The goals of the investment policy are as follows: preservation of capital, fulfillment of liquidity needs, 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.

Recently Adopted Accounting Standards

Effective January 1, 2011, the Company adopted the Accounting Standards Update, ("ASU") No. 2009-13 *Multiple-Deliverable Revenue Arrangements* ("ASU No. 2009-13") on a prospective basis. ASU No. 2009-13 applies to multiple-deliverable revenue arrangements that are currently within the scope of ASC Topic 605-25. ASU No. 2009-13 provides principles and application guidance on whether multiple deliverables exist and how the arrangement should be separated and the consideration allocated. ASU No. 2009-13 requires an entity to allocate revenue in an arrangement using estimated selling prices of deliverables, if a vendor does not have vendor-specific objective evidence or third party evidence of selling price. The update eliminates the use of the residual method and requires an entity to allocate revenue using the relative selling price method and also significantly expands the disclosure requirements for multiple-deliverable revenue arrangements. The adoption of ASU No. 2009-13 did not have a material impact on the Company's results of operations and financial condition. However, the adoption may result in different accounting treatment for future collaboration arrangements than the accounting treatment applied to previous and existing collaboration arrangements.

In January 2010, the FASB issued additional disclosure requirements for fair value measurements. The guidance requires previous fair value hierarchy disclosures to be further disaggregated by class of assets and liabilities. A class is often a subset of assets or liabilities within a line item in the statement of financial position. In addition, significant transfers between Levels 1 and 2 of the fair value hierarchy are required to be disclosed. These additional requirements became effective January 1, 2010 for quarterly and annual reporting. These amendments did not have an impact on the Company's consolidated financial results as this guidance relates only to additional disclosures. See Note 5, "Fair Value" for further information. In addition, the fair value disclosure amendments also require more detailed disclosures of the changes in Level 3 instruments. These changes were effective January 1, 2011 and did not have an impact on the Company's consolidated financial results as this guidance only relates to additional disclosures.

Effective January 1, 2011, the Company adopted ASU No. 2010-17, *Milestone Method of Revenue Recognition* on a prospective basis. Under the milestone method, contingent consideration received from the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity's performance or on the occurrence of a specific outcome resulting from the entity's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to the entity. A milestone does not include events for which the occurrence is contingent solely on the passage of time or solely on a collaboration partner's performance. A milestone is substantive if the consideration earned from the achievement of the milestone is consistent with the Company's performance required to achieve the milestone or the increase in value to the collaboration resulting from the Company's performance, relates solely to the Company's past performance, and is reasonable relative to all of the other deliverables and payments within the arrangement. The adoption of ASU No. 2010-17 did not have a material impact on the Company's consolidated results of operations and financial condition.

Transcept Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (continued)

Recent Accounting Pronouncements

In June 2011, the FASB issued ASU No. 2011-05, "*Presentation of Comprehensive Income*" which 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 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. This pronouncement is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. Early adoption of the new guidance is permitted and full retrospective application is required. The Company does not expect that the adoption of this ASU will have any material impact on its results of operations or financial position.

In May 2011, the FASB issued ASU No. 2011-04, "*Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and International Financial Reporting Standards ("IFRS").*" 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. This pronouncement is effective for reporting periods beginning on or after December 15, 2011, with early adoption prohibited. The new guidance will require prospective application. The Company is currently evaluating the impact, if any, that the adoption of this pronouncement may have on its results of operations or financial position.

2. Merger Agreement

As described in Note 1, the Company completed the Merger on January 30, 2009. Pursuant to the Merger, stockholders of TPI exchanged their shares of TPI stock for a total of 7,882,622 shares of Transcept common stock and a total of 156,007 warrants to purchase Transcept common stock. Immediately following the Merger, approximately 61% of the fully-diluted shares of Transcept common stock were owned by former stockholders of TPI. For accounting purposes, TPI was deemed to be the acquiring company, and the Merger was accounted for as a reverse acquisition.

The purchase consideration was approximately $83.1 million. The purchase consideration was determined based on the fair value of the net assets exchanged.

Transcept and Novacea completed the Merger principally to utilize the cash resources held by Novacea to continue the development of the late-stage product candidate held by TPI.

Transcept Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (continued)

Allocation of total purchase consideration:

Under the purchase method of accounting, the total purchase consideration was allocated to the net tangible and identifiable intangible assets acquired and liabilities assumed based on their fair values as of January 30, 2009. The excess of the purchase price over the fair value of assets acquired and liabilities assumed was allocated to goodwill. The allocation of the purchase price was as follows (in thousands):

	Allocation of Purchase Price
Cash, cash equivalents and marketable securities	$ 80,861
Other assets	3,794
Goodwill	2,962
Existing assumed liabilities	(1,466)
Assumed lease liability	(856)
Assumed severance, retention and other merger related obligations	(2,177)
Total	$ 83,118

Goodwill is derived from the value obtained from the additional resources of the combined company. None of the goodwill will be deductible for tax purposes as the Merger was structured as a stock purchase transaction.

Assumed severance, retention and other merger related obligations:

Upon completion of the Merger on January 30, 2009, the Company became liable to pay approximately $2.2 million in payments due to Novacea employees upon a change in control, all of which had been paid as of December 31, 2009. None of these payments required on-going services of the employees subsequent to the change in control.

Pro forma information:

The following unaudited pro forma information presents a summary of the Company's consolidated results of operations as if the Merger had taken place as of January 1, 2009 (in thousands, except per share information):

	Year Ended December 31, 2009
Revenue (1)	$ 5,208
Net income (loss)	$ (22,572)
Basic and diluted pro forma net income (loss) per share:	$ (1.71)
Basic and diluted shares used in computing net income (loss) per share:	13,162

(1) Revenue related to the Collaboration Agreement between the Company and Purdue Pharma (see Note 12).

The unaudited pro forma results of operations are not necessarily indicative of what would have occurred had the Merger been completed at the beginning of the respective periods or of the results that may occur in the future.

Transcept Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (continued)

3. 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):

	2011	2010	2009
Numerator:			
Net loss	$ (3,880)	$ (9,303)	$(21,800)
Denominator:			
Weighted average common shares outstanding	13,535	13,430	12,205
Less: Weighted average common shares subject to repurchase	(1)	(14)	(39)
Denominator for basic and diluted net loss per share	13,534	13,416	12,166
Basic and diluted net loss per share	$ (0.29)	$ (0.69)	$ (1.79)

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,		
	2011	2010	2009
Excluded potentially dilutive securities (1):			
Shares subject to options to purchase common stock	2,877	2,345	1,718
Shares subject to warrants to purchase common stock	156	156	156
Common stock subject to repurchase	—	5	22
Total	3,033	2,506	1,896

(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.

Transcept Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (continued)

4. Cash, Cash Equivalents and Marketable Securities

The following is a summary of the fair value of cash, cash equivalents, restricted cash and available-for-sale securities (in thousands):

	December 31, 2011			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Cash	$ 1,421	$ —	$ —	$ 1,421
Certificates of deposit	200	—	—	200
Money market funds	9,238	—	—	9,238
U.S. Treasury securities	51,674	29	—	51,703
	$62,533	$ 29	$ —	$62,562

	December 31, 2010			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Cash	$ 582	$ —	$ —	$ 582
Certificates of deposit	200	—	—	200
Money market funds	13,138	—	—	13,138
U.S. Treasury securities	54,249	2	—	54,251
	$68,169	$ 2	$ —	$68,171

There were no sales of available-for-sale marketable securities during 2011 or 2010. The amortized cost and estimated fair value of cash, cash equivalents, restricted cash and available-for-sale marketable securities at December 31, 2011 and 2010 were as follows (in thousands):

	2011		2010	
	Cost	Fair value	Cost	Fair value
Cash equivalents	$10,659	$10,659	$13,720	$13,720
Marketable securities	51,674	51,703	54,249	54,251
Restricted cash	200	200	200	200
	$62,533	$62,562	$68,169	$68,171

Based on the fair value of the Company's marketable securities at December 31, 2011, $9,876,000 had a maturity of between one and two years, and the remaining $41,827,000 had maturities of one year or less.

Transcept Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (continued)

5. 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, 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	$ —

Transcept Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (continued)

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, 2010 (in thousands):

		Fair Value Measurements at Reporting Date Using		
	December 31, 2010	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	13,138	13,138	—	—
U.S. Treasury securities	54,251	—	54,251	—
	$ 67,589	$ 13,338	$ 54,251	$ —

During the years ended December 31, 2011 and 2010, 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, 2011.

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.

6. Prepaid and other current assets

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

	December 31,	
	2011	2010
Receivable from Purdue Pharma	$1,552	$ —
Prepaid expenses	610	959
Interest receivable	288	237
Other current assets	825	56
	$3,275	$1,252

The receivable from Purdue Pharma consists of reimbursement of certain Intermezzo manufacturing-related costs. These purchases and reimbursements were recorded as Other Revenue during the fourth quarter of 2011. Payment was received in full in January 2012.

Transcept Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (continued)

7. Property and Equipment, Net

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

	December 31,	
	2011	2010
Computer equipment and software	$ 593	$ 648
Furniture and fixtures	569	569
Research equipment	797	794
Leasehold improvements	624	624
Construction in progress	—	2
	2,583	2,637
Less accumulated depreciation and amortization	(2,269)	(2,023)
Property and equipment, net	$ 314	$ 614

The Company recorded depreciation and amortization expense of $357,000, $500,000 and $550,000 for the years ended December 31, 2011, 2010 and 2009, respectively.

8. Loans and Security Agreement

In February 2006, the Company entered into a Loan and Security Agreement (the "Agreement") with Hercules Technology Growth Capital ("Hercules"). Under the terms of the Agreement, the Company was initially entitled to draw up to $4.0 million. This amount was raised to $10.0 million upon reaching certain development milestones, which were achieved in October 2006. Interest under the loan was fixed at prime plus 2.69% at the date of the initial draw. The Company drew down an advance of $4.0 million on May 31, 2006, and drew down the remaining available advance of $6.0 million on December 28, 2006, against which interest accrued at rates of 10.69% and 10.94%, respectively. The draw required interest only repayment for the period from initial borrowing to December 31, 2006. Principal and interest repayment commenced in January 2007, to be continued for 33 months. Under the terms of the Agreement, the Loan was secured by a perfected first priority security interest in all of the Company's tangible and intangible assets owned or subsequently acquired, except for intellectual property. On February 3, 2009, the Company repaid the remaining outstanding principal and interest under this loan, in the amount of $2,763,000, which included a 2% prepayment charge. The prepayment charge of $54,000 was included in interest expense during the first quarter of 2009.

In connection with the Agreement, the Company was required to pay approximately $123,000 in facility and other fees. These fees were capitalized in other assets and were being amortized to interest expense over the term of the loan. In conjunction with the full repayment of the loan in February 2009, as noted above, the remaining facility and other fees of $28,000 were amortized to interest expense during the first quarter of 2009. Amortization expense was $28,000 for the year ended December 31, 2009.

In addition, in connection with the Agreement in May and December 2006, the Company issued warrants to purchase 61,451 shares of Series C convertible preferred stock at an exercise price of $8.136 per share with an expiration date in April 2016. These warrants were valued using the Black-Scholes valuation model, and the resulting estimated fair value of the warrants at the date of issuance was $440,000, which was recorded as a debt discount to the credit facility in 2006. The discount was amortized to interest expense over the repayment period. In conjunction with the full repayment of the loan in February 2009, as noted above, the remaining debt discount of $47,000 was charged to interest expense during the first quarter of 2009. Interest expense relating to the Agreement was $179,000 for the year ended December 31, 2009, of which $47,000 related to amortization of the debt discount.

Transcept Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (continued)

The Agreement did not have financial covenants. See Note 11 for discussion of the assumptions and methodology used to estimate the fair value of the warrant.

9. 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 $60,000 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 12, the Company vacated this property in August 2009 and recorded a charge to rent expense of $309,000 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.

In June 2007, Novacea entered into an operating lease for 25,288 square feet for corporate facilities located in South San Francisco, California. The lease for the facilities is non-cancelable and has a five-year term with a total obligation of $3.6 million. The lease provides for periodic rent increases based upon previously negotiated or consumer price indexed adjustments, or in the case of an extension, market adjusted rates. As of December 31, 2011, the Company maintained a Certificate of Deposit acting as a security deposit of $770,000 required under conditions of the lease, which was recorded as a current asset on the Company's balance sheet. On March 25, 2009, the Company entered into a sublease agreement dated as of March 24, 2009 for 18,368 square feet of the 25,288 square feet located in South San Francisco. The term of the sublease commenced on June 1, 2009 and ends on October 31, 2012. Total base rent payable by the sublessee through the end of the term of the sublease was approximately $1.1 million. In connection with this sublease, on April 6, 2009 the Company received an irrevocable standby letter of credit in the amount of $100,000, expiring May 31, 2012, as a security deposit. On June 16, 2009, the Company entered into a sublease agreement dated for reference purposes as of June 11, 2009 for the remaining 6,920 square feet of the South San Francisco facility. The term of the sublease commenced on July 1, 2009 and ends on October 31, 2012. Total base rent payable by the sublessee through the end of the term of the sublease was approximately $0.4 million.

Future minimum payments under these leases as of December 31, 2011 are as follows (in thousands):

Year ending December 31,	
2012	$ 886
2013	131
2014	—
2015	—
2016	—
Thereafter	—
Total	$1,017

Transcept Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (continued)

In addition, as noted above, the Company has subleased certain of these facilities under operating leases to third parties. The future minimum sublease payments due from lessees under those arrangements are $422,000 in 2012.

Rent expense, net of sublease income as applicable, for the years ended December 31, 2011, 2010 and 2009 was $302,000, $350,000 and $986,000, respectively. Sublease income for the years ended December 31, 2011, 2010 and 2009 was $493,000, $433,000 and $123,000, 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, 2011.

Legal Proceedings

From time to time, the Company may be involved in litigation relating to claims arising out of its operations. The Company is not currently involved in any material legal proceedings.

10. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2011	2010
Accrued payroll and related	$ 825	$ 9
Accrued vacation pay	144	159
Accrued professional fees	372	391
Accrued franchise taxes—Delaware	36	36
Accrued clinical trials	611	365
Other accrued liabilities	120	433
	$2,108	$1,393

11. Warrant liability

In conjunction with the sale of the 2005 subordinated convertible promissory notes, the Company issued warrants for the purchase of 94,554 shares of Series C convertible preferred stock at $8.136 per share in October 2005. These warrants have a contractual life of seven years. The fair value of these warrants was determined to be $535,000 at the date of issuance using the Black-Scholes Merton option valuation model with the following assumptions: a risk-free interest rate of 4.40%; no dividend yield; expected volatility of 70%; and an expected life of seven years.

In addition, the Company issued warrants to purchase 24,581 and 36,872 shares of Series C convertible preferred stock at an exercise price of $8.136 per share in May and December 2006, respectively. The aggregate fair value of these warrants was determined to be $440,000 at the dates of issuance using the Black-Scholes Merton option valuation model with the following assumptions: risk-free interest rates from 4.7% – 5.1%; no dividend yield; expected volatilities from 61%—62%; and remaining contractual lives of 9.3 – 9.9 years.

Transcept Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements (continued)

Pursuant to ASC Topic 480, all preferred stock warrants were recorded as liabilities at the time of issuance and remeasured to current fair value at each reporting date.

In conjunction with the closing of the Merger on January 30, 2009, all outstanding warrants converted into warrants to purchase shares of common stock, at which point the warrants were no longer subject to ASC Topic 480. As of January 30, 2009, $400,000, the then-current aggregate fair value of these warrants, was reclassified from a liability to additional paid-in capital, a component of stockholders' equity (net capital deficiency).

At January 30, 2009, the fair value of all outstanding Series C convertible preferred stock warrants was remeasured based on the then-current reassessed fair value of the Company's convertible preferred stock and the assumptions in the following table:

	Period Ended January 30, 2009
Risk-free interest rate	1.32 - 2.27%
Remaining contractual terms	3.8 -7.2 years
Volatility	79 - 92%

The net change in fair value of $200,000 was included in other income (expense), net for the year ended December 31, 2009. All 156,007 of these common stock warrants remain outstanding at December 31, 2011. If not exercised, 94,556 of the common stock warrants expire during 2012, and the remaining 61,451 expire in 2016 (see Note 8).

12. 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;
- The Company has 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 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;
- 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 and an additional $10.0 million upon meeting a second intellectual property milestone.

The Company has retained an option to co-promote Intermezzo to psychiatrists in the United States. This option allows it to begin co-promoting Intermezzo as early as 12 months after the commercial launch of Intermezzo and as late as 55 months after such launch. The option can be exercised as late as 40 months after

such commercial launch. 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 revenue that is generated by psychiatrist prescriptions. This additional co-promote royalty ranges from 40%, if it begins marketing to psychiatrists in the first month following the one year anniversary of commercial launch of Intermezzo in the United States, down to approximately 22%, if it does not begin marketing to psychiatrists until 55 months after the commercial launch of Intermezzo. Net revenue qualifying for this additional co-promote royalty is limited by an annual cap of 15% of total Intermezzo annual net sales in the United States. The co-promotion 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 recorded as revenue the $10 million milestone payment received in December 2011. The patent-related milestone was substantive and at-risk given 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. The Company has no additional performance obligations under the Collaboration Agreement related to this milestone.

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. During the fourth quarter of 2011, the Company recorded revenue of $750,000 in Other Revenue 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, 2010 and 2009 was $7.3 million, $12.5 million and $5.2 million, respectively.

13. Restructuring

On July 15, 2011, the Company implemented a reduction of approximately 45% of the Company's workforce. Affected employees were notified on July 15, 2011. The reduction plan carried out a realignment of the Company's workforce and operations after receipt of the July 14, 2011 Intermezzo® Complete Response

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Notes to Consolidated Financial Statements (continued)

Letter from the FDA. Employees subject to the workforce reduction plan were eligible for one-time severance benefits that include severance and benefits continuation expenses of approximately $1.0 million in total. The Company substantially completed the reduction plan and paid out severance benefits during the third quarter of 2011. Further, the affected employees received one year accelerated vesting on outstanding options upon signing a separation and release agreement with the Company, and the affected employees were given the choice to extend the exercise period of their options to one year following termination. Total expense related to the modification of these stock option awards was approximately $197,000.

The Company records restructuring activities in accordance with ASC topic 420 *Exit or Disposal Cost Obligations*. The following table summarizes the charges recorded during the year ended December 31, 2011 related to the restructuring plan by type of activity (no such charges were recorded in the comparable prior year periods) (in thousands).

Year ended December 31, 2011	Severance benefits	Stock option modification	Total
Research and development	$ 535	$ 47	$ 582
General and administrative	504	150	654
	$ 1,039	$ 197	$1,236

14. Convertible Preferred Stock

In connection with the Company's merger with Novacea on January 30, 2009, all shares of convertible preferred stock were converted to common stock.

15. 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.

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, 2011, there were no shares available for future grant under either the 2001 or the 2002 Plans.

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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 cancelled 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 and 258,344 of the Company's common stock becoming available for issuance on January 1, 2010 and 2009, respectively 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 695,226 and 672,488 of the Company's common stock becoming available for issuance on 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, 2011, stock options to purchase 1,782,416 shares of common stock were vested and exercisable and 531,468 shares remain available for future grant under the Amended and Restated 2006 Plan.

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Notes to Consolidated Financial Statements (continued)

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, 2008	93,068	1,065,920	$ 2.080
Options authorized	258,344	—	
Options granted	(553,016)	553,016	$ 4.009
Options exercised	—	(292,760)	$ 1.313
Options forfeited	125,571	(125,571)	$ 9.613
2002 Plan shares expired	(150,576)	—	
Acquired in the Merger	564,090	517,653	$19.627
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

The total intrinsic value of options exercised during the years ended December 31, 2011, 2010 and 2009 was $2,280,000, $159,000 and $2,420,000, respectively. The amount of cash received from exercise of stock options during the years ended December 31, 2011, 2010 and 2009 was $1,334,000, $38,000 and $385,000, respectively.

Additional information related to the status of options at December 31, 2011 is as follows:

	Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding	2,876,510	$ 6.157	7.06	$7,649,318
Vested and exercisable	1,782,416	$ 6.232	5.95	$5,441,452

The intrinsic value of options is the fair value of the Company's stock at December 31, 2011 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

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Notes to Consolidated Financial Statements (continued)

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, 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, 2011:

	Options Outstanding		
Range of Exercise Prices	Number Outstanding	Number Exercisable	Weighted-Average Remaining Contractual Life (Years)
$0.8844	120,676	120,676	3.66
$1.7688 - $2.1225	319,557	319,557	4.91
$2.6800	666,750	303,625	9.65
$2.9600 - $4.1400	307,996	227,144	6.45
$4.5000 - $8.0700	120,843	107,470	6.46
$8.2000	524,962	148,081	8.29
$8.2100	598,462	347,353	6.98
$8.5500 - $32.5000	217,264	208,510	2.67
	2,876,510	1,782,416	7.06

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 $3,677,000, $1,759,000 and $1,057,000 during 2011, 2010 and 2009, respectively.

On January 14, 2010, the Company granted 225,500 options in the aggregate to select employees and one consultant that vest 50% upon approval by the U.S. Food and Drug Administration ("FDA") of Intermezzo and the remaining 50% vest on the first anniversary of any such approval; provided in each case, such approval occurs no later than January 14, 2012. The fair value of these options at grant date was $5.79 per share or approximately $1,306,000. On August 24, 2011, the Company granted 803,750 options in the aggregate to employees and one consultant that vest 50% upon approval by the U.S. Food and Drug Administration ("FDA") of Intermezzo and the remaining 50% vest on the first anniversary of any such approval; provided in each case, such approval occurs 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 recording 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 these performance-based options recognized during 2011 was $1,899,000, which is included in the above total employee-related stock option compensation.

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Notes to Consolidated Financial Statements (continued)

The following table shows the range of assumptions used to compute the employee stock-based compensation costs for the stock options granted during the years ended December 31, 2011, 2010 and 2009 using the Black-Scholes option pricing model:

	Year Ended December 31,		
	2011	2010	2009
Risk-free interest rate	1.16 - 2.95%	2.73 - 2.95%	1.79 - 2.90%
Expected life of the options	5.27 - 6.08 years	6.00 - 6.08 years	5.27 - 6.08 years
Dividend yield	None	None	None
Volatility	80.99 - 95.70%	81.18 - 95.92%	82.82 - 90.25%

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, 2011, 2010 and 2009 was $3.718, $5.798 and $2.894 per share, respectively. As of December 31, 2011, there is approximately $3,840,000 of total unrecognized compensation cost related to the unvested share-based compensation arrangements granted under the Company's equity incentive plan. The remaining unrecognized compensation cost, will be recognized over a weighted-average period of 1.81 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 $355,000, including $231,000 related to performance based options as described below, for the year ended December 31, 2011 and $31,000 and $121,000 for the years ended December 31, 2010 and 2009, respectively.

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, 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

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Notes to Consolidated Financial Statements (continued)

remaining 50% vest on November 23, 2012. During 2009, the Company granted 30,000 options to purchase shares of common stock to one non-employee that vest over four years, with an exercise price of $2.96 per share. Total expense related to the performance-based options recognized during 2011 was $231,000 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, 2011, 2010, and 2009 using the Black-Scholes option pricing model:

	Year Ended December 31,		
	2011	2010	2009
Risk-free interest rate	1.35 - 3.47%	2.12 - 3.84%	2.28 - 3.85%
Expected life of the options	7.26 - 9.92 years	8.33 - 9.91 years	6.25 - 9.92 years
Dividend yield	None	None	None
Volatility	76.68 - 93.19%	63.11 - 87.77%	80.47 - 88.36%

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 and $127,000 recorded in the years ended December 31, 2010 and 2009, respectively. 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 $197,000 that was recorded during the year ended December 31, 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 $154,000 during the year ended December 31, 2011. The Company accounted for the modifications of stock option awards in accordance with the provisions of ASC Topic 718.

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.

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Notes to Consolidated Financial Statements (continued)

The following table summarized the Company's ESPP activity through December 31, 2011:

	Number of Shares Available for Grant	Number of Shares Granted	Weighted-Average Grant Date Fair Value
Balance at December 31, 2008	—	—	
Authorized	500,000	—	
Purchases	(22,060)	22,060	$ 2.235
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	

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, 2011, 2010 and 2009 using the Black-Scholes option pricing model:

	Year Ended December 31,		
	2011	2010	2009
Risk-free interest rate	0.05 - 0.11%	0.20 - 0.23%	0.15 - 0.24%
Expected life of the options	0.50 years	0.50 years	0.38 - 0.50 years
Dividend yield	None	None	None
Volatility	40.64 - 147.47%	33.68 - 93.20%	75.48 to 122.57%

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 recorded compensation expense for employee stock-based purchase plan awards of approximately $22,000, $75,000 and $62,000 during 2011, 2010 and 2009, respectively.

Reserved Shares

At December 31, 2011, the Company has reserved shares of common stock for future issuance as follows:

	Number of Shares
Employee stock purchase plan	447,686
Stock option plans:	
Subject to outstanding options	2,876,510
Available for future grants	531,468
Warrants	156,007
Total	4,011,671

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16. 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,		
	2011	2010	2009
Computed tax benefit at federal statutory rate	$(1,358)	$(3,255)	$(7,630)
State tax benefit, net of effect on Federal income taxes	(223)	(534)	(1,253)
State tax credits, net of Federal benefit	(121)	(116)	(154)
Federal tax credits	(365)	(313)	(298)
Permanent differences:			
Nondeductible stock option expense	180	324	231
Merger related costs	—	—	1,467
State tax effect from permanent differences	17	56	272
Other	(79)	(66)	(70)
Change in valuation allowance	2,805	3,699	6,188
IRS section 382 NOL limitation	—	—	1,196
Other, net	(856)	205	51
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,	
	2011	2010
Current deferred tax assets	$ 518	$ 166
Valuation Allowance—current	518	166
Total current deferred assets	—	—
Non-current deferred tax assets:		
Net operating loss carryforwards	28,122	27,469
Depreciation	410	413
Research and development credits	2,590	1,896
Capitalized research and development expense	6,272	3,712
Deferred revenue	—	2,971
Stock-based compensation	1,815	544
Other	74	(175)
	39,283	36,830
Valuation allowance—non-current	39,283	36,830
Total non-current deferred tax assets	—	—
Total deferred tax assets	$ —	$ —

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Notes to Consolidated Financial Statements (continued)

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 $2,805,000 during 2011 and $3,699,000 during 2010.

As of December 31, 2011, the Company had federal net operating loss carryforwards of approximately $70,422,000, which expire in the years 2022 through 2031 if not utilized. The Company had net operating loss carryforwards for state income tax purposes of $60,472,000, which expire in the years 2012 through 2031 if not utilized.

The Company has carryforwards from the federal Credit for Increasing Research Expenditures of approximately $1,690,000 which expire in years 2023 through 2031. The Company also has state credit carryforwards of approximately $1,385,000 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, 2011 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 $650,000 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, 2011 and December 31, 2010. 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.

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Notes to Consolidated Financial Statements (continued)

17. 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, 2011. 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, 2011	June 30, 2011	September 30, 2011	December 31, 2011	Total for year 2011
Revenue:					
License fee revenue	$ 3,125	$ 3,125	$ 625	$ 417	$ 7,292
Milestone revenue	—	—	—	10,000	10,000
Other revenue	—	—	—	2,402	2,402
Total 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
Income (loss) from operations	(1,910)	(2,220)	(4,962)	5,328	(3,764)
Interest income	24	21	18	16	79
Interest expense	(3)	(2)	(2)	(2)	(9)
Other income (expense), net	(50)	(45)	(45)	(46)	(186)
Net income (loss)	$ (1,939)	$ (2,246)	$ (4,991)	$ 5,296	$ (3,880)
Net income (loss) 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

	Three months ended				
	March 31, 2010	June 30, 2010	September 30, 2010	December 31, 2010	Total for year 2010
Revenue:					
License fee revenue	$ 3,125	$ 3,125	$ 3,125	$ 3,125	$ 12,500
Total revenue	3,125	3,125	3,125	3,125	12,500
Operating expenses:					
Research and development	2,360	2,407	2,885	3,032	10,684
General and administrative	2,604	2,769	2,984	2,681	11,038
Total operating expenses	4,964	5,176	5,869	5,713	21,722
Loss from operations	(1,839)	(2,051)	(2,744)	(2,588)	(9,222)
Interest income	44	37	25	21	127
Interest expense	(3)	(4)	(3)	(2)	(12)
Other income (expense), net	(44)	(43)	(45)	(64)	(196)
Net loss	$ (1,842)	$ (2,061)	$ (2,767)	$ (2,633)	$ (9,303)
Basic and diluted net loss per share	$ (0.14)	$ (0.15)	$ (0.21)	$ (0.20)	$ (0.69)
Weighted average common shares outstanding	13,392	13,402	13,426	13,442	13,416

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

Not applicable.

Item 9A. Controls and Procedures

(a) Evaluation of 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.

(b) 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, 2011, 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, 2011 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.

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, 2011 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

This annual report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent registered public accounting firm pursuant to Section 989G of the Dodd-Frank Act.

The information contained under this caption "Internal control over financial reporting" shall not be deemed to be filed with the SEC, nor shall such information be incorporated by reference into any future filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that we specifically incorporate it by reference into such filing.

(c) 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.

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, 2011.

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	2,876,510(2)	$ 6.16(3)	979,154(4)
Equity compensation plans not approved by stockholders	156,007	$ 8.14	—
Total	3,032,517	$ 6.26	979,154

(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 2,876,510 shares relating to outstanding options.
(3) Represents the weighted-average exercise price of outstanding options.
(4) Includes 447,686 shares available under the 2009 Employee Stock Purchase Plan and 531,468 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 on page 63.

(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
2.1(1)	Agreement and Plan of Merger and Reorganization, dated as of August 29, 2008, by and among Novacea Inc. ("Novacea"), Pivot Acquisition, Inc. and Transcept Pharmaceuticals, Inc., a privately held corporation that is now named Transcept Pharma, Inc. ("TPI") and is a wholly-owned subsidiary of Transcept Pharmaceuticals, Inc., a publicly-traded corporation formerly known as Novacea.
2.2(1)	Amendment to Agreement and Plan of Merger and Reorganization, dated as of December 23, 2008, by and among Novacea, Pivot Acquisition, Inc. and TPI.
3.1(2)	Amended and Restated Certificate of Incorporation of Transcept Pharmaceuticals, Inc.
3.2(2)	Bylaws of Transcept Pharmaceuticals, Inc., as amended.
4.1(3)	Specimen Common Stock certificate of Transcept Pharmaceuticals, Inc.
4.2(3)	Form of Preferred Stock Purchase Warrant issued to certain TPI investors as of March 21, 2005.
4.3(3)	Preferred Stock Purchase Warrant issued by TPI to Hercules Technology Growth Capital, Inc., dated as of April 13, 2006.
4.4(4)	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(12)	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(12)	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(4)+	Novacea 2001 Stock Option Plan and forms of agreements relating thereto.
10.2(13)+	2006 Equity Incentive Plan, as amended and restated.
10.3(14)+	Form of Option Agreement under 2006 Incentive Award Plan.
10.4(3)+	TPI Amended and Restated 2002 Stock Option Plan and forms of agreements relating thereto.
10.5(10) +	Transcept Pharmaceuticals, Inc. 2009 Employee Stock Purchase Plan.

Exhibit No.	Description of Exhibit
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(5)	Office Lease, by and between Kashiwa Fudosan America, Inc. and Novacea, dated as of May 15, 2007.
10.9(7)	Sublease dated as of March 24, 2009 by and between Transcept Pharmaceuticals, Inc. and BiPar Sciences, Inc.
10.10(9)	Sublease dated for reference purposes as of June 11, 2009 by and between Transcept Pharmaceuticals, Inc. and Bay Area Bioscience Association.
10.11(3)	Lease, by and between TPI and Point Richmond R&D Associates, L.P., dated as of February 22, 2006.
10.12(3)	First Amendment to Lease, by and between TPI and Point Richmond R&D Associates, L.P., dated as of June 27, 2007.
10.13(6)	Second Amendment to Lease, by and between Transcept Pharmaceuticals, Inc. and Point Richmond R&D Associates, L.P., dated as of February 20, 2009.
10.14(6)	Lease, by and between Transcept and Point Richmond R&D Associates II, LLC, dated as of February 20, 2009.
10.15(3)+	Offer Letter dated April 15, 2008, by and between TPI and Terrence Moore, including Side Letter dated August 20, 2008 and Side Letter dated December 23, 2008.
10.16(16)+	Second Amended and Restated Director Compensation Policy.
10.17(6)+	Offer Letter dated March 4, 2009, by and between Transcept Pharmaceuticals, Inc. and Joseph Kennedy.
10.18(6)+	Change of Control and Severance Benefits Agreement, by and between Transcept Pharmaceuticals, Inc. and Joseph Kennedy dated March 4, 2009.
10.19(8)+	Form of Indemnification Agreement for officers and non-institutional investor affiliated directors.
10.20(8)+	Form of Indemnification Agreement for institutional investor affiliated directors.
10.21(9)+	Change of Control and Severance Benefits Agreement by and between Transcept Pharmaceuticals, Inc. and Nipun Davar, Ph.D. dated April 30, 2009.
10.22(9)+	Change of Control and Severance Benefits Agreement by and between Transcept Pharmaceuticals, Inc. and Dennie Dyer dated April 30, 2009.
10.23(9)+	Change of Control and Severance Benefits Agreement by and between Transcept Pharmaceuticals, Inc. and Terrence Moore dated April 30, 2009.
10.24(9)+	Change of Control and Severance Benefits Agreement by and between Transcept Pharmaceuticals, Inc. and Glenn A. Oclassen dated April 30, 2009.
10.25(9)+	Change of Control and Severance Benefits Agreement by and between Transcept Pharmaceuticals, Inc. and Sharon Sakai, Ph.D. dated April 30, 2009.
10.26(9)+	Change of Control and Severance Benefits Agreement by and between Transcept Pharmaceuticals, Inc. and Nikhilesh Singh, Ph.D. dated April 30, 2009.

Exhibit No.	Description of Exhibit
10.27(9)+	Change of Control and Severance Benefits Agreement by and between Transcept Pharmaceuticals, Inc. and Thomas P. Soloway dated April 30, 2009.
10.28(9)+	Change of Control and Severance Benefits Agreement by and between Transcept Pharmaceuticals, Inc. and Marilyn E. Wortzman dated April 30, 2009.
10.29(11) †	United States License and Collaboration Agreement by and between Transcept Pharmaceuticals, Inc. and Purdue Pharmaceutical Products L.P. dated July 31, 2009.
10.30††	First Amendment to the United States License and Collaboration Agreement by and between Transcept Pharmaceuticals, Inc. and Purdue Pharmaceutical Products L.P. dated November 1, 2011.
10.31(11) †	Letter agreement by and between Transcept Pharmaceuticals, Inc. and Purdue Pharmaceutical Products L.P. dated July 31, 2009.
10.32(11) †	Letter agreement by and between Transcept Pharmaceuticals, Inc. and LP Clover Limited dated July 31, 2009.
21.1(15)	Subsidiaries of the Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.
31.1	Certification of the Company's Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Company's Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of the Company's Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101**	The following materials from Registrant's Quarterly Report on Form 10-K for the year ended December 31, 2011, formatted in Extensible Business Reporting Language (XBRL) includes: (i) Condensed Consolidated Balance Sheets at December 31, 2011 and December 31, 2010, (ii) Condensed Consolidated Statements of Income for each of the Three Years Ended December 31, 2011, (iii) Condensed Consolidated Statements of Cash Flows for each of the Three Years Ended December 31, 2011, and (iv) Notes to Condensed Consolidated Financial Statements, tagged as blocks of text.

(1) Incorporated by reference from the Registration Statement on Form S-4, Securities and Exchange Commission file number 333-153844, as declared effective on December 29, 2008.
(2) Incorporated by reference from the Current Report on Form 8-K filed with the Securities and Exchange Commission on February 5, 2009.
(3) Incorporated by reference from the Current Report on Form 8-K filed with the Securities and Exchange Commission on February 5, 2009.
(4) Incorporated by reference from the Registration Statement on Form S-1, Securities and Exchange Commission file number 333-131741, filed on February 10, 2006.
(5) Incorporated by reference from the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 17, 2008.
(6) Incorporated by reference from the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2009.
(7) Incorporated by reference from the Current Report on Form 8-K filed with the Securities and Exchange Commission on March 31, 2009.
(8) Incorporated by reference from the Current Report on Form 8-K filed with the Securities and Exchange Commission on April 9, 2009.

(9) Incorporated by reference from the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 14, 2009.
(10) Incorporated by reference from the Current Report on Form 8-K filed with the Securities and Exchange Commission on June 9, 2009.
(11) Incorporated by reference from the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 16, 2009.
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(13) Incorporated by reference from the Current Report on Form 8-K filed with the Securities and Exchange Commission on June 3, 2010.
(14) Incorporated by reference from the Registration Statement on Form S-8, Securities and Exchange Commission file number 333-172041, filed on February 3, 2011.
(15) Incorporated by reference from the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2010.
(16) Incorporated by reference from the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2011.
† Confidential treatment has been granted as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.
†† Confidential treatment has been requested 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 30th day of March, 2012.

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 Thomas P. Soloway 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 30, 2012
/s/ THOMAS P. SOLOWAY **Thomas P. Soloway**	Senior Vice President, Operations and Chief Financial Officer *(Principal Financial Officer)*	March 30, 2012
/s/ MARILYN E. WORTZMAN **Marilyn E. Wortzman**	Vice President, Finance *(Principal Accounting Officer)*	March 30, 2012
/s/ CHRISTOPHER B. EHRLICH **Christopher B. Ehrlich**	Director	March 30, 2012
/s/ THOMAS D. KILEY **Thomas D. Kiley**	Director	March 30, 2012
/s/ KATHLEEN D. LAPORTE **Kathleen D. LaPorte**	Director	March 30, 2012
/s/ JAKE R. NUNN **Jake R. Nunn**	Director	March 30, 2012
/s/ G. KIRK RAAB **G. Kirk Raab**	Chairman of the Board of Directors	March 30, 2012
/s/ FREDERICK J. RUEGSEGGER **Frederick J. Ruegsegger**	Director	March 30, 2012

Exhibit Index

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10.30††	First Amendment to the United States License and Collaboration Agreement by and between Transcept Pharmaceuticals, Inc. and Purdue Pharmaceutical Products L.P. dated November 1, 2011.
10.31(11) †	Letter agreement by and between Transcept Pharmaceuticals, Inc. and Purdue Pharmaceutical Products L.P. dated July 31, 2009.
10.32(11) †	Letter agreement by and between Transcept Pharmaceuticals, Inc. and LP Clover Limited dated July 31, 2009.
21.1(15)	Subsidiaries of the Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.

Exhibit No.	Description of Exhibit
31.1	Certification of the Company's Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Company's Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of the Company's Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101**	The following materials from Registrant's Quarterly Report on Form 10-K for the year ended December 31, 2011, formatted in Extensible Business Reporting Language (XBRL) includes: (i) Condensed Consolidated Balance Sheets at December 31, 2011 and December 31, 2010, (ii) Condensed Consolidated Statements of Income for each of the Three Years Ended December 31, 2011, (iii) Condensed Consolidated Statements of Cash Flows for each of the Three Years Ended December 31, 2011, and (iv) Notes to Condensed Consolidated Financial Statements, tagged as blocks of text.

(1) Incorporated by reference from the Registration Statement on Form S-4, Securities and Exchange Commission file number 333-153844, as declared effective on December 29, 2008.
(2) Incorporated by reference from the Current Report on Form 8-K filed with the Securities and Exchange Commission on February 5, 2009.
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(4) Incorporated by reference from the Registration Statement on Form S-1, Securities and Exchange Commission file number 333-131741, filed on February 10, 2006.
(5) Incorporated by reference from the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 17, 2008.
(6) Incorporated by reference from the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2009.
(7) Incorporated by reference from the Current Report on Form 8-K filed with the Securities and Exchange Commission on March 31, 2009.
(8) Incorporated by reference from the Current Report on Form 8-K filed with the Securities and Exchange Commission on April 9, 2009.
(9) Incorporated by reference from the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 14, 2009.
(10) Incorporated by reference from the Current Report on Form 8-K filed with the Securities and Exchange Commission on June 9, 2009.
(11) Incorporated by reference from the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 16, 2009.
(12) Incorporated by reference from the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 14, 2010.
(13) Incorporated by reference from the Current Report on Form 8-K filed with the Securities and Exchange Commission on June 3, 2010.
(14) Incorporated by reference from the Registration Statement on Form S-8, Securities and Exchange Commission file number 333-172041, filed on February 3, 2011.
(15) Incorporated by reference from the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2010.
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† Confidential treatment has been granted as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.

†† Confidential treatment has been requested 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.

Exhibit 10.30

FIRST AMENDMENT
TO UNITED STATES LICENSE AND COLLABORATION AGREEMENT

This FIRST AMENDMENT TO UNITED STATES LICENSE AND COLLABORATION AGREEMENT (this "Amendment"), is made as of November 1, 2011, by and between TRANSCEPT PHARMACEUTICALS, INC., a Delaware corporation ("Transcept"), and PURDUE PHARMACEUTICAL PRODUCTS L.P., a Delaware limited partnership ("Purdue").

WHEREAS, Transcept owns certain intellectual property rights relating to a therapeutic drug candidate known as Intermezzo® (sublingual zolpidem tartrate tablet); and

WHEREAS, Transcept and Purdue are parties to that certain United States License and Collaboration Agreement dated as of July 31, 2009 (as the same has been and may be further amended, supplemented or otherwise modified from time to time and including all exhibits, attachments and appendices thereto, the "Agreement"); and

WHEREAS, Transcept and Purdue desire to make certain modifications and amendments to the Agreement; and

WHEREAS, Transcept and Purdue are willing to agree to such amendments, subject to the terms and conditions set forth in this Amendment.

NOW, THEREFORE, in consideration of the foregoing premises, and other good and valuable consideration, the receipt and legal sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

1. Definitions. Unless otherwise defined herein, capitalized terms used herein shall have the meanings assigned to them in the Agreement, as amended hereby.

2. Modifications and Amendments to the Agreement. Subject to the execution and delivery of this Amendment in accordance with Section 5 below, and in reliance on the representations, warranties, covenants and agreements contained in this Amendment, from and after the date hereof the Agreement shall be modified and amended as follows:

(a) **Section 6.7 and Section 7.6**. Section 6.7 and Section 7.6 of the Agreement are modified as follows:

If Transcept delivers to Purdue written notice of the exercise of the Psychiatrist Co-Promotion Option any time between November 1, 2011 through and including December 31, 2011, then:

(i) notwithstanding the provisions of Section 6.7 of the Agreement to the contrary, Transcept will be permitted to specify a Co-Promotion Commencement Date **[*]** (with the exact start date to be mutually agreed upon by Transcept and Purdue); and

[*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

(ii) the royalty rate for royalties payable to Transcept under Section 7.6(a) of the Agreement shall be equal to the royalty rate set forth under "Royalty Rate on Psychiatric Net Sales" for **[*]** in the table within Section 7.6(a) notwithstanding the proviso following the table, but subject to subsequent adjustments in accordance with Section 7.5 of the Agreement.

To the extent, following the designation of a date **[*]**, as contemplated in paragraph (i) above, that the Parties mutually agree to delay the Co-Promotion Commencement Date to a later date, **[*]** such delay shall not affect the royalty rate for royalties payable to Transcept under Section 7.6 of the Agreement, as modified herein.

(b) **Section 8.4(b)(ii)**. Section 8.4(b)(ii) of the Agreement is replaced with the following:

"(ii) Subject to Section 8.4(d) and the remainder of this Section 8.4(b), during the Term, the Parties shall have the right, but not the obligation, to prepare for patent litigation involving the Transcept Patents in the U.S. Territory (it being understood that the Parties' respective rights to bring suit to enforce the Transcept Patents in the U.S. Territory shall be as set forth in Section 8.4(b)(i)). Each Party shall provide to the Party conducting such patent litigation preparation under this Section 8.4(b) reasonable assistance in such undertaking. The Party initiating the preparation shall keep the other Party regularly informed of the status and progress of such preparation efforts, and shall reasonably consider the other Party's comments on any such efforts."

(c) **Section 8.4(b)(iii)**. Section 8.4(b)(ii) of the Agreement is re-numbered as Section 8.4(b)(iii) and amended and restated in its entirety as follows:

"(iii) In the event that either (*x*) a Party brings a claim, suit or action under Section 8.4(b)(i) against any person or entity engaged in Product Infringement of the Transcept Patents in the U.S. Territory or (*y*) the Parties approve the preparation for patent litigation involving the Transcept Patents in the U.S. Territory under Section 8.4(b)(ii), then Purdue shall be responsible for sixty percent (60%) and Transcept shall be responsible for forty percent (40%) of the costs and expenses (including attorneys' fees and expenses) incurred by the Parties as a result. Notwithstanding the foregoing, in connection with any and all such claims, suits or actions initiated by Purdue under Section 8.4(b)(i) or preparation for any and all patent litigations approved by the Parties under Section 8.4(b)(ii), Transcept's responsibility for costs and expenses shall not exceed one million dollars ($1,000,000) per calendar year or four million dollars ($4,000,000) in aggregate over the Term, except with

Transcept's written consent. If either Party expends less than its respective percentage share of such costs and expenses, such Party shall pay the other Party the amount required to satisfy its percentage share for the relevant time period in cash or by offset against other amounts due to such Party from the other Party under this Agreement on a calendar quarter basis; provided that if Purdue is the Party that (*x*) brings such claim, suit, or action under Section 8.4(b)(i) or (*y*) incurs expenses in connection with the preparation for patent litigation involving the Transcept Patents in the U.S. Territory approved by the Parties under Section 8.4(b)(ii), then Purdue shall have the right to offset such costs and expenses against payments due to Transcept under Article 7 so long as such payments are not reduced by more than **[*]**, with any unused offset carried forward. If a Party recovers monetary damages or any other payments from such Third Party in such suit or action (including as a result of settlement), such recovery shall be allocated first to the reimbursement of any unreimbursed costs and expenses incurred by the Parties, and any remaining amount shall be distributed as follows: sixty percent (60%) to Purdue and forty percent (40%) to Transcept.

3. Acknowledgement. The agreement of the parties to make the amendments contained herein does not and shall not create any obligation of a party to consider or agree to any further waiver, consent or amendment and, in the event that the parties subsequently agree to consider any further waivers, consents or amendments, neither the waivers, consents or amendments contained herein nor any other conduct of any party shall be of any force or effect on any party's consideration or decision with respect to any such requested consent or amendment and no party shall have any further obligation whatsoever to consider or agree to further amendment, waiver, consent or agreement.

4. Representations, Warranties, Covenants and Acknowledgments. To induce the parties to enter into this Amendment, each party:

(a) represents and warrants to the other party that, after giving effect to this Amendment, (i) all of the representations and warranties contained in Section 9.1 of the Agreement are true and correct in all material respects on and as of the date hereof to the same extent as though made on and as of the date hereof, except to the extent such representations and warranties specifically relate to an earlier date, in which case such representations and warranties shall have been true and correct in all material respects on and as of such earlier date; (ii) as of the date hereof, no default, event of default or breach of the Agreement has occurred and is continuing under the Agreement; (iii) each party has the power and is duly authorized to enter into, deliver and perform this Amendment; (iv) this Amendment is the legal, valid and binding obligation of each party enforceable against each party in accordance with its terms, and (v) the execution, delivery and performance of this Amendment does not conflict with, result in a material breach of or constitute (with due notice or lapse of time or both) a material default under any material contract or agreement of either party;

(b) reaffirms each of such party's agreements, covenants, and undertakings set forth in the Agreement, as amended by the terms of this Amendment; and

[*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

(c) acknowledges and agrees that (i) the parties have agreed to pursue the pre-litigation work contemplated by Section 8.4(b)(ii) of the Agreement (as amended by this Amendment) and (ii) with Transcept's approval, Purdue has engaged Covington & Burling LLP for this purpose.

5. Conditions to Effectiveness. The effectiveness of this Amendment is subject to delivery of an executed counterpart of this Amendment by each party to the other.

6. Effect; Relationship of Parties.

(a) Except as expressly amended hereby, the Agreement (including the Exhibits and Schedules thereto) shall be and remains in full force and effect as originally written, and shall constitute the legal, valid, binding and enforceable obligations of Transcept and Purdue. On and after the date hereof, each reference in the Agreement to "this Agreement", "hereunder", "hereof", "herein" or words of like import referring to the Agreement, and each reference in the Exhibits or Schedules to the "Agreement", "thereunder", "thereof" or words of like import referring to the Agreement shall mean and be a reference to the Agreement as amended by this Amendment.

(b) This Amendment embodies the entire agreement and understanding between the parties hereto with respect to the subject matter hereof and supersedes all prior oral or written negotiations, agreements and understandings of the parties with respect to the subject matter hereof.

(c) The relationship of Transcept and Purdue has been and shall continue to be, at all times, that of independent contractors and nothing in this Amendment shall be construed to give either party the power or authority to act for, bind, or commit the other party in any way. Nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners between the parties.

7. Miscellaneous.

(a) Any notice required or permitted to be given under this Amendment shall be made in conformity with the notice provisions set forth in Section 14.3 of the Agreement.

(b) This Amendment has been prepared jointly and shall not be strictly construed against either party. Ambiguities, if any, in this Amendment shall not be construed against any party, irrespective of which party may be deemed to have authored the ambiguous provision. The headings of each Article or Section in this Amendment have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.

(c) Resolution of all disputes arising out of or related to this Amendment or the validity, construction, interpretation, enforcement, breach, performance, application or termination of this Amendment and any remedies relating thereto, shall be governed by and construed under the substantive laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Amendment to the substantive laws of another jurisdiction.

[*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

(d) This Amendment will be binding upon and inure solely to the benefit of the parties and their successors and permitted assigns and no provision of this Amendment, express or implied, is intended to or will be deemed to confer upon third parties any right, benefit, remedy, claim, liability, reimbursement, claim of action or other right of any nature whatsoever under or by reason of this Amendment other than the parties.

(e) This Amendment may be executed in one (1) or more counterparts, including by facsimile or other electronic transmission, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, Transcept and Purdue have caused this Amendment to be duly executed as of the date first set forth above.

TRANSCEPT PHARMACEUTICALS, INC.

By: /s/ Glenn A. Oclassen
Name: Glenn A. Oclassen
Title: President & CEO

PURDUE PHARMACEUTICAL PRODUCTS L.P.

By: Purdue Pharmaceutical Products Inc., its general partner

By: /s/ John H. Stewart
Name: John H. Stewart
Title: President and Chief Executive Officer

[*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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, and No. 333-172041) 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 report dated March 30, 2012, with respect to the consolidated financial statements of Transcept Pharmaceuticals, Inc., included in this Annual Report (Form 10-K) of Transcept Pharmaceuticals, Inc. for the year ended December 31, 2011.

/s/ Ernst & Young LLP

Redwood City, California
March 30, 2012

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 30, 2012

/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, Thomas P. Soloway, 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 30, 2012

/s/ Thomas P. Soloway
Thomas P. Soloway
Senior Vice President, Operations 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, 2011 (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 30, 2012

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

/s/ Thomas P. Soloway
Thomas P. Soloway
Senior Vice President, Operations 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.