File	Filename
8-K - FORM 8-K - Transcept Pharmaceuticals Inc	d313745d8k.htm

Exhibit 99.1

Transcept PHARMACEUTICALS, INC.

A specialty pharmaceutical company focused on the development and commercialization of proprietary products to address important therapeutic needs in the field of neuroscience

March 2012

Forward looking statements

This presentation contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this presentation are forward-looking statements. Examples of such statements include our expectation regarding the potential market for Intermezzo ® and the potential market size for a middle of the night sleep aid; our expectations regarding an ideal therapeutic; the average value of a branded insomnia prescription and the resulting revenue for each 1% of market share; Purdue plans to hire 275 sales representatives to exclusively promote Intermezzo; Purdue plans to invest approximately $100 million to support sales and marketing over the first 12 months of commercialization of Intermezzo in the U.S.; the expected timing for and the success of the commercial launch of Intermezzo by Purdue in the U.S.; the receipt of royalty and milestone payments from Purdue pursuant to our Collaboration Agreement; anticipated reimbursement coverage; intellectual property protection being obtained and maintained; plans for the Phase 2 study of TO-2061, including the expected timing of clinical trial results; and our expectations regarding the potential market size for TO-2061 as augmentation treatment for patients with OCD. All of these forward-looking statements are based on estimates and assumptions by our management that, although we believe to be reasonable, are inherently uncertain. Forward-looking statements involve risks and uncertainties, including, but not limited to, achieving acceptance of Intermezzo by physicians, patients and third-party payors; supplying sufficient quantities of Intermezzo from third-party manufacturers and suppliers to meet anticipated market demand; the impact of competitive products and the market for Intermezzo generally; our dependence on Purdue's commercialization efforts and our Collaboration Agreement with Purdue; obtaining, maintaining and protecting regulatory exclusivity and intellectual property protection for Intermezzo; competitive product commercialization; manufacturing and supply risks for TO-2061; adverse patent decisions at the USPTO or in court; and variability in the business of Transcept generally. These and other risks are described in greater detail in the "Risk Factors" section of Transcept periodic reports filed with the Securities and Exchange Commission. Forward-looking statements do not reflect the potential impact of any future in-licensing, collaborations, acquisitions, mergers, dispositions, joint ventures, or investments Transcept may enter into or make. Transcept does not assume any obligation to update any forward-looking statements, except as may be required by law.

Transcept: preparing for Intermezzo ® commercialization

Therapeutic focus	■ Neuroscience / psychiatry
Large markets, unmet needs	■ Intermezzo: middle of the night awakenings ■ *TO-2061*: treatment resistant OCD
Commercial platform	■ U.S. primary care partnership: Purdue Pharma ■ Option to co-promote Intermezzo® 1 yr post launch

Strong balance sheet

- 9/30/11: ~$54 M cash, equivalents & investments
- $10M milestone payment from Purdue: Q4 2011
- No debt

Near term catalysts

- Intermezzo product launch: early April 2012
- *TO-2061* Phase 2 results: estimated Q1 2013

Intermezzo®

(zolpidem tartrate) sublingual tablet C-IV

Intermezzo: the first and only prescription sleep aid approved for middle-of-the-night dosing

- Indication statement as approved by FDA:
  - 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 planned time of waking.

Intermezzo: the first and only prescription sleep aid approved for middle-of-the-night dosing

Middle of the night (MOTN) awakening: a major unmet medical need in the insomnia category

- Large U.S. insomnia market
  - 79 million new and refill prescriptions[1]
- Insomnia is an under-treated condition [2]
  - 11 million patients receive Rx[3]
  - 4x to 6x more are not diagnosed or treated by a physician[3]
- MOTN awakening: the most common insomnia symptom [4]
  - 35% of Americans suffer from MOTN awakenings at least 3x / week[4]
  - >90% report awakenings persist more than six months; 50% report awakenings persist more than five years[5]

(1) IMS Oct 2010 to Sep 2011; (2) Institutes of Medicine - Sleep disorders and sleep deprivation Apr. 2006; (3) BluePrint Research Group; (4) Ohayon, Nocturnal awakenings and comorbid disorders in the American general population. J of Psych Research (2009); (5) Ohayon, Difficulty in resuming or inability to resume sleep and the links to daytime impairment, J of Psych Research (2009).

Commonly prescribed sleep aids are indicated only for bedtime use

- MOTN awakenings typically do not occur every night
- 7-8 hr sleep aids (Ambien®, Ambien CR®, Lunesta®) require bedtime prophylactic dosing to prevent awakenings
- An ideal therapeutic would:
  - Be used only at the time patients need help returning to sleep, not every night in advance of a problem that may not occur
  - Return patients to sleep rapidly
  - Be effective despite the low dose necessary to avoid next day residual effects when used in the middle of the night

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Intermezzo: the first and only sleep aid approved for middle-of-the night dosing

- Novel zolpidem formulation
  - Sublingual tablet
  - Bicarbonate-carbonate buffers
- Approved dose
  - 1.75 mg in women & patients > 65 years
  - 3.5 mg in non-elderly men
- Rapidly absorbed in both men and women
- Effective vs. placebo in sleep laboratory & outpatient studies
- Instructions to patients
  - Take Intermezzo "while in bed"
  - "When you wake up in the morning, be sure that at least 4 hours have passed since you have taken Intermezzo and you feel fully awake before driving. Do not do dangerous activities until you know how Intermezzoaffects you."

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Intermezzo®
(ZOLPIDEM TARTRATE) sublingual tablet Ⓒ

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Significant Rx insomnia market opportunity: each 1% share ≈ $130M at branded prices

U.S. insomnia market	79 million TRx per year[1]
Branded pricing	~$5 to $6 per tablet[2] 30 tablets per Rx[3] Average Rx value: $165
Hypothetical market	1% Intermezzo share

Hypothetical market penetration	1% Intermezzo share ⬇ 790,000 TRx, approx $130M sales

(1) IMS Health, National Prescription Audit, Sept 2011; (2) Wolters Kluwer WAC pricing (branded) Jan 2011, $5.05 to $5.67 (products evaluated: Ambien®, Ambien CR®, Lunesta®, Silenor®; Ambien® and Ambien CR® are currently available in generic form; Lunesta® WAC pricing was $6.13); (3) Transcept estimate based on IMS Health, National Prescription Audit, Sept 2011.

Intermezzo launch plans

- Initial shipments and physician promotion planned for early April 2012
- Purdue plans to invest ~$100M during first 12 months of Intermezzo launch
- ~275 field representatives in new national sales force devoted exclusively to the promotion of Intermezzo to highest insomnia prescribers
- Purdue began contacting drug wholesaler, retailer and managed care decision makers in early 2012

Purdue commercialization agreement: key Transcept benefits

- Co-promote option: foundation for a commercial future
  - Transcept option: co-promote to psychiatrists can begin as early as 1 year and as late as 4.5 years after Purdue launch
- Royalty structure
  - Base royalty: mid-teens up to mid 20% level on net sales
  - Co-promote royalty:
    - 22% to 40% on psychiatrist Rx net sales, based on timing of opt-in
    - Net revenue qualifying for this additional co-promote royalty is capped at 15% of total Intermezzo annual net U.S. sales
- Milestone payments
  - $10M for first formulation patent listed in Orange Book, paid in Q4 2011
  - Up to $80M additional upon the achievement of certain patent milestones and net sales targets

Intermezzo managed markets advisory board with

decision makers covering >170M lives

- Broad formulary access expected
- Unmet medical need generally recognized by payers
  - Unique insomnia indication
  - Low dose used less often
  - Rapidly absorbed
- Tier 3 formulary placement anticipated by most plans
- Utilization management criteria consistent with other brands
- Intermezzo brand parity pricing not viewed as a major barrier with managed markets

Intermezzo: intellectual property

Two U.S. patents issued, additional patent applications pending

- Two issued U.S. patents - 7,682,628 and 7,658,945
  - Buffered formulations
  - Compositions and methods of treating insomnia
  - Claims require absorption of zolpidem across the oral mucosa
  - Patents expire no sooner than February 2025
- Patent applications pending
  - Claims are not limited to use of buffers
  - Compositions and methods of treating middle of the night awakenings

– Any patents issuing from these applications would expire no sooner than February 2025

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TO-2061
(low dose ondansetron)

Proposed indication: adjunctive therapy in adult patients with obsessive compulsive disorder (OCD) not adequately responsive to currently approved OCD medication

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Significant unmet medical need: OCD patients not responding adequately to approved medication

- Obsessive Compulsive Disorder
  - Intrusive thoughts and repetitive actions to reduce distress
  - Affects 1% to 2% of U.S. adult population, 40% to 50% seek treatment
  - Significantly impacts everyday life activities of patients and their families
  - 40% to 60% of OCD patients do not respond adequately to approved medications, which include the SSRIs Prozac®, Luvox®, Paxil®, Zoloft®
- No FDA approved medication for treatment resistant OCD
  - Atypical antipsychotics are often used off-label to augment approved medications
    - ~68% of treatment resistant OCD patients do not respond
    - Frequently reported adverse events: weight gain, metabolic disorder

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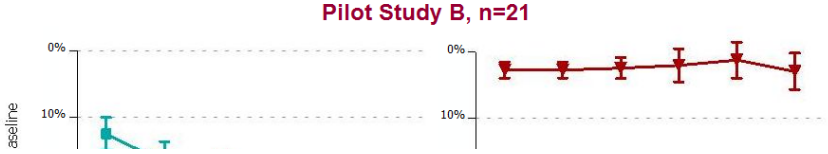
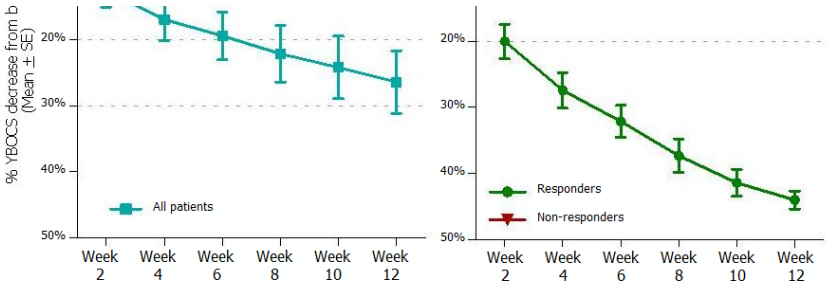
Pilot Study B:
Improvement measured as % decrease below baseline





All Patients: n=21
26.3% improvement at 12 weeks

Responders: n=12 of 21 (57%)
44.3% improvement at 12 weeks

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TO-2061: development overview

- 505b2 NDA pathway
- Phase 2 double blind, placebo controlled study, n≈150, complete enrollment est. Fall 2012, top line data est. Q1 2013
- Intellectual property
  - Method of use patent application filed, priority date May 19, 2009
  - Ondansetron, up to ~1.5 mg/day
  - Pending claims for treating SSRI resistant OCD with ondansetron augmentation
- Managed care survey (~108M lives): unmet medical need acknowledged, Tier 3 formulary placement expected
- Strategic fit: psychiatry
  - ~87% of patient visits for OCD were to psychiatrists in 2009*
  - Complementary to Intermezzo psychiatry co-promote option with Purdue

* SDI Physician Drug and Diagnosis Audit

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Financial overview

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Financial position – Q4 2011 release and teleconference on 3/14/12 at 1:30 PM PT

9/30/11

- Cash & investments: $54.1 M
- Q3 2011 cash burn rate*: $ 1.9 M / month

2/1/12 update

- Milestone payment recvd (12/21/11): $10.0 M
- Shares outstanding: 13.9 M
  - Options / warrants / other: 3.6
  - Total: 17.5 M
- Employees: 18

*During Q3 2011, Transcept paid severance of approximately $1.0 million to former employees whose positions were eliminated in the July 15, 2011 reduction in force. Excluding this severance payout, cash use during the quarter averaged approximately $1.5 million per month.

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