

Transcept Pharmaceuticals Reports Third Quarter 2009 Financial Results

Conference call scheduled for 5:00 PM Eastern time today

POINT RICHMOND, Calif., Nov 12, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Transcept Pharmaceuticals, Inc. (Nasdaq: TSPT), a specialty pharmaceutical company focused on the development and commercialization of proprietary products that address important therapeutic needs in neuroscience, today announced financial results for the three and nine months ended September 30, 2009.

Transcept previously announced that on October 28, 2009, the FDA issued a Complete Response Letter regarding the New Drug Application (NDA) for *Intermezzo*(R) (zolpidem tartrate sublingual tablet), the lead Transcept product candidate. The NDA seeks approval to market *Intermezzo*(R) for use as-needed for the treatment of insomnia when a middle of the night awakening is followed by difficulty returning to sleep. Transcept and Purdue Pharmaceutical Products, L.P. have entered into a collaboration agreement for the development and commercialization of *Intermezzo*(R) in the United States.

Glenn A. Oclassen, President and Chief Executive Officer commented, "Our focus is now on moving *Intermezzo*(R) forward through the remainder of the regulatory review process. With \$93 million of cash, cash equivalents and marketable securities at September 30, 2009, we believe we have substantial resources on hand to cover a range of potential additional expenses that may be required to address the issues raised by the recent FDA Complete Response Letter. We expect to have more clarity on the FDA's remaining requirements for the *Intermezzo*(R) NDA after our planned meeting to discuss the Complete Response Letter. We are working with the FDA to schedule this meeting in early 2010."

"Purdue Pharma, our U.S. commercialization partner for *Intermezzo*(R), has been actively engaged in our collaboration since we received the Complete Response Letter. We are working closely with the Purdue clinical, regulatory and packaging teams to address the concerns raised by FDA."

"With regard to other key *Intermezzo*(R) milestones, we announced last week that the United States Patent and Trademark Office issued a Notice of Allowance for one of our patent applications with claims that cover the use of our low-dose sublingual *Intermezzo*(R) formulation. Transcept is actively pursuing additional patents to protect *Intermezzo*(R) in the United States and key non-U.S. markets, and, as part of the NDA submission, has requested that the FDA grant three years of Hatch-Waxman marketing exclusivity to *Intermezzo*(R)."

Third Quarter 2009 Financial Results

Transcept recorded \$2.08 million of revenue for the three month period ended September 30, 2009, related to recognition of a portion of the \$25 million non-refundable license fee received from Purdue in connection with the signing of our collaboration agreement. Transcept plans to amortize the \$25 million license fee over a 24 month period. There was no revenue for the three month period ended September 30, 2008.

Research and development expense for the quarter ended September 30, 2009 was approximately \$2.14 million, compared to approximately \$2.45 million for the same period in 2008. This decrease is primarily attributable to lower *Intermezzo*(R) development costs, the majority of which were incurred prior to the submission of the NDA in September 2008. The decrease was partially offset by severance expense incurred in connection with the reduction in force announced in August 2009. Research and development expense included non-cash stock compensation expense in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 718 Compensation - Stock Compensation ("ASC Topic 718") (formerly Statement of Financial Accounting Standards No. 123R (SFAS No. 123R)) of approximately \$234,000 for the quarter ended September 30, 2009 and approximately \$62,000 for the quarter ended September 30, 2008.

General and administrative expense for the quarter ended September 30, 2009 was approximately \$3.84 million, compared to approximately \$2.14 million for the same period in 2008. The \$1.70 million increase consists primarily of higher professional fees to operate as a public company and to negotiate our collaboration with Purdue, increased personnel costs primarily in marketing and administration functions, an increase in operating expenses associated with additional office space and severance expense for the reduction in force noted above. General and administrative expense included non-cash stock compensation expense in accordance with ASC Topic 718 of approximately \$299,000 for the quarter ended September 30, 2009, as compared to approximately \$106,000 for the quarter ended September 30, 2008.

Net loss for the quarter ended September 30, 2009 was approximately \$3.8 million or \$0.29 per share (basic and diluted), compared to a net loss of approximately \$4.3 million or \$10.08 per share (basic and diluted) for the quarter ended September 30, 2008. The weighted average shares used to calculate basic and diluted net loss per share were 13,174,807 and 422,777 for the quarters ended September 30, 2009 and September 30, 2008, respectively. At September 30, 2009 there were 13,336,431 common shares outstanding and 1,984,385 outstanding options, warrants and common stock subject to repurchase.

Nine months ended September 30, 2009 Financial Results

Revenue for the nine months ended September 30, 2009 was \$2.08 million related to recognition of a portion of the \$25 million non-refundable license fee received from Purdue in connection with the signing of our collaboration agreement, compared to no revenue for the nine months ended September 30, 2008.

Research and development expense for the nine months ended September 30, 2009 was approximately \$6.61 million, compared to approximately \$8.84 million for the same period in 2008. The \$2.23 million decrease is primarily attributable to lower *Intermezzo*(R) development costs, the majority of which were incurred prior to the submission of the *Intermezzo*(R) NDA on September 30, 2008. Research and development expense included non-cash stock compensation expense in accordance with ASC Topic 718 of approximately \$391,000 for the nine months ended September 30, 2009 and approximately \$192,000 for the nine months ended September 30, 2008.

General and administrative expense for the nine months ended September 30, 2009 was approximately \$13.07 million, compared to approximately \$5.37 million for the same period in 2008. The \$7.70 million increase consists primarily of higher professional fees to operate as a public company and to negotiate our collaboration with Purdue, increased personnel costs primarily in marketing and administration, increased marketing expense as we prepared to commercialize *Intermezzo*(R) and an increase in operational expenses associated with additional office space. General and administrative expense included non-cash stock compensation expense in accordance with ASC Topic 718 of approximately \$693,000 for the nine months ended September 30, 2009, as compared to approximately \$268,000 for the nine months ended September 30, 2008.

Year-to-date merger-related transaction costs of approximately \$2.22 million were expensed during the first quarter of 2009.

Net loss for the nine months ended September 30, 2009 was approximately \$19.5 million or \$1.65 per share, compared to a net loss of approximately \$13.8 million or \$35.93 per share for the nine months ended September 30, 2008. The weighted average shares used to calculate net loss per share were 11,764,652 and 385,214, respectively, for the nine months ended September 30, 2009 and 2008.

Cash, cash equivalents and marketable securities totaled \$93.0 million at September 30, 2009.

Financial Guidance

Transcept believes it has substantial cash resources to cover a range of potential additional expenses that may be required to address the issues raised by the recent FDA Complete Response Letter on the *Intermezzo*(R) NDA.

General and administrative expense declined from approximately \$5.02 million in the quarter ended June 30, 2009 to approximately \$3.84 million in the quarter ended September 30, 2009. We anticipate that general and administrative expense will be closer to the lower end of this range during the fourth quarter of 2009 and the first half of 2010.

Research and development expense was approximately \$2.25 million in the quarter ended June 30, 2009 and approximately \$2.14 million in the quarter ended September 30, 2009. During the fourth quarter of 2009 and the first half of 2010, we anticipate:

- Baseline research and development expense will remain substantially in line with these prior quarters;
- Additional research and development expense of approximately \$1.05 million will be incurred in connection with manufacturing activities undertaken in anticipation of the previously planned launch of *Intermezzo*(R) in 2010; and
- Additional research and development expense will be incurred as Transcept determines and undertakes activities to support the planned resubmission of the *Intermezzo*(R) NDA.

Transcept is working with the FDA to schedule a meeting in early 2010, and plans to provide an update to investors as appropriate.

Conference Call and Webcast Information

Transcept will host a conference call and webcast on Thursday, November 12, 2009, at 5:00 p.m. Eastern time to discuss third quarter 2009 financial results. Telephone numbers for the live conference call are 877-874-1589 (U.S.) or 719-325-4805 (International). The webcast can be accessed on the Investors page of the Transcept website at www.transcept.com and will be available for replay until close of business on November 27, 2009. A playback of the call will be available through November 27, 2009 by dialing 888-203-1112 (U.S.) or 719-457-0820 (International), replay passcode: 2918743.

About Intermezzo(R)

Intermezzo(R) (zolpidem tartrate sublingual tablet), the lead product candidate at Transcept, has the potential to be the first prescription sleep aid specifically approved for use in the middle of the night at the time a patient awakens and has difficulty returning to sleep. *Intermezzo(R)* is a sublingual low dose formulation of zolpidem, the active agent most commonly prescribed in the United States for the treatment of insomnia. *Intermezzo(R)* uses approximately one-quarter to one-third of the dose of active drug contained in currently marketed zolpidem-based sleep aids, in a formulation designed to promote rapid sublingual absorption.

Two Phase 3 clinical studies evaluated 376 patients receiving either *Intermezzo(R)* or placebo. In the first study, a sleep laboratory trial using an objective polysomnographic endpoint, *Intermezzo(R)* demonstrated a statistically significant decrease versus placebo in the time it took patients to return to sleep as measured by Latency to Persistent Sleep. In the second study, an outpatient trial, *Intermezzo(R)* demonstrated a statistically significant decrease in Latency to Sleep Onset, a subjective patient reported endpoint. The most common adverse event seen in these trials was headache (2.7 percent active versus 1.4 percent placebo in the outpatient study).

In September 2008 Transcept submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval of *Intermezzo(R)* as a prescription sleep aid for use in the middle of the night at the time a patient awakens and has difficulty returning to sleep. In October 2009 Transcept received a Complete Response Letter from the FDA on the *Intermezzo(R)* NDA and is working to respond to issues raised in the letter. Transcept and Purdue Pharmaceutical Products, L.P. have entered into a collaboration agreement for the development and commercialization of *Intermezzo(R)* in the United States. For further information, please visit the company's website at: www.transcept.com.

The United States Patent and Trademark Office granted a Notice of Allowance for claims that cover *Intermezzo(R)* under U.S. patent application no. 11/833,323. If issued, this patent will expire in 2025. Transcept is actively pursuing additional patents to protect *Intermezzo(R)* in the United States and key non-U.S. markets, and, as part of the NDA submission, has requested that the FDA grant three years of Hatch-Waxman marketing exclusivity to *Intermezzo(R)*.

About Transcept

Transcept Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the development and commercialization of proprietary products that address important therapeutic needs in neuroscience. For further information, please visit the company's website at: www.transcept.com.

Forward Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this press release regarding our strategy, future operations, future financial position, future revenues, projected expenses, prospects, plans and objectives of management are forward-looking statements. Examples of such statements include, but are not limited to, statements relating to expectations with respect to the following: the ability of Transcept to successfully obtain direction from the FDA that will effectively guide Transcept in support of its plans to resubmit the *Intermezzo(R)* NDA; the ability of Transcept to resubmit the *Intermezzo(R)* NDA to the FDA with sufficient data and other content to warrant FDA approval to market the drug candidate in its intended indication; the sufficiency of Transcept cash resources to cover a range of potential additional expenses that may be required to address the issues raised by the FDA Complete Response Letter; the potential approval and timing of regulatory decisions with respect to the NDA for *Intermezzo(R)*; *Intermezzo(R)* being the first commercially available sleep aid in the United States specifically approved for use in the middle of the night at the time a patient awakens and has difficulty returning to sleep; the ability of Transcept to obtain and maintain patent protection and regulatory exclusivity for *Intermezzo(R)*; and financial guidance with respect to general and administrative expenses and research and development expenses. Transcept may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. Various important factors could cause actual results or events to differ materially from the forward-looking statements that Transcept makes, including risks related to the following: the willingness and ability of the FDA

to provide reliable guidance that will enable Transcept to make decisions in support of the *Intermezzo*(R) NDA; the ability of Transcept to design or successfully carry out additional safety studies in support of potential resubmission of an NDA for *Intermezzo*(R); the sufficiency of the content in the planned resubmission in support of the *Intermezzo*(R) NDA; a decision by Purdue to not devote time or resources to support the approval of *Intermezzo*(R) or to terminate the Purdue collaboration agreement, even if the *Intermezzo*(R) NDA is approved; unforeseen expenses related to efforts in support of FDA approval, general and administrative expenses; other research and development expenses and the business of Transcept generally; dependence on third parties to manufacture *Intermezzo*(R); obtaining, maintaining and protecting the intellectual property incorporated into *Intermezzo*(R); other difficulties or delays in the commercialization of *Intermezzo*(R); and the ability of Transcept to obtain additional funding, if needed, to support its business activities. These and other risks are described in greater detail in the "Risk Factors" section of Transcept periodic reports filed with the SEC. 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 required by law.

FINANCIAL TABLES FOLLOW

Transcept Pharmaceuticals, Inc.
Statements of Operations
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Revenue:				
License fee revenue	\$2,083,334	\$-	\$2,083,334	\$-
Operating expenses:				
Research and development	2,135,622	2,453,237	6,607,022	8,844,666
General and administrative	3,839,612	2,141,535	13,072,734	5,365,574
Merger related transaction costs	-	-	2,223,860	-
Total operating expenses	5,975,234	4,594,772	21,903,616	14,210,240
Loss from operations	(3,891,900)	(4,594,772)	(19,820,282)	(14,210,240)
Interest income	54,729	133,878	239,661	682,117
Interest expense	(4,176)	(176,060)	(175,100)	(618,188)
Other income (expense), net	36,499	377,264	299,995	306,307
Net loss	\$(3,804,848)	\$(4,259,690)	\$(19,455,726)	\$(13,840,004)
Basic and diluted net loss per share	\$(0.29)	\$(10.08)	\$(1.65)	\$(35.93)
Weighted average shares outstanding	13,174,807	422,777	11,764,652	385,214

Transcept Pharmaceuticals, Inc.
Balance Sheets

	September 30, ----- 2009 ----	December 31, ----- 2008 ----
Assets	(Unaudited)	
Current assets:		
Cash and cash equivalents	\$10,729,594	\$4,431,505
Marketable securities	82,267,092	7,250,987
Prepaid and other current assets	1,714,064	381,836
Restricted cash	200,000	200,000
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Total current assets	94,910,750	12,264,328
Property and equipment, net	1,318,083	1,450,216
Goodwill	2,961,664	-
Other assets	826,243	65,970
	-----	-----
Total assets	\$100,016,740	\$13,780,514
	=====	=====
Liabilities, convertible preferred stock and stockholders' equity (net capital deficiency)		
Current liabilities:		
Accounts payable	\$605,529	\$575,269
Accrued liabilities	2,185,011	1,468,415
Lease liability, short-term portion	297,853	-
Deferred revenue, short-term portion	12,500,000	-
Loan payable, short-term portion	43,908	3,347,010
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Total current liabilities	15,632,301	5,390,694
Deferred revenue, long-term portion	10,416,666	-
Warrant liability	-	599,845
Deposit for stock purchase	51,780	87,656
Deferred rent	100,161	77,044
Lease liability, long-term portion	639,325	-
Loan payable, long-term portion	136,370	169,636
Other liabilities	12,500	-
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Total liabilities	26,989,103	6,324,875
Convertible preferred stock:		
\$0.001 par value; 7,593,091 shares authorized;		
0 shares issued and outstanding at September 30, 2009;		
Series A - 60,212, Series B - 1,126,020, Series C - 2,838,091 and Series D - 3,325,647 shares issued and outstanding at		
December 31, 2008	-	71,036,951
Stockholders' equity (net capital		

deficiency):

Common stock, \$0.001 par value; 100,000,000 shares authorized; 13,336,431 and 454,676 shares issued and outstanding at September 30, 2009 and December 31, 2008, respectively	13,336	455
Additional paid-in capital	157,516,702	1,503,841
Accumulated deficit	(84,567,159)	(65,111,433)
Accumulated other comprehensive income	64,758	25,825
	-----	-----
Total stockholders' equity (net capital deficiency)	73,027,637	(63,581,312)
	-----	-----
Total liabilities, convertible preferred stock and stockholders' equity (net capital deficiency)	\$100,016,740	\$13,780,514
	=====	=====

Contact:

Transcept Pharmaceuticals, Inc.
Greg Mann
Director, Corporate Communications
(510) 215-3567
gmann@transcept.com

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