March 18, 2013

Intercept Pharmaceuticals Announces 2012 Financial Results and Provides Business Update

Continued Development Progress and a Strong Cash Position

Conference Call Scheduled Today at 5:30 p.m. ET

NEW YORK, March 18, 2013 (GLOBE NEWSWIRE) -- Intercept Pharmaceuticals, Inc. (Nasdaq:ICPT) (Intercept), a clinical stage biopharmaceutical company focused on the development and commercialization of novel bile acid therapeutics to treat chronic liver diseases, today reported financial results for the fourth quarter and full year ended December 31, 2012 and provided an update on corporate developments.

"2012 was an extraordinary year for Intercept with the significant progress we made advancing our lead product candidate OCA, while raising over $115 million in equity capital through the completion of our Series C financing and IPO, which improved our cash position while diversifying our stockholder base. These accomplishments have set the stage for what we expect will be an important year in 2013 as we move toward completion of our Phase 3 POISE trial in PBC and build further on the analyses from two large international clinical data sets closely correlating the biochemical response we are evaluating in POISE with clinical outcomes," said Mark Pruzanski, M.D., Chief Executive Officer and President of Intercept.

OCA Development

Completion of Enrollment in POISE

We completed enrollment of POISE in December 2012. By randomizing 217 patients, we exceeded the target of 180 patients by approximately 20% while completing enrollment in POISE more than three months faster than originally anticipated. The demographics and baseline disease characteristics of the patients enrolled are similar to those seen in our Phase 2 trial of OCA as a combination therapy in PBC patients. Results from the 12-month double-blind portion of POISE are anticipated to be available in the second quarter of 2014.

Strong Statistical Correlation of PBC Endpoint with Clinical Outcomes

We are sponsoring an independent study involving at least 15 leading PBC centers worldwide, collectively named the Global PBC Study Group, that are pooling their long-term patient data to further corroborate the ability of the biochemical parameters alkaline phosphatase (ALP) and bilirubin to predict clinical outcomes such as liver transplant and death. We anticipate data from at least 4,000 patients will be collected and analyzed as part of this study. Results for more than 2,100 patients will be disclosed in a poster presentation at the annual meeting of the European Association for the Study of the Liver (EASL) to be held in April 2013. The analysis confirms that the POISE trial primary endpoint, a composite of ALP and bilirubin, has a highly statistically significant correlation with improved long-term liver transplant-free survival. We anticipate that final results will be available by the end of 2013 and will support what we believe is an emerging consensus among PBC opinion leaders concerning the clinical utility of our selected endpoint.

Another independent PBC study group in the United Kingdom (UK) recently published data in the March 2013 issue of *Gastroenterology* from an observational study of over 2,300 PBC patients recruited from every hospital in the UK. The results show that there is a highly statistically significant correlation between ALP, both alone and together with other biochemical parameters such as bilirubin, and clinical outcomes. Several different threshold values of ALP were tested and it was demonstrated that reductions in ALP levels down through to less than 1.5 times upper limit normal (ULN) are strongly predictive of clinical benefit.

Positive Initial Data in Phase 2 Portal Hypertension Trial (PESTO):

We announced initial results from PESTO, an open-label Phase 2a trial evaluating the effects of OCA for the treatment of portal hypertension. Twelve patients with established alcoholic cirrhosis and portal hypertension were administered a 10mg daily dose of OCA for seven or more days. OCA was well tolerated in all twelve patients and five of the eight patients assessed for changes in portal pressure met the primary efficacy endpoint of a reduction in hepatic venous pressure gradient (HVPG) of at least 15% or to less than 12 mm Hg. These results were presented at the American Association for the Study of Liver

Disease (AASLD)'s annual Liver Meeting in Boston on November 12, 2012. We anticipate completing the trial in the fourth quarter of 2013.

***Progress in Phase 2 NASH Trials (FLINT and DSP Japanese Trial)*:**

In November 2012, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH) informed us that enrollment of the FLINT trial had been completed with 280 adult NASH patients randomized to either a once-daily 25mg dose of OCA or placebo. The trial duration is 72 weeks and we anticipate that final results will be available in late 2014.

Our collaborator Dainippon Sumitomo Pharma (DSP) has initiated a second Phase 2 clinical trial of OCA in adult NASH patients in Japan. The trial is evaluating the efficacy and safety of a once-daily dose of OCA as compared to placebo, with the goal of enrolling 200 patients. DSP expects to complete the trial in the first half of 2016.

Positive Data in Phase 2 Primary Bile Acid Diarrhea Trial (OBADIAH)

Investigators at the Imperial College of London are conducting an ongoing Phase 2a trial of OCA, named OBADIAH, as a treatment for primary bile acid diarrhea (PBAD). PBAD is a common chronic diarrheal condition caused by excessive bile acid production and loss due to inadequate release of FGF19, a hormone that directly regulates bile acid synthesis in the liver. The initial results from this trial demonstrate that treatment with OCA is associated with a statistically significant improvement in clinical symptoms and increased levels of FGF19. An abstract based on initial results in OBADIAH has been accepted for presentation at the 2013 Digestive Diseases Week (DDW) annual conference in May 2013. We currently anticipate that the enrollment for the OBADIAH trial will be completed in mid-2013 and that final results for all three study groups will be available in the second half of 2013.

2012 Fourth Quarter and Full-Year Financial Results

Cash Position

As of December 31, 2012, our cash, cash equivalents and investment securities available for sale totaled approximately $110.2 million, compared to $17.7 million at December 31, 2011. In October 2012, we sold 5.75 million shares of common stock at $15.00 per share in our IPO for net proceeds of approximately $78.7 million. In August 2012, we completed a $30 million private placement led by OrbiMed Advisors. Based upon our currently expected level of operating expenditures, we believe that we will be able to fund our operations through mid-2015. This estimate reflects our enrollment of a greater number of patients in our POISE trial than originally planned; additional nonclinical studies and clinical trials to support our planned regulatory submissions for OCA in PBC; and an anticipated increase in pre-commercial activities for OCA in PBC.

Net Income/Loss

Year Ended December 31, 2012

Net loss attributable to common stockholders for the full year 2012 was $46.3 million, or $7.36 per share, compared to a net loss of $15.7 million, or $4.73 per share, for the full year 2011.

Our results show an increase in research and development expenses of $4.8 million in 2012 as compared to 2011, primarily due to increased activities in our development program for OCA. This increase in R&D expense includes $1.2 million of additional non-cash stock-based compensation compared to 2011. General and administrative expenses increased by $1.0 million compared to 2011, primarily due to a $243,000 increase in non-cash stock-based compensation.

Other expenses increased by $25.8 million in 2012 as compared to 2011, primarily due to an increase of $25.7 million in the non-cash charge related to the periodic revaluation of our warrant liability in 2012 as compared to 2011. This increase was primarily attributable to the significant increase in the market price of our common stock in 2012 subsequent to our IPO. In connection with prior equity financings, Intercept issued warrants that are classified as liabilities and are adjusted to fair value on a quarterly basis with the change in fair value being included in net loss. The amount included in net loss is a non-cash item as Intercept is not required to expend any cash to settle the warrant liability. The warrant liability is primarily affected by changes in Intercept's stock price during each financial reporting period, which causes the warrant liability to fluctuate as the market price of Intercept's stock fluctuates.

Quarter Ended December 31, 2012

Net loss attributable to common stockholders for the fourth quarter ended December 31, 2012 was $30.8 million, or $2.02 per share, compared to a net loss of $4.4 million, or $1.32 per share, for the same period in 2011. The increase in net loss is primarily due to the increase of $25.0 million in the non-cash charge related to the periodic revaluation of our warrant liability,

caused by the significant increase in the market price of our common stock compared to 2011, and to a lesser extent an increase in operating expenses of $1.8 million, reflecting increased expenses for development of OCA.

Today's Conference Call at 5:30 p.m. ET

We will hold our 2012 financial results and business update conference call and webcast today at 5:30 p.m. ET. The live event will be available on the investor page of our website at http://ir.interceptpharma.com or by calling (877) 312-5376 (domestic) or (216) 586-6841 (international) five minutes prior to the start time and providing the pass code 22293430. A replay of the call will be available on our website approximately two hours after the completion of the call and will be archived for two weeks.

About Intercept

Intercept is a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat orphan and more prevalent liver diseases utilizing its expertise in bile acid chemistry. The company's lead product candidate, obeticholic acid (OCA), is a bile acid analog and first-in-class agonist of the farnesoid X receptor (FXR). OCA is initially being developed for the second line treatment of primary biliary cirrhosis (PBC) in patients with an inadequate response to, or who are unable to tolerate, ursodiol, the only approved therapy for this indication. OCA has received orphan drug designation in both the United States and Europe for the treatment of PBC. Intercept owns worldwide rights to OCA outside of Japan and China, where it has out-licensed the product candidate to Dainippon Sumitomo Pharma. For more information about Intercept, please visit the Company's website at: www.interceptpharma.com.

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the clinical, preclinical and regulatory developments for our product candidates, the anticipated results of our clinical and preclinical trials and other development activities, potential timeframes for our and our collaborators' clinical and preclinical trials and other development activities, the clinical utility of our selected endpoint and any potential consensus relating thereto, anticipated trends relating to our financial position, and our strategic directives under the caption "About Intercept." These "forward-looking statements" are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: the initiation, cost, timing, progress and results of Intercept's development activities, preclinical studies and clinical trials; the timing of and Intercept's ability to obtain and maintain regulatory approval of OCA and any other product candidates it may develop, and any related restrictions, limitations, and/or warnings in the label of any approved product candidates; Intercept's plans to research, develop and commercialize future product candidates; the election by Intercept's collaborators to pursue research, development and commercialization activities; Intercept's ability to attract collaborators with development, regulatory and commercialization expertise; Intercept's ability to obtain and maintain intellectual property protection for its product candidates; Intercept's ability to successfully commercialize its product candidates; the size and growth of the markets for Intercept's product candidates and its ability to serve those markets; the rate and degree of market acceptance of any future products; the success of competing drugs that are or become available; regulatory developments in the United States and other countries; the performance of third-party suppliers and manufacturers; Intercept's ability to obtain additional financing; Intercept's use of the proceeds from its recently completed initial public offering; the accuracy of Intercept's estimates regarding expenses, future revenues, capital requirements and the need for additional financing; the loss of key scientific or management personnel; and other factors discussed under the heading "Risk Factors" contained in Intercept's quarterly report on Form 10-Q filed on November 26, 2012 and its annual report on Form 10-K for the year ended 2012 to be filed with the Securities and Exchange Commission, as well as any updates to these risk factors filed from time to time in Intercept's other filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Intercept undertakes no duty to update this information unless required by law.

Intercept Pharmaceuticals, Inc.

Condensed Consolidated Statements of Operations

(In thousands, except per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2011	2012	2011	2012
	(Unaudited)	(Unaudited)		(Unaudited)
Licensing revenue	$ 759	$ 405	$ 1,805	$ 2,446
Costs and expenses:				

Research and development	4,163	4,787	11,426	16,183
General and administrative	1,035	2,183	4,209	5,177
Total operating expenses	$ 5,198	$ 6,970	$ 15,635	$ 21,360
Other income (expense)				
Revaluation of warrants	776	(24,187)	1,045	(24,626)
Other income (expense), net	18	61	48	(104)
Net loss	$ (3,645)	$ (30,691)	$ (12,737)	$ (43,644)
Dividends on preferred stock, not declared	(750)	(130)	(3,000)	(2,630)
Net loss attributable to common stockholders	$ (4,395)	$ (30,821)	$ (15,737)	$ (46,274)
Net loss per common share, basic and diluted:	$ (1.32)	$ (2.02)	$ (4.73)	$ (7.36)
Weighted average number of shares of common stock outstanding, basic and diluted:	3,329,266	15,223,010	3,329,666	6,283,238

Condensed Consolidated Balance Sheet Information

(In thousands)

	December 31,	
	2011	**2012**
		(Unaudited)
Cash, cash equivalents and investment securities	$ 17,707	$ 110,194
Total assets	$ 19,470	$ 112,179
Working capital	$ 14,872	$ 98,814
Deferred revenue, total	$ 14,608	$ 12,162
Warrant liability, total	$ 5,836	$ 30,359
Total liabilities	$ 22,030	$ 46,267
Stockholders' equity	$ (2,560)	$ 65,912

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For Investors

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