August 13, 2013

Intercept Pharmaceuticals Reports Second Quarter 2013 Financial Results

NEW YORK, Aug. 13, 2013 /PRNewswire/ -- 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, such as primary biliary cirrhosis, today reported financial results for the quarter and six months ended June 30, 2013 and announced presentations at an upcoming medical conference and upcoming investor conferences.

Second Quarter 2013 Financial Results

Results of Operations

Six Months Ended June 30, 2013

For the six months ended June 30, 2013, Intercept reported a net loss of $23.7 million, or $1.41 per share, compared to a net loss of $9.3 million, or $2.78 per share, for the six months ended June 30, 2012. The $14.4 million increase in net loss was primarily due to the increase in the non-cash charge related to the periodic revaluation of warrant liability of $10.2 million and the increase in non-cash stock compensation of $2.7 million.

Licensing revenue decreased by $707,000 to $811,000 for the six months ended June 30, 2013, compared to $1.5 million for the corresponding period of the prior year, because the up-front payment related to the Servier collaboration was fully amortized as of the third quarter of 2012, and therefore no amortized revenue related to this upfront payment was recognized in 2013.

Research and development expenses increased to $10.0 million for the six months ended June 30, 2013, from $8.1 million for the corresponding period of the prior year, primarily as a result of increased activities in Intercept's development program for its product candidate, obeticholic acid (OCA). The increase in R&D expense includes an increase of $1.3 million in non-cash stock-based compensation for the six months ended June 30, 2013 compared to the corresponding period of the prior year.

General and administrative expenses increased to $5.3 million for the six months ended June 30, 2013 from $2.0 million for the corresponding period of the prior year, primarily as a result of costs associated with operating as a public company. The increase in G&A includes an increase of $1.5 million in non-cash stock-based compensation compared to the corresponding period of the prior year.

Non-operating expenses increased by $10.0 million in the six months ended June 30, 2013 as compared to the corresponding period of the prior year, primarily due to an increase of $10.2 million in the non-cash charge related to the periodic revaluation of warrant liability. This increase was primarily attributable to the increased market price of Intercept's common stock in 2013. In connection with equity financings prior to its IPO, 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 June 30, 2013

Net loss attributable to common stockholders for the second quarter ended June 30, 2013 was $13.5 million, or $0.79 per share, compared to a net loss of $5.8 million, or $1.75 per share, for the same period in 2012. The $7.6 million increase in net loss is primarily due to the increase of $5.9 million in the non-cash charge related to the periodic revaluation of warrant liability, primarily caused by the increase in the market price of Intercept's common stock, and increased non-cash stock compensation expense of $1.5 million.

Cash Position

As of June 30, 2013, Intercept's cash, cash equivalents and investment securities available for sale totaled approximately $161.8 million, compared to $110.2 million at December 31, 2012. In June 2013, Intercept sold 1,989,500 shares of common stock at $33.01 per share in a public offering for net proceeds of $61.4 million, after deducting underwriting discounts and

offering expenses. Based upon currently expected level of operating expenditures, Intercept believes that it will be able to fund its operations through early 2016. This estimate reflects the ongoing POISE trial and long-term safety extension of the POISE trial; nonclinical studies and clinical trials and consulting expenditures to support Intercept's planned regulatory submissions for OCA in PBC; anticipated pre-commercial activities for OCA in PBC; and IND-enabling studies of INT-767.

Symposium at Upcoming International Congress of Immunology

On the afternoon of August 25, 2013, Intercept will host a satellite symposium for physicians at the International Congress of Immunology being held in Milan, Italy from August 22-27, 2013. The satellite symposium will be moderated by Luciano Adorini, M.D., Intercept's Chief Scientific Officer, and focus on the genetics, pathogenesis and therapy of primary biliary cirrhosis.

Upcoming Investor Conferences

Intercept's Chief Executive Officer, Mark Pruzanski, M.D., will present at the following investor conferences in September:

- Morgan Stanley 2013 Global Healthcare Conference on September 9, 2013 at 2:25 p.m. Eastern Time at the Grand Hyatt hotel in New York City.
- Stifel Healthcare Conference 2013 on September 12, 2013 at 10:20 a.m. Eastern Time at the Four Seasons Hotel in Boston.

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.

Safe Harbor Statements

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 initial public offering and recently completed follow-on 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 annual report on Form 10-K for the year ended December 31, 2013 filed on April 1, 2013 and its quarterly report on Form 10-Q for the quarter ended March 31, 2013 filed on May 14, 2013, 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.

Condensed Consolidated Statements of Operations
(Unaudited and in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2013	2012	2013
Licensing revenue	$ 759	$ 405	$ 1,518	$ 811
Costs and expenses:				
Research and development	5,018	5,133	8,078	9,966
General and administrative	944	2,891	2,003	5,287
Total operating expenses	5,962	8,024	10,081	15,253
Other income (expense)				
Revaluation of warrants	302	(5,572)	979	(9,255)
Other income (expense), net	(184)	(287)	(182)	10
Net loss	$ (5,085)	$ (13,478)	$ (7,766)	$ (23,687)
Dividends on preferred stock, not declared	(750)	-	(1,500)	-
Net loss attributable to common stockholders	$ (5,836)	$ (13,477)	$ (9,266)	$ (23,687)
Net loss per common share, basic and diluted:	$ (1.75)	$ (0.79)	$ (2.78)	$ (1.41)
Weighted average number of shares of common stock outstanding, basic and diluted:	3,329,266	16,970,519	3,329,266	16,765,464

Condensed Consolidated Balance Sheet Information
(In thousands)

	December 31, 2012	June 30, 2013
	(audited)	(unaudited)
Cash, cash equivalents and investment securities	$ 110,194	$ 161,799
Total assets	112,179	163,869
Working capital	98,814	156,299
Deferred revenue, total	12,162	11,351
Warrant liability, total	30,359	32,574
Total liabilities	46,267	47,597
Stockholders' equity	65,912	116,272

SOURCE Intercept Pharmaceuticals

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