March 2, 2015

Intercept Pharmaceuticals Announces 2014 Financial Results

Conference Call Scheduled Monday, March 2nd at 8:30 a.m. ET

NEW YORK, March 2, 2015 (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, 2014. Intercept will hold a conference call and audio webcast today at 8:30 a.m. ET to review this information with conference call details provided below.

2014 Full-Year Financial Results

As of December 31, 2014, Intercept's cash, cash equivalents and investment securities available for sale totaled approximately $239.7 million, compared to $144.8 million at December 31, 2013. The net $94.9 million increase is primarily due to the net proceeds of $183.5 million from a public equity offering in April 2014 offset by $87.7 million in cash outflows from operations.

In February 2015, Intercept completed an underwritten public offering of 1,150,000 shares of common stock. All shares in the offering were sold by Intercept at a public offering price of $176.00 per share. Intercept estimates that net proceeds were approximately $191.2 million, after deducting underwriting discounts and commissions and estimated offering expenses.

Net loss attributable to common stockholders for the full year 2014 was $283.2 million, or $13.63 per share, compared to a net loss of $67.8 million, or $3.76 per share, for the full year 2013, representing an increase of $215.4 million, or $9.87 per share. The 2014 net loss includes $170.8 million of non-cash warrant revaluation expense, an increase of $142.4 million from 2013, and $20.1 million in non-cash stock-based compensation expense, an increase of $10.7 million from 2013.

During 2014, expenditures in the OCA development program increased by $34.8 million as Intercept focused its resources on completing the work and studies necessary for its planned New Drug Application and Marketing Authorization Application filings for OCA for the treatment of PBC, which are currently planned to be completed during the first half of 2015. In addition, Intercept also expanded its pre-commercialization activities resulting in an increase of approximately $6.8 million in expenses. Intercept also increased its operating costs such as legal, office and technology related expenses by approximately $5.1 million. In 2014, Intercept had an increase in cash compensation expenses of $12.4 million, primarily due to an overall increase in the personnel base by 96 employees.

As previously described, for the full year 2015, Intercept continues to project adjusted operating expenses in the range of $180 to $200 million, which exclude stock-based compensation and other non-cash items. These expenses will support the clinical development program for OCA in PBC, NASH and PSC, expansion of Intercept's clinical, regulatory, medical affairs and commercial infrastructure in the United States and Europe, expansion of OCA manufacturing activities, as well as advancement of INT-767 and other preclinical pipeline programs. Adjusted operating expense, as presented above, is a non-GAAP financial measure. Intercept anticipates that stock-based compensation expense will represent the most significant non-cash item that is excluded in adjusted operating expenses as compared to operating expenses under GAAP.

Conference Call on March 2 at 8:30 a.m. ET

Intercept will hold its 2014 financial results conference call and webcast on Monday, March 2 at 8:30 a.m. ET. The live event will be available on the investor page of Intercept's website at http://ir.interceptpharma.com or by calling (855) 232-3919 (toll-free domestic) or (315) 625-6894 (international) five minutes prior to the start time. A replay of the call will be available on Intercept's website approximately two hours after the completion of the call and will be archived for two weeks.

AASLD Colloquium and Investor Event on March 20, 2015

New subgroup analyses from the Phase 2b FLINT trial of obeticholic acid (OCA) in patients with nonalcoholic steatohepatitis (NASH) will be presented at a poster session at the American Association for the Study of Liver Disease (AASLD) Industry Colloquium for Novel Targets and Therapies in Liver Disease on March 20, 2015 in Durham, North Carolina. Presentation details are as follows:

Poster Session Date and Time: March 20, 2015, 12:20 PM - 1:45 PM

Location: University Ballroom Hall, Hilton Durham, Durham/Research Triangle Park, North Carolina

Presentation 1: Obeticholic Acid For The Treatment Of NASH: Characterization Of Effects On Cardiometabolic Parameters

Presentation 2: Obeticholic Acid For The Treatment Of NASH: Efficacy In High-Risk Patients

Intercept management will host an event for analysts and investors after the market close on Friday, March 20, 2015 to discuss these subgroup analyses. Additional details on this event will be made available on Intercept's investor relations website at ir.interceptpharma.com.

About Intercept

Intercept is a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat neglected chronic 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 being developed for a variety of chronic liver diseases, including primary biliary cirrhosis (PBC), nonalcoholic steatohepatitis (NASH), primary sclerosing cholangitis (PSC) and biliary atresia. The FDA has designated OCA as a breakthrough therapy for the treatment of NASH with fibrosis and granted OCA fast track designation for the treatment of patients with PBC who have an inadequate response to or are intolerant of ursodiol. OCA has also received orphan drug designation in both the United States and Europe for the treatment of PBC and PSC. Intercept owns worldwide rights to OCA outside of Japan, China and Korea, where it has out-licensed the product candidate to Sumitomo Dainippon Pharma. For more information about Intercept, please visit the Company's website at: www.interceptpharma.com.

Non-GAAP Financial Measures

This press release presents projected adjusted operating expense, which is a non-GAAP measure and should be considered in addition to, but not as a substitute for, operating expense that Intercept prepares and announces in accordance with GAAP. Intercept excludes certain items from adjusted operating expense, such as stock-based compensation and other non-cash items, that management does not believe affect Intercept's basic operations and that do not meet the GAAP definition of unusual or non‑recurring items. A reconciliation of projected non-GAAP adjusted operating expense to operating expense calculated in accordance with GAAP is not available on a forward-looking basis without unreasonable effort due to an inability to make accurate projections and estimates related to certain information needed to calculate, for example, future stock-based compensation expense. Management also uses adjusted operating expense to establish budgets and operational goals and to manage Intercept's business. Other companies may define this measure in different ways. Intercept believes this presentation provides investors and management with supplemental information relating to operating performance and trends that facilitate comparisons between periods and with respect to projected information.

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 anticipated trends relating to our financial position, including expected adjusted operating expense, 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 important 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 our development activities, preclinical studies and clinical trials; the timing of and our ability to obtain and maintain regulatory approval of OCA, INT-767 and any other product candidates we may develop, particularly the possibility that regulatory authorities may require clinical outcomes data (and not just results based on achievement of a surrogate endpoint) as a condition to any marketing approval for OCA, and any related restrictions, limitations, and/or warnings in the label of any approved product candidates; our plans to research, develop and commercialize our product candidates; the election by our collaborators to pursue research, development and commercialization activities; our ability to attract collaborators with development, regulatory and commercialization expertise; our ability to obtain and maintain intellectual property protection for its product candidates; our ability to successfully commercialize our product candidates; the size and growth of the markets for our product candidates and our 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; our need for and ability to obtain additional financing; our estimates regarding expenses, future revenues and capital requirements and the accuracy thereof; our ability to retain key scientific or management personnel; and other factors discussed under the heading "Risk Factors" contained in our annual report on Form 10-K for the year ended December 31, 2013 as well as any updates to these risk factors filed from time to time in our 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

(In thousands, except per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2013	2014	2013	2014
Licensing revenue	$ 405	$ 445	$ 1,622	$ 1,742
Costs and expenses:				
Research and development	9,583	23,718	27,942	80,311
General and administrative	4,729	11,859	13,132	34,601
Total operating expenses	$ 14,313	$ 35,577	$ 41,073	$ 114,912
Other income (expense)				
Revaluation of warrants	1,570	--	(28,441)	(170,832)
Other (expense) income net	(31)	308	100	776
	1,539	308	(28,341)	(170,056)
Net loss	$ (12,369)	$ (34,824)	$ (67,792)	$ (283,226)
Net loss per common share, basic and diluted:	$ (0.64)	$ (1.63)	$ (3.76)	$ (13.63)
Weighted average number of shares of common stock outstanding, basic and diluted:	19,343,880	21,381,752	18,028,731	20,784,438

Condensed Consolidated Balance Sheet Information

(In thousands)

	December 31,	
	2013	2014
Cash, cash equivalents and investment securities	$ 144,832	$ 239,724
Total assets	$ 150,319	$ 254,149
Working capital	$ 138,683	$ 230,587
Deferred revenue, total	$ 10,541	$ 9,799
Warrant liability, total	$ 50,112	$ --
Total liabilities	$ 67,912	$ 23,258
Stockholders' equity	$ 82,406	$ 230,891

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