May 7, 2014

Intercept Pharmaceuticals Reports First Quarter 2014 Financial Results

NEW YORK, May 7, 2014 (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, such as primary biliary cirrhosis (PBC) and nonalcoholic steatohepatitis (NASH), today reported financial results for the first quarter of 2014 and provided other general business updates. Intercept will hold a conference call and audio webcast today at 4:30 p.m. ET to review this information with conference call details provided below.

Summary of Key Development Programs, Updates and Anticipated Milestones

- PBC Program
  - Phase 3 POISE trial met primary and secondary endpoints
  - Dose titration of OCA in POISE resulted in the lowest incidence of pruritus in PBC patients to date; pruritus severity (assessed by a visual analog scale) after six months of OCA therapy no different than placebo
  - Phase 3 confirmatory trial protocol finalization anticipated in 3Q 2014 and initiation around year-end 2014
  - Planned and ongoing Phase 1 clinical trials required for regulatory filings anticipated to be completed in early 2015
  - Pre-NDA and pre-MAA meetings anticipated in 2H 2014 with completed filings anticipated in 1H 2015
- NASH Program
  - FLINT unblinded data anticipated to be provided to Intercept in July 2014
  - NIDDK anticipates submitting FLINT as late-breaker to AASLD conference in November
  - Phase 3 program initiation anticipated in 1H 2015 pending FLINT data review and regulatory feedback
  - Phase 2 lipid metabolism trial initiation anticipated in 4Q 2014
  - Preclinical data on prevention of cirrhosis complications presented at EASL conference
- Primary Sclerosing Cholangitis (PSC) Program
  - Double-blind phase 2 trial initiation anticipated year-end 2014
  - First clinical trial of OCA in this disease
  - PSC is an orphan indication with high unmet medical need
- Portal Hypertension: PESTO Phase 2 Trial
  - Results from primary enrolling center presented at EASL conference
- Bile Acid Diarrhea: OBADIAH Phase 2 Trial
  - Positive results in primary and secondary BAD presented at DDW conference
  - Data demonstrate improvement in clinical symptoms related to increase in FGF19 and reduction in bile acid levels
- INT-767 Phase 1 Trial Initiation Anticipated in 1H 2015

First Quarter 2014 Financial Results

Intercept reported a net loss of $257.7 million, or $13.21 per share, for the first quarter of 2014, compared to a net loss of $10.2 million, or $0.62 per share, for the first quarter of 2013. Included in the net loss are non-cash expenses totaling $245.7 million comprised primarily of warrant revaluation expense of $226.6 million and stock-based compensation expense of $19.1 million.

Research and development expenses increased to $25.9 million for the first quarter of 2014, compared to $4.8 million for the first quarter of 2013, primarily as a result of an increase in non-cash stock-based compensation of $16.9 million and increased activities in our PBC development program for our product candidate, obeticholic acid (OCA).

General and administrative expenses increased to $5.7 million for the first quarter of 2014, compared to $2.4 million for the comparable period in the previous year, primarily as a result of increased pre-commercial activities and an increase in costs associated with operating as a public company. The increase in G&A includes an increase of $500,000 in non-cash stock-based compensation compared to the first quarter of 2013.

Non-operating expenses increased by $223.1 million in the first quarter of 2014 as compared to the same period in 2013, primarily due to an increase of $222.9 million in the non-cash charge related to the periodic revaluation of our warrant liability in the first quarter of 2014 as compared to 2013. This increase was primarily attributable to the significant increase in the market price of our common stock in the first quarter of 2014 following the news that the double-blind treatment phase of the FLINT trial was stopped early after a planned interim analysis showing that OCA had met the primary efficacy endpoint of the trial based on a pre-defined interim efficacy criterion. 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.

On April 10, 2014, all 865,381 warrants outstanding as of March 31, 2014 were exercised on a cashless basis and converted into 834,758 shares of Intercept common stock. As such, the Company will record a final adjustment of approximately $56 million in non-cash income in the second quarter of 2014.

As of March 31, 2014, Intercept had cash, cash equivalents and investment securities available for sale of approximately $134.1 million, compared to $144.8 million as of December 31, 2013. In April 2014, Intercept completed an underwritten public offering of 1,000,000 shares of common stock, of which 600,000 shares were sold by Intercept and 400,000 shares were sold by certain selling stockholders, at a public offering price of $320.00 per share. Intercept received net proceeds of approximately $183.4 million, after deducting underwriting discounts and estimated offering expenses. Intercept's cumulative cash, cash equivalents and investments securities inclusive of the proceeds from the April 2014 public offering are expected to fund operations through 2016.

Conference Call on May 7 at 4:30 p.m. ET

The company will hold its first quarter 2014 financial results and business update conference call and webcast on Wednesday, May 7 at 4:30 p.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 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 and intestinal 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), portal hypertension, bile acid diarrhea and primary sclerosing cholangitis (PSC). OCA has 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 and China, where it has out-licensed the product candidate to Dainippon Sumitomo Pharma (DSP). 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, our potential development and regulatory milestones and the timeframes under which we anticipate such milestones may be achieved, the clinical utility of our selected endpoint and any potential consensus relating thereto, anticipated trends relating to our financial position, including the sufficiency of our cumulative cash, cash equivalents and investments securities, 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 filed on March 14, 2014 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 March 31,	
	2013	**2014**
	(unaudited)	(unaudited)
Licensing revenue	$ 405	$ 405
Costs and expenses:		
Research and development	4,833	25,930
General and administrative	2,397	5,651
Total operating expenses	7,229	31,581
Other income (expense)		
Revaluation of warrants	(3,683)	(226,627)
Other income (expense), net	296	136
Net loss	$ (10,210)	$ (257,666)
Net loss attributable to common stockholders	$ (10,210)	$ (257,666)
Net loss per common share, basic and diluted:	$ (0.62)	$ (13.21)
Weighted average number of shares of common stock outstanding, basic and diluted:	16,558,297	19,504,748

Condensed Consolidated Balance Sheet Information

(In thousands)

	Period Ended	
	December 31, 2013	**March 31, 2014**
	(audited)	(unaudited)
Cash, cash equivalents and investment securities	$ 144,832	$ 134,105
Total assets	$ 150,319	$ 141,894
Working capital	$ 138,683	$ (148,223)
Deferred revenue, total	$ 10,541	$ 10,135
Warrant liability, total	$ 50,112	$ 276,739
Total liabilities	$ 67,912	$ 295,638
Stockholders' equity (deficit)	$ 82,406	$ (153,744)

CONTACT: For more information about Intercept,

please contact Barbara Duncan or Senthil Sundaram,

both of Intercept Pharmaceuticals at 1-646-747-1000.

Media inquiries: media@interceptpharma.com

Investor inquiries: investors@interceptpharma.com