February 23, 2016

Intercept Pharmaceuticals Reports 2015 Financial Results and Provides Business Update

NEW YORK, Feb. 23, 2016 (GLOBE NEWSWIRE) -- Intercept Pharmaceuticals, Inc. (Nasdaq:ICPT), a clinical stage biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat non-viral, progressive liver diseases, today reported financial results for the fourth quarter and full year ended December 31, 2015 and provided other general business updates. Intercept will hold a conference call and audio webcast today at 8:00 a.m. Eastern Time to review this information with conference call details provided below.

Summary of Program Progress

- Primary Biliary Cirrhosis (recently renamed Primary Biliary Cholangitis [PBC]) Program
  - Completed NDA/MAA filings for PBC June 2015
  - Priority Review granted by FDA August 2015
- Nonalcoholic Steatohepatitis (NASH) Program
  - Breakthrough therapy designation granted from FDA for OCA in NASH with liver fibrosis in January 2015
  - REGENERATE Phase 3 trial in non-cirrhotic NASH patients with liver fibrosis initiated September 2015
  - CONTROL Phase 2 statin trial initiated December 2015
- Primary Sclerosing Cholangitis (PSC) Program
  - AESOP Phase 2 trial continued enrollment
- Biliary Atresia Program
  - CARE Phase 2 trial initiated October 2015
- INT-767 Program
  - Phase 1 trial initiated November 2015

Planned 2016 Milestones

- PBC Program
  - Scheduled FDA Advisory Committee meeting April 7, 2016
  - PDUFA date May 29, 2016 with planned US launch in June if NDA is approved
  - Anticipated EU marketing authorization application decision in late 2016
- NASH Program
  - Continued enrollment of REGENERATE and CONTROL trials
  - Planning of NASH cirrhosis and non-invasive technology trials
- INT-767 Program
  - Completion of Phase 1 trial and planning of Phase 2 trial

"2015 was a transformative year for Intercept, highlighted by the filing of our first NDA and MAA for OCA, the transition of the company to a commercial ready organization, and the initiation of REGENERATE, the first Phase 3 registrational trial ever conducted in NASH," said Mark Pruzanski, M.D., Chief Executive Officer and President of Intercept. "We remain focused on obtaining regulatory approval of OCA in PBC in both the U.S. and Europe in 2016 and are preparing to launch OCA in these markets. At the same time, we plan to continue executing in our global NASH development program across our various ongoing and planned clinical trials."

2015 Full Year Financial Results

Net loss for the full year 2015 was $226.4 million, compared to a net loss of $283.2 million for the full year 2014, representing a decrease of $56.8 million. Net loss for the full year 2015 included $34.2 million of non-cash stock-based compensation expense. The 2014 net loss included $170.8 million of non-cash warrant revaluation expense and $20.1 million in non-cash stock-based compensation expense. GAAP operating expenses for the full year 2015 was $231.9 million as compared to $114.9 million for the full year 2014, representing an increase of approximately $117.0 million. Adjusted operating expenses[1] for the full year 2015 was $196.1 million as compared to $94.3 million for the full year 2014,

representing an increase of approximately $101.7 million.

Research and development (R&D) expenses increased to $128.2 million for the full year 2015 from $80.3 million for the full year 2014. The $47.9 million net increase is primarily due to additional personnel on Intercept's development team to manage the increased activities around the OCA development program; increased non-personnel expenses for the OCA development program; and increased expenses related to the INT-767 and preclinical programs.

General and administrative (G&A) expenses increased to $103.7 million for the full year 2015 from $34.6 million for the full year 2014. The increase in G&A expenses of $69.1 million was primarily due to increased expenses related to pre-commercialization activities both in the U.S. and internationally; and additional personnel to manage the increased operational activities, as well as increased operating costs such as legal, facilities and technology-related expenses.

For the full year 2014, Intercept recorded a $170.8 million non-cash charge related to the periodic revaluation of a warrant liability primarily attributable to the significant increase in the market price of Intercept's common stock in that period. In connection with equity financings prior to its initial public offering, Intercept had issued warrants that were classified as liabilities and were 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 was a non-cash item as Intercept was not required to expend any cash to settle the warrant liability. On April 10, 2014, all warrants outstanding as of March 31, 2014 were exercised on a cashless basis and converted into shares of Intercept common stock. As such, Intercept recorded a final adjustment of approximately $56 million in non-cash income in the second quarter of 2014 and no further revaluations are necessary.

Cash Position & 2016 Operating Guidance

As of December 31, 2015, Intercept had cash, cash equivalents and investment securities available for sale of approximately $628.1 million, compared to $239.7 million as of December 31, 2014. The increase is primarily due to the completion of two follow-on public equity offerings during 2015 resulting in net proceeds of approximately $558.7 million, offset by increased adjusted operating expenses discussed above.

Intercept currently projects adjusted operating expenses in the range of $360 million to $400 million in the fiscal year ending December 31, 2016, which excludes stock-based compensation and other non-cash items. These expenses are planned to support the continued clinical development program for OCA in PBC, NASH and PSC, increased OCA manufacturing activities, the continued development of INT-767 and other preclinical programs, as well as pre-commercial and commercial activities in both the U.S. and internationally. The build out of Intercept's U.S. commercial infrastructure is mostly complete with the recent hiring of the U.S. territory business managers and other field personnel in October 2015. Intercept also significantly expanded its commercial and other international infrastructure in 2015, and plans on making additional investments over 2016 should key regulatory milestones be achieved.

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. Adjusted operating expense is a financial measure not calculated in accordance with GAAP.

Conference Call on February 23rd at 8:00 a.m. ET

Intercept will hold its 2015 full year financial results conference call and webcast on Tuesday, February 23rd at 8:00 a.m. ET. The live event will be available on the investor page of the Intercept 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 (no passcode is required). A replay of the call will be available on the Intercept 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 chronic non-viral, progressive liver diseases. The Company's lead product candidate, obeticholic acid (OCA), is a farnesoid X receptor (FXR) agonist. OCA is being developed to treat a variety of chronic liver diseases, including primary biliary cirrhosis, also known as primary biliary cholangitis (PBC), nonalcoholic steatohepatitis (NASH), primary sclerosing cholangitis (PSC) and biliary atresia. The FDA has granted OCA breakthrough therapy designation for the treatment of NASH with liver fibrosis and granted OCA fast track designation for the treatment of patients with PBC. 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. Intercept's pipeline of product candidates includes other novel bile acid analogs such as INT-767, which is in clinical development. For more information about Intercept, please visit the Company's website at: www.interceptpharma.com.

Non-GAAP Financial Measures

This press release presents adjusted operating expense, which is a non-GAAP measure, both on a historical and projected basis. Adjusted operating expense 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 depreciation, that management does not believe affect Intercept's basic operations and that do not meet the GAAP definition of unusual or nonrecurring items.

A table reconciling historical operating expense to non-GAAP adjusted operating expense is included below under the heading "Reconciliation of GAAP to Non-GAAP Operating Expense." A reconciliation of projected adjusted operating expense calculated in accordance with GAAP to non-GAAP operating expense 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 our financial position, including expected adjusted operating expenses, the activities anticipated to be undertaken by us, the initiation, conduct and completion of clinical trials, the regulatory process with respect to our product candidates, our ongoing and anticipated buildout and hiring to support our growing business operations 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 our 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, 2014 filed on March 2, 2015 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.

[1] Adjusted operating expense, as presented above, is a non-GAAP financial measure. Adjusted operating expense excludes stock-based compensation and other non-cash items from GAAP operating expenses. A table reconciling adjusted operating expense to GAAP operating expense is included below under the heading "Reconciliation of GAAP to Non-GAAP Operating Expense."

Condensed Consolidated Statements of Operations
(In thousands, except per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2015	**2014**	**2015**	**2014**
Licensing revenue	$ 447	$ 445	$ 2,782	$ 1,742
Costs and expenses:				

Research and development	44,445	23,718	128,193	80,311
General and administrative	44,891	11,859	103,745	34,601
Total operating expenses	89,336	35,577	231,937	114,912
Other income (expense)				
Revaluation of warrants	-	-	-	(170,832)
Other income (expense), net	637	308	2,727	776
Net loss	$ (88,252)	$ (34,824)	$ (226,429)	$ (283,226)
Net loss attributable to common stockholders	$ (88,252)	$ (34,824)	$ (226,429)	$ (283,226)
Net loss per common share:				
Basic	$ (3.62)	$ (1.63)	$ (9.56)	$ (13.63)
Weighted average number of shares of common stock outstanding:				
Basic	24,351	21,382	23,694	20,784

Condensed Consolidated Balance Sheet Information
(In thousands)

	December 31,	
	2015	**2014**
Cash, cash equivalents and investment securities	$ 628,055	$ 239,724
Total assets	$ 655,758	$ 254,149
Deferred revenue, total	$ 8,017	$ 9,799
Total liabilities	$ 53,609	$ 23,258
Stockholders' equity	$ 602,149	$ 230,891

Reconciliation of GAAP to Non-GAAP Operating Expense
(In thousands)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2015	**2014**	**2015**	**2014**
Total operating expense	$ 89,336	$ 35,577	$ 231,937	$ 114,912
Adjustments:				
Stock-based compensation	12,151	3,663	34,189	20,127
Depreciation	623	233	1,691	443
Adjusted operating expense	$ 76,562	$ 31,681	$ 196,057	$ 94,342

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