Intec Pharma Reports 2015 Fourth Quarter and Full-Year Financial Results

March 14, 2016

JERUSALEM, ISRAEL--(Marketwired - Mar 14, 2016) - Intec Pharma Ltd. (NASDAQ: NTEC) (TASE: INTP), an Israeli clinical stage biopharmaceutical company focused on developing drugs based on its proprietary Accordion Pill platform technology, today announced its financial results for the year ended December 31, 2015 and provided a business update. Results are presented in New Israel Shekels (NIS) with a convenience translation to US Dollars ($) provided using the Bank of Israel exchange rate of NIS 3.902 to $1.00 at December 31, 2015.

Financial highlights for the year ended December 31, 2015 and for the fourth quarter of 2015

- **Research and Development Expenses, net** for the quarter ended December 31, 2015 were approximately NIS 7.9 million ($2 million), compared to NIS 3.3 million in the comparable quarter of 2014. Research and development expenses, net, for the year ended December 31, 2015 were approximately NIS 18.7 million ($4.8 million), compared to NIS 12.2 million for the year ended December 31, 2014. The increase in both periods resulted primarily from an increase in expenses related to preparation for our Phase III clinical trial for our lead product, the Accordion Pill Carbidopa/Levodopa, or AP-CDLD, for the treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients, payroll and related expenses and other expenses associated with our Phase III clinical trial for AP-CDLD, which were partially offset by increases in research and development-related grants and participation in research and development expenses from the Office of the Chief Scientist of the Israeli Ministry of Economy received in 2015 compared to 2014.

- **General and Administrative Expenses** for the quarter ended December 31, 2015 were approximately NIS 3.4 million ($871,000), compared to NIS 2.4 million in the comparable quarter of 2014. General and administrative expenses for the year ended December 31, 2015 were approximately NIS 10.8 million ($2.8 million) compared to NIS 9.3 million for the year ended December 31, 2014. The increase in both periods resulted primarily due to an increase in professional services, payroll and related expenses and other expenses associated with being a public company in the United States since August 2015.

- **Financial Income, net** for the year ended December 31, 2015 was approximately NIS 1.6 million ($402,000) compared to approximately NIS 324,000 for the year ended December 31, 2014. The increase resulted primarily due from increase in foreign currency exchange, which was partially offset by a decrease in financial income from interest on cash equivalents and short term bank deposits.

- **Loss and Comprehensive Loss** for the year ended December 31, 2015 was NIS 27.9 million ($7.1 million) or NIS 3.58 ($0.92) per share, based on 7.8 million basic and diluted shares, compared with a loss and comprehensive loss of NIS 20.4 million or NIS 4.22 per share, based on 4.8 million basic and diluted shares, for the year ended December 31, 2014.

- **Net Cash Used in Operating Activities** for the year ended December 31, 2015 was approximately NIS 30.8 million ($7.9 million) compared to approximately NIS 17 million in the year ended December 31, 2014. This increase primarily resulted from an increase in our loss and comprehensive loss of approximately NIS 7.5 million and an increase in changes in operating asset and liability items of approximately NIS 6.3 million.

- **Net Cash Used in Investment Activities** for the year ended December 31, 2015 was approximately NIS 24.8 million ($6.4 million), compared to approximately NIS 9.7 million of net cash provided by investment activities for the year ended December 31, 2014. The change primarily resulted from an increase in the purchase of property and equipment in the amount of approximately NIS 5.4 million and from investment in a short-term bank deposit in the amount of approximately NIS 19.4 million.

- **Net Cash Provided by Financing Activities** for the year ended December 31, 2015 was approximately NIS 124.1 million ($31.8 million) compared to approximately NIS 17.2 million for the year ended December 31, 2014. The positive cash flow from financing activities for the year ended December 31, 2015 was primarily due to proceeds from our initial public offering in the United States in the amount of approximately NIS 116.8 million.

- **Cash, cash equivalents, short term bank deposits and financial assets at fair value** as of December 31, 2015 were

approximately NIS 119.7 million (approximately $30.7 million) as compared to approximately NIS 30.1 million as of December 31, 2014.

Zeev Weiss, CEO of Intec Pharma, said:

"2015 was an exciting year for Intec Pharma. During the year we addressed a number of very important milestones related to our platform technology, the Accordion Pill, as well as to our leading product candidate, AP-CDLD.

With respect to AP-CDLD, in May 2015 we agreed with the FDA on the remaining clinical development program for AP-CDLD for the treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients, including the main principles of the single required pivotal Phase III clinical trial in advanced Parkinson's disease patients, under the 505(b) (2) regulatory pathway. In December 2015, we received a U.S. centralized IRB approval to initiate a Phase III clinical trial of AP-CDLD.

With respect to the Accordion Pill technology, we significantly enhanced the manufacturing capabilities of Accordion Pills by completing the installation of a fully automated assembly line in September 2015. We have also expanded the IP protection of our technology with the grant of several important patents. In 2015, we also entered into an exciting collaboration agreement with Biogen and, in addition, we initiated a Phase I clinical trial with our third pipeline product, which is being developed for the prevention and treatment of gastroduodenal and small bowel NSAID induced ulcers.

In addition to the very important clinical, development and regulatory milestones that we achieved in 2015, this year was exciting for Intec Pharma, as we became a public company traded on NASDAQ after we successfully completed our US IPO, raising net proceeds of approximately $30 million.

We look forward to continuing the achievement of major milestones in 2016."

Recent highlights

- On March 10, 2016, we announced that we completed a Phase I clinical trial of our third pipeline product, which is being developed for the prevention and treatment of gastroduodenal and small bowel Nonsteroidal Anti-Inflammatory Drug (NSAID) induced ulcers and is based on a new Accordion Pill formulation with an existing drug. The Pharmacokinetics (PK) results demonstrated in this Phase I trial were within the well-defined safety levels of the drug, which enable us to proceed with further development of the Accordion Pill with the existing drug.
- On December 23, 2015, the European Patent Office (EPO) granted a European patent on our European Patent Application for a "Zaleplon gastroretentive drug delivery system." The patent, number EP 237883, protects one of our product candidates, Accordion Pill Zaleplon, which is being developed for the indication of treatment of insomnia, including sleep induction and the improvement of sleep maintenance. The patent is currently scheduled to remain in force until October 19, 2029.
- On December 14, 2015, we announced that we received a US centralized institutional review board (IRB) approval to initiate our Phase III clinical trial for our lead product, AP-CDLD for the treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients. Approximately 460 patients will be enrolled in this single pivotal Phase III study in advanced Parkinson's disease patients. The total treatment period for each patient will be 25 weeks. The primary efficacy endpoint will be a change from baseline to termination of treatment in the percent of daily off time during waking hours.
- On November 4, 2015, the European Patent Office (EPO) be granted our European Patent Application for a "Method and Apparatus for Forming Delivery Devices for Oral Intake of an Agent". The patent, number EP 1981465, protects a method of producing our Accordion Pill platform, and the Accordion Pill produced thereby. The platform may be made from any suitable substances, and is intended for oral delivery of any pharmaceutically active agent of interest. The patent is currently scheduled to remain in force until January 18, 2027.
- On October 12, 2015, we announced topline results of a Food Effect PK study of AP-CDLD 50/500mg for the treatment of Parkinson's disease symptoms. The results demonstrated that plasma concentrations of carbidopa and levodopa were similar, with no statistically significant differences in all PK parameters measured, when AP-CDLD was taken with various food compositions. This suggests that the treatment with AP-CDLD, intended to be taken b.i.d (two times a day) or t.i.d (three times a day) with food, is independent of the food content.
- On August 9, 2015, we closed an underwritten public offering in the U.S. of 5,025,000 ordinary shares at a price to the public of $6.00 per share. We received proceeds from the public offering of approximately $26.5 million, net of commissions to the underwriters and offering expenses. On September 17, 2015, the underwriters partially exercised their overallotment option and purchased an additional 638,750 ordinary shares at a price to the public of $6 per share. We received proceeds of approximately $3.48 million related to the overallotment exercise, net of commissions to the underwriters and offering expenses, bringing the total net proceeds to us from the initial public offering to approximately $30 million. Maxim Group LLC and Roth Capital Partners acted as joint book-running managers for the offering.

INTEC PHARMA LTD.

STATEMENTS OF FINANCIAL POSITION

	December 31	**Convenience translation into USD**

	2014	2015	December 31, 2015
	NIS in thousands		In thousands
Assets			
CURRENT ASSETS:			
Cash and cash equivalents	22,287	92,277	23,649
Short-term bank deposits		19,510	5,000
Financial assets at fair value through profit or loss	7,820	7,897	2,024
Restricted bank deposits	292	240	62
Other receivables	1,120	9,211	2,361
	31,519	129,135	33,096
NON-CURRENT ASSETS -			
Property and equipment	17,101	15,906	4,076
TOTAL ASSETS	48,620	145,041	37,172
Liabilities and equity			
CURRENT LIABILITIES -			
Accounts payable and accruals:			
Trade	716	2,394	614
Other	6,503	2,731	701
	7,219	5,125	1,315
NON-CURRENT LIABILITIES -			
Derivative financial instruments	4,528	1,277	327
COMMITMENTS AND CONTINGENT LIABILITIES			
TOTAL LIABILITIES	11,747	6,402	1,642
EQUITY:			
Ordinary shares	2,701	2,701	692
Share premium	198,566	328,985	84,312
Warrants	2,249	-	-
Accumulated deficit	(166,643)	(193,047)	(49,474)
TOTAL EQUITY	36,873	138,639	35,530
TOTAL LIABILITIES AND EQUITY	48,620	145,041	37,172

STATEMENT OF COMPREHENSIVE LOSS

	Year ended December 31			Convenience translation into USD
	2013	2014	2015	December 31, 2015
	NIS in thousands			In thousands
RESEARCH AND DEVELOPMENT EXPENSES	(17,410)	(17,740)	(29,257)	(7,498)
LESS- PARTICIPATION IN RESEARCH AND DEVELOPMENT EXPENSES	8,393	5,544	10,556	2,705
RESEARCH AND DEVELOPMENT EXPENSES, net	(9,017)	(12,196)	(18,701)	(4,793)
GENERAL AND ADMINISTRATIVE EXPENSES	(9,633)	(9,332)	(10,828)	(2,775)
OTHER GAINS, net	474	836	76	19
OPERATING LOSS	(18,176)	(20,692)	(29,453)	(7,549)
FINANCIAL INCOME	434	1,136	2,458	630
FINANCIAL EXPENSES	(648)	(812)	(889)	(228)
FINANCIAL INCOME (EXPENSES), net	(214)	324	1,569	402
LOSS AND COMPREHENSIVE LOSS	(18,390)	(20,368)	(27,884)	(7,147)
	NIS			USD
BASIC AND DILUTED LOSS PER ORDINARY SHARE	(4.25)	(4.22)	(3.58)	(0.92)

STATEMENTS OF CASH FLOWS

	Year ended December 31			Convenience translation into USD
	2013	2014	2015	December 31, 2015
	NIS in thousands			In thousands
CASH FLOWS FROM OPERATING ACTIVITIES:				
Loss for the year	(18,390)	(20,368)	(27,884)	(7,147)
Adjustments to reconcile loss and comprehensive loss to net cash provided from operations:				
Depreciation	2,176	2,092	2,898	743
Exchange differences on restricted deposits	(6)	(1)	3	*
Changes in the fair value of derivative financial instruments	(32)	729	829	212
Exchange differences on cash and cash equivalents	223	(535)	(1,478)	(379)
Exchange differences on short-term bank deposit			(85)	(22)
Losses (gains) on financial assets at fair value through profit or loss	(474)	51	(76)	(19)
Share-based compensation to investors	88	-	-	-
Share-based compensation to employees and service providers	1,829	1,207	1,480	379
Changes in operating asset and liability items:				
Decrease (increase) in other receivables	871	1,463	(8,091)	(2,073)
Increase (decrease) in accounts payable and accruals	1,497	(1,635)	1,608	413
Net cash used in operating activities	(12,218)	(16,997)	(30,796)	(7,893)
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchase of property and equipment	(5,376)	(271)	(5,405)	(1,385)
Investments in short-term deposits	-	-	(19,425)	(4,978)
Proceeds from disposal (purchase) of financial assets at fair value through profit or loss, net	(5,955)	10,016	(1)	*
Changes in restricted bank deposits, net	76	(31)	49	12
Net cash provided by (used in) investing activities	(11,255)	9,714	(24,782)	(6,351)
CASH FLOWS FROM FINANCING ACTIVITIES:				
Issuance of shares through public offering, net of issuance costs	-	-	116,780	29,928
Exercise of warrants (series 7)	-	-	7,310	1,874
Exercise of warrants (series 3)	251	-	-	-
Exercise of options by employees and service providers	548	579	*	*
Issuance of shares and warrants as part of an investment agreement, net of issuance costs	17,692	-	-	-
Issuance of shares as part of an addendum to the investment agreement	-	101	-	-
Issuance of shares and warrants, net of issuance costs	15,015	16,592	-	-
Net cash provided by financing activities	33,506	17,272	124,090	31,802
INCREASE IN CASH AND CASH EQUIVALENTS	10,033	9,989	68,512	17,558
CASH AND CASH EQUIVALENTS - BEGINNING OF YEAR	1,953	11,763	22,287	5,712
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(223)	535	1,478	379
CASH AND CASH EQUIVALENTS - END OF YEAR	11,763	22,287	92,277	23,649
Information regarding investment and financing activities not involving cash flows:				
Liability with respect to property purchase order		3,931		
Settlement of liability in respect to derivative financial instrument to equity		6,499	4,080	1,046
Supplementary information to the statement of cash flows -				
Interest received	402	617	171	44

About Intec Pharma Ltd.

Intec Pharma is a clinical stage biopharmaceutical company focused on developing drugs based on its proprietary Accordion Pill platform technology. The Company's Accordion Pill is an oral drug delivery system that is designed to improve the efficacy and safety of existing drugs and drugs in

development by utilizing an efficient gastric retention and specific release mechanism. The Company's product pipeline currently includes three product candidates in clinical trial stages: Accordion Pill Carbidopa/Levodopa, or AP-CDLD, is being developed for the indication of treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients, Accordion Pill Zaleplon, or AP-ZP, is being developed for the indication of treatment of insomnia, including sleep induction and the improvement of sleep maintenance and an Accordion Pill that is being developed for the prevention and treatment of gastroduodenal and small bowel Nonsteroidal Anti-Inflammatory Drug induced ulcers.

Forward Looking Statements

This press release contains forward-looking statements about the Company's expectations, beliefs and intentions. Forward-looking statements can be identified by the use of forward-looking words such as "believe", "expect", "intend", "plan", "may", "should", "could", "might", "seek", "target", "will", "project", "forecast", "continue" or "anticipate" or their negatives or variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical matters. These forward-looking statements are based on assumptions and assessments made in light of management's experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements in this press release are made as of the date of this press release, and the company undertakes no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties, many of which are outside of the company's control. Important factors that could cause actual results, developments and business decisions to differ materially from forward-looking statements are described in the sections titled "Risk Factors" in the company's filings with the Securities and Exchange Commission, and include the following: the company's ability to develop and commercialize its product candidates and obtain additional financing necessary therefor; the length, cost and uncertain results of the company's clinical trials; the availability of reimbursement from government authorities and health insurance companies for the company's products; the impact of product liability lawsuits; and the influence of extensive and costly government regulation.

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