



## Intec Pharma Reports 2016 Fourth Quarter and Full Year Financial Results

April 7, 2017

JERUSALEM, April 7, 2017 /PRNewswire/ -- Intec Pharma Ltd. (Nasdaq and TASE: NTEC), a clinical-stage biopharmaceutical company focused on developing drugs based on its proprietary Accordion Pill™ platform technology, today reported financial results for the three and 12 months ended December 31, 2016.

Highlights of the fourth quarter of 2016 and recent weeks include:

- Initiated a Phase I clinical trial of AP-CBD/THC, the Company's Accordion Pill platform with the two primary cannabinoids contained in *Cannabis sativa*, cannabidiol (CBD) and tetrahydrocannabinol (THC), which is being developed for various indications including low back neuropathic pain and fibromyalgia. The Company expects to have topline results from this trial in the third quarter of 2017;
- Raised approximately \$10 million through a private placement that included participation by the Company's Chairman, Dr. John Kozarich, and two other directors;
- Announced a protocol amendment to the ACCORDANCE study, the Company's Phase III clinical trial of Accordion Pill Carbidopa/Levodopa (AP-CD/LD) for the treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients that reduced the sample size from 460 to 328 patients without altering the trial's objectives, endpoints or statistical powering;
- Entered into an agreement with the Michael J. Fox Foundation for Parkinson's Research to support patient recruitment and retention for the ACCORDANCE study; and
- Announced the granting of European and Chinese patents for an Accordion Pill containing certain drugs, including the combination Carbidopa and Levodopa. The patents are currently scheduled to remain in force until April 2029, and complement patents already granted in the U.S. and Israel.

### Management Commentary

"Intec made very significant progress over the past several months with key clinical and corporate initiatives that we believe position us to achieve a number of important milestones throughout the balance of 2017. Patient recruitment into the ACCORDANCE study continues on pace and we currently expect to complete enrollment during the fourth quarter of 2017. In addition, we were very pleased to initiate the Phase I clinical trial of AP-CBD/THC, our first demonstration of the Accordion Pill platform for cannabinoid therapies, which we believe holds significant opportunities as a therapy for pain management," said Zeev Weiss, Chief Executive Officer of Intec Pharma. "Importantly, we strengthened our balance sheet to support these efforts with the \$10 million private placement that we completed in March. We see great opportunities to continue building Intec throughout 2017 and look forward to advancing our vision to become a leader in Parkinson's disease treatment and in oral drug delivery with our Accordion Pill platform, which is under development to bring innovative new therapies to patients across various important indications, with significant unmet needs."

### Financial Highlights for the Three and 12 Months Ended December 31, 2016

Research and development expenses, net, for the fourth quarter of 2016 were approximately \$2.7 million, compared with approximately \$2.1 million for the fourth quarter of 2015. Research and development expenses, net, for 2016 were approximately \$10.7 million, compared with approximately \$4.8 million for 2015. The increases in both periods resulted primarily from higher expenses related to the Company's Phase III clinical trial of its lead product, AP-CD/LD, and payroll and related expenses, partially offset by an increase in participation in research and development expenses from the Office of the Chief Scientist of the Ministry of Economy and Industry received in 2016 compared with 2015.

General and administrative expenses for the fourth quarter of 2016 were approximately \$831,000 compared with approximately \$869,000 for the fourth quarter of 2015. General and administrative expenses for 2016 were approximately \$3.1 million compared with approximately \$2.8 million for 2015. The increase for the year was primarily due to expenses associated with being a public company in the U.S. since August 2015.

Financial income, net, for 2016 was approximately \$450,000, which included financial income from interest on cash equivalents and bank deposits of approximately \$176,000, financial income from change in fair value of derivative financial instruments of approximately \$230,000 and foreign currency exchange income of approximately \$60,000, partially offset by financial expenses from bank fees of approximately \$16,000. Financial income, net, for 2015 was approximately \$404,000, which included financial income from interest on cash equivalents and bank deposits of approximately \$44,000 and foreign currency exchange income of approximately \$589,000, partially offset by financial expenses from change in fair value of derivative financial instruments of approximately \$213,000 and financial expenses from bank fees of approximately \$16,000.

Loss and comprehensive loss for 2016 was approximately \$13.4 million, or \$1.17 per share based on 11.4 million shares outstanding, compared with a loss and comprehensive loss for 2015 of approximately \$7.8 million, or \$0.92 per share based on 7.8 million shares outstanding. The loss and comprehensive loss for the fourth quarter of 2016 was approximately \$3.6 million, or \$0.32 per share based on 11.4 million shares outstanding, compared with a loss and comprehensive loss for the fourth quarter of 2015 of approximately \$2.8 million, or \$0.26 per share based on 11.4 million shares outstanding.

Net cash used in operating activities for 2016 was approximately \$12.0 million compared with approximately \$7.9 million for 2015, primarily due to an increase in net loss of approximately \$6.2 million, partially offset by a decrease in changes in operating assets and liability items of approximately \$2.1 million.

Net cash provided by investing activities for 2016 was approximately \$4.7 million compared with approximately \$6.4 million of net cash used in investing activities for 2015. The change resulted from the maturities of short-term deposits, net, in the amount of approximately \$5.0 million that were invested in 2015, the decrease in purchase of property and equipment in the amount of approximately \$900,000 and the disposal of financial assets at fair value through profit and loss, net in the amount of approximately \$0.2 million.

Cash, cash equivalents and financial assets at fair value as of December 31, 2016 were approximately \$18.2 million compared with approximately \$30.7 million cash, cash equivalents, short-term bank deposits and financial assets at fair value as of December 31, 2015. In March 2017, the Company completed a private placement of 2,289,638 ordinary shares with various investors at a price of \$4.40 per share, for gross proceeds of approximately \$10 million.

The annual report on Form 20-F, containing audited financial statements for the year ended December 31, 2016, as filed with the Securities and Exchange Commission on April 7, 2017, is available through the Company's website (<http://intecpharma.com>). Shareholders may receive a hard copy of the annual report free of charge upon request to the Company.

#### **About Intec Pharma Ltd.**

Intec Pharma Ltd. 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 includes four product candidates in clinical trial stages: Accordion Pill Carbidopa/Levodopa, or AP-CD/LD, which is being developed for the treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients; Accordion Pill Zaleplon, or AP-ZP, which is being developed for the treatment of insomnia, including sleep induction and the improvement of sleep maintenance; an Accordion Pill that is being developed for the prevention and treatment of gastroduodenal and small bowel Nonsteroidal Anti-Inflammatory Drug (NSAID)-induced ulcers; and AP-CBD/THC, an Accordion Pill with the two primary cannabinoids contained in *Cannabis sativa*, cannabidiol (CBD) and tetrahydrocannabinol (THC), which is being developed for various indications including low back neuropathic pain and fibromyalgia.

#### **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; including uncertainty regarding the Company's ability to enroll the required number of patients therein; the potential of adverse side effects, other safety risks, or legal prohibitions on the use of certain products in certain jurisdictions that could preclude the approval of the company's drug candidates; 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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#### **-Tables to Follow-**

#### **INTEC PHARMA LTD.**

#### **STATEMENTS OF FINANCIAL POSITION**

**December 31**

2015 2016

US Dollars

in thousands

**Assets**

**CURRENT ASSETS:**

Cash and cash equivalents	23,649	16,376
Short-term bank deposits	5,000	
Financial assets at fair value through profit or loss	2,024	1,852
Restricted bank deposits	62	62
Other receivables	2,361	2,384
	33,096	20,674

**NON-CURRENT ASSETS -**

Property and equipment	4,076	4,047
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**TOTAL ASSETS**

37,172 24,721

**Liabilities and equity**

**CURRENT LIABILITIES -**

Accounts payable and accruals:

Trade	614	1,152
Other	701	768
	1,315	1,920

**NON-CURRENT LIABILITIES -**

Derivative financial instruments	327	97
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**COMMITMENTS AND CONTINGENT LIABILITIES**

**TOTAL LIABILITIES**

1,642 2,017

**EQUITY:**

Ordinary shares	727	727
Share premium	84,980	84,980

Currency translation differences	(378)	(378)
Warrants		
Accumulated deficit	(49,799)	(62,625)
<b>TOTAL EQUITY</b>	<b>35,530</b>	<b>22,704</b>
<b>TOTAL LIABILITIES AND EQUITY</b>	<b>37,172</b>	<b>24,721</b>

**INTEC PHARMA LTD.**

STATEMENTS OF COMPREHENSIVE LOSS

	<b>Year ended December 31</b>		
	<b>2014</b>	<b>2015</b>	<b>2016</b>
	<b>U.S. dollars in thousands</b>		
<b>RESEARCH AND DEVELOPMENT EXPENSES</b>	(4,959)	(7,533)	(15,349)
<b>LESS- PARTICIPATION IN RESEARCH AND DEVELOPMENT EXPENSES</b>	1,550	2,718	4,600
<b>RESEARCH AND DEVELOPMENT EXPENSES, net</b>	(3,409)	(4,815)	(10,749)
<b>GENERAL AND ADMINISTRATIVE EXPENSES</b>	(2,609)	(2,788)	(3,097)
<b>OTHER GAINS, net</b>	234	19	34
<b>OPERATING LOSS</b>	(5,784)	(7,584)	(13,812)
<b>FINANCIAL INCOME</b>	318	633	466
<b>FINANCIAL EXPENSES</b>	(227)	(229)	(16)
<b>FINANCIAL INCOME, net</b>	91	404	450
<b>NET LOSS</b>	(5,693)	(7,180)	(13,362)
<b>OTHER COMPREHENSIVE LOSS -</b>			
<b>CURRENCY TRANSLATION DIFFERENCES</b>	(805)	(664)	-
<b>LOSS AND COMPREHENSIVE LOSS</b>	(6,498)	(7,844)	(13,362)
	<b>\$</b>		
<b>BASIC AND DILUTED LOSS PER ORDINARY SHARE</b>	(1.18)	(0.92)	1.17)

**INTEC PHARMA LTD.**

STATEMENTS OF CHANGES IN EQUITY

	Ordinary shares						
	Number of shares	Issued and paid-up share capital	Share premium	Warrant	Currency translation differences	Accumulated deficit	Total
	U.S. dollars in thousands						
<b>BALANCE AT JANUARY 1, 2014</b>	4,555,531	614	42,805	2,356	1,091	(37,571)	9,295
<b>CHANGES DURING 2014:</b>							
Proceeds from issuance of shares and warrants net of issuance costs	577,795	78	4,166	246			4,490
Proceeds from issuance of shares as part of an addendum to an investment agreement	202,018	26	1,665				1,691
Issuance of shares to former related party	50,909	7	66			(73)	-
Expiration of warrants (Series 1)			1,385	(1,385)			-
Expiration of non-tradable warrants			612	(612)			-
Exercise of options by employees and service providers	14,214	2	164				166
Share-based compensation						337	337
Other comprehensive loss					(805)		(805)
Comprehensive loss						(5,693)	(5,693)
<b>BALANCE AT DECEMBER 31, 2014</b>	5,400,467	727	50,863	605	286	(43,000)	9,481
<b>CHANGES DURING 2015:</b>							
Expiration of non-tradable warrants			359	(359)			-
Exercise of warrants (Series 7)	208,843		1,933	(89)			1,844
Expiration of warrants (Series 7)			157	(157)			-

Proceeds from issuance of shares through public offering, net of issuance costs	5,663,750		30,608			30,608	
Shares issued as part of an anti-dilution right	174,566		1,060			1,060	
Exercise of options by employees and service providers	565		*			*	
Share-based compensation					381	381	
Other comprehensive loss					(664)	(664)	
Comprehensive loss					(7,180)	(7,180)	
<b>BALANCE AT DECEMBER 31, 2015</b>	11,488,191	727	84,980	-	(378)	(49,799)	35,530
<b>CHANGES DURING 2016:</b>							
Share-based compensation					536	536	
Comprehensive loss					(13,362)	(13,362)	
<b>BALANCE AT DECEMBER 31, 2016</b>	11,488,191	727	84,980	-	(378)	(62,625)	22,704

\* Represents an amount less than \$ 1,000

**INTEC PHARMA LTD.**

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STATEMENTS OF CASH FLOWS

**Year ended December 31**

**2014 2015 2016**

**U.S. dollars in thousands**

**CASH FLOWS FROM OPERATING ACTIVITIES:**

Net loss	(5,693)	(7,180)	(13,362)
Adjustments to reconcile net loss to net cash from operations (see appendix A)	942	(751)	1,357
Net cash used in operating activities	(4,751)	(7,931)	(12,005)

**CASH FLOWS FROM INVESTING ACTIVITIES:**

Purchase of property and equipment	(76)	(1,384)	(482)
Short-term deposits, net	-	(5,000)	5,000
Proceeds from disposal of financial assets at fair value through profit or loss, net	2,865	*	206
Changes in restricted bank deposits, net	(9)	13	*
Net cash provided by (used in) investing activities	2,780	(6,371)	4,724

**CASH FLOWS FROM FINANCING ACTIVITIES:**

Issuance of shares through public offering, net of issuance costs	-	30,608	-
Exercise of warrants (series 7)	-	1,844	-
Exercise of options by employees and service providers	166	-	-
Issuance of shares as part of an addendum to the investment agreement	26	-	-
Issuance of shares and warrants, net of issuance costs	4,490	-	-
Net cash provided by financing activities	4,682	32,452	-
<b>INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>2,711</b>	<b>18,150</b>	<b>(7,281)</b>
<b>CASH AND CASH EQUIVALENTS – BEGINNING OF YEAR</b>	<b>3,389</b>	<b>5,731</b>	<b>23,649</b>
<b>EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS</b>	<b>(369)</b>	<b>(232)</b>	<b>8</b>
<b>CASH AND CASH EQUIVALENTS - END OF YEAR</b>	<b>5,731</b>	<b>23,649</b>	<b>16,376</b>

\* Represents an amount less than \$ 1,000

(Concluded) - 2

**INTEC PHARMA LTD.**

STATEMENTS OF CASH FLOWS

Year ended December 31

2014 2015 2016

U.S. dollars in thousands

**APPENDIX A**

**Adjustments to reconcile net loss to net cash provided from operations:**

Income and expenses not involving cash flows:

Depreciation	585	746	701
Changes in the fair value of derivative financial instruments	204	213	(230)
Exchange differences on cash and cash equivalents	(150)	(402)	(8)
Exchange differences on short-term bank deposit		*	
Losses (gains) on financial assets at fair value through profit or loss	14	(20)	(34)
Share-based compensation to employees and service providers	337	381	536
	990	918	965

Changes in operating asset and liability items:

Decrease (increase) in other receivables	409	(2,083)	(23)
Increase (decrease) in accounts payable and accruals	(457)	414	415
	(48)	(1,669)	392
	942	(751)	1,357

**APPENDIX B:**

Information regarding investment and financing activities not involving cash flows:

Liability with respect to property purchase order	1,116	-	190
Settlement of liability in respect to derivative financial instrument to equity	1,665	1,060	-

Supplementary information to the statement of cash flows -

Interest received	172	44	168
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\* Represents an amount less than \$ 1,000

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/intec-pharma-reports-2016-fourth-quarter-and-full-year-financial-results-300436522.html>

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