Intec Pharma Reports Fourth Quarter and Year End 2017 Financial Results and Business Update

March 9, 2018

More than 300 patients enrolled in pivotal Phase 3 ACCORDANCE Trial

Gastroscopy safety sub-study successfully completed

JERUSALEM, March 9, 2018 /PRNewswire/ -- Intec Pharma LTD (NASDAQ: NTEC) (TASE: NTEC) today announces financial results for the three and twelve months ended December 31, 2017 and provides a corporate update.

"The past quarter capped what continues to be a transformational time for Intec Pharma. We made significant progress expanding our clinical and regulatory teams while advancing our clinical development programs. We continue to focus on execution of the ACCORDANCE Trial, our pivotal Phase 3 trial in Parkinson's Disease. Additionally, we are building our organizational capabilities to fully develop and commercialize the Accordion Pill™. Toward that end, we enhanced our leadership with a number of key hires and initiated an in-depth market access analysis of the potential for our Accordion Pill Carbidopa/Levodopa (AP-CD/LD) in the Parkinson's Disease market," said Jeffrey A. Meckler, Chief Executive Officer of Intec Pharma. "Finally, we were pleased to enter into a research agreement with Novartis to explore using the Accordion Pill platform for one of their proprietary compounds, which we believe underscores the interest in and potential of our Accordion Pill technology to enhance the delivery and retention of a wide variety of compounds."

"As we enter 2018, we believe we are well-positioned to advance our exciting proprietary drug delivery platform into new areas and to achieve a number of value-creating milestones throughout the balance of the year and beyond," added Mr. Meckler.

Recent Corporate Highlights

Phase 3 ACCORDANCE Clinical Trial

The pivotal Phase 3 clinical trial assessing the safety and efficacy of the AP-CD/LD to treat Parkinson's Disease has enrolled more than 300 patients to date. During the fourth quarter of 2017, the Company developed a Medical Affairs team in the United States, and added staff in the medical, regulatory and quality areas in Israel. The U.S. Medical Affairs team is serving as a resource to support study conduct in the United States and is taking steps to improve enrollment rates globally. Importantly, the gastroscopy safety sub-study has been completed, and the Data Monitoring Committee unanimously recommended the continuation of the main Phase 3 study without modification as per its charter. The Company believes enrollment will be completed some time in the second half of 2018.

Manufacturing

The construction of a commercial-scale Accordion Pill production line, by an international manufacturer, is progressing as planned and Intec continues to expect completion by third quarter 2018. In addition, the Company is currently in advanced discussions with a Commercial Manufacturing Organization (CMO) to enter into an agreement whereby the CMO would manufacture the AP-CD/LD capsules using Intec's proprietary production line within the CMO's FDA-licensed facility.

Commercialization

The Company has retained a leading biopharma consulting firm to conduct a market assessment for AP-CD/LD to treat the symptoms associated with advanced Parkinson's Disease. Initial progress indicates there is a substantial market for AP-CD/LD serving hundreds of thousands of patients suffering with Parkinson's Disease.

Strengthened Leadership with Key Additions to the Board and Management

In October 2017, Intec appointed Walt Linscott, Esq. as Chief Administrative Officer. Mr. Linscott is an accomplished life sciences executive with experience in senior level executive positions at public and private medical device and pharmaceutical companies.

In December 2017, the Company elected Anthony Maddaluna, former Executive Vice President and President of Pfizer Global Supply, to its Board of Directors.

In January 2018, R. Michael Gendreau, M.D., Ph.D. joined Intec as Chief Medical Officer. Dr. Gendreau brings over 25 years of experience in the drug development and pharmaceutical industry.

Accordion Pill – Carbidopa/Levodopa

A new pharmacokinetic (PK) study to determine the performance of the pill used in the Phase 3 Parkinson's study when dosed three time per day (TID) is being planned. The study will compare Sinemet dosed five times per day to the AP-CD/LD dosed TID. The goal will be to show the reduction in excursions above and below the mean plasma concentration of levodopa over a 24-hour interval when compared to Sinemet. The Company expects that these results will be available in the second half of 2018.

Accordion Pill – CBD/THC

In August 2017, the Company announced positive results from its Phase 1 trial of AP-CBD/THC, the Company's Accordion Pill platform technology containing the two cannabinoids, cannabidiol (CBD) and tetrahydrocannabinol (THC). CBD and THC are the two primary cannabinoids contained in *Cannabis sativa*. The trial demonstrated the ability to deliver these cannabinoids via an oral route with superior bioavailability as compared to reference cannabinoid preparations.

The single-center, single-dose, randomized, three-way crossover study compared the PK, safety and tolerability of two formulations of AP-CBD/THC with Sativex® in 21 normal healthy volunteers. Sativex is a commercially available oral buccal spray containing CBD and THC. The study results showed that patients in the AP-CBD/THC arm demonstrated significant improvements in exposure to AP-CBD (290% to 330%) and THC (25% to 50%) compared with Sativex. The median time to peak concentration was 2-3 times longer than Sativex and absorption was significantly higher.

Following the Phase 1 clinical trial, we evaluated the program and decided as a next step to develop two new Accordion Pills containing only the individual cannabinoid components, namely CBD and THC. Two Phase 1 PK studies are planned to be initiated in the second half of 2018. The Company believes exploring the individual components will provide additional indications to pursue.

Patent Grant / Intellectual Property

Intec continues to build a strong and differentiated global intellectual property portfolio with the addition of a Canadian patent grant that broadly covers the Accordion Pill containing certain drugs, including the combination of Carbidopa and Levodopa, and provides patent protection through April 2029. The patent belongs to the Company's IN-7 patent family, which includes patents granted in the United States, Europe, China, Japan, South Korea, Hong Kong, South Africa, and Israel.

Financial highlights for the year ended December 31, 2017, and for the fourth quarter of 2017.

Research and Development Expenses (R&D), net, for the fourth quarter of 2017 were approximately $8.9 million, an increase of $ 6.2 million, or approximately 230%, compared to approximately $2.7 million for the fourth quarter of 2016. R&D, net, for the year ended December 31, 2017 were approximately $24.3 million, an increase of $13.6 million, or approximately 127%, compared with approximately $10.7 million for the year ended December 31, 2016. The increases in both periods were primarily due to increases in expenses related to the progression of the Phase 3 ACCORDANCE trial and payroll and related expenses mostly due to an increase in headcount and salary raises. In addition, the Company had a decrease in the Israeli Innovation Authority's (IIA) participation in R&D for 2017, as the Company declined to accept the IIA grant for 2017 due to its conditions and also repaid part of the IIA grants the Company had received in 2016 following IIA's notice for repayment.

General and administrative expenses for the fourth quarter of 2017 were approximately $1.6 million, an increase of $0.8 million, or approximately 100%, compared to approximately $0.8 million for the fourth quarter of 2016. General and administrative expenses for the year ended December 31, 2017 were approximately $5.1 million, an increase of $2.0 million, or approximately 65%, compared to approximately $3.1 million for 2016. The increases in both periods were primarily due to the increase in professional services, share-based compensation to employees and payroll and related expenses primarily related to the creation of a subsidiary in the United States and hiring of management personnel in the United States during 2017.

For the year ended December 31, 2017, Intec had financial income from interest on cash equivalents and bank deposits of approximately $286,000 and foreign currency exchange income of approximately $72,000, which were partially offset by financial expenses from a change in fair value of derivative financial instruments of approximately $184,000. In 2016, the Company had financial income of $466,000, which were partially offset by financial expenses of $16,000.

During 2017 and 2016, Intec did not generate taxable income in Israel. However, in 2017 the Company incurred tax expenses of $29,000 through its U.S. subsidiary.

Comprehensive loss attributable to common stockholders for the fourth quarter of 2017 was approximately $10.2 million, an increase of $6.6 million, or approximately 183%, compared to the Company's comprehensive loss for the fourth quarter of 2016 of approximately $3.6 million. The comprehensive loss attributable to common stockholders for the full-year 2017 was approximately $29.1 million, an increase of $15.7 million, or approximately 117%, compared to the Company's comprehensive loss for 2016 of approximately $13.4 million.

Loss per share attributed to common stockholders for the fourth quarter of 2017 was $(0.39) compared with $(0.32) for the fourth quarter of 2016. Loss per share attributed to common stockholders for the full-year 2017 was $(1.65) compared with $(1.17) for 2016.

As of December 31, 2017, the Company had cash and cash equivalents and financial assets at fair value through profit or loss of approximately $55.2 million compared with approximately $64.7 million at September 30, 2017. The net cash used of $9.5 million during the fourth quarter of 2017 was primarily for the Phase 3 ACCORDANCE trial and the construction of a commercial-scale Accordion Pill production line.

Net cash used in operating activities was approximately $22.1 million for full-year 2017 compared to approximately $12.0 million in 2016. This increase primarily resulted from an increase in comprehensive loss of approximately $15.7 million, which was partially offset by a decrease in changes in operating asset and liability items of approximately $4.7 million.

Net cash used in investing activities was approximately $4.7 million for full-year 2017 compared with approximately $4.7 million net cash provided by investing activities for 2016. The change resulted primarily from the reductions in short-term deposits as they matured in the amount of $5.0 million in 2016 and an increase in purchase of property and equipment in the amount of approximately $4.5 million.

During 2017, the Company raised approximately $10.0 million in gross proceeds from a private placement of ordinary shares and approximately $57.5 million in gross proceeds from an underwritten public offering of ordinary shares on the NASDAQ Capital Market.

Sativex® is a registered trademark of GW Pharmaceuticals.

The annual report on Form 20-F, containing audited financial statements for the year ended December 31, 2017, as filed with the Securities and Exchange Commission on March 9, 2018, 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 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 two 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, and AP-cannabinoids, an Accordion Pill to deliver either or both of the primary cannabinoids contained in Cannabis sativa, cannabidiol (CBD) and tetrahydrocannabinol (THC).

Cautionary Note Regarding 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.

INTEC PHARMA LTD.

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	December 31	
	2016	**2017**
	U.S. dollars in thousands	
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	16,376	53,324
Financial assets at fair value through profit or loss	1,852	1,825
Restricted bank deposits	62	69
Other receivables	2,384	1,125
	20,674	56,343
NON-CURRENT ASSETS -		
Property and equipment	4,047	8,206
TOTAL ASSETS	24,721	64,549
Liabilities and equity		

CURRENT LIABILITIES -		
Accounts payable and accruals:		
Trade	1,152	1,854
Other	768	3,893
	1,920	5,747
NON-CURRENT LIABILITIES -		
Derivative financial instruments	97	-
COMMITMENTS AND CONTINGENT LIABILITIES		
TOTAL LIABILITIES	2,017	5,747
EQUITY:		
Ordinary shares	727	727
Share premium	84,980	148,968
Currency translation differences	(378)	(378)
Accumulated deficit	(62,625)	(90,515)
TOTAL EQUITY	22,704	58,802
TOTAL LIABILITIES AND EQUITY	24,721	64,549

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CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Year ended December 31		
	2015	**2016**	**2017**
	U.S. dollars in thousands		
RESEARCH AND DEVELOPMENT EXPENSES	(7,533)	(15,349)	(21,492)
PARTICIPATION IN (REPAYMENT OF) RESEARCH AND DEVELOPMENT EXPENSES	2,718	4,600	(2,803)
RESEARCH AND DEVELOPMENT EXPENSES, net	(4,815)	(10,749)	(24,295)
GENERAL AND ADMINISTRATIVE EXPENSES	(2,788)	(3,097)	(5,144)

OTHER GAINS, net	19	34	218
OPERATING LOSS	(7,584)	(13,812)	(29,221)
FINANCIAL INCOME	633	466	358
FINANCIAL EXPENSES	(229)	(16)	(201)
FINANCIAL INCOME, net	404	450	157
LOSS BEFORE TAXES ON INCOME	(7,180)	(13,362)	(29,064)
TAXES ON INCOME	-	-	(29)
NET LOSS	(7,180)	(13,362)	(29,093)
OTHER COMPREHENSIVE LOSS -			
CURRENCY TRANSLATION DIFFERENCES	(664)	-	-
COMPREHENSIVE LOSS	(7,844)	(13,362)	(29,093)
	$		
BASIC AND DILUTED LOSS PER ORDINARY SHARE	(0.92)	(1.17)	(1.65)

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CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	Ordinary shares						
	Number of shares	**Issued and paid-up share capital**	**Share premium**	**Warrants**	**Currency translation differences**	**Accumulated deficit**	**Total**
		U.S. dollars in thousands					
BALANCE AT JANUARY 1, 2015	5,400,467	727	50,863	605	286	(43,000)	9,481
CHANGES DURING 2015:							
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, 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	565	*				*
Share-based compensation					381	381
Other comprehensive loss				(664)		(664)
Comprehensive loss					(7,180)	(7,180)
BALANCE AT DECEMBER 31, 2015	11,448,191 727	84,980	-	(378)	(49,799)	35,530
CHANGES DURING 2016:						
Share-based compensation					536	536
Comprehensive loss					(13,362)	(13,362)
BALANCE AT DECEMBER 31, 2016	11,448,191 727	84,980	-	(378)	(62,625)	22,704
CHANGES DURING 2017:						
Proceeds from issuance of shares, net of issuance costs	14,514,138	63,131				63,131
Exercise of warrants	102,058	812				812
Exercise of options by employees	11,383	45				45
Share-based compensation					1,203	1,203
Comprehensive loss					(29,093)	(29,093)
BALANCE AT DECEMBER 31, 2017	26,075,770 727	148,968	-	(378)	(90,515)	58,802

* Represents an amount less than $ 1,000

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CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31		
	2015	**2016**	**2017**
	U.S. dollars in thousands		
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	(7,180)	(13,362)	(29,093)
Adjustments to reconcile net loss to net cash from operations (see appendix A)	(751)	1,357	6,961
Net cash used in operating activities	(7,931)	(12,005)	(22,132)
CASH FLOWS FROM INVESTING ACTIVITIES:			

Purchase of property and equipment	(1,384)	(482)	(620)
Advances payments for property and equipment	-	-	(4,381)
Short-term deposits, net	(5,000)	5,000	-
Proceeds from disposal of financial assets at fair value through profit or loss, net	*	206	247
Proceeds from sale of property and equipment	-	-	7
Changes in restricted bank deposits, net	13	*	-
Net cash provided by (used in) investing activities	(6,371)	4,724	(4,747)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Issuance of shares, net of issuance costs	30,608	-	63,131
Exercise of warrants (series 7)	1,844	-	-
Exercise of warrants	-	-	531
Exercise of options by employees	-	-	45
Net cash provided by financing activities	32,452	-	63,707
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	18,150	(7,281)	36,828
CASH AND CASH EQUIVALENTS – BEGINNING OF YEAR	5,731	23,649	16,376
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(232)	8	120
CASH AND CASH EQUIVALENTS - END OF YEAR	23,649	16,376	53,324

* Represents an amount less than $ 1,000

	Year ended December 31		
	2015	**2016**	**2017**
	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	746	701	829
Changes in the fair value of derivative financial instruments	213	(230)	184
Exchange differences on cash and cash equivalents	(403)	(8)	(120)

Exchange differences on restricted deposits	*	*	(7)
Exchange differences on short-term bank deposit	*	-	-
Gains on financial assets at fair value through profit or loss	(19)	(34)	(220)
Loss on sale of property and equipment	-	-	2
Share-based compensation to employees	381	536	1,203
	918	965	1,871
Changes in operating asset and liability items:			
Decrease (increase) in other receivables	(2,083)	(23)	1,259
Increase in accounts payable and accruals	414	415	3,831
	(1,669)	392	5,090
	(751)	1,357	6,961

APPENDIX B:

Information regarding investment and financing activities not involving cash flows:			
Liability with respect to property purchase order	-	190	-
Settlement of liability in respect to derivative financial instrument to equity	1,060	-	281
Supplementary information to the statement of cash flows -			
Interest received	44	168	244

* Represents an amount less than $ 1,000

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