Intec Pharma Reports Financial Results for the First Six Months of 2017

August 9, 2017

JERUSALEM, Aug. 9, 2017 /PRNewswire/ -- Intec Pharma Ltd. (Nasdaq: NTEC) (TASE: NTEC), a clinical-stage biopharmaceutical company focused on developing drugs based on its proprietary Accordion Pill™ (AP) platform technology, today reported financial results for the six months ended June 30, 2017.

Highlights of the first half of 2017 and recent weeks include:

- Initiated and completed a Phase I clinical trial of AP-CBD/THC, the Company's AP platform with cannabidiol (CBD) and tetrahydrocannabinol (THC), the two primary cannabinoids contained in *Cannabis sativa,* which is being developed for various indications including low back neuropathic pain and fibromyalgia;
- Reported topline data from the Phase I clinical trial of AP-CBD/THC, which showed that AP-CBD/THC had significant improvements in exposure of CBD (+290% - +330%) and THC (+25% - +50%) compared with Sativex®. The median time of peak concentration was two to three times longer than with Sativex and absorption was significantly higher. Importantly, the formation of THC metabolites were meaningfully reduced (>25%) and AP-CBD/THC was found to be safe and well tolerated with no serious adverse events reported;
- Advanced enrollment in the ACCORDANCE study, Intec Pharma's Phase III clinical trial of AP Carbidopa/Levodopa (AP-CD/LD) for the treatment of symptoms in advanced Parkinson's disease, affirming the Company's expectation to complete enrollment during the fourth quarter of 2017 or the first quarter of 2018;
- Expanded the Company intellectual property portfolio with the addition of U.S. and international patents that protect key elements of the AP technology platform and AP-CD/LD in significant markets; and
- Strengthened the Company's balance sheet through a $10 million private placement in March 2017.

Management Commentary

"Throughout the first half of 2017, Intec made substantial advances across the company, including key corporate, clinical and financial initiatives," stated Jeffrey A. Meckler, Chief Executive Officer of Intec Pharma. "We significantly advanced the ACCORDANCE study and are currently on target to complete enrollment by year end. In anticipation of completing this pivotal program, we are moving forward with a variety of pre-commercial activities including Key Opinion Leader engagement and manufacturing scale-up.

"We were delighted to report encouraging results from our Phase I study of AP-CBD/THC as the data show the AP platform is well suited to deliver these cannabinoids with significant improvements in exposure compared with Sativex. We are particularly pleased with the reduction in THC metabolite, which tells us that AP-CBD/THC avoids some of the hepatic first-pass metabolism of THC. These favorable data give us continued confidence in the potential for AP-CBD/THC as a therapy for pain management.

"We remain focused on our goals to bring the AP-CD/LD clinical development program to data readout, advance our pre-commercial initiatives, move forward with the development of AP-CBD/THC and execute a broad development program for the Accordion Pill technology.

"It is an exciting time of growth and expansion for Intec as we look to achieve a number of key milestones throughout the balance of the year and beyond. We believe that the significant headway we are making positions us to advance our vision to become a leader in Parkinson's disease treatment and in oral drug delivery with our Accordion Pill platform to bring innovative new therapies to patients across various important indications, with significant unmet needs."

Financial Highlights for the Six Months Ended June 30, 2017

The Company's research and development expenses, net, for the six-month period ended June 30, 2017, amounted to approximately $9.5 million, an increase of $4.1 million, or approximately 76%, compared to approximately $5.4 million for the six-month period ended June 30, 2016. The increase was primarily due to increased activity in the Company's Phase III clinical trial for AP-CDLD, payroll and related expenses and a decrease in the Israeli National Authority for Technological Innovation's (NATI) participation in research and development expenses from $2.2 million in 2016 to $0 in 2017 as a result of a NATI grant condition requiring that AP-CDLD be manufactured in Israel, which the Company is currently evaluating.

The Company's general and administrative expenses for the six-month period ended June 30, 2017 amounted to approximately $2.1 million, an increase of $0.6 million, or approximately 40%, compared to approximately $1.5 million for the six-month period ended June 30, 2016. The increase was primarily due to an increase in share-based compensation to employees and professional services.

Financial income, net for the six-month period ended June 30, 2017, amounted to approximately $0.25 million, a decrease of $0.21 million, or approximately 46%, compared to approximately $0.46 million for the six-month period ended June 30, 2016. The decrease resulted primarily from less interest income due to lower cash and cash equivalents balances and the change in fair value of derivative financial instruments.

For the six-month period ended June 30, 2017, loss and comprehensive loss was approximately $11.2 million, an increase of $4.8 million, or

approximately 75%, compared to loss and comprehensive loss for the six-month period ended June 30, 2016 of approximately $6.4 million. This increase primarily resulted from an increase in expenses related to the Phase III clinical trial for AP-CDLD, payroll and related expenses, share-based compensation to employees and professional services and a decrease in participation in research and development expenses from NATI.

As of the six-month period ended June 30, 2017, the Company had cash and cash equivalents and financial assets at fair value through profit or loss of approximately $17.9 million.

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 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-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.

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.

Tables to Follow

INTEC PHARMA LTD.

CONDENSED INTERIM STATEMENTS OF FINANCIAL POSITION

	December 31, 2016	June 30, 2017
	U.S. dollars in thousands	
A s s e t s		
CURRENT ASSETS:		
Cash and cash equivalents	16,376	16,062
Financial assets at fair value through profit or loss	1,852	1,806
Restricted bank deposits	62	69
Other receivables	2,384	1,326
	20,674	19,263
NON-CURRENT ASSETS -		

Property and equipment	4,047	5,354
TOTAL ASSETS	24,721	24,617
Liabilities and equity		
CURRENT LIABILITIES -		
Accounts payable and accruals:		
Trade	1,152	888
Other	768	2,128
	1,920	3,016
NON-CURRENT LIABILITIES -		
Derivative financial instruments	97	17
COMMITMENTS AND CONTINGENT LIABILITIES		
TOTAL LIABILITIES	2,017	3,033
EQUITY:		
Ordinary shares	727	727
Share premium	84,980	94,505
Currency translation differences	(378)	(378)
Accumulated deficit	(62,625)	(73,270)
TOTAL EQUITY	22,704	21,584
TOTAL LIABILITIES AND EQUITY	24,721	24,617

INTEC PHARMA LTD.

CONDENSED INTERIM STATEMENT OF COMPREHENSIVE LOSS

	Three months ended		**Six months ended**	
	June 30		**June 30**	
	2016	**2017**	**2016**	**2017**
	U.S. dollars in thousands			

RESEARCH AND DEVELOPMENT EXPENSES	(3,524)	(5,621)	(7,664)	(9,538)
LESS - PARTICIPATION IN RESEARCH AND DEVELOPMENT EXPENSES	2,241	-	2,241	-
RESEARCH AND DEVELOPMENT EXPENSES, net	(1,283)	(5,621)	(5,423)	(9,538)
GENERAL AND ADMINISTRATIVE EXPENSES	(756)	(1,075)	(1,515)	(2,086)
OTHER GAINS (LOSSES), net	(34)	75	30	171
OPERATING LOSS	(2,073)	(6,621)	(6,908)	(11,453)
FINANCIAL INCOME	97	104	473	258
FINANCIAL EXPENSES	(35)	(4)	(9)	(10)
FINANCIAL INCOME (EXPENSES), net	62	100	464	248
LOSS AND COMPREHENSIVE LOSS	(2,011)	(6,521)	(6,444)	(11,205)
	$			
BASIC AND DILUTED LOSS PER ORDINARY SHARE	(0.18)	(0.47)	(0.56)	(0.88)

INTEC PHARMA LTD.

CONDENSED INTERIM STATEMENTS OF CHANGES IN EQUITY

	Ordinary shares					
	Number of shares	**Issued and paid-up share capital**	**Share premium**	**Currency translation differences**	**Accumulated deficit**	**Total**
		U.S. dollars in thousands				
BALANCE AT JANUARY 1, 2016	11,448,191	727	84,980	(378)	(49,799)	35,530
CHANGES IN THE SIX MONTH PERIOD ENDED JUNE 30, 2016:						
Share-based compensation					150	150
Comprehensive loss					(6,444)	(6,444)
BALANCE AT JUNE 30, 2016	11,448,191	727	84,980	(378)	(56,093)	29,236
BALANCE AT JANUARY 1, 2017	11,448,191	727	84,980	(378)	(62,625)	22,704

CHANGES IN THE SIX MONTH PERIOD ENDED JUNE 30, 2017:						
Proceeds of issuance shares, net of issuance costs	2,289,638		9,525			9,525
Share-based compensation					560	560
Exercise of options by employees and service providers	377		*			*
Comprehensive loss					(11,205)	(11,205)
BALANCE AT JUNE 30, 2017	13,738,206	727	94,505	(378)	(73,270)	21,584

* Represents an amount less than $ 1,000

INTEC PHARMA LTD.

CONDENSED INTERIM STATEMENTS OF CASH FLOWS

	Six months ended June 30	
	2016	2017
	U.S. dollars in thousands	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Comprehensive loss	(6,444)	(11,205)
Adjustments to reconcile loss and comprehensive loss to net cash used in operating activities (see appendix A)	(2,918)	2,677
Net cash used in operating activities	(9,362)	(8,528)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(55)	(1,636)
Proceeds from disposal of financial assets at fair value through profit or loss, net	129	219
Proceeds from sale of property and equipment	-	7
Net cash provided by (used in) investing activities	74	(1,410)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Issuance of shares, net of issuance costs	-	9,525

Exercise of options by employees and service providers	-	*
Net cash provided by financing activities	-	9,525
DECREASE IN CASH AND CASH EQUIVALENTS	(9,288)	(413)
CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD	23,649	16,376
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	93	99
CASH AND CASH EQUIVALENTS - END OF PERIOD	14,454	16,062

* Represents an amount less than $ 1,000

INTEC PHARMA LTD.

CONDENSED INTERIM STATEMENTS OF CASH FLOWS

	Six months ended June 30	
	2016	**2017**
	U.S. dollars in thousands	
APPENDIX A:		
Adjustments to reconcile loss and comprehensive loss to net cash used in operating activities:		
Income and expenses not involving cash flows:		
Depreciation	356	400
Changes in the fair value of derivative financial instruments	(217)	(80)
Exchange differences on cash and cash equivalents	(93)	(99)
Exchange differences on restricted deposits	-	(7)
Gains on financial assets at fair value through profit or loss	(30)	(173)
Loss on sale of property and equipment	-	2
Share-based compensation to employees and service providers	150	560
	166	603
Changes in operating asset and liability items:		

Decrease (increase) in other receivables	(3,118)	1,058
Increase in accounts payable and accruals	34	1,016
	(3,084)	2,074
	(2,918)	2,677

APPENDIX B:

Information regarding investment and financing activities not involving cash flows:		
Liability with respect to property purchase		80
Supplementary information to the statement of cash flows -		
Interest received	109	73

Contacts:

Jeffrey A. Meckler
Chief Executive Officer
Intec Pharma
646-374-8050
jeffrey@intecpharma.com

Anne Marie Fields
Senior Vice President
LHA Investor Relations
212-838-3777
afields@lhai.com

View original content:http://www.prnewswire.com/news-releases/intec-pharma-reports-financial-results-for-the-first-six-months-of-2017-300502300.html

SOURCE Intec Pharma Ltd.

Source: PR Newswire (August 9, 2017 - 5:00 PM EDT)