



Intec Pharma Reports First Quarter 2018 Financial Results and Corporate Update

May 15, 2018

More than 350 patients enrolled in pivotal Phase 3 ACCORDANCE trial and more than 80% of eligible patients entered the open label extension study

JERUSALEM, May 15, 2018 /PRNewswire/ -- Intec Pharma Ltd. (NASDAQ: NTEC) (TASE: NTEC) ("Intec" or "the Company") today announces financial results for the three months ended March 31, 2018 and provides a corporate update.

Highlights of the first quarter 2018 and recent weeks include:

- Presented favorable data from two Phase 1 studies of the Accordion Pill[®] Carbidopa/Levodopa (AP-CD/LD) in a poster presentation titled, "*Optimizing Delivery of Carbidopa/Levodopa via the Accordion Pill: Comparative PK and Safety from 2 Randomized Crossover Studies in Healthy Volunteers*," at the American Academy of Neurology 2018 Annual Meeting (AAN).
- **Raised approximately \$37.5 million in a public offering of 6.75 million ordinary shares and 400,000 ordinary shares following the exercise of part of the underwriters' over-allotment option.**
- Hosted a Key Opinion Leader event highlighting the treatment landscape in Parkinson's disease and rang the Nasdaq Capital Markets Closing Bell on World Parkinson's Disease Day.
- Appointed Roger J. Pomerantz, M.D., Chief Executive Officer of Seres Therapeutics, Inc. and former Worldwide Head of Licensing & Acquisitions, Senior Vice President at Merck & Co., to the Company's Board of Directors.
- **Partnered with LTS Lohmann Therapie-Systeme AG ("LTS"), the global leader in formulation and film technology manufacture, to establish commercial scale production capabilities for AP-CD/LD in LTS' U.S. Food and Drug Administration (FDA) compliant facility in Germany.**

Management Commentary

"We continue to build on the momentum established in 2017 and are pleased with our continued growth in 2018 as we made meaningful progress advancing our clinical, commercial and corporate objectives. We are especially pleased by the developments in our Phase 3 program of AP-CD/LD as a treatment for advanced Parkinson's disease. To date, we have enrolled more than 350 patients and remain on track to complete enrollment of this pivotal trial later this year, with top-line results expected in mid-2019. We continue to be encouraged by the number of patients entering the open label extension study, as more than 80% of patients who completed the double-blind portion of the study have opted into the extension study. In addition, we are nearing initiation of a pharmacokinetic (PK) study of the 500 mg AP-CD/LD three times a day (TID) dose in order to demonstrate the PK profile of LD provided by AP-CD/LD. This dosing regimen is one frequently used in our ACCORDANCE study and we believe this important PK data will be of interest to potential partners and for commercialization. Finally, we were delighted to present Phase 1 PK data at AAN that are supportive of our clinical development program for AP-CD/LD and demonstrated that our technology provided more consistent LD plasma levels and less peak-trough fluctuation when compared to IR-CD/LD," stated Jeffrey A. Meckler, Vice Chairman and Chief Executive Officer of Intec Pharma.

"We also made great inroads with our pre-commercial activities, particularly with regard to manufacturing where we have partnered for the commercial production of AP-CD/LD at LTS' cGMP facilities in Germany. We have invested in the build-out of the commercial scale machine and expect it to be ready for delivery to LTS in the third quarter. In the meantime, a dedicated Accordion Pill manufacturing area is under construction at LTS and the scale-up and commercial manufacturing project is underway.

"Following on favorable PK data from our Phase 1 study of AP-CBD/THC, which combined two key components of cannabis, we are moving forward with a series of Phase 1 PK studies of each of these components alone and in combination. We will initiate the AP-THC study in the second half of 2018. We believe that exploring the individual components of cannabis provides the potential to pursue additional opportunities in target pain indications.

"During the first quarter we enhanced our Board with the addition of Dr. Pomerantz, expanded our executive team with the addition of Michael Gendreau, M.D., Ph.D. as Chief Medical Officer and strengthened our balance sheet with the recent \$37.5 million public offering. We now have the resources to support our objectives into 2020 and the team to lead us to achieve a number of key milestones that should significantly enhance shareholder value," concluded Mr. Meckler.

First Quarter 2018 Financial Results

Research and Development expenses (R&D), net, for the first quarter of 2018 were approximately \$8.9 million, an increase of \$ 5.0 million, or approximately 128%, compared to approximately \$3.9 million for the first quarter of 2017. The increase was primarily due to an increase in expenses related to the progression of our Phase 3 ACCORDANCE clinical trial for AP-CD/LD, expenses related to the establishment of the commercial scale production capabilities for AP-CD/LD and payroll and related expenses, mostly due to an increase in headcount.

General and administrative expenses for the first quarter of 2018 were approximately \$1.9 million, an increase of \$0.9 million, or approximately 90%, compared to approximately \$1.0 million for the first quarter of 2017. The increase was primarily due to the increase in share-based compensation to

employees and payroll and related expenses primarily related to the hiring of personnel in the United States and expenses related to investor relations activities.

Comprehensive loss attributable to common stockholders for the first quarter of 2018 was approximately \$10.7 million, an increase of \$6.0 million, or approximately 128%, compared to the Company's comprehensive loss for the first quarter of 2017 of approximately \$4.7 million.

Loss per share attributed to common stockholders for the first quarter of 2018 was \$0.40 compared with \$0.41 for the first quarter of 2017.

As of March 31, 2018, the Company had cash and cash equivalents and financial assets at fair value through profit or loss of approximately \$42.8 million compared with approximately \$55.2 million at December 31, 2017. The Company used net cash of \$12.4 million during the first quarter of 2018, primarily for the Phase 3 ACCORDANCE trial, the construction of a commercial-scale Accordion Pill production line and repayment of \$2.3 million of the Israeli Innovation Authority grants, as previously reported.

Following the close of the quarter, the Company raised approximately \$37.5 million in gross proceeds from a public offering of 6.75 million ordinary shares on the NASDAQ Capital Market, together with the exercise of the underwriters' option to purchase 400,000 ordinary shares.

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) for various indications including low back neuropathic pain and fibromyalgia.

For more information, visit www.intecpharma.com.

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 CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION (Unaudited)

	December 31, 2017	March 31, 2018
	<u>U.S. dollars in thousands</u>	
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	53,324	41,134
Financial assets at fair value through profit or loss	1,825	1,706
Restricted bank deposits	69	68
Other receivables	1,125	1,223
TOTAL CURRENT ASSETS	<u>56,343</u>	<u>44,131</u>

NON-CURRENT ASSETS-

Property and equipment	8,206	10,022
TOTAL ASSETS	<u>64,549</u>	<u>54,153</u>

Liabilities and equity**CURRENT LIABILITIES -**

Accounts payable and accruals:

Trade	1,854	3,575
Other	3,893	1,782
	<u>5,747</u>	<u>5,357</u>

**NON-CURRENT LIABILITIES -
COMMITMENTS AND CONTINGENT LIABILITIES**

TOTAL LIABILITIES	<u>5,747</u>	<u>5,357</u>
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EQUITY:

Ordinary shares	727	727
Share premium	148,968	148,968
Currency translation differences	(378)	(378)
Accumulated deficit	(90,515)	(100,521)
TOTAL EQUITY	<u>58,802</u>	<u>48,796</u>
TOTAL LIABILITIES AND EQUITY	<u>64,549</u>	<u>54,153</u>

INTEC PHARMA LTD.
CONDENSED CONSOLIDATED INTERIM STATEMENT OF COMPREHENSIVE LOSS
(Unaudited)

	Three months ended	
	March 31	
	2017	2018
	U.S. dollars in thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(3,917)	(9,215)
LESS - PARTICIPATION IN RESEARCH AND DEVELOPMENT EXPENSES	-	335
RESEARCH AND DEVELOPMENT EXPENSES, net	(3,917)	(8,880)
GENERAL AND ADMINISTRATIVE EXPENSES	(1,011)	(1,910)
OTHER GAINS (LOSSES), net	96	(73)
OPERATING LOSS	(4,832)	(10,863)
FINANCIAL INCOME	156	203
FINANCIAL EXPENSES	(8)	(6)
FINANCIAL INCOME, net	148	197
LOSS BEFORE TAXES ON INCOME	(4,684)	(10,666)
TAXES ON INCOME	-	(63)
LOSS AND COMPREHENSIVE LOSS	<u>(4,684)</u>	<u>(10,729)</u>
	\$	
BASIC AND DILUTED LOSS PER ORDINARY SHARE	<u>0.40</u>	<u>0.41</u>

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CHANGES IN EQUITY
(Unaudited)

	<u>Ordinary shares</u>		Share premium	Currency translation differences	Accumulated deficit	Total
	Number of shares	Issued and paid-up share capital				
BALANCE AT JANUARY 1, 2018	26,075,770	727	148,968	(378)	(90,515)	58,802
CHANGES IN THE THREE-MONTH PERIOD ENDED MARCH 31, 2018:						
Share-based compensation					723	723
Comprehensive loss for the period					(10,729)	(10,729)
BALANCE AT MARCH 31, 2018	<u>26,075,770</u>	<u>727</u>	<u>148,968</u>	<u>(378)</u>	<u>(100,521)</u>	<u>48,796</u>
BALANCE AT JANUARY 1, 2017	11,448,191	727	84,980	(378)	(62,625)	22,704
CHANGES IN THE THREE-MONTH PERIOD ENDED MARCH 31, 2017:						
Share-based compensation					216	216
Proceeds of issuance shares, net of issuance costs	2,289,638		9,525			9,525
Comprehensive loss for the period					(4,684)	(4,684)
BALANCE AT MARCH 31, 2017	<u>13,737,829</u>	<u>727</u>	<u>94,505</u>	<u>(378)</u>	<u>(67,093)</u>	<u>27,761</u>

INTEC PHARMA LTD.
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CASH FLOWS
(Unaudited)

	<u>Three months ended March 31</u>	
	<u>2017</u>	<u>2018</u>
	<u>U.S. dollars in thousands</u>	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Comprehensive loss	(4,684)	(10,729)
Adjustments to reconcile loss and comprehensive loss to net cash used in operating activities (see appendix A)	488	474
Net cash used in operating activities	<u>(4,196)</u>	<u>(10,255)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(332)	(77)
Advances payments for property and equipment	-	(1,945)
Proceeds from disposal of financial assets at fair value through profit or loss, net	179	46
Proceeds from sale of property and equipment	7	-
Net cash used in investing activities	<u>(146)</u>	<u>(1,976)</u>
CASH FLOWS FROM FINANCING ACTIVITIES -		

Issuance of shares, net of issuance costs	9,525	-
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	5,183	(12,231)
CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD	16,376	53,324
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	28	41
CASH AND CASH EQUIVALENTS - END OF PERIOD	<u>21,587</u>	<u>41,134</u>

INTEC PHARMA LTD.
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CASH FLOWS
(Unaudited)

**Three months ended
March 31**

<u>2017</u>	<u>2018</u>
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	198	206
Changes in the fair value of derivative financial instruments	(69)	-
Exchange differences on cash and cash equivalents	(28)	(41)
Exchange differences on restricted deposits	(4)	1
Losses (gains) on financial assets at fair value through profit or loss	(98)	73
Loss on sale of property and equipment	2	-
Share-based compensation to employees and service providers	<u>216</u>	<u>723</u>
	<u>217</u>	<u>962</u>

Changes in operating asset and liability items:

Decrease (increase) in other receivables	99	(98)
Increase (decrease) in accounts payable and accruals	<u>172</u>	<u>(390)</u>
	<u>271</u>	<u>(488)</u>
	<u>488</u>	<u>474</u>

APPENDIX B:

Information regarding investment activities not involving cash flows -

Liability with respect to property purchase	<u>141</u>	-
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Supplementary information to the statement of cash flows -

Interest received	<u>38</u>	<u>117</u>
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