



Intec Pharma Reports Second Quarter 2018 Financial Results and Corporate Update

August 15, 2018

Enrolled more than 95% of patients in pivotal Phase 3 ACCORDANCE trial and more than 85% of eligible patients entered the open label extension study

JERUSALEM, Aug. 15, 2018 /PRNewswire/ -- Intec Pharma Ltd. (NASDAQ: NTEC) ("Intec" or "the Company") today announces financial results for the three and six months ended June 30, 2018 and provides a corporate update.

Highlights of the second quarter 2018 and recent weeks include:

- Global enrollment reached more than 400 of the projected 420 patients into the Phase 3 ACCORDANCE clinical trial of Accordion Pill Carbidopa/Levodopa (AP-CD/LD) for the treatment of advanced Parkinson's disease patients;
- Completed enrollment at the European and Israeli sites in the ACCORDANCE clinical trial with the balance of the study's patients to be recruited from the trial's U.S. clinical sites;
- More than 85% of eligible patients from the ACCORDANCE clinical trial are opting to participate in the Open Label Extension (OLE) study;
- Created a Scientific Advisory Board (SAB) comprised of internationally renowned scientists, whose mission will be to provide scientific and clinical advice on the advancement of AP-cannabinoids in various indications;
- Multiple poster presentations accepted at the upcoming International Parkinson and Movement Disorder Society (MDS) bi-annual meeting taking place October 5-9, 2018;
- Appointed Brad Hayes, former Executive Vice President, Chief Financial Officer and Treasurer of Laboratory Corporation of America (LabCorp), to the Company's Board of Directors;
- Voluntarily filed for and completed de-listing from the Tel Aviv Stock Exchange, with NASDAQ Capital Market now the sole trading exchange; and
- Raised gross proceeds of approximately \$37.5 million in an underwritten public offering of 6.75 million ordinary shares and 400,000 ordinary shares following the partial exercise of the underwriters' over-allotment option.

Management Commentary

"We continue to be pleased with the progress Intec has made during the first half of 2018, as we made significant advances that position us to achieve a number of important clinical, commercial and corporate milestones throughout the balance of the year and beyond," stated Jeffery A. Meckler, Vice Chairman and Chief Executive Officer of Intec Pharma.

"We are particularly excited about the progress we've made with our Phase 3 program for AP-CD/LD as a new backbone therapy for advanced Parkinson's disease patients. As we near completion of global enrollment, we have completed planned enrollment at our sites located in Europe and Israel, leaving the balance of enrollment to our U.S. sites. We remain on track to report topline data in mid-2019. The strong interest in participating in the OLE study is encouraging and gives us confidence that these extended safety data will be available in the second half of 2019. We look forward to the results from our pharmacokinetic (PK) study of the 50/500 mg AP-CD/LD dosed three times a day (TID), as we believe these PK data will be important to potential partners and for physician education at commercial launch. In addition, we are pleased to be presenting multiple posters from our Parkinson's therapy development program at the upcoming MDS meeting.

"The scale-up and commercial manufacturing project with our partner, LTS Lohmann Therapie-Systeme AG (LTS), is well underway. Fabrication of the commercial scale manufacturing systems is complete, initial system testing is being conducted in preparation for delivery to LTS, and ongoing technology transfer and process development work advances. We are making plans for our validation, bridging and stability studies and expect to have greater clarity on these timelines around the end of the year. Our market assessment and payor access work continue and the findings strongly support a significant market opportunity in Parkinson's disease where a more effective backbone therapy is greatly needed.

"We continue to advance our pipeline opportunities for the Accordion platform and are moving forward with PK studies to individually evaluate CBD and THC, two key components of cannabis. We plan to initiate the AP-THC study in the second half of 2018 and the AP-CBD study in early 2019. Based on earlier Phase 1 work, we are very encouraged by the potential for the Accordion technology to enhance the bioavailability of these cannabinoids and improve their therapeutic potential. We have established an advisory board of global leaders to assist us in planning our development program utilizing the AP-cannabinoids.

"We are building a blue-chip Board of seasoned leaders who have relevant experience to guide Intec to its next level of achievement. Toward that end, we were delighted to welcome Brad Hayes, former CFO of LabCorp, as our newest director and Chairman of our Audit Committee.

"We continue to advance our strategic initiatives and are committed to maximizing our current near-term opportunity in Parkinson's disease and to pursuing new growth initiatives to create both near- and long-term value for shareholders," concluded Mr. Meckler.

Financial Highlights for the Three and Six Months Ended June 30, 2017

Research and development expenses, net, for the three-month period ended June 30, 2018 amounted to approximately \$8.4 million, an increase of \$2.8 million, or approximately 50%, compared with approximately \$5.6 million in the three-month period ended June 30, 2017. Research and development expenses, net, for the six-month period ended June 30, 2018 amounted to approximately \$17.3 million, an increase of \$7.8 million, or approximately 82%, compared with approximately \$9.5 million in the six-month period ended June 30, 2017. The increase in both periods 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, share based compensation to employees and payroll and related expenses, mostly due to an increase in headcount.

General and administrative expenses for the three-month period ended June 30, 2018 amounted to approximately \$2.2 million, an increase of \$1.1 million, or approximately 100%, compared with approximately \$1.1 million in the three-month period ended June 30, 2017. General and administrative expenses for the six-month period ended June 30, 2018 amounted to approximately \$4.1 million, an increase of \$2.0 million, or approximately 95%, compared with approximately \$2.1 million in the six-month period ended June 30, 2017. The increase in both periods 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, professional services and expenses related to investor relations activities.

Loss and comprehensive loss for the three-month period ended June 30, 2018 was approximately \$11.0 million, an increase of \$4.5 million, or approximately 69%, compared with the loss and comprehensive loss for the three-month period ended June 30, 2017 of approximately \$6.5 million. Loss and comprehensive loss for the six-month period ended June 30, 2018 was approximately \$21.8 million, an increase of \$10.6 million, or approximately 95%, compared with the loss and comprehensive loss for the six-month period ended June 30, 2017 of approximately \$11.2 million.

Loss per ordinary share for the six-month period ended June 30, 2018 was \$0.75 compared with \$0.88 for the six-month period ended June 30, 2017.

As of June 30, 2018, the Company had cash and cash equivalents and financial assets at fair value through profit or loss of approximately \$66.2 million compared with approximately \$55.2 million at December 31, 2017. The Company used net cash of approximately \$24.3 million during the six-month period ended June 30, 2018, primarily for the Phase 3 ACCORDANCE trial, the construction of a commercial-scale Accordion Pill production line and repayment of the Israeli Innovation Authority grants, which was offset by a public offering with net proceeds of approximately \$35.0 million.

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 our 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 we undertake 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 our control. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements, including, but not limited to, the following: our limited operating history and history of operating losses, our ability to continue as a going concern, our ability to obtain additional financing, our ability to successfully operate our business or execute our business plan, the timing and cost of our clinical trials, the completion and receiving favorable results in our clinical trials, our ability to obtain and maintain regulatory approval of our product candidates, our ability to protect and maintain our intellectual property and licensing arrangements, our ability to develop, manufacture and commercialize our product candidates, the risk of product liability claims, the availability of reimbursement, and the influence of extensive and costly government regulation. More detailed information about the risks and uncertainties affecting us is contained under the heading "Risk Factors" included in our most recent Annual Report on Form 20-F filed with the SEC on March 9, 2018, and in other filings that we have made and may make with the Securities and Exchange Commission in the future.

- Tables to Follow -

INTEC PHARMA LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION
(Unaudited)

<u>December 31,</u>	<u>June 30,</u>
<u>2017</u>	<u>2018</u>
<u>U.S. dollars in thousands</u>	

A s s e t s

CURRENT ASSETS:

Cash and cash equivalents	53,324	64,481
Financial assets at fair value through profit or loss	1,825	1,670
Restricted bank deposits	69	147
Other receivables	1,125	2,869
TOTAL CURRENT ASSETS	56,343	69,167

NON-CURRENT ASSETS:

Other assets		1,696
Property and equipment	8,206	12,143
TOTAL NON-CURRENT ASSETS	8,206	13,839
TOTAL ASSETS	64,549	83,006

Liabilities and equity

CURRENT LIABILITIES -

Accounts payable and accruals:		
Trade	1,854	5,256
Other	3,893	4,079
TOTAL CURRENT LIABILITIES	5,747	9,335

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

EQUITY:

Ordinary shares	727	727
Share premium	148,968	183,998
Currency translation differences	(378)	(378)
Accumulated deficit	(90,515)	(110,676)
TOTAL EQUITY	58,802	73,671
TOTAL LIABILITIES AND EQUITY	64,549	83,006

INTEC PHARMA LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENT OF COMPREHENSIVE LOSS

(Unaudited)

	Three months ended		Six months ended	
	June 30		June 30	
	2017	2018	2017	2018
	U.S. dollars in thousands			
RESEARCH AND DEVELOPMENT EXPENSES	(5,621)	(8,523)	(9,538)	(17,738)

LESS - PARTICIPATION IN RESEARCH AND DEVELOPMENT EXPENSES	-	123	-	458
RESEARCH AND DEVELOPMENT EXPENSES, net	(5,621)	(8,400)	(9,538)	(17,280)
GENERAL AND ADMINISTRATIVE EXPENSES	(1,075)	(2,194)	(2,086)	(4,104)
OTHER GAINS (LOSSES), net	75	(81)	171	(154)
OPERATING LOSS	(6,621)	(10,675)	(11,453)	(21,538)
FINANCIAL INCOME	104	239	258	389
FINANCIAL EXPENSES	(4)	(450)	(10)	(403)
FINANCIAL INCOME (EXPENSES), net	100	(211)	248	(14)
LOSS BEFORE TAXES ON INCOME	(6,521)	(10,886)	(11,205)	(21,552)
TAXES ON INCOME	-	(147)	-	(210)
LOSS AND COMPREHENSIVE LOSS	(6,521)	(11,033)	(11,205)	(21,762)
		\$		
BASIC AND DILUTED LOSS PER ORDINARY SHARE	(0.47)	(0.34)	(0.88)	(0.75)

INTEC PHARMA LTD.
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CHANGES IN EQUITY
(Unaudited)

	<u>Ordinary shares</u>					<u>Total</u>
	<u>Number of shares</u>	<u>Issued and paid-up share capital</u>	<u>Share premium</u>	<u>Currency translation differences</u>	<u>Accumulated deficit</u>	
	<u>U.S. dollars in thousands</u>					
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	377		*			*
Comprehensive loss					(11,205)	(11,205)
BALANCE AT JUNE 30, 2017	<u>13,738,206</u>	<u>727</u>	<u>94,505</u>	<u>(378)</u>	<u>(73,270)</u>	<u>21,584</u>
BALANCE AT JANUARY 1, 2018	26,075,770	727	148,968	(378)	(90,515)	58,802
CHANGES IN THE SIX MONTH PERIOD ENDED JUNE 30, 2018:						
Proceeds of issuance shares, net of issuance costs	7,150,000		35,029			35,029
Share-based compensation					1,601	1,601
Exercise of options by employees	218		1			1
Comprehensive loss					(21,762)	(21,762)
BALANCE AT JUNE 30, 2018	<u>33,225,988</u>	<u>727</u>	<u>183,998</u>	<u>(378)</u>	<u>(110,676)</u>	<u>73,671</u>

* Represents an amount less than \$ 1,000

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CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CASH FLOWS
(Unaudited)

	Six months ended June 30	
	2017	2018
	U.S. dollars in thousands	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Comprehensive loss	(11,205)	(21,762)
Adjustments to reconcile loss and comprehensive loss to net cash used in operating activities (see appendix A)	2,677	1,907
Net cash used in operating activities	(8,528)	(19,855)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(1,636)	(2,613)
Other assets	-	(1,696)
Proceeds from disposal of financial assets at fair value through profit or loss, net	219	1
Changes in restricted bank deposits, net	-	(85)
Proceeds from sale of property and equipment	7	-
Net cash used in investing activities	(1,410)	(4,393)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Issuance of shares, net of issuance costs	9,525	35,029
Exercise of options by employees	*	1
Net cash provided by financing activities	9,525	35,030
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(413)	10,782
CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD	16,376	53,324
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	99	375
CASH AND CASH EQUIVALENTS - END OF PERIOD	16,062	64,481

* Represents an amount less than \$ 1,000

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

	Six months ended June 30	
	2017	2018
	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	400	416
Changes in the fair value of derivative financial instruments	(80)	-
Exchange differences on cash and cash equivalents	(99)	(375)
Exchange differences on restricted deposits	(7)	7
Losses (gains) on financial assets at fair value through profit or loss	(173)	154
Loss on sale of property and equipment	2	-
Share-based compensation	560	1,601
	<u>603</u>	<u>1,803</u>

Changes in operating asset and liability items:

Decrease (increase) in other receivables	1,058	(502)
Increase in accounts payable and accruals	1,016	606
	<u>2,074</u>	<u>104</u>
	<u>2,677</u>	<u>1,907</u>

APPENDIX B:

Information regarding investment activities not involving cash flows:

Liability with respect to property purchase	<u>80</u>	<u>1,740</u>
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Supplementary information to the statement of cash flows:

Taxes paid	-	31
Interest received	<u>73</u>	<u>209</u>

Intec Pharma Investor Contact:

Anne Marie Fields
VP-Corporate Communications & Investor Relations
646-200-8808
amf@intec-us.com

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