



Intec Pharma Reports Third Quarter 2020 Financial Results and Provides Corporate Update

November 5, 2020

JERUSALEM, Nov. 5, 2020 /PRNewswire/ -- Intec Pharma Ltd. (NASDAQ: NTEC) ("Intec" or "the Company") today announces financial results for the third quarter ended September 30, 2020 and provides a corporate update.

"We maintain our focus on executing strategic partnerships and collaborations. As such, we were delighted in recent weeks to announce a new research collaboration with Merck. While we are unable to provide the specifics of the agreement, it speaks to Merck's keen understanding of the Accordion Pill (AP) technology and their continued interest in working with us to realize its potential," stated Jeffrey A. Meckler, Vice Chairman and Chief Executive Officer of Intec Pharma.

"In addition, we continue to innovate and progress our next generation gastric retentive technologies. We are working on a variety of new approaches to meet unmet needs such as a once-a-day gastric retentive Accordion Pill."

"We also look forward to advancing our newly designed AP-THC program into clinical development by year-end as we now have the active pharmaceutical ingredients needed for the clinical material production."

"Importantly, we strengthened our balance sheet during the third quarter which allows us to move our AP-THC program forward, advance our discussions with potential business partners and to support the initiation of future collaborations, such as the one with Merck," added Mr. Meckler.

Financial Highlights for Third Quarter Ended September 30, 2020

Research and development expenses, net, for the three-month period ended September 30, 2020 were approximately \$2.1 million, a decrease of \$6.3 million, or approximately 75%, compared with approximately \$8.4 million in the three-month period ended September 30, 2019. Research and development expenses, net, for the nine-month period ended September 30, 2020 were approximately \$5.4 million, a decrease of approximately \$19.5 million, or approximately 80%, compared with approximately \$24.9 million in the nine-month period ended September 30, 2019. The decrease for the three and nine-month periods was primarily due to the completion of the ACCORDANCE study and Open Label Extension study during 2019, a decrease in expenses related to the scale up activities of the commercial scale manufacturing line, a decrease in payroll and related expenses, mostly due to reduction in headcount, and a decrease in share-based compensation.

General and administrative expenses for the three-month period ended September 30, 2020 were approximately \$1.5 million, a decrease of \$700,000, or approximately 32%, compared with approximately \$2.2 million in the three-month period ended September 30, 2019. General and administrative expenses for the nine-month period ended September 30, 2020 amounted to approximately \$4.9 million, a decrease of approximately \$1.6 million, or approximately 25%, compared to approximately \$6.5 million for the nine-month period ended September 30, 2019. The decrease for the three and nine-month periods was primarily related to a decrease in payroll and related expenses, including reduction in headcount, a decrease in share-based compensation and reduction in associated expenses.

Net loss for the three-month period ended September 30, 2020 was approximately \$3.7 million, a decrease of \$16.7 million, or approximately 82%, compared with the net loss for the three-month period ended September 30, 2019 of approximately \$20.4 million. Net loss for the nine-month period ended September 30, 2020 was approximately \$10.6 million, a decrease of \$30.4 million, or approximately 74%, compared with the net loss for the nine-month period ended September 30, 2019 of approximately \$41.0 million. The decrease for the three and nine-month periods was mainly due to a decrease in research and development expenses, net, and general and administrative expenses, as detailed above, and an impairment charge incurred in 2019.

Loss per ordinary share for the three-month period ended September 30, 2020, was \$0.95 compared with \$12.16 for the three-month period ended September 30, 2019. Loss per ordinary share for the nine-month period ended September 30, 2020, was \$3.35 compared with \$24.61 for the nine-month period ended September 30, 2019.

As of September 30, 2020, the Company had cash and cash equivalents of approximately \$17.1 million. As of December 31, 2019, the Company had cash and cash equivalents and marketable securities of approximately \$10.1 million.

Net cash used in operating activities was approximately \$8.9 million for the nine-month period ended September 30, 2020 compared with net cash used in operating activities of approximately \$23.9 million for the nine-month period ended September 30, 2019. This decrease resulted primarily from a decrease in research and development activities in the amount of approximately \$19.4 million, offset by changes in operating asset and liability items of approximately \$4.1 million.

The Company had positive cash flow from investing activities of approximately \$756,000 for the nine-month period ended September 30, 2020 compared to negative cash flow from investing activities of approximately \$2.5 million for the nine-month period ended September 30, 2019. This change resulted primarily from an investment in the establishment of the commercial scale manufacturing line in the amount of approximately \$2.3 million in the nine-month period ended September 30, 2019 and an increase in purchase of property and equipment in the amount of approximately \$775,000.

Net cash provided by financing activities for the nine-month period ended September 30, 2020 was approximately \$15.9 million, which was provided primarily by the proceeds from the Company's registered direct offering in August 2020 that resulted in net proceeds of approximately \$4.6 million, proceeds from the Company's registered direct offering in May 2020 that resulted in net proceeds of approximately \$4.5 million, and proceeds from the

Company's underwritten public offering in February 2020 that resulted in net proceeds of approximately \$5.7 million.

In August 2020, the Company raised \$4.9 million in a registered direct offering of 356,250 ordinary shares at a purchase price of \$7.022 per share. In addition, the Company also sold and issued to the purchasers in the offering pre-funded warrants to purchase 356,250 ordinary shares at a purchase price of \$6.822 per share. The pre-funded warrants have an exercise price of \$0.20 per share, are immediately exercisable, and may be exercised at any time until all of the pre-funded warrants are exercised in full.

On October 30, 2020, we effected a 1-for-20 reverse share split. All share and per share amounts have been retroactively adjusted to reflect the reverse share split.

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 in late-stage Phase 3 development 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 pain indications. In addition, the Company has a research collaboration with Merck & Co.

For more information, visit www.intecpharma.com. Intec Pharma routinely posts information that may be important to investors in the Investor Relations section of its website.

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, the impact of the outbreak of coronavirus, 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 10-K filed with the SEC on March 13, 2020, and in other filings that we have made and may make with the Securities and Exchange Commission in the future.

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INTEC PHARMA LTD.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	September 30, 2020	December 31, 2019
	U.S. dollars in thousands	
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 17,076	\$ 9,292
Investment in marketable securities	-	770
Prepaid expenses and other receivables	609	3,683
TOTAL CURRENT ASSETS	17,685	13,745
NON-CURRENT ASSETS:		
Property and equipment, net	1,680	2,575
Operating lease right-of-use assets	954	1,243
Other assets	3,717	3,717
TOTAL NON-CURRENT ASSETS	6,351	7,535
TOTAL ASSETS	\$ 24,036	\$ 21,280

Liabilities and shareholders' equity
CURRENT LIABILITIES -

Accounts payable and accruals:		
Trade	\$ 531	\$ 3,507
Other	4,019	4,835
TOTAL CURRENT LIABILITIES	<u>4,550</u>	<u>8,342</u>
LONG-TERM LIABILITIES -		
Non-current operating lease liabilities	458	799
Other liabilities	951	604
TOTAL LONG-TERM LIABILITIES	<u>1,409</u>	<u>1,403</u>
TOTAL LIABILITIES	<u>5,959</u>	<u>9,745</u>

COMMITMENTS AND CONTINGENT LIABILITIES
SHAREHOLDERS' EQUITY:

Ordinary shares, with no par value - authorized: 17,500,000 and 5,000,000 Ordinary Shares as of September 30, 2020 and December 31, 2019, respectively; issued and outstanding: 3,948,226 and 1,794,611 Ordinary Shares as of September 30, 2020 and December 31, 2019, respectively	727	727
Additional paid-in capital	217,330	200,231
Accumulated deficit	(199,980)	(189,423)
TOTAL SHAREHOLDERS' EQUITY	<u>18,077</u>	<u>11,535</u>
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	<u>\$ 24,036</u>	<u>\$ 21,280</u>

INTEC PHARMA LTD.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three months ended		Nine months ended	
	September 30		September 30	
	2020	2019	2020	2019
	U.S. dollars		U.S. dollars	
	in thousands		in thousands	
OPERATING EXPENSES:				
RESEARCH AND DEVELOPMENT EXPENSES , net	\$ (2,112)	\$ (8,448)	\$ (5,411)	\$ (24,850)
GENERAL AND ADMINISTRATIVE EXPENSES	(1,529)	(2,157)	(4,874)	(6,491)
IMPAIRMENT OF LONG-LIVED ASSETS	-	(9,759)	-	(9,759)
OPERATING LOSS	(3,641)	(20,364)	(10,285)	(41,100)
FINANCIAL INCOME (EXPENSES) , net	(57)	14	(123)	157
LOSS BEFORE INCOME TAX	(3,698)	(20,350)	(10,408)	(40,943)
INCOME TAX	(42)	(28)	(149)	(100)
NET LOSS	<u>\$ (3,740)</u>	<u>\$ (20,378)</u>	<u>\$ (10,557)</u>	<u>\$ (41,043)</u>
	U.S. dollars			
LOSS PER SHARE BASIC AND DILUTED	<u>\$ (0.95)</u>	<u>\$ (12.16)</u>	<u>\$ (3.35)</u>	<u>\$ (24.61)</u>
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER ORDINARY SHARE IN THOUSANDS	<u>3,952</u>	<u>1,676</u>	<u>3,153</u>	<u>1,668</u>

INTEC PHARMA LTD.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

(Unaudited)

	Ordinary Shares		Additional paid-in capital	Accumulated Deficit	Total
	Number of shares	Amounts			
	U.S. dollars in thousands				
BALANCE AT JANUARY 1, 2019	1,661,649	\$ 727	\$ 194,642	\$ (141,824)	\$ 53,545
CHANGES IN THE NINE-MONTH PERIOD ENDED SEPTEMBER 30, 2019:					
Issuance of ordinary shares, net of issuance costs	85,834	-	1,969	-	1,969
Exercise of options	3,491	-	268	-	268

Share-based compensation		-		2,748		-		2,748
Net loss		-		-		(41,043)		(41,043)
BALANCE AT SEPTEMBER 30, 2019		1,750,974	\$	727	\$	199,627	\$	(182,867) \$ 17,487
BALANCE AT JANUARY 1, 2020		1,794,611	\$	727	\$	200,231	\$	(189,423) \$ 11,535
CHANGES IN THE NINE-MONTH PERIOD ENDED SEPTEMBER 30, 2020:								
Issuance of ordinary shares, net of issuance costs		41,569		-		421		- 421
Issuance of ordinary shares and warrants, net of issuance costs		812,500		-		5,692		- 5,692
Issuance of ordinary shares and warrants, net of issuance costs		814,598		-		4,426		- 4,426
Issuance of ordinary shares and pre-funded warrants, net of issuance costs		356,250		-		4,599		- 4,599
Exercise of warrants		128,698		-		769		- 769
Share-based compensation		-		-		1,192		- 1,192
Net loss		-		-		-		(10,557) (10,557)
BALANCE AT SEPTEMBER 30, 2020		3,948,226	\$	727	\$	217,330	\$	(199,980) \$ 18,077

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

	Ordinary Shares		Additional paid-in capital	Accumulated Deficit	Total
	Number of shares	Amounts			
U.S. dollars in thousands					
BALANCE AT JULY 1, 2019	1,665,140	\$ 727	\$ 196,871	\$ (162,489)	\$ 35,109
CHANGES IN THE THREE-MONTH PERIOD ENDED SEPTEMBER 30, 2019:					
Issuance of ordinary shares, net of issuance costs	85,834	-	1,969	-	1,969
Share-based compensation	-	-	787	-	787
Net loss	-	-	-	(20,378)	(20,378)
BALANCE AT SEPTEMBER 30, 2019	1,750,974	\$ 727	\$ 199,627	\$ (182,867)	\$ 17,487
BALANCE AT JULY 1, 2020	3,471,403	\$ 727	\$ 211,691	\$ (196,240)	\$ 16,178
CHANGES IN THE THREE-MONTH PERIOD ENDED SEPTEMBER 30, 2020:					
Issuance of ordinary shares and pre-funded warrants, net of issuance costs	356,250	-	4,599	-	4,599
Exercise of warrants	120,573	-	704	-	704
Share-based compensation	-	-	336	-	336
Net loss	-	-	-	(3,740)	(3,740)
BALANCE AT SEPTEMBER 30, 2020	3,948,226	\$ 727	\$ 217,330	\$ (199,980)	\$ 18,077

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

	Nine months ended September 30	
	2020	2019
U.S. dollars in thousands		
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (10,557)	\$ (41,043)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	911	643
Impairment of long-lived asset	-	9,759
Exchange differences on cash and cash equivalents	18	69
Change in right of use asset	372	523
Change in lease liabilities	(410)	(380)
Gains on marketable securities	(2)	(10)
Share-based compensation	1,192	2,748
Changes in operating assets and liabilities:		
Decrease in prepaid expenses and other receivables	3,074	483

Increase in deferred tax assets	-	(223)
Increase (decrease) in accounts payable and accruals	(3,806)	3,268
Increase in other liabilities	347	245
Net cash used in operating activities	(8,861)	(23,918)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(16)	(791)
Investment in other assets	-	(2,315)
Proceeds from disposal of marketable securities, net	772	576
Net cash provided by (used in) investing activities	756	(2,530)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of ordinary shares, net of issuance costs	421	1,969
Proceeds from issuance of ordinary shares and warrants, net of issuance costs	5,692	-
Proceeds from issuance of ordinary shares and warrants, net of issuance costs	4,426	-
Proceeds from issuance of ordinary shares and pre-funded warrants, net of issuance costs	4,599	-
Proceeds from exercise of warrants	769	-
Proceeds from exercise of options	-	268
Net cash provided by financing activities	15,907	2,237
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	7,802	(24,211)
CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD	9,292	39,246
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(18)	(69)
CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	\$ 17,076	\$ 14,966
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING ACTIVITIES:		
Liability with respect to property and equipment	\$ -	\$ 123
Liability with respect to other assets	\$ -	\$ 549
SUPPLEMENTARY DISCLOSURE OF CASH FLOW INFORMATION -		
Taxes paid	\$ 9	\$ 50
Interest received	\$ 32	\$ 315

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