# Intec Pharma Reports Third Quarter 2018 Financial Results and Corporate Update

November 9, 2018

**Completed enrollment in pivotal Phase 3 ACCORDANCE trial; on track for topline data in mid-2019**

JERUSALEM, Nov. 9, 2018 /PRNewswire/ -- Intec Pharma Ltd. (NASDAQ: NTEC) ("Intec" or "the Company") today announces financial results for the three and nine months ended September 30, 2018 and provides a corporate update.

**Highlights of the third quarter 2018 and recent weeks include:**

- Reported completion of global enrollment in the pivotal Phase 3 ACCORDANCE clinical trial of Accordion Pill™ Carbidopa/Levodopa (AP-CD/LD) for the treatment of advanced Parkinson's disease patients;
- Announced that more than 90% of eligible patients from the ACCORDANCE clinical trial are opting to participate in the Open Label Extension (OLE) study;
- Initiated the pharmacokinetic (PK) study of AP-CD/LD 50/500 mg dosed three times per day (TID) in advanced Parkinson's disease patients;
- Presented multiple poster presentations at the International Parkinson and Movement Society (MDS) annual meeting in early October; and
- Voluntarily delisted from the Tel Aviv Stock Exchange; trading solely on the NASDAQ Capital Market.

**Management Commentary**

"Throughout the third quarter, we continued to make significant progress across a number of key areas important to advancing our AP platform and for building Intec Pharma into a leading drug delivery company," stated Jeffrey A. Meckler, Vice Chairman and Chief Executive Officer of Intec Pharma.

"We recently reported the completion of enrollment in our pivotal Phase 3 clinical trial of AP-CD/LD, which keeps us on track to report topline data in mid-2019. We remain encouraged by the continued strong participation in our OLE study, which gives us confidence that these data will be available in the second half of 2019 and will provide the long-term safety data required for our regulatory submission. We expect to have data from the PK study of AP-CD/LD 50/500 mg TID by year-end and believe these data will be important as this is a popular dosing regimen in the ACCORDANCE study and having this PK information will be of interest to potential partners and clinicians upon commercial launch. Last month, the three posters presented at MDS related to our platform and the Phase 3 development program for AP-CD/LD were very well received. We are delighted with the growing interest among clinicians and industry experts in this pivotal program to bring an innovative new baseline levodopa to Parkinson's disease patients in need of a better baseline therapy. Additionally, we are encouraged by the number of inquiries we are receiving from prospective commercial partners regarding this potentially best-in-class therapy.

"As we approach completion of our Phase 3 program in Parkinson's disease, we remain focused on advancing a number of important commercial activities that will support regulatory submission and product launch. Our ongoing market assessment continues to strongly support our value proposition and potential market opportunity. The commercial manufacturing project with our partner, LTS Lohmann Therapie-Systeme AG (LTS) is advancing as planned with delivery of the commercial scale manufacturing machine expected by year-end. Thereafter, we will provide timelines for the validation, bridging and stability studies for the commercial manufacturing process.

"We are also investing in and building out our next phase of growth through the AP platform's innovation engine that can provide multiple opportunities for further in-house development programs and partnerships. To that end, we look forward to advancing our AP cannabinoid program with the initiation of a PK study of AP-THC by year-end and to continuing our work with Novartis on the feasibility study underway. We are encouraged by advancements in our AP-THC, AP-CBD and Novartis programs and will continue to seek new additions to our intellectual property portfolio from this work.

"We anticipate achieving a number of milestones in the fourth quarter that we expect will strengthen our value proposition and position us for continued growth throughout the balance of 2018 and beyond," concluded Mr. Meckler.

**Financial Highlights for the Three and Nine Months Ended September 30, 2018**

Research and development expenses, net, for the three-month period ended September 30, 2018 were approximately $7.8 million, an increase of $1.9 million, or approximately 32%, compared with approximately $5.9 million in the three-month period ended September 30, 2017. Research and development expenses, net, for the nine-month period ended September 30, 2018 were approximately $25.1 million, an increase of $9.7 million, or approximately 63%, compared with approximately $15.4 million in the nine-month period ended September 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 September 30, 2018 were approximately $1.7 million, an increase of $200,000, or approximately 13%, compared with approximately $1.5 million in the three-month period ended September 30, 2017. The increase was primarily related 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.

General and administrative expenses for the nine-month period ended September 30, 2018 were approximately $5.8 million, an increase of $2.2 million, or approximately 61%, compared with approximately $3.6 million in the nine-month period ended September 30, 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, professional services, expenses related to investor relations activities and travel expenses.

Loss and comprehensive loss for the three-month period ended September 30, 2018 was approximately $9.2 million, an increase of $1.5 million, or approximately 19%, compared with the loss and comprehensive loss for the three-month period ended September 30, 2017 of approximately $7.7 million. Loss and comprehensive loss for the nine-month period ended September 30, 2018 was approximately $30.9 million, an increase of $12.0 million, or approximately 63%, compared with the loss and comprehensive loss for the nine-month period ended September 30, 2017 of approximately $18.9 million. The increase in both periods was mainly due to an increase in research and development expenses and general and administrative expenses as detailed above.

Loss per ordinary share for the nine-month period ended September 30, 2018 was $1.01 compared with $1.27 for the nine-month period ended September 30, 2017.

As of September 30, 2018, the Company had cash and cash equivalents and financial assets at fair value through profit or loss of approximately $54.5 million compared with approximately $55.2 million at December 31, 2017. The Company used net cash of approximately $31.0 million in operating activities and approximately $5.2 million in investing activities during the nine-month period ended September 30, 2018, primarily for the Phase 3 ACCORDANCE trial, the establishment of the commercial scale production capabilities for AP-CD/LD and repayment of the Israeli Innovation Authority grants, which was offset by a public offering with net proceeds of approximately $35.0 million that took place in April 2018 and exchange differences in cash and cash equivalents of approximately $533,000.

**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.

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.

**INTEC PHARMA LTD.**

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION

(Unaudited)

| | December 31, 2017 | September 30, 2018 |
|---|---|---|
| | U.S. dollars in thousands | |
| **Assets** | | |
| **CURRENT ASSETS:** | | |
| Cash and cash equivalents | 53,324 | 52,733 |
| Financial assets at fair value through profit or loss | 1,825 | 1,722 |
| Restricted bank deposits | 69 | 149 |
| Other receivables | 1,125 | 2,104 |
| **TOTAL CURRENT ASSETS** | 56,343 | 56,708 |
| **NON-CURRENT ASSETS:** | | |

| | | |
|---|---|---|
| Other assets | - | 2,694 |
| Property and equipment | 8,206 | 12,097 |
| **TOTAL NON-CURRENT ASSETS** | 8,206 | 14,791 |
| **TOTAL ASSETS** | 64,549 | 71,499 |
| **Liabilities and equity** | | |
| **CURRENT LIABILITIES -** | | |
| Accounts payable and accruals: | | |
| Trade | 1,854 | 1,742 |
| Other | 3,893 | 4,413 |
| **TOTAL CURRENT LIABILITIES** | 5,747 | 6,155 |
| **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) | (119,003) |
| **TOTAL EQUITY** | 58,802 | 65,344 |
| **TOTAL LIABILITIES AND EQUITY** | 64,549 | 71,499 |

**INTEC PHARMA LTD.**

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

| | Three months ended September 30 | | Nine months ended September 30 | |
|---|---|---|---|---|
| | 2017 | 2018 | 2017 | 2018 |
| | U.S. dollars in thousands | | | |
| **RESEARCH AND DEVELOPMENT EXPENSES** | (5,888) | (7,901) | (15,426) | (25,639) |
| **LESS - PARTICIPATION IN RESEARCH AND DEVELOPMENT EXPENSES** | - | 92 | - | 550 |
| **RESEARCH AND DEVELOPMENT EXPENSES,** net | (5,888) | (7,809) | (15,426) | (25,089) |
| **GENERAL AND ADMINISTRATIVE EXPENSES** | (1,480) | (1,696) | (3,566) | (5,800) |
| **OTHER GAINS (LOSSES),** net | (5) | 13 | 166 | (141) |
| **OPERATING LOSS** | (7,373) | (9,492) | (18,826) | (31,030) |
| **FINANCIAL INCOME** | 29 | 254 | 209 | 643 |
| **FINANCIAL EXPENSES** | (308) | (104) | (240) | (507) |
| **FINANCIAL INCOME (EXPENSES),** net | (279) | 150 | (31) | 136 |
| **LOSS BEFORE TAXES ON INCOME** | (7,652) | (9,342) | (18,857) | (30,894) |
| **TAXES ON INCOME** | - | 164 | - | (46) |
| **LOSS AND COMPREHENSIVE LOSS** | (7,652) | (9,178) | (18,857) | (30,940) |
| | $ | | | |
| **BASIC AND DILUTED LOSS PER ORDINARY SHARE** | (0.40) | (0.28) | (1.27) | (1.01) |

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CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CHANGES IN EQUITY

(Unaudited)

| | 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, 2017** | 11,448,191 | 727 | 84,980 | (378) | (62,625) | 22,704 |
| **CHANGES IN THE NINE MONTH PERIOD ENDED SEPTEMBER 30, 2017**: | | | | | | |
| Proceeds from issuance of shares, net of issuance costs | 14,514,138 | - | 63,131 | - | - | 63,131 |
| Exercise of warrants as part of an investment agreement | 102,058 | - | 812 | - | - | 812 |
| Share-based compensation | - | - | - | - | 914 | 914 |
| Exercise of options by employees | 5,064 | - | 19 | - | - | 19 |
| Comprehensive loss | - | - | - | - | (18,857) | (18,857) |
| **BALANCE AT SEPTEMBER 30, 2017** | 26,069,451 | 727 | 148,942 | (378) | (80,568) | 68,723 |
| | | | | | | |
| **BALANCE AT JANUARY 1, 2018** | 26,075,770 | 727 | 148,968 | (378) | (90,515) | 58,802 |
| **CHANGES IN THE NINE MONTH PERIOD ENDED SEPTEMBER 30, 2018**: | | | | | | |
| Proceeds of issuance shares, net of issuance costs | 7,150,000 | - | 35,029 | - | - | 35,029 |
| Share-based compensation | - | - | - | - | 2,452 | 2,452 |
| Exercise of options by employees | 218 | - | 1 | - | - | 1 |
| Comprehensive loss | - | - | - | - | (30,940) | (30,940) |
| **BALANCE AT SEPTEMBER 30, 2018** | 33,225,988 | 727 | 183,998 | (378) | (119,003) | 65,344 |

**INTEC PHARMA LTD.**

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CASH FLOWS

(Unaudited)

| | Nine months ended September 30 | |
|---|---|---|
| | **2017** | **2018** |
| | **U.S. dollars in thousands** | |
| **CASH FLOWS FROM OPERATING ACTIVITIES:** | | |
| Comprehensive loss | (18,857) | (30,940) |
| Adjustments to reconcile loss and comprehensive loss to net cash used in operating activities (see appendix A) | 3,897 | (9) |
| Net cash used in operating activities | (14,960) | (30,949) |
| **CASH FLOWS FROM INVESTING ACTIVITIES:** | | |
| Purchase of property and equipment | (2,447) | (2,632) |
| Investments in other assets | - | (2,450) |
| Proceeds from disposal (acquisition) of financial assets at fair value through profit or loss, net | 254 | (38) |
| Changes in restricted bank deposits, net | - | (85) |
| Proceeds from sale of property and equipment | 7 | - |
| Net cash used in investing activities | (2,186) | (5,205) |
| **CASH FLOWS FROM FINANCING ACTIVITIES**: | | |
| Issuance of shares, net of issuance costs | 63,131 | 35,029 |
| Exercise of warrants as part of an investment agreement | 531 | - |
| Exercise of options by employees | 19 | 1 |
| Net cash provided by financing activities | 63,681 | 35,030 |
| **INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS** | 46,535 | (1,124) |
| **CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD** | 16,376 | 53,324 |
| **EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS** | 66 | 533 |
| **CASH AND CASH EQUIVALENTS - END OF PERIOD** | 62,977 | 52,733 |

**INTEC PHARMA LTD.**

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CASH FLOWS

(Unaudited)

| | Nine months ended September 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 | 613 | 639 |
| Changes in the fair value of derivative financial instruments | 184 | - |
| Exchange differences on cash and cash equivalents | (66) | (533) |
| Exchange differences on restricted deposits | (6) | 5 |
| Losses (gains) on financial assets at fair value through profit or loss | (168) | 141 |
| Loss on sale of property and equipment | 2 | - |
| Share-based compensation | 914 | 2,452 |
| | 1,473 | 2,704 |
| Changes in operating asset and liability items: | | |
| Decrease (increase) in other receivables | 1,051 | (979) |
| Increase (decrease) in accounts payable and accruals | 1,373 | (1,734) |
| | 2,424 | (2,713) |
| | 3,897 | (9) |
| **APPENDIX B:** | | |
| Information regarding investment and financing activities not involving cash flows: | | |
| Liability with respect to property purchase | 30 | 1,898 |
| Liability with respect to other assets | - | 244 |
| Settlement of liability in respect to derivative financial instrument to equity | 281 | - |
| Supplementary information to the statement of cash flows: | | |
| Taxes paid | - | 31 |
| Interest received | 99 | 522 |

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