# Intec Pharma Reports Fourth Quarter and Year End 2019 Financial Results and Corporate Update

March 13, 2020

JERUSALEM, March 13, 2020 /PRNewswire/ -- Intec Pharma Ltd. (NASDAQ: NTEC) ("Intec" or "the Company") today announces financial results for the fourth quarter and year ended December 31, 2019 and provides a corporate update.

**Highlights from the Quarter and Recent Weeks**

- Developed an Accordion Pill (AP) for a Merck & Co. (MSD) proprietary compound that met the *in vitro* specifications set forth in the companies' research collaboration and are now in discussions with MSD to determine advancing the program into human pharmacokinetic (PK) studies;
- Concluded the Feasibility and Option Agreement (FOA) with Novartis Pharmaceuticals, under which Intec Pharma built a custom-designed AP for a Novartis proprietary compound that met the technical and PK clinical specifications set forth but following an internal and revised commercial strategic assessment, Novartis determined not to take the program forward;
- Novartis agreed to pay Intec Pharma $1.5 million upon conclusion of the program FOA and those funds were transferred to the Company in February 2020;
- Completed the qualifying production runs for the commercial scale manufacturing of AP Carbidopa/Levodopa (AP-CD/LD) with our manufacturing partner, LTS Lohmann Therapie-Systeme AG (LTS);
- Secured $10 million in committed financing from Aspire Capital, a long-term institutional investor; and
- Enhanced the balance sheet with a $6.5 million public offering.

**Management Commentary**

"We entered 2020 with a focused agenda for leveraging our Accordion Pill platform in both the near- and long-term, with goals to outlicence our late-stage Parkinson's disease program, to advance our research collaboration with Merck into human PK studies, to move our cannabinoid program into a second PK study and to expand our pipeline by adding new partnered programs, such as the one we have with Merck. Our team is diligently working toward executing these objectives and we look forward to achieving a number of these in the coming months," said Jeffrey A. Meckler, Vice Chairman and Chief Executive Officer of Intec.

"In tandem with these initiatives, we continue to work with our manufacturing partner, LTS, to advance the commercial scale production of AP-CD/LD, confident that having these critical processes in place enhances our business development efforts. We are pleased to report that LTS has completed the qualification studies for the commercial scale production and have initiated the validation and stability studies of the batches which are expected to serve as the clinical material for the next Phase 3 clinical trial plan. This is particularly beneficial for our partnering discussions for the Parkinson's disease program.

"In addition to advances with commercial manufacturing, we continue to engage in dialogues with potential new partners. Toward that end, our business development and technical operations teams are actively participating in a number of key drug delivery conferences worldwide in the coming months. We expect the enhanced visibility for the AP and its capabilities to increase the interest in the platform among audiences seeking new technologies and improved delivery formulations.

"Importantly, we strengthened our balance sheet believing that a stronger financial position enhances our ability to negotiate with partners and provides us with a longer runway to achieve key objectives. We believe our cash will now take us into the second quarter of 2021, without tapping into our Aspire commitment," added Mr. Meckler.

**Financial Highlights for the Fourth Quarter Ended December 31, 2019**

Research and development expenses, net, for the three-month period ended December 31, 2019 were approximately $1.8 million, a decrease of $8.5 million, or approximately 82.5%, compared with approximately $10.3 million in the three-month period ended December 31, 2018. The decrease was primarily due to a decrease in expenses related to the ACCORDANCE Phase 3 study of AP-CD/LD and the Open Label Extension study, both of which were completed during 2019 and a decrease in expenses related to the scale up activities for the commercial scale production capabilities for AP-CD/LD at LTS.

General and administrative expenses for the three-month period ended December 31, 2019 were approximately $1.8 million, a decrease of $300,000, or approximately 14.3%, compared with approximately $2.1 million in the three-month period ended December 31, 2018. The decrease was primarily due to a decrease in professional services and expenses related to investor relations activities. This decrease was offset by an increase in insurance expenses.

Impairment of long-lived assets was recorded as the top-line results of the ACCORDANCE trial were considered a triggering event for impairment. For the three-month period ended December 31, 2019, the Company recorded an impairment charge of approximately $3.9 million. This impairment represents the excess carrying value of the long-lived assets compared to its fair value.

The Company recorded other income for the three-month period ended December 31, 2019, of $1.5 million on conclusion of the program with

Novartis.

Net loss for the three-month period ended December 31, 2019 was approximately $6.6 million, a decrease of $6.0 million, or approximately 47.6%, compared with the net loss for the three-month period ended December 31, 2018 of approximately $12.6 million. The decrease was mainly due to the decrease in research and development expenses as detailed above and the other income associated with the conclusion of the Novartis program offset by the impairment of the Company's long-lived assets.

Loss per ordinary share for the fourth quarter ended December 31, 2019 was $0.19 compared with $0.38 for the fourth quarter ended December 31, 2018.

**Financial Highlights for the Year Ended December 31, 2019**

Research and development expenses, net, for the year ended December 31, 2019 were approximately $26.7 million, a decrease of $8.7 million, or approximately 24.6%, compared with approximately $35.4 million in the prior year period. The decrease was primarily due to a decrease in expenses related to the ACCORDANCE Phase 3 study of AP-CD/LD and the Open Label Extension study, both of which were completed during 2019.

General and administrative expenses for the year ended December 31, 2019 were approximately $8.3 million, an increase of $400,000, or approximately 5.1%, compared with approximately $7.9 million in the year ended December 31, 2018. The increase was primarily related to the increase in insurance expenses. This increase was offset by a decrease in professional services.

Impairment of long-lived assets was recorded as the top-line results of the ACCORDANCE trial were considered a triggering event for impairment. For the year ended December 31, 2019, the Company recorded an impairment charge of approximately $13.7 million. This impairment represents the excess carrying value of the long-lived assets compared to its fair value.

The Company recorded other income for the year ended December 31, 2019, of $1.5 million on conclusion of the program with Novartis.

Net loss for the fiscal year ended December 31, 2019 was approximately $47.6 million, an increase of $4.1 million, or approximately 9.4%, compared with the net loss for the year ended December 31, 2018 of approximately $43.5 million. The increase was mainly due to the impairment of the Company's long-lived assets and an increase in general and administrative expenses as detailed above offset by the other income associated with the conclusion of the Novartis program and the decrease in research and development expenses, as detailed above.

Loss per ordinary share for the full-year 2019 was $1.41 compared with $1.40 for the full-year 2018.

As of December 31, 2019, the Company had cash and cash equivalents and marketable securities of approximately $10.1 million compared with approximately $40.6 million at December 31, 2018.

Net cash used in operating activities was approximately $29.0 million for the year ended December 31, 2019 compared with net cash used in operating activities of approximately $39.1 million for the year ended December 31, 2018. This decrease resulted primarily from a decrease in research and development activities in the amount of approximately $8.7 million and changes in operating asset and liability items of approximately $1.2 million.

The Company had negative cash flow from investing activities of approximately $3.2 million for the year ended December 31, 2019 compared with negative cash flow from investing activities of approximately $9.3 million for the year ended December 31, 2018. This decrease resulted primarily from a reduction of approximately $2.1 million in investment in other assets related to the establishment of the commercial scale production capabilities for AP-CD/LD at LTS and a decrease in purchase of property and equipment in the amount of approximately $3.8 million.

Net cash provided by financing activities was approximately $2.4 million for the year ended December 31, 2019 compared with net cash provided by financing activities of approximately $35.1 million for the year ended December 31, 2018. The principal source of the cash provided by financing activities during 2019 was the funds received from the Company's "at-the-market" equity offering program of $2.1 million. The principal source of the cash provided by financing activities during 2018 was the funds received from the Company's April 2018 underwritten public offering of ordinary shares that resulted in net proceeds of approximately $35.0 million.

In January 2020, the Company raised $6.5 million in an underwritten public offering of 16,250,000 ordinary shares (which included pre-funded warrants to purchase ordinary shares in lieu thereof) and warrants to purchase up to 16,250,000 ordinary shares, at a public offering price of $0.40 per ordinary share and warrant. The warrants have an exercise price of $0.40 per share, are immediately exercisable, and will expire five years from the date of issuance.

More detailed information can be found in the Company's Annual Report, a copy of which has been filed with the Securities and Exchange Commission and posted on the Company's website at www.intecpharma.com. You may request a copy of the Company's Form 10-K, at no cost to you, by writing to the Chief Financial Officer of the Company at 12 Hartom Street, Har Hotzvim, Jerusalem 9777512, Israel or by calling the Company at +972 (2) 586 4657.

**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, 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.

**INTEC PHARMA LTD.**

CONSOLIDATED BALANCE SHEETS

| | December 31 | |
|---|---|---|
| | **2019** | **2018** |
| | **U.S. dollars in thousands** | |
| **Assets** | | |
| **CURRENT ASSETS:** | | |
| Cash and cash equivalents | $ 9,292 | $ 39,246 |
| Investment in marketable securities | 770 | 1,333 |
| Prepaid expenses and other receivables | 3,683 | 2,986 |
| **TOTAL CURRENT ASSETS** | 13,745 | 43,565 |
| **NON-CURRENT ASSETS:** | | |
| Property and equipment, net | 2,575 | 12,233 |
| Operating lease right-of-use assets | 1,243 | - |
| Other assets | 3,717 | 5,431 |
| Deferred tax assets | - | 281 |
| **TOTAL NON-CURRENT ASSETS** | 7,535 | 17,945 |
| **TOTAL ASSETS** | $ 21,280 | $ 61,510 |
| **Liabilities and shareholders' equity** | | |
| **CURRENT LIABILITIES -** | | |
| Accounts payable and accruals: | | |
| Trade | $ 3,507 | $ 2,849 |
| Other | 4,835 | 4,807 |
| **TOTAL CURRENT LIABILITIES** | 8,342 | 7,656 |
| **LONG-TERM LIABILITIES -** | | |
| Operating lease liabilities | 799 | - |
| Other liabilities | 604 | 309 |
| **TOTAL LONG-TERM LIABILITIES -** | 1,403 | 309 |
| **TOTAL LIABILITIES** | 9,745 | 7,965 |
| **COMMITMENTS AND CONTINGENT LIABILITIES** | | |
| **SHAREHOLDERS' EQUITY:** | | |
| Ordinary shares, with no par value - authorized: 100,000,000 as of December 31, 2019 and December 31, 2018, respectively; issued and outstanding: 35,892,209 and 33,232,988 Ordinary Shares as of December 31, 2019 and December 31, 2018, respectively | 727 | 727 |
| Additional paid-in capital | 200,231 | 194,642 |
| Accumulated deficit | (189,423) | (141,824) |
| **TOTAL SHAREHOLDERS' EQUITY** | 11,535 | 53,545 |
| **TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY** | $ 21,280 | $ 61,510 |

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CONSOLIDATED STATEMENTS OF OPERATIONS

| | Year ended December 31 | |
|---|---|---|
| | 2019 | 2018 |
| | U.S. dollars in thousands | |
| **OPERATING EXPENSES:** | | |
| **RESEARCH AND DEVELOPMENT EXPENSES,** net | $ (26,659) | $ (35,402) |
| **GENERAL AND ADMINISTRATIVE EXPENSES** | (8,287) | (7,926) |
| **IMPAIRMENT OF LONG-LIVED ASSETS** | (13,663) | - |
| **OTHER INCOME** | 1,500 | - |
| **OPERATING LOSS** | (47,109) | (43,328) |
| **FINANCIAL INCOME (EXPENSES),** net | 148 | (112) |
| **LOSS BEFORE INCOME TAX** | (46,961) | (43,440) |
| **INCOME TAX** | (638) | (103) |
| **NET LOSS** | $ (47,599) | $ (43,543) |
| | | $ |
| **LOSS PER ORDINARY SHARE- BASIC AND DILUTED** | $ (1.41) | $ (1.40) |
| **WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER ORDINARY SHARE IN THOUSANDS** | 33,776 | 31,193 |

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CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

| | Ordinary Shares | | Additional paid-in capital | Accumulated Deficit | Total |
|---|---|---|---|---|---|
| | Number of shares | Amounts | Amounts | | |
| | U.S. dollars in thousands | | | | |
| **BALANCE AT JANUARY 1, 2018** | 26,075,770 | $ 727 | $ 156,356 | $ (98,281) | $ 58,802 |
| **CHANGES DURING 2018:** | | | | | |
| Issuance of ordinary shares, net of issuance costs | 7,150,000 | - | 35,029 | - | 35,029 |
| Exercise of options by employees | 7,218 | - | 30 | - | 30 |
| Share-based compensation | - | - | 3,227 | - | 3,227 |
| Net loss | - | - | - | (43,543) | (43,543) |
| **BALANCE AT DECEMBER 31, 2018** | 33,232,988 | $ 727 | $ 194,642 | $ (141,824) | 53,545 |
| **CHANGES DURING 2019:** | | | | | |
| Issuance of ordinary shares, net of issuance costs | 1,944,512 | - | 2,086 | - | 2,086 |
| Issuance of ordinary shares per equity line agreement | 612,520 | - | - | - | - |
| Exercise of options by employees | 102,189 | - | 282 | - | 282 |
| Share-based compensation | - | | 3,221 | | 3,221 |
| Net loss | - | - | - | (47,599) | (47,599) |
| **BALANCE AT DECEMBER 31, 2019** | 35,892,209 | $ 727 | $ 200,231 | $ (189,423) | 11,535 |

**INTEC PHARMA LTD.**

CONSOLIDATED STATEMENTS OF CASH FLOWS

| | Year ended December 31 | |
|---|---|---|
| | 2019 | 2018 |
| | U.S. dollars in thousands | |
| **CASH FLOWS FROM OPERATING ACTIVITIES:** | | |
| Net loss | $ (47,599) | $ (43,543) |

| | | |
|---|---|---|
| Adjustments required to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 854 | 859 |
| Impairment of long-lived assets | 13,663 | - |
| Exchange differences on cash and cash equivalents | 67 | 829 |
| Change in right of use asset | 967 | - |
| Change in lease liabilities | (713) | - |
| Losses (gains) on marketable securities | (13) | 194 |
| Share-based compensation | 3,221 | 3,227 |
| Changes in operating asset and liabilities: | | |
| Increase in prepaid expenses and other receivables | (747) | (1,861) |
| Increase (decrease) in deferred tax assets | 281 | (281) |
| Increase in accounts payable and accruals | 679 | 1,191 |
| Increase in other liabilities | 295 | 309 |
| Net cash used in operating activities | (29,045) | (39,076) |
| **CASH FLOWS FROM INVESTING ACTIVITIES:** | | |
| Purchase of property and equipment | (921) | (4,667) |
| Investment in other assets | (2,865) | (4,932) |
| Proceeds from disposal of marketable securities, net | 576 | 298 |
| Net cash used in investing activities | (3,210) | (9,301) |
| **CASH FLOWS FROM FINANCING ACTIVITIES:** | | |
| Proceeds from issuance of ordinary shares, net of issuance costs | 2,086 | 35,029 |
| Proceeds from exercise of options by employees | 282 | 30 |
| Net cash provided by financing activities | 2,368 | 35,059 |
| **DECREASE IN CASH AND CASH EQUIVALENTS** | (29,887) | (13,318) |
| **CASH AND CASH EQUIVALENTS AT BEGINNING OF THE YEAR** | 39,246 | 53,393 |
| **EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS** | (67) | (829) |
| **CASH AND CASH EQUIVALENTS AT END OF THE YEAR** | $ 9,292 | $ 39,246 |
| | | |
| **SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING ACTIVITIES:** | | |
| Liability with respect to property and equipment | - | 170 |
| Liability with respect to other assets | - | 499 |
| | | |
| **SUPPLEMENTARY DISCLOSURE OF CASH FLOW INFORMATION:** | | |
| Taxes paid | 75 | 96 |
| Interest received | 327 | 734 |

**Intec Pharma Investor Contact:**

Will O'Connor
Stern IR
+1 212-362-1200
will@sternir.com

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