



## Intec Pharma Reports Third Quarter 2017 Operating and Financial Results

November 15, 2017

- Closed equity offering of \$57.5 million; Cash of \$64.7 million at September 30, 2017
- Expanding planned enrollment to 420 patients in its Phase 3 ACCORDANCE Trial; enrollment to be completed in the third quarter of 2018
- Formed new U.S. Medical Affairs and U.S. Business Development teams providing the support and infrastructure to fully develop the Accordion Pill

JERUSALEM, Nov. 15, 2017 /PRNewswire/ -- Intec Pharma LTD (NASDAQ:[NTEC](#)) (TASE: NTEC) today announced its third quarter 2017 financial results and provided a corporate update.

"The third quarter was truly transformational for Intec Pharma. We advanced our clinical development programs and are continuing to move forward with our pivotal Phase 3 trial in Parkinson's Disease. Additionally, we enhanced our organizational capabilities to fully develop and commercialize the Accordion Pill, taking us another step closer to our goal of becoming a global drug delivery company. We made significant additions in Medical Affairs, Business Development and to our senior leadership team," said Jeffrey Meckler, Chief Executive Officer of Intec Pharma. "Finally, we successfully completed a public equity offering to provide additional funding for our clinical program in Parkinson's Disease, on-going operations and product development. We are well-positioned to advance our exciting proprietary drug delivery platform into new areas and continue to build a world-class organization."

### Recent Corporate Highlights

#### *Phase 3 ACCORDANCE Clinical Trial*

The pivotal Phase 3 clinical trial assessing the safety and efficacy of the Accordion Pill Carbidopa/Levodopa combination in Parkinson's Disease continues to enroll and randomize patients. The Company is expanding planned enrollment to 420 patients to account for a higher than expected attrition rate during the titration period that precedes patient randomization. The attrition to date is largely due to patient withdrawals related to endoscopy procedures performed on the initial 100 patients, as well as withdrawals occurring during the open-label Sinemet® titration period that precedes exposure to the Accordion pill. Additionally, the Company has undertaken measures to optimize study activities, including enhancing patient selection, providing better site engagement to boost the rate of enrollment, and eliminate selected clinical sites with low enrollment. Given the increased patient target, the trial is expected to now complete enrollment in the third quarter of 2018.

#### *Phase 1 Accordion Pill – CBD/THC*

Announced positive results from its Phase 1 clinical trial of AP-CBD/THC, the Company's Accordion Pill platform technology with cannabidiol (CBD) and tetrahydrocannabinol (THC), the two primary cannabinoids contained in *Cannabis sativa*. The trial demonstrated the safety and efficacy of Accordion Pill technology.

The single-center, single-dose, randomized, three-way crossover study compared the pharmacokinetics, safety and tolerability of two formulations of Accordion Pill CBD/THC with Sativex in 21 normal healthy volunteers. The study results showed that patients in the Accordion Pill CBD/THC arm demonstrated significant improvements in exposure to CBD (290% to 330%) and THC (25% to 50%) compared with Sativex. The median time to peak concentration was 2-3 times longer than Sativex and absorption was significantly higher. Additionally, the formation of THC metabolites was meaningfully reduced, and the drug was found to be safe and well-tolerated with no serious adverse events reported.

Following the Phase 1 clinical trial, the Company evaluated the entire pharmacokinetic (PK) dataset and decided to re-design the Accordion Pill for CBD/THC to improve the overall performance. A Phase 1 PK study of the revised AP CBD/THC is planned and will be initiated in the near future.

#### *Manufacturing*

Announced the Company has contracted for a commercial-scale Accordion Pill Manufacturing system, which is expected to be completed by third quarter 2018. Additionally, the Company is evaluating commercial manufacturing organizations for the commercial-scale production of AP-CD/LD capsules and expects to engage a partner at the appropriate time.

#### *Clinical Affairs and Business Development Teams*

Created a new U.S. Medical Affairs team to oversee clinical trial operations, including U.S. site engagement and enrollment rates. The Medical Affairs team is comprised of four senior executives located in the U.S. with decades of experience in medical affairs at biotechnology and pharmaceutical companies,

Expanded its Clinical and Regulatory teams in Israel with additional hires to monitor and oversee clinical sites in Europe and Israel.

Created a U.S.-based Business Development team to identifying additional new opportunities and partnerships for the Accordion Pill platform with both pipeline products and with approved pharmaceuticals. The Business Development team will be located in the U.S. and Israel.

## *Financing and Corporate Operations*

Appointed Jeffrey A. Meckler as Chief Executive Officer. Mr. Meckler joined Intec's Board of Directors in April 2017 before being named CEO. He has more than 25 years of life sciences executive experience, including Chief Executive Officer of several biopharma companies and more than 17 years at Pfizer, where he held leadership positions in corporate strategic planning, acquisitions and business development, market research, manufacturing systems and sales operations analysis.

Named Nadav Navon, Ph.D., as Chief Operating Officer. Dr. Navon has served as Executive Vice President of Research & Development and Operations since March 2015 and has been with Intec Pharma since March 2006.

Appointed Walt Linscott to the position of Chief Administrative Officer. Mr. Linscott held senior level executive positions at Cocrystal Pharma, Carestream, and Solvay Pharmaceuticals. In addition to his years of direct industry experience, he was a partner in an international law firm where he served as Partner in Charge and Chair of the firm's Life Science Practice Group.

Announced Anthony Maddaluna, former Executive Vice President and President of Pfizer Global Supply, will seek election to the Board of Directors at the upcoming Annual General Meeting.

Completed a \$57.5 million primary equity offering of approximately 12.2 million ordinary shares at a public offering price of \$4.70 per ordinary share.

Opened a U.S. office for Administration, Business Development and U.S. Medical Affairs.

### **Financial Results for the nine months ended September 30, 2017**

The Company's research and development expenses, net, for the nine-month period ended September 30, 2017 amounted to approximately \$15.4 million, an increase of \$7.4 million, or approximately 93%, compared to approximately \$8.0 million in the comparable period in the preceding year. The increase was primarily due to increased activity in the Company's Phase III clinical trial for AP-CD/LD, payroll and related expenses and a decrease in the Israeli National Authority for Technological Innovation's, or NATI, participation in research and development expenses from \$3.1 million in 2016 to \$0 in 2017 as the Company decided not to accept NATI grant given its conditions.

The Company's general and administrative expenses for the nine-month period ended September 30, 2017 amounted to approximately \$3.6 million, an increase of \$1.3 million, or approximately 57%, compared to approximately \$2.3 million in the comparable period in the preceding year. The increase was primarily due to the increases in share-based compensation to employees, payroll and related expenses and professional services.

Net loss attributable to common stockholders for nine-month period ended September 30, 2017 was \$18.9 million, compared with \$9.7 million in the same period in 2016.

Net loss per share attributed to common stockholders for the nine-month period ended September 30, 2017, was (\$1.27), compared with (\$0.85) in the same period of 2016.

At September 30, 2017, the Company had cash and cash equivalents and financial assets at fair value through profit or loss of approximately \$64.7 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-CBD/THC, an Accordion Pill with the two primary cannabinoids contained in Cannabis sativa, cannabidiol (CBD) and tetrahydrocannabinol (THC), which is being developed for various indications including low back neuropathic pain and fibromyalgia.

### **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.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION

(Unaudited)

December 31, September 30,  
2016 2017

U.S. dollars in thousands

**A s s e t s**

**CURRENT ASSETS:**

|   |        |        |
|---|--------|--------|
| Cash and cash equivalents                             | 16,376 | 62,977 |
| Financial assets at fair value through profit or loss | 1,852  | 1,766  |
| Restricted bank deposits                              | 62     | 68     |
| Other receivables                                     | 2,384  | 1,333  |
|   | 20,674 | 66,144 |

**NON-CURRENT ASSETS -**

|                        |       |       |
|------------------------|-------|-------|
| Property and equipment | 4,047 | 5,902 |
|------------------------|-------|-------|

|                     |        |        |
|---------------------|--------|--------|
| <b>TOTAL ASSETS</b> | 24,721 | 72,046 |
|---------------------|--------|--------|

**Liabilities and equity**

**CURRENT LIABILITIES -**

Accounts payable and accruals:

|       |       |       |
|-------|-------|-------|
| Trade | 1,152 | 833   |
| Other | 768   | 2,490 |
|       | 1,920 | 3,323 |

**NON-CURRENT LIABILITIES -**

|                                  |    |   |
|----------------------------------|----|---|
| Derivative financial instruments | 97 | - |
|----------------------------------|----|---|

**COMMITMENTS AND CONTINGENT LIABILITIES**

|                          |       |       |
|--------------------------|-------|-------|
| <b>TOTAL LIABILITIES</b> | 2,017 | 3,323 |
|--------------------------|-------|-------|

**EQUITY:**

|                 |     |     |
|-----------------|-----|-----|
| Ordinary shares | 727 | 727 |
|-----------------|-----|-----|

|                                     |          |          |
|-------------------------------------|----------|----------|
| Share premium                       | 84,980   | 148,942  |
| Currency translation differences    | (378)    | (378)    |
| Accumulated deficit                 | (62,625) | (80,568) |
| <b>TOTAL EQUITY</b>                 | 22,704   | 68,723   |
| <b>TOTAL LIABILITIES AND EQUITY</b> | 24,721   | 72,046   |

**INTEC PHARMA LTD.**

CONDENSED CONSOLIDATED INTERIM STATEMENT OF COMPREHENSIVE LOSS

(Unaudited)

|   | Three months ended        |         | Nine months ended |          |
|---|---------------------------|---------|-------------------|----------|
|   | September 30              |         | September 30      |          |
|   | 2016                      | 2017    | 2016              | 2017     |
|   | U.S. dollars in thousands |         |                   |          |
| <b>RESEARCH AND DEVELOPMENT EXPENSES</b>  | (3,510)                   | (5,888) | (11,174)          | (15,426) |
| <b>LESS - PARTICIPATION IN RESEARCH AND DEVELOPMENT EXPENSES</b> <sup>928</sup> | -                         | -       | 3,169             | -        |
| <b>RESEARCH AND DEVELOPMENT EXPENSES, net</b>                                   | (2,582)                   | (5,888) | (8,005)           | (15,426) |
| <b>GENERAL AND ADMINISTRATIVE EXPENSES</b>                                      | (751)                     | (1,480) | (2,266)           | (3,566)  |
| <b>OTHER GAINS (LOSSES), net</b>  | 49                        | (5)     | 79                | 166      |
| <b>OPERATING LOSS</b>   | (3,284)                   | (7,373) | (10,192)          | (18,826) |
| <b>FINANCIAL INCOME</b>   | 103                       | 29      | 492               | 209      |
| <b>FINANCIAL EXPENSES</b>   | (93)                      | (308)   | (18)              | (240)    |
| <b>FINANCIAL INCOME (EXPENSES), net</b>   | 10                        | (279)   | 474               | (31)     |
| <b>LOSS AND COMPREHENSIVE LOSS</b>  | (3,274)                   | (7,652) | (9,718)           | (18,857) |
|   | <b>\$</b>                 |         |                   |          |
| <b>BASIC AND DILUTED LOSS PER ORDINARY SHARE</b>                                | (0.29)                    | (0.40)  | (0.85)            | (1.27)   |

**INTEC PHARMA LTD.**

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CHANGES IN EQUITY

(Unaudited)

| <b>Ordinary shares</b>  |                             |   |                          |   |                                |              |
|---|-----------------------------|---|--------------------------|---|--------------------------------|--------------|
|   | <b>Number of<br/>shares</b> | <b>Issued and<br/>paid-up<br/>share capital</b> | <b>Share<br/>premium</b> | <b>Currency<br/>translation<br/>differences</b> | <b>Accumulated<br/>deficit</b> | <b>Total</b> |
| <b>U.S. dollars in thousands</b>  |                             |   |                          |   |                                |              |
| <b>BALANCE AT JANUARY 1, 2016</b>   | 11,448,191                  | 727   | 84,980                   | (378)   | (49,799)                       | 35,530       |
| <b>CHANGES IN THE NINE MONTH PERIOD ENDED<br/>SEPTEMBER 30, 2016:</b>           |                             |   |                          |   |                                |              |
| Share-based compensation  |                             |   |                          |   | 266                            | 266          |
| Comprehensive loss  |                             |   |                          |   | (9,718)                        | (9,718)      |
| <b>BALANCE AT SEPTEMBER 30, 2016</b>  | 11,448,191                  | 727   | 84,980                   | (378)   | (59,251)                       | 26,078       |
| <b>BALANCE AT JANUARY 1, 2017</b>   | 11,448,191                  | 727   | 84,980                   | (378)   | (62,625)                       | 22,704       |
| <b>CHANGES IN THE NINE MONTH PERIOD ENDED<br/>SEPTEMBER 30, 2017:</b>           |                             |   |                          |   |                                |              |
| Proceeds of issuance shares, net of issuance costs                              | 2,289,638                   | -   | 9,525                    |   |                                | 9,525        |
| Proceeds from issuance of shares through public offering, net of issuance costs | 12,224,500                  | -   | 53,606                   |   |                                | 53,606       |
| Exercise of warrants as part of an investment agreement                         | 102,058                     | -   | 812                      |   |                                | 812          |
| Share-based compensation  |                             |   |                          |   | 914                            | 914          |
| Exercise of options by employees and service providers                          | 5,064                       | -   | 19                       |   |                                | 19           |
| Comprehensive loss  |                             |   |                          |   | (18,857)                       | (18,857)     |
| <b>BALANCE AT SEPTEMBER 30, 2017</b>  | 26,069,451                  | 727   | 148,942                  | (378)   | (80,568)                       | 68,723       |

**INTEC PHARMA LTD.**

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CASH FLOWS

(Unaudited)

**Nine months ended  
September 30**

2016 2017

U.S. dollars  
in thousands

**CASH FLOWS FROM OPERATING ACTIVITIES:**

|  |         |          |
|--|---------|----------|
| Comprehensive loss   | (9,718) | (18,857) |
| Adjustments to reconcile loss and comprehensive loss to net cash used in operating activities (see appendix A)96 |         | 3,897    |
| Net cash used in operating activities  | (9,622) | (14,960) |

**CASH FLOWS FROM INVESTING ACTIVITIES:**

|  |       |         |
|--|-------|---------|
| Purchase of property and equipment   | (247) | (2,447) |
| Proceeds from disposal of financial assets at fair value through profit or loss, net | 189   | 254     |
| Proceeds from sale of property and equipment   | -     | 7       |
| Net cash used in investing activities  | (58)  | (2,186) |

**CASH FLOWS FROM FINANCING ACTIVITIES:**

|   |   |        |
|---|---|--------|
| Issuance of shares, net of issuance costs                           | - | 9,525  |
| Issuance of shares through a public offering, net of issuance costs | - | 53,606 |
| Exercise of warrants as part of an investment agreement             | - | 531    |
| Exercise of options by employees and service providers              | - | 19     |
| Net cash provided by financing activities                           | - | 63,681 |

**INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS** (9,680) 46,535

**CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD** 23,649 16,376

**EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS** 133 66

**CASH AND CASH EQUIVALENTS - END OF PERIOD** 14,102 62,977

**INTEC PHARMA LTD.**

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CASH FLOWS

(Unaudited)

**Nine months ended**

**September 30**

2016 2017

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   | 529   | 613   |
| Changes in the fair value of derivative financial instruments  | (129) | 184   |
| Exchange differences on cash and cash equivalents              | (133) | (66)  |
| Exchange differences on restricted deposits                    | -     | (6)   |
| Gains on financial assets at fair value through profit or loss | (79)  | (168) |
| Loss on sale of property and equipment                         | -     | 2     |
| Share-based compensation to employees and service providers    | 266   | 914   |
|  | 454   | 1,473 |
| Changes in operating asset and liability items:                |       |       |
| Decrease (increase) in other receivables                       | (798) | 1,051 |
| Increase in accounts payable and accruals                      | 440   | 1,373 |
|  | (358) | 2,424 |
|  | 96    | 3,897 |

**APPENDIX B:**

Information regarding investment and financing activities not  
involving cash flows:

|   |     |     |
|---|-----|-----|
| Liability with respect to property purchase                                     |     | 30  |
| Settlement of liability in respect to derivative financial instrument to equity |     | 281 |
| Supplementary information to the statement of cash flows -                      |     |     |
| Interest received   | 127 | 99  |

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