

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 or 15d-16  
UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the Month of November 2018

001-37521  
(Commission File Number)

**INTEC PHARMA LTD.**  
(Translation of registrant's name into English)

**12 Hartom Street**  
**Har Hotzvim, Jerusalem 9777512, Israel**  
**(+972) (2) 586-4657**  
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover  
Form 20-F or Form 40-F.

Form 20-F  Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by  
Regulation S-T Rule 101(b)(1): \_\_\_\_\_

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by  
Regulation S-T Rule 101(b)(7): \_\_\_\_\_

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**EXPLANATORY NOTE**

On November 9, 2018, Intec Pharma Ltd. issued a press release titled “Intec Pharma Reports Third Quarter 2018 Financial Results and Corporate Update.”

A copy of the press release is attached hereto as Exhibit 99.1. Also attached are the unaudited condensed interim financial information and Management’s Discussion and Analysis of Financial Condition and Results of Operation (as Exhibits 99.2 and 99.3, respectively), both of which are incorporated by reference into the Company’s registration statements on Form S-8 (Files No. 333-209700, No. 333-212801, No. 333-222217 and No. 333-227027).

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

INTEC PHARMA LTD.

By: */s/ Nir Sassi*

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Name: Nir Sassi

Title: Chief Financial Officer

Date: November 9, 2018

**Exhibit No.**    **Description**

[99.1](#)            [Press Release Dated November 9, 2018.](#)

[99.2](#)            [Unaudited Condensed Interim Financial Information for the Period Ended September 30, 2018.](#)

[99.3](#)            [Management's Discussion and Analysis of Financial Condition and Results of Operation for the Period Ended September 30, 2018.](#)



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

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

**JERUSALEM (November 9, 2018)** – 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.

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“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.

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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.

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For more information, visit [www.intecpharma.com](http://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 Investor Contact:**

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**-Tables to Follow-**

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**INTEC PHARMA LTD.**  
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION  
(Unaudited)

	<b>December 31, 2017</b>	<b>September 30, 2018</b>
	<b>U.S. dollars in thousands</b>	
<b>Assets</b>		
<b>CURRENT ASSETS:</b>		
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
<b>TOTAL CURRENT ASSETS</b>	<b>56,343</b>	<b>56,708</b>
<b>NON-CURRENT ASSETS:</b>		
Other assets	-	2,694
Property and equipment	8,206	12,097
<b>TOTAL NON-CURRENT ASSETS</b>	<b>8,206</b>	<b>14,791</b>
<b>TOTAL ASSETS</b>	<b>64,549</b>	<b>71,499</b>
<b>Liabilities and equity</b>		
<b>CURRENT LIABILITIES -</b>		
Accounts payable and accruals:		
Trade	1,854	1,742
Other	3,893	4,413
<b>TOTAL CURRENT LIABILITIES</b>	<b>5,747</b>	<b>6,155</b>
<b>NON-CURRENT LIABILITIES -</b>		
<b>COMMITMENTS AND CONTINGENT LIABILITIES</b>		
<b>EQUITY:</b>		
Ordinary shares	727	727
Share premium	148,968	183,998
Currency translation differences	(378)	(378)
Accumulated deficit	(90,515)	(119,003)
<b>TOTAL EQUITY</b>	<b>58,802</b>	<b>65,344</b>
<b>TOTAL LIABILITIES AND EQUITY</b>	<b>64,549</b>	<b>71,499</b>

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

**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.S. dollars in thousands					
<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 SEPTEMBER 30, 2017:</b>						
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)
<b>BALANCE AT SEPTEMBER 30, 2017</b>	<u>26,069,451</u>	<u>727</u>	<u>148,942</u>	<u>(378)</u>	<u>(80,568)</u>	<u>68,723</u>
<b>BALANCE AT JANUARY 1, 2018</b>	26,075,770	727	148,968	(378)	(90,515)	58,802
<b>CHANGES IN THE NINE MONTH PERIOD ENDED SEPTEMBER 30, 2018:</b>						
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)
<b>BALANCE AT SEPTEMBER 30, 2018</b>	<u>33,225,988</u>	<u>727</u>	<u>183,998</u>	<u>(378)</u>	<u>(119,003)</u>	<u>65,344</u>

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

	<b>Nine months ended</b>	
	<b>September 30</b>	
	<b>2017</b>	<b>2018</b>
	<b>U.S. dollars</b>	
	<b>in thousands</b>	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
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	<u>(14,960)</u>	<u>(30,949)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
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	<u>(2,186)</u>	<u>(5,205)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
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	<u>63,681</u>	<u>35,030</u>
<b>INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>46,535</b>	<b>(1,124)</b>
<b>CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD</b>	<b>16,376</b>	<b>53,324</b>
<b>EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS</b>	<b>66</b>	<b>533</b>
<b>CASH AND CASH EQUIVALENTS - END OF PERIOD</b>	<b><u>62,977</u></b>	<b><u>52,733</u></b>

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

<b>Nine months ended</b>	
<b>September 30</b>	
<b>2017</b>	<b>2018</b>
<b>U.S. dollars</b>	
<b>in thousands</b>	

**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
	<u>1,473</u>	<u>2,704</u>
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)
	<u>2,424</u>	<u>(2,713)</u>
	<u>3,897</u>	<u>(9)</u>

**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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**INTEC PHARMA LTD.**

CONDENSED CONSOLIDATED INTERIM FINANCIAL INFORMATION

(UNAUDITED)

SEPTEMBER 30, 2018

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**INTEC PHARMA LTD.**

CONDENSED CONSOLIDATED INTERIM FINANCIAL INFORMATION

(UNAUDITED)

SEPTEMBER 30, 2018

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**INTEC PHARMA LTD.**

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION

(Unaudited)

	<b>December 31, 2017</b>	<b>September 30, 2018</b>
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Other assets	—	2,694
Property and equipment	8,206	12,097
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<b>TOTAL ASSETS</b>	<b>64,549</b>	<b>71,499</b>
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Trade	1,854	1,742
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<b>TOTAL LIABILITIES AND EQUITY</b>	<b>64,549</b>	<b>71,499</b>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements



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

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements

INTEC PHARMA LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CHANGES IN EQUITY

(Unaudited)

	Ordinary shares		Share premium	Currency translation differences	Accumulated deficit	Total
	Number of shares	Issued and paid-up share capital				
	U.S. dollars in thousands					
<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 SEPTEMBER 30, 2017:</b>						
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)
<b>BALANCE AT SEPTEMBER 30, 2017</b>	<u>26,069,451</u>	<u>727</u>	<u>148,942</u>	<u>(378)</u>	<u>(80,568)</u>	<u>68,723</u>
<b>BALANCE AT JANUARY 1, 2018</b>	26,075,770	727	148,968	(378)	(90,515)	58,802
<b>CHANGES IN THE NINE MONTH PERIOD ENDED SEPTEMBER 30, 2018:</b>						
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)
<b>BALANCE AT SEPTEMBER 30, 2018</b>	<u>33,225,988</u>	<u>727</u>	<u>183,998</u>	<u>(378)</u>	<u>(119,003)</u>	<u>65,344</u>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements

## INTEC PHARMA LTD.

## CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine months ended September 30	
	2017	2018
	U.S. dollars in thousands	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
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)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
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)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
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
<b>INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>46,535</b>	<b>(1,124)</b>
<b>CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD</b>	<b>16,376</b>	<b>53,324</b>
<b>EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS</b>	<b>66</b>	<b>533</b>
<b>CASH AND CASH EQUIVALENTS - END OF PERIOD</b>	<b>62,977</b>	<b>52,733</b>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements

## INTEC PHARMA LTD.

## CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine months ended September 30	
	2017	2018
	U.S. dollars in thousands	
<b>APPENDIX A:</b>		
<b>Adjustments to reconcile loss and comprehensive loss to net cash used in operating activities:</b>		
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
	<u>1,473</u>	<u>2,704</u>
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)
	<u>2,424</u>	<u>(2,713)</u>
	<u>3,897</u>	<u>(9)</u>
<b>APPENDIX B:</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

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

## INTEC PHARMA LTD.

### NOTES TO THE CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

(Unaudited)

#### NOTE 1 - GENERAL:

##### a. General:

- 1) Intec Pharma Ltd. ("Intec") is engaged in the development of proprietary technology, which enables the gastric retention of certain drugs. The technology is intended to significantly improve the efficiency of the drugs and substantially reduce their side-effects or the effective doses.

Intec is a limited liability public company incorporated and domiciled in Israel. The registered address of its offices is 12 Hartom St., Jerusalem, Israel

Intec's ordinary shares are traded on the Nasdaq Capital Market ("NASDAQ"). Intec's ordinary shares delisted from the Tel-Aviv Stock Exchange Ltd. in August 2018.

In September 2017, Intec incorporated a wholly-owned subsidiary in the United States of America in the State of Delaware – Intec Pharma Inc. (the "Subsidiary"). The Subsidiary was incorporated mainly to provide Intec executive and management services, including business development, medical affairs and investor relationship activities outside of Israel.

- 2) Intec together with its Subsidiary (the "Company") engage in research and development activities and as a group have not yet generated revenues from their operations. Accordingly, there is no assurance that the Company's operations will generate positive cash flows. As of September 30, 2018, the cumulative losses of the Company were approximately \$119.0 million. Management expects that the Company will continue to incur losses from its operations, which will result in negative cash flows from operating activities. The Company's management estimates that its current cash resources, will allow the Company to complete its Phase III clinical trial for AP-CD/LD. However, management estimates that further fund raising will be required in order for the Company to complete the research and development of all of its product candidates including the manufacturing activities of the AP-CD/LD in the foreseeable future. As a result, there is substantial doubt about the Company's ability to continue as a going concern.

The Company plans to fund its future operations through submissions of applications for grants from private funds, license agreements with third parties and raising capital from the public and/or private investors and/or institutional investors. There is no assurance, however, that the Company will be successful in obtaining the level of financing needed for its operations and the research and development of its product candidates. If the Company is unsuccessful in securing sufficient financing, it may need to make the necessary changes to its operations to reduce the level of expenditures in line with available resources.

The financial statements do not include any adjustments relating to the recoverability and classification of recorded assets and the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

- 3) On April 13, 2018, the Company completed an underwritten public offering of its ordinary shares. The Company raised, together with the partial exercise of the underwriters' over-allotment option, a total of approximately \$35.0 million (net of underwriting discounts, commissions and other offering expenses in the amount of \$2.5 million). For more details see note 6(a).

##### b. Approval of consolidated financial statements

These condensed consolidated interim financial statements were approved by the Board of Directors on November 8, 2018.

**INTEC PHARMA LTD.**

NOTES TO THE CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS (continued)

(Unaudited)

**NOTE 2 - BASIS OF PREPARATION**

The Company's condensed consolidated interim financial statements as of September 30, 2018 and for the three and nine months then ended (the "condensed consolidated interim financial statements") have been prepared in accordance with International Accounting Standard IAS 34, "Interim Financial Reporting". These condensed interim consolidated financial statements, which are unaudited, do not include all disclosures necessary for a complete statement of financial position, results of operations, and cash flow in conformity with International Financial Reporting Standards ("IFRS"). The condensed consolidated interim financial statements should be read in conjunction with the annual financial statements as of December 31, 2017 and for the year then ended and their accompanying notes, which have been prepared in accordance with IFRS as published by the International Accounting Standards Board. The results of operations for the three and nine months ended September 30, 2018 are not necessarily indicative of the results that may be expected for the entire fiscal year or for any other interim period.

**NOTE 3 - SIGNIFICANT ACCOUNTING POLICIES:**

- a. The accounting policies and calculation methods applied in the preparation of the condensed consolidated interim financial statements are consistent with those applied in the preparation of the annual financial statements as of December 31, 2017 and for the year then ended, except for the adoption of International Financial Reporting Standard No. 9 "Financial Instruments", effective from January 1, 2018, which did not have a material effect on the Company's financial statements.
- b. International Financial Reporting Standard No. 16 "Leases" is effective for periods beginning on or after January 1, 2019. The Company currently anticipates that the adoption will result in an increase in assets and liabilities on our consolidated statements of financial position and will not have a material impact on our consolidated statements of comprehensive loss or consolidated statements of cash flows.

**NOTE 4 - CRITICAL ACCOUNTING ESTIMATES**

As part of the preparation of the condensed consolidated interim financial statements, Company management is required to make estimates that affect the value of assets, liabilities, income, expenses and certain disclosures included in the Company's condensed consolidated interim financial statements. By their very nature, such estimates are subjective and complex and consequently may differ from actual results.

The critical accounting estimates applied in the preparation of the condensed consolidated interim financial statements are consistent with those applied in the preparation of the annual financial statements as of December 31, 2017.

**NOTE 5 - FINANCIAL INSTRUMENTS:**

- a. As of September 30, 2018 and as of December 31, 2017, the Company holds financial assets at fair value through profit and loss in an amount of approximately \$1.7 million and \$1.8 million, respectively, which are included in Level 1.
- b. The fair value of restricted bank deposits, other receivables and other payables which constitute financial assets and financial liabilities, approximates their carrying amount.

**INTEC PHARMA LTD.**

NOTES TO THE CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS (continued)

(Unaudited)

**NOTE 6 - EQUITY:**

**a. Changes in share capital:**

On April 13, 2018, the Company completed an underwritten public offering of its ordinary shares pursuant to which the Company issued 6,750,000 ordinary shares with no par value at a price of \$5.25 per ordinary share. On May 10, 2018, the underwriters partially exercised their over-allotment option and purchased 400,000 additional ordinary shares. The total net proceeds were approximately \$35.0 million, after deducting underwriting discounts, commissions and other offering expenses.

**b. Share-based payment to employees:**

1) The following are the grants of options to employees:

<u>Date of grant</u>	<u>Number of options granted</u>	<u>Exercise price per option (USD)</u>	<u>Fair value on grant date- USD in thousands</u>	<u>Expiration date</u>
January 2018	135,000	5.19	389	January 2025
February 2018	865,000	6.10 - 6.67	2,089	February 2025
March 2018	75,000	6.40 - 6.45	209	March 2025
June 2018	220,000	4.44	387	June 2025

Vesting conditions of all of the above options are service conditions and the options will vest over a three-year period, with one third of the options vesting at the end of the first year from the date of grant, and the remaining vesting in eight equal quarterly tranches, subsequent to the first year from the grant date.

Each one option is exercisable into one ordinary share.

The fair value of all of the options was calculated using the Black-Scholes options pricing model, and based on the following assumptions:

<u>Date of grant</u>	<u>Share price on date of grant- in USD</u>	<u>Expected dividend</u>	<u>Expected volatility</u>	<u>Risk free interest*</u>	<u>Expected term</u>
January 2018	6.05	None	46.32%	2.3%	5 years
February 2018	5.70 - 6.10	None	45.87% - 46.47%	2.5% - 2.7%	5 years
March 2018	6.40 - 6.45	None	46.03%	2.6%	5 years
June 2018	4.20	None	46.15%	2.7%	5 years

\* The risk-free interest rate was determined on the basis of the yield rates to maturity of unlinked government bonds bearing a fixed interest rate, whose maturity dates correspond to the expected exercise dates of the options.

2) During the nine-month period ended September 30, 2018, options to purchase 59,482 ordinary shares granted to employees were forfeited or expired.

**INTEC PHARMA LTD.**

NOTES TO THE CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS (continued)

(Unaudited)

**NOTE 7 - COMMITMENTS AND CONTINGENT LIABILITIES:**

- a. In April 2017, the Company engaged with an international manufacturer for ordering a large scale automated production line for manufacturing Accordion Pills in the amount of approximately €7.5 million. The order covers engineering, manufacture and assembly of the automated production line. As of September 30, 2018, the Company had transferred payments of €5.25 million (approximately \$6.2 million), of which €1.5 million (approximately \$1.8 million) was paid during the nine-month period ended September 30, 2018, and recognized a liability in an additional amount of €1.6 million (approximately \$1.9 million).
- b. In January 2018, the Company entered into a Feasibility and Option Agreement with Novartis Pharmaceuticals to explore using the Accordion Pill platform for a proprietary Novartis compound. Under the agreement and the research plan, the Company's activities will be funded by Novartis subject to the achievement of agreed milestones.
- c. In March 2018, the Company entered into a Term Sheet for Manufacturing Services with an international manufacturer (the "Manufacturer") for the manufacture of AP-CD/LD. Under the Term Sheet, the Company will bear the costs incurred by the Manufacturer to acquire the production equipment for AP-CD/LD ("Equipment") in the amount of approximately €7.0 million, however such amount will later be reimbursed to the Company by the Manufacturer in the form of a reduction in the purchase price of the AP-CD/LD product. As of September 30, 2018, the Company has recognized the Equipment as non-current other assets in total amount of approximately €2.3 million (approximately \$2.7 million). As of that date, the Company had transferred payments of approximately €2.1 million (approximately \$2.5 million) in costs of the Equipment and recognized a liability in an additional amount of approximately €210,000 (approximately \$244,000).

The Term Sheet contains several termination rights which are expected to be included in a definitive manufacturing and supply agreement. According to the Term Sheet, upon early termination, the Manufacturer has the right to purchase the Equipment from the Company.



**INTEC PHARMA LTD.**

NOTES TO THE CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS (continued)

(Unaudited)

**NOTE 8 - TRANSACTIONS AND BALANCES WITH RELATED PARTIES:**

Key management includes members of the Board of Directors and the Chief Executive Officer.

**a. Transactions with related parties:**

	<b>Three months ended September 30</b>		<b>Nine months ended September 30</b>	
	<b>2017</b>	<b>2018</b>	<b>2017</b>	<b>2018</b>
	<b>U.S. dollars in thousands</b>			
Key management compensation expenses:				
Salaries and short-term employee benefits	453	240	795	662
Long term employment benefits	12	—	34	—
Share-based compensation expenses	193	225	574	638
	<u>658</u>	<u>465</u>	<u>1,403</u>	<u>1,300</u>

**b. Balances with related parties:**

	<b>December 31, 2017</b>	<b>September 30, 2018</b>
	<b>U.S. dollars in thousands</b>	
Statements of financial position items -		
current liabilities - Accounts payable and accruals - other	<u>190</u>	<u>121</u>

## Management's Discussion and Analysis of Financial Condition and Results of Operation

### General

The following discussion and analysis provides information that we believe to be relevant to an assessment and understanding of our results of operations and financial condition for the periods described. This discussion should be read together with our condensed consolidated interim financial statements and the notes to the financial statements, which are included in this Report of Foreign Private Issuer on Form 6-K. This information should also be read in conjunction with the information contained in our Annual Report on Form 20-F for the year ended December 31, 2017, filed with the Securities and Exchange Commission on March 9, 2018, including the consolidated annual financial statements as of December 31, 2017 and their accompanying notes included therein.

This Report of Foreign Private Issuer on Form 6-K of Intec Pharma Ltd. 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 Report of Foreign Private Issuer on Form 6-K are made as of the date of this Report of Foreign Private Issuer on Form 6-K, 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.

All references to “we,” “us,” “our,” “Intec”, “the Company” and “our Company” in this Report of Foreign Private Issuer on Form 6-K are to Intec Pharma Ltd. and its U.S. subsidiary Intec Pharma Inc., unless the context otherwise requires.

### Overview

We are a clinical stage biopharmaceutical company focused on developing drugs based on our proprietary Accordion Pill platform technology, which we refer to as the Accordion Pill. Our 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, or GR, and specific release mechanism. Our product pipeline currently includes several product candidates in various clinical trial stages. Our leading product candidate, Accordion Pill Carbidopa/Levodopa, or AP-CD/LD, is being developed for the indication of treatment of Parkinson’s disease symptoms in advanced Parkinson’s disease patients.

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We have successfully completed a Phase II clinical trial for AP-CD/LD for the treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients and have agreed with the U.S. Food and Drug Administration, or the FDA, on the remaining clinical development program for AP-CD/LD for the treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients, including the main principles of the single required pivotal Phase III clinical trial in advanced Parkinson's disease patients. In October 2018, we completed patient enrollment in the ACCORDANCE study, the pivotal Phase III clinical trial for AP-CD/LD, and we expect to report topline results in mid-2019.

In our correspondence with the FDA, the FDA previously agreed that an acceptable regulatory pathway for AP-CD/LD would be to file a new drug application, or NDA, pursuant to Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or FDCA, which is a streamlined approval pathway that may accelerate the time to commercialize and decrease the costs of FDA approval for AP-CD/LD, as compared to those typically associated with a new chemical entity.

In addition, we have initiated a clinical development program for our Accordion Pill platform with the two primary cannabinoids contained in cannabis sativa, cannabidiol, or CBD, and 9-tetrahydrocannabinol, or THC, both individually and combined, which we refer to as AP-Cannabinoids. We are formulating and testing CBD and THC for the treatment of various pain indications, including fibromyalgia. AP-Cannabinoids are designed to extend the absorption phase of CBD and THC, resulting in more consistent levels for an improved therapeutic effect, which may address several major drawbacks of current methods of treatments, such as short duration of effect, delayed onset, variability of exposure, variability of the administered dose and adverse events that correlate with peak levels.

In August 2017, we announced the results of a Phase I clinical trial that compared the safety, tolerability and pharmacokinetic (PK) of AP-CBD/THC with Sativex®. This Phase I trial was a single-center, single-dose, randomized, three-way crossover study in Israel to compare the safety, tolerability and PK of two formulations of AP-CBD/THC with Buccal Sativex® in 21 normal, healthy volunteers. The results showed that patients in the AP-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. Sativex® is an oral buccal spray containing CBD and THC that is commercially available outside the United States. Following the Phase I clinical trial, we evaluated the program and decided as a next step to develop two new Accordion Pills containing only the individual cannabinoid components, namely CBD and THC. A Phase I PK study with AP-THC is planned to be initiated by the end of 2018. We believe that exploring the individual components will provide additional indications to pursue.

In March 2018, we entered into a Term Sheet for Manufacturing Services with LTS Lohmann Therapie-Systeme AG, or LTS, for the manufacture of AP-CD/LD. Under the term sheet, LTS will exclusively manufacture and supply us with AP-CD/LD capsules using our proprietary Accordion Pill production technology in LTS' manufacturing facility in Andernach, Germany upon the completion of assembly of the production line and subject to the execution and terms of a manufacturing and supply agreement to be negotiated and entered into between us and LTS.

Under the terms of the term sheet, we will bear the costs incurred by LTS to acquire the production equipment for AP-CD/LD ("Production Equipment"); however, such amount will later be reimbursed to us by LTS in the form of a reduction in the purchase price of the product. The term sheet contains several termination rights which are expected to be included in a definitive manufacturing and supply agreement, including, among others, in the cases of breach by either party, as well as our right to terminate in the case of change of control of LTS or us, and in the event, we decide to halt the development of AP-CD/LD.

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## **Basis of Presentation**

Our condensed consolidated interim financial statements as of September 30, 2018 and for the three and nine months then ended, or the condensed consolidated interim financial statements, have been prepared in accordance with International Accounting Standard IAS 34, "Interim Financial Reporting". These condensed consolidated interim financial statements, which are unaudited, do not include all disclosures necessary for a complete statement of financial position, results of operations, and cash flow in conformity with International Financial Reporting Standards, or IFRS. The condensed consolidated interim financial statements should be read in conjunction with the annual financial statements as of December 31, 2017 and for the year then ended and their accompanying notes, which have been prepared in accordance with IFRS as published by the International Accounting Standards Board, or IASB.

## **Results of Operations**

### **Comparison of Three and Nine Months Ended September 30, 2018 and 2017**

#### *Research and Development Expenses, Net*

Our research and development expenses, net, for the three-month period ended September 30, 2018 amounted to approximately \$7.8 million, an increase of \$1.9 million, or approximately 32%, compared to approximately \$5.9 million in the comparable period in the preceding year. Our research and development expenses, net, for the nine-month period ended September 30, 2018 amounted to approximately \$25.1 million, an increase of \$9.7 million, or approximately 63%, compared to approximately \$15.4 million in the comparable period in the preceding year. The increase in both periods was primarily due to an increase in expenses related to the progression of the ACCORDANCE study, our Phase III 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*

Our general and administrative expenses for the three-month period ended September 30, 2018 amounted to approximately \$1.7 million, an increase of \$200,000, or approximately 13%, compared to approximately \$1.5 million in the comparable period in the preceding year. 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.

Our general and administrative expenses for the nine-month period ended September 30, 2018 amounted to approximately \$5.8 million, an increase of \$2.2 million, or approximately 61%, compared to approximately \$3.6 million in the comparable period in the preceding year. 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.

#### *Financial Income (Expenses), Net*

Our financial income, net for the three-month period ended September 30, 2018 amounted to approximately \$150,000 compared to financial expenses, net of \$279,000 recorded in the comparable period in the preceding year. Our financial income, net for the nine-month period ended September 30, 2018 amounted to approximately \$136,000 compared to financial expenses, net of \$31,000 recorded in the comparable period in the preceding year. The financial income, net for the three and nine-month period ended September 30, 2018 resulted primarily from income from interest on cash equivalents and financial assets at fair value through profit or loss offset by foreign currency exchange expenses.

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### ***Loss and Comprehensive Loss***

Our 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 to approximately \$7.7 million in the comparable period in the preceding year. Our 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 to approximately \$18.9 million in the comparable period in the preceding year. The increase in both periods was mainly due to an increase in research and development expenses and general and administrative expenses as detailed above.

### **Liquidity and Capital Resources**

Since our inception, we have funded our operations primarily through public and private offerings (in Israel and in the United States) of our equity securities, grants from the Israeli Innovation Authority (IIA) and grants from other organizations such as the Michael J. Fox Foundation, as well as payments received under feasibility and related agreements that we have entered into with multinational pharmaceutical companies, pursuant to which we have historically been entitled to full coverage of our development costs with regard to the projects specified in those agreements.

As of September 30, 2018, we had cash and cash equivalents and financial assets at fair value through profit or loss of approximately \$54.5 million. As of December 31, 2017, we had cash and cash equivalents and financial assets at fair value through profit or loss of approximately \$55.2 million. During the nine-month period ended September 30, 2018, we used approximately \$31.0 million in operating activities and approximately \$5.2 million in investing activities, primarily for the ACCORDANCE study, the establishment of the commercial scale production capabilities for AP-CD/LD and repayment of the IIA grants, which was offset by a public offering with net proceeds of approximately \$35.0 million and exchange differences in cash and cash equivalents amounted to approximately \$533,000.

Net cash used in operating activities was approximately \$30.9 million for the nine-month period ended September 30, 2018 compared with net cash used in operating activities of approximately \$15.0 million for the nine-month period ended September 30, 2017. This increase resulted from an increase in our loss and comprehensive loss of approximately \$12.0 million and a decrease in changes in operating asset and liability items of approximately \$5.1 million which was offset by an increase in income and expenses not involving cash flows of approximately \$1.2 million.

We had negative cash flow from investing activities of approximately \$5.2 million for the nine-month period ended September 30, 2018 compared to negative cash flow from investing activities of approximately \$2.2 million for the nine-month period ended September 30, 2017. This increase resulted primarily from an increase in purchase of property and equipment in the amount of approximately \$200,000 and investment in other assets related to Production Equipment in the amount of approximately \$2.5 million. For more information see note 7(c) in our condensed consolidated interim financial statements as of September 30, 2018.

Net cash provided by financing activities was approximately \$35.0 for the nine-month period ended September 30, 2018 compared with net cash provided by financing activities of approximately \$63.7 million for the nine-month period ended September 30, 2017. The principal source of the cash provided by financing activities during the nine months ended September 30, 2018, was the funds received from our April 2018 public offering of ordinary shares that resulted in net proceeds of approximately \$35.0 million. The principal source of the cash provided by financing activities during the nine months ended September 30, 2017, was the funds received from our March 2017 private placement of ordinary shares that resulted in net proceeds of approximately \$9.5 million and the funds received from our August 2017 public offering of ordinary shares that resulted in net proceeds of approximately \$53.6 million.

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## **Current Outlook**

We estimate that our current cash resources will allow us to complete our Phase III clinical trial for AP-CD/LD. We believe however, that further fund raising will be required in order to complete the research and development of all of our product candidates, including the manufacturing activities of the AP-CD/LD in the foreseeable future. As a result, there is substantial doubt about our ability to continue as a going concern. We expect to satisfy our future cash needs through submissions of applications for grants from private funds, license agreements with third parties and capital raising from the public, private investors and institutional investors, such as through the public offering of ordinary shares that we completed in April 2018. We may also engage with a partner in order to share the costs associated with the development and manufacturing of our product candidates. For more information see note 1a(2) in our condensed consolidated interim financial statements as of September 30, 2018.

## **Foreign Private Issuer Status**

As of June 30, 2018, the last business day of our second quarter, we determined that we no longer qualify as a foreign private issuer. Effective January 1, 2019, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive in certain respects, and which must be filed more promptly, than the forms available to a foreign private issuer. In addition, we will be required to comply with U.S. proxy requirements and Regulation FD (Fair Disclosure) and our officers, directors and principal shareholders will become subject to the beneficial ownership reporting and short-swing profit recovery requirements in Section 16 of the Securities Exchange Act of 1934, as amended. We will also no longer be eligible to rely upon exemptions from corporate governance requirements that are available to foreign private issuers or to benefit from other accommodations for foreign private issuers under the rules of the SEC or the Nasdaq, which would involve additional costs. Our next Annual Report for the year ending December 31, 2018 will be filed as a domestic issuer, on Form 10-K. The consolidated financial statements included on Form 10-K will be presented in accordance with accounting principles generally accepted in the United States (U.S. GAAP) with such change being applied retrospectively.

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