

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

**FORM 10-Q**

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2019

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE TRANSITION PERIOD FROM TO

Commission File Number 001-37521

**INTEC PHARMA LTD.**

(Exact name of Registrant as specified in its Charter)

**Israel**

(State or other jurisdiction of  
incorporation or organization)

**Not Applicable**

(I.R.S. Employer  
Identification No.)

**12 Hartom Street  
Har Hotzvim, Jerusalem**

(Address of principal executive offices)

**9777512**

(Zip Code)

Registrant's telephone number, including area code: +972-2-586-4657

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES  NO

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). YES  NO

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES  NO

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary Shares, no par value	NTEC	Nasdaq Capital Market

The number of shares of Registrant's ordinary shares outstanding as of August 7, 2019: 33,302,800.

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**PART I. FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**INTEC PHARMA LTD.**

**UNAUDITED CONDENSED CONSOLIDATED  
FINANCIAL STATEMENTS**

AS OF JUNE 30, 2019

**INTEC PHARMA LTD.**

**UNAUDITED CONDENSED CONSOLIDATED  
FINANCIAL STATEMENTS**

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**INTEC PHARMA LTD.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(Unaudited)

	<b>June 30, 2019</b>	<b>December 31, 2018</b>
	<b>U.S. dollars in thousands</b>	
<b>Assets</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 20,796	\$ 39,246
Investment in marketable securities (Note 3)	762	1,333
Prepaid expenses and other receivables	3,072	2,986
<b>TOTAL CURRENT ASSETS</b>	<b>24,630</b>	<b>43,565</b>
<b>NON-CURRENT ASSETS:</b>		
Other assets (Note 4c)	7,487	5,431
Property and equipment, net	12,455	12,233
Operating lease right-of-use assets (Note 4a)	1,859	-
Deferred tax assets	429	281
<b>TOTAL NON-CURRENT ASSETS</b>	<b>22,230</b>	<b>17,945</b>
<b>TOTAL ASSETS</b>	<b>\$ 46,860</b>	<b>\$ 61,510</b>
<b>Liabilities and shareholders' equity</b>		
<b>CURRENT LIABILITIES -</b>		
Accounts payable and accruals:		
Trade	\$ 2,331	\$ 2,849
Other (Note 6)	7,679	4,807
<b>TOTAL CURRENT LIABILITIES</b>	<b>10,010</b>	<b>7,656</b>
<b>LONG-TERM LIABILITIES -</b>		
Non-current operating lease liabilities (Note 4a)	1,269	-
Other liabilities	472	309
<b>TOTAL LONG-TERM LIABILITIES</b>	<b>1,741</b>	<b>309</b>
<b>TOTAL LIABILITIES</b>	<b>11,751</b>	<b>7,965</b>
<b>COMMITMENTS AND CONTINGENT LIABILITIES (Note 4)</b>		
<b>SHAREHOLDERS' EQUITY:</b>		
Ordinary shares, with no par value - authorized: 100,000,000 Ordinary Shares as of June 30, 2019 and December 31, 2018; issued and outstanding: 33,302,800 and 33,232,988 Ordinary Shares as of June 30, 2019 and December 31, 2018, respectively	727	727
Additional paid-in capital	196,871	194,642
Accumulated deficit	(162,489)	(141,824)
<b>TOTAL SHAREHOLDERS' EQUITY</b>	<b>35,109</b>	<b>53,545</b>
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b>\$ 46,860</b>	<b>\$ 61,510</b>

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

**INTEC PHARMA LTD.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(Unaudited)

	<b>Three months ended</b>		<b>Six months ended</b>	
	<b>June 30</b>		<b>June 30</b>	
	<b>2019</b>	<b>2018</b>	<b>2019</b>	<b>2018</b>
	<b>U.S. dollars</b>		<b>U.S. dollars</b>	
	<b>in thousands</b>		<b>in thousands</b>	
<b>OPERATING EXPENSES:</b>				
<b>RESEARCH AND DEVELOPMENT EXPENSES, net</b>	\$ (7,860)	\$ (8,400)	\$ (16,402)	\$ (17,280)
<b>GENERAL AND ADMINISTRATIVE EXPENSES</b>	(2,144)	(2,194)	(4,334)	(4,104)
<b>OPERATING LOSS</b>	(10,004)	(10,594)	(20,736)	(21,384)
<b>FINANCIAL INCOME (EXPENSES), net</b>	33	(292)	143	(168)
<b>LOSS BEFORE INCOME TAX</b>	(9,971)	(10,886)	(20,593)	(21,552)
<b>INCOME TAX</b>	(38)	(147)	(72)	(210)
<b>NET LOSS</b>	\$ (10,009)	\$ (11,033)	\$ (20,665)	\$ (21,762)
	\$		\$	
<b>LOSS PER SHARE BASIC AND DILUTED</b>	(0.30)	(0.34)	(0.62)	(0.75)
<b>WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER ORDINARY SHARE IN THOUSANDS</b>	33,300	32,086	33,274	29,114

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

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

	Ordinary Shares		Additional paid-in capital		Accumulated Deficit		Total	
	Number of shares	Amounts		Amounts		Amounts		
		U.S. dollars in thousands						
<b>BALANCE AT JANUARY 1, 2018</b>	26,075,770	\$ 727	\$ 156,356	\$ (98,281)	\$	\$	58,802	
<b>CHANGES IN THE SIX-MONTH PERIOD ENDED JUNE 30, 2018:</b>								
Issuance of ordinary shares, net of issuance costs	7,150,000	-	35,029	-	-	-	35,029	
Exercise of options	218	-	1	-	-	-	1	
Share-based compensation (Note 5)	-	-	1,601	-	-	-	1,601	
Net loss	-	-	-	(21,762)	-	-	(21,762)	
<b>BALANCE AT JUNE 30, 2018</b>	<u>33,225,988</u>	<u>\$ 727</u>	<u>\$ 192,987</u>	<u>\$ (120,043)</u>	<u>\$</u>	<u>\$</u>	<u>73,671</u>	
<b>BALANCE AT JANUARY 1, 2019</b>	33,232,988	\$ 727	\$ 194,642	(141,824)	\$	\$	53,545	
<b>CHANGES IN THE SIX-MONTH PERIOD ENDED JUNE 30, 2019:</b>								
Exercise of options	69,812	-	268	-	-	-	268	
Share-based compensation (Note 5)	-	-	1,961	-	-	-	1,961	
Net loss	-	-	-	(20,665)	-	-	(20,665)	
<b>BALANCE AT JUNE 30, 2019</b>	<u>33,302,800</u>	<u>\$ 727</u>	<u>\$ 196,871</u>	<u>\$ (162,489)</u>	<u>\$</u>	<u>\$</u>	<u>35,109</u>	

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

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

	Ordinary Shares		Additional	Accumulated	Total
	Number of	Amounts	paid-in capital	Deficit	
	shares		Amounts		
		U.S. dollars in thousands			
<b>BALANCE AT APRIL 1, 2018</b>	26,075,770	\$ 727	\$ 157,079	\$ (109,010)	\$ 48,796
<b>CHANGES IN THE THREE-MONTH PERIOD ENDED</b>					
<b>  JUNE 30, 2018:</b>					
Issuance of ordinary shares, net of issuance costs	7,150,000	-	35,029	-	35,029
Exercise of options	218	-	1	-	1
Share-based compensation	-	-	878	-	878
Net loss	-	-	-	(11,033)	(11,033)
<b>BALANCE AT JUNE 30, 2018</b>	33,225,988	\$ 727	\$ 192,987	\$ (120,043)	\$ 73,671
<b>BALANCE AT APRIL 1, 2019</b>	33,297,371	\$ 727	\$ 195,842	(152,480)	\$ 44,089
<b>CHANGES IN THE THREE-MONTH PERIOD ENDED</b>					
<b>  JUNE 30, 2019:</b>					
Exercise of options	5,429	-	11	-	11
Share-based compensation	-	-	1,018	-	1,018
Net loss	-	-	-	(10,009)	(10,009)
<b>BALANCE AT JUNE 30, 2019</b>	33,302,800	\$ 727	\$ 196,871	\$ (162,489)	\$ 35,109

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



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

	<b>Six months ended June 30</b>	
	<b>2019</b>	<b>2018</b>
	<b>U.S. dollars in thousands</b>	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (20,665)	\$ (21,762)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	431	416
Exchange differences on cash and cash equivalents	(19)	(368)
Right of use asset	351	-
Lease liability	(243)	-
Losses (gains) on marketable securities	(5)	154
Share-based compensation	1,961	1,601
Changes in operating assets and liabilities:		
Increase in prepaid expenses and other receivables	(136)	(502)
Increase in deferred tax assets	(148)	-
Increase in accounts payable and accruals	583	606
Increase in other liabilities	163	-
Net cash used in operating activities	<u>(17,727)</u>	<u>(19,855)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	(151)	(2,613)
Investment in other assets	(1,435)	(1,696)
Proceeds from disposal of marketable securities, net	576	1
Net cash used in investing activities	<u>(1,010)</u>	<u>(4,308)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of ordinary shares, net of issuance costs	-	35,029
Proceeds from exercise of options	268	1
Net cash provided by financing activities	<u>268</u>	<u>35,030</u>
<b>DECREASE IN CASH AND CASH EQUIVALENTS</b>	<u>(18,469)</u>	<u>10,867</u>
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD</b>	<u>39,246</u>	<u>53,393</u>
<b>EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS</b>	<u>19</u>	<u>368</u>
<b>CASH AND CASH EQUIVALENTS AT END OF THE PERIOD</b>	<u>\$ 20,796</u>	<u>\$ 64,628</u>
<b>SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:</b>		
Liability with respect to property and equipment (see note 4b)	<u>\$ 502</u>	<u>\$ 1,740</u>
Liability with respect to other assets (see note 4c)	<u>\$ 1,114</u>	<u>\$ -</u>
<b>SUPPLEMENTARY DISCLOSURE OF CASH FLOW INFORMATION -</b>		
Taxes paid	<u>\$ 50</u>	<u>\$ 31</u>
Interest received	<u>\$ 263</u>	<u>\$ 209</u>

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

**INTEC PHARMA LTD.**  
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(Unaudited)

**NOTE 1 - NATURE OF OPERATIONS AND BASIS OF PRESENTATION:**

**a. Nature of operations**

- 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 in Israel.

Intec’s ordinary shares are traded on the NASDAQ Capital Market (“NASDAQ”).

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”, together with Intec - “the Company”). 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) On July 22, 2019, the Company announced top-line results according to which its Phase III clinical trial for AP-CD/LD did not achieve its primary and secondary endpoints. The Company has begun to analyze the full data set of the Phase III clinical trial and expects to complete this process in the third quarter of 2019. The Company expects that such findings will help to form its strategy for AP-CD/LD moving forward. The Company evaluated these subsequent events and determined that they were non-adjusting to the June 30, 2019 balance sheet as they were not known or expected as of that date. As the results are considered as a triggering event, the Company will perform an impairment test on all of its long-lived assets in the third quarter of 2019 that may result in an impairment charge on such assets.
- 3) The Company has not yet generated revenues from their operations. Accordingly, there is no assurance that the Company’s operations will generate positive cash flows. As of June 30, 2019, the cumulative losses of the Company were approximately \$162.5 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 believes that it has adequate cash to fund its ongoing activities into early in the first quarter of 2020. Its ability to execute its operating plan beyond early in the first quarter of 2020 is dependent on its ability to obtain additional capital during 2019 principally through entering into license agreements with third parties and/or raising capital from the public and/or private investors and/or institutional investors. The negative outcome of the Phase III clinical trial and uncertainty regarding the Company’s development programs is expected to adversely affect its ability to obtain funding and there is no assurance that it will be successful in obtaining the level of financing needed for its activities. As the analysis of the full data set of the Phase III clinical trial proceeds, the Company is evaluating measures to reduce its costs to preserve existing capital. If the Company is unsuccessful in securing sufficient financing, it may need to curtail or cease operations. As a result, there is substantial doubt about the Company’s ability to continue as a going concern within one year after the issuance date of these financial statements.

These financial statements have been prepared assuming that the Company will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty.

**INTEC PHARMA LTD.**  
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (continued)  
(Unaudited)

**NOTE 1 - NATURE OF OPERATIONS AND BASIS OF PRESENTATION** (continued):

**b. Basis of presentation**

The unaudited interim condensed consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP") and S-X Article 10 for interim financial statements. Accordingly, they do not contain all information and notes required by US GAAP for annual financial statements. In the opinion of management, these unaudited condensed consolidated interim financial statements reflect all adjustments, which include normal recurring adjustments, necessary for a fair statement of the Company's consolidated financial position as of June 30, 2019, the consolidated results of operations, changes in equity and cash flows for the six-month periods ended June 30, 2019 and 2018.

These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's annual financial statements for the year ended December 31, 2018, as filed in the 10-K on February 27, 2019. The condensed balance sheet data as of December 31, 2018 included in these unaudited condensed consolidated financial statements was derived from the audited financial statements for the year ended December 31, 2018 but does not include all disclosures required by US GAAP for annual financial statements.

The results for the six-month period ended June 30, 2019 are not necessarily indicative of the results expected for the year ending December 31, 2019.

**NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES:**

**a. Principles of consolidation**

The consolidated financial statements include the accounts of Intec and its Subsidiary. Intercompany balances and transactions have been eliminated upon consolidation.

**b. Fair value measurement**

Fair value is based on the price that would be received from the sale of an asset or that would be paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, the guidance establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into six broad levels, which are described as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and considers counterparty credit risk in its assessment of fair value.

The marketable securities which are measured at fair value are categorized as Level 1.

The carrying amount of the cash and cash equivalents, other receivable and accrued expenses and other liabilities approximates their fair value.

**INTEC PHARMA LTD.**  
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (continued)  
(Unaudited)

**NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES** (continued):

**c. Loss per share**

Loss per share, basic and diluted, is computed on the basis of the net loss for the six-month period divided by the weighted average number of ordinary shares outstanding during the six-month period. Diluted loss per share is based upon the weighted average number of ordinary shares and of ordinary shares equivalents outstanding when dilutive. Ordinary share equivalents include outstanding stock options which are included under the treasury stock method when dilutive.

The following share options were excluded from the calculation of diluted loss per ordinary share because their effect would have been anti-dilutive for the periods presented (share data):

	<b>Six months ended June 30</b>	
	<b>2019</b>	<b>2018</b>
Outstanding stock options	4,389,696	3,472,270

**d. Research and development expenses, net**

Research and development expenses, net for the six-month period ended June 30, 2019 and 2018, include participation in research and development expenses in the amount of approximately \$815 thousand and approximately \$458 thousand, respectively.

**e. Newly issued accounting pronouncements**

- 1) In February 2016, the FASB established ASC Topic 842, "Leases" (Topic 842), by issuing ASU No. 2016-02, which requires lessees to recognize leases on-balance sheet and disclose key information about leasing arrangements. The new standard establishes a right-of-use (ROU) model that requires a lessee to recognize a ROU asset and lease liability on the balance sheet. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the statement of operations. The Company adopted the new standard on April 1, 2019 using the modified retrospective transition method and has not restated comparative periods. The new standard provides a number of optional practical expedients in transition. The Company has elected the 'package of practical expedients', which permits it not to reassess under the new standard its prior conclusions about lease identification, lease classification and initial direct costs for leases entered into prior to adoption of Topic 842.

Additionally, the Company did not separate lease and non-lease components for all of its leases. The Company elected the short-term lease recognition exemption for all leases that qualify. This means, for those leases that qualify, the Company will not recognize ROU assets or lease liabilities, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition. Instead, the Company will continue to recognize the lease payments for those leases in profit or loss on a straight-line basis over the lease term.

The most significant effects of adoption relate to (1) the recognition of new ROU assets and lease liabilities on its balance sheet for real estate operating leases; and (2) providing significant new disclosures about its leasing activities.

**INTEC PHARMA LTD.**  
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (continued)  
(Unaudited)

**NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES** (continued):

Upon adoption, the Company recognized additional operating lease liabilities, of approximately \$2.2 million based on the present value of the remaining lease payments under current leasing standards for existing operating leases. The Company also recognized corresponding ROU assets of approximately \$2.2 million. Lease terms may include options to extend or terminate the lease when the Company is reasonably certain that the option will be exercised. Lease expense is recognized on a straight-line basis over the lease term. The Company's leases may include variable payments based on measures that include changes in price index which are expensed as incurred and presented as operating expense on the condensed consolidated statements of operations in the same line item as expense arising from fixed lease payments.

The new standard also provides practical expedients for an entity's ongoing accounting. Beginning in 2019, the Company changed its disclosed lease recognition policies and practices, as well as to other related financial statement disclosures due to the adoption of this standard. See Note 4a.

- 2) In June 2018, the FASB issued ASU 2018-07, "Compensation-Stock Compensation" (Topic 718" or "ASU 2018-07") to improve the usefulness of information provided to users of financial statements while reducing cost and complexity in financial reporting and provide guidance aligning the measurement and classification for share-based payments to nonemployees with the guidance for share-based payments to employees. Under the guidance, the measurement of equity-classified nonemployee awards will be fixed at the grant date. This standard, adopted as of April 1, 2019, had no material impact on the Company's consolidated financial statements.

**NOTE 3 - MARKETABLE SECURITIES**

The Company's marketable securities have a minimum of A rating by global rating agencies. These marketable securities are recorded at fair value with changes recorded in the statement of operations as "financial income, net", as the Company chose to apply the fair value option.

As of June 30, 2019, and December 31, 2018, the amount of the marketable securities is approximately \$0.8 million and \$1.3 million, respectively.

The gain, net from changes in marketable securities amounted to approximately \$5 thousand in the six-month period ended June 30, 2019 and the loss, net from changes in marketable securities amounted to approximately \$154 thousand in the six-month period ended June 30, 2018.

**INTEC PHARMA LTD.**  
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (continued)  
(Unaudited)

**NOTE 4 - COMMITMENTS AND CONTINGENT LIABILITIES:**

**a. Lease Agreements**

- 1) The Company is a tenant under a lease agreement in respect of offices and operational spaces in Jerusalem until June 30, 2021. The lease agreement includes an option to extend the lease term until June 30, 2022 (the "Extension Option"). The exercise of the Extension Option may be made in the Company's sole discretion. Rent payments are denominated in NIS and linked to the Israeli CPI.

To secure the Company's obligations to the lease agreement in Jerusalem, the Company granted a bank guarantee to the lessor, which amounted to approximately \$141 thousand as of June 30, 2019.

The Company also leases office space in Modi'in and New York City for a short-term period.

- 2) The Company has entered into operating lease agreements for vehicles used by its employees. The lease periods are generally for six years and the payments are linked to the Israeli CPI. To secure the terms of the lease agreements, the Company has made certain prepayments to the leasing company, representing approximately six months of lease payments.

Lease expense for the three and six month periods ended June 30, 2019 was comprised of the following:

	<b>Three months ended June 30, 2019</b>	<b>Six months ended June 30, 2019</b>
	<b>U.S. dollars in thousands</b>	
Operating lease expense	\$ 196	\$ 386
Short-term lease expense	25	50
Variable lease expense	1	1
	<u>\$ 222</u>	<u>\$ 437</u>

Supplemental information related to leases are as follows:

	<b>June 30 2019</b>
	<b>U.S. dollars in thousands</b>
Operating lease right-of-use assets	\$ 1,859
Current Operating lease liabilities	\$ 648
Non-current operating lease liabilities	\$ 1,269

Other information:

Operating cash flows from operating leases (cash paid in thousands)	\$ 378
Weighted Average Remaining Lease Term	2.88 years
Weighted Average Discount Rate	5.40%

**INTEC PHARMA LTD.**  
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (continued)  
(Unaudited)

**NOTE 4 - COMMITMENTS AND CONTINGENT LIABILITIES** (continued):

Maturities of lease liabilities are as follows:

<b>Year</b>	<b>Amount U.S. dollars in thousands</b>
2019 (excluding the six months ended June 30, 2019)	\$ 367
2020	714
2021	652
2022	325
Total lease payments	2,058
Less imputed interest	(140)
<b>Total</b>	<b>\$ 1,918</b>

3) ASC 840 Disclosures-

The Company elected the modified retrospective transition method and included the following tables previously disclosed.

Future contractual obligations under the abovementioned operating lease agreements (not including the Extension Option) as of December 31, 2018 are as follows:

<b>Year</b>	<b>Amount U.S. dollars in thousands</b>
2019	\$ 772
2020	721
2021	332
<b>Total</b>	<b>\$ 1,825</b>

**b. Automated Production Line**

In April 2017, the Company engaged with an international manufacturer for ordering a large-scale automated production line for manufacturing Accordion Pills (the "Production Line"). The total cost of the Production Line amounted to approximately €8.1 million. As of June 30, 2019, and December 31, 2018, the Company transferred payments of approximately €7.5 million (approximately \$8.7 million) and €7.4 million (approximately \$8.6 million), respectively. In addition, as of June 30, 2019 and December 31, 2018 the Company recognized a liability in the amount of approximately €592 thousand (approximately \$675 thousand) and €148 thousand (approximately \$170 thousand), respectively. As of the date of the issuance of these condensed consolidated financial statements, the installation process and qualification studies of the Production Line at the commercial site at Lohmann Therapie-Systeme AG ("LTS") was completed. For more details regarding the Manufacturing Services with LTS see note c below.

**INTEC PHARMA LTD.**  
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (continued)  
(Unaudited)

**NOTE 4 - COMMITMENTS AND CONTINGENT LIABILITIES** (continued):

**c. Establishment of the Commercial Scale Production Capabilities for AP-CD/LD**

In December 2018, the Company entered into a Process Development Agreement for Manufacturing Services with LTS for the manufacture of AP-CD/LD (the "Agreement"). Under the Agreement, the Company will bear the costs incurred by LTS 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 LTS in the form of a reduction in the purchase price of the AP-CD/LD product. As of June 30, 2019, the Company transferred payments of approximately €5.6 million (approximately \$6.4 million) in costs of the Equipment, of which approximately €1.3 million (approximately \$1.4 million) was paid during the six-month period ended June 30, 2019 and recognized a liability in an additional amount of approximately €984 thousand (approximately \$1,114 thousand) and as of December 31, 2018 recognized a liability of €436 thousand (approximately \$499 thousand). The Company has recognized the Equipment as non-current other assets.

The Agreement contains several termination rights which are expected to be included in a definitive manufacturing and supply agreement. As of June 30, 2019, the Company recognized a liability that was recorded against research and development expenses, net in the amount of approximately €3.0 million (approximately \$3.4 million), for LTS's facility upgrading costs, of which approximately €2.0 million (approximately \$2.2 million) will be paid to LTS only if the Company decides to not continue with the project or commercialization of AP-CD/LD. The liability that was recorded as of December 31, 2018, was approximately €1.65 million (approximately \$1.9 million).

- d.** During 2019 the Company received letters (each a "Letter" and collectively the "Letters") from several of its former directors and officers. The Letters include several claims related, among others, to a purported vesting of certain options that were issued to them due to the execution by the Company of a manufacturing agreement with LTS for the production of the Company's AP-CD/LD. On July 30, 2019, the board of directors of the Company resolved that the vesting conditions have not been met. As of the date of the issuance of these condensed consolidated financial statements, the Company is yet to receive their response, and at this stage cannot assess whether a claim would be filed, and if filed, its likelihood of success.

**NOTE 5 - SHARE CAPITAL:**

**a. Changes in share capital**

During the six-month period ended June 30, 2019, options to purchase 69,812 ordinary shares granted to employees and service providers were exercised for consideration of approximately \$268 thousand.

**b. Share-based compensation:**

- 1) In April 2016, the Company's board of directors approved a new option plan (the "2015 Plan"). Originally, the maximum number of ordinary shares reserved for issuance under the 2015 Plan was 700,000 ordinary shares for grants to directors, employees and consultants. In July 2016 an increase of 700,000 ordinary shares was approved by the board of directors.

In December 2017 and June 2018, an increase of 2,100,000 and 1,000,000 ordinary shares, respectively, was approved by the Company's shareholders at a general meeting of shareholders.

As of June 30, 2019, 190,657 shares remain available for grant under the Plan.



**INTEC PHARMA LTD.**  
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (continued)  
(Unaudited)

**NOTE 5 - SHARE CAPITAL** (continued):

In the six months ended June 30, 2019 and 2018, the Company granted options as follows:

	<b>Six months ended June 30, 2019</b>			
	<b>Number of options granted</b>	<b>Exercise price range</b>	<b>Vesting period</b>	<b>Expiration</b>
Employees	1,065,000	\$ 7.63-\$7.64	3 years	7 years
Directors	120,000	\$ 4.86	3 years	7 years

  

	<b>Six months ended June 30, 2018</b>			
	<b>Number of options granted</b>	<b>Exercise price range</b>	<b>Vesting period range</b>	<b>Expiration</b>
Employees	1,175,000	\$ 4.44-\$6.67	3 years	7 years
Directors	120,000	\$ 4.44	3 years	7 years

The fair value of options granted to employees during the six months ended June 30, 2019, and 2018 was \$4.0 million and \$3.1 million, respectively

The fair value of options granted to employees on the date of grant was computed using the Black-Scholes model. The underlying data used for computing the fair value of the options are as follows:

	<b>Six months ended June 30</b>	
	<b>2019</b>	<b>2018</b>
Value of ordinary share	\$4.34-\$7.46	\$4.20-\$6.45
Dividend yield	0%	0%
Expected volatility	53.32%-54.55%	45.87%-46.47%
Risk-free interest rate	1.76%-2.57%	2.25%-2.73%
Expected term	5 years	5 years

2) The following table illustrates the effect of share-based compensation on the statements of operations:

	<b>Three months ended June 30</b>		<b>Six months ended June 30</b>	
	<b>2019</b>	<b>2018</b>	<b>2019</b>	<b>2018</b>
	<b>U.S. dollars in thousands</b>		<b>U.S. dollars in thousands</b>	
Research and development expenses, net	\$ 597	\$ 496	\$ 1,167	\$ 856
General and administrative expenses	421	382	794	745
	<u>\$ 1,018</u>	<u>\$ 878</u>	<u>\$ 1,961</u>	<u>\$ 1,601</u>

**NOTE 6 - ACCOUNTS PAYBLE AND ACCRUALS - OTHER:**

	<b>June 30, 2019</b>	<b>December 31, 2018</b>
	<b>U.S. dollars in thousands</b>	
Expenses payable	\$ 5,750	\$ 3,400
Current operating lease liabilities (see Note 4a)	648	-
Salary and related expenses, including social security and other taxes	796	1,078
Accrual for vacation days and recreation pay for employees	463	309
Other	22	20
	<u>\$ 7,679</u>	<u>\$ 4,807</u>

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

*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 Quarterly Report on Form 10-Q. This information should also be read in conjunction with the information contained in our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the Securities and Exchange Commission on February 27, 2019, including the consolidated annual financial statements as of December 31, 2018 and their accompanying notes included therein. We have prepared our condensed consolidated interim financial statements in accordance with U.S. GAAP.*

*This Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q are made as of the date of this Quarterly Report on Form 10-Q, 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 February 27, 2019, 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 Quarterly Report on Form 10-Q 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 and specific release mechanism. Our product pipeline currently includes several product candidates in various clinical trial stages. Our leading product candidate, AP-CD/LD, is being developed for the indication of treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients.

In July 2019, we announced top-line results from our pivotal Phase III clinical for AP-CD/LD for the treatment of advanced Parkinson's disease known as the ACCORDANCE study in which the ACCORDANCE study did not meet its target endpoints. While AP-CD/LD provided treatment for Parkinson's disease symptoms, it did not demonstrate statistically superiority over immediate release CD/LD on the primary endpoint of OFF time reduction under the conditions established in the protocol. Treatment-emergent adverse effects observed with AP-CD/LD were generally consistent with the known safety profile of CD/LD formulations and no new safety issues were observed throughout the double-blinded study, during the gastroscopy safety sub-study or the 12-month open-label extension study. From our on-going preliminary review of the data, we have observed a meaningful reduction in OFF time in certain subsets of patients. We are in the process of analyzing the full data set and expect to complete this process during the third quarter of 2019 and expect that such findings will help inform our strategy for AP-CD/LD moving forward.

Previously, we 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 in February 2019, we announced that AP-CD/LD met the primary endpoint in a pharmacokinetic, or PK, study comparing the AP-CD/LD 50/500mg dosed three times daily, the most common dose used in our on-going ACCORDANCE study, to 1.5 tablets of CD/LD immediate release (Sinemet™) 25/100 dosed five times per day in Parkinson's disease patients.

We have invested in the commercial scale manufacture of AP-CD/LD, for which we are in partnership with LTS Lohmann Therapie-Systeme AG, or LTS. In December 2018, the large commercial scale production line was delivered to LTS in Andemach, Germany and recently we completed the qualification studies for the commercial scale manufacture of the Accordion Pill.

In addition, we have initiated a clinical development program for our Accordion Pill platform with the two primary cannabinoids contained in cannabis sativa, which we refer to as AP-Cannabinoids. We are formulating and testing CBD and THC for the treatment of various pain indications. AP-Cannabinoids are designed to extend the absorption phase of CBD and THC, with the goal of more consistent levels for an improved therapeutic effect, which may address several major drawbacks of current methods of treatment, 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 March 2017, we initiated a Phase I single-center, single-dose, randomized, three-way crossover clinical trial in Israel to compare the safety, tolerability and PK of AP-THC/CBD with Sativex®, an oral buccal spray containing CBD and THC that is commercially available outside of the United States. Initial results demonstrated that the Accordion Pill platform is well suited to safely deliver CBD and THC with significant improvements in exposure compared with Sativex®. In December 2018, we initiated a PK study of AP-THC and the results of the study demonstrate that the custom designed AP delivery system in the AP-THC PK study did not meet our expectations. We are continuing to advance the AP-Cannabinoids clinical development program and we expect to provide new timelines before the end of the year.

While the ACCORDANCE results were not what we expected, we continue to believe in the potential of the Accordion Pill platform. In December 2018, we reported that we successfully developed an Accordion Pill for a Novartis proprietary compound that met the required *in vitro* specifications set forth in a feasibility agreement with Novartis. We recently completed the human PK study that was initiated during the first quarter of 2019 and we are seeking to advance this program into potential partnership discussions with Novartis.

In May 2019, we reported entering into a research collaboration agreement with Merck for the development of a custom-designed AP for one of Merck's proprietary compounds and are now initiating the design and construction of this new AP.

## Results of Operations

The table below provides our results of operations for the periods indicated.

	Three months ended June 30		Six months ended June 30	
	2018	2019	2018	2019
	(dollars in thousands)		(dollars in thousands)	
Research and development expenses, net	\$ (7,860)	\$ (8,400)	\$ (16,402)	\$ (17,280)
General and administrative expenses	(2,144)	(2,194)	(4,334)	(4,104)
Operating loss	(10,004)	(10,594)	(20,736)	(21,384)
Financial income (expenses), net	33	(292)	143	(168)
Loss before income tax	(9,971)	(10,886)	(20,593)	(21,552)
Income tax	(38)	(147)	(72)	(210)
Net loss	\$ (10,009)	\$ (11,033)	\$ (20,665)	\$ (21,762)

### Three and Six Months Ended June 30, 2019 Compared to Three and Six Months Ended June 30, 2018

#### Research and Development Expenses, Net

Our research and development expenses, net, for the three months ended June 30, 2019 amounted to approximately \$7.9 million, a decrease of approximately \$500,000, or 6%, compared to approximately \$8.4 million for the three months ended June 30, 2018. Our research and development expenses, net, for the six months ended June 30, 2019 amounted to approximately \$16.4 million, a decrease of approximately \$900,000, or 5%, compared to approximately \$17.3 million for the six months ended June 30, 2018. The decrease for the three and six-month periods was primarily due to a decrease in expenses related to our ACCORDANCE study and open label extension study. This decrease was offset by an increase in expenses related to the scale up activities for the commercial scale production capabilities for AP-CD/LD at LTS.

#### General and Administrative Expenses

Our general and administrative expenses for the three months ended June 30, 2019 amounted to approximately \$2.1 million, a decrease of approximately \$100,000, or 5%, compared to approximately \$2.2 million for the three months ended June 30, 2018. Our general and administrative expenses for the six months ended June 30, 2019 amounted to approximately \$4.3 million, an increase of approximately \$200,000, or 5%, compared to approximately \$4.1 million for the six months ended June 30, 2018. The increase in the six-month period was primarily related to the increase in payroll and related expenses mainly due to an increase in headcount and salary raises and insurance expenses. This increase was offset by a decrease in professional services.

#### Operating Loss

As a result of the foregoing, for the three months ended June 30, 2019 our operating loss was approximately \$10.0 million, a decrease of approximately \$600,000, or 6%, compared to our operating loss for the three months ended June 30, 2018 of approximately \$10.6 million. For the six months ended June 30, 2019 our operating loss was approximately \$20.7 million, a decrease of approximately \$700,000, or 3%, compared to our operating loss for the six months ended June 30, 2018 of approximately \$21.4 million. The changes in the three and six-month periods were mainly due to changes in research and development expenses and general and administrative expenses, as detailed above.

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

For the three months ended June 30, 2019, we had financial income from interest on cash and cash equivalents in the amount of approximately \$92,000, offset by financial expenses from foreign currency exchange expenses in the amount of approximately \$54,000 and bank fees. For the three months ended June 30, 2018, we had financial expenses from foreign currency exchange expenses in the amount of approximately \$446,000, financial expenses from change in fair value of marketable securities in the amount of approximately \$79,000 and bank fees offset by financial income from interest on cash equivalents in the amount of approximately \$241,000.

For the six months ended June 30, 2019, we had financial income from interest on cash and cash equivalents in the amount of approximately \$282,000 offset by financial expenses from foreign currency exchange expenses in the amount of approximately \$128,000 and bank fees. For the six months ended June 30, 2018, we had financial expenses from foreign currency exchange expenses in the amount of approximately \$389,000, financial expenses from change in fair value of marketable securities in the amount of approximately \$154,000 and bank fees offset by financial income from interest on cash equivalents in the amount of approximately \$387,000.

### ***Income tax***

For the three and six months ended June 30, 2019 and 2018, we have not generated taxable income in Israel. However, for the three months ended June 30, 2019 and 2018, we incurred tax expenses in our U.S. subsidiary in the amount of \$38,000 and \$147,000, respectively, and for the six months ended June 30, 2019 and 2018 we incurred tax expenses in our U.S. subsidiary in the amount of \$72,000 and \$210,000, respectively.

### ***Net Loss***

Based on the foregoing, for the three months ended June 30, 2019 our net loss was approximately \$10.0 million, a decrease of approximately \$1.0 million, or 9%, compared to net loss for the three months ended June 30, 2018 of approximately \$11.0 million while for the six months ended June 30, 2019 our net loss was approximately \$20.7 million, a decrease of approximately \$1.1 million, or 5%, compared to our net loss for the six months ended June 30, 2018 of approximately \$21.8 million.

### ***Liquidity and Capital Resources***

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

As of June 30, 2019, we had cash and cash equivalents and marketable securities of approximately \$21.6 million. As of December 31, 2018, we had cash and cash equivalents and marketable securities of approximately \$40.6 million.

Net cash used in operating activities was approximately \$17.7 million for the six months ended June 30, 2019 compared with net cash used in operating activities of approximately \$19.9 million for the six months ended June 30, 2018. This decrease resulted primarily from the decrease in the net loss for the period in the amount of \$1.1 million and from changes in operating assets and liabilities items of approximately \$300,000.

We had negative cash flow from investing activities of approximately \$1.0 million for the six months ended June 30, 2019 compared to negative cash flow from investing activities of approximately \$4.3 million for the six months ended June 30, 2018. This decrease resulted primarily from a decrease in purchase of property and equipment in the amount of approximately \$2.5 million, an increase in proceeds from the disposal of marketable securities in the amount of approximately \$576,000 and a decrease of approximately \$261,000 in investment in other assets related to the establishment of the commercial scale production capabilities for AP-CD/LD at LTS. For more information, see note 4(c) in our condensed consolidated financial statements for the six months ended June 30, 2019.

Net cash provided by financing activities for the six months ended June 30, 2019 was approximately \$268,000, which was provided by the proceeds from the exercise of options by employees. Net cash provided by financing activities for the six months ended June 30, 2018 was approximately \$35.0 million which was mainly provided by funds received from our April 2018 public offering of ordinary shares.

## **Current Outlook**

In July 2019, we announced that our Phase III clinical trial for AP-CD/LD did not meet its target endpoints. We have begun to analyze the full data set of the Phase III clinical trial and expect to complete this process in the third quarter of 2019. We expect that such findings will help inform our strategy for AP-CD/LD moving forward. We expect that these activities, together with general and administrative costs, will result in continuing operating losses for the foreseeable future. We believe that we have adequate cash to fund these ongoing activities into early in the first quarter of 2020. Our ability to execute our operating plan beyond early in the first quarter of 2020 is dependent on our ability to obtain additional capital during 2019 principally through entering into a license agreement with Novartis or another third party and/or raising capital from the public and/or private investors and/or institutional investors. The negative outcome of the Phase III clinical trial and uncertainty regarding our development programs is expected to adversely affect our ability to obtain funding and there is no assurance that we will be successful in obtaining the level of financing needed for our activities. As the analysis of the full data set of the Phase III clinical trial proceeds, we are evaluating measures to reduce our costs to preserve existing capital and may incur impairment charges on our long-lived assets in the third quarter of 2019 which could have a material adverse effect on our future results of operations. If we are unsuccessful in securing sufficient financing, we may need to scale back our administrative and clinical development activities and may be required to cease our operations entirely. As a result, there is substantial doubt about our ability to continue as a going concern. For more information, see note 1a(2) and (3) in our condensed consolidated financial statements for the six months ended June 30, 2019.

On March 1, 2019, we entered into a Sales Agreement with Cowen and Company, LLC (“Cowen”), pursuant to which we may sell from time to time, at our option, up to \$75.0 million of our ordinary shares through an “at-the-market” equity offering program under which Cowen will act as sales agent. The issuance and sale of ordinary shares by us under the program will be made pursuant to our effective “shelf” registration statement on Form S-3 (Registration Statement No. 333-230016) filed with the SEC on March 1, 2019, and declared effective on March 28, 2019. No ordinary shares have been sold under the program.

Developing drugs, conducting clinical trials, obtaining commercial manufacturing capabilities and commercializing products is expensive and we will need to raise substantial additional funds to achieve our strategic objectives. We will require significant additional financing in the future to fund our operations, including if and when we progress into additional clinical trials of our product candidates, obtain regulatory approval for one or more of our product candidates, obtain commercial manufacturing capabilities and commercialize one or more of our product candidates. Our future capital requirements will depend on many factors, including, but not limited to:

- the progress and costs of our clinical trials and other research and development activities;
- the scope, prioritization and number of our clinical trials and other research and development programs;
- the amount of revenues and contributions we receive under future licensing, collaboration, development and commercialization arrangements with respect to our product candidates;
- the costs of the development and expansion of our operational infrastructure;
- the costs and timing of obtaining regulatory approval for one or more of our product candidates;
- the ability of us, or our collaborators, to achieve development milestones, marketing approval and other events or developments under our potential future licensing agreements;
- the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs and timing of securing manufacturing arrangements for clinical or commercial production;
- the costs of contracting with third parties to provide sales and marketing capabilities for us or establishing such capabilities ourselves;
- the costs of acquiring or undertaking development and commercialization efforts for any future products, product candidates or technology;
- the magnitude of our general and administrative expenses; and
- any cost that we may incur under future in- and out-licensing arrangements relating to one or more of our product candidates.

## **Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements that have had or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors.

## **Critical Accounting Policies**

This discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates that affect the reported amounts of our assets, liabilities and expenses. Significant accounting policies employed by us, including the use of estimates, are presented in the notes to the consolidated financial statements included elsewhere in this Annual Report. We periodically evaluate our estimates, which are based on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Critical accounting policies are those that are most important to the portrayal of our financial condition and results of operations and require our subjective or complex judgments, resulting in the need to make estimates about the effect of matters that are inherently uncertain. If actual performance should differ from historical experience or if the underlying assumptions were to change, our financial condition and results of operations may be materially impacted.

Our critical accounting policies and estimates are disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018. With the exception of the change for the accounting of leases as a result of the adoption of ASC Topic 842 on January 1, 2019 there have been no material changes to those policies during the six months ended June 30, 2019.

## **Recently Issued Accounting Pronouncements**

See Note 2, Significant Accounting Policies, to the condensed consolidated financial statements included in “Item 1- Condensed Consolidated Financial Statements” of this Quarterly Report on Form 10-Q.

## **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

Not required for smaller reporting companies.

## **Item 4. Disclosure Controls and Procedures**

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we have evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of June 30, 2019. Based on that evaluation, our principal executive officer and principal financial officer have concluded that as of June 30, 2019 these disclosure controls and procedures were effective at the reasonable assurance level.

## **Changes in Internal Control over Financial Reporting**

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) under the Exchange Act that occurred during the quarter ended June 30, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

### Item 1. Legal Proceedings

From time to time, we may become involved in various lawsuits and legal proceedings, which arise in the ordinary course of business. Litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. There are currently no pending material legal proceedings, and we are currently not aware of any legal proceedings or claims against us or our property that we believe will have any significant effect on our business, financial position or operating results. None of our officers or directors is a party against us in any legal proceeding.

### Item 1A. Risk Factors

Not required for smaller reporting companies.

### Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

### Item 3. Defaults Upon Senior Securities

None.

### Item 4. Mine Safety Disclosures

Not applicable.

### Item 5. Other Information

None.

### Item 6. Exhibits

<u>Exhibit No.</u>	<u>Exhibit Description</u>
3.1	<a href="#">Articles of Association of Intec Pharma Ltd., as amended (incorporated herein by reference to Exhibit 3.4 of the Company's Annual Report on Form 10-K filed with the SEC on February 27, 2019)</a>
31.1*	<a href="#">Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a), promulgated under the Securities Exchange Act of 1934, as amended</a>
31.2*	<a href="#">Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a), promulgated under the Securities Exchange Act of 1934, as amended</a>
32.1#	<a href="#">Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>
32.2#	<a href="#">Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

\* Filed herewith

# Furnished herewith

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Intec Pharma Ltd.

Date: August 9, 2019

By: /s/ Jeffrey A. Meckler

Jeffrey A. Meckler  
Chief Executive Officer and Vice Chairman  
(Principal Executive Officer)

Date: August 9, 2019

By: /s/ Nir Sassi

Nir Sassi  
Chief Financial Officer  
(Principal Financial and Accounting Officer)



## CERTIFICATIONS

I, Jeffrey A. Meckler, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2019 of Intec Pharma Ltd. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of registrant’s board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: August 9, 2019

/s/ Jeffrey A. Meckler

Jeffrey A. Meckler

Chief Executive Officer and Vice Chairman

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## CERTIFICATIONS

I, Nir Sassi, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2019 of Intec Pharma Ltd. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of registrant’s board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: August 9, 2019

/s/ Nir Sassi  
Nir Sassi  
Chief Financial Officer

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**Intec Pharma Ltd.**  
**Certification Pursuant to**  
**18 U.S.C. Section 1350,**  
**as Adopted Pursuant to**  
**Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Quarterly Report of Intec Pharma Ltd. (the "Company") on Form 10-Q for the period ended June 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jeffrey A. Meckler, Chief Executive Officer and Vice Chairman of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (a) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (b) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Jeffrey A. Meckler

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Jeffrey A. Meckler  
Chief Executive Officer and Vice Chairman

Date: August 9, 2019

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**Intec Pharma Ltd.**  
**Certification Pursuant to**  
**18 U.S.C. Section 1350,**  
**as Adopted Pursuant to**  
**Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Quarterly Report of Intec Pharma Ltd. (the "Company") on Form 10-Q for the period ended June 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Nir Sassi, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (a) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (b) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Nir Sassi

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Nir Sassi  
Chief Financial Officer

Date: August 9, 2019

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