UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported)

August 9, 2019

INTEC PHARMA LTD.
(Exact name of registrant as specified in its charter)

Israel	**001-37521**	**N/A**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

12 Hartom St. **Har Hotzvim** **Jerusalem, Israel**	**9777512**
(Address of principal executive offices)	(Zip Code)

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

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

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. ☒

Item 2.02. Results of Operation and Financial Condition.

On August 9, 2019, Intec Pharma Ltd. (the "Company") issued a press release announcing the Company's results of operations for the second quarter ended June 30, 2019. The press release is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein in its entirety.

The information included in this Item 2.02 of Current Report on Form 8-K, including the attached Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date of this Current Report, regardless of any general incorporation language in any such filing, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated August 9, 2019

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 hereunto duly authorized.

Date: August 9, 2019

INTEC PHARMA LTD.

By: /s/ Nir Sassi
Nir Sassi
Chief Financial Officer

Exhibit 99.1

Intec Pharma Reports Second Quarter 2019 Financial Results and Business Update

Jerusalem (August 9, 2019) – Intec Pharma Ltd. (NASDAQ: NTEC) ("Intec" or "the Company") today announces financial results for the three and six months ended June 30, 2019.

Highlights of the second quarter 2019 and recent weeks include:

- Completed the qualification studies for the commercial scale manufacture of Accordion Pill®-Carbidopa/Levodopa (AP-CD/LD) with LTS LohmanTherapie-Systeme;
- Announced topline results from the Company's pivotal Phase 3 trial (the ACCORDANCE trial) evaluating the safety and efficacy of the AP-CD/LD compared with immediate release CD/LD (IR-CD/LD; Sinemet®) as a treatment for the symptoms of advanced Parkinson's disease (PD), reporting that AP-CD/LD provided treatment for Parkinson's disease symptoms but did not demonstrate statistically superiority to IR-CD/LD in terms of reduction in OFF time from baseline under the conditions established in the protocol;
- Completed the pharmacokinetic (PK) study of the custom-designed AP developed for a proprietary compound under the previously announced feasibility and option agreement with Novartis Pharmaceuticals;
- Entered into an agreement with Merck to explore using the AP platform for an undisclosed development program;
- Published a review highlighting the benefits of the AP oral drug delivery platform in the peer-reviewed journal, *Therapeutic Delivery*;
- Published the results from an earlier Phase 2 clinical study of the AP-CD/LD in PD patients in the peer-reviewed journal, *Parkinsonism and Related Disorders;*
- Presented data from the PK study of AP-CD/LD 50/500 mg TID in a poster at the XXIV World Congress on Parkinson's Disease and Related Disorders; and
- Granted European patent titled, "Delivery Device for Oral Intake of an Agent," which covers Intec's gastro-retentive drug delivery device with perforated external film.

Management Commentary

"We were very disappointed that the ACCORDANCE study did not meet its target endpoints. In our preliminary review of the top-line data, we noted sub-sets of patients that performed particularly well, showing meaningful reduction in OFF time compared with IR-CD/LD. Based on our preliminary review, we believe we may not have been able to administer enough LD to certain patients as it was agreed with the U.S. Food and Drug Administration (FDA) that the maximum dose would be three APs per day. Given the long-term safety profile established by this trial, we believe this limitation should be removed and that this could present a method of providing additional LD to those patients who need it. We believe the on-going analyses of this study will lead to an improved understanding of what will be required in future studies to generate approvable clinical data with the AP delivery platform in PD," stated Jeffrey A. Meckler, Vice Chairman and Chief Executive Officer of Intec Pharma.

"During the second quarter, we made significant progress advancing and expanding our partner-sponsored programs. We are excited to have successfully completed the PK study for our custom-designed AP for Novartis' proprietary compound and are looking forward to advancing this program into potential partnership discussions. This partnership holds significant promise as the market opportunity for this proprietary compound is in excess of $1 billion. In addition, we entered into a research collaboration 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 for this very promising program.

"We continue to make progress refining the AP for our cannabis program and hope to advance our proprietary AP containing synthetic tetrahydrocannabinol (AP-THC), one of the primary cannabinoids contained in cannabis, into a new PK study next year. The Accordion Pill has the potential to address several major drawbacks of current methods of use and treatment with cannabis and cannabinoids, such as short duration of effect, delayed onset, variability of exposure, variable potency batch to batch, variability of the administered dose and adverse events that correlate with rate of rise and peak levels. Given the known analgesic properties of cannabinoids, we remain enthusiastic about the potential for these programs and believe our AP-cannabinoids will be applicable to a variety of pain indications.

"While the ACCORDANCE results were not what we expected, we continue to believe in the potential of the AP platform. Toward that end, we plan to seek to move forward with a commercial agreement with Novartis. In addition, once we obtain the final data from our ACCORDANCE study, we plan to look for ways to advance this program forward, whether on our own or through a potential partnership. In tandem, we plan to continue to build our AP drug delivery platform with the addition of both partner-sponsored R&D programs, such as Novartis and Merck, and through internally led drug reformulation programs, such as our cannabis program in pain indications. We believe this strategy provides the best opportunities for both short- and long-term growth," concluded Mr. Meckler.

Financial Highlights for the Three and Six Months Ended June 30, 2019

Research and development expenses, net, for the three-month period ended June 30, 2019 were approximately $7.9 million, a decrease of approximately $500,000, or 6%, compared with approximately $8.4 million for the second quarter of 2018. Research and development expenses, net, for the six-month period ended June 30, 2019 amounted to approximately $16.4 million, a decrease of approximately $900,000, or 5%, compared with approximately $17.3 million in the six-month period ended June 30, 2018. The decrease in both periods was primarily due to a decrease in expenses related to our ACCORDANCE study and open label extension study, 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 for the three-month period ended June 30, 2019 were approximately $2.1 million, a decrease of approximately $100,000 or 5%, compared with approximately $2.2 million in the three-month period ended June 30, 2018. General and administrative expenses for the six-month period ended June 30, 2019 amounted to approximately $4.3 million, an increase of approximately $200,000, or 5%, compared with approximately $4.1 million in the six-month period 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, offset by a decrease in professional services.

Net loss for the three-month period ended June 30, 2019 was approximately $10.0 million, compared with a net loss of $11.0 million in the prior year's second quarter. Net loss for the six-month period ended June 30, 2019 was $20.7 million compared with $21.8 million during the six-month period ended June 30, 2018.

Loss per ordinary share for the three-month period ended June 30, 2019 was $0.30 compared with a loss per ordinary share of $0.34 for the three-month period ended June 30, 2018. Loss per ordinary share for the six-month period ended June 30, 2019 was $0.62 compared with a loss per ordinary share of $0.75 for the six-month period ended June 30, 2018.

As of June 30, 2019, the Company had cash and cash equivalents and marketable securities of approximately $21.6 million compared with approximately $40.6 million at December 31, 2018.

Net cash used in operating activities during the six-month period ended June 30, 2019 was approximately $17.7 million compared with net cash used in operating activities of approximately $19.9 million during the six-month period 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.

The Company had negative cash flow from investing activities of approximately $1.0 million during the six-month period ended June 30, 2019 compared to negative cash flow from investing activities of approximately $4.3 million during the six-month period 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.

Net cash provided by financing activities during the six-month period 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.

About Intec Pharma Ltd.

Intec Pharma is a clinical-stage biopharmaceutical company focused on developing drugs based on its proprietary Accordion Pill platform technology. The Company's Accordion Pill is an oral drug delivery system that is designed to improve the efficacy and safety of existing drugs and drugs in development by utilizing an efficient gastric retention and specific release mechanism. The Company's product pipeline includes two product candidates in clinical trial stages: Accordion Pill Carbidopa/Levodopa, or AP-CD/LD, which is in late-stage Phase 3 development for the treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients, and AP-cannabinoids, an Accordion Pill to deliver either or both of the primary cannabinoids contained in Cannabis sativa, cannabidiol (CBD) and tetrahydrocannabinol (THC) for various pain indications. In addition, the Company has a feasibility agreement for the development of a custom-designed Accordion Pill for a proprietary compound with Novartis Pharmaceuticals and a research collaboration with Merck & Co.

For more information, visit www.intecpharma.com. Intec Pharma routinely posts information that may be important to investors in the Investor Relations section of its website.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward looking statements about our expectations, beliefs and intentions. Forward-looking statements can be identified by the use of forward-looking words such as "believe", "expect", "intend", "plan", "may", "should", "could", "might", "seek", "target", "will", "project", "forecast", "continue" or "anticipate" or their negatives or variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical matters. These forward-looking statements are based on assumptions and assessments made in light of management's experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements in this press release are made as of the date of this press release, and we undertake no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties, many of which are outside of our control. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements, including, but not limited to, the following: our limited operating history and history of operating losses, our ability to continue as a going concern, our ability to obtain additional financing, our ability to successfully operate our business or execute our business plan, the timing and cost of our clinical trials, the completion and receiving favorable results in our clinical trials, our ability to obtain and maintain regulatory approval of our product candidates, our ability to protect and maintain our intellectual property and licensing arrangements, our ability to develop, manufacture and commercialize our product candidates, the risk of product liability claims, the availability of reimbursement, and the influence of extensive and costly government regulation. More detailed information about the risks and uncertainties affecting us is contained under the heading "Risk Factors" included in our most recent Annual Report on Form 10-K filed with the SEC on February 27, 2019, 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 -

INTEC PHARMA LTD.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	June 30, 2019	December 31, 2018
	U.S. dollars in thousands	
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 20,796	$ 39,246
Investment in marketable securities	762	1,333
Prepaid expenses and other receivables	3,072	2,986
TOTAL CURRENT ASSETS	24,630	43,565
NON-CURRENT ASSETS:		
Other assets	7,487	5,431
Property and equipment, net	12,455	12,233
Operating lease right-of-use assets	1,859	-
Deferred tax assets	429	281
TOTAL NON-CURRENT ASSETS	22,230	17,945
TOTAL ASSETS	$ 46,860	$ 61,510
Liabilities and shareholders' equity		
CURRENT LIABILITIES -		
Accounts payable and accruals:		
Trade	$ 2,331	$ 2,849
Other	7,679	4,807
TOTAL CURRENT LIABILITIES	10,010	7,656
LONG-TERM LIABILITIES -		
Non-current operating lease liabilities	1,269	-
Other liabilities	472	309
TOTAL LONG-TERM LIABILITIES	1,741	309
TOTAL LIABILITIES	11,751	7,965
COMMITMENTS AND CONTINGENT LIABILITIES		
SHAREHOLDERS' EQUITY:		
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)
TOTAL SHAREHOLDERS' EQUITY	35,109	53,545
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 46,860	$ 61,510

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

	Three months ended June 30		Six months ended June 30	
	2019	2018	2019	2018
	U.S. dollars in thousands		U.S. dollars in thousands	
OPERATING EXPENSES:				
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)
	$		$	
LOSS PER SHARE BASIC AND DILUTED	(0.30)	(0.34)	(0.62)	(0.75)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER ORDINARY SHARE IN THOUSANDS	33,300	32,086	33,274	29,114

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

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		
	U.S. dollars in thousands				
BALANCE AT APRIL 1, 2018	26,075,770	$ 727	$ 157,079	$ (109,010)	$ 48,796
CHANGES IN THE THREE-MONTH PERIOD ENDED JUNE 30, 2018:					
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)
BALANCE AT JUNE 30, 2018	33,225,988	$ 727	$ 192,987	$ (120,043)	$ 73,671
BALANCE AT APRIL 1, 2019	33,297,371	$ 727	$ 195,842	(152,480)	$ 44,089
CHANGES IN THE THREE-MONTH PERIOD ENDED JUNE 30, 2019:					
Exercise of options	5,429	-	11	-	11
Share-based compensation		-	1,018	-	1,018
Net loss	-	-	-	(10,009)	(10,009)
BALANCE AT JUNE 30, 2019	33,302,800	$ 727	$ 196,871	$ (162,489)	$ 35,109

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

	Six months ended June 30	
	2019	2018
	U.S. dollars in thousands	
CASH FLOWS FROM OPERATING ACTIVITIES:		
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	(17,727)	(19,855)
CASH FLOWS FROM INVESTING ACTIVITIES:		
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	(1,010)	(4,308)
CASH FLOWS FROM FINANCING ACTIVITIES:		
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	268	35,030
DECREASE IN CASH AND CASH EQUIVALENTS	(18,469)	10,867
CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD	39,246	53,393
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	19	368
CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	$ 20,796	$ 64,628
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Liability with respect to property and equipment	$ 502	$ 1,740
Liability with respect to other assets	$ 1,114	$ -
SUPPLEMENTARY DISCLOSURE OF CASH FLOW INFORMATION -		
Taxes paid	$ 50	$ 31
Interest received	$ 263	$ 209

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