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)

November 12, 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 November 12, 2019, Intec Pharma Ltd. (the "Company") issued a press release announcing the Company's results of operations for the third quarter ended September 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 November 12, 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: November 12, 2019

INTEC PHARMA LTD.

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

Exhibit 99.1

Intec Pharma Reports Third Quarter 2019 Financial Results and Provides Business Update

Jerusalem (November 12, 2019) – Intec Pharma Ltd. (NASDAQ: NTEC) ("Intec" or "the Company") today announces financial results for the three and nine months ended September 30, 2019.

Highlights of the third quarter 2019 and recent weeks include:

- Presented two posters highlighting data from the Company's Phase 3 clinical development program for the Accordion Pill® Carbidopa/Levodopa (AP-CD/LD) at the International Congress of Parkinson's and Movement Disorder Society (MDS 2019);
- Completed the qualification studies for the commercial scale manufacture of AP-CD/LD with our partner, LTS LohmanTherapie-Systeme (LTS);
- Announced topline results from the Company's pivotal Phase 3 trial (ACCORDANCE) 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 statistical superiority to IR-CD/LD in terms of reduction in OFF time from baseline under the conditions established in the protocol; and
- 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.

Management Commentary

"We gained important information and knowledge from the ACCORDANCE study that we believe makes AP-CD/LD an attractive partnership opportunity for late-stage development and commercialization. First, the ACCORDANCE results validate the AP platform and provide very important long-term safety data. The responder analysis and subset analyses provide key insights for future study design and dosing that should be invaluable to a potential partner. We have qualified the commercial scale manufacturing process with LTS, which can also be used to provide clinical supply for the next Phase 3 study. This is a key advantage as Chemistry, Manufacturing and Controls (CMC) is a critical component in drug development and one that often trips up small companies. Importantly, there continues to be a large unmet need for a better baseline LD, which we believe provides a significant market opportunity of between $200 - $500 million," stated Jeffrey A. Meckler, Vice Chairman and Chief Executive Officer of Intec Pharma.

"We were delighted to present two posters highlighting AP-CD/LD at MDS 2019 in late September. We were particularly pleased to have our Phase 3 ACCORDANCE clinical trial poster chosen for the conference's Guided Tour, a distinction that drives attendees to view the approximately ten percent of posters selected for inclusion. Consequently, there was considerable interest in our program's results. We believe the data underscored the potential of AP-CD/LD as a better baseline levodopa therapy in PD while highlighting its long-term safety data. In tandem, we are in the process of seeking to partner AP-CD/LD in PD and found it most beneficial to have these data delivered at this important medical meeting. The continued understanding of the full dataset from ACCORDANCE will be important as we seek to partner AP-CD/LD for late-stage clinical development and commercialization in PD patients.

"Moving forward, we continue to glean important learnings from the ongoing data analysis. As we present these to potential partners, we continue to advance the buildout of our commercial manufacturing process with LTS. As noted, having these state-of-the art commercial scale production facilities in place is expected to be of great value to any potential partner. We will also be completing the required regulatory submissions and reports that are necessary for clinical and CMC filings, which we expect to further enhance partnership opportunities.

“In July 2019, Intec provided Novartis with the results from a human PK study of a custom-designed AP for one of Novartis’ proprietary compounds. The study demonstrated that the AP met the technical requirements set forth by Novartis. Novartis undertook a full commercial assessment of the program, and to date, has not definitively decided whether they will opt into negotiations for a commercial agreement. As a result, we have determined that we will not need the volume of clinical manufacturing to support that program at this time and plan to restructure those dedicated to the Novartis program in order to reduce our burn.

“We continued to invest in building out the Company’s next phase of growth through the AP platform's innovation engine as it can provide multiple opportunities for pipeline expansion. Toward that end, we were delighted to partner with Merck & Co. on a research collaboration to develop a custom-designed AP for one of Merck’s proprietary compounds in May 2019. Our team is hard at work constructing the films for this research collaboration and we aim to have a final construct completed and *in-vitro* tested by the middle of next year.

“The development of our AP containing synthetic tetrahydrocannabinol (THC), one of the primary cannabinoids contained in cannabis, completed an initial PK study earlier this year. The results showed that the delivery of THC did not meet our full expectations for this program. Our R&D team is in the process of refining the AP-THC in order to fully meet our specifications for the oral delivery of THC and CBD. We are seeking to launch a PK study with the optimized AP-THC next year.

“In addition to our current development pipeline, our team continues to advance discussions with other potential pharmaceutical partners for the development of new custom-designed APs. We believe the data from our ACCORDANCE trial enhances those discussions as it validates the AP platform and provides long-term safety data. Our goal remains to add one or two new programs per year. We believe this is the most efficient strategy for building our pipeline and for creating value from our platform.

“Our mission remains steadfast; to build value by leveraging the potential of our AP platform to enhance the characteristics of a number of proprietary compounds and to develop innovative approaches to the treatment of diseases. Our growth strategy continues to focus on advancing a mix of internally-led programs with partnered programs believing that having a variety of ‘shots on goal’ will provide Intec with a growing pipeline and long-term royalty stream with the potential to create significant value over time,” concluded Mr. Meckler.

Financial Highlights for the Three and Nine Months Ended September 30, 2019

Research and development expenses, net, for the three-month period ended September 30, 2019 were approximately $8.4 million, an increase of approximately $600,000 or 8%, compared with approximately $7.8 million for the third quarter of 2018. The increase for the three-month period was primarily due to an increase in expenses related to the open label extension study. This increase was offset by a decrease in expenses related to the ACCORDANCE study and a decrease in expenses related to the scale up activities for the commercial scale production capabilities for AP-CD/LD at LTS. Research and development expenses, net, for the nine-month period ended September 30, 2019 amounted to approximately $24.9 million, a decrease of approximately $200,000, or 1%, compared with approximately $25.1 million in the nine-month period ended September 30, 2018. The decrease for the nine-month period was primarily due to a decrease in expenses related to the ACCORDANCE 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 and expenses related to our open label extension study.

General and administrative expenses for the three-month period ended September 30, 2019 were approximately $2.2 million, an increase of approximately $500,000 or 29%, compared with approximately $1.7 million in third quarter of 2018. General and administrative expenses for the nine-month period ended September 30, 2019 amounted to approximately $6.5 million, an increase of approximately $700,000, or 12%, compared with approximately $5.8 million in the nine-month period ended September 30, 2018. The increase for the three and nine-month periods was primarily related to the increase in payroll and related expenses mainly due to salary raises and increase in insurance expenses, offset by a decrease in professional services.

Impairment of long-lived assets was recorded as the top-line results of the ACCORDANCE trial were considered a triggering event for impairment. For the three and nine months ended September 30, 2019, we recorded an impairment charge of approximately $9.8 million. This impairment represents the excess carrying value of the long-lived assets compared to its fair value.

Net loss for the three-month period ended September 30, 2019 was approximately $20.4 million, compared with a net loss of $9.2 million in the prior year's third quarter. Net loss for the nine-month period ended September 30, 2019 was $41.0 million compared with $30.9 million during the nine-month period ended September 30, 2018.

Loss per ordinary share for the three-month period ended September 30, 2019 was $0.61 compared with a loss per ordinary share of $0.28 for the three-month period ended September 30, 2018. Loss per ordinary share for the nine-month period ended September 30, 2019 was $1.23 compared with a loss per ordinary share of $1.01 for the nine-month period ended September 30, 2018.

As of September 30, 2019, the Company had cash and cash equivalents and marketable securities of approximately $15.7 million compared with approximately $40.6 million at December 31, 2018.

Net cash used in operating activities during the nine-month period ended September 30, 2019 was approximately $23.9 million compared with net cash used in operating activities of approximately $30.9 million during the nine-month period ended September 30, 2018. This decrease resulted from changes in operating assets and liabilities items of approximately $6.5 million and a decrease in the net loss for the period in the amount of $500,000.

The Company had negative cash flow from investing activities of approximately $2.5 million during the nine-month period ended September 30, 2019 compared to negative cash flow from investing activities of approximately $5.1 million during the nine-month period ended September 30, 2018. This decrease resulted primarily from a decrease in purchase of property and equipment in the amount of approximately $1.8 million, an increase in proceeds from the disposal of marketable securities in the amount of approximately $576,000 and a decrease of approximately $135,000 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 nine-month period ended September 30, 2019 was approximately $2.2 million, which was provided by approximately $2.0 million in funds received from the sale of 1,716,679 ordinary shares under the Company's "at-the-market" equity offering program and $268,000 in proceeds from the exercise of options by employees.

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 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, our ability to enter into collaborative, licensing, and other commercial relationships and on terms commercially reasonable to us, 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 and our ability to remain listed on the Nasdaq Capital Market. 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)

	September 30, 2019	December 31, 2018
	U.S. dollars in thousands	
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 14,966	$ 39,246
Investment in marketable securities	767	1,333
Prepaid expenses and other receivables	2,453	2,986
TOTAL CURRENT ASSETS	18,186	43,565
NON-CURRENT ASSETS:		
Other assets	4,204	5,431
Property and equipment, net	6,200	12,233
Operating lease right-of-use assets	1,687	-
Deferred tax assets	504	281
TOTAL NON-CURRENT ASSETS	12,595	17,945
TOTAL ASSETS	$ 30,781	$ 61,510
Liabilities and shareholders' equity		
CURRENT LIABILITIES -		
Accounts payable and accruals:		
Trade	$ 4,834	$ 2,849
Other	6,774	4,807
TOTAL CURRENT LIABILITIES	11,608	7,656
LONG-TERM LIABILITIES -		
Non-current operating lease liabilities	1,132	-
Other liabilities	554	309
TOTAL LONG-TERM LIABILITIES	1,686	309
TOTAL LIABILITIES	13,294	7,965
COMMITMENTS AND CONTINGENT LIABILITIES		
SHAREHOLDERS' EQUITY:		
Ordinary shares, with no par value - authorized: 100,000,000 Ordinary Shares as of September 30, 2019 and December 31, 2018; issued and outstanding: 35,019,479 and 33,232,988 Ordinary Shares as of September 30, 2019 and December 31, 2018, respectively	727	727
Additional paid-in capital	199,627	194,642
Accumulated deficit	(182,867)	(141,824)
TOTAL SHAREHOLDERS' EQUITY	17,487	53,545
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 30,781	$ 61,510

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

	Three months ended September 30		Nine months ended September 30	
	2019	2018	2019	2018
	U.S. dollars in thousands		U.S. dollars in thousands	
OPERATING EXPENSES:				
RESEARCH AND DEVELOPMENT EXPENSES, net	(8,448)	(7,809)	(24,850)	(25,089)
GENERAL AND ADMINISTRATIVE EXPENSES	(2,157)	(1,696)	(6,491)	(5,800)
IMPAIRMENT OF LONG-LIVED ASSETS	(9,759)		(9,759)	
OPERATING LOSS	(20,364)	(9,505)	(41,100)	(30,889)
FINANCIAL INCOME (EXPENSES), net	14	163	157	(5)
LOSS BEFORE INCOME TAX	(20,350)	(9,342)	(40,943)	(30,894)
TAX BENEFIT (INCOME TAX)	(28)	164	(100)	(46)
NET LOSS	(20,378)	(9,178)	(41,043)	(30,940)
	U.S. dollars			
LOSS PER SHARE BASIC AND DILUTED	(0.61)	(0.28)	(1.23)	(1.01)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER ORDINARY SHARE IN THOUSANDS	33,516	33,226	33,356	30,505

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					
CHANGES IN THE NINE-MONTH PERIOD ENDED SEPTEMBER 30, 2018:	26,075,770	$ 727	$ 156,356	$ (98,281)	$ 58,802
Issuance of ordinary shares, net of issuance costs	7,150,000	-	35,029	-	35,029
Exercise of options	218	-	1	-	1
Share-based compensation	-	-	2,452	-	2,452
Net loss	-	-	-	(30,940)	(30,940)
BALANCE AT SEPTEMBER 30, 2018	33,225,988	$ 727	$ 193,838	$ (129,221)	$ 65,344
BALANCE AT JANUARY 1, 2019					
CHANGES IN THE NINE-MONTH PERIOD ENDED SEPTEMBER 30, 2019:	33,232,988	$ 727	$ 194,642	$ (141,824)	$ 53,545
Issuance of ordinary shares, net of issuance costs	1,716,679	-	1,969	-	1,969
Exercise of options	69,812	-	268	-	268
Share-based compensation	-	-	2,748	-	2,748
Net loss	-	-	-	(41,043)	(41,043)
BALANCE AT SEPTEMBER 30, 2019	35,019,479	$ 727	$ 199,627	$ (182,867)	$ 17,487

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 JULY 1, 2018	33,225,988	$ 727	$ 192,987	$ (120,043)	$ 73,671
CHANGES IN THE THREE-MONTH PERIOD ENDED SEPTEMBER 30, 2018:					
Share-based compensation	-	-	851	-	851
Net loss	-	-	-	(9,178)	(9,178)
BALANCE AT SEPTEMBER 30, 2018	33,225,988	$ 727	$ 193,838	$ (129,221)	$ 65,344
BALANCE AT JULY 1, 2019	33,302,800	$ 727	$ 196,871	$ (162,489)	$ 35,109
CHANGES IN THE THREE-MONTH PERIOD ENDED SEPTEMBER 30, 2019:					
Issuance of ordinary shares, net of issuance costs	1,716,679	-	1,969	-	1,969
Share-based compensation	-	-	787	-	787
Net loss	-	-	-	(20,378)	(20,378)
BALANCE AT SEPTEMBER 30, 2019	35,019,479	$ 727	$ 199,627	$ (182,867)	$ 17,487

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

	Nine months ended September 30	
	2019	2018
	U.S. dollars in thousands	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	(41,043)	(30,940)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	643	639
Impairment of long-lived asset	9,759	
Exchange differences on cash and cash equivalents	69	(528)
Right of use asset	523	-
Lease liability	(380)	-
Losses (gains) on marketable securities	(10)	141
Share-based compensation	2,748	2,452
Changes in operating assets and liabilities:		
Decrease in prepaid expenses and other receivables	483	(979)
Increase in deferred tax assets	(223)	-
Increase in accounts payable and accruals	3,268	(1,734)
Increase in other liabilities	245	-
Net cash used in operating activities	(23,918)	(30,949)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(791)	(2,632)
Investment in other assets	(2,315)	(2,450)
Proceeds from disposal (purchase) of marketable securities, net	576	(38)
Net cash used in investing activities	(2,530)	(5,120)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of ordinary shares, net of issuance costs	1,969	35,029
Proceeds from exercise of options	268	1
Net cash provided by financing activities	2,237	35,030
DECREASE IN CASH AND CASH EQUIVALENTS	(24,211)	(1,039)
CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD	39,246	53,393
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(69)	528
CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	14,966	52,882
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING ACTIVITIES:		
Liability with respect to property and equipment	123	1,898
Liability with respect to other assets	549	244
SUPPLEMENTARY DISCLOSURE OF CASH FLOW INFORMATION -		
Taxes paid	50	31
Interest received	315	522

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