

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)
May 11, 2020

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

<u>Israel</u> (State or other jurisdiction of incorporation)	<u>001-37521</u> (Commission File Number)	<u>N/A</u> (IRS Employer Identification No.)
<u>12 Hartom St. Har Hotzvim Jerusalem, Israel</u> (Address of principal executive offices)		<u>9777512</u> (Zip Code)
	<u>+ 972-2-586-4657</u> (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(s)	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 May 11, 2020, Intec Pharma Ltd. (the “Company”) issued a press release announcing the Company’s results of operations for the first quarter ended March 31, 2020. 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 Statement and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release, dated May 11, 2020

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: May 11, 2020

INTEC PHARMA LTD.

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



Intec Pharma Reports First Quarter 2020 Financial Results and Provides Corporate Update

JERUSALEM (May 11, 2020) - Intec Pharma Ltd. (NASDAQ: NTEC) (“Intec” or “the Company”) today announces financial results for the first quarter ended March 31, 2020 and provides a corporate update.

Highlights from the Quarter and Recent Weeks

- Announced that the Accordion Pill (AP) developed for a Merck & Co. (MSD) proprietary compound met the *in vitro* specifications set forth in the companies’ research collaboration and the Company is now in discussions with MSD regarding advancing the program into the clinic;
- Enhanced the balance sheet with a \$6.5 million public offering in February 2020 and with a \$5 million registered direct offering in May 2020;
- Received a \$1.5 million payment from Novartis related to the conclusion of the Feasibility Option Agreement the Company had with Novartis;
- Initiated AP-Carbidopa/Levodopa (AP CD/LD) commercial manufacturing stability lots with LTS Lohmann Therapie-Systeme AG (LTS);
- Completed the redesign of AP-Tetrahydrocannabinol (AP-THC) and are awaiting delivery of synthetic THC to initiate clinical material production; and
- Initiated next generation AP technologies to include longer retention times (e.g. 24 hour gastric retention) as well as larger molecules (e.g. peptides).

Management Commentary

“We continue to build the company’s scientific and technical expertise in oral drug delivery and drug-on-film technologies. Our research and manufacturing teams continue to drive innovation as we expand our capabilities and build out our portfolio of potential applications,” stated Jeffrey A. Meckler, Vice Chairman and Chief Executive Officer of Intec Pharma.

“In collaboration with our partner, LTS, we demonstrated our ability to manufacture at commercial scale. This proficiency, coupled with our recent successes in developing unique APs to meet the technical specifications set forth by Novartis and Merck, enhances our ability to engage in partnership discussions with other large biopharma companies as we actively seek to add more collaborative agreements in 2020.

“Our partnering activities for the AP-CD/LD program in Parkinson’s disease continue and there remain multiple parties with interest in this program. Unfortunately, this has not progressed to an agreement and believe this is related to certain commercialization concerns as well as to the overall market environment as a result of the COVID-19 pandemic. In addition, we continue our discussions with Merck with an aim to advance that program into human pharmacokinetic (PK) trials.

“We are delighted to report the completion of a new AP design for our AP-THC program that we expect will meet our stringent PK specifications. We are currently awaiting receipt of the active pharmaceutical ingredients so we can initiate clinical material production and, hopefully, advance this program into the clinic later this year.

“In February and May 2020 we strengthened our balance sheet believing that a stronger financial position enhances our ability to negotiate with partners and provides us with a longer runway to achieve key objectives.

“As the COVID-19 situation rapidly evolves, we are committed to protecting and supporting our workforce and the communities where we live and work and we implemented remote working and workplace protocols for our employees in accordance with government requirements. Our partnering efforts depend in part, on attendance at in-person meetings, industry conferences and other events, and as a result there has been disruption to our efforts to advance this process. We continue to closely evaluate the evolving pandemic as it unfolds and look forward to the end of this healthcare crisis,” added Mr. Meckler.

Financial Highlights for First Quarter Ended March 31, 2020

Research and development expenses, net, for the three-month period ended March 31, 2020 were approximately \$2.0 million, a decrease of \$6.5 million, or approximately 76%, compared with approximately \$8.5 million in the three-month period ended March 31, 2019. The decrease was primarily due to the ACCORDANCE study and Open Label Extension study, both of which were completed during 2019, decrease in expenses related to the scale up activities for the commercial scale manufacturing and a decrease in payroll and related expenses, mostly due to a reduction in headcount.

General and administrative expenses for the three-month period ended March 31, 2020 were approximately \$1.7 million, a decrease of \$500,000, or approximately 23%, compared with approximately \$2.2 million in the three-month period ended March 31, 2019. The decrease was primarily related to a decrease in payroll and related expenses, including reduction in headcount, share-based compensation and reduction in certain expenses related to investor relations activities and professional services.

Net loss for the three-month period ended March 31, 2020 was approximately \$3.9 million, a decrease of \$6.8 million, or approximately 64%, compared with the net loss for the three-month period ended March 31, 2019 of approximately \$10.7 million. The decrease was mainly due to a decrease in research and development expenses, net and general and administrative expenses, as detailed above.

Loss per ordinary share for the first quarter ended March 31, 2020, was \$0.08 compared with \$0.32 for the first quarter ended March 31, 2019.

As of March 31, 2020, the Company had cash and cash equivalents of approximately \$10.9 million. As of December 31, 2019, the Company had cash and cash equivalents and marketable securities of approximately \$10.1 million. In February 2020, the Company raised \$6.5 million in an underwritten public offering of 16,250,000 ordinary shares (which included pre-funded warrants to purchase ordinary shares in lieu thereof) and warrants to purchase up to 16,250,000 ordinary shares, at a public offering price of \$0.40 per ordinary share and warrant. The warrants have an exercise price of \$0.40 per share, are immediately exercisable, and will expire five years from the date of issuance.

Net cash used in operating activities was approximately \$5.1 million for the quarter ended March 31, 2020 compared with net cash used in operating activities of approximately \$7.3 million for the quarter ended March 31, 2019. This decrease resulted primarily from a decrease in research and development activities in the amount of approximately \$6.5 million, offset by changes in operating asset and liability items of approximately \$4.3 million.

The Company had positive cash flow from investing activities of approximately \$769,000 for the quarter ended March 31, 2020 compared to negative cash flow from investing activities of approximately \$640,000 for the quarter ended March 31, 2019. This change resulted primarily from an investment in the establishment of the commercial scale manufacturing in the amount of approximately \$1.2 million in the quarter ended March 31, 2019 and an increase in proceeds from the disposal of marketable securities in the amount of approximately \$200,000.

Net cash provided by financing activities for the quarter ended March 31, 2020 was approximately \$6.1 million, which was provided by the proceeds from the Company's underwritten public offering in February 2020 that resulted in net proceeds of approximately \$5.7 million and by the funds received from the sale of our ordinary shares under the "at-the-market" equity offering program that resulted in net proceeds of approximately \$421,000. Net cash provided by financing activities for the quarter ended March 31, 2019 was approximately \$161,000, which was provided by the proceeds from the exercise of options by employees.

In May, 2020, the Company raised \$5 million in a registered direct offering of 16,291,952 ordinary shares at a purchase price of \$0.3069 per share. In addition, in a concurrent private placement, the Company also sold and issued to the purchasers in the offering unregistered warrants to purchase 8,145,976 ordinary shares. The warrants have an exercise price of \$0.245 per share, are immediately exercisable, and will expire five and one-half years from the date of issuance.

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 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, the impact of the outbreak of coronavirus, 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 March 13, 2020, and in other filings that we have made and may make with the Securities and Exchange Commission in the future.

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-Tables to Follow-

INTEC PHARMA LTD.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	March 31, 2020	December 31, 2019
	U.S. dollars in thousands	
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 10,892	\$ 9,292
Investment in marketable securities	-	770
Prepaid expenses and other receivables	2,638	3,683
TOTAL CURRENT ASSETS	13,530	13,745
NON-CURRENT ASSETS:		
Property and equipment, net	2,272	2,575
Operating lease right-of-use assets	1,117	1,243
Other assets	3,717	3,717
TOTAL NON-CURRENT ASSETS	7,106	7,535
TOTAL ASSETS	\$ 20,636	\$ 21,280
Liabilities and shareholders' equity		
CURRENT LIABILITIES -		
Accounts payable and accruals:		
Trade	\$ 930	\$ 3,507
Other	4,187	4,835
TOTAL CURRENT LIABILITIES	5,117	8,342
LONG-TERM LIABILITIES -		
Operating lease liabilities	647	799
Other liabilities	652	604
TOTAL LONG-TERM LIABILITIES	1,299	1,403
TOTAL LIABILITIES	6,416	9,745
COMMITMENTS AND CONTINGENT LIABILITIES		
SHAREHOLDERS' EQUITY:		
Ordinary shares, with no par value - authorized: 100,000,000 Ordinary Shares as of March 31, 2020 and December 31, 2019; issued and outstanding: 52,973,580 and 35,892,209 Ordinary Shares as of March 31, 2020 and December 31, 2019, respectively	727	727
Additional paid-in capital	206,786	200,231
Accumulated deficit	(193,293)	(189,423)
TOTAL SHAREHOLDERS' EQUITY	14,220	11,535
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 20,636	\$ 21,280

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

	Three months ended	
	March 31	
	2020	2019
	U.S. dollars	
	in thousands	
OPERATING EXPENSES:		
RESEARCH AND DEVELOPMENT EXPENSES, net	\$ (2,024)	\$ (8,542)
GENERAL AND ADMINISTRATIVE EXPENSES	(1,715)	(2,190)
OPERATING LOSS	(3,739)	(10,732)
FINANCIAL INCOME (EXPENSES), net	(70)	110
LOSS BEFORE INCOME TAX	(3,809)	(10,622)
INCOME TAX	(61)	(34)
NET LOSS	<u>\$ (3,870)</u>	<u>\$ (10,656)</u>
		U.S. dollars
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	<u>\$ (0.08)</u>	<u>\$ (0.32)</u>
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER ORDINARY SHARE IN THOUSANDS	<u>46,918</u>	<u>33,247</u>

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	U.S. dollars in thousands		
BALANCE AT JANUARY 1, 2019	33,232,988	\$ 727	\$ 194,642	(141,824)	\$ 53,545
CHANGES IN THE THREE-MONTH PERIOD ENDED MARCH 31, 2019:					
Exercise of options	64,383	-	257	-	257
Share-based compensation	-	-	943	-	943
Net loss	-	-	-	(10,656)	(10,656)
BALANCE AT MARCH 31, 2019	33,297,371	\$ 727	\$ 195,842	\$ (152,480)	\$ 44,089
BALANCE AT JANUARY 1, 2020	35,892,209	\$ 727	\$ 200,231	(189,423)	\$ 11,535
CHANGES IN THE THREE-MONTH PERIOD ENDED MARCH 31, 2020:					
Issuance of ordinary shares, net of issuance costs	831,371	-	421	-	421
Issuance of ordinary shares and warrants, net of issuance costs	16,250,000	-	5,692	-	5,692
Share-based compensation	-	-	442	-	442
Net loss	-	-	-	(3,870)	(3,870)
BALANCE AT MARCH 31, 2020	52,973,580	\$ 727	\$ 206,786	\$ (193,293)	\$ 14,220

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

	Three months ended	
	March 31	
	2020	2019
U.S. dollars in thousands		
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (3,870)	\$ (10,656)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	306	218
Exchange differences on cash and cash equivalents	135	8
Change in right of use asset	126	163
Change in lease liabilities	(152)	(98)
Gains on marketable securities	(2)	-
Share-based compensation	442	943
Changes in operating assets and liabilities:		
Decrease in prepaid expenses and other receivables	1,045	340
Increase in deferred tax assets	-	(69)
Increase (decrease) in accounts payable and accruals	(3,225)	1,813
Increase in other liabilities	48	76
Net cash used in operating activities	<u>(5,147)</u>	<u>(7,262)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(3)	(10)
Investment in other assets	-	(1,206)
Proceeds from disposal of marketable securities, net	772	576
Net cash (used in) provided by investing activities	<u>769</u>	<u>(640)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of ordinary shares, net of issuance costs	421	-
Proceeds from issuance of ordinary shares and warrants, net of issuance costs	5,692	-
Proceeds from exercise of options	-	161
Net cash provided by financing activities	<u>6,113</u>	<u>161</u>
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	1,735	(7,741)
CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD	9,292	39,246
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(135)	(8)
CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	<u>\$ 10,892</u>	<u>\$ 31,497</u>
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Liability with respect to property and equipment	\$ -	\$ 462
Liability with respect to other assets	\$ -	\$ 648
Receivables with respect to exercise of options	\$ -	\$ 96
SUPPLEMENTARY DISCLOSURE OF CASH FLOW INFORMATION -		
Interest received	<u>\$ 9</u>	<u>\$ 128</u>

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