

**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 6, 2019**

Idera Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other
Jurisdiction of
Incorporation)

001-31918
(Commission File
Number)

04-3072298
(I.R.S. Employer
Identification No.)

505 Eagleview Blvd., Suite 212
Exton, Pennsylvania
(Address of Principal Executive Offices)

19341
(Zip Code)

Registrant's telephone number, including area code: **(484) 348-1600**

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 Exchange Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.001 per share	IDRA	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 Operations and Financial Condition.

On November 6, 2019, Idera Pharmaceuticals, Inc. (the “Company”) issued a press release announcing the Company’s financial results for the quarter ended September 30, 2019. As set forth below, the Company is furnishing the press release as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(a) Financial Statements of Businesses Acquired.

None.

(b) Pro Forma Financial Information.

None.

(c) Shell Company Transactions.

None.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Financial Statements and Exhibits.</u>
99.1	Press Release by the Company, dated November 6, 2019, furnished in accordance with Item 2.02 of this Current Report on Form 8-K.

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.

IDERA PHARMACEUTICALS, INC.

By: /s/ Bryant D. Lim
Bryant D. Lim
Senior V.P., General Counsel

Dated: November 6, 2019



**Idera Pharmaceuticals Provides Corporate Update and Reports
Third Quarter 2019 Financial Results**

EXTON, PA, November 6, 2019 — Idera Pharmaceuticals, Inc. (“Idera”) (NASDAQ: IDRA), a clinical-stage biopharmaceutical company focused on the development, and ultimately the commercialization, of therapeutic drug candidates for both oncology and rare disease indications, today reported its operational and financial results for the third quarter ended September 30, 2019.

“The third quarter of this year marked another consecutive period of focused execution for our company as we continue advancing tilsotolimod for patients and their families,” stated Vincent Milano, Idera’s Chief Executive Officer. “During this quarter, we implemented adjustments for ILLUMINATE-301 and continue to make meaningful progress with patient enrollment. Additionally, we also had strong execution within the broader tilsotolimod program, highlighted by the initiation of our first tumor expansion efforts in ILLUMINATE-206, the lengthening of our exclusivity period and the strategic clinical collaboration with AbbVie.”

Milano continued, “Overall, our team is executing on a high level and we are well positioned to continue to accelerate our activity through the end of this year and, importantly, into 2020.”

ILLUMINATE (tilsotolimod) Clinical Development

ILLUMINATE 301 — Randomized phase 3 trial of tilsotolimod in combination with ipilimumab versus ipilimumab alone in patients with anti-PD-1 refractory metastatic melanoma:

- Approximately 90 sites active in 11 countries;
- Planned enrollment target of 454 patients;
- As of October 23, 2019, 342 patients enrolled representing 75% enrollment;
- Targeting completion of enrollment during first half of 2020; and
- Clinical trial collaboration and supply agreement in place with BMS for supply of ipilimumab for the trial.

ILLUMINATE 204 — Phase 1/2 trial of tilsotolimod in combination with ipilimumab or pembrolizumab in patients with PD-1 refractory metastatic melanoma:

- Completed enrollment with 52 patients (49 evaluable) at tilsotolimod 8 mg with ipilimumab in February 2019;
 - Of the four unconfirmed responders of the 13 responders reported on Aug. 8, 2019:
 - Two were confirmed per RECIST v1.1 criteria, one remains unconfirmed, and one experienced disease progression, leading to a total of 11 of 12 confirmed responses, as of Oct. 23, 2019;
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- 3 confirmed complete responses (CR);
 - 71% (35) achieving disease control (best response of CR, PR or Stable Disease (SD)); and
 - Durable responses (greater than six months) were observed in five of 10 confirmed responses per RECIST v1.1.
- Safety profile observed consistent with previously reported results; and
 - Final results from the ILLUMINATE 204 trial are expected to be submitted for an abstract at a medical conference during the first half of 2020.

ILLUMINATE 206 — Phase 2, multi-center trial to test the safety and effectiveness of tilsotolimod in combination with ipilimumab and nivolumab in treating patients with anti-PD-1 Refractory Squamous Cell Carcinoma of the Head and Neck (SCCHN) and Relapsed/Refractory Immunotherapy-Naïve Microsatellite Stable Colorectal Cancer (MSS-CRC).

- Trial initiated on September 30, 2019, leading with the MSS-CRC cohort.

ILLUMINATE 101 — Phase 1b trial of tilsotolimod monotherapy in patients with refractory solid tumors:

- Completed enrollment in all dose cohorts of the trial;
- Data presented at the European Society for Medical Oncology (ESMO) 2019 Conference in Barcelona Spain;
 - Of 45 evaluable patients, 15 (33.3%) had best response of stable disease (SD);
- One patient with uterine leiomyosarcoma has been on tilsotolimod treatment for more than a year with durable stable disease and is continuing under a treatment investigational new drug;
- One patient in the melanoma cohort achieved an unconfirmed partial response (uPR). This patient discontinued from the study prior to the confirmation of response.

AbbVie Collaboration — On September 4, 2019, we announced we had entered into an immuno-oncology clinical research collaboration with AbbVie, a global, research-based biopharmaceutical company. The purpose of the collaboration is to conduct a clinical study evaluating whether combinations of an OX40 agonist (ABBV-368), a TLR-9 agonist (tilsotolimod), chemotherapy (nab-paclitaxel) and/or an anti-programmed cell death 1 (PD-1) antagonist (ABBV-181) stimulate the immune system resulting in anti-tumor responses.

Intellectual Property — On November 5, 2019, the U.S. Patent and Trademark Office issued U.S. Patent No. 10,10,463,686 entitled “Immune Modulation With TLR9 Agonists For Cancer Treatment,” which includes the Company’s investigational therapy tilsotolimod (IMO-2125). The patent includes 24 claims directed to methods of treating melanoma with intratumoral administration of tilsotolimod in combination with certain immune checkpoint inhibitor therapies including inhibitors of the CTLA-4 and PD-1/PD-L1 pathways. The patent is expected to expire in September 2037.

Financial Results

Third Quarter Results

Net loss applicable to common stockholders for the three months ended September 30, 2019 was \$11.1 million, or \$0.39 per basic and diluted share, compared to net loss applicable to common stockholders of \$11.6 million, or \$0.43 per basic and diluted share, for the same period in 2018. Research and development expenses for the three months ended September 30, 2019 totaled \$8.4 million compared to \$8.9 million for the same period in 2018. General and administrative expense for the three months ended September 30, 2019 totaled \$3.0 million compared to \$4.0 million for the same period in 2018. Merger-related costs, net for the three months ended September 30, 2018 amounted to a net credit of \$3.8 million and was comprised of a \$6.0 million fixed expense reimbursement received in connection with the termination of a merger agreement in July 2018, partially offset by \$2.2 million of expenses incurred in connection with transactions contemplated by such merger agreement. No such costs were incurred for the same period in 2019. Restructuring costs for the three months ended September 30, 2019 were less than \$0.1 million compared to \$3.0 million for the same period in 2018 and related to our decision in July 2018 to wind-down our discovery operations.

As of September 30, 2019, our cash, cash equivalents and short-term investments totaled \$41.6 million compared to \$71.4 million as of December 31, 2018. We currently anticipate that, based on our current operating plan, our existing cash, cash equivalents and investments on hand as of September 30, 2019, will fund our operations into the third quarter of 2020.

About Idera Pharmaceuticals

Harnessing the approach of the earliest researchers in immunotherapy and the company's vast experience in developing proprietary immunomodulatory platforms, Idera's TLR agonist development program is focused on priming the immune system to play a more powerful role in fighting cancer, ultimately increasing the number of people who can benefit from immunotherapy. Idera also continues to focus on the acquisition, development and ultimate commercialization of drug candidates for both oncology and rare disease indications characterized by small, well-defined patient populations with serious unmet needs. To learn more about Idera, visit www.iderapharma.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical fact, included or incorporated in this press release, including statements regarding the company's strategy, future operations, collaborations, cash resources, financial position, future revenues, projected costs, prospects, clinical trials, plans and objectives of management, are forward-looking statements. The words "believes," "anticipates," "estimates," "plans," "expects," "intends," "may," "could," "should," "potential," "likely," "projects," "continue," "will," and "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Idera cannot guarantee that it will actually achieve the plans, intentions or expectations disclosed in its forward-looking statements and you should not place undue reliance on the company's forward-looking statements. There are a number of important factors that could cause Idera's actual results to differ materially from those indicated or implied by its forward-looking statements, including whether the company's cash resources will be sufficient to fund the company's continuing operations and the further development of the

company's programs for the period anticipated; whether interim results from a clinical trial will be predictive of the final results of the trial; whether results obtained in preclinical studies and clinical trials will be indicative of the results that will be generated in future clinical trials; whether products based on the company's technology will advance into or through the clinical trial process when anticipated or at all or warrant submission for regulatory approval; whether such products will receive approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies; whether, if the company's products receive approval, they will be successfully distributed and marketed; whether the Company's collaborations will be successful; and such other important factors set forth under the caption "Risk Factors" in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018. Although Idera may elect to do so at some point in the future, the company does not assume any obligation to update any forward-looking statements and it disclaims any intention or obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Idera Pharmaceuticals, Inc.
Condensed Statements of Operations
(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended June 30,	
	2019	2018	2019	2018
Alliance revenue	\$ —	\$ 145	\$ 1,448	\$ 563
Operating expenses:				
Research and development	8,359	8,860	26,485	32,912
General and administrative	3,023	3,984	9,061	11,849
Merger-related costs, net	—	(3,836)	—	1,245
Restructuring costs	5	3,017	181	3,017
Total operating expenses	11,387	12,025	35,727	49,023
Loss from operations	(11,387)	(11,880)	(34,279)	(48,460)
Other income (expense), net	254	275	996	729
Net loss	<u>\$ (11,133)</u>	<u>\$ (11,605)</u>	<u>\$ (33,283)</u>	<u>\$ (47,731)</u>
Net loss per common share applicable to common stockholders				
— basic and diluted	<u>\$ (0.39)</u>	<u>\$ (0.43)</u>	<u>\$ (1.17)</u>	<u>\$ (1.81)</u>
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders — basic and diluted	<u>28,847</u>	<u>27,175</u>	<u>28,332</u>	<u>26,404</u>

Idera Pharmaceuticals, Inc.
Condensed Balance Sheet Data
(In thousands)

	September 30, 2019	December 31, 2018
Cash, cash equivalents and short-term investments	\$ 41,586	\$ 71,431
Other assets	3,806	1,592
Total assets	<u>\$ 45,392</u>	<u>\$ 73,023</u>
Total liabilities	\$ 7,766	\$ 9,029
Total stockholders' equity	37,626	63,994
Total liabilities and stockholders' equity	<u>\$ 45,392</u>	<u>\$ 73,023</u>

Source: Idera Pharmaceuticals, Inc.

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