

**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): **March 1, 2021**

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:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
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 March 1, 2021, Idera Pharmaceuticals, Inc. (the “Company”) issued a press release announcing the Company’s financial results for the fourth quarter and year ended December 31, 2020. 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.

(d) Exhibits.

Exhibit No.	Financial Statements and Exhibits.
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99.1	Press Release by the Company, dated March 1, 2021, furnished in accordance with Item 2.02 of this Current Report on Form 8-K.
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104	Cover Page Interactive Data File (embedded within the Inline XBRL document)
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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: March 1, 2021



Idera Pharmaceuticals Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Corporate Update

ILLUMINATE-301 Continues on Track for Data Later this Month

EXTON, PA, March 1, 2021 — Idera Pharmaceuticals, Inc. (“Idera” or the “Company”) (Nasdaq: IDRA) today reported its financial and operational results for the fourth quarter and year ended December 31, 2020.

“Tilsotolimod is the most advanced TLR-9 agonist therapy in development, and we are eagerly anticipating objective response rate and other important data from ILLUMINATE-301, our pivotal registration trial in anti-PD-1 refractory advanced melanoma, later this month,” stated Vincent Milano, Idera’s Chief Executive Officer. “I’m very proud of our team’s resiliency and tenacity as they work diligently toward that goal, as well as the ongoing work in ILLUMINATE-206, our trial in micro-satellite stable colorectal cancer. In addition, we are in a healthy financial position and expect our current cash to fund our activities into the second quarter of 2022, with the potential of additional capital from our existing security purchase agreements to extend our runway into the second quarter of 2023. These resources will be instrumental in helping us advance tilsotolimod for patients in need.”

Corporate Update

Since September 30, 2020, the following corporate updates were announced:

- The Company closed a second tranche under its April 7, 2020 securities purchase agreement for additional aggregate gross proceeds of \$5.0 million. With this tranche, the Company has received \$25.2 million in proceeds from three financings since December 2019, with anticipated further proceeds of up to \$113.2 million to fund the potential NDA filing and commercial launch of tilsotolimod.
- The Company appointed Daniel Soland as Senior Vice President and Chief Operating Officer as of January 4, 2021. Mr. Soland is responsible for the Company’s commercial strategy and manufacturing.
- R. Clayton Fletcher, Senior Vice President of Business Development and Strategic Planning, retired from the Company as of December 31, 2020. Mr. Fletcher remains engaged with the Company as a consultant, continuing to lead its business development activities.

ILLUMINATE (tilsotolimod) Clinical Development Updates

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

- Primary endpoint family of objective response rate (ORR) by blinded independent central review using RECIST v1.1 and overall survival (OS);
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- Trial initiated in March 2019;
- Enrollment completed in March 2020; and
- ORR and other preliminary data expected in the first quarter of 2021.

ILLUMINATE-206: Phase 2, open-label, multicohort, multicenter study to test the safety and effectiveness of tilsotolimod in combination with ipilimumab and nivolumab for the treatment of solid tumors:

- Trial initiated in September 2019 with the microsatellite stable colorectal cancer (MSS-CRC) cohort;
- Initial safety run-in of 10 patients, which included ipilimumab at 1 mg/kg every 8 weeks and nivolumab at 3 mg/kg every 2 weeks, showed that the regimen was generally well tolerated;
- Changes in the study design intended to improve potential outcomes in this patient population include increasing ipilimumab dosing frequency to every 3 weeks and limiting the number of allowed prior lines of treatment to 2; and
- The Company has opened enrollment for the next 10 patients under the modified study design, with data anticipated in the third quarter of 2021.

Fourth Quarter Financial Results

Research and development expenses for the three months ended December 31, 2020 totaled \$5.1 million compared to \$8.4 million for the same period in 2019. General and administrative expense for the three months ended December 31, 2020 totaled \$2.9 million compared to \$3.4 million for the same period in 2019. Additionally, during the three months ended December 31, 2020 and 2019, we recorded a \$3.2 million and \$0.6 million non-cash warrant revaluation loss, respectively, and a \$65.4 million and \$11.0 million non-cash future tranche right revaluation loss, respectively, related to securities issued in connection with our December 2019 private placement transaction.

As a result of the factors above, net loss applicable to common stockholders for the three months ended December 31, 2020 was \$76.7 million, or \$2.11 per basic and diluted share, compared to net loss applicable to common stockholders of \$51.3 million, or \$1.76 per basic and diluted share, for the same period in 2019. Excluding non-cash loss of approximately \$68.6 million and \$11.6 million for the three months ended December 31, 2020 and 2019, respectively, and deemed dividends of approximately \$28.0 million for the three months ended December 31, 2019, all related to the securities issued in connection with the December 2019 private placement transaction, net loss applicable to common stockholders was \$8.0 million, or \$0.22 per basic and diluted share, and \$11.7 million, or \$0.40 per basic and diluted share, respectively (calculated based upon the basic weighted-average number of common shares, due to the antidilutive effect of net loss).

Full Year Results

Research and development expenses for the year ended December 31, 2020 totaled \$24.8 million compared to \$34.9 million for the same period in 2019. General and administrative expenses for the year ended December 31, 2020 totaled \$11.9 million compared to \$12.5 million for the same period in 2019. Additionally, for the year ended December 31, 2020 and 2019, we recorded a \$3.7 million and \$72.4 million of non-cash warrant revaluation loss, respectively, and a \$0.6 million and \$11.0 million non-cash future tranche right revaluation loss, respectively, as well as non-cash deemed dividends of approximately \$28.0 million during the year ended December 31, 2019, increasing net loss attributable to common stockholders, as further discussed above under fourth quarter results.

As a result of the factors above, net loss applicable to common stockholders for the year ended December 31, 2020 was \$112.7 million or \$3.33 per basic and diluted share, compared to net loss applicable to common stockholders of \$84.6 million, or \$2.96 per basic and diluted share, for the same period in 2019. Excluding non-cash loss of approximately \$76.1 million and \$11.6 million for the years ended December 31, 2020 and 2019, respectively, and deemed dividends of approximately \$28.0 million for the year ended December 31, 2019, all related to the securities issued in connection with the December 2019 private placement transaction, net loss applicable to common stockholders was \$36.6 million, or \$1.08 per basic and diluted share, and \$45.0 million, or \$1.57 per basic and diluted share, respectively (calculated based upon the basic weighted-average number of common shares, due to the antidilutive effect of net loss).

As of December 31, 2020, our cash, cash equivalents, and short-term investments totaled \$37.7 million. Based on our current operating plan, we anticipate that our current cash, cash equivalents, and short-term investments, will fund our operations through the second quarter of 2022.

About Idera Pharmaceuticals

Harnessing the approach of the earliest researchers in immunotherapy and the Company's vast experience in developing proprietary immunology platforms, Idera's lead 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 IderaPharma.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the safe harbor of the Private Securities Litigation Reform Act of 1995 and the Federal securities laws. All statements, other than statements of historical fact, included or incorporated in this press release, including statements regarding the Company's strategy, financial position, funding for continued operations, and clinical trials, including the enrollment, timing, and future results thereof, are forward-looking statements. The words "believes," "anticipates," "estimates," "plans," "expects," "intends," "may," "could," "should," "potential," "likely," "projects," "continue," "will," "schedule," and "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are predictions based on the Company's current expectations and projections about future events and various assumptions. 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. These forward-looking statements involve known and unknown risks, uncertainties, and other factors, which may be beyond Idera's control, and which may cause the actual results, performance, or achievements of the Company to be materially different from future results, performance, or achievements expressed or implied by such 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, without limitation: 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; 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, including in clinical trials in different disease indications; whether products based on Idera'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 FDA 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 the impact of public health crises, including the novel coronavirus (COVID-19) global pandemic. All forward-looking statements included in this release are made as of the date hereof, and are expressly qualified in their entirety by this cautionary notice, including, without limitation, those risks and uncertainties described in the Company's Annual Report on Form 10-K for the year ended December 31, 2020, and otherwise in the Company's filings and reports filed with Securities and Exchange Commission. While 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, except as may be required by law.

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2020	2019	2020	2019
Alliance revenue	\$ -	\$ -	\$ -	\$ 1,448
Operating expenses:				
Research and development	5,117	8,368	24,772	34,853
General and administrative	2,923	3,420	11,915	12,481
Restructuring costs	-	-	-	181
Total operating expenses	<u>8,040</u>	<u>11,788</u>	<u>36,687</u>	<u>47,515</u>
Loss from operations	(8,040)	(11,788)	(36,687)	(46,067)
Other income (expense)				
Warrant revaluation loss	(3,247)	(598)	(3,742)	(598)
Future tranche right revaluation loss	(65,379)	(10,964)	(72,367)	(10,964)
Other income (expense), net	<u>(35)</u>	<u>118</u>	<u>134</u>	<u>1,114</u>
Net loss	<u>\$ (76,701)</u>	<u>\$ (23,232)</u>	<u>\$ (112,662)</u>	<u>\$ (56,515)</u>
Deemed dividend related to December 2019 Private Placement	<u>-</u>	<u>(28,043)</u>	<u>-</u>	<u>(28,043)</u>
Net loss attributable to common stockholders	<u>\$ (76,701)</u>	<u>\$ (51,275)</u>	<u>\$ (112,662)</u>	<u>\$ (84,558)</u>
Net loss per common share applicable to common stockholders — basic and diluted	<u>\$ (2.11)</u>	<u>\$ (1.76)</u>	<u>\$ (3.33)</u>	<u>\$ (2.96)</u>
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders — basic and diluted	<u>36,271</u>	<u>29,177</u>	<u>33,821</u>	<u>28,545</u>

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

	December 31, 2020	December 31, 2019
Cash, cash equivalents and short-term investments	\$ 37,728	\$ 42,793
Other assets	4,671	4,696
Total assets	\$ 42,399	\$ 47,489
Total liabilities	\$ 133,571	\$ 58,657
Total stockholders' deficit	(91,172)	(11,168)
Total liabilities and stockholders' deficit	\$ 42,399	\$ 47,489

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IDERA PHARMACEUTICALS Contacts:

Jill Conwell
Investor Relations &
Corporate Communications
Phone (484) 348-1675
JCONWELL@IDERAPHARMA.COM

John J. Kirby
Chief Financial Officer
Phone (484) 348-1627
JKIRBY@IDERAPHARMA.COM
