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): **December 14, 2021**

Idera Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-31918**	**04-3072298**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

505 Eagleview Blvd., Suite 212 Exton, Pennsylvania	**19341**
(Address of Principal Executive Offices)	(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 7.01. Regulation FD Disclosure.

On December 14, 2021, Idera Pharmaceuticals, Inc. (the "Company") issued a press release regarding certain clinical updates. As set forth below, the Company is furnishing the press release as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K, including the accompanying 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 liability of such section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of the general incorporation language of such filing, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

See the Exhibit Index below, which is incorporated by reference herein.

Exhibit No.	Financial Statements and Exhibits.
99.1	Press Release by the Company, dated December 14, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: December 14, 2021

Exhibit 99.1

Idera Pharmaceuticals Announces Tilsotolimod Updates

EXTON, PA, December 14, 2021 — Idera Pharmaceuticals, Inc. ("Idera," the "Company," "we," "us," and "our") (Nasdaq: IDRA) today announced clinical updates regarding tilsotolimod, its synthetic Toll-like receptor 9 agonist.

ILLUMINATE-206 Trial for the Treatment of Previously Treated Patients with Immunotherapy-Naïve Micro-Satellite Stable Colorectal Cancer (MSS-CRC)

Preliminary data from the second 10 patients dosed in the safety cohort of ILLUMINATE-206, which involves tilsotolimod in combination with ipilimumab and nivolumab, showed a safety profile consistent with the first 10 patients in ILLUMINATE-206 and with prior studies. Eight patients had a post-baseline disease assessment evaluated per Response Evaluation Criteria in Solid Tumors v1.1 (RECIST v1.1). Of those, one patient experienced Stable Disease (SD) with disease control for more than six months; the remaining patients experienced Progressive Disease (PD). However, one of the RECIST v1.1 PD patients was determined to have experienced pseudo-progression, meaning that the initial increase from baseline in overall tumor burden was followed by a decrease from baseline in overall tumor burden. At the most recent disease assessment, the total decrease from baseline was 46.2%, which is considered an Immune-Related Partial Response (irPR) by Immune-Related RECIST (irRECIST). Per protocol, the patient is continuing in active treatment. No further enrollment in ILLUMINATE-206 is planned at this time.

Collaboration with AbbVie for the Treatment of Head and Neck Squamous Cell Carcinoma

AbbVie Inc. ("AbbVie") is conducting a Phase 1b study for treatment of patients with recurrent/metastatic head and neck squamous cell carcinoma with ABBV-368 plus tilsotolimod and other therapy combinations. AbbVie has discontinued further patient enrollment in the study; this decision was not related to safety concerns. Current patient treatment and follow-up is ongoing. AbbVie is solely responsible for the conduct of the study, with Idera contributing tilsotolimod supply.

Investigator-Sponsored Trial for the Intradermal Treatment of Melanoma

The VU University Medical Center (VUmc) Amsterdam, which is conducting a randomized, controlled trial of a single, intradermal injection of tilsotolimod at the primary melanoma excision site in 214 patients, recently shared with the Company early translational data supporting the mechanism of action of tilsotolimod. "As expected, immune activation, including elevated frequencies of key dendritic cells, was seen in early analysis by flow cytometry of sentinel lymph node biopsies collected seven days post-injection," said Dr. Tanja de Gruijl of VUMC. "These data are consistent with previously reported translational data relating to tilsotolimod in other pre-clinical and clinical settings. We are eager to see if this evidence of immune system stimulation will translate to clinical benefit in this patient population." Enrollment in this study is ongoing.

Investigator-Sponsored Trial for the Treatment of Advanced Cancers

The Gustave Roussy Cancer Campus in Paris is conducting an open-label, Phase 1b study of intratumoral tilsotolimod in combination with intratumoral ipilimumab and intravenous nivolumab in advanced cancers, including non-squamous cell lung cancer, refractory advanced melanoma, and MSS-CRC. Dosing in Part A of the study, which involved 24 patients across two different dose frequencies of ipilimumab and tilsotolimod, is complete; patient follow up is ongoing.

Out-Licensing Consideration

“While our clinical trials with tilsotolimod have not yet translated into a new treatment alternative for patients, data supporting tilsotolimod’s mechanism of action and encouraging safety profile from across the array of pre-clinical and clinical work to date, together with its intellectual property protection, are noteworthy,” stated Vincent Milano, Idera’s Chief Executive Officer. “As a result, we will consider an out-licensing arrangement for tilsotolimod so that its full potential may continue to be explored on behalf of patients who do not respond to traditional immunotherapy. We also continue both to preserve cash and to identify and explore potential development or commercial-stage assets for Idera’s portfolio, and we are encouraged by the opportunities presented to us.”

About Tilsotolimod (IMO-2125)

Tilsotolimod is an investigational, synthetic Toll-like receptor 9 agonist. Intratumoral injection of tilsotolimod has been shown to promote both innate (Type-I IFN, antigen presentation) and adaptive (T cells) immune activation. Tumors with an active immune response appear to respond better to checkpoint inhibitors (CPIs) than those that exclude or inhibit anti-tumor immune cells. Tilsotolimod in combination with CPIs may cause regression of locally injected and distant tumor lesions and increase the number of patients who benefit from immunotherapy.

Tilsotolimod is being evaluated in multiple tumor types and in combination with multiple CPIs. For more information on tilsotolimod trials, please visit www.ClinicalTrials.gov.

About Idera Pharmaceuticals

Idera is focused on the acquisition, development, and ultimate commercialization of drug candidates for 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 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, opportunities, prospects, potential collaborations or licensing arrangements, development or commercialization of Idera's portfolio assets, clinical trials and related endpoints and the timing thereof, and the 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," "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 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 differ materially 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 topline 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 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; the Company's ability to satisfy the requirements for continued listing of our common stock on the Nasdaq Capital Market; and the impact of public health crises, including the coronavirus (COVID-19) pandemic. All forward-looking statements included in this press 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.