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 17, 2022**

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 May 17, 2022, Idera Pharmaceuticals, Inc. (the "Company") issued a press release announcing positive results from its investigator-sponsored trial, INTRIM 1, involving tilsotolimod, the Company's synthetic Toll-like receptor 9 agonist. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

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 Number	Description
99.1	Press Release dated May 17, 2022.
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 Vice President, General Counsel and Corporate Secretary

Dated: May 17, 2022

Exhibit 99.1

Idera Pharmaceuticals Shares Positive Results from Investigator-Sponsored Trial in Melanoma Patients at Amsterdam UMC

– Enrollment Stopped Early for Efficacy –

EXTON, PA, May 17, 2022— Idera Pharmaceuticals, Inc. ("Idera," "we," and "our") (Nasdaq: IDRA) today shared positive interim results from Amsterdam UMC, Vrije Universiteit Amsterdam, the Netherlands, regarding its investigator-sponsored trial, INTRIM 1, involving tilsotolimod, Idera's synthetic Toll-like receptor 9 agonist. Based on these results, the trial has been stopped early.

INTRIM 1 is a randomized, double-blind, placebo-controlled Phase 2 trial among patients with localized, excised melanoma (pathological tumor stage 3-4) with no regional metastases detected and no evidence of distant metastasis. The trial involved a single, intradermal injection of 8 mg tilsotolimod or saline placebo given at the primary tumor excision site, followed by re-excision and sentinel lymph node (SLN) biopsy 7-10 days later. Noting that there were more patients with ulcerated lesions in the placebo arm compared to the tilsotolimod arm, topline interim results of the respective SLN-positivity rates showed a 70% lower SLN+ rate among patients injected with tilsotolimod as compared to those injected with placebo; the placebo SLN+ rate was in the mid-40%s. Statistical significance exceeded the pre-specified p-value of 0.008. Adverse reactions included injection site reactions, malaise, fever and flu-like symptoms.

"This is an exciting result from tilsotolimod, and we are pleased for the patients and their families to whom it offers hope for the future," said Vincent Milano, Idera's Chief Executive Officer. "These results, together with data supporting tilsotolimod's mechanism of action and encouraging safety profile from across the array of earlier pre-clinical and clinical work, reinforce the potential of tilsotolimod to offer benefit to patients with certain cancers. As a result, we plan to actively pursue a strategic partnership for tilsotolimod so that its full potential for patients may continue to be explored."

This interim result validates previously reported results from INTRIM 1 that showed immune activation, including elevated frequencies of key dendritic cells, in early analysis by flow cytometry of the SLN biopsies. The trial will continue to relapse-free survival (RFS) and overall survival (OS) at 5 and 10 years after SLN biopsy.

"Currently, there are limited adjuvant treatments available to improve survival after surgical excision of a primary melanoma," said Prof. Tanja de Gruijl of Amsterdam UMC. "We are delighted with the results we have seen in this study, which suggest that tilsotolimod administered at the excision site lowers the extent of tumor-positive lymph nodes and, if it improves overall survival, offers early melanoma patients a potential new treatment option." Amsterdam UMC investigators plan to present the full data set at an upcoming medical meeting.

About Melanoma
Melanoma is a cancer that begins in a type of skin cell called melanocytes. While melanoma is the least common type of skin cancer, it has a poor prognosis when not detected and treated early. Early stages of melanoma are treated by removing, or excising, the tumor surgically. However, even after surgery, nearly one-third of all melanoma patients will experience disease recurrence and most relapses eventually will progress to metastatic disease. When regional lymphatic metastases are present, the 10-year survival rate is 68% - 24%. SLN biopsy is a useful prognostic tool for the assessment of melanoma relapse and mortality risk. Ulceration is associated with more SLN positivity.

In many cases, additional cancer treatment, referred to as adjuvant therapy, is given after the primary excision of the melanoma. The goal of adjuvant therapy is to reduce the risk of melanoma returning and potentially metastasizing. The adjuvant market size for melanoma excision cases is over 1 million cases globally and about 300,000 in the US annually. As is the case in many forms of cancer, melanoma becomes more difficult to treat once the disease has spread, or metastasized, beyond the skin to other parts of the body.

About INTRIM 1
INTRIM 1 is a multi-center investigator-sponsored trial conducted by UMC Amsterdam among patients with pT3-4 cN0M0 melanoma. The study is a randomized, double-blind, placebo-controlled Phase 2 trial of a single, intradermal injection of 8 mg tilsotolimod or of saline placebo given at the primary tumor excision site 7-10 days prior to SLN biopsy.

INTRIM 1 is intended to examine the ability of tilsotolimod to induce loco-regional and systemic immune stimulation, and therefore, improve survival among the targeted patient population. Outcome measures of the trial include the following:

- Primary endpoint: rate of tumor positive SLN at the time of biopsy.
- Secondary endpoints:
  - Immune response in the SLN and peripheral blood 7-10 days post-biopsy, as measured by frequency and activation state of lymph node resident (LNR) conventional dendritic cells (DC) and melanoma antigen-specific T cell responses in the SLN and peripheral blood.
  - RFS, determined by the length of time from intradermal injection of tilsotolimod to first documentation of recurrence (RFS), measured at 5 and 10 years after SLN biopsy.
  - OS at 5 and 10 years after SLN biopsy, determined by the length of time from intradermal injection of tilsotolimod to death from any cause.

While enrollment for the primary endpoint has been halted early as a result of the primary endpoint being met, the study will continue to its secondary endpoints. For more information on the INTRIM 1 trial, please visit www.ClinicalTrials.gov (NCT04126876).

About Tilsotolimod (IMO-2125)
Tilsotolimod is an investigational, synthetic Toll-like receptor 9 agonist. Tilsotolimod has been shown to promote both innate (Type-I IFN, antigen presentation) and adaptive (T cells) immune activation and may, in turn, contribute to tumor suppression and regression. 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, 2021, 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.