UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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 9, 2018

ADURO BIOTECH, INC.
(Exact name of Registrant as Specified in its Charter)

Delaware	001-37345	94-3348934
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

740 Heinz Avenue
Berkeley, California 94710
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (510) 848-4400

Not Applicable
(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:

☐ Written communication 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))

Indicate by check mark whether the registrant is an emerging growth company 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 8.01. Other Events.

On November 9, 2018, Aduro Biotech, Inc. announced preliminary results from ongoing Phase 1 trials of STING agonist ADU-S100 (MIW815) in patients with advanced solid tumors or lymphomas. The full text of the press release announcing the preliminary results is filed as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated November 9, 2018.

SIGNATURE

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: November 9, 2018

ADURO BIOTECH, INC.

By: /s/ Jennifer Lew
Name: Jennifer Lew
Title: Chief Financial Officer

Exhibit 99.1

Contact:
Noopur Liffick
Investor Relations & Corporate Affairs
510-809-2465

Media Contact:
Aljanae Reynolds
510-809-2452
press@aduro.com

Aduro Biotech Presents Preliminary Results from Ongoing Phase 1 Trials of STING agonist ADU-S100 (MIW815) in Patients with Advanced Solid Tumors or Lymphomas

- Data presented at Society for Immunotherapy of Cancer 33rd Annual Meeting (SITC 2018) demonstrate ADU-S100 (MIW815) is well-tolerated with no dose-limiting toxicities reported
- Preliminary signs of clinical and biomarker activity observed in patients with advanced cancers, including those pretreated with checkpoint inhibitor therapy
- Single agent data supports further evaluation of ADU-S100 in combination with checkpoint inhibitor therapies
- ADU-S100 is currently in a combination trial with investigational anti-PD-1 monoclonal antibody spartalizumab (PDR001) and with ipilimumab in an ongoing FIH study

BERKELEY, Calif., November 9, 2018 – Aduro Biotech, Inc. (NASDAQ: ADRO) today announced presentation of preliminary data from its ongoing Phase 1 dose-finding study of ADU-S100 (MIW815), a novel STING (stimulator of interferon genes) pathway activator, at SITC 2018 in Washington, D.C. Aduro and collaborator Novartis embarked on this first-in-human trial (see www.clinicaltrials.gov, identifier NCT02675439) as an important first step in characterizing the safety profile and mechanism of ADU-S100 and its ability to activate the STING pathway.

Data Highlights from ADU-S100 Monotherapy Trial (Data cut-off: August 16, 2018)

The Phase 1 dose escalation and dose expansion clinical trial is designed to evaluate the safety, tolerability and clinical activity of ADU-S100 in patients with advanced, metastatic treatment-refractory solid tumors or lymphomas. In this multicenter, open-label trial, ADU-S100 is administered intratumorally on Days 1, 8 and 15 of a 28-day cycle.

- The trial has enrolled 41 patients, with 40 patients evaluated for response. The median number of prior anti-cancer treatments was four (range 0-15). More than half of patients (53.7%) received prior therapy with a checkpoint inhibitor.

- More than 20 types of cancer have been treated in this trial, including Merkel cell, parotid gland, colorectal, endometrial, ER+ and triple-negative breast cancer, esophageal, collecting duct carcinoma, ovarian, Hodgkin's disease, hemangioepithelioma and other cancers.
- Doses of 50-3200 mcg have been explored in this presentation; enrollment is ongoing for additional patient cohorts.
- No dose-limiting toxicities have been reported at these dose levels. The most common (□10% of patients) treatment-related adverse events (TRAEs) were pyrexia, injection site pain and headache. Grade 3/4 TRAEs included increased lipase and elevated amylase, tumor pain, dyspnea, respiratory failure and injection site reaction.

Clinical and Biomarker Activity

- Importantly, increases in key systemic cytokines, including IL-6, MCP-1 and IFN-ß, were observed after administration, indicating target engagement of ADU-S100 and activation of the STING pathway.
- Two of the 40 patients treated had a partial response (PR) – one patient with Merkel cell carcinoma and one patient with parotid gland cancer who had received prior anti-PD-1 therapy.
- 11 patients achieved stable disease (SD), including five patients who had received prior checkpoint inhibitor therapy.
- Three patients with SD remain on study and continue to receive treatment, including one patient with collecting duct carcinoma who has been on study for greater than one year.
- On-treatment tumor biopsies showed increases in CD8+ T cells in injected tumors in a subset of patients, including those with Merkel cell, collecting duct and esophageal carcinomas. Aduro and Novartis are continuing to evaluate additional pathology and other biomarkers to assess the pharmacological activity of ADU-S100 in these patients.

"We are encouraged by the data obtained from the dose escalation portion of this first-in-human trial of ADU-S100 in heavily pre-treated patients with a diverse set of advanced cancers," commented Stephen T. Isaacs, chairman and chief executive officer of Aduro Biotech. "Based on the safety profile and interesting signals observed from the clinical approach to date, we expect to collect additional biomarker data and have begun to enrich monotherapy dose cohorts with additional patients of select tumor types. At the same time, we have expanded the breadth of our joint development program with our colleagues at Novartis to focus on combination with checkpoint inhibitors in melanoma and other homogeneous patient populations where we seek to deliver clinical benefit to patients in need."

In September 2018, this trial was amended to include a study arm evaluating ADU-S100 in combination with ipilimumab at its approved dose and schedule. Following a short dose escalation, the expansion phase aims to enroll patients with cutaneously and viscerally accessible melanoma who have relapsed or are refractory to PD-1 inhibitors.

Ongoing Phase 1b Trial of ADU-S100 + Anti-PD-1 Monoclonal Antibody Spartalizumab (PDR001)

A Phase 1b dose escalation and dose expansion clinical trial is ongoing to evaluate the safety and preliminary efficacy of ADU-S100 in combination with spartalizumab (PDR001), Novartis' investigational anti-PD-1 monoclonal antibody (see www.clinicaltrials.gov, identifier NCT03172936). The multicenter, open-label trial is currently enrolling patients with advanced, metastatic treatment-refractory solid tumors or lymphomas and is evaluating two treatment schedules of ADU-S100 in dose escalation with a

fixed dose of spartalizumab. Patients in Group A receive a fixed dose of intravenous spartalizumab on day 1 and an intratumoral injection of ADU-S100 three times (day 1, 8, 15) in a 28-day cycle. Patients in Group B receive a fixed dose of intravenous spartalizumab on day 1 and an intratumoral injection of ADU-S100 on day 1 of every 28-day cycle.

- The dose escalation combination trial has enrolled 50 patients with multiple cancers and who received multiple lines of prior therapies including prior immunotherapy.
- Patients have been treated with full-dose PDR001 and increasing dosing of intratumoral ADU-S100 (50-400mcg); enrollment is ongoing for additional patient cohorts.
- No dose-limiting toxicities have been reported.

In the early dosing cohorts of the ongoing study of ADU-S100 in combination with spartalizumab, preliminary observations include: 1) clinical responses observed in several tumor types, including two patients who had previously demonstrated responses to checkpoint inhibitor therapy alone; 2) reduced tumor volume in injected and non-injected lesions in some patients; 3) several patients remained on study longer than 6 months; and 4) safety profile consistent with what has been observed in the ADU-S100 monotherapy study.

Isaacs continued, “While still early, the preliminary observations emerging from initial dose cohorts of ADU-S100 plus spartalizumab are promising. In particular, the observation of clinical benefit in patients who received prior PD-1 therapy may provide further evidence supporting the synergy between STING and checkpoint inhibitor therapy that was previously demonstrated by our preclinical results. Extensive biomarker analysis is ongoing to assess biological activity. We and Novartis are committed to further exploration of the potential of ADU-S100 as a combination agent with both spartalizumab and ipilimumab in dose escalation and expansion into homogeneous patient populations. We look forward to seeing how these data evolve over time and expect to report on the results of these studies at future medical meetings.”

About STING Pathway Activator Technology

The Aduro-proprietary STING pathway activator product candidates, including ADU-S100 (MIW815), are synthetic small molecule immune modulators that are designed to target and activate human STING. STING is generally expressed at high levels in immune cells, including dendritic cells. Natural activation of STING is not always sufficient to prevent the growth and spread of cancer cells. In preclinical models, ADU-S100 directly activates STING to further amplify the natural anti-tumor response. Once activated, the STING receptor initiates a profound innate immune response through multiple pathways, inducing the expression of a broad profile of cytokines, including interferons and chemokines. This subsequently leads to the development of a systemic tumor antigen-specific T cell adaptive immune response.

Aduro’s lead molecule, ADU-S100, is the first therapeutic in development specifically targeting STING. In collaboration with Novartis, it is being tested in a Phase 1 clinical trial as a single agent and in combination with ipilimumab, and in a Phase 1b combination trial with spartalizumab (PDR001), an investigational anti-PD-1 monoclonal antibody. These studies are enrolling patients with cutaneously accessible, advanced/metastatic solid tumors or lymphomas. The trials are evaluating the ability of ADU-S100 to activate the immune system and recruit specialized immune cells to attack the injected tumor, leading to a broad immune response that seeks out and kills distant metastases.

About Aduro

Aduro Biotech, Inc. is an immunotherapy company focused on the discovery, development and commercialization of therapies that are intended to transform the treatment of challenging diseases. Aduro's technologies, which are designed to harness the body's natural immune system, are being investigated in cancer indications, autoimmune diseases and have the potential to expand into infectious diseases. Aduro's STING pathway activator technology is designed to activate the STING receptor in immune cells, which may result in a potent tumor-specific immune response. ADU-S100 (MIW815) is the first STING pathway activator compound to enter the clinic and is currently being evaluated in a Phase 1 clinical trial as a single agent and in combination with ipilimumab and in a Phase 1b combination trial with spartalizumab (PDR001), an investigational anti-PD-1 monoclonal antibody. Aduro's B-select monoclonal antibody technology, including BION-1301, an anti-APRIL antibody, is comprised of a number of immune modulating assets in research and development. Aduro is collaborating with leading global pharmaceutical companies to expand its products and technologies. For more information, please visit www.aduro.com.

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding our intentions or current expectations concerning, among other things, the potential for ADU-S100 alone or in combination, preliminary observations from early dose cohorts in the Phase 1b trial of ADU-S100 in combination with spartalizumab, the timing of clinical data, our and Novartis' commitment to continue to explore ADU-S100 as a combination agent and our ability to advance our drug development programs on our own or with our collaborators. In some cases you can identify these statements by forward-looking words such as "may," "will," "continue," "anticipate," "intend," "could," "project," "expect" or the negative or plural of these words or similar expressions. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results and events to differ materially from those anticipated, including, but not limited to, early or preliminary clinical trial results may not be predictive of future results, our history of net operating losses and uncertainty regarding our ability to achieve profitability, our ability to develop and commercialize our product candidates, our ability to use and expand our technologies to build a pipeline of product candidates, our ability to obtain and maintain regulatory approval of our product candidates, our ability to operate in a competitive industry and compete successfully against competitors that have greater resources than we do, our reliance on third parties, and our ability to obtain and adequately protect intellectual property rights for our product candidates. We discuss many of these risks in greater detail under the heading "Risk Factors" contained in our quarterly report on Form 10-Q for the quarter ended September 30, 2018, which is on file with the Securities and Exchange Commission. Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.