
**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): December 11, 2019

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

Delaware
(State or other jurisdiction
of incorporation)

001-37345
(Commission
File Number)

94-3348934
(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	ADRO	The Nasdaq Global Select Market

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 December 11, 2019, Aduro Biotech, Inc. (“Aduro”) received notification from Novartis Pharmaceuticals Corporation (“Novartis”) that Novartis has removed ADU-S100 (MIW815), an intratumoral STING pathway activator product candidate, from its portfolio based on clinical data generated to date. This decision is not the result of any safety concern. Novartis has begun winding down the ongoing Phase 1b dose escalation clinical trial to evaluate the safety and preliminary efficacy of ADU-S100 in combination with spartalizumab (PDR001), Novartis’ investigational anti-PD-1 monoclonal antibody, in advanced, metastatic treatment-refractory solid tumors or lymphomas, and no dose expansion cohorts will be opened. Enrollment in this Phase 1b trial will be discontinued and, per protocol, patients currently enrolled or consented in this trial will remain on treatment until progression or toxicity. Novartis is also terminating enrollment of the ongoing Phase 1 clinical trial arm evaluating ADU-S100 in relapsed and refractory melanoma in combination with YERVOY® (ipilimumab), an approved anti-CTLA-4 antibody. Per protocol, patients currently enrolled or consented in this trial will remain on treatment until progression or toxicity.

Under the collaboration and license agreement with Novartis, Aduro is continuing to enroll the Phase 2 clinical trial of ADU-S100 in combination with KEYTRUDA® (pembrolizumab), an approved anti-PD-1 antibody, as a first-line treatment for recurrent or metastatic head and neck squamous cell carcinoma (HNSCC), with interim data to be presented in the second half of 2020. Aduro is also preparing to initiate a clinical trial of ADU-S100 as an intravesical monotherapy for non-muscle invasive bladder cancer (NMIBC) in the second half of 2020. The HNSCC and NMIBC studies are being solely funded by Aduro. Under the terms of the collaboration and license agreement between Novartis and Aduro, if Novartis opts out of funding an early stage clinical trial and the product progresses into a pivotal clinical trial, then both Aduro and Novartis would be required to fund and participate in the pivotal clinical trial, and Novartis may have certain reimbursement obligations for prior development expenses for the early stage clinical trial.

The collaboration and license agreement between Novartis and Aduro otherwise remains in effect, and both parties continue to jointly pursue STING pathway activation through systemic delivery as a therapeutic strategy.

Special Note on Forward-Looking Statements

This current report on Form 8-K (“Current Report”) 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 our therapies, the progress of our clinical programs, including the timing of initiation of clinical trials and the timing for presentation of clinical data, and funding for future development activities. 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, 2019, which is on file with the Securities and Exchange Commission. Any forward-looking statements that we make in this Current Report speak only as of the date of this Current Report. 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 Current Report.

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.

ADURO BIOTECH, INC.

Dated: December 17, 2019

By: /s/ Celeste Ferber

Name: Celeste Ferber

Title: SVP, General Counsel and Secretary