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): April 9, 2020

Aduro Biotech, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-37345	**94-3348934**
(Commission File No.)	**(IRS Employer Identification No.)**

740 Heinz Avenue
Berkeley, California
(Address of principal executive offices)

94710
(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 (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 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.

In light of the exceptional circumstances related to the COVID-19 global pandemic, the focus of healthcare workers on fighting the virus, "shelter in place" orders and other public health guidance measures that have been implemented across much of the United States and Europe and the U.S. Food and Drug Administration's updated industry guidance for conducting clinical trials issued on March 18, 2020, Aduro Biotech, Inc. ("Aduro" or the "Company") is providing an update on its clinical trial timelines and business operations. The COVID-19 global pandemic is rapidly evolving, and the timing of delays and overall impact to Aduro's clinical trials and business are currently unknown. The current status of each clinical program and our business operations are as follows:

Clinical Programs

BION-1301 for the Treatment of IgA Nephropathy (IgAN)

In April 2019, we initiated a Phase 1 clinical trial of BION-1301 in healthy volunteers and IgA nephropathy patients. As previously announced, we plan to present data on the single ascending dose and multiple ascending dose healthy volunteer portions of this clinical trial (Parts 1 and 2) at a virtual medical conference in the first half of 2020, which will include:

- the safety profile of BION-1301 in healthy volunteers, and
- the PK/PD relationship of BION-1301 in healthy volunteers, including the impact on IgA, IgG and IgM in response to single and multiple doses over time.

Though we have begun activating clinical trial sites for Part 3 of this study, we expect there will be delays in our ability to activate additional sites and enroll IgA nephropathy patients at existing and any additional sites depending upon the duration and nature of COVID-19 public health guidance measures in much of the United States and Europe. These measures are also likely to impact our ability to conduct patient follow-up. As a result, our ability to report data in IgA nephropathy patients will likely be delayed until the first half of 2021.

ADU-S100 + KEYTRUDA® (pembrolizumab) for the Treatment of Squamous Cell Carcinoma of the Head and Neck (SCCHN)

We do not have any updates to timelines for this clinical trial. As we previously announced, we are continuing to enroll patients in this trial and expect to report interim data in the second half of 2020. However, the evolving situation surrounding COVID-19 and resulting public health guidance measures that have been implemented in much of the United States may delay enrollment of new patients, our ability to conduct patient follow-up and our ability to complete analyses of data from this study.

ADU-S100 for the Treatment of Non-Muscle Invasive Bladder Cancer (NMIBC)

We do not have any updates to our timelines for the initiation of this clinical trial. As we previously announced, we are preparing to initiate a Phase 1 clinical trial in the second half of 2020. However, the evolving situation surrounding COVID-19 and resulting public health guidance measures may delay study start-up activities.

ADU-S100 + Spartalizumab (PDR001) for the Treatment of Advanced/Metastatic Solid Tumors or Lymphomas

As we previously announced in December 2019, Novartis has discontinued enrollment of patients in this clinical trial and no dose expansion cohorts will be opened. There are patients currently enrolled in this trial who will remain on treatment until progression or toxicity. The evolving situation surrounding COVID-19 and resulting regional public health guidance measures that have been implemented may delay our ability to conduct patient follow-up and our ability to complete analyses of data from this study with Novartis. As a result, our ability to report complete dose escalation and enrichment results will likely be delayed.

Business Operations

As the COVID-19 global pandemic continues to evolve, we remain committed to keeping our staff and their families safe and doing our part to slow the community spread of COVID-19. As such, we are adhering to all local, state and federal guidelines with respect to the operation of facilities and reinforcement of shelter-in-place orders. We have implemented a work-from-home policy for all staff members, excluding those necessary to maintain minimum basic operations. For those employees, we have implemented safety measures designed to comply with applicable local, state and federal guidelines. We may be required to take additional actions that impact our operations as required by applicable laws or regulations, or which we determine to be in the best interest of our employees.

Community Support

Our team members are working with our local communities to facilitate donations of personal protective equipment, such as masks and gloves, to healthcare workers. In the San Francisco Bay Area, initial donations have been made to UCSF hospitals. In the Netherlands, PPE donations have been made to local front-line physician practices.

Supplemental Risk Factor

In light of recent developments relating to the COVID-19 global pandemic, Aduro is supplementing the risk factors previously disclosed in Item 1A of its Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the Securities and Exchange Commission on March 9, 2020, to include the following risk factor under the heading "Risks Related to our Business":

Public health crises such as pandemics or similar outbreaks could materially and adversely affect our clinical trials, business, financial condition and results of operations.

In March 2020, the World Health Organization declared COVID-19 a global pandemic and the United States declared a national emergency with respect to COVID-19. In response to the COVID-19 outbreak, "shelter in place" orders and other public health guidance measures have been implemented across much of the United States and Europe, including in the locations of our offices, clinical trial sites, key vendors and partners. We expect that our clinical development program timelines will be negatively affected by COVID-19, which could materially and adversely affect our business, financial condition and results of operations. Further, due to "shelter in place" orders and other public health guidance measures, we have implemented a work-from-home policy for all staff members excluding those necessary to maintain minimum basic operations. Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay or otherwise adversely impact our business. For example, with our personnel working from home, some of our research activities that require our personnel to be in our laboratories will be delayed.

As a result of the COVID-19 outbreak, or similar pandemics, and related "shelter in place" orders and other public health guidance measures, we have and may in the future experience disruptions that could materially and adversely impact our clinical trials, business, financial condition and results of operations. Potential disruptions include but are not limited to:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in initiating or expanding clinical trials, including delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19 or other health conditions or being forced to quarantine;
- interruption of key clinical trial activities, such as clinical trial site data monitoring and efficacy, safety and translational data collection, processing and analyses, due to limitations on travel imposed or recommended by federal, state or local governments, employers and others or interruption of clinical trial subject visits, which may impact the collection and integrity of subject data and clinical study endpoints;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- delays or disruptions in preclinical experiments and investigational new drug application-enabling studies due to restrictions of on-site staff and unforeseen circumstances at contract research organizations and vendors;
- interruption or delays in the operations of the U.S. Food and Drug Administration and comparable foreign regulatory agencies;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems; and
- limitations on employee resources that would otherwise be focused on the conduct of our clinical trials and pre-clinical work, including because of sickness of employees or their families, the desire of employees to avoid travel or contact with large groups of people, an increased reliance on working from home, school closures or mass transit disruptions.

These and other factors arising from the COVID-19 global pandemic could worsen in countries that are already afflicted with COVID-19, could continue to spread to additional countries or could return to countries where the pandemic has been partially contained, each of which could further adversely impact our ability to conduct clinical trials and our business generally, and could materially and adversely affect our business, financial condition and results of operations.

The COVID-19 global pandemic continues to rapidly evolve. The extent to which the outbreak may affect our clinical trials, business,

financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted at this time, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. Future developments in these and other areas present material uncertainty and risk with respect to our clinical trials, business, financial condition and results of operations.

In addition, the trading prices for our common stock and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms.

Please also refer to the complete Item 1A of our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 9, 2020 for additional risks and uncertainties facing Aduro that may materially and adversely affect Aduro's business, financial condition and results of operations.

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 the Company's intentions or current expectations concerning, among other things, the status of our clinical programs and business operations and the impact of COVID-19 and related "shelter in place" orders and other public health guidance measures on our clinical programs and business operations. 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, the effects of COVID-19 on the Company's clinical programs and business operations, early or preliminary clinical trial results may not be predictive of future results, the Company's history of net operating losses and uncertainty regarding its ability to achieve profitability, the Company's ability to develop and commercialize its product candidates, the Company's ability to use and expand its technologies to build a pipeline of product candidates, the Company's ability to obtain and maintain regulatory approval of its product candidates, the Company's ability to operate in a competitive industry and compete successfully against competitors that have greater resources than the Company does, the success of the Company's restructuring, the Company's reliance on third parties, and the Company's ability to obtain and adequately protect intellectual property rights for its product candidates. Many of these risks are discussed in greater detail under the heading "Risk Factors" contained in the Company's annual report on Form 10-K for the year ended December 31, 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. The Company assumes no obligation to update its forward-looking statements, whether as a result of new information, future events or otherwise, after the date of this Current Report.

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.

Dated: April 9, 2020

Aduro Biotech, Inc.

By: /s/ William G. Kachioff
William G. Kachioff
Interim Chief Financial Officer