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): March 26, 2020

MYOKARDIA, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-37609**	**44-5500552**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

1000 Sierra Point Parkway
Brisbane, CA 94005
(Address of principal executive offices, including zip code)

(650) 741-0900
(Registrant's telephone number, including area code)

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 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	MYOK	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 Items.

Clinical Trial Update

On March 26, 2020, MyoKardia, Inc. (the "Company") issued a press release titled "MyoKardia Provides Clinical Trial Update in the Context of the COVID-19 Pandemic." A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Supplemental Risk Factor

In light of recent developments relating to the COVID-19 global pandemic, the Company 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 February 27, 2020, to include the following risk factor under the heading "Risks Related to Our Business and Industry":

The outbreak of the novel strain of coronavirus, SARS-CoV-2, which causes COVID-19, could adversely impact our business.

The outbreak of the novel strain of coronavirus, SARS-CoV-2, which causes coronavirus disease 2019 (COVID-19) has evolved into a global pandemic. In response to the spread of COVID-19, we have closed our executive offices with our administrative employees continuing their work outside of our offices, and restricted on-site staff to only those required to maintain the facilities and equipment.

As a result of the COVID-19 outbreak, or similar pandemics, we have and may in the future experience disruptions that could severely impact our business, research and clinical development activities, including:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays or disruptions in non-clinical studies due to the inability of our research and development personnel to perform their regular duties or unforeseen circumstances at contract research organizations and vendors along their supply chain;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19, being forced to quarantine, or not accepting home health visits;
- 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;
- interruption of key clinical trial activities, such as clinical trial site data monitoring and site inspections, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (particularly any procedures that may be deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the U.S. Food and Drug Administration and comparable foreign regulatory agencies, which may impact review, inspection and approval timelines;
- 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 preclinical studies and clinical trials, including because of sickness of employees or their families, the desire of employees to avoid contact with large groups of people, an increased reliance on working from home or mass transit disruptions.

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

The COVID-19 outbreak continues to rapidly evolve, and it is unknown how long disruptions to our research, clinical development and other business operations resulting from the COVID-pandemic, including any disruptions relating to the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and actions by businesses and governmental authorities to contain the outbreak, such as quarantines or “stay at home” orders and business closures, will continue. However, any prolonged disruption could have a material adverse impact our business, financial condition and results of operations, and we will continue to monitor the situation closely. The information in Item 2.02 of this Form 8-K (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated March 26, 2020
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.

MyoKardia, Inc.

Date: March 26, 2020

By: /s/ Taylor Harris
Taylor Harris
Chief Financial Officer **(principal financial officer)**

MyoKardia Provides Clinical Trial Update in the Context of the COVID-19 Pandemic

Reaffirms Second Quarter 2020 Expected Timing for Topline Data from Phase 3 EXPLORER-HCM Clinical Trial of Mavacamten and Phase 2a Danicamtiv Study

Brisbane, Calif., March 26, 2020 -- MyoKardia, Inc. (Nasdaq: MYOK) today provided an update to the status of its clinical programs in the context of the COVID-19 (coronavirus) pandemic given the impact of the pandemic on the global healthcare system's present ability to support the conduct of clinical trials.

At this time, the company does not foresee changes to key clinical and regulatory milestones associated with the development of mavacamten for obstructive hypertrophic cardiomyopathy (HCM), including reporting topline data from the Phase 3 EXPLORER-HCM study in the second quarter of 2020. Enrollment in EXPLORER-HCM concluded in August 2019 and as of this month, all patient visits have been conducted through the 30-week treatment period. Similarly, enrollment and patient dosing in the Phase 2a multiple-ascending dose trial of danicamtiv in patients with stable heart failure is complete, and MyoKardia still expects to report results from this study in the second quarter of 2020. MyoKardia has temporarily suspended enrollment in two ongoing studies and new clinical trials planned to commence in the second quarter of 2020 will be delayed.

"The COVID-19 pandemic reminds us of the vital importance of our clinical communities, our commitment to our patients and our collective responsibility to support each other. Our primary focus remains on the safety and well-being of our study participants, clinical investigators and their site staffs, as well as enabling the healthcare professionals in our network to focus critical resources on those affected by COVID-19," said Tassos Gianakakos, MyoKardia's Chief Executive Officer. "We are learning that people with HCM and DCM are among the most at risk from COVID-19 infections and have put in place several measures intended to protect our study participants, as well as the investigators, site coordinators and support staff who care for them. We are suspending enrollment in certain ongoing clinical trials and will not initiate new studies until we can proceed safely, without unnecessarily adding risk to study participants or site staff, as part of our efforts to lighten the incredible burden facing the healthcare system."

The company, together with its steering committees, patient advocacy and other expert clinical advisors, assessed each of its clinical programs with the goals of protecting the safety of study participants, investigators and staff, and ensuring consistent and appropriate clinical trial conduct. All efforts will be made to allow patients to continue in ongoing mavacamten studies, including the MAVA-LTE long-term extension and the PIONEER open-label extension (OLE) studies. MyoKardia has temporarily suspended the rollover of patients from EXPLORER into the MAVA-LTE and plans to resume enrollment when conditions permit. The company has also paused the enrollment of healthy volunteers in the Phase 1 clinical trial evaluating MYK-224.

Studies that were planned to initiate in the second quarter of 2020 will be delayed until conditions change, including the VALOR-HCM Phase 3 clinical study of mavacamten as an alternative to septal reduction therapy (SRT) procedures, the Phase 2 proof-of-concept study for mavacamten in subgroups of patients with heart failure with preserved ejection fraction (HFpEF), and the Phase 2 study of danicamtiv in patients with genetic dilated cardiomyopathy (DCM).

MyoKardia will continue to closely monitor the evolving situation and expects to resume patient enrollment and to initiate delayed studies as soon as conditions safely permit.

Driven by the **Heart**

About MyoKardia
MyoKardia is a clinical-stage biopharmaceutical company discovering and developing targeted therapies for the treatment of serious cardiovascular diseases. The company is pioneering a precision medicine approach to its discovery and development efforts by 1) understanding the biomechanical underpinnings of disease; 2) targeting the proteins that modulate a given condition; 3) identifying patient populations with shared disease characteristics; and 4) applying learnings from research and clinical studies to inform and guide pipeline growth and product advancement. MyoKardia's initial focus is on small molecule therapeutics aimed at the proteins of the heart that modulate cardiac muscle contraction to address diseases driven by excessive contraction, impaired relaxation, or insufficient contraction. Among its discoveries are three clinical-stage therapeutics: mavacamten (formerly MYK-461); danicamtiv (formerly MYK-491) and MYK-224.

MyoKardia's mission is to change the world for people with serious cardiovascular disease through bold and innovative science.

Forward-Looking Statements
Statements we make in this press release may include statements which are not historical facts and are considered forward-looking 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, which are usually identified by the use of words such as "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "seeks," "should," "will," and variations of such words or similar expressions. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Securities Exchange Act and are making this statement for purposes of complying with those safe harbor provisions. These forward-looking statements, including statements regarding the clinical and therapeutic potential of our product candidates, the conduct of, and our anticipated announcement of topline data and complete results from, our Phase 3 EXPLORER-HCM trial of mavacamten for the treatment of obstructive HCM; our plans to present data from our Phase 2 MAVERICK-HCM study of mavacamten for the treatment of non-obstructive HCM; the conduct of our PIONEER-OLE trial of mavacamten; the conduct of, and our plans to resume enrollment in, our MAVA-LTE study; the initiation of our planned VALOR-HCM Phase 3 clinical study of mavacamten as an alternative to septal reduction therapy (SRT) procedures and our Phase 2 proof-of-concept study for mavacamten in subgroups of patients with heart failure with preserved ejection fraction (HFpEF); the conduct of, and our planned announcement of complete results from our Phase 2a multiple-ascending dose trial of danicamtiv in patients with stable heart failure; and our plans to resume enrollment in our Phase 1 clinical trial of MYK-224 in healthy volunteers and to initiate a Phase 2 study of MYK-224 in HCM patients, reflect our current views about our plans, intentions, expectations, strategies and prospects, which are based on the information currently available to us and on assumptions we have made. Although we believe that our plans, intentions, expectations, strategies and prospects as reflected in or suggested by those forward-looking statements are reasonable, we can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a variety of risks and factors that are beyond our control including, without limitation, risks associated with the development and regulation of our product candidates, as well as those set forth in our Annual Report on Form 10-K for the year ended December 31, 2019, and our other filings with the SEC. Except as required by law, we assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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