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): July 17, 2019

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.)

333 Allerton Ave.
South San Francisco, CA 94080
(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	**MYOK**	**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 1.01 Entry into a Material Definitive Agreement.

On July 17, 2019 (the "Effective Date"), MyoKardia, Inc. (the "Company") entered into a Termination Agreement (the "Termination Agreement") with Aventis, Inc., a wholly-owned subsidiary of Sanofi S.A. ("Sanofi"), whereby the parties clarified or amended certain rights and obligations of the parties surviving the termination of that certain License and Collaboration Agreement, dated August 1, 2014 (the "Collaboration Agreement") by and between the Company and Sanofi.

Pursuant to the Termination Agreement, Sanofi granted to the Company an exclusive, worldwide, fully paid-up and royalty-free, perpetual and irrevocable license with the right to grant sublicenses under the Sanofi Licensed Technology to develop, commercialize and manufacture product candidates under three main programs: HCM-1 (mavacamten and MYK-224) , HCM-2, and DCM-1 (MYK-491). Sanofi will transfer to the Company the information, data and know-how pertaining to Sanofi's activities in relation to the programs and the development and manufacturing of program compounds (the "Sanofi Licensed Technology"). Any additional technology transfer activities will be further memorialized into a detailed technology transfer plan developed and approved by both the Company and Sanofi. The parties have agreed to complete all technology transfer activities by December 31, 2019.

In addition, the Termination Agreement specifies that the non-compete restrictions on the parties pursuant to Section 3.7 of the Collaboration Agreement have terminated as of December 31, 2018 with respect to the mechanism of action for DCM-1 and HCM-2 and, as of April 1, 2019, with respect to HCM-1.

Among other payments payable by the Company to Sanofi pursuant to the Termination Agreement, the Company will pay to Sanofi a non-refundable and non-creditable, amount of $80,000,000 net of any broker's, financial advisor's or other similar fees or commissions in consideration of Sanofi releasing the Company from its royalty payment obligations on net sales of HCM-1 products set forth in the Collaboration Agreement, with $50,000,000 of such fee to be paid to Sanofi within 5 days of the Effective Date and the remaining $30,000,000 to be deposited concurrently into escrow and released to Sanofi on or before June 30, 2020.

The foregoing description of the Termination Agreement does not purport to be complete and is qualified in its entirety by reference to the Termination Agreement, a complete copy of which the Company intends to file with the Securities and Exchange Commission as an exhibit to its Quarterly Report on Form 10-Q for the quarter ending September 30, 2019.

Item 7.01 Regulation FD Disclosure

On July 18, 2019, the Company issued a press release announcing its entry into the Termination Agreement (the "Press Release"). A copy of the Press Release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 and Exhibit 99.1 attached hereto is intended to be furnished and 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 liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated July 18, 2019

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.

Date: July 18, 2019

MyoKardia, Inc.

By: /s/ Cynthia Ladd
Cynthia Ladd
General Counsel

Exhibit 99.1

MYOKARDIA

News Release

MyoKardia Announces HCM Program Updates: Accelerates Timing for Mavacamten Topline Phase 3 Data; Re-acquires U.S. Royalty Rights to HCM Programs from Sanofi

EXPLORER-HCM Patient Screening Closes Ahead of Schedule – Initial Results Now Anticipated in the Second Quarter of 2020

Royalty Purchase Creates Additional Economic Value for MyoKardia's Emerging HCM Treatment Portfolio

SOUTH SAN FRANCISCO, Calif., July 18, 2019 — MyoKardia, Inc. (Nasdaq: MYOK) today announced updates related to its hypertrophic cardiomyopathy (HCM) treatment portfolio, including lead therapeutic candidate, mavacamten.

Patient screening has closed for the Phase 3 EXPLORER-HCM registrational clinical study to assess the effect of mavacamten in treating patients with obstructive hypertrophic cardiomyopathy (oHCM). Clinical site engagement remains high, and enrollment into the pivotal trial is expected to be completed by mid-August. MyoKardia now anticipates reporting topline data from the EXPLORER-HCM trial in the second quarter of 2020, ahead of previous guidance of the second half of 2020.

"The enthusiasm for mavacamten, along with the hard work and partnership of the EXPLORER-HCM clinical sites and our MyoKardia team, enabled this first-of-its kind study to enroll ahead of expectations," said Tassos Gianakakos, MyoKardia's Chief Executive Officer. "We are greatly appreciative of the investigators, support staff and the oHCM patients and their families who have participated in this pioneering study. The data generated from our mavacamten program to date indicate that this first-in-class medicine has the potential to provide substantial benefit to individuals with symptomatic, obstructive HCM."

MyoKardia also announced the re-acquisition of U.S. royalty rights to mavacamten and MYK-224 from Sanofi S.A. (Sanofi). As consideration for the buyback of the U.S. royalty rights to these programs, MyoKardia is paying Sanofi $50 million upfront, with an additional $30 million payable by June 30, 2020. Under the terms of the former license and collaboration agreement with Sanofi, Sanofi was eligible for tiered royalties, ranging from 5 percent to 10 percent, on U.S. sales of mavacamten and MYK-224 in HCM or any additional indications.

"Regaining U.S. royalty rights for mavacamten and MYK-224 allows us to capture the economic value of our HCM therapies on a global basis and increases our strategic flexibility and control over their development and commercialization," Mr. Gianakakos said. "This was an important strategic step for us as we look ahead to mavacamten's potential registration and commercial launch in the U.S. and the imminent advancement of MYK-224 into clinical studies."

MyoKardia's cash guidance remains unchanged. The company anticipates that current cash, cash equivalents and investments will be sufficient to fund planned operations into the second half of 2021. The company will announce second quarter financial results on August 7, 2019.

About EXPLORER-HCM Trial

Mavacamten is currently being tested in the pivotal, Phase 3 EXPLORER-HCM clinical trial for the treatment of symptomatic, obstructive HCM. HCM is the most common form of genetic heart disease. It is a chronic, progressive condition estimated to affect one in every 500 people worldwide and is characterized by the thickening of the heart walls due to excessive contraction. EXPLORER-HCM is a multi-national, randomized, double-blind study that will enroll more than 220 patients. Patients will be randomized 1:1 to receive mavacamten or placebo for 30 weeks with a primary endpoint of clinical response designed to assess improvements in patient symptoms and function. Topline data from the Phase 3 EXPLORER-HCM trial is anticipated in the second quarter of 2020.

About the MyoKardia-Sanofi Collaboration

MyoKardia and Sanofi entered into a multi-product collaboration in 2014 focused on developing novel treatments for cardiomyopathies, including HCM. The companies discontinued that agreement in conjunction with the end of the Research term of the collaboration in December 2018 and the collaboration agreement with Sanofi concluded in its entirety on April 1, 2019. Over the course of the collaboration, MyoKardia received approximately $230 million in funding from Sanofi, advanced mavacamten from preclinical development into a late-stage pivotal study for the treatment of HCM, and MYK-491 from discovery to a Phase 2 proof-of-concept study in patients with dilated cardiomyopathy (DCM).

About MyoKardia

MyoKardia is a clinical-stage biopharmaceutical company pioneering a precision medicine approach to discover, develop and commercialize targeted therapies for the treatment of serious cardiovascular diseases. MyoKardia's initial focus is on the development of small molecule therapeutics aimed at the cardiac muscle proteins that modulate cardiac muscle contraction and underlie diseases of systolic and diastolic dysfunction. Based on an in-depth understanding of disease biology, MyoKardia applies a precision medicine approach to develop its therapeutic candidates for patient populations with shared characteristics, such as causal genetic mutations or disease subtypes. MyoKardia's most advanced product candidate is mavacamten (formerly MYK-461), a novel, oral, allosteric modulator of cardiac myosin intended to reduce hypercontractility. Mavacamten has advanced into a pivotal Phase 3 clinical trial, known as EXPLORER-HCM in patients with symptomatic, obstructive hypertrophic cardiomyopathy (HCM). MyoKardia is also developing mavacamten in a second indication, non-obstructive HCM, in the Phase 2 MAVERICK-HCM clinical trial. MYK-491, MyoKardia's second product candidate, is designed to increase cardiac output among patients with systolic heart dysfunction by increasing the overall extent of the heart's cardiac contractility. MyoKardia is currently evaluating MYK-491 in a Phase 1b/2a study in stable heart failure patients.

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 Company's ability to enroll patients in its Phase 3 EXPLORER-HCM study of mavacamten in symptomatic oHCM and the timing of the completion of enrollment, the availability of data from EXPLORER-HCM, the Company's expectation with respect to release of data from these studies, the Company's ability to advance MYK-224 into clinical development, and the timing of these events, as well as the Company's projected cash runway, 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 Quarterly Report on Form 10-Q for the quarter ended March 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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