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 31, 2018

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))

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 1.02 Termination of a Material Definitive Agreement

On January 2, 2019, MyoKardia, Inc. (the "Company") announced that effective as of December 31, 2018, the initial research term (the "Research Term") under the Company's License and Collaboration Agreement, dated August 1, 2014 (the "Collaboration Agreement"), with Aventis Inc., a wholly-owned subsidiary of Sanofi S.A. ("Sanofi") expired, and the parties elected not to extend the Research Term. In addition, Sanofi provided the Company with notice of termination of the Collaboration Agreement with respect to the HCM-1 program pursuant to Section 12.2(a)(iii) thereof, effective 90 days after January 1, 2019 (the "Effective Date"), resulting in termination of the Collaboration Agreement in its entirety at that time. During the period leading up to the end of the Research Term, it was important for the Company to maintain 100 percent of the U.S. commercial rights for mavacamten as well as not giving additional rights in expanded indications. Sanofi subsequently provided the Company with notification of its decision to conclude the collaboration in conjunction with the end of the Research Term. Sanofi also cited broader portfolio prioritization needs.

The Collaboration Agreement covered three main research programs: HCM-1 (mavacamten and MYK-224) , HCM-2, and DCM-1 (MYK-491). Under the Collaboration Agreement, the Company retained rights to develop and commercialize mavacamten, MYK-224 and HCM-2 in the United States, as well as co-commercialization rights to MYK-491 in the United States, at the Company's option. The Company granted to Sanofi: (i) worldwide rights to commercialize MYK-491; and (ii) regulatory and commercialization rights outside the United States for the two HCM programs. After the Effective Date, Sanofi will remain eligible to receive royalties associated with any potential HCM-1 products that will range from mid-single to low-double digits in the U.S. There is no royalty obligation to Sanofi for sales outside the U.S. There are no material early termination penalties that will be incurred by the Company.

For purposes of this Form 8-K, the Company refers to Sanofi as the co-party to the Collaboration Agreement.

Item 7.01 Regulation FD Disclosure

On January 2, 2019, the Company issued a press release announcing the termination of the Collaboration 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 8.01 Other Events

In connection with the termination of the Collaboration Agreement, the Company has updated its cash guidance. The Company anticipates that its current cash, cash equivalents and investments are sufficient to fund operations through the second half of 2020.

Forward-Looking Statements

Statements made by the Company in this Form 8-K 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. The Company intends 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 is making this statement for purposes of complying with those safe harbor provisions. These forward-looking statements, including statements regarding the Company's expected cash runway, reflect the Company's current views about its plans, intentions, expectations, strategies and prospects, which are based on the information currently available to the Company and on assumptions the Company has made. Although the Company believes that its plans, intentions, expectations, strategies and

prospects as reflected in or suggested by those forward-looking statements are reasonable, it 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 the Company's control including, without limitation, risks associated with the development and regulation of the Company's product candidates, as well as those set forth in its Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, and its other filings with the SEC. Except as required by law, the Company assumes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated January 2, 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: January 2, 2019

MyoKardia, Inc.

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

Exhibit 99.1

News Release

MyoKardia Regains Global Rights to Mavacamten and MYK-491 Programs from Sanofi

Management to Host Conference Call at 8:30 a.m. ET/5:30 a.m. PT

SOUTH SAN FRANCISCO, Calif., January 2, 2019 – MyoKardia, Inc. (Nasdaq: MYOK), a clinical-stage biopharmaceutical company pioneering precision medicine for the treatment of cardiovascular diseases, today announced it has regained worldwide rights to all programs covered under its license and collaboration agreement with Sanofi. The collaboration will not be extended beyond the initial research term, which ended on December 31, 2018, and the collaboration will conclude in its entirety effective April 1, 2019. As a result, MyoKardia now has global rights to all programs in its portfolio, including lead clinical-stage candidates, mavacamten and MYK-491.

"We are grateful for Sanofi's support over the past four years in what was a highly productive relationship. Since entering into the collaboration, MyoKardia has become a leading research and development organization with a robust pipeline of targeted cardiovascular therapeutics," said Tassos Gianakakos, MyoKardia's chief executive officer. "Regaining worldwide rights enables us to capture the full value of the data being generated in the next 12-24 months as we prepare for the potential registration of mavacamten in obstructive HCM and obtain proof-of-concept for MYK-491 in patients with stable heart failure. Importantly, consolidated control over our entire portfolio allows us to make decisions about how we advance each of our therapeutic candidates in alignment with our precision medicine approach."

MyoKardia and Sanofi initiated their collaboration in 2014 to advance up to three programs through discovery and into clinical development for the treatment of hypertrophic cardiomyopathy (HCM) and dilated cardiomyopathy (DCM). During the course of the collaboration, MyoKardia has received approximately $230 million in funding from Sanofi and has advanced mavacamten from preclinical development into 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 DCM. During the period leading up to the end of the research term, it was important for MyoKardia to maintain 100 percent of the U.S. commercial rights for mavacamten in HCM as well as additional rights in expanded indications. Sanofi subsequently provided MyoKardia with notification of its decision to conclude the collaboration in conjunction with the end of the research term.

MyoKardia is positioned to achieve several significant clinical milestones over the next 12 to 24 months and reaffirmed timing for anticipated data read-outs:

- 6-month and 12-month data for mavacamten in obstructive HCM (oHCM) from the ongoing PIONEER open-label extension study
- Data from the Phase 2 MAVERICK study in non-obstructive HCM in the second half of this year
- Topline data from the Phase 3 EXPLORER-HCM clinical trial of mavacamten in obstructive HCM (oHCM) in the second half of 2020
- Phase 2a proof-of-concept data for MYK-491 in DCM before the end of the year

The company anticipates that current cash, cash equivalents and investments are sufficient to fund operations past the read-out of EXPLORER-HCM data in the second half of 2020. This reflects an anticipated increase in R&D- expenses due to the termination of the Sanofi collaboration agreement. As of September 30, 2018, MyoKardia had cash, cash equivalents and investments totaling $412 million. MyoKardia will report fourth quarter and year-end 2018 financial results in late February of 2019.

Conference Call and Webcast Information

MyoKardia management will host a conference call today at 8:30 a.m. EST to discuss today's announcement. Investors and analysts are invited to participate in the call by dialing +1-844-494-0193 (U.S.) or +1-508-637-5584 using the conference ID 8546868. The webcast may be accessed live on the Investor Relations section of the MyoKardia website at http://investors.myokardia.com. A replay of the webcast will be available on MyoKardia's website for 90 days following the call.

Driven by the Heart
333 Allerton Avenue, South San Francisco, CA 94080 / +1 650 351 4705 / myokardia.com

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 and rare 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 patients 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 mavacamten, MYK-491 and other product candidates that the Company may identify and pursue, the progress of and availability of data from the Company's ongoing Phase 3 EXPLORER-HCM trial of mavacamten in oHCM patients, Phase 2 MAVERICK-HCM trial of mavacamten in nHCM patients and PIONEER-OLE study of mavacamten, the progress of and availability of data from the Company's ongoing Phase 1b/2a study of MYK-491 in DCM patients, the Company's late-stage development plans for MYK-491, the advancement of the Company's research programs into clinical development, as well as the timing of these events, and the Company's expected 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 September 30, 2018, 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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