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): August 7, 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, 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 2.02 Results of Operations and Financial Condition.

On August 7, 2019, MyoKardia, Inc. announced its financial results for the second quarter ended June 30, 2019. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

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 issued by MyoKardia, Inc. on August 7, 2019, furnished herewith

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: August 7, 2019

MyoKardia, Inc.

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

EXHIBIT 99.1

MyoKardia Reports Second Quarter 2019 Financial Results

Announces Last Patient to be Enrolled in EXPLORER-HCM Phase 3 during the Week of August 12th, Topline Data Accelerated to 2nd Quarter 2020

Topline Phase 2 Clinical Data from MAVERICK-HCM and MYK-491 on Track for Fourth Quarter 2019

Company to Host Conference Call and Webcast Today at 4:30 p.m. ET (1:30 p.m. PT)

SOUTH SAN FRANCISCO, Calif., Aug. 07, 2019 -- MyoKardia, Inc. (Nasdaq: MYOK) today reported financial results for the second quarter ended June 30, 2019.

"We are now less than a year away from potentially game-changing pivotal data from our EXPLORER-HCM clinical trial of mavacamten in obstructive HCM, with activities in full swing for NDA preparation and potential commercial introduction of MyoKardia's first product," said Tassos Gianakakos, MyoKardia's Chief Executive Officer. "The remainder of this year will see us share multiple meaningful clinical results including topline data from our Phase 2 MAVERICK-HCM study in patients with non-obstructive HCM and from our Phase 2 study of MYK-491 for patients with stable heart failure. We will also be advancing our third clinical-stage compound, MYK-224, into a Phase 1 clinical trial. Taken together, these events highlight the meaningful progress we continue to make in the development of much-needed new treatments for serious cardiovascular diseases."

Recent Clinical Program Highlights

Mavacamten for Hypertrophic Cardiomyopathy (HCM)

- **Enrollment in EXPLORER-HCM Phase 3 Clinical Study Nearing Completion:** Patient enrollment for the Phase 3 EXPLORER-HCM registrational clinical study to assess the effect of mavacamten in treating patients with symptomatic, obstructive HCM is scheduled to end next week. Clinical site engagement was high, allowing for enrollment above the target of 220 patients to be completed ahead of expectations. MyoKardia now anticipates reporting topline data from the EXPLORER-HCM trial in the second quarter of 2020, ahead of the previous guidance of the second half of 2020.

- **Completed Enrollment in the MAVERICK-HCM Phase 2 Clinical Trial:** In May, MyoKardia announced the completion of enrollment in the Phase 2 MAVERICK-HCM study of mavacamten for the treatment of non-obstructive HCM. The randomized, double-blind, placebo-controlled MAVERICK-HCM Phase 2 clinical trial is designed to assess the safety and tolerability of a 16-week treatment course of mavacamten in patients with non-obstructive HCM. MyoKardia plans to report topline data from the MAVERICK-HCM study in the fourth quarter of 2019.

- **Published Data in Nature Digital Medicine Showing Potential of Wrist-Worn Biosensor to Screen for Hypertrophic Cardiomyopathy:** Results from an exploratory study demonstrated the potential to screen for obstructive HCM using a photoplethysmography (PPG) digital health device, similar to the optical sensors that monitor heart rate on commercially available fitness trackers. Continuous monitoring with a wrist-worn biosensor revealed differences in arterial pulse wave patterns between obstructive HCM patients and those of individuals without obstructive HCM. MyoKardia's proprietary machine learning algorithm identified individuals with obstructive HCM with a sensitivity of 0.95 and a specificity of 0.98. The digital health substudy was conducted by MyoKardia as part of the company's Phase 2 PIONEER-HCM trial of mavacamten.

Driven by the **Heart**

MYK-491 for Dilated Cardiomyopathy (DCM)

- **Presented results from Phase 1a Clinical Trial of MYK-491 at the European Society of Cardiology Heart Failure Congress:** First-in-human data from the Phase 1a clinical trial of MYK-491 in healthy volunteers showed the drug to be well tolerated. MYK-491 increased cardiac contractility by 5-20 percent across multiple echocardiographic parameters at higher drug concentrations, with minimal impact on diastolic function. MYK-491 is currently being studied in a Phase 2a multiple-ascending dose clinical trial for the treatment of patients with systolic heart failure, in which the heart is unable to contract sufficiently to meet the demands of the body. Data from this study are anticipated in the fourth quarter of 2019.

Recent Corporate Highlights

- **Re-acquired U.S. Royalty Rights to HCM Programs from Sanofi:** MyoKardia completed the re-acquisition of U.S. royalty rights to mavacamten and MYK-224 from Sanofi. As consideration for the buyback of the U.S. royalty rights to these programs, MyoKardia paid 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.

Second Quarter 2019 Financial Results

- **Cash Position:** Cash, cash equivalents and investments (short-term and long-term) as of June 30, 2019 were $602.4 million, compared to $394.8 million as of December 31, 2018. The increase in the company's cash position is primarily attributable to net proceeds of approximately $271.2 million from MyoKardia's follow-on offering of common stock, which priced in March 2019.

- **Revenue:** In the second quarter of 2019, MyoKardia recorded no revenue from collaborations, compared with $6.6 million during the same period in 2018. As of December 31, 2018, MyoKardia had fulfilled all of its performance obligations to Sanofi, and no further revenue will be recorded from the Sanofi collaboration agreement.

- **R&D Expenses:** Research and development expenses were $27.7 million in the second quarter 2019, up from $17.2 million (net of Sanofi credits of $8.6 and $4.3 million) for the same period in 2018. For the six months ended June 30, 2019, R&D expenses were $53.9 million compared to $33.8 million in the first half of 2018, net of Sanofi credits of $18.5 million and $7.1 million, respectively. The increase in R&D expenses was primarily driven by increases in clinical expenses related to the mavacamten and MYK-491 clinical trials, an increase in personnel-related costs and increases in contract research, chemistry and biology expenses related to discovery and pre-clinical programs.

- **G&A Expenses:** General and administrative expenses were $13.9 million for the three months ended June 30, 2019, compared to $8.9 million for the same period in 2018. For the first half of 2019, G&A expenses totaled $27.4 million compared to $16.2 million in the first half of 2018. The increase in G&A expense was primarily driven by an increase in personnel expenses and stock compensation due to higher headcount, as well as an increase in professional service and consulting fees.

- **Net Loss**: Net loss was $38.2 million ($0.83 loss per share) for the second quarter of 2019, compared to a net loss of $18.4 million ($0.49 loss per share) for the second quarter of 2018. For the six months ended June 30, 2019, net loss was $75.6 million ($1.75 loss per share) compared to $36.2 million ($0.99 loss per share) during the same period of 2018.

Financial Guidance

Based on its current operating plans, MyoKardia anticipates that current cash, cash equivalents and investments are sufficient to fund operations into the second half of 2021.

Conference Call and Webcast
MyoKardia management will host a conference call and live audio webcast on Wednesday, August 7, 2019, at 4:30 p.m. ET / 1:30 p.m. PT to discuss current operations and second quarter 2019 financial results. The call may be accessed by phone by calling 844-494-0193 from the U.S. and Canada or 508-637-5584 internationally and using the conference ID 7881918. The webcast may be accessed live on the Investor Relations section of the Company's website at http://investors.myokardia.com. A replay of the webcast will be available on the MyoKardia website for approximately 90 days following the call.

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 underlying 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 clinical and therapeutic potential of mavacamten and MYK-491, the Company's ability to complete the enrollment of patients in its Phase 3 EXPLORER-HCM study of mavacamten in symptomatic oHCM, the availability of data from EXPLORER-HCM, as well as from the Phase 2 MAVERICK-HCM study in patients with non-obstructive HCM, and the MYK-491 Phase 2 study for patients with stable heart failure, 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 ad 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 June 30, 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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MYOKARDIA, INC.

Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	June 30, 2019	December 31, 2018
	(Unaudited)	
Assets		
Current assets		
Cash and cash equivalents	$ 443,693	$ 246,122
Short-term investments	114,792	68,564
Prepaid expenses and other current assets	4,316	4,760
Total current assets	562,801	319,446
Property and equipment, net	5,435	5,138
Operating lease right-of-use assets	1,756	—
Long-term investments	43,952	80,148
Restricted cash and other	2,109	2,521
Total assets	$ 616,053	$ 407,253
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	3,037	$ 2,946
Accrued liabilities	24,744	20,758
Prepayment from collaboration partner	2,256	12,973
Operating lease liabilities - current	1,831	—
Total current liabilities	31,868	36,677
Other long-term liabilities	—	9
Total liabilities	31,868	36,686
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized; none issued and outstanding	—	—
Common stock, $0.0001 par value, 150,000,000 shares authorized at June 30, 2019 and December 31, 2018; 46,098,059 and 40,288,949 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	5	4
Additional paid-in capital	861,880	573,183
Accumulated other comprehensive income (loss)	497	(67)
Accumulated deficit	(278,197)	(202,553)
Total stockholders' equity	584,185	370,567
Total liabilities and stockholders' equity	$ 616,053	$ 407,253

MYOKARDIA, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Collaboration and license revenue	$ —	$ 6,639	$ —	$ 11,970
Operating expenses:				
Research and development	27,708	17,218	53,898	33,836
Selling, general and administrative	13,856	8,912	27,407	16,225
Total operating expenses	41,564	26,130	81,305	50,061
Loss from operations	(41,564)	(19,491)	(81,305)	(38,091)
Interest and other income, net	3,172	1,078	5,443	1,858
Loss before income taxes	(38,392)	(18,413)	(75,862)	(36,233)
Income tax benefits	(218)	—	(218)	—
Net loss	(38,174)	(18,413)	(75,644)	(36,233)
Other comprehensive gain (loss), net of tax effect of $219, $0, $219, $0, respectively	201	70	564	(67)
Comprehensive loss	$ (37,973)	$ (18,343)	$ (75,080)	$ (36,300)
Net loss per share, basic and diluted	$ (0.83)	$ (0.49)	$ (1.75)	$ (0.99)
Weighted average number of shares used to compute net loss per share, basic and diluted	46,065,901	37,440,024	43,301,417	36,620,747