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

On November 7, 2018, MyoKardia, Inc. announced its financial results for the third quarter ended September 30, 2018. 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 November 7, 2018, furnished herewith

EXHIBIT INDEX

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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: November 7, 2018

MyoKardia, Inc.

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

Exhibit 99.1

MyoKardia Reports Third Quarter 2018 Financial Results

SOUTH SAN FRANCISCO, Calif., November 7, 2018 – MyoKardia, Inc. (Nasdaq: MYOK), a clinical-stage biopharmaceutical company pioneering precision medicine for the treatment of cardiovascular diseases, today reported financial results for the quarter ended September 30, 2018.

"MyoKardia continues to make encouraging progress toward our mission of changing the world for patients with serious cardiovascular disease. Within just the past few months, we have initiated the MAVA-LTE clinical study of mavacamten and the Phase 2a portion of our active clinical trial of MYK-491, unveiled three new preclinical programs and through our efforts with the SHaRe registry, our MyoSeeds grant program and newly formed collaboration with 23andMe, demonstrated our commitment to supporting the HCM community and helping to build awareness of this debilitating and progressive disease," said Tassos Gianakakos, Chief Executive Officer. "We'll be sharing additional progress across our programs in the coming weeks, with the presentation of clinical, preclinical and registry data at the upcoming American Heart Association Scientific Sessions and the release of topline data from our Phase 1b clinical trial of MYK-491 in patients with dilated cardiomyopathy before the end of the year."

Recent Clinical Program Highlights

Mavacamten for Hypertrophic Cardiomyopathy (HCM)

- **Dosed first patient in MAVA Long-Term Extension (LTE) Study of Mavacamten in HCM:** The MAVA-LTE study will assess long-term safety of mavacamten, as well as its effects on hypertrophic cardiomyopathy (HCM) symptoms and cardiac function in patients who successfully complete either MyoKardia's MAVERICK-HCM or EXPLORER-HCM clinical trials of mavacamten. Data from the MAVA-LTE clinical trial, along with results of the pivotal Phase 3 EXPLORER-HCM trial, are intended to support the registration submission for mavacamten for the treatment of obstructive HCM (oHCM).

- **Reported encouraging initial data from PIONEER Open-Label Extension (OLE) Study:** Twelve of twenty patients with oHCM who previously completed MyoKardia's Phase 2 PIONEER-HCM study of mavacamten for the treatment of symptomatic oHCM have enrolled in the PIONEER-OLE trial. Interim data for seven patients at twelve weeks of treatment with mavacamten demonstrated statistically significant reductions in left ventricular outflow tract (LVOT) obstruction compared to baseline. All patients maintained ejection fraction well in the normal range of greater than 50 percent, and there have been no significant adverse events reported. Individualized dose adjustments in PIONEER-OLE are consistent with the regimen being used in MyoKardia's pivotal Phase 3 EXPLORER-HCM trial of mavacamten for the treatment of oHCM.

- **Announced acceptance of twelve abstracts at the 2018 AHA Scientific Sessions**: Among the highlights of the data being presented are an analysis of mavacamten's effect on left ventricular relaxation based on an analysis of patient data from the Phase 2 PIONEER-HCM clinical trial, which will be presented in a poster session on Saturday, November 10, and preclinical data examining the *in vivo* effect of myosin inhibition in a proprietary large-animal model of non-obstructive hypertrophic cardiomyopathy (nHCM), which will be shared in an oral presentation on Sunday, November 11. MyoKardia management will host a call on Monday, November 12 at 8:00 a.m. ET to review the data being presented.

- **Published new data from the Sarcomeric Human Cardiomyopathy Registry (SHaRe) in *Circulation*:** Results from a multicenter, international, longitudinal study of data from nearly 4,600 HCM patients were published in the October 2, 2018 issue of *Circulation*. These data revealed that HCM patients are at substantially elevated risks of long-term complications and comorbidities, as well as increased mortality rates compared to that of the general U.S. population.

- **Launched the MyoSeeds™ Grant Program:** MyoKardia issued a call for proposals for its MyoSeeds initiative to support original, independent research in the biology and underlying mechanisms of cardiomyopathies and precision treatment for heart disease. Through this program, MyoKardia will fund up to four awards, with a total investment of up to $1 million in funding over 2018-2019. Grants will be awarded by December 31, 2018.

- **Established partnership with 23andMe to form the first-of-its-kind HCM patient community:** MyoKardia and 23andMe will create a patient community where 23andMe customers can access regularly-updated disease information and HCM research opportunities. De-identified genotypic and phenotypic data will be collected to provide new insights into how HCM manifests across diverse patient groups. This resource is expected to launch in 2019.

MYK-491 for Systolic Dysfunction

- **Advanced MYK-491 to Phase 2a Study**: Enrollment of patients in the ongoing Phase 1b study of MYK-491 has completed, and MyoKardia plans to report topline data in the fourth quarter of 2018. Additionally, the protocol for this study was recently modified to incorporate a Phase 2a multiple-ascending dose trial in patients with stable heart failure. Enrollment in the Phase 2a clinical trial has begun, with data anticipated in late 2019.

- **Reported healthy volunteer data supporting initial proof-of-mechanism**: At its recent R&D Day, MyoKardia detailed results of its Phase 1a study in healthy volunteers, showing that MYK-491, the company's lead compound targeting impaired systolic function, increased cardiac contractility by 5-20 percent across multiple echocardiographic parameters at higher drug concentrations, with minimal impact on diastolic function. These data are consistent with preclinical data.

Research Pipeline

- **Introduced three new research programs, each with distinct mechanisms targeting diseases of cardiac contractility:** At its recent R&D Day on October 30th, 2018, MyoKardia unveiled three new research programs: MYK-224, the company's second candidate addressing HCM, which the company anticipates will enter a Phase 1 clinical study in 2019; ACT-1, a proprietary, wholly-owned cardiac muscle activator which is being developed for the treatment of genetic dilated cardiomyopathy (DCM); and LUS-1, the first known compound to specifically target impaired cardiac relaxation for patients with diseases of diastolic dysfunction, also wholly owned.

Third Quarter 2018 Financial Results

- **Cash Position:** Cash, cash equivalents and investments (short-term and long-term) as of September 30, 2018 were $411.6 million, compared to $276.4 million as of December 31, 2017. The increase in the company's cash position is primarily attributable to MyoKardia's follow-on financing in the second quarter of 2018, which raised $181.9 million in net proceeds.

- **Revenues:** Collaboration and license revenue was $9.2 million during the third quarter of 2018, compared with $3.1 million during the third quarter of 2017. For the nine months ended September 30, 2018, collaboration and license revenue was $21.2 compared to $8.5 million for the first nine months of 2017. The increase in collaboration revenue in 2018 is attributable to the adoption of Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). Under ASC 606, the $45 million payment received from Sanofi S.A. (Sanofi) in the first quarter of 2017 is now being recognized based on research and development costs incurred in a particular period relative to the estimated total program costs to be incurred in the two-year period ending December 31, 2018.

- **R&D Expenses:** Research and development expenses were $15.9 million, net of Sanofi reimbursement credits of $7.7 million, for the third quarter of 2018, up from $14.4 million for the same period in 2017. There were no reimbursement credits in the three months ending September 30, 2017. R&D expenses in the first nine months of 2018 were $49.7 million, net of reimbursement credits of $14.8 million, up from $40.0 million for the same period in 2017. The $14.8 million includes $2.6 million due from Sanofi for the MYK-224 R&D program. Cash received from Sanofi for R&D reimbursements on the mavacamten program totaled $6.9 million and $18.7 million for the three- and nine-month periods, respectively. The increase in R&D expenses was driven by clinical trial activity for mavacamten, MYK-491 and preclinical programs, an increase in headcount, and stock-based compensation expense.

- **G&A Expenses:** General and administrative expenses were $11.0 million for the three months ended September 30, 2018, compared to $5.9 million for the same period in 2017. For the first nine months of 2018,

G&A expenses were $27.2 million compared to $16.4 million in the same period in 2017. The increase in G&A expenses was primarily attributable to an increase in headcount, stock-based compensation expense, facilities-related and other administrative expenses.

- **Net Loss**: Net loss was $15.8 million ($0.39 per share) for the third quarter of 2018, compared to a net loss of $16.7 million ($0.50 per share) for the third quarter of 2017. For the nine months ended September 30, 2018, net loss was $52.0 million ($1.38 per share) compared to $46.9 million ($1.47 per share) during the same period of 2017.

Based on the company's current balance of cash and investments, plus anticipated payments from Sanofi, MyoKardia estimates having sufficient funds to execute on current operating plans into 2021.

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 has formed a* collaboration with Sanofi to support the commercialization of mavacamten outside the U.S. and for MYK-491's worldwide late-stage development and commercialization. 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 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 commencement of the Company's planned LTE study of mavacamten, the progress of and availability of data from the Company's ongoing Phase 1 study of MYK-491 in DCM patients, the commencement of the Company's planned Phase 2 study of MYK-491, the advancement of the Company's research programs, as well as the timing of these events, and the Company's expected cash runway and ability to receive additional payments from its collaboration agreement with Sanofi, 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, 2017, 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)
(Unaudited)

	September 30, 2018	December 31, 2017 (As Revised)
Assets		
Current assets		
Cash and cash equivalents	$ 335,279	$ 224,571
Short-term investments	43,845	31,933
Receivable from collaboration partner	2,565	1,013
Prepaid expenses and other current assets	2,566	1,876
Total current assets	384,255	259,393
Property and equipment, net	4,905	3,147
Long-term investments	32,506	19,900
Restricted cash and other	2,312	368
Total assets	$ 423,978	$ 282,808
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 2,454	$ 2,301
Accrued liabilities	18,790	11,639
Prepayment from collaboration partner	10,943	4,432
Deferred revenue	12,400	33,558
Total current liabilities	44,587	51,930
Other long-term liabilities	54	202
Total liabilities	44,641	52,132
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 and 150,000,000 shares authorized at September 30, 2018 and December 31, 2017, respectively; 40,240,530 and 35,812,791 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	4	4
Additional paid-in capital	566,432	365,719
Accumulated other comprehensive loss	(222)	(192)
Accumulated deficit	(186,877)	(134,855)
Total stockholders' equity	379,337	230,676
Total liabilities and stockholders' equity	$ 423,978	$ 282,808

MYOKARDIA, INC.
Condensed Consolidated Statement of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017 (As Revised)	2018	2017 (As Revised)
Collaboration and license revenue	$ 9,188	$ 3,077	$ 21,158	$ 8,488
Operating expenses:				
Research and development	15,910	14,361	49,746	39,967
General and administrative	10,957	5,884	27,182	16,442
Total operating expenses	26,867	20,245	76,928	56,409
Loss from operations	(17,679)	(17,168)	(55,770)	(47,921)
Interest and other income, net	1,890	447	3,748	977
Net loss	(15,789)	(16,721)	(52,022)	(46,944)
Other comprehensive gain (loss)	37	2	(30)	60
Comprehensive loss	(15,752)	(16,719)	(52,052)	(46,884)
Net loss attributable to common stockholders	$ (15,789)	$ (16,721)	$ (52,022)	$ (46,944)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.39)	$ (0.50)	$ (1.38)	$ (1.47)
Weighted average number of shares used to compute net loss per share attributable to common stockholders, basic and diluted	40,116,644	33,525,567	37,765,631	31,951,631

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