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): May 9, 2019

Calithera Biosciences, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-36644**	**27-2366329**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

343 Oyster Point Blvd. Suite 200 **South San Francisco, California**	**94080**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 870-1000

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. ☒

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, 0.0001 par value	**CALA**	**The Nasdaq Global Select Market**

Item 2.02. Results of Operations and Financial Condition.

On May 9, 2019, Calithera Biosciences, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2019. A copy of this press release is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on 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 (the "Exchange Act"), or otherwise subject to the liability 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, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits.*

Exhibit No.	Description
99.1	Press Release, dated May 9, 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.

Calithera Biosciences, Inc.

Dated: May 9, 2019

By: /s/ Susan M. Molineaux
Susan M. Molineaux
President and Chief Executive Officer

Exhibit 99.1

Calithera Biosciences Reports First Quarter 2019 Financial Results and Recent Highlights

—Calithera to Provide Corporate Update via Conference Call and Webcast at
2:00 p.m. PT on May 9, 2019—

SOUTH SAN FRANCISCO, Calif., May 9, 2019 (GLOBE NEWSWIRE) – Calithera Biosciences, Inc. (Nasdaq: CALA), a clinical-stage biopharmaceutical company pioneering the discovery and development of targeted therapies that disrupt cellular metabolic pathways, announced today its financial results for the first quarter ended March 31, 2019. As of March 31, 2019, cash equivalents and investments totaled $117.0 million.

"This year we expect to achieve multiple, key milestones in our clinical development program and several data readouts, including top-line results of the ENTRATA trial mid-year, and with our partner Incyte, data from the INCB001158 program in the second half of the year," said Susan Molineaux, PhD, president and chief executive officer of Calithera. "In the first quarter, we've also made great strides in our earlier stage programs, moving our cystic fibrosis program into the clinic and presenting preclinical data on our CD73 inhibitor, which is poised to enter the clinic by year end."

First Quarter 2019 and Recent Highlights

- **Completed enrollment of the Phase 2 renal cell carcinoma ENTRATA trial.** The ENTRATA trial (NCT03163667) is a Phase 2 randomized, double blind trial designed to evaluate the safety and efficacy of telaglenastat in combination with everolimus versus placebo with everolimus in patients with advanced clear cell RCC who have been treated with at least two prior lines of systemic therapy, including at least one prior VEGFR-targeted tyrosine kinase inhibitor. The trial enrolled 69 patients at multiple centers in the United States. The primary endpoint of ENTRATA is progression-free survival (PFS). Calithera plans to report top-line results including key efficacy and safety data in mid-2019.
- **Initiated Phase 1/2 clinical trial of telaglenastat (CB-839) in combination with talazoparib for solid tumors.** The Phase 1/2 clinical trial is evaluating telaglenastat in combination with Pfizer's PARP inhibitor talazoparib in patients with solid tumors. Calithera expects to initiate an additional trial of the combination of telaglenastat plus the CDK4/6 inhibitor palbociclib in patients with KRAS-mutated colorectal cancer and KRAS-mutated non-small cell lung cancer in the second quarter of 2019.
- **Initiated Phase 1 trial of arginase inhibitor CB-280 for the treatment of cystic fibrosis.** Arginase is believed to be critical in the pathology of cystic fibrosis. It impairs production of nitric oxide and generates metabolites of arginine that may impair lung function. CB-280 is an orally administered small molecule inhibitor of arginase. The first-in-human Phase 1 trial initiated in February 2019 will evaluate the safety, tolerability and pharmacokinetic profile of oral CB-280 in healthy volunteers.
- **Presented preclinical data for CB-708 at AACR Annual Meeting 2019**. The preclinical data presented at the 2019 American Association for Cancer Research (AACR) Annual Meeting demonstrate that CB-708 is a potent and selective inhibitor of CD73 that has immune-mediated, single-agent activity in syngeneic mouse tumor models. In the pre-clinical studies presented, CB-708 was well-tolerated and shows enhanced anti-tumor activity in combination with checkpoint inhibitors as well as chemotherapy. Calithera anticipates that CB-708 will enter clinical trials in 2019.

Selected First Quarter 2019 Financial Results

Cash, cash equivalents and investments totaled $117.0 million at March 31, 2019.

Research and development expenses were $20.2 million for the three months ended March 31, 2019, compared with $15.5 million for the same period in the prior year. The increase of $4.7 million was primarily due to a $2.3 million increase in the telaglenastat program, including our Phase 2 CANTATA trial, an increase of $1.1 million in the INCB001158 program, an increase of $1.0 million in the CB-280 program, as well as investment in early stage research.

General and administrative expenses were $4.2 million for the three months ended March 31, 2019, compared with $3.5 million for the same period in the prior year. The increase of $0.7 million was related to higher personnel-related costs and professional services costs.

Net loss for the three months ended March 31, 2019 was $23.7 million, or $0.61 per share.

Conference Call Information

Calithera will host an update conference call today, Thursday, May 9 at 5:00 p.m. Eastern Time/2:00 p.m. Pacific Time. The call may be accessed by dialing (855) 783-2599 (domestic) or (631) 485-4877 and referring to conference ID 1182244. To access the live audio webcast or the subsequent archived recording, visit the Investors section of the Calithera website at www.calithera.com. The webcast will be recorded and available for replay on Calithera's website for 30 days.

About Calithera

Calithera Biosciences is a clinical-stage biopharmaceutical company pioneering the discovery and development of targeted therapies that disrupt cellular metabolic pathways to preferentially starve tumor cells and enhance immune-cell activity. Driven by a commitment to rigorous science and a passion for improving the lives of people impacted by cancer and other life-threatening diseases, Calithera is advancing a pipeline of first-in-clinic, oral therapeutics to meaningfully expand treatment options available to patients. Calithera is headquartered in South San Francisco, California. For more information about Calithera, please visit www.calithera.com.

Forward Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "anticipate," "estimate," "intend," "poised" and similar expressions (as well as other words or expressions referencing future events, conditions, or circumstances) are intended to identify forward-looking statements. These statements include those related to Calithera's clinical trials, the clinical and commercial potential of its product candidates, Calithera's plans to report data from its Phase 2 ENTRATA trial in 2019; the trial design and enrollment of patients in the ENTRATA and CANTATA trials; Calithera's plan to initiate additional clinical trials of CB-839 in collaboration with Pfizer; and the timing that CB-708 will enter clinical trials in 2019. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. The potential product candidates that Calithera develops may not progress through clinical development or receive required regulatory approvals within expected timelines or at all. In addition, clinical trials may not confirm any safety, potency or other product characteristics described or assumed in this press release. Such product candidates may not be beneficial to patients or successfully commercialized. The failure to meet expectations with respect to any of the foregoing matters may have a negative effect on Calithera's stock price. Additional information concerning these and other risk factors affecting Calithera's business can be found in Calithera's periodic filings with the Securities and Exchange Commission at www.sec.gov. These forward-looking statements are not guarantees of future performance and speak only as of the date hereof, and, except as required by law, Calithera disclaims any obligation to update these forward-looking statements to reflect future events or circumstances.

SOURCE: Calithera Biosciences, Inc.

Calithera Biosciences, Inc.
Selected Consolidated Statements of Operations Financial Data
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended March 31,	
	2019	**2018**
Revenue:		
Collaboration revenue	$ —	$ 5,189
Total revenue	—	5,189
Operating expenses:		
Research and development	20,239	15,493
General and administrative	4,164	3,508
Total operating expenses	24,403	19,001
Loss from operations	(24,403)	(13,812)
Interest income, net	716	606
Net loss	$(23,687)	$(13,206)
Net loss per share, basic and diluted	$ (0.61)	$ (0.37)
Weighted average common shares used to compute net loss per share, basic and diluted	38,866	35,779

Calithera Biosciences, Inc.
Selected Consolidated Balance Sheet Financial Data
(in thousands)
(unaudited)

	March 31, 2019	**December 31, 2018**
Balance Sheet Data:		
Cash, cash equivalents and investments	$ 116,999	$ 136,153
Working capital	103,254	125,371
Total assets	131,906	142,725
Total liabilities	25,932	16,011
Accumulated deficit	(219,928)	(196,170)
Total stockholders' equity	105,974	126,714

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