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): March 7, 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. ☒

Item 2.02. Results of Operations and Financial Condition.

On March 7, 2019, Calithera Biosciences, Inc. issued a press release announcing its financial results for the quarter ended December 31, 2018. 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 March 7, 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: March 7, 2019

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

Exhibit 99.1

Calithera Biosciences Reports

Fourth Quarter 2018 Financial Results and Recent Highlights

-Calithera to Provide Corporate Update via Conference Call and Webcast at 1:30 p.m. PT on March 7, 2019

SOUTH SAN FRANCISCO, Calif., March 7, 2019 (GLOBE NEWSWIRE) — Calithera Biosciences, Inc. (Nasdaq: CALA), a clinical stage biotechnology company focused on discovering and developing novel small molecule drugs for the treatment of cancer and other life-threatening diseases, announced today its financial results for the fourth quarter and year ended December 31, 2018. As of December 31, 2018, cash, cash equivalents and investments totaled $136.2 million.

"This is a time of significant progress for Calithera's clinical development program as we continue to advance our novel onco-metabolism clinical candidates through robust clinical studies," said Susan M. Molineaux, PhD, president and chief executive officer of Calithera. "In the fourth quarter, we broadened development of the novel glutaminase inhibitor telaglenastat through two new clinical trial collaborations with Pfizer. We recently completed enrollment of the ENTRATA trial of telaglenastat for the treatment of patients with renal cell carcinoma. We anticipate that this momentum will continue in 2019 with data from the ENTRATA trial and, with our partner Incyte, data from the INCB001158 program, both expected in the second half of the year."

Fourth Quarter 2018 and Recent Highlights

- **Completed patient enrollment in the randomized phase 2 ENTRATA trial of telaglenastat (CB-839) and everolimus in renal cell carcinoma (RCC).** 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 a 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 efficacy and safety data from the trial in the second half of 2019.
- **Announced two new clinical trial collaborations to evaluate Pfizer's CDK4/6 inhibitor palbociclib, also known as IBRANCE®, and the dual-mechanism poly (ADP-ribose) polymerase (PARP) inhibitor talazoparib also known as TALZENNA®, each in combination with Calithera's glutaminase inhibitor telaglenastat**. Preclinical data suggest that telaglenastat synergizes with PARP inhibitors to impair DNA synthesis, enhance DNA damage, and block cancer cell proliferation. Calithera will initiate a Phase 1/2 clinical trial of the combination of telaglenastat plus talazoparib in patients with RCC and TNBC in the first quarter of 2019. Telaglenastat also synergizes with CDK4/6 inhibitors by enhancing cell cycle arrest and blocking cancer cell proliferation. Calithera will initiate a Phase 1/2 clinical trial of the combination of telaglenastat plus palbociclib in patients with KRAS-mutated colorectal cancer (CRC) and patients with KRAS-mutated non-small cell lung cancer (NSCLC) in the second quarter of 2019.
- **Advanced INCB001158 arginase inhibitor immuno-oncology program.** INCB001158 is being evaluated in multiple clinical trials for the treatment of patients with cancer both as a monotherapy, and in combination with immunotherapies and chemotherapy. INCB001158 is being developed as part of a collaboration and license agreement with Incyte. Data from the INCB001158 program are expected to be presented at a medical meeting in the second half 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. The study will be conducted under a United States Food and Drug Administration (FDA) Investigational New Drug (IND) application.

- **Initiated IND-enabling studies with CB-708, an oral small molecule CD73 inhibitor.** The immuno-oncology target CD73 is an enzyme that plays a critical role in the process of ATP conversion to adenosine. Initiation of a Phase 1 study of CB-708, an orally administered small molecule inhibitor of CD73, is planned for 2019. A preclinical abstract describing CB-708 has been accepted for presentation at the 2019 American Association for Cancer Research annual meeting in March.

Selected Fourth Quarter 2018 Financial Results

Cash, cash equivalents and investments totaled $136.2 million at December 31, 2018.

Collaboration revenue for the full year 2018 was $22.2 million, compared with $26.0 million in the prior year. In June 2018, we completed the manufacturing services and technology transfer under our collaboration and license agreement with Incyte, which satisfied the performance obligation under ASC 606, and as a result, all remaining deferred revenue was recognized.

Research and development expenses for the full year 2018 were $66.2 million, compared with $43.1 million in the prior year. The increase of $23.1 million was due to an increase in the telaglenastat program to support our new and ongoing clinical trials, including for our Phase 2 CANTATA trial which opened in 2018, increases in the INCB001158 and CB-280 programs, as well as investment in early stage research. Research and development expenses for the fourth quarter of 2018 were $17.0 million, compared to $15.5 million for the same period last year.

General and administrative expenses for the full year 2018 were $13.3 million, compared with $12.5 million in the prior year. The increase of $0.8 million in 2018 was primarily due to higher personnel-related costs to support our clinical trials, offset partially by lower outside professional services, including activities related to our Incyte collaboration and license agreement and sublease in 2017. General and administrative expenses for the fourth quarter of 2018 were $3.2 million, compared to $3.3 million for the same period last year.

Interest Income, net for the full year 2018 was $2.7 million, compared with $1.9 million in the prior year. The increase of $0.8 million related to higher returns on our investments, partially offset by lower cash equivalents and investment balances. Interest income, net for the fourth quarter of 2018 was $0.7 million, compared to $0.6 million for the same period last year.

Net loss from operations for the three months and year ended December 31, 2018 was $19.5 million and $54.6 million, respectively.

Conference Call Information

Calithera will host an update conference call today, Thursday, March 7th at 4:30 p.m. Eastern Time/ 1:30 p.m. Pacific Time. The call may be accessed by dialing (855) 783-2599 (domestic) or (631) 485-4877 (international), and referring to conference ID 9577446. 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 is a clinical-stage biopharmaceutical company focused on fighting cancer by discovering, developing, and commercializing novel small molecule drugs that target tumor and immune cell metabolism. 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 the timing of Calithera's clinical trials, the safety, tolerability and efficacy of CB-839, INCB001158, CB-280 and CB-708 and the overall advancement in clinical trials, Calithera's collaborations with Incyte and Pfizer, Calithera's ability to fund its clinical programs, and Calithera's receipt of clinical data from its clinical trials. 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.

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
Revenue:				
Collaboration revenue	$ —	$ 7,254	$ 22,254	$ 25,955
Total revenue	—	7,254	22,254	25,955
Operating expenses:				
Research and development	16,977	15,496	66,195	43,111
General and administrative	3,247	3,300	13,340	12,530
Total operating expenses	20,224	18,796	79,535	55,641
Loss from operations	(20,224)	(11,542)	(57,281)	(29,686)
Interest income, net	725	568	2,652	1,860
Net loss	$(19,499)	$(10,974)	$(54,629)	$(27,826)
Net loss per share, basic and diluted	$ (0.51)	$ (0.31)	$ (1.49)	$ (0.84)
Weighted average common shares used to compute net loss per share, basic and diluted	38,333	35,560	36,604	32,951

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

	December 31, 2018	December 31, 2017
Balance Sheet Data:		
Cash, cash equivalents and investments	$ 136,153	$ 186,154
Working capital	125,371	128,640
Total assets	142,725	192,455
Deferred revenue	—	31,045
Total liabilities	16,011	42,148
Accumulated deficit	(196,170)	(150,333)
Total stockholders' equity	126,714	150,307

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