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 12, 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))

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**

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 12, 2019, Calithera Biosciences, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2019. A copy of this press release is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form8-K, the information in this Current Report on Form8-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 November 12, 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: November 12, 2019

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

Exhibit 99.1

Calithera Biosciences Reports Third Quarter 2019 Financial Results and Recent Highlights

—Calithera to Provide Corporate Update via Conference Call and Webcast at
2:00 p.m. PT on November 12, 2019—

SOUTH SAN FRANCISCO, Calif., November 12, 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 third quarter ended September 30, 2019. As of September 30, 2019, cash equivalents and investments totaled $133.6 million.

“This was a productive quarter for Calithera, during which we achieved multiple, key milestones in our clinical and pipeline programs,” said Susan Molineaux, PhD, president and chief executive officer of Calithera. “This includes completing enrollment in our registrational CANTATA trial evaluating telaglenastat for the treatment of patients with renal cell carcinoma, and presenting new data on several programs at both the ESMO and SITC annual meetings. In addition, we successfully completed a Phase 1 trial in healthy volunteers of CB-280, an oral arginase inhibitor for the treatment of cystic fibrosis.”

Third Quarter 2019 and Recent Highlights

- **Completed patient enrollment of randomized CANTATA trial of telaglenastat with cabozantinib in advanced renal cell carcinoma.** The CANATA trial is a global, randomized, double-blind clinical trial of telaglenastat combined with cabozantinib, in patients with advanced or metastatic renal cell carcinoma who have received one or two prior treatments. The CANTATA trial enrolled 445 patients at multiple centers globally. The primary endpoint is progression-free survival. Calithera plans to report top-line efficacy and safety data from the trial in the second half of 2020.
- **Presented results of Phase 2 ENTRATA study of telaglenastat(CB-839) with everolimus in renal cell carcinoma at the ESMO 2019 Congress.** The ENTRATA trial (NCT03163667) was 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 was progression-free survival (PFS). Telaglenastat, when added to everolimus, doubled the median PFS in heavily pretreated patients with advanced RCC to 3.8 months as compared to 1.9 months for everolimus alone, and reduced the risk of disease progression or death by 36% (HR=0.64, p=0.079 one-sided). The primary endpoint of the trial was PFS per investigator assessment with a predetermined threshold of $p \leq 0.2$ one-sided. The secondary endpoint of overall survival is not yet mature.
- **Initiated Phase 1/2 clinical trial of telaglenastat in combination with palbociclib for solid tumors.** The Phase 1/2 clinical trial is evaluating telaglenastat in combination with Pfizer’s CDK4/6 inhibitor palbociclib, also known as Ibrance®. The study will evaluate the safety and anti-tumor activity of telaglenastat plus palbociclib in patients with KRAS-mutated colorectal cancer (CRC) and KRAS-mutated non-small cell lung cancer (NSCLC).
- **Presented new INCB001158 data at the ESMO 2019 Congress.**Calithera and Incyte are collaborating to conduct this Phase 1 study evaluating INCB001158 as monotherapy and in combination with the PD-1 inhibitor pembrolizumab in checkpoint inhibitor refractory and naïve advanced/metastatic solid tumors. Responses were observed in patients with microsatellite stable (MSS) colorectal cancer, a disease not historically sensitive to checkpoint inhibition.

- **Completed a Phase 1 clinical trial of CB-280 in healthy volunteers**. The first-in-human Phase 1 trial evaluated the safety, tolerability and pharmacokinetic profile of oral CB-280 in healthy volunteers. A phase 1b clinical study in cystic fibrosis patients is expected to start enrollment in the first half of 2020.
- **Presented new preclinical data for IL4I1 and CD73 programs at the SITC Annual Meeting.**CB-708 is a selective, oral inhibitor of CD73, an enzyme that synthesizes the immunosuppressive agent adenosine and is over-expressed in multiple tumor types. By blocking adenosine production in the tumor, CB-708 is designed to enhance T-cell activation, leading to anti-tumor activity. Interleukin 4 (IL-4)-Induced Gene 1 (IL4I1) is an enzyme that is primarily expressed by tumor cells and antigen presenting cells, and produces hydrogen peroxide, an inhibitor of T-cell function. IL4I1 has a potential role in immune evasion, and inhibition may enhance an effective anti-tumor immune response. Calithera announced the IL4I1 inhibitor program this quarter.

Selected Third Quarter 2019 Financial Results

Cash, cash equivalents and investments totaled $133.6 million at September 30, 2019.

Research and development expenses were $17.2 million for the three months ended September 30, 2019, compared with $16.4 million for the same period in the prior year. The increase of $0.8 million was primarily due to a $0.7 million increase in the telaglenastat program, including for the CANTATA trial, an increase of $0.4 million in the INCB001158 program, and an increase of $0.5 million in our early-stage research programs, partially offset by a decrease of $0.8 million in our CB-280 program.

General and administrative expenses were $3.9 million for the three months ended September 30, 2019, compared with $3.1 million for the same period in the prior year. The increase of $0.8 million primarily related to higher professional services costs and personnel-related costs.

Net loss for the three months ended September 30, 2019 was $20.3 million, or $0.38 per share.

Conference Call Information

Calithera will host an update conference call today, Tuesday, November 12, 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 6499000. 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 block 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; the receipt of top-line efficacy and safety data in the CANTATA trial; the safety and anti-tumor activity of telaglenastat plus palbociclib; the timing that CB-280 will enter clinical trials; and the role of IL4I1 and CD73. 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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue:				
Collaboration revenue	$ —	$ —	$ —	$ 22,254
Total revenue	—	—	—	22,254
Operating expenses:				
Research and development	17,221	16,420	58,388	49,218
General and administrative	3,906	3,087	12,054	10,093
Total operating expenses	21,127	19,507	70,442	59,311
Loss from operations	(21,127)	(19,507)	(70,442)	(37,057)
Interest and other income, net	834	658	2,310	1,927
Net loss	$(20,293)	$(18,849)	$(68,132)	$(35,130)
Net loss per share, basic and diluted	$ (0.38)	$ (0.52)	$ (1.52)	$ (0.98)
Weighted average common shares used to compute net loss per share, basic and diluted	53,775	36,405	44,703	36,021

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

	September 30, 2019	December 31, 2018
Balance Sheet Data:		
Cash, cash equivalents and investments	$ 133,594	$ 136,153
Working capital	118,293	125,371
Total assets	146,319	142,725
Total liabilities	25,660	16,011
Accumulated deficit	(264,373)	(196,170)
Total stockholders' equity	120,659	126,714

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CONTACT:
Jennifer McNealey
ir@Calithera.com
650-870-1071