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 6, 2021

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 May 6, 2021, Calithera Biosciences, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2021. 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 6, 2021
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL document)

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 6, 2021

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

Calithera Biosciences Reports First Quarter 2021 Financial Results and Recent Highlights

–$102.9 Million in Cash and Investments at March 31, 2021–

– Conference Call and Webcast Scheduled for
2:00 p.m. PT on May 6, 2021–

SOUTH SAN FRANCISCO, Calif., May 6, 2021 (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 first quarter ended March 31, 2021.

“In the first quarter, we continued to enroll patients in each of our two key clinical development programs. These include the randomized KEAPSAKE trial evaluating telaglenastat in combination with standard-of-care chemoimmunotherapy for non-small cell lung cancer patients with KEAP1/NRF2 genetic mutations and the Phase 1b clinical trial evaluating CB-280 for the treatment of cystic fibrosis,” said Susan Molineaux, PhD, president and chief executive officer of Calithera. “We look forward to maintaining our focus on these key programs and plan to release interim data from CB-280 in cystic fibrosis in the second half, and from KEAPSAKE in the fourth quarter of this year”.

First Quarter 2021 and Recent Highlights

- **Continued enrollment of the Phase 2 randomized KEAPSAKE trial in non-small cell lung cancer (NSCLC) patients with genetic mutation KEAP1/NRF2.** The double-blind KEAPSAKE trial will enroll approximately 120 patients with stage IV non-squamous NSCLC with tumors that have the KEAP1 or NRF2 mutation. Patients will be randomized to receive telaglenastat or placebo, in combination with pembrolizumab, carboplatin and pemetrexed. The study will evaluate the safety and investigator-assessed progression-free survival (PFS) of telaglenastat plus this standard-of-care chemoimmunotherapy regimen. Calithera anticipates releasing interim data from the KEAPSAKE trial in the fourth quarter of 2021.
- **Ongoing enrollment of the Phase 1b clinical trial of CB-280 in patients with cystic fibrosis (CF)**. CB-280 is an oral inhibitor of arginase, an enzyme that depletes the amino acid arginine. The randomized, double blind, placebo-controlled, dose escalation trial is evaluating multiple ascending doses of CB-280, dosed orally twice daily for 14 days, compared to placebo in up to 32 adult CF patients to determine a safe dose range for CB-280. In October 2020, Calithera was awarded up to $2.4 million from the Cystic Fibrosis Foundation to support clinical development of CB-280. Enrollment in the Phase 1b study is ongoing and Calithera expects to announce data from this study in the second half of 2021.
- **Final results of the CANTATA trial to be presented at the American Society of Clinical Oncology (ASCO) 2021 Annual Meeting.** The Phase 2 CANTATA trial is a global, randomized, double-blind clinical trial of telaglenastat combined with cabozantinib, in patients with advanced or metastatic RCC who have received one or two prior treatments. On January 4, 2021, Calithera announced topline results from the CANTATA clinical study and reported the trial did not meet the primary endpoint of improving PFS in the study population. Data will be presented at the American Society of Clinical Oncology Annual Meeting on June 7, 2021.

Selected First Quarter 2021 Financial Results

Cash, cash equivalents and investments totaled $102.9 million at March 31, 2021.

Research and development expenses for the first quarter 2021 were $15.3 million, compared to $20.1 million in the same period prior year. The decrease of $4.8 million was primarily due to a $3.3 million decrease in expenses associated with the telaglenastat program, a $1.6 million decrease in the INCB001158 program and a $0.2 million decrease in our early stage research programs, partially offset by an increase of $0.3 million in the CB-280 program.

General and administrative expenses for the first quarter 2021 were $5.4 million, compared to $4.9 million in the same period prior year. The increase of $0.5 million was primarily related to a $0.9 million increase in personnel-related costs, partially offset by a $0.4 million decrease in professional services costs.

Interest and other income, net for the first quarter 2021 was $0.4 million, compared to $0.6 million in the same period prior year.

Net loss for the three months ended March 31, 2021 was $20.4 million.

Conference Call Information

Calithera will host an update conference call today, Thursday, May 6, 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 (international) and referring to conference ID 6250035. 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 timing of enrollment of the KEAPSAKE and CB-280 Ph1b 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 be 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,	
	2021	**2020**
Operating expenses:		
Research and development	$ 15,339	$ 20,125
General and administrative	5,428	4,946
Total operating expenses	20,767	25,071
Loss from operations	(20,767)	(25,071)
Interest and other income, net	372	625
Net loss	$(20,395)	$(24,446)
Net loss per share, basic and diluted	$ (0.28)	$ (0.38)
Weighted-average common shares used to compute net loss per share, basic and diluted	72,247	64,556

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

	March 31, 2021	**December 31, 2020**
Balance Sheet Data:		
Cash, cash equivalents and investments	$ 102,851	$ 115,151
Working capital	92,717	100,302
Total assets	110,657	125,587
Total liabilities	16,499	23,216
Accumulated deficit	(396,633)	(376,238)
Total stockholders' equity	94,158	102,371

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