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 10, 2022

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** **(Address of principal executive offices)**	**94080** **(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 May 10, 2022, Calithera Biosciences, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2022. 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 10, 2022
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 10, 2022

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

Calithera Biosciences Reports First Quarter 2022 Financial Results and Recent Highlights

— Conference Call and Webcast Scheduled for 2:00 p.m. PT / 5:00 p.m. ET on Tuesday, May 10, 2022 —

SOUTH SAN FRANCISCO, Calif., May 10, 2022 (GLOBE NEWSWIRE) – Calithera Biosciences, Inc. (Nasdaq: CALA), a clinical-stage, precision-oncology biopharmaceutical company, today announced its financial results for the first quarter ended March 31, 2022.

“We made significant headway in the transfer of mivavotinib and sapanisertib materials to Calithera during the first quarter and are well into site start-up activities. We are on track to begin enrolling patients in both mivavotinib and sapanisertib trials in the second quarter of 2022 and expect to share data from these studies by the first quarter of 2023,” said Susan Molineaux, PhD, president and chief executive officer of Calithera. “We are also excited about our preclinical synthetic lethality program, having presented the first data from our internally-discovered, first-of-their-kind VPS4A inhibitors at the AACR Annual Meeting. This year has shaped up to be an exciting one for Calithera, given the potential we see in both our clinical and preclinical programs.”

First Quarter 2022 and Recent Highlights

- **Mivavotinib (SYK inhibitor):** Based on clinical data showing enhanced activity of mivavotinib in activated B-cell-like (ABC) diffuse large B-cell lymphoma (DLBCL) and preclinical data demonstrating enhanced SYK activity and inhibition in DLBCL with MyD88/CD79 mutations, Calithera designed a phase 2 trial of mivavotinib in relapsed or refractory non-GCB (ABC) DLBCL with enrichment of MYD88/CD79b-mutated tumors using liquid next-generation sequencing (NGS) testing. The phase 2a portion of the study will confirm activity in the biomarker-defined subsets and further refine dose and schedule. The trial will enroll non-GCB (ABC) DLBCL patients based on Hans algorithm, and researchers will collect MyD88 and CD79 mutation status using ctDNA-based liquid NGS to accrue a pre-specified number of patients harboring MyD88 or CD79b mutations. Approximately 50% of all ABC DLBCL tumors have one or both of these mutations. Calithera anticipates the first patient enrolled in the second quarter of 2022. Data generated from this study could position the company to initiate a study with registrational intent in biomarker-specific populations in DLBCL.
- **Sapanisertib (Dual mTORC 1/2 inhibitor):** In a recent investigator-led study, sapanisertib demonstrated durable single-agent activity in patients with heavily pretreated NRF2 (NFE2L2)-mutated squamous non-small cell lung cancer (NSCLC). These mutations occur in approximately 15% of patients with squamous NSCLC. Calithera is initiating a phase 2 study intended to strengthen the existing data in patients with NRF2-mutated squamous NSCLC and evaluate its activity in NRF2 wildtype (WT) squamous NSCLC. Sapanisertib has the potential to be a first-in-class treatment for individuals with NRF2-mutated squamous NSCLC, a patient population with poorer prognosis, unmet clinical need, and no targeted therapies. Sapanisertib could also be a possible treatment for other NRF2-mutated cancers beyond NSCLC. Calithera anticipates the first patient enrolled in this study in the second quarter of 2022.
- **Presented data on its novel series of VPS4A inhibitors.** Calithera presented the first data from its preclinical synthetic lethality pipeline at the American Association for Cancer Research (AACR) 2022 Annual Meeting. The presented poster detailed Calithera’s discovery of a novel series of VPS4A (vacuolar protein sorting-associated protein 4A) inhibitors that are currently advancing through lead optimization. These data validate the synthetic lethal interaction between the gene paralogs VPS4A and VPS4B, and we believe, provide the first preclinical evidence supporting a newly discovered series of compounds designed to target these proteins for cancer treatment. To our knowledge, these are the first active, on-target VPS4 inhibitors described to date.
- **Closed a $10.0 Million Underwritten Public Offering of Common Stock and Warrants to Purchase Common Stock.** On April 1, 2022, Calithera closed an underwritten public offering of 18,518,519 shares of

its common stock at a combined price to the public of $0.54 per share and accompanying warrants. Each share of common stock is accompanied by a warrant to purchase one share of common stock at an exercise price of $0.54 per share, which is immediately exercisable and will expire 18 months from the date of issuance, or a short-term warrant, and a warrant to purchase one share of common stock at an exercise price of $0.54 per share, which is immediately exercisable and will expire 5 years from the date of issuance, or a long-term warrant. Calithera received gross proceeds of $10.0 million, resulting in $8.5 million of net proceeds after deducting underwriting discounts and commissions and offering expenses.

Selected First Quarter 2022 Financial Results

Cash and cash equivalents totaled $44.7 million at March 31, 2022, which Calithera expects, together with proceeds from its public offering, will be sufficient to meet its operating plan through the second quarter of 2023.

Research and development expenses for the first quarter 2022 were $9.6 million, compared to $15.3 million in the same period prior year. The decrease of $5.8 million was primarily due to a decrease in the telaglenastat program, partially offset by increases in the sapanisertib and mivavotinib programs.

General and administrative expenses for the first quarter 2022 were $4.3 million, compared to $5.4 million in the same period prior year. The decrease of $1.2 million was primarily due to decreases in personnel-related costs.

Net loss for the three months ended March 31, 2022 was $13.8 million.

Conference Call Information

Calithera will host an update conference call today, Tuesday, May 10, at 2:00 p.m. Pacific Time/5:00 p.m. Eastern Time. The call may be accessed by dialing (855) 783-2599 (domestic) or (631) 485-4877 (international) and referring to conference ID 4979639. 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, precision oncology biopharmaceutical company developing targeted therapies to redefine treatment for biomarker-specific patient populations. 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 robust pipeline of investigational, small-molecule oncology compounds with a biomarker-driven approach that targets genetic vulnerabilities in cancer cells to deliver new therapies for patients suffering from aggressive hematologic and solid tumor cancers for which there are currently limited treatment options.

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 safety, tolerability and efficacy of Calithera's product candidates, the overall advancement of Calithera's product candidates in preclinical development and clinical trials, including Calithera's plan to initiate two phase 2 clinical trials for mivavotinib and sapanisertib and plan to share data from these trials by the first quarter 2023, Calithera's ability to potentially initiate registrational studies in biomarker-specific populations in DLBC and relapsed or refractory squamous NSCLC, the unmet need in the treatment of patients with advanced disease, and management's expectation that Calithera's cash and cash equivalents will be sufficient to meet its operating plan through the second quarter of 2023. 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.

Calithera Biosciences, Inc.

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

	Three Months Ended March 31,	
	2022	2021
Operating expenses:		
Research and development	9,566	15,339
General and administrative	4,260	5,428
Total operating expenses	13,826	20,767
Loss from operations	(13,826)	(20,767)
Interest and other income (expense), net	(9)	372
Net loss	$(13,835)	$(20,395)
Net loss per share, basic and diluted	$ (0.18)	$ (0.28)
Weighted average common shares used to compute net loss per share, basic and diluted	78,468	72,247

Calithera Biosciences, Inc.

Selected Consolidated Balance Sheet Financial Data
(in thousands)
(unaudited)

	March 31, 2022	December 31, 2021
Balance Sheet Data:		
Cash and cash equivalents	$ 44,664	$ 59,537
Working capital	35,894	47,446
Total assets	50,236	64,756
Total liabilities	12,670	15,672
Convertible preferred stock	40,702	40,702
Accumulated deficit	(505,161)	(491,326)
Total stockholders' (deficit) equity	(3,136)	8,382

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