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 9, 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))

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 9, 2021, Calithera Biosciences, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 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 November 9, 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: November 9, 2021

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

Calithera Biosciences Reports Third Quarter 2021 Financial Results and Recent Highlights

— Company strengthened precision oncology clinical pipeline through acquisition of mTORC 1/2 inhibitor sapanisertib and SYK inhibitor mivavotinib from Takeda Pharmaceuticals —

— Cash, cash equivalents and investments totaled $84.5 million as of September 30, 2021 —

— Conference call and webcast scheduled for 2:00 p.m. PT on November 9, 2021—

SOUTH SAN FRANCISCO, Calif., November 9, 2021 (GLOBE NEWSWIRE) – Calithera Biosciences, Inc. (Nasdaq: CALA), a clinical-stage, precision oncology biopharmaceutical company, today announced its financial results for the third quarter ended September 30, 2021.

“The last month has been one of significant change for Calithera, following the acquisition of two clinical-stage investigational therapies, sapanisertib and mivavotinib, and the presentation of interim data from our cystic fibrosis program for CB-280 that supports our approach to the treatment of CF via this mechanism,” said Susan Molineaux, PhD, president and chief executive officer of Calithera. “During this quarter, we also announced the disappointing news of the discontinuation of the telaglenastat program based on an interim analysis of the KEAPSAKE trial. Finally, we announced the promotion of Emil Kuriakose to chief medical officer and the strengthening of our board of directors with the addition of Calithera’s former chief medical officer, Keith Orford.

“We move into the end of 2021 with a keen focus on biomarker-defined cancer patient populations and remain committed to our pursuit of developing medicines to improve outcomes for people with diseases of high unmet need. Our near-term clinical development plans include leveraging our clinical and biomarker expertise in the KEAP1/NRF2 pathway by developing our mTORC1/2 inhibitor sapanisertib in squamous non-small cell lung cancer, and advancing the development of our SYK inhibitor mivavotinib in specific biomarker-defined populations of diffuse large B-cell lymphoma. By focusing on well-characterized genetic vulnerabilities with molecules that have already shown single-agent activity, we will be able to generate phase 2 data with targeted, efficient study designs over the next 12 to 18 months.”

Third Quarter 2021 and Recent Highlights

- **Acquired clinical stage dual mTORC 1/2 inhibitor sapanisertib and SYK inhibitor mivavotinib from Takeda Pharmaceuticals.** The acquisition significantly strengthens Calithera’s precision oncology pipeline with addition of two drugs that have both demonstrated single-agent activity in the clinic, with the greatest potential in biomarker-defined cancer patient populations. Calithera plans to initiate a phase 2 study to begin in the first quarter of 2022 that will strengthen the existing data on sapanisertib as an active single-agent drug in patients with squamous non-small cell lung cancer (NSCLC) harboring a NRF2 or KEAP1 mutation. In addition, Calithera will initiate a phase 2 study of mivavotinib in the first quarter of 2022 for the treatment of patients with diffuse large B-cell lymphoma (DLBCL) with and without mutations in MyD88 and CD79. Data from these studies generated over the next 12 to 18 months could position the company to initiate registrational studies for both molecules.
- **Presented interim data from the Phase 1b clinical trial of CB-280 in patients with cystic fibrosis (CF) at North American Cystic Fibrosis Conference**. Data showed CB-280 was well-tolerated, had linear PK, and demonstrated robust dose-related PD effects. Encouraging trends were seen in disease biomarkers, including increased fractional exhaled nitric oxide (FeNO) and decreased sweat chloride. A pooled analysis of treatment vs. placebo showed a positive trend in forced expiratory volume in one second (FEV1) compared to placebo. Dose escalation is ongoing with cohort 4 (300mg BID) and on track to complete enrollment by the end of the year, with the option for an additional dose cohort to enroll in 2022 if warranted.

- **Announced discontinuation of phase 2 telaglenastat KEAPSAKE clinical trial in patients with NSCLC with genetic mutations in KEAP1/NRF2.** Interim analysis from 40 patients demonstrated lack of clinical benefit among patients treated with telaglenastat. No differences in safety profile were seen between the two arms.
- **Promoted Emil Kuriakose, MD, from vice president and head of clinical development to chief medical officer.** Dr. Kuriakose succeeds Keith Orford, MD, PhD who has resigned from his position and joined the Calithera Board of Directors.
- **Preclinical focus on synthetic lethality targets**. In addition to the company's clinical programs, Calithera continues to leverage its discovery engine to build a robust preclinical pipeline of undisclosed synthetic lethality targets with a focus on paralog genes. These will be announced as Calithera advances preclinical development.

Selected Third Quarter 2021 Financial Results

Cash, cash equivalents and investments totaled $84.5 million at September 30, 2021. Calithera expects its cash, cash equivalents and investments will be sufficient to meet its current operating plan into 2023.

Revenue was $6.8 million for the three months ended September 30, 2021, and represents the milestone payment received in September 2021 under Calithera's Incyte Collaboration Agreement.

Research and development expenses for the third quarter 2021 were $11.6 million, compared to $18.2 million in the same period prior year. The decrease of $6.6 million was primarily due to decreases in the telaglenastat and INCB001158 programs, partially offset by investments in early-stage research.

General and administrative expenses for the third quarter 2021 were $6.3 million, compared to $4.7 million in the same period prior year. The increase of $1.6 million was primarily due to increased legal expenses.

Net loss for the three months ended September 30, 2021, was $11.2 million.

Conference Call Information

Calithera will host an update conference call today, Tuesday, November 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 (international) and referring to conference ID 3797324. 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 Calithera's clinical trials, timing of enrollment of the CB-280 Ph1b, sapanisertib

Phase 2 and mivavotinib Phase 2 clinical trials, and the overall advancement of Calithera's product candidates in clinical trials and Calithera's plans to continue development of its product candidates. 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue:				
License revenue	$ 6,750	$ —	$ 9,750	$ —
Total revenue	6,750	—	9,750	—
Operating expenses:				
Research and development	11,556	18,157	39,715	53,938
General and administrative	6,344	4,744	16,259	14,786
Total operating expenses	17,900	22,901	55,974	68,724
Loss from operations	(11,150)	(22,901)	(46,224)	(68,724)
Interest and other income (expense), net	(22)	167	346	1,153
Net loss	$ (11,172)	$ (22,734)	$ (45,878)	$ (67,571)
Net loss per share, basic and diluted	$ (0.15)	$ (0.32)	$ (0.62)	$ (0.99)
Weighted average common shares used to compute net loss per share, basic and diluted	74,114	70,559	73,480	68,219

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

	September 30, 2021	December 31, 2020
Balance Sheet Data:		
Cash, cash equivalents and investments	$ 84,493	$ 115,151
Working capital	72,804	100,302
Total assets	89,971	125,587
Total liabilities	15,552	23,216
Accumulated deficit	(422,116)	(376,238)
Total stockholders' equity	74,419	102,371

###

CONTACTS:
Stephanie Wong
ir@Calithera.com
650.870.1063

INVESTORS:
Burns McClellan
Lee Roth
212.213.0006
lroth@burnsmc.com

MEDIA:
Sam Brown, Inc.
Hannah Hurdle
805.338.4752
hannahhurdle@sambrown.com