
**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 7, 2018

Calithera Biosciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36644
(Commission
File Number)

27-2366329
(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))

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 7, 2018, Calithera Biosciences, Inc. issued a press release announcing its financial results for the quarter ended September 30, 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.*

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated November 7, 2018

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.

Dated: November 7, 2018

Calithera Biosciences, Inc.

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



Calithera Biosciences Reports

Third Quarter 2018 Financial Results and Recent Highlights

-Calithera to Host Conference Call Today at 2:00 p.m. Pacific Time/ 5:00 p.m. Eastern Time

SOUTH SAN FRANCISCO, Calif., November 7, 2018 (GLOBE NEWSWIRE) — Calithera Biosciences, Inc. (Nasdaq: CALA), a clinical-stage pharmaceutical company focused on discovering and developing novel small molecule drugs directed against tumor metabolism and tumor immunology targets for the treatment of cancer, announced today its financial results for the third quarter ended September 30, 2018. As of September 30, 2018, cash, cash equivalents and investments totaled \$141.5 million.

“Calithera continues to advance the development of our novel oncometabolism clinical candidates,” said Susan Molineaux, PhD, President and Chief Executive Officer of Calithera. “In this quarter we broadened the development of the novel glutaminase inhibitor CB-839 with two new clinical trial collaborations with Pfizer. We are actively enrolling CANTATA and ENTRATA, two randomized trials of CB-839 for the treatment of patients with renal cell carcinoma, with data from the ENTRATA trial expected in 2019. In addition, we and our partner Incyte expect data on INCB001158 to be presented at a medical meeting in the first half of 2019.”

Third Quarter 2018 and Recent Highlights

- **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 CB-839.** Calithera will initiate Phase 1/2 clinical studies in the first quarter of 2019. Preclinical data suggest that CB-839 synergizes with CDK4/6 inhibitors by enhancing cell cycle arrest and blocking cancer cell proliferation. CB-839 also synergizes preclinically with PARP inhibitors to impair DNA synthesis, enhance DNA damage, and block cancer cell proliferation.
- **Two Randomized Combination Trials of CB-839 in Combination for the Treatment of Renal Cell Carcinoma.** The ENTRATA trial, a randomized double-blind study of late line patients, will enroll approximately 66 patients to receive either CB-839 plus everolimus or everolimus alone. Topline results are expected in 2019. The CANTATA trial is a randomized, global, double-blind trial comparing patients treated with cabozantinib and CB-839 to patients treated with cabozantinib alone. Topline results are expected in 2020. The trial will enroll patients with clear cell renal cell carcinoma who have previously received one or two prior lines of therapy. The trial, originally designed to enroll 300 patients has been enlarged to approximately 400 patients. The U.S. Food and Drug Administration (FDA) has granted Fast Track designation for CB-839 in combination with cabozantinib for the treatment of this patient population. Updated Phase 1b data of CB-839 combined with cabozantinib presented in the quarter demonstrated a disease control rate of 100%, and response rate of 50% in 10 evaluable patients with clear cell RCC.
- **INCB001158 Arginase Inhibitor Immuno-oncology Program.** INCB001158 is being evaluated in multiple clinical trials for the treatment of patients with solid tumors 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 INCB001158 is expected to be presented at a medical meeting in the first half of 2019.
- **CB-280 Arginase Inhibitor 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. An investigational new drug (IND) application for CB-280 with the FDA is planned for the first half of 2019.

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- **CB-708 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. An IND application for CB-708, an orally administered small molecule inhibitor of CD73, is planned for 2019.

Selected Third Quarter 2018 Financial Results

Cash, cash equivalents and investments totaled \$141.5 million at September 30, 2018.

Research and development expenses were \$16.4 million for the three months ended September 30, 2018, compared with \$10.8 million for the same period in the prior year. The increase of \$5.6 million was due to an increase in the CB-839 program, including for the CANTATA trial which opened in 2018, an increase in the INCB001158 program, including Incyte's co-funding of development costs, an increase in the CB-280 program, as well as investment in early stage research.

General and administrative expenses were \$3.1 million for both the three months ended September 30, 2018 and 2017 due to consistent headcount and stock-based compensation expense.

Net loss from operations for the three months ended September 30, 2018 was \$18.8 million, or \$0.52 per share.

Conference Call Information

Calithera will host an update conference call today, November 7, at 2:00 p.m. Pacific Time/ 5:00 p.m. Eastern Time. The call can be accessed by dialing (855) 783-2599 (domestic) or (631) 485-4877 (international), and referring to conference ID 9368596. 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 and enrollment of Calithera's clinical trials, the clinical and commercial potential of its product candidates, Calithera's collaboration with Pfizer and Incyte, 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue:				
Collaboration revenue	\$ —	\$ 7,254	\$ 22,254	\$ 18,701
Total revenue	—	7,254	22,254	18,701
Operating expenses:				
Research and development	16,420	10,833	49,218	27,615
General and administrative	3,087	3,074	10,093	9,230
Total operating expenses	19,507	13,907	59,311	36,845
Loss from operations	(19,507)	(6,653)	(37,057)	(18,144)
Interest income, net	658	582	1,927	1,292
Net loss	<u>\$(18,849)</u>	<u>\$(6,071)</u>	<u>\$(35,130)</u>	<u>\$(16,852)</u>
Net loss per share, basic and diluted	<u>\$ (0.52)</u>	<u>\$ (0.17)</u>	<u>\$ (0.98)</u>	<u>\$ (0.53)</u>
Weighted average common shares used to compute net loss per share, basic and diluted	<u>36,405</u>	<u>35,475</u>	<u>36,021</u>	<u>32,072</u>

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

	September 30, 2018	December 31, 2017
Balance Sheet Data:		
Cash, cash equivalents and investments	\$ 141,456	\$ 186,154
Working capital	134,213	128,640
Total assets	147,674	192,455
Deferred revenue	—	31,045
Total liabilities	11,764	42,148
Accumulated deficit	(176,671)	(150,333)
Total stockholders' equity	135,910	150,307

Contact:

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