

**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): August 16, 2021

COGENT BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38443
(Commission
File Number)

46-5308248
(I.R.S. Employer
Identification No.)

200 Cambridge Park Drive, Suite 2500
Cambridge, Massachusetts
(Address of principal executive offices)

02140
(Zip Code)

Registrant's telephone number, including area code (617) 945-5576

Not Applicable

(Former name or former address, if changed since last report)

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, \$0.001 Par Value	COGT	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 or Rule 12b-2 of the Securities Exchange Act of 1934.

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 August 16, 2021, Cogent Biosciences, Inc., a Delaware corporation (the “Company”), issued a press release announcing its financial results for the quarter ended June 30, 2021. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference in its entirety.

The information in this Item 2.02 and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Cogent Biosciences, Inc. on August 16, 2021, furnished herewith.
104	The cover page from the Company’s Current Report on Form 8-K formatted in Inline XBRL.

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.

Date: August 16, 2021

COGENT BIOSCIENCES, INC.

By: /s/ John Green

John Green

Chief Financial Officer



**Cogent Biosciences Provides Corporate Updates and
Reports Second Quarter 2021 Financial Results**

Initiated Phase 2 open-label clinical study (APEX) for bezuclastinib (CGT9486) in patients with Advanced Systemic Mastocytosis (AdvSM)

SUMMIT study for patients with Non-Advanced Systemic Mastocytosis (NonAdvSM) on track to start 2H 2021 following recent positive interactions with FDA

Formed Cogent Scientific Advisory Board, including several world-class experts in targeted therapy

Ended Q2 2021 with \$218.1 million in cash, sufficient to fund operations into 2024

CAMBRIDGE, Mass. and BOULDER, Colo., August 16, 2021 – Cogent Biosciences, Inc. (Nasdaq: COGT), a biotechnology company focused on developing precision therapies for genetically defined diseases, today announced financial results for the second quarter ended June 30, 2021 and provided corporate updates.

“People fighting advanced systemic mastocytosis live every day in need of additional treatment options. We initiated the Phase 2 APEX clinical study for our lead program bezuclastinib, designed to specifically target the underlying genetic cause of advanced systemic mastocytosis with the goal of providing new therapeutic options for patients,” said Andrew Robbins, President and CEO of Cogent Biosciences. “In addition, we look forward to advancing bezuclastinib into two new clinical studies by the end of 2021, including the SUMMIT study for patients with non-advanced systemic mastocytosis, while actively progressing novel discovery programs with the recently formed Cogent Research Team.”

Recent Program and Corporate Highlights

- **APEX Study in AdvSM Patients Initiated**
 - Cogent initiated APEX, a Phase 2 clinical study of bezuclastinib in patients with AdvSM. APEX is an open-label, global, multicenter study that will evaluate the safety, efficacy, pharmacokinetic, and pharmacodynamic profiles of bezuclastinib. Learn more about the APEX study at www.cogentclinicaltrials.com



- Cogent expects to report preliminary clinical data from the APEX study in the first half of 2022, including levels of serum tryptase, a validated biomarker of mast cell activity.
- **SUMMIT Study of bezuclastinib in NonAdvSM Patients on track to start 2H 2021**
 - Following recent positive interactions with FDA, Cogent is on track to initiate SUMMIT, a randomized, double-blind placebo-controlled Phase 2 clinical study of bezuclastinib in patients with NonAdvSM.
- **FDA Granted Orphan Drug Designation for bezuclastinib in GIST (Gastrointestinal Stromal Tumors)**
 - FDA granted orphan drug designation for bezuclastinib for the treatment of GIST with an estimated 4,000 to 6,000 GIST cases diagnosed annually in the United States.
 - Cogent remains on track to initiate a new study of bezuclastinib and sunitinib in GIST patients during 2H 2021.
- **Cogent Research Team continues to evolve efforts in pioneering best-in-class, small molecule therapeutics**
 - Based in Boulder, Colorado, the Cogent Research Team continues to focus on developing best-in-class, small molecule therapeutics to expand Cogent's pipeline and deliver novel precision therapies for patients living with unmet medical needs.
 - Announced long-term lease on ~40,000 sq. ft. facility which will serve as laboratory and office space headquarters for Cogent Research Team.
- **Formed the Cogent Scientific Advisory Board**
 - Comprised of world-class experts involved in the discovery and development of novel therapeutics for patients with genetically-driven diseases, this group has been brought together to provide external perspective for the Cogent Research Team as it develops a robust portfolio of novel, small molecule discovery programs designed to address significant patient unmet needs.
 - **Dr. Ryan Corcoran, MD, PhD** - Director of the Gastrointestinal Cancer Center Program and Scientific Director, Termeer Center for Targeted Therapy at the Massachusetts General Hospital Cancer Center and Associate Professor of Medicine at Harvard Medical School



- **Dr. Michael Vasconcelles, MD** - Chief Medical Officer of Flatiron Health, a healthcare technology and services company focused on accelerating cancer research and improving patient care
- **Dr. Srdan Verstovsek, MD, PhD** - United Energy Resources, Inc. Professor of Medicine and a hematologist-oncologist at the MD Anderson Cancer Center, Houston, Texas, USA
- **Dr. Kwok-Kin Wong, MD, PhD** - Director, Division of Hematology and Medical Oncology, Anne Murnick Cogan and David H. Cogan Professor of Oncology, Department of Medicine, Laura and Isaac Perlmutter Cancer Center, NYU Langone Health

Second Quarter 2021 Summarized Financial Results

- **R&D Expenses:** Research and development expenses were \$12.4 million for the second quarter of 2021 as compared to \$5.1 million for the second quarter of 2020. R&D expenses include non-cash stock compensation expense of \$1.0 million for the second quarter of 2021 compared to \$0.5 million for the second quarter of 2020.
- **G&A Expenses:** General and administrative expenses were \$4.9 million for the second quarter of 2021 as compared to \$2.8 million for the second quarter of 2020. G&A expenses include non-cash stock compensation expense of \$1.6 million for the second quarter of 2021 compared to \$0.4 million for the second quarter of 2020.
- **Net Loss:** Net loss was \$16.5 million for the second quarter of 2021 as compared to a net loss of \$7.4 million for the second quarter of 2020. During the second quarter of 2021, the company spent \$12.6 million of its cash and cash equivalents.
- **Cash and Cash Equivalents:** As of June 30, 2021, Cogent had cash and cash equivalents of \$218.1 million. The company believes that its cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements into 2024.



About Cogent Biosciences, Inc.

Cogent Biosciences is a biotechnology company focused on developing precision therapies for genetically defined diseases. The most advanced clinical program, bezuclastinib, is a selective tyrosine kinase inhibitor that is designed to potently inhibit the KIT D816V mutation as well as other mutations in KIT exon 17. KIT D816V is responsible for driving systemic mastocytosis, a serious disease caused by unchecked proliferation of mast cells. Exon 17 mutations are also found in patients with advanced gastrointestinal stromal tumors (GIST), a type of cancer with strong dependence on oncogenic KIT signaling. In addition to bezuclastinib, the newly formed Cogent Research Team is developing a portfolio of novel targeted therapies to help patients fighting serious, genetically driven diseases. Cogent Biosciences is based in Cambridge, MA and Boulder, CO. Visit our website for more information at www.cogentbio.com. Follow Cogent Biosciences on social media: [Twitter](#) and [LinkedIn](#). Information that may be important to investors will be routinely posted on our website and Twitter.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding: discussion of the company's business and operations; projected cash runways; future product development plans; clinical development plans and timelines including for its lead program, bezuclastinib, and the expectation to initiate two new clinical trials before the end of 2021; the anticipated contributions of the Cogent Research Team; and the company's expectation to report preliminary data from its Apex study in the first half of 2022. The use of words such as, but not limited to, "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "will," or "would" and similar words expressions are intended to identify forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our clinical results, the rate of enrollment in our clinical trials and other future conditions. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements. We may not actually achieve the forecasts or milestones disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Such



forward-looking statements are subject to a number of material risks and uncertainties including but not limited to those set forth under the caption “Risk Factors” in Cogent’s most recent Annual Report on Form 10-K filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the SEC. Any forward-looking statement speaks only as of the date on which it was made. Neither we, nor our affiliates, advisors or representatives, undertake any obligation to publicly update or revise any forward-looking statement, whether as result of new information, future events or otherwise, except as required by law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date hereof.



COGENT BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share amounts)
(unaudited)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	2021	2020	2021	2020
Collaboration revenue	\$ —	\$ 528	\$ —	\$ 7,559
Operating expenses:				
Research and development	12,388	5,129	20,601	14,627
General and administrative	4,904	2,802	9,491	6,476
Total operating expenses	<u>17,292</u>	<u>7,931</u>	<u>30,092</u>	<u>21,103</u>
Loss from operations	<u>(17,292)</u>	<u>(7,403)</u>	<u>(30,092)</u>	<u>(13,544)</u>
Other income:				
Interest income	120	3	245	50
Other income	623	7	1,227	7
Change in fair value of CVR liability	—	—	343	—
Total other income	<u>743</u>	<u>10</u>	<u>1,815</u>	<u>57</u>
Net loss and comprehensive loss	<u>\$ (16,549)</u>	<u>\$ (7,393)</u>	<u>\$ (28,277)</u>	<u>\$ (13,487)</u>
Net loss per share attributable to common shareholders, basic and diluted	<u>\$ (0.43)</u>	<u>\$ (0.95)</u>	<u>\$ (0.77)</u>	<u>\$ (1.76)</u>
Weighted average common shares outstanding, basic and diluted	<u>38,441,729</u>	<u>7,777,487</u>	<u>36,670,353</u>	<u>7,655,837</u>

COGENT BIOSCIENCES, INC.
CONSOLIDATED SELECTED BALANCE SHEET DATA
(in thousands)
(unaudited)

	June 30, 2021	December 31, 2020
Cash and cash equivalents	\$ 218,105	\$ 242,190
Working capital	\$ 207,669	\$ 231,818
Total assets	\$ 228,516	\$ 250,916
Total liabilities	\$ 15,712	\$ 16,249
Total stockholders' equity	\$ 212,804	\$ 234,667

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