
**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): March 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 March 16, 2021, Cogent Biosciences, Inc., a Delaware corporation (the “Company”), issued a press release announcing its financial results for the quarter and year ended December 31, 2020. 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.

Exhibit No.**Description**

99.1 [Press release issued by Cogent Biosciences, Inc. on March 16, 2021, furnished herewith.](#)

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: March 16, 2021

COGENT BIOSCIENCES, INC.

By: /s/ John Green

John Green

Chief Financial Officer



**Cogent Biosciences Reports Fourth Quarter 2020
and Full Year 2020 Financial Results**

CGT9486 clinical trial initiations on-track: Advanced Systemic Mastocytosis (1H21), Non-Advanced Systemic Mastocytosis (2H21), Gastrointestinal Stromal Tumors (GIST) (2H21)

Final data from CGT9486 + sunitinib Phase 1/2 study presented at CTOS 2020 demonstrated 12 months median PFS and 20% ORR, including a complete response, in heavily pre-treated advanced GIST patients. Randomized GIST clinical trial initiation expected in 2H21

*Rapidly Growing with Several Key Additions to Management Team and Board of Directors
Ended Q4 2020 with \$242.2 million in cash, funding operations into 2024*

CAMBRIDGE, Mass., March 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 fourth quarter ended December 31, 2020 and provided several corporate updates.

“Cogent Biosciences was formed in July 2020, and we are extremely proud of the progress our team has made in such a short amount of time,” said Andrew Robbins, President and CEO of Cogent Biosciences. “We remain on track and plan to initiate clinical trials of CGT9486 in advanced systemic mastocytosis in the first half of this year, and will follow in non-advanced systemic mastocytosis and GIST in the second half of this year. We are excited to demonstrate the role of this novel, potent, selective KIT-mutant inhibitor for these patient populations with significant remaining unmet medical need.”

Recent Program and Corporate Highlights

- **Encouraging data from CGT9486 + sunitinib in Phase 1/2 combination study in heavily pre-treated patients with GIST support a randomized trial in 2H21**
 - Data presented at the Connective Tissue Oncology Society (CTOS) 2020 virtual meeting demonstrated that treatment with a combination of CGT9486, a KIT inhibitor with activity against exon 17 mutations, and sunitinib, a KIT inhibitor with activity against exon 13 mutations, is associated with encouraging clinical activity in heavily pre-treated patients with GIST.



- Data showed median progression free survival (PFS) of 12 months in a heavily pre-treated population of advanced GIST patients and an objective response rate (ORR) of 20%.
- The combination was well-tolerated across three dose levels with no maximum tolerated dose level reached. The most common minor adverse events were anemia, hypophosphatemia, diarrhea, and lymphopenia.
- Based on these encouraging data, Cogent plans to initiate a randomized trial in patients with imatinib-resistant GIST during the second half of 2021.
- **Upsized Public Offering with gross proceeds of approximately \$115 million support advancement of CGT9486 into three clinical trials in 2021**
 - On December 4, 2020, Cogent Biosciences announced the closing of its upsized underwritten public offering; net proceeds from which will be used for the continued clinical development of CGT9486 to treat patients with systemic mastocytosis and GIST.
- **Appointed new individuals to several key leadership positions**
 - Todd E. Shegog to Board of Directors
 - Mr. Shegog currently serves as the Chief Financial Officer for Forma Therapeutics and brings more than 25 years of financial, operations, corporate strategy, and compliance expertise in the biotechnology and pharmaceutical industries to Cogent Biosciences' Board. Todd has past experience as CFO at Synlogic, FORUM, and Millennium and received degrees in electrical engineering from Lafayette College and an MBA from the Tepper School of Management at Carnegie Mellon University.
 - Sara Saltzman as Senior Vice President, Regulatory Affairs
 - Ms. Saltzman has built extensive experience in Regulatory Affairs working for top-tier life sciences companies such as Genzyme, Takeda, and Alexion; most recently serving as the Vice President of Regulatory Affairs for Unum Therapeutics. Sara holds a degree in Biology from Colby College.
 - Ben Exter as Vice President, Pharmacovigilance and Risk Management
 - Dr. Exter spent several years in clinical development at Biogen and Takeda, culminating with his role as Global Head of Risk Management at Takeda. Most recently he was VP of Pharmacovigilance at Unum Therapeutics. Ben received his Doctorate of Pharmacy degree from Northeastern University.



- Mark Lohman as Vice President, CGT9486 Program Team Leader
 - Mr. Lohman has spent over 20 years in program and alliance management and leadership roles at Array BioPharma and most recently at Pfizer as Executive Director, Alliance and Program Management for Oncology. Mark holds a degree in Chemistry from Kent State University and an MBA from the University of Colorado Denver.

Fourth Quarter and Year End 2020 Summarized Financial Results

- **R&D Expenses:** Research and development expenses were \$6.1 million for the fourth quarter of 2020 and \$25.7 million for the year ended December 31, 2020, as compared to \$10.4 million for the fourth quarter of 2019 and \$43.7 million for the year ended December 31, 2019. This decrease is primarily related to the reduction in clinical activity of legacy cell therapy clinical trials.
- **G&A Expenses:** General and administrative expenses were \$5.3 million for the fourth quarter of 2020 and \$17.4 million for the year ended December 31, 2020, as compared to \$2.7 million for the fourth quarter of 2019 and \$11.0 million for the year ended December 31, 2019. The increase is primarily related to higher professional fees and stock compensation.
- **Net Loss:** Net loss was \$11.3 million for the fourth quarter of 2020 and \$74.8 million for the year ended December 31, 2020 as compared to a net income of \$2.3 million for the fourth quarter of 2019 and a net loss of \$31.8 million for the year ended December 31, 2019.
- **Cash and Cash Equivalents:** As of December 31, 2020, Cogent Biosciences had cash and cash equivalents of \$242.2 million. We believe our cash and cash equivalents will be sufficient to fund our 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, CGT9486, 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. Cogent Biosciences is headquartered in Cambridge, MA. Visit our website for more information at www.cogentbio.com. Follow Cogent Biosciences on social media: [Twitter](#) and [LinkedIn](#).

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; upcoming results from clinical trials including from its lead program, CGT9486. 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 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 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 Biosciences' 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.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)
(unaudited)

	<u>Year Ended December 31,</u>		<u>Three Months Ended December 31,</u>	
	2020	2019	2020	2019
Collaboration revenue	\$ 7,871	\$ 22,499	\$ —	\$ 15,288
Operating expenses:				
Research and development	25,738	43,709	6,107	10,354
General and administrative	17,422	10,968	5,348	2,694
Acquired in-process research and development	46,910	—	—	—
Total operating expenses	<u>90,070</u>	<u>54,677</u>	<u>11,455</u>	<u>13,048</u>
Loss from operations	<u>(82,199)</u>	<u>(32,178)</u>	<u>(11,455)</u>	<u>2,240</u>
Other income (expense):				
Interest income	144	267	70	61
Gain on disposal of long-lived assets	7,493	78	31	—
Other income	779	—	531	(4)
Change in fair value of CVR liability	(1,025)	—	(516)	—
Total other income (expense), net	<u>7,391</u>	<u>345</u>	<u>116</u>	<u>57</u>
Net income (loss)	<u>\$ (74,808)</u>	<u>\$ (31,833)</u>	<u>\$ (11,339)</u>	<u>\$ 2,297</u>
Net income (loss) attributable to common shareholders	<u>\$ (179,208)</u>	<u>\$ (31,833)</u>	<u>\$ (115,739)</u>	<u>\$ 2,297</u>
Net loss per common share, basic and diluted	<u>\$ (16.17)</u>	<u>\$ (4.18)</u>	<u>\$ (6.06)</u>	<u>\$ 0.28</u>
Weighted average common shares outstanding, basic and diluted	<u>11,081,257</u>	<u>7,620,082</u>	<u>19,088,362</u>	<u>7,798,905</u>

COGENT BIOSCIENCES, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)
(unaudited)

	<u>December 31,</u>	<u>December 31,</u>
	2020	2019
Cash, cash equivalents and marketable securities	\$ 242,190	\$ 37,424
Working capital	\$ 231,818	\$ 27,343
Total assets	<u>\$ 250,916</u>	<u>\$ 49,423</u>
Total liabilities	\$ 16,249	\$ 17,661
Total stockholders' equity	<u>\$ 234,667</u>	<u>\$ 31,762</u>

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