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 4, 2021

CATALYST BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**000-51173**	**56-2020050**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

611 Gateway Blvd, Suite 710, South San Francisco, CA 94080
(Address of principal executive offices)

(650) 871-0761
(Registrant's telephone number, including area code)

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	**CBIO**	**Nasdaq**

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 March 4, 2021, Catalyst Biosciences, Inc., issued a press release announcing its financial results for the fourth quarter and fiscal year ended December 31, 2020. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information set forth in this Item 2.02 (including Exhibit 99.1) is being furnished and 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 liabilities 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, regardless of any general incorporation language in such filing, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated March 4, 2021.
104	Cover Page Interactive Data File (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.

CATALYST BIOSCIENCES, INC.

Date: March 4, 2021

/s/ Clinton Musil
Clinton Musil
Chief Financial Officer

Catalyst Biosciences Reports Fourth Quarter and Full-Year 2020 Operating & Financial Results and Provides a Corporate Update

SOUTH SAN FRANCISCO, Calif. – March 4, 2021 – Catalyst Biosciences, Inc. (NASDAQ: CBIO) today announced its operating and financial results for the fourth quarter and full-year ending December 31, 2020 and provided a corporate update.

“The past year was transformational for Catalyst. We expanded our complement pipeline, introducing an enhanced complement factor I (CFI) development candidate CB 4332, announced a classical pathway regulator of C4b program, and received Fast Track designation for MarzAA,” said Nassim Usman, Ph.D., president, and chief executive officer of Catalyst. “Our year-end cash plus the net proceeds from our January financing provide a total of over $130.0 million in capital to achieve several value building milestones, including executing on our two MarzAA clinical trials, initiating an observational trial for CB 4332, and continuing to deepen our pipeline with additional drug candidates in our complement portfolio.”

Recent Milestones

- **Marzeptacog alfa (activated) – MarzAA:** The U.S. Food and Drug Administration (FDA) granted Fast Track Designation for Marzeptacog alfa (activated) – or MarzAA, the Company’s subcutaneously (SQ) administered next-generation engineered coagulation Factor VIIa (FVIIa) for the treatment of episodic bleeding in subjects with hemophilia A or B with inhibitors. The Company also presented a poster at the Annual American Society of Hematology (ASH) meeting in December 2020. Linda Neuman, MD, vice president of clinical development, presented the rationale and design of the Crimson 1 (MAA-304) Phase 3 study.
- **Systemic Complement Regulator Program:** In December 2020, the Catalyst team hosted a research and development meeting on the Company’s first subcutaneously dosed systemic complement development candidate, CB 4332, an extended half-life CFI, and a C4b degrader program that targets classical complement disorders. Catalyst is leveraging its proprietary protease engineering platform expertise to develop several proteases that regulate the complement cascade that can be applied to treat many diseases.
- **Completed a $52.8 million financing:** Catalyst raised approximately $52.8 million in gross proceeds during the first quarter of 2021, before deducting underwriting discounts and commissions and other estimated offering expenses, in a total offering of 9,185,000 shares of its common stock. Net proceeds from the offering were approximately $49.3 million. Cash, cash equivalents and investments, as of December 31, 2020 were $81.9 million.

Expected Near-Term Milestones

- **MarzAA**:
  - Initiate and enroll the Crimson 1 Phase 3 open-label trial evaluating the efficacy of SQ MarzAA to treat episodic bleeding in individuals with hemophilia A or B with inhibitors;
  - Initiate and enroll a Phase 1/2 trial (MAA 202) in FVII Deficiency, Glanzmann Thrombasthenia, and Hemlibra® patients;
  - Submit the first Crimson 1 report to the Data and Safety Monitoring Board (DSMB).
- **Systemic Complement Program**:
  - Commence enrollment of an observational trial in mid-2021 assessing CFI activity and genotype in patients who have diseases associated with CFI deficiency to identify those who would benefit from CB 4332 treatment.

Fourth Quarter and Full-Year 2020 Results and Financial Highlights

- Cash, cash equivalents and investments, as of December 31, 2020 were $81.9 million. During the first quarter of 2021, the Company completed equity financing raising approximately $49.3 million in net proceeds.
- Research and development expense for the three-months and year-ended December 31, 2020 was $14.6 million and $53.0 million, respectively, compared with $10.8 million and $43.9 million for the prior year periods, respectively. The increase was due primarily to an increase in personnel-related costs, pre-clinical research and facilities costs, partially offset by a decrease in clinical manufacturing costs.
- General and administrative expense for the three-months and year-ended December 31, 2020 was $4.3 million and $16.2 million, respectively, compared with $3.2 million and $13.4 million for the prior year periods, respectively. The increase was due primarily to an increase in professional services and personnel-related costs.
- Interest and other income, net, for the three-months and year-ended December 31, 2020 was ($0.1) million and $1.1 million, respectively, compared with $0.4 million and $2.1 million for the prior year periods, respectively.
- In connection with its Biogen Agreement, the Company received a $15.0 million upfront license fee on January 10, 2020 and made a $3.0 million payment to Mosaic Biosciences that was recorded as the cost of the license. The Company also recognized reimbursable out-of-pocket third-party expenses of $2.0 million and $6.1 million for the three-months and year-ended December 31, 2020, respectively, which were recorded as costs of collaboration revenue.
- Net loss attributable to common stockholders for the three-months and year-ended December 31, 2020 was $18.9 million, or ($0.86) per basic and diluted share, and $56.2 million, or ($2.93) per basic and diluted share, respectively, compared with $13.6 million, or ($1.23) per basic and diluted share, and $55.2 million, or ($4.60) per basic and diluted share, for the prior year periods, respectively.
- As of December 31, 2020, the Company had 22,097,820 shares of common stock outstanding.

About Catalyst Biosciences, the Protease Medicines company

Catalyst is a research and clinical development biopharmaceutical company focused on addressing unmet medical needs in rare disorders of the complement and coagulation systems. Our protease engineering platform has generated two late-stage clinical programs, including MarzAA, a subcutaneously (SQ) administered next-generation engineered coagulation Factor VIIa (FVIIa) for the treatment of episodic bleeding in subjects with rare bleeding disorders. Our complement pipeline includes a pre-clinical C3-degrader program partnered with Biogen for dry age-related macular degeneration, an improved complement factor I protease for SQ replacement therapy in patients with CFI deficiency and C4b-degraders designed to target disorders of the classical complement pathway as well as other complement programs in development.

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include statements about the potential benefits of products based on Catalyst's engineered protease platform, plans to initiate and enroll a Phase 3 open-label trial and a Phase 1/2 trial of MarzAA, submit the first report to the Data and Safety Monitoring Board (DSMB) in 2021, commence enrollment of an observational trial in CB 4332 in mid-2021, and to deepen the Company's pipeline. Actual results or events could differ materially from the plans, intentions, expectations and projections disclosed in the forward-looking statements. Various important factors could cause actual results or events to differ materially, including, but not limited to, the risk that trials and studies may be delayed as a result of COVID-19, competitive products and other factors, that trials may not have satisfactory outcomes, that additional human trials will not replicate the results from earlier trials, that potential adverse effects may arise from the testing or use of MarzAA, including the generation of neutralizing antibodies, the risk that costs required to develop or manufacture the Company's products will be higher than anticipated, including as a result of delays in trial enrollment, development and manufacturing resulting from COVID-19 and other factors, the risk that Biogen will terminate Catalyst's agreement, competition and other risks

described in the “Risk Factors” section of the Company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 4, 2021, and in other filings with the Securities and Exchange Commission. The Company does not assume any obligation to update any forward-looking statements, except as required by law.

Contact:

Ana Kapor
Catalyst Biosciences, Inc.
investors@catbio.com

+++

Catalyst Biosciences, Inc.
Consolidated Balance Sheets
(In thousands, except shares and per share amounts)

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 30,360	$ 15,369
Short-term investments	48,994	61,496
Accounts receivable, net	3,313	15,000
Prepaid and other current assets	6,844	4,201
Total current assets	89,511	96,066
Long-term investments	2,543	—
Other assets, noncurrent	528	257
Right-of-use assets	1,832	1,927
Property and equipment, net	433	304
Total assets	$ 94,847	$ 98,554
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,931	$ 4,279
Accrued compensation	2,477	2,106
Deferred revenue	1,983	15,000
Other accrued liabilities	6,743	7,031
Operating lease liability	663	483
Total current liabilities	17.797	28,899
Operating lease liability, noncurrent	981	1,319
Total liabilities	18,778	30,218
Commitments and Contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized; zero shares issued and outstanding	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized; 22,097,820 and 12,040,835 shares issued and outstanding at December 31, 2020 and 2019, respectively	22	12
Additional paid-in capital	390,803	326,810
Accumulated other comprehensive income	5	34
Accumulated deficit	(314,761)	(258,520)
Total stockholders' equity	76,069	68,336
Total liabilities and stockholders' equity	$ 94,847	$ 98,554

Catalyst Biosciences, Inc.
Consolidated Statements of Operations
(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2020	2019
License	$ 15,100	$ —
Collaboration	5,848	—
License and collaboration revenue	20,948	—
Operating expenses:		
Cost of license	3,102	—
Cost of collaboration	6,061	—
Research and development	52,975	43,859
General and administrative	16,180	13,418
Total operating expenses	78,318	57,277
Loss from operations	(57,370)	(57,277)
Interest and other income, net	1,129	2,099
Net loss	$ (56,241)	$ (55,178)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.93)	$ (4.60)
Shares used to compute net loss per share attributable to common stockholders, basic and diluted	19,179,299	12,004,489