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 5, 2020

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 November 5, 2020, Catalyst Biosciences, Inc., issued a press release announcing its financial results for the quarter ended September 30, 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 November 5, 2020 and titled "Catalyst Biosciences Reports Third Quarter 2020 Operating & Financial Results and Provides a Corporate Update."
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: November 5, 2020

/s/ Clinton Musil
Clinton Musil
Chief Financial Officer

Catalyst Biosciences Reports Third Quarter 2020 Operating & Financial Results and Provides a Corporate Update

SOUTH SAN FRANCISCO, Calif. – Nov. 5, 2020 – Catalyst Biosciences, Inc. (NASDAQ: CBIO) today announced its operating and financial results for the third quarter ended September 30, 2020 and provided a corporate update.

“In the third quarter we focused on preparing to initiate two clinical trials for MarzAA and building our complement programs. We plan to enroll patients in a pivotal Phase 3 study of MarzAA for the treatment of bleeding in hemophilia A or B patients with inhibitors and initiate a Phase 1/2 trial of MarzAA for the treatment of bleeding in Factor VII Deficiency, Glanzmann thrombasthenia, and Hemlibra patients by the end of the year”, said Nassim Usman, Ph.D., president and chief executive officer of Catalyst Biosciences. “In addition, we are on track to deliver on other important program milestones including disclosing a development candidate for our systemic complement program this year.”

Recent Milestones:

- **Complement intellectual property**: The United States Patent and Trademark Offices issued a patent covering Catalyst’s portfolio of engineered proteases that selectively cleave and degrade complement factor 3 (C3), including the lead candidate CB 2782-PEG, a potential best-in-class treatment for dry AMD currently under development under a license and collaboration agreement with Biogen. These modified proteases inhibit complement activation and have the potential to treat multiple diseases in which complement activation plays a role. The newly issued patent provides protection until at least 2038.

Expected Milestones:

- **Marzeptacog alfa (activated) – MarzAA,** a subcutaneously (SQ) administered next-generation engineered coagulation Factor VIIa (FVIIa):
  - Enroll the first patient in a Phase 3 open-label trial before the end of the year, evaluating the efficacy of SQ MarzAA to treat episodic bleeding in individuals with hemophilia A or B with inhibitors, and
  - Initiate a Phase 1/2 trial in FVII Deficiency, Glanzmann Thrombasthenia, and Hemlibra patients before year-end.
- **Systemic complement:** Announce a development candidate in December 2020.

Third Quarter 2020 Results and Financial Highlights:

- Cash, cash equivalents and, investments, as of September 30, were $104.1 million.
- Research and development expenses were $12.2 million and $9.9 million during the three months ended September 30, 2020 and 2019, respectively, an increase of $2.3 million, or 23%. The increase was due primarily to an increase of $1.1 million in personnel and facilities costs, an increase of $0.7 million in preclinical research, and an increase of $0.3 million in clinical manufacturing costs.

- General and administrative expenses were $3.8 million and $3.3 million during the three months ended September 30, 2020 and 2019, respectively, an increase of $0.5 million, or 17%. The increase was due primarily to an increase of $0.4 million in professional services and an increase of $0.4 million in payroll and payroll related costs, partially offset by a decrease of $0.2 million in indirect employee and facilities costs.
- Interest and other income, net was $0.1 million and $0.5 million during the three months ended September 30, 2020 and 2019, respectively, a decrease of $0.4 million. The decrease was primarily due to a decrease in interest income on investments.
- Net loss attributable to common stockholders for the three months ended September 30, 2020 was $16.0 million, or ($0.73) per basic and diluted share, compared with $12.7 million, or ($1.06) per basic and diluted share, for the prior year period.
- As of September 30, 2020, the Company had 22,082,924 shares of common stock outstanding.

About Catalyst Biosciences

Catalyst is a research and clinical development biopharmaceutical company focused on addressing unmet medical needs in rare hematologic and complement-mediated disorders. Our protease engineering platform generated two late-stage clinical programs in hemophilia; a research program on engineering of subcutaneous (SQ) complement inhibitors; a discovery stage Factor IX gene therapy construct - CB 2679d-GT - for Hemophilia B, and a partnered preclinical development program with Biogen for dry age-related macular degeneration (AMD). The product candidates generated by our protease engineering platform have improved functionality and potency that allow for: SQ administration of recombinant coagulation factors and complement inhibitors; low-dose, high activity gene therapy constructs; and less frequently dosed intravitreal therapeutics.

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include statements about Catalyst’s plans to enroll the first patient in a Phase 3 open-label trial of MarzAA and initiate a Phase 1/2 trial of MarzAA in FVII Deficiency, Glanzmann Thrombasthenia, and Hemlibra patients before year-end, the potential for MarzAA to effectively and therapeutically treat hemophilia subcutaneously, the superiority of CB 2679d-GT over other gene therapy candidates and the Company’s collaboration with Biogen for the development and commercialization of pegylated CB 2782 for the potential treatment of geographic atrophy-associated dry age-related macular degeneration. 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 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 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 quarterly report filed with the Securities and Exchange Commission on November 5, 2020, 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.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	September 30, 2020 (Unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 24,923	$ 15,369
Short-term investments	77,959	61,496
Accounts receivable	1,555	15,000
Prepaid and other current assets	3,535	4,201
Total current assets	107,972	96,066
Long-term investments	1,171	—
Other assets, noncurrent	698	257
Right-of-use assets	1,524	1,927
Property and equipment, net	439	304
Total assets	$ 111,804	$ 98,554
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,244	$ 4,279
Accrued compensation	2,543	2,106
Deferred revenue	764	15,000
Other accrued liabilities	8,750	7,031
Operating lease liability	519	483
Total current liabilities	16,820	28,899
Operating lease liability, noncurrent	925	1,319
Total liabilities	17,745	30,218
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; 22,082,924 and 12,040,835 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	22	12
Additional paid-in capital	389,883	326,810
Accumulated other comprehensive income	8	34
Accumulated deficit	(295,854)	(258,520)
Total stockholders' equity	94,059	68,336
Total liabilities and stockholders' equity	$ 111,804	$ 98,554

The accompanying notes are an integral part of these condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
License	$ 32	$ —	$ 15,100	$ —
Collaboration	861	—	3,817	—
License and collaboration revenue	893	—	18,917	—
Operating expenses:				
Cost of license	32	—	3,102	—
Cost of collaboration	879	—	4,030	—
Research and development	12,249	9,927	38,419	33,066
General and administrative	3,833	3,268	11,895	10,224
Total operating expenses	16,993	13,195	57,446	43,290
Loss from operations	(16,100)	(13,195)	(38,529)	(43,290)
Interest and other income, net	67	489	1,195	1,722
Net loss	$ (16,033)	$ (12,706)	$ (37,334)	$ (41,568)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.73)	$ (1.06)	$ (2.05)	$ (3.47)
Shares used to compute net loss per share attributable to common stockholders, basic and diluted	22,072,243	12,022,620	18,199,575	11,992,240

The accompanying notes are an integral part of these condensed consolidated financial statements.