

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

March 4, 2021

SOUTH SAN FRANCISCO, Calif., March 04, 2021 (GLOBE NEWSWIRE) -- 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.

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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	1	9,179,299	1:	2,004,489



Source: Catalyst Biosciences, Inc.