Catalyst Biosciences Reports First Quarter 2021 Operating & Financial Results and Provides a Corporate Update

May 6, 2021

SOUTH SAN FRANCISCO, Calif., May 06, 2021 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ: CBIO) today announced its operating and financial results for the first quarter ended March 31, 2021 and provided a corporate update.

“We made significant progress across our Protease Medicines platform, specifically in our complement and hemostasis programs. We are preparing to initiate an observational trial in patients who have diseases related to CFI deficiency in mid-year 2021 to support our SQ enhanced CFI development candidate CB 4332 that will enter the clinic in 2022,” said Nassim Usman, Ph.D., president and chief executive officer of Catalyst. “In hemostasis, we dosed our first subject in the Crimson 1 Phase 3 registrational study of MarzAA, our next generation SQ FVIIa, in hemophilia A or B with inhibitors and are enrolling patients in a Phase 1/2 trial in other rare bleeding disorders.”

Recent Milestones

- **Marzeptacog alfa (activated) – MarzAA:** Catalyst announced the dosing of the first patient in the Company's Phase 3 registration trial (Crimson 1– MAA-304).

- **Complement Factor 3 Degrader Program:** Catalyst expanded its intellectual property estate and protection of its complement assets with the issuance of U.S. Patent Number 10,954,501 B2 entitled: “Nucleic Acid Encoding Modified Membrane Type Serine Protease 1 (MTSP-1) Polypeptides and Methods of Use.” The patent covers nucleic acids encoding modified proteases that selectively cleave and degrade complement factor 3 (C3) including CB 2782-PEG licensed to Biogen for dry age-related macular degeneration.

- **Factor IX (FIX) Gene Therapy Program:** Catalyst announced publication of preclinical FIX gene therapy data for CB 2679d-GT in *Blood,* the Journal of American Society of Hematology. The paper, entitled: ″Gene Therapy for Hemophilia B Using CB 2679d-GT: A Novel Factor IX Variant with Higher Potency than Factor IX Padua,″ demonstrated superiority of the Company's CB 2679d-GT gene therapy candidate over that of the R338L-Padua variant, which is currently used in clinical trials.

Expected Milestones

- **Systemic Complement Program:**
    - Commence enrollment of an observational trial in mid-2021 assessing the blood levels of CFI in patients who have diseases related to CFI deficiency in order to identify those who would benefit from CB 4332 treatment;
    - Provide additional preclinical data supporting continued development of the C4b degrader program and other complement assets.
- **MarzAA**
    - Announce first patient dosed in the Phase 1/2 trial (MAA 202) for the treatment of episodic bleeding in FVII Deficiency, Glanzmann Thrombasthenia, and Hemlibra patients;
    - Submit the first Crimson 1 report to the Data and Safety Monitoring Board (DSMB).

First Quarter 2021 Results and Financial Highlights

- Cash, cash equivalents and short-term investments, as of March 31, 2021 were $107.0 million.

- Research and development expenses were $17.0 million and $13.3 million during the three months ended March 31, 2021 and 2020, respectively, an increase of $3.7 million, or 28%. The increase was due primarily to preclinical and personnel related costs.

- General and administrative expenses were $5.4 million and $3.7 million during the three months ended March 31, 2021 and 2020, respectively, an increase of $1.7 million, or 47%. The increase was due primarily to an increase of $0.8 million in personnel-related costs, and an increase of $0.8 million in professional services.

- Interest and other (expense), net was $0.0 million and $1.0 million during the three months ended March 31, 2021 and 2020, respectively, a decrease of $1.0 million, or 100%. The decrease was primarily due to a decreased interest rate and due to the payment received in the first quarter of 2020 under an agreement associated with neuronal nicotinic receptor asset sold in 2016.

- Net loss attributable to common stockholders for the three-months ended March 31, 2021 was $22.4 million, or ($0.79) per basic and diluted share, compared with $4.1 million, or ($0.28) per basic and diluted share, for the prior year period.

- As of March 31, 2021, the Company had 31,331,027 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 preclinical C3-degrader program licensed to 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 continue enrolling 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), commence enrollment of an observational trial in CB 4332 in mid-2021 and a clinical trial in 2022, and the scope of the Company's intellectual property protection for its complement programs. 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 the Company's patents may be held invalid or may not provide the scope of coverage anticipated, competition and other risks described in the "Risk Factors" sections 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.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	March 31, 2021 (Unaudited)	December 31,2020
Assets		
Current assets:		
Cash and cash equivalents	$ 83,044	$ 30,360
Short-term investments	23,956	48,994
Accounts receivable	1,006	3,313
Prepaid and other current assets	8,514	6,843
Total current assets	116,520	89,510
Long-term investments	—	2,543
Other assets, noncurrent	528	528
Right-of-use assets	1,646	1,832
Property and equipment, net	382	433
Total assets	$ 119,076	$ 94,846
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,956	$ 5,931
Accrued compensation	2,232	2,476

Deferred revenue	1,332	1,983
Other accrued liabilities	6,983	6,743
Operating lease liability	678	663
Total current liabilities	14,181	17,796
Operating lease liability, noncurrent	806	981
Total liabilities	14,987	18,777
Commitments and Contingencies (Note 10)		
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; 31,331,027 and 22,097,820 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	31	22
Additional paid-in capital	441,252	390,803
Accumulated other comprehensive income	5	5
Accumulated deficit	(337,199)	(314,761)
Total stockholders' equity	104,089	76,069
Total liabilities and stockholders' equity	$ 119,076	$ 94,846

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

	Three Months Ended March 31, 2021	Three Months Ended March 31, 2020
License	$ —	$ 15,045
Collaboration	1,467	1,321
License and collaboration revenue	1,467	16,366
Operating expenses:		
Cost of license	—	3,047
Cost of collaboration	1,480	1,432
Research and development	17,013	13,264
General and administrative	5,412	3,691
Total operating expenses	23,905	21,434
Loss from operations	(22,438)	(5,068)
Interest and other income (expense), net	—	1,015
Net loss	$ (22,438)	$ (4,053)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.79)	$ (0.28)
Shares used to compute net loss per share attributable to common stockholders, basic and diluted	28,385,432	14,592,451

Source: Catalyst Biosciences, Inc.