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

August 5, 2021

SOUTH SAN FRANCISCO, Calif., Aug. 05, 2021 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ: CBIO) today announced its operating and financial results for the second quarter ended June 30, 2021, and provided a corporate update.

"We continue to make progress in our complement and hemostasis programs. In complement, we are advancing the development of our SQ enhanced CFI development candidate, CB 4332, where we screened the first patient in our natural history study for CFI deficiency ("ConFIrm"). We also recently disclosed new proteases from our ProTUNE™; C3b-C4b degrader and ImmunoTUNE™; C3a-C5a degrader platforms designed to targe specific disorders of the complement or inflammatory pathways," said Nassim Usman, Ph.D., president and chief executive officer of Catalyst. "With the initiation of the ConFIrm study and our plans to enter the clinic with CB 4332 in 2022 on track, we are building a robust pipeline in complement. We also continue to make progress in our Crimson 1 Phase 3 registrational study of MarzAA, in hemophilia A or B with inhibitors as well as in our Phase 1/2 trial in other rare bleeding disorders."

Recent Milestones

Marzeptacog alfa (activated) – MarzAA

- The Food and Drug Administration (FDA) has granted Fast Track Designation for MarzAA for treatment of episodic bleeding in subjects with Factor FVII deficiency in June 2021. The FDA granted the Fast Track Designation for the treatment of episodic bleeding in subjects with Hemophilia A or B with inhibitors in December 2020.

- Presented four posters at the International Society for Thrombosis and Haemostasis (ISTH) 2021 Virtual Congress in July 2021. The data presented support the Company's ongoing trials of MarzAA in hemostasis.

Systemic Complement Program

- Launched the ConFIrm study with the screening of the first patient in its CFI-deficiency study in the CB 4332 program, Catalyst's wholly-owned, first-in-class, enhanced Complement Factor I (CFI), intended for prophylactic subcutaneous (SQ) administration in individuals with CFI deficiency. The ConFIrm screening study will measure CFI levels and activity in patients who have diseases related to a CFI deficiency and who may potentially benefit from CB 4332 treatment.

- Hosted a research and development day on its protease medicines platform focusing on the regulation of complement, including CB 4332. The event featured a presentation by Filomeen Haerynck, M.D., Ph.D., University of Ghent, Belgium, who discussed the clinical phenotype, current treatment landscape and unmet medical need in treating patients with complement factor I (CFI) deficiency and other complement system disorders. Members of the Catalyst management team also discussed the proteases from the Company's degrader platforms, designed to target specific disorders of the complement and other inflammatory pathways as well as other complement programs in development.

Corporate

- Catalyst announced that it has promoted Grant Blouse, Ph.D., to chief scientific officer and Tom Knudsen, DVM, Ph.D., to senior vice president, corporate development. Howard Levy, M.B.B.Ch, Ph.D., M.M.M., chief medical officer, announced his plan to retire and transition to a senior clinical advisor role to Catalyst.

Expected Milestones

Systemic Complement Program

- Advance CB 2782-PEG, the C3 degrader for the potential treatment of dry AMD in collaboration with Biogen towards the clinic

- Provide additional preclinical data supporting continued development of the C4b degrader program and other complement assets

- Submit an IND and initiate global clinical trial of CB 4332

- Announce development candidates in lead discovery programs

- Present PK and biomarker data for CB 4332

MarzAA

- Continue enrolling the Crimson 1 Phase 3 registrational and the Phase 1/2 trials
- Submit the first Crimson 1 report to the Data and Safety Monitoring Board (DSMB)
- Present PK data from the Phase 1/2 trial

Second Quarter 2021 Results and Financial Highlights

- Cash, cash equivalents and short-term investments, as of June 30, 2021 were $86.5 million.
- Research and development expenses were $15.4 million and $12.9 million during the three months ended June 30, 2021 and 2020, respectively, an increase of $2.5 million, or 19%. The increase was due primarily to an increase of $1.4 million in personnel and facilities costs and an increase of $1.5 million in clinical and manufacturing costs, partially offset by a decrease of $0.4 million in preclinical spending.
- General and administrative expenses were $4.5 million and $4.4 million during the three months ended June 30, 2021 and 2020, respectively, an increase of $0.1 million, or 3%. This increase was due primarily to an increase of $0.3 in personnel-related costs, partially offset by $0.2 million in facilities and overhead costs.
- Interest and other income (expense), net was $0.0 million and $0.1 million during the three months ended June 30, 2021 and 2020, respectively, a decrease of $0.1 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 June 30, 2021 was $19.9 million, or ($0.64) per basic and diluted share, compared with $17.2 million, or ($0.96) per basic and diluted share, for the prior year period.
- As of June 30, 2021, the Company had 31,349,740 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 proteases from our ProTUNE™ C3b-C4b degrader and ImmunoTUNE™ C3a-C5a degrader platforms designed to target specific disorders of the complement or inflammatory pathways 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, without limitation, statements about the product candidates of Catalyst Biosciences, Inc. (the “Company”) and the benefits of its protease engineering platform; plans to complete the ConFIrm and ConFIdence studies and the expectation that the studies will inform opportunities to develop CB 4332; plans to submit an IND for CB 4332; plans to announce development candidates in lead discovery programs and present PK and biomarker data for CB 4332; plans to continue enrollment of the Phase 3 and Phase 1/2 trials of MarzAA; the potential markets for and advantages of the Company's complement product candidates, including CB 2782-PEG, CB 4332 and complement degraders; plans for the Company's collaboration with Biogen; and plans to start a clinical trial of CB 4332 in 2022.

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, the risk that the ConFIrm and ConFIdence trials will not validate the potential market for CB 4332; the risk Catalyst may elect to terminate or postpone ongoing development programs, including development of MarzAA or any of the Company's complement assets; the risk that the Company will need to raise additional capital, which may not be available on faorable terms if at all; the risk that Biogen will terminate Catalyst's agreement, and other risks described in the "Risk Factors" section of the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 6, 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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Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	June 30, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 73,621	$ 30,360
Short-term investments	12,902	48,994
Accounts receivable	1,971	3,313
Prepaid and other current assets	8,332	6,843
Total current assets	96,826	89,510
Long-term investments	—	2,543
Other assets, noncurrent	1,169	528
Right-of-use assets	3,107	1,832
Property and equipment, net	684	433
Total assets	$ 101,786	$ 94,846
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,834	$ 5,931
Accrued compensation	2,516	2,476
Deferred revenue	2,038	1,983
Other accrued liabilities	7,366	6,743
Operating lease liability	1,814	663
Total current liabilities	15,568	17,796
Operating lease liability, noncurrent	1,054	981
Total liabilities	16,622	18,777
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; 31,349,740 and 22,097,820 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	31	22
Additional paid-in capital	442,258	390,803
Accumulated other comprehensive income	2	5
Accumulated deficit	(357,127)	(314,761)
Total stockholders' equity	85,164	76,069
Total liabilities and stockholders' equity	$ 101,786	$ 94,846

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue:				
License	$ —	$ 23	$ —	$ 15,068
Collaboration	1,132	1,635	2,599	2,956
License and collaboration revenue	1,132	1,658	2,599	18,024
Operating expenses:				
Cost of license	—	23	—	3,070
Cost of collaboration	1,139	1,719	2,619	3,151
Research and development	15,389	12,906	32,402	26,170
General and administrative	4,518	4,371	9,930	8,062
Total operating expenses	21,046	19,019	44,951	40,453
Loss from operations	(19,914)	(17,361)	(42,352)	(22,429)
Interest and other income (expense), net	(14)	113	(14)	1,128
Net loss	$ (19,928)	$ (17,248)	$ (42,366)	$ (21,301)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.64)	$ (0.96)	$ (1.42)	$ (1.31)

Shares used to compute net loss per share attributable to common stockholders, basic and diluted	31,348,602	17,891,475	29,875,202	16,241,963

Source: Catalyst Biosciences, Inc.