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

August 6, 2020

SOUTH SAN FRANCISCO, Calif., Aug. 06, 2020 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ: CBIO) today announced its operating and financial results for the second quarter ended June 30, 2020 and provided a corporate update.

"We continued to make significant progress across our pipeline, delivering on all milestones during the first half of the year," said Nassim Usman, Ph.D., president and chief executive officer of Catalyst Biosciences. "We are currently on track to achieve additional important milestones in the second half of 2020 including enrolling patients in our pivotal Phase 3 study of subcutaneous (SQ) MarzAA treatment of bleeding in individuals with hemophilia A or B with inhibitors. Further, we expect to identify development candidates in our complement and gene therapy programs. We closed the quarter with approximately $117 million in cash putting us in a strong position to deliver on these upcoming milestones."

Recent Milestones:

- **Marzeptacog alfa (activated) – MarzAA,** a SQ administered next-generation engineered coagulation Factor VIIa (FVIIa): The Company presented two posters at the International Society for Thrombosis and Haemostasis (ISTH) Virtual Congress in July. The MAA-102 PK results and population PK simulations confirm that Catalyst has optimized dosing for its Phase 3 MarzAA registration trial. The open-label trial will evaluate the efficacy of SQ MarzAA compared with standard of care to treat episodic bleeding in individuals with hemophilia A or B with inhibitors.
- **Dalcinonacog alfa – DalcA,** a subcutaneously administered next-generation engineered coagulation Factor IX (FIX) being developed for Hemophilia B: Presented final efficacy and safety data from its Phase 2b trial of DalcA at the World Federation of Hemophilia in June. Data from the trial showed that 28 days of daily SQ dosing of DalcA achieved protective target FIX levels of >12% in all participants, with FIX levels of up to 27% and a half-life of 2.5 to 5.1 days with no bleeds, demonstrating effective prophylaxis and the potential for lower or less frequent dosing.
- **Factor IX gene therapy construct – CB 2679-GT,** The Company's proprietary FIX gene therapy construct CB 2679d-GT is being developed for the treatment of hemophilia B and has demonstrated superiority compared with the Padua variant in preclinical models. Catalyst presented data from preclinical studies of its hemophilia B gene therapy CB 2679d-GT at the World Federation of Hemophilia Virtual Summit. The preclinical data from the Company's constructs demonstrated a strong dose response and improved reduction in bleeding compared with the Padua variant. Catalyst believes that the enhanced FIX activity and reduced viral dose may offer advantages over current AAV-based gene therapies in clinical development.
- **Corporate:** Appointed Clinton J. Musil as a chief financial officer and Charles Democko as a senior vice president, regulatory affairs. Completed an underwritten public offering of 4,615,384 shares of its common stock, offered at a price of $6.50 per share to the public. The gross proceeds to Catalyst from this offering were approximately $30.0 million, before deducting underwriting discounts and commissions and other estimated offering expenses payable by Catalyst.

Expected Milestones:

- **MarzAA:** Enroll the first patient in a Phase 3 open-label trial in late 2020, evaluating the efficacy of SQ MarzAA to treat episodic bleeding in individuals with hemophilia A or B with inhibitors. Initiate a Phase 1/2 trial in FVII Deficiency, Glanzmann Thrombastenia, and patients using Hemlibra, in late 2020. Timelines for both trials are subject to the readiness of trial sites and potential effects of COVID-19 on clinical trial execution.
- **CB 2679d-GT (**FIX Gene Therapy): Announce a development candidate in late 2020.
- **Systemic complement inhibitor:** Announce a development candidate in late 2020.

Second Quarter 2020 Results and Financial Highlights:

- Cash, cash equivalents and short-term investments, as of June 30, were $117.4 million.
- Research and development expenses were $12.9 million and $11.1 million during the three months ended June 30, 2020 and 2019, respectively, an increase of $1.8 million, or 16%. The increase was due primarily to an increase of $2.7 million in preclinical spending, an increase of $0.6 million in personnel and facilities costs offset by a decrease of $1.6 million in clinical and manufacturing costs.
- General and administrative expenses were $4.4 million and $3.3 million during the three months ended June 30, 2020 and 2019, respectively, an increase of $1.1 million. The increase was primarily due to an increase in professional services.

- Interest and other income, net was $0.1 million and $0.6 million during the three months ended June 30, 2020 and 2019, respectively, a decrease of $0.5 million. The decrease was primarily due a decrease in interest income on investments.
- Net loss attributable to common stockholders for the three-months ended June 30, 2020 was $17.2 million, or ($0.96) per basic and diluted share, compared with $13.8 million, or ($1.15) per basic and diluted share, for the prior year period.
- As of June 30, 2020, the Company had 22,050,745 shares of common stock outstanding.

About Catalyst Biosciences

Catalyst is a research and clinical development biopharmaceutical company focused on addressing unmet needs in rare hematologic and complement-mediated disorders. Our protease engineering platform includes two late-stage clinical programs in hemophilia; a research program on engineering of subcutaneous (SQ) complement inhibitors; 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. Our most advanced product candidate is marzeptacog alfa (activated) (MarzAA), a next-generation SQ FVIIa entering a Phase 3 registration study in late 2020. Our next late-stage product candidate is dalcinonacog alfa (DalcA), a next-generation SQ FIX, which has demonstrated efficacy and safety in a Phase 2b clinical trial in individuals with Hemophilia B. We have a discovery stage Factor IX gene therapy construct - CB 2679d-GT - for Hemophilia B, that has demonstrated superiority compared with the Padua variant in preclinical models. Finally, we have a global license and collaboration agreement with Biogen for the development and commercialization of anti-complement Factor 3 (C3) pegylated CB 2782.

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 enroll the first patients in a Phase 3 registration study of MarzAA to treat episodic bleeding in individuals with hemophilia A or B with inhibitors, initiate a Phase 1/2 trial in FVII Deficiency, Glanzmann Thrombastenia, and patients treated with Hemlibra in late 2020, the potential for MarzAA and DalcA to effectively and therapeutically treat hemophilia subcutaneously, plans to declare development candidates in our Factor IX Gene Therapy and systemic complement programs, 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 (AMD). 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 the novel coronavirus (COVID-19) outbreak 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 DalcA or MarzAA, including the generation of neutralizing antibodies, which has been observed in patients treated with DalcA, 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 SARS-CoV-2 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 August 6, 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.

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

	June 30, 2020 (Unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 59,273	$ 15,369
Short-term investments	58,091	61,496
Accounts receivable	1,988	15,000
Prepaid and other current assets	1,993	4,201
Total current assets	121,345	96,066
Other assets, noncurrent	198	257
Right-of-use assets	1,660	1,927

Property and equipment, net	481	304
Total assets	$ 123,684	$ 98,554
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,499	$ 4,279
Accrued compensation	1,778	2,106
Deferred revenue	330	15,000
Other accrued liabilities	9,550	7,031
Operating lease liability	507	483
Total current liabilities	13,664	28,899
Operating lease liability, noncurrent	1,059	1,319
Total liabilities	14,723	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; 22,050,745 and 12,040,835 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	22	12
Additional paid-in capital	388,719	326,810
Accumulated other comprehensive income	41	34
Accumulated deficit	(279,821)	(258,520)
Total stockholders' equity	108,961	68,336
Total liabilities and stockholders' equity	$ 123,684	$ 98,554

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,	
	2020	**2019**	**2020**	**2019**
License	$ 23	$ —	$ 15,068	$ —
Collaboration	1,635	—	2,956	—
License and collaboration revenue	1,658	—	18,024	—
Operating expenses:				
Cost of license	23	—	3,070	—
Cost of collaboration	1,719	—	3,151	—
Research and development	12,906	11,111	26,170	23,138
General and administrative	4,371	3,270	8,062	6,956
Total operating expenses	19,019	14,381	40,453	30,094
Loss from operations	(17,361)	(14,381)	(22,429)	(30,094)
Interest and other income, net	113	601	1,128	1,232
Net loss	$ (17,248)	$ (13,780)	$ (21,301)	$ (28,862)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.96)	$ (1.15)	$ (1.31)	$ (2.41)
Shares used to compute net loss per share attributable to common stockholders, basic and diluted	17,891,475	11,989,866	16,241,963	11,976,799

Source: Catalyst Biosciences, Inc.