Catalyst Biosciences Reports First Quarter 2019 Operating & Financial Results and Provides a Corporate Update

May 2, 2019

Final MarzAA Phase 2 data to be presented at upcoming International Society for Thrombosis & Hemostasis (ISTH) meeting in July 2019

MarzAA Orphan Drug Designation received from the European Commission

Initiated DalcA Phase 2b Trial for the Treatment of Hemophilia B

SOUTH SAN FRANCISCO, Calif., May 02, 2019 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ: CBIO) today announced its operating and financial results for the first quarter ended March 31, 2019 and provided a corporate update.

"We are pleased with the clinical progress this quarter and look forward to several clinical read outs from both our MarzAA and DalcA hemophilia programs during 2019," said Nassim Usman, Ph.D., president and chief executive officer of Catalyst. "The data continue to demonstrate that our therapies are safe, highly efficacious and provide clinically meaningful reductions in bleeding in hemophilia patients. We believe that subcutaneous delivery is the future for hemophilia treatments and that our candidates have the potential to disrupt the current $3.7 billion intravenous factor replacement market."

Recent Milestones:

- **Marzeptacog alfa (activated) – MarzAA**, Catalyst's next-generation engineered subcutaneous (SQ) coagulation Factor VIIa (FVIIa) for individuals with hemophilia A or B with inhibitors: Completed enrollment and dosing for the Phase 2 open-label SQ efficacy trial. Reported data on seven subjects who completed dosing to date who had a pre-dose mean annualized bleed rate (ABR) of 18.2 (range of 12.2-26.7) that was reduced to 2.1 (>90% reduction); and five of the seven subjects had no bleeds for 50 days at the lowest MarzAA dose (30 µg/kg). The Company's interim data indicates MarzAA is safe and well tolerated and had no anti-drug antibody development.

  MarzAA received orphan drug designation for the treatment of hemophilia B from the European Commission.

- **Dalcinonacog alfa – DalcA**, Catalyst's next-generation engineered SQ coagulation Factor IX (FIX) for individuals with hemophilia B: Initiated a Phase 2b trial for the treatment of hemophilia B. The open-label study will evaluate the ability of DalcA to maintain steady state FIX levels above 12%, the minimum factor level required to prevent spontaneous bleeds, in individuals with severe hemophilia B. The trial will enroll up to six subjects who will receive a single intravenous dose followed by daily SQ doses of DalcA for 28 days.

- **CB 2679d-GT –** Factor IX Gene Therapy: Completed pre-clinical proof-of-concept study of FIX Gene Therapy for the treatment of hemophilia B. Demonstrated 3-fold superior clotting activity and a 4-to-5-fold reduction in bleeding time in a hemophilia B mouse model using an AAV vector containing the CB 2679d gene construct compared with an AAV-Padua gene construct.

- **Anti-C3 Protease – CB 2782-PEG** (long ocular half-life): Completed an intravitreal pre-clinical pharmacokinetics study and an intravitreal pre-clinical pharmacokinetic and pharmacodynamic study comparing CB 2782-PEG with CB 2782 (conventional half-life). A single intravitreal injection of 125 µg of CB 2782-PEG had a greater than 99% elimination of C3 in non-human primates for at least 28 days. Data from these studies indicate the CB 2782-PEG is potentially a best-in-class anti-complement factor 3 therapy, with an expected intravitreal administration frequency of three to four times a year.

- **Financial**: Ended Q1 2019 with a cash and short-term investments balance of $105 million.

Expected Milestones

- Present final results for all subjects from the MarzAA Phase 2 open-label SQ efficacy trial at the ISTH meeting in July 2019; initiate a MarzAA Phase 1 pharmacokinetic and pharmacodynamic study in Q2 2019 with final data read out in Q4 2019; and request an End of Phase 2 meeting with the FDA by the end of 2019.

- Complete the DalcA Phase 2b open-label SQ long-term dosing study, with final data readout in Q4 2019.

First Quarter 2019 Results and Financial Highlights

- Cash, cash equivalents and short-term investments as of March 31, 2019 were $105.3 million.

- Research and development expense for the three months ended March 31, 2019 was $12.0 million, compared with $3.8 million for the prior year period. The increase was due primarily to investments in the clinical and manufacturing development for the MarzAA and DalcA clinical programs.

- General and administrative expense for the three months ended March 31, 2019 was $3.7 million, compared with $2.9 million for the prior year period. The increase was due primarily to increases in personnel and professional service costs.

- Interest and other income for the three months ended March 31, 2019 was $0.6 million, compared with $1.6 million for the prior year period. The decrease was due primarily to receiving a non-recurring milestone payment of $1.4 million in 2018, which was partially offset by higher interest income in 2019.

- Net loss attributable to common stockholders for the three months ended March 31, 2019 was $15.1 million, or ($1.26) per basic and diluted share, compared with $5.0 million, or ($0.56) per basic and diluted share for the prior year period.

- As of March 31, 2019, the Company had 11,974,104 shares of common stock outstanding.

About Catalyst Biosciences
Catalyst is a clinical-stage biopharmaceutical company focused on developing novel medicines to address serious medical conditions for individuals who need new or better treatment options. We are focusing our product development efforts in the field of hemostasis (the process that regulates bleeding) and have a mission to develop valuable therapies for individuals with hemophilia. For more information, please visit www.catalystbiosciences.com.

Forward-Looking Statements
This press release contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include statements about the potential commercial market for MarzAA and DalcA, Catalyst's clinical trial plans for MarzAA and DalcA, the timing of clinical trials and anticipated results, plans for an end of Phase2 meeting for MarzAA, and the potential uses and benefits of CB 2679d-GT and CB 2782-PEG. 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 and 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 or DalcA, including the generation of 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, competition and other factors that affect our ability to establish collaborations on commercially reasonable terms and other risks described in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the quarter and the year ended December 31, 2018 filed with the Securities and Exchange Commission on March 8, 2019, and with 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, 2019	December 31, 2018
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 25,024	$ 31,213
Short-term investments	80,253	88,914
Restricted cash	50	50

Prepaid and other current assets	3,675	3,814
Total current assets	109,002	123,991
Other assets, noncurrent	197	543
Right-of-use assets	2,315	—
Property and equipment, net	356	386
Total assets	$ 111,870	$ 124,920
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 282	$ 1,248
Accrued compensation	876	1,495
Other accrued liabilities	2,762	2,043
Deferred rent, current portion	—	15
Operating lease liability	450	—
Total current liabilities	4,370	4,801
Operating lease liability, noncurrent	1,686	—
Deferred rent, noncurrent portion	—	174
Total liabilities	6,056	4,975
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; 11,974,104 and 11,954,528 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	12	12
Additional paid-in capital	324,214	323,279
Accumulated other comprehensive income (loss)	13	(4)
Accumulated deficit	(218,425)	(203,342)
Total stockholders' equity	105,814	119,945
Total liabilities and stockholders' equity	$ 111,870	$ 124,920

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 March 31,	
	2019	**2018**
Contract revenue	$ —	$ 6
Operating expenses:		
Research and development	12,027	3,771
General and administrative	3,687	2,914
Total operating expenses	15,714	6,685
Loss from operations	(15,714)	(6,679)
Interest and other income, net	631	1,637
Net loss	$ (15,083)	$ (5,042)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.26)	$ (0.56)
Shares used to compute net loss per share attributable to common stockholders, basic and diluted	11,963,586	8,989,669

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

Source: Catalyst Biosciences, Inc.