Catalyst Biosciences Reports Fourth Quarter and Full-Year 2019 Operating & Financial Results and Provides a Corporate Update

February 20, 2020

Presented positive clinical and pre-clinical data from its MarzAA and DalcA hemophilia programs

Announced a global license and collaboration agreement with Biogen to develop and commercialize pegylated CB 2782 for Dry AMD

SOUTH SAN FRANCISCO, Calif., Feb. 20, 2020 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ: CBIO), today announced its operating and financial results for the fourth quarter and full-year ending December 31, 2019 and provided a corporate update.

"We made exceptional progress in both our subcutaneously-dosed (SQ) MarzAA (FVIIa) and SQ DalcA (FIX) programs this past year. Earlier this month at EAHAD, positive data was presented in an oral presentation from the Company's Phase 2b SQ DalcA trial in subjects with hemophilia B clearly demonstrating efficacy and safety. We also presented data from MarzAA and Factor IX gene therapy programs in three posters," said Nassim Usman, Ph.D., president and chief executive officer of Catalyst. "Catalyst's therapies have demonstrated the potential to effectively treat hemophilia subcutaneously in a $3.4 billion market."

Dr. Usman continued, "Additionally, our February 2020 financing combined with our current cash provides funding through several major milestones for our lead Phase 3 ready MarzAA and Phase 2b DalcA product candidates, as well as our FIX gene therapy and complement inhibitor programs."

Recent Milestones:

- Announced a global license and collaboration agreement with Biogen Inc. to develop and commercialize pegylated CB 2782 and other anti-C3 proteases for the potential treatment of dry age-related macular degeneration (dAMD) and other disorders. Under terms of the agreement, Biogen is solely responsible for funding the pre-clinical and manufacturing activities and performing IND-enabling activities, worldwide clinical development, and commercialization. Catalyst received a $15 million upfront payment for the transfer of an exclusive license and the related know-how; and is eligible to receive up to $340 million in clinical, regulatory and commercial milestone payments plus future tiered royalties based on net sales.

- Appointed Sharon Tetlow and Geoffrey Shiu Fei Ling, M.D., to its Board of Directors.

- Marzeptacog alfa (activated) – MarzAA, subcutaneously administered next-generation engineered coagulation Factor VIIa: Presented two posters at the annual ASH meeting in December 2019, highlighting MarzAA's broad potential as a safe and effective therapy in hemophilia. The Company also presented two MarzAA posters at the EAHAD Congress in February 2020. In the first poster, Dr. Linda Neuman, vice president, clinical development, presented data from a Phase 1 study to evaluate the pharmacokinetics, pharmacodynamics and safety of ascending doses of SQ MarzAA in adult subjects with hemophilia, which showed that SQ dosing reaches target levels consistent with treatment of a bleed. The second poster, presented by Dr. Grant Blouse, senior vice president, translational research, showed data on SQ MarzAA demonstrating that on-demand treatment in Hemophilia A mice treated after a tail clip injury was as efficient as intravenous NovoSeven at reducing bleeding.

- Dalcinonacog alfa – DalcA, subcutaneously administered next-generation engineered coagulation Factor IX: Presented positive data from the company's phase 2b trial of subcutaneous DalcA at EAHAD. Data from the trial showed that 28 days of daily SQ dosing of DalcA achieved protective target FIX levels of >12% with steady sate FIX levels of up to 27% after 14 days with no bleeds and no anti-drug antibodies (ADAs) detected, demonstrating effective prophylaxis and the potential for lower or less frequent dosing. The data were presented in an oral presentation given by Johnny Mahlangu, MB.B.Ch., M.Med, F.C. Path, professor of haematology, faculty of health sciences, head of the School of Pathology at the University of Witwatersrand in Johannesburg, South Africa, and principal investigator in the clinical trial. Dr. Blouse presented a poster on Hemophilia B gene therapy in mice demonstrating that a novel chimeric AAV capsid combined with the Company's proprietary potency enhanced CB 2679d-GT FIX variant may reduce the vector dose required in gene therapy while maintaining high FIX levels.

- Raised $34.5 million in gross proceeds, before deducting underwriting discounts and offering expenses, in an offering of 5,307,692 shares of common stock in February 2020.

Expected Milestones

- **MarzAA**: Initiate a Phase 3 trial in the second half of 2020 following the end of Phase 2 meeting with the FDA and report

final data in the second quarter of 2020 from a MarzAA Phase 1 pharmacokinetic and pharmacodynamic study to support future SQ treatment of bleed studies.

- **DalcA**: Report final Phase 2b trial data in the second quarter of 2020.
- **Factor IX Gene Therapy (CB 2679d-GT):** Present primate data in the second quarter of 2020.
- **Complement Inhibitor:** Continue developing Catalyst's wholly-owned SQ systemic complement inhibitor program.

Fourth Quarter and Full-year 2019 Results and Financial Highlights

- Cash, cash equivalents and short-term investments, as of December 31, 2019 were $76.9 million. This does not include the $15M upfront payment from the Biogen CB 2782-PEG collaboration.
- Research and development expense for the three-months and full-year ended December 31, 2019 was $10.8 million and $43.9 million, respectively, compared with $8.2 million and $21.5 million for the prior year periods, respectively. The increase was due primarily to furthering development of Catalyst's programs and compounds.
- General and administrative expense for the three-months and year-ended December 31, 2019 was $3.2 million and $13.4 million, respectively, compared with $3.4 million and $12.4 million for the prior year periods, respectively.
- Interest and other income for the three-months and year-ended ended December 31, 2019 was $0.4 million and $2.1 million, respectively, compared with $0.8 million and $3.8 million for the prior year periods, respectively. Interest income was higher in 2018 due to the higher cash balances from the 2018 financing and warrant exercises.
- Net loss attributable to common stockholders for the three-months and year-ended December 31, 2019 was $13.6 million, or ($1.23) per basic and diluted share, and $55.2 million, or ($4.60) per basic and diluted share, respectively, compared with $10.8 million, or ($0.97) per basic and diluted share, and $30.1 million, or ($2.68) per basic and diluted share, for the prior year periods, respectively.
- As of December 31, 2019, the Company had 12,040,835 shares of common stock outstanding.

About Catalyst Biosciences

Catalyst is a clinical-stage biopharmaceutical company focused on addressing unmet needs in rare diseases and systemic complement mediated disorders. Our protease engineering platform includes development programs in hemophilia and a research program on subcutaneous (SQ) systemic complement inhibitors. Our engineered coagulation factors are designed to overcome the significant limitations of current IV treatment options, facilitate prophylaxis, and ultimately deliver substantially better outcomes for patients using SQ dosing. Our lead asset, MarzAA has completed Phase 2 development having met its primary endpoint of significantly reducing the annualized bleed rate (ABR) in individuals with hemophilia A or B with inhibitors. Our second hemophilia asset, DalcA is completing a Phase 2b clinical trial and is being developed for the treatment of hemophilia B. We also have a global license and collaboration agreement with Biogen for the development and commercialization of pegylated CB 2782 for the potential treatment of geographic atrophy associated dry age-related macular degeneration.

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 uses and benefits of MarzAA and DalcA to effectively and therapeutically treat hemophilia subcutaneously, the potential market opportunity for MarzAA and DalcA, plans to start a Phase 3 trial of MarzAA in second half of 2020 and report final data in the second quarter of 2020 from a MarzAA Phase 1 pharmacokinetic and pharmacodynamic study to support future SQ treatment of bleed studies, to announce final Phase 2b trial data for DalcA in the second quarter of 2020, plans to announce primate data for Factor IX gene therapy in the second quarter of 2020, and potential future milestone and royalty payments from Biogen. 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 DalcA, or MarzAA, including the generation of antibodies, which has been observed in patients previously treated with DalcA, the risk that costs required to develop or manufacture the Company's products will be higher than anticipated, the risk that Biogen will terminate our agreement with them, competition and other risks described in the "Risk Factors" section of the Company's quarterly report filed with the Securities and Exchange Commission on November 7, 2019, 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, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 15,369	$ 31,213
Short-term investments	61,496	88,914
Restricted cash	—	50
Accounts receivable	15,000	—
Prepaid and other current assets	4,201	3,814
Total current assets	96,066	123,991
Other assets, noncurrent	257	543
Right-of-use assets	1,927	—
Property and equipment, net of $0.4 million and $0.3 million of accumulated depreciation in 2019 and 2018, respectively	304	386
Total assets	$ 98,554	$ 124,920
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,279	$ 1,248
Accrued compensation	2,106	1,495
Deferred revenue	15,000	—
Other accrued liabilities	7,031	2,043
Operating lease liability	483	—
Deferred rent, current portion	—	15
Total current liabilities	28,899	4,801
Operating lease liability, noncurrent	1,319	—
Deferred rent, noncurrent portion	—	174
Total liabilities	30,218	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; 12,040,835 and 11,954,528 shares issued and outstanding at December 31, 2019 and 2018, respectively	12	12
Additional paid-in capital	326,810	323,279
Accumulated other comprehensive income (loss)	34	(4)
Accumulated deficit	(258,520)	(203,342)
Total stockholders' equity	68,336	119,945
Total liabilities and stockholders' equity	$ 98,554	$ 124,920

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

	Year Ended December 31,	
	2019	2018
Contract revenue	$ —	$ 6
Operating expenses:		
Research and development	43,859	21,474
General and administrative	13,418	12,354
Total operating expenses	57,277	33,828
Loss from operations	(57,277)	(33,822)

Interest and other income, net	2,099	3,767
Net loss	$ (55,178)	$ (30,055)
Net loss per share attributable to common stockholders, basic and diluted	$ (4.60)	$ (2.68)
Shares used to compute net loss per share attributable to common stockholders, basic and diluted	12,004,489	11,213,884

Source: Catalyst Biosciences, Inc.