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

August 1, 2019

*Phase 2 trial of subcutaneously administered MarzAA met primary endpoint of reduction in annualized bleed rate demonstrating safety and clinical efficacy, with >90% reduction in bleeding*

*DalcA Phase 2b study ongoing and enrolling patients*

SOUTH SAN FRANCISCO, Calif., Aug. 01, 2019 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ: CBIO) today announced its operating and financial results for the second quarter ended June 30, 2019 and provided a corporate update.

"We continue to focus on advancing the clinical development for MarzAA and DalcA," said Nassim Usman, Ph.D., president and chief executive officer of Catalyst. "In July, we presented final data from our Phase 2 trial of MarzAA at the ISTH meeting. The data demonstrated MarzAA's ability to reduce median bleeds to zero with daily subcutaneous prophylactic therapy. MarzAA has the potential to enable individuals with hemophilia A or B with inhibitors to lead more normal, active lives. We look forward to an end of Phase 2 meeting on MarzAA with the FDA."

**Recent Milestones:**

- **Marzeptacog alfa (activated) – MarzAA**, a subcutaneously (SQ) administered next-generation engineered coagulation Factor VIIa (FVIIa): The Phase 2 trial of MarzAA for prophylaxis met the primary endpoint of significantly reducing the annualized bleed rate (ABR) in patients with hemophilia A or B with inhibitors. The study also met all secondary endpoints of safety, tolerability and lack of anti-drug antibody or inhibitor formation. The results were presented in an oral presentation at the 2019 Congress of the International Society on Thrombosis and Haemostasis (ISTH), on July 7, 2019. Additionally, the Company is conducting a Phase 1 pharmacokinetic and pharmacodynamic study. This study will evaluate the pharmacokinetics and pharmacodynamics of MarzAA in individuals with hemophilia A or B (with or without inhibitors) to determine time to peak levels. Finally, the Company received agreement from the FDA that it has demonstrated comparability of the clinical drug substance and drug product between its previously manufactured batches and those recently manufactured.

- **Dalcinonacog alfa – DalcA,** a subcutaneously administered next-generation engineered coagulation Factor IX (FIX): The Phase 2b open-label long-term dosing study is open and enrolling patients. The 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 Company expects to enroll up to six patients, each with 28 days of dosing. Two posters were presented at the recent 2019 ISTH conference: a comprehensive *in silico* and *in vitro* immunogenicity risk assessment of the Company's next-generation engineered SQ coagulation FIX dalcinonacog alfa (DalcA) compared with wildtype FIX, and the trial design of the ongoing Phase 2b study of DalcA.

- **Factor IX gene therapy construct – CB 2679-GT**, Catalyst licensed AAV technology from Stanford University and the Company is currently optimizing the vector under a sponsored research agreement.

**Expected Milestones:**

- **MarzAA:** Report data from a MarzAA Phase 1 pharmacokinetic and pharmacodynamic study in 2020.

- **DalcAA**: Provide topline data from the ongoing Phase 2b study in Q4 2019 and final data in 2020.

**Second Quarter 2019 Results and Financial Highlights:**

- Cash, cash equivalents and short-term investments, as of June 30, 2019 were $94.0 million.

- Research and development expense for the three-months ended June 30, 2019 were $11.1 million compared with $3.9 million for the prior year period. The increase was due primarily to a net increase of $5.8 million in manufacturing development as the Company continued to advance the development of the MarzAA and DalcA product candidates, an increase of $0.9 million in personnel-related costs and an increase of $0.5 million in preclinical third-party research and development service contracts.

- General and administrative expense for the three months ended June 30, 2019 was $3.3 million compared with $3.2

million for the prior year period. The increase was due primarily to personnel-related expenses.

- Interest and other income was $0.6 million during the three months ended June 30, 2019 and 2018.
- Net loss attributable to common stockholders for the three-months ended June 30, 2019 was $13.8 million, or ($1.15) per basic and diluted share, compared with $6.5 million, or ($0.54) per basic and diluted share, for the prior year period.
- As of June 30, 2019, the Company had 12,008,528 shares of common stock outstanding.

**About Catalyst Biosciences**
Catalyst is a clinical-stage biopharmaceutical company focused on developing novel treatments for hemophilia and other rare bleeding disorders using its potent, subcutaneous (SQ) coagulation factors that promote blood clotting. The Company's engineered coagulation factors are designed to overcome the significant limitations of current intravenous (IV) treatment options, facilitate prophylaxis, and ultimately deliver substantially better outcomes for patients using SQ dosing. 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 use of MarzAA as a prophylactic therapy for patients with hemophilia A or B with inhibitors, clinical trial results for MarzAA, plans to request an FDA End of Phase 2 meeting, plans to report data from the MarzAA Phase 1 pharmacokinetic and pharmacodynamic study in 2020, clinical trial plans for DalcA and plans to provide topline data from the ongoing Phase 2b study in Q4 2019 and final data in 2020, and immunogenicity risks of DalcA. 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 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 enrollment of clinical trials may be slower than expected, the risk that the FDA will not grant an end of Phase 2 meeting for MarzAA, 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 Form 10-K filed with the Securities and Exchange Commission on March 8, 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.**
**Condensed Consolidated Balance Sheets**
(In thousands, except share and per share amounts)

| | June 30, 2019 (Unaudited) | December 31, 2018 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 17,348 | $ 31,213 |
| Short-term investments | 76,587 | 88,914 |
| Restricted cash | 50 | 50 |
| Prepaid and other current assets | 4,072 | 3,814 |
| Total current assets | 98,057 | 123,991 |
| Other assets, noncurrent | 257 | 543 |
| Right-of-use assets | 2,188 | — |
| Property and equipment, net | 371 | 386 |
| **Total assets** | $ 100,873 | $ 124,920 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |

| | | |
|---|---|---|
| Accounts payable | $ 393 | $ 1,248 |
| Accrued compensation | 1,410 | 1,495 |
| Other accrued liabilities | 3,932 | 2,043 |
| Deferred rent, current portion | — | 15 |
| Operating lease liability | 461 | — |
| Total current liabilities | 6,196 | 4,801 |
| Operating lease liability, noncurrent | 1,566 | — |
| Deferred rent, noncurrent portion | — | 174 |
| Total liabilities | 7,762 | 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; 12,008,528 and 11,954,528 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively | 12 | 12 |
| Additional paid-in capital | 325,246 | 323,279 |
| Accumulated other comprehensive income (loss) | 57 | (4) |
| Accumulated deficit | (232,204) | (203,342) |
| Total stockholders' equity | 93,111 | 119,945 |
| **Total liabilities and stockholders' equity** | $ 100,873 | $ 124,920 |

**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, | |
|---|---|---|---|---|
| | **2019** | **2018** | **2019** | **2018** |
| Contract revenue | $ — | $ — | $ — | $ 6 |
| Operating expenses: | | | | |
| Research and development | 11,111 | 3,889 | 23,138 | 7,660 |
| General and administrative | 3,270 | 3,225 | 6,956 | 6,139 |
| Total operating expenses | 14,381 | 7,114 | 30,094 | 13,799 |
| Loss from operations | (14,381) | (7,114) | (30,094) | (13,793) |
| Interest and other income, net | 601 | 632 | 1,232 | 2,269 |
| Net loss | $ (13,780) | $ (6,482) | (28,862) | (11,524) |
| Net loss per share attributable to common stockholders, basic and diluted | $ (1.15) | $ (0.54) | $ (2.41) | $ (1.10) |
| Shares used to compute net loss per share attributable to common stockholders, basic and diluted | 11,989,866 | 11,938,401 | 11,976,799 | 10,472,180 |

Source: Catalyst Biosciences, Inc.