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

November 7, 2019

SOUTH SAN FRANCISCO, Calif., Nov. 07, 2019 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ: CBIO) today announced its operating and financial results for the third quarter ended September 30, 2019 and provided a corporate update.

"We continued to make progress in both the marzeptacog alfa (activated) (MarzAA – FVIIa) and dalcinonacog alfa (DalcA – FIX) clinical programs," said Nassim Usman, Ph.D., president and chief executive officer of Catalyst. "We presented final MarzAA Phase 2 clinical data that clearly demonstrated the potential for subcutaneously (SQ) dosed MarzAA as a prophylactic treatment for hemophilia A or B patients with inhibitors. In addition, we showed that SQ MarzAA can treat a bleed in a preclinical model and completed GMP manufacturing of MarzAA at commercial scale, important steps as we prepare for a pivotal Phase 3 trial in 2020. In the DalcA Phase 2b trial, we successfully completed dosing in two subjects, achieving high FIX activity levels with a long SQ half-life without eliciting anti-drug antibodies (ADAs)."

Recent Milestones:

- **Marzeptacog alfa (activated) – MarzAA**, a subcutaneously administered next-generation engineered coagulation Factor VIIa (FVIIa):

  Presented final Phase 2 data for MarzAA at ISTH in July: The study met the primary endpoint of significantly reducing (>90%) the annualized bleed rate (ABR) in patients with hemophilia A or B with inhibitors from 19.8 to 1.6 ($p<0.01$). The study also met all secondary endpoints of safety, tolerability and absence of ADAs or inhibitor formation. Additionally, the Proportion of Days with Bleeding (PDB), was significantly reduced from a 6-month pretreatment mean of 12.3% to 0.8% during treatment ($p<0.01$). The median ABR and PDB were both reduced to zero during treatment, with seven of nine subjects experiencing no bleeds, either traumatic or spontaneous, at their final dose level. Subcutaneous treatment with MarzAA was safe and well-tolerated. Six mild to moderate localized skin reactions were observed in 2 subjects. No ADAs or inhibitors to MarzAA were detected after administration of a total of 517 SQ doses.

  Hosted a Key Opinion Leader meeting in August highlighting the current treatment landscape, market opportunity and unmet medical need for MarzAA in treating individuals with hemophilia A or B with inhibitors, Factor VII deficiency and other bleeding disorders, and the potential for an SQ therapy to treat bleeding.

  Completed a GMP drug product batch at commercial scale that is expected to support pivotal studies and commercialization requirements.

  Continued to enroll a Phase 1 SQ pharmacokinetic and pharmacodynamic study of MarzAA in individuals with hemophilia A or B (with or without inhibitors). The purpose of the trial is to guide dose selection to treat a bleed with SQ dosing.

- **Dalcinonacog alfa – DalcA,** a subcutaneously administered next-generation engineered coagulation Factor IX (FIX):

  Completed 28-day SQ dosing and 30-day washout and safety follow-up of two subjects in the open-label Phase 2b study evaluating the efficacy and safety of DalcA with long-term dosing in individuals with severe hemophilia B. Factor IX levels in these two subjects exceeded the efficacy endpoint of >12% activity and no ADAs or inhibitors were detected. Enrollment is ongoing and the Company anticipates reporting final data in the first half of 2020.

Expected Milestones:

- **MarzAA:** Initiate a Phase 3 trial in 2020 following the end of Phase 2 meeting with the FDA and report final data from a MarzAA Phase 1 pharmacokinetic and pharmacodynamic study to support future SQ treatment of bleed studies.

- **DalcAA**: Report final Phase 2b trial data in the first half of 2020.

Third Quarter 2019 Results and Financial Highlights:

- Cash, cash equivalents and short-term investments, as of September 30, 2019 were $85.0 million.

- Research and development expenses were $9.9 million and $5.6 million during the three months ended September 30, 2019 and 2018, respectively, an increase of $4.4 million, or 78%. The increase was due primarily to an increase of $1.7

million in clinical and manufacturing development as the Company continued to advance the development of the MarzAA and DalcA product candidates, an increase of $1.6 million in preclinical research inclusive of projects supportive of the product candidates, and an increase of $1.0 million in personnel-related costs.

- General and administrative expenses were $3.3 million and $2.8 million during the three months ended September 30, 2019 and 2018, respectively, an increase of $0.5 million, or 18%. The increase was due to an increase in professional services driven by corporate activities.

- Interest and other income was $0.5 million and $0.7 million during the three months ended September 30, 2019 and 2018, respectively. The decrease was due to lower average cash equivalent and short-term investments balances during the 2019 period.

- Net loss attributable to common stockholders for the three-months ended September 30, 2019 was $12.7 million, or ($1.06) per basic and diluted share, compared with $7.7 million, or ($0.64) per basic and diluted share, for the prior year period.

- As of September 30, 2019, the Company had 12,029,992 shares of common stock outstanding.

About Catalyst Biosciences
Catalyst is a clinical-stage biopharmaceutical company developing novel medicines to address hematology indications. Catalyst has engineered a portfolio of compounds that have increased potency over the naturally occurring proteases. Catalyst is focused on the field of hemostasis, including the subcutaneous treatment of hemophilia and facilitating surgery in individuals with hemophilia. For more information, please visit www.catalystbiosciences.com.

Forward-Looking Statements
This press release may contain forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include statements about the potential uses and benefits of Catalyst's products in development to address hemophilia indications, plans to initiate a Phase 3 MarzAA trial following the planned FDA End of Phase 2 meeting, plans to report data from the MarzAA Phase 1 pharmacokinetic and pharmacodynamic study in 2020, statements about Catalyst's clinical trial plans for DalcA, the timing of the clinical trial, anticipated reporting of data in the first half of 2020, and the potential for the DalcA 2b trial to meet its endpoints. 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, competition and other factors that affect the Company's ability to establish collaborations on commercially reasonable terms 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.

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

	September 30, 2019	December 31, 2018
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 23,018	$ 31,213
Short-term investments	61,928	88,914
Restricted cash	—	50
Prepaid and other current assets	4,188	3,814
Total current assets	89,138	123,991
Other assets, noncurrent	257	543
Right-of-use assets	2,058	—
Property and equipment, net	339	386

Total assets	$ 91,792	$ 124,920
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,123	$ 1,248
Accrued compensation	1,576	1,495
Other accrued liabilities	4,906	2,043
Deferred rent, current portion	—	15
Operating lease liability	472	—
Total current liabilities	9,077	4,801
Operating lease liability, noncurrent	1,443	—
Deferred rent, noncurrent portion	—	174
Total liabilities	10,520	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; 12,029,992 and 11,954,528 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	12	12
Additional paid-in capital	326,139	323,279
Accumulated other comprehensive income (loss)	31	(4)
Accumulated deficit	(244,910)	(203,342)
Total stockholders' equity	81,272	119,945
Total liabilities and stockholders' equity	$ 91,792	$ 124,920

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Contract revenue	$ —	$ —	$ —	$ 6
Operating expenses:				
Research and development	9,927	5,575	33,066	13,235
General and administrative	3,268	2,770	10,224	8,909
Total operating expenses	13,195	8,345	43,290	22,144
Loss from operations	(13,195)	(8,345)	(43,290)	(22,138)
Interest and other income, net	489	651	1,722	2,920
Net loss	$ (12,706)	$ (7,694)	(41,568)	(19,218)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.06)	$ (0.64)	$ (3.47)	$ (1.75)
Shares used to compute net loss per share attributable to common stockholders, basic and diluted	12,022,620	11,942,729	11,992,240	10,967,750

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

CATALYST BIOSCIENCES

Source: Catalyst Biosciences, Inc.