



Catalyst Biosciences Reports Fourth Quarter and Full Year 2016 Financial Results and Provides Corporate Update

March 8, 2017

- Phase 1/2 Proof-of-Concept Clinical Trial of High Potency Factor IX CB 2679d/ISU304 in Individuals with Hemophilia B to Commence in the Second Quarter of 2017 -

- Phase 2 Part of a Phase 2/3 Efficacy Clinical Trial of Next-Generation Coagulation Factor VIIa Variant Marzeptacog Alfa (Activated) in Individuals with Hemophilia A & B with an Inhibitor to Commence in the Fourth Quarter of 2017 -

SOUTH SAN FRANCISCO, Calif., March 08, 2017 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ:CBIO), a clinical-stage biopharmaceutical company focused on developing novel medicines to address hematology indications, today announced financial results for the fourth quarter and full year ended December 31, 2016, and provided an update on its hemostasis programs that include marzeptacog alfa (activated), a next-generation Factor VIIa, and CB 2679d/ISU304, a next-generation coagulation Factor IX.

"2016 was a very productive year – we continued to advance the development of our two highly potent next-generation coagulation factors in development. We presented positive results for both product candidates in subcutaneous non-clinical PK/PD studies at medical conferences, completed the marzeptacog alfa (activated) manufacturing technology transfer from Pfizer to CMC Biologicals, and successfully manufactured a commercial scale engineering batch of marzeptacog alfa (activated)," said Nassim Usman, Ph.D., Catalyst's President and Chief Executive Officer. "Having laid the groundwork in 2016 to initiate clinical trials of our Factor VIIa and IX candidates, we are looking forward to developing therapies with a simpler dosing method and improved long-term clinical outcomes for individuals with hemophilia."

Recent Highlights

- Presented positive preclinical results at the American Society of Hematology (ASH) 2016 and the European Association of Hemophilia and Allied Diseases (EAHAD) 2017 meetings in well-validated models of hemophilia A and B with marzeptacog alfa (activated) and CB 2679d/ISU304:
 - The pharmacodynamics and pharmacokinetic profiles of both coagulation factors demonstrated attractive subcutaneous dosing profiles based on bioavailability, potency, time to maximal concentration and half-life
 - Both candidates have the potential to be dosed by subcutaneous injection sufficient to correct coagulation abnormalities in individuals with hemophilia
 - CB 2679d/ISU304 could potentially achieve stable normal Factor IX activity levels
- Secured all license rights to the manufacturing materials and processes that apply to marzeptacog alfa (activated) from Wyeth LLC, a wholly-owned subsidiary of Pfizer
- Demonstrated the ability to manufacture marzeptacog alfa (activated) at commercial scale with our Drug Substance CMO partner, CMC Biologicals
- Signed a drug product fill-finish manufacturing services agreement with Symbiosis Pharmaceutical Services Limited for marzeptacog alfa (activated) for clinical trial applications

Anticipated Milestones

- **CB 2679d/ISU304:** Catalyst plans to initiate a Phase 1/2 proof-of-concept study in individuals with hemophilia B in the second quarter of 2017; the trial will be conducted by Catalyst's collaborator, ISU Abxis (KOSDAQ: 086890) in South Korea.
- **Marzeptacog alfa (activated):** Catalyst plans to initiate the Phase 2 portion of a Phase 2/3 efficacy study in individuals with hemophilia A & B with an inhibitor in the fourth quarter of 2017.

Financial Results for the Fourth Quarter and Year Ended December 31, 2016

- Contract revenue was \$0.1 million for both the three months ended December 31, 2016 and December 31, 2015. Contract revenue for the years ended December 31, 2016 and 2015 was \$0.4 million and \$1.8 million, respectively. The decrease in contract revenue was due primarily to the termination of our collaboration agreement with Pfizer in April 2015.
- Research and development expense for the three months ended December 31, 2016 was \$3.1 million, compared with \$1.8 million for the prior year period. The increase was due to an increase in manufacturing expenses of \$1.0 million and amortization expense of \$0.3 million. Research and development expenses for the years ended December 31, 2016 and 2015 were \$11.6 million and \$6.0 million, respectively, an increase of \$5.6 million. The increase was due primarily to an increase of \$3.6 million related to manufacturing expenses for marzeptacog alfa (activated), \$1.0 million in personnel-related costs, driven by our strategic restructuring and an increase of \$1.0 million in lab supply costs and costs related to preclinical third-party research and development service contracts.

- General and administrative expense for the three months ended December 31, 2016 was \$2.2 million, compared with \$3.0 million for the prior year period. The decrease was due primarily to a decrease in the cost of professional services (resulting from expenses related to the filing of the S-4 and preparations to be a public company). General and administrative expenses for the years ended December 31, 2016 and 2015 were \$9.3 million and \$9.6 million, respectively, a decrease of \$0.3 million.
- Interest and other income for the three months ended December 31, 2016 was \$1.5 million, compared with (\$0.5) million for the prior year period. The increase was due primarily to the gain related to the sale of noncore NNR assets. Interest and other income for the years ended December 31, 2016 and 2015, were \$3.5 million and \$0.5 million, respectively, an increase of \$3.0 million.
- Net loss for the three months ended December 31, 2016 was \$3.7 million, or (\$4.68) per basic and diluted share, compared to \$5.1 million, or (\$6.73) per basic and diluted share, for the prior year period. Net loss for the years ended December 31, 2016 and 2015 was \$16.9 million, or (\$21.75) basic and diluted share, compared to \$14.8 million, or (\$49.99) per basic and diluted share, for the prior year.
- Cash, cash equivalents and short-term investments as of December 31, 2016 and 2015 were \$17.1 million and \$32.5 million, respectively. The Company believes that its existing capital resources will be sufficient to meet its projected operating requirements for at least the next 12 months.

About Catalyst Biosciences

Catalyst is a clinical-stage biopharmaceutical company focused on developing novel medicines to address hematology indications. Catalyst is focused on the field of hemostasis, including the subcutaneous prophylaxis of hemophilia and facilitating surgery in individuals with hemophilia. Catalyst's most advanced program is an improved next-generation coagulation Factor VIIa variant, marzeptacog alfa (activated), that has successfully completed an intravenous Phase 1 clinical trial in individuals with severe hemophilia A or B. Catalyst is also developing a next-generation Factor IX variant, CB 2679d/ISU304, that is in advanced preclinical development. For more information, please visit www.catbio.com.

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statement of historical facts, included in this press release regarding our strategy, future operations, and plans are forward-looking statements. Examples of such statements include, but are not limited to, statements relating to Catalyst's clinical trial timelines, including the anticipated initiation of a Phase 1/2 clinical trial for Factor IX CB 2679d/ISU304 in the second quarter of 2017 and the entry of marzeptacog alfa (activated) into the Phase 2 part of a Phase 2/3 efficacy clinical trial in the fourth quarter of 2017, the potential uses and benefits of subcutaneously dosed marzeptacog alfa (activated) and CB 2679d/ISU304, and the Company's belief regarding sufficiency of its existing capital resources to meet its projected operating requirements for at least the next 12 months. 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 from the forward-looking statements that Catalyst makes, including, but not limited to, the risk that trials and studies may be delayed and may not have satisfactory outcomes, that potential adverse effects may arise from the testing or use of Catalyst's products, the risk that costs required to develop or manufacture Catalyst's products will be higher than anticipated, competition and other factors that affect our ability to successfully develop and commercialize our product candidates described in the "Risk Factors" section of the Company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the SEC. Catalyst does not assume any obligation to update any forward-looking statements, except as required by law.

Catalyst Biosciences, Inc. Consolidated Balance Sheets

(In thousands, except shares and per share amounts)

	December 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 10,264	\$ 29,096
Short-term investments	6,800	3,402
Restricted cash	19,468	33,794
Deposits	—	133
Accounts receivable	31	492
Prepaid and other current assets	958	1,781
Total current assets	37,521	68,698
Restricted cash, noncurrent	125	125
Property and equipment, net	444	698
Total assets	\$ 38,090	\$ 69,521
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 837	\$ 939

Accrued compensation	596	926
Other accrued liabilities	805	535
Deferred revenue, current portion	283	438
Deferred rent, current portion	41	19
Redeemable convertible notes	19,403	33,743
Derivative liability	—	1,156
Total current liabilities	21,965	37,756
Deferred revenue, noncurrent portion	47	292
Deferred rent, noncurrent portion	7	48
Total liabilities	22,019	38,096
Stockholders' equity:		
Preferred stock, \$0.001 par value, 5,000,000 shares and no shares authorized and outstanding at both December 31, 2016 and December 31, 2015	—	—
Common stock, \$0.001 par value, 100,000,000 shares authorized; 801,756 and 762,005 shares issued and outstanding at December 31, 2016 and December 31, 2015	1	1
Additional paid-in capital	164,053	162,460
Accumulated other comprehensive income (loss)	(1)	1
Accumulated deficit	(147,982)	(131,037)
Total stockholders' equity	16,071	31,425
Total liabilities and stockholders' equity	\$ 38,090	\$ 69,521

Catalyst Biosciences, Inc.
Consolidated Statements of Operations

(In thousands, except shares and per share amounts)

	Year Ended December 31,	
	2016	2015
Contract revenue	\$ 399	\$ 1,750
Operating expenses:		
Research and development	11,555	5,958
General and administrative	9,262	9,594
Total operating expenses	20,817	15,552
Loss from operations	(20,418)	(13,802)
Interest and other income, net	3,473	518
Interest expense	—	(1,478)
Net loss	\$ (16,945)	\$ (14,762)
Net loss per common share, basic and diluted	\$ (21.75)	\$ (49.99)
Shares used to compute net loss per common share, basic and diluted	779,166	295,272

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