Catalyst Biosciences Announces Change in Corporate Strategy

November 12, 2021

Reports Third Quarter 2021 Operating & Financial Results

Company to discontinue MarzAA development; focus on developing its complement portfolio

Management to host a call today at 8:30 am ET

SOUTH SAN FRANCISCO, Calif., Nov. 12, 2021 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ: CBIO) today announced a strategic decision to halt the clinical development of MarzAA, report data to date, and seek a buyer for its hemophilia assets. Catalyst plans to focus its resources on its complement therapeutics and protease medicines platform. The Company also reported its operating and financial results for the third quarter ended September 30, 2021.

"We have made a strategic decision to stop the clinical development of MarzAA (engineered FVIIa) and focus solely on our complement programs and protease medicines platform. Based on several factors including a recently updated feasibility assessment, we determined that we cannot continue to develop MarzAA through completion of the ongoing trials. Enrollment in our MarzAA clinical trials has been adversely impacted by several factors, including pandemic-related logistical challenges, competition for subjects, and increasing availability of prophylaxis therapy globally. Given these factors, it is no longer feasible for us to deliver topline data in 2022. We will report on the data obtained in the Crimson-1 trial to date showing that we have successfully treated bleeds with subcutaneous (SQ) MarzAA and have not observed any treatment-related adverse or thrombotic events," said Nassim Usman, Ph.D., chief executive of Catalyst Biosciences.

Dr. Usman continued: "We are exploring opportunities to license or sell our MarzAA and DalcA (engineered FIX) portfolios and will donate any standard-of-care to the centers where patients are enrolled. Halting development of MarzAA will allow us to reduce our burn rate by approximately 40% and focus our investment on our highly promising complement therapeutics and protease medicines platform. We want to thank our study subjects, clinical trial investigators and site staff, employees, and investors for their partnership and commitment to the MarzAA programs over the last several years."

"Candidates from our protease platform offer a differentiated approach to complement regulation by rapidly engaging and degrading high abundancy targets in a way antibodies and small molecule inhibitors cannot. We believe that investing in novel solutions for complement-mediated disease will open opportunities in multiple settings ranging from ultra-orphan to large markets with significant unmet needs, including nephrology, inflammation and ophthalmology. We will advance the clinical development of CB 4332, an SQ-dosed enhanced complement Factor I (CFI), as swiftly as possible and continue to generate development candidates from our protease platform that we will either license out or develop on our own. We believe that the complement therapeutics market holds tremendous potential and that investing our resources in these programs is the optimal strategy going forward," concluded Dr. Usman.

Complement Program Updates

- Presented positive preclinical data on CB 4332 at the International Conference on Complement Therapeutics (ICCT) in September 2021, indicating that CB 4332 has the potential to be an effective, longer-acting SQ therapy in CFI-deficient patients by replacing the underlying, deficient protease.
- Presented preclinical data on the ProTUNE™ platform at the International Conference on Complement Therapeutics (ICCT in September and the 5th Annual Complement-Based Drug Development Summit 2021 in October, demonstrating the potential for the platform to generate molecules for use in multiple complement-related indications and support advancing Catalyst's lead molecules towards a development candidate nomination in the Company's first targeted indication.
- Enrolled the first two CFI deficient subjects in the ConFIdence study, Catalyst's global natural history study designed to assess the clinical outcomes of patients with CFI deficiency and support the CB 4332 development program.

Expected Milestones

- Submit an IND for CB 4332.
- Announce a development candidate from Catalyst's ProTUNE™ platform that leverages the Company's knowledge of CFI.
- Complete transfer of CBIO supported activities to Biogen for CB 2782-PEG, the C3 degrader for the potential treatment of dry AMD.

Third Quarter 2021 Results and Financial Highlights:

- Cash, cash equivalents and, investments, as of September 30, 2021 were $64.5 million.
- Research and development expenses were $20.4 million and $12.2 million during the three months ended September 30, 2021 and 2020, respectively, an increase of approximately $8.1 million, or 66%. The increase was due primarily to an increase of $5.1 million in clinical manufacturing costs and an increase of $3.5 million in preclinical research costs, partially offset by a decrease of $0.5 million in personnel and facilities costs.

- General and administrative expenses were $4.9 million and $3.8 million during the three months ended September 30, 2021 and 2020, respectively, an increase of approximately $1.0 million, or 27%. This increase was due primarily to an increase of $0.6 million in professional services and $0.4 million in personnel-related costs.
- Interest and other income (expense), net was $0.0 million and $0.1 million during the three months ended September 30, 2021 and 2020, respectively, a decrease of $0.1 million. The decrease was primarily due to a decrease in interest income on investments.
- Net loss attributable to common stockholders for the three months ended September 30, 2021 was $25.2 million, or $(0.80) per basic and diluted share, compared with $16.0 million, or $(0.73) per basic and diluted share, for the prior year period.
- As of September 30, 2021, the Company had 31,392,618 shares of common stock outstanding.

Conference call
Company management will host a call today, Friday, November 12, 2021 at 8:30 am Eastern Time to discuss the changes to the corporate strategy and answer questions. Shareholders and other interested parties may participate in the conference call by dialing 877-425-9470 (in the U.S.) or 201-389-0878 (International) and entering passcode 13725012. The call also will be webcast live on the Events and Presentations page of Company's website.

About Catalyst Biosciences, the Protease Medicines company
Catalyst is a research and clinical development biopharmaceutical company focused on developing protease therapeutics to address unmet medical needs in disorders of the complement system. Proteases are natural regulators of this biological system. We engineer proteases to create improved or novel molecules to treat diseases that result from dysregulation of the complement cascade. Our complement pipeline consists of a preclinical C3-degrader program licensed to Biogen for dry age-related macular degeneration (dAMD), an improved Complement Factor I protease CB 4332 for SQ replacement therapy in patients with Complement Factor I (CFI) deficiency and proteases from our ProTUNE™ C3b/C4b degrader and ImmunoTUNE™ C3a/C5a degrader platforms designed to target specific disorders of the complement or inflammatory pathways.

Forward-Looking Statements
This press release contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include, without limitation, those regarding swiftly moving forward with clinical development of CB 4332, the continued generation of candidates from the protease platform that will either be licensed or self-developed, reduction of burn rate, the potential that complement will open opportunities in multiple disease settings, submitting an IND for CB 4332, announcing a development candidate from our ProTUNE™ platform that leverages our knowledge of CFI, and successfully completing the transfer of CBIO supported activities to Biogen for CB 2782-PEG, as well as statements about the benefits of our protease engineering platform. 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 clinical trials and preclinical studies may be delayed as a result of COVID-19, competitive products, and other factors, that Biogen could terminate our agreement for the development of CB 2782-PEG, that the Company's complement degraders are not yet in human clinical trials and will require additional manufacturing validation and preclinical testing before entering human clinical trials, that the Company may need to raise additional capital, and other risks described in the "Risk Factors" section of the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 4, 2021, the Quarterly Report on Form 10-Q to be filed with the SEC on November 12, 2021, and in other filings filed from time to time with the SEC. 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)

	September 30, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 59,157	$ 30,360
Short-term investments	5,371	48,994
Accounts receivable	1,114	3,313
Prepaid and other current assets	8,322	6,843
Total current assets	73,964	89,510
Long-term investments	—	2,543
Other assets, noncurrent	869	528
Right-of-use assets	2,613	1,832
Property and equipment, net	1,091	433
Total assets	$ 78,537	$ 94,846
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,862	$ 5,931

Accrued compensation	2,548	2,476
Deferred revenue	853	1,983
Other accrued liabilities	8,144	6,743
Operating lease liability	1,844	663
Total current liabilities	17,251	17,796
Operating lease liability, noncurrent	550	981
Total liabilities	17,801	18,777
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; 31,392,618 and 22,097,820 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	31	22
Additional paid-in capital	443,069	390,803
Accumulated other comprehensive income	1	5
Accumulated deficit	(382,365)	(314,761)
Total stockholders' equity	60,736	76,069
Total liabilities and stockholders' equity	$ 78,537	$ 94,846

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,	
	2021	**2020**	**2021**	**2020**
Revenue:				
License	$ —	$ 32	$ —	$ 15,100
Collaboration	2,299	861	4,898	3,817
License and collaboration revenue	2,299	893	4,898	18,917
Operating expenses:				
Cost of license	—	32	—	3,102
Cost of collaboration	2,307	879	4,926	4,030
Research and development	20,352	12,249	52,754	38,419
General and administrative	4,869	3,833	14,799	11,895
Total operating expenses	27,528	16,993	72,479	57,446
Loss from operations	(25,229)	(16,100)	(67,581)	(38,529)
Interest and other income (expense), net	(9)	67	(23)	1,195
Net loss	$ (25,238)	$ (16,033)	$ (67,604)	$ (37,334)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.80)	$ (0.73)	$ (2.23)	$ (2.05)
Shares used to compute net loss per share attributable to common stockholders, basic and diluted	31,379,755	22,072,243	30,382,231	18,199,575