



Cytokinetics Reports Second Quarter 2020 Financial Results

August 6, 2020 8:00 PM EDT

Top-line Results from GALACTIC-HF Expected in Q4 2020

Licensing Collaboration, Royalty Monetizations and Financing Provide Additional Capital to Support Commercial Development and Pipeline Expansion; Company Expects to End 2020 With More Than \$500 Million Cash

SOUTH SAN FRANCISCO, Calif., Aug. 06, 2020 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) reported financial results for the second quarter of 2020. Net loss for the second quarter was \$40.8 million, or \$0.68 per share, compared to net loss for the second quarter of 2019 of \$32.1 million, or \$0.56 per share. Cash, cash equivalents and investments totaled \$213.1 million at June 30, 2020.

After the quarter, Cytokinetics executed a series of transactions which contribute up to \$250 million in cash plus committed cash, as well as up to \$200 million in potential milestone payments plus royalties. Also, after the quarter, the company raised \$189 million through a public offering of common stock. Cytokinetics expects to end 2020 with more than \$500 million in cash plus committed cash, subject to closing conditions.

"Despite challenges related to the COVID-19 pandemic, Cytokinetics achieved significant progress against our key objectives during the second quarter," said Robert I. Blum, Cytokinetics' President and Chief Executive Office. "After suspending enrollment in METEORIC-HF and REDWOOD-HCM earlier in the quarter, we resumed screening and enrollment in both trials during June. In addition, GALACTIC-HF continued toward conclusion on schedule with top-line results expected in the fourth quarter. Moreover, our recent licensing collaboration, royalty monetization deals and follow-on offering position the company operationally and financially to expand development activities and execute our Vision 2025."

Recent Highlights

Cardiac Muscle Programs

omecamtiv mecarbil (cardiac myosin activator)

- Received Fast Track designation for ***omecamtiv mecarbil*** for the potential treatment of chronic heart failure with reduced ejection fraction (HFrEF).
- Continued conduct of and initiated closeout activities for GALACTIC-HF (**Global Approach to Lowering Adverse Cardiac Outcomes Through Improving Contractility in Heart Failure**), the Phase 3 cardiovascular outcomes clinical trial of ***omecamtiv mecarbil***. We expect top-line results in Q4 2020. GALACTIC-HF is being conducted by Amgen in collaboration with Cytokinetics.
- Continued conduct of METEORIC-HF (**Multicenter Exercise Tolerance Evaluation of *omecamtiv mecarbil* Related to Increased Contractility in Heart Failure**), the second Phase 3 trial of ***omecamtiv mecarbil***. After suspending enrollment in METEORIC-HF due to the COVID-19 pandemic earlier this year, we resumed enrollment in June. We expect enrollment to be completed in early 2021. METEORIC-HF is being conducted by Cytokinetics in collaboration with Amgen.
- Collaborated with Amgen and Servier on preparations for a potential Marketing Application dossier for ***omecamtiv mecarbil*** and prepared for possible meetings with regulatory authorities as may be requested to discuss Phase 3 trial results and potential Marketing Applications.
- Continued to conduct commercial readiness activities in collaboration with Amgen, in preparation for the commercialization of ***omecamtiv mecarbil***, including market research related to product branding elements, potential positioning, physician preferences and potential customer accounts.
- Continued joint disease state education with Amgen to educate the heart failure community on the unmet needs of heart failure patients and the role of cardiac contractility related to cardiac performance in HFrEF.

- Collaborated with providers and healthcare systems to generate health economics and outcomes research related to the healthcare costs associated with the treatment of heart failure patients.
- Conducted analyses related to the United States heart failure institutional care market segment, including potential target account assessment and prioritization for planned commercialization.

AMG 594 (cardiac troponin activator)

- The Phase 1 study of AMG 594 is now complete with data analyses ongoing. Amgen and Cytokinetics are discussing potential next steps in the development program.
- Conducted market research relating to potential indications to inform Phase 2 trial planning.

CK-3773274 (CK-274, cardiac myosin inhibitor)

- Continued conduct of REDWOOD-HCM (**R**andomized **E**valuation of **D**osing **W**ith CK-274 in **O**bststructive **O**utflow **D**isease in **H**CM), the Phase 2 clinical trial designed to determine the safety and tolerability of CK-274 in patients with obstructive hypertrophic cardiomyopathy (HCM). After suspending enrollment in REDWOOD-HCM due to the COVID-19 pandemic earlier this year, we resumed enrollment in June. We expect data from the first cohort of patients in REDWOOD-HCM, which will inform progression of the trial to the second cohort, to be available by the end of 2020.

CK-271 (CK-271, second cardiac myosin inhibitor)

- Prepared for the start of a Phase 1 study of CK-271 which is expected to begin in Q3 2020.

Skeletal Muscle Program

reldesemtiv (next-generation fast skeletal muscle troponin activator (FSTA))

- Obtained advice from the European Medicines Agency (EMA) through Protocol Assistance related to the design of a potential Phase 3 clinical trial of *reldesemtiv* in patients with ALS.
- Convened meetings with clinical experts, ALS patient advocates and health technology assessment organizations to obtain feedback on endpoints and other matters relating to the design of the trial.

Pre-Clinical Development and Ongoing Research

- Continued pre-clinical development of CK-3762601 (CK-601), a next-generation FSTA. We expect to continue the conduct of IND-enabling studies of CK-601 in 2020.
- Continued research in collaboration with Astellas directed to the discovery of next-generation skeletal muscle activators.
- Continued independent research activities directed to our other muscle biology research programs.

Corporate

- Participated in the launch of Kainomyx, Inc., a new biopharmaceutical company focused on the discovery and development of small molecule therapeutics for the treatment of parasitic

diseases.

- Executed a series of transactions in July with RTW Investments, LP, and Ji Xing Pharmaceuticals Limited related to CK-274 whereby Cytokinetics will receive a combination of committed capital, funding and sale proceeds of up to \$250 million and is eligible to receive up to \$200 million in milestone payments plus royalties on future sales of CK-274 in certain Asian countries.
- Raised \$189 million in net proceeds, after deducting underwriting discounts and commissions, from an underwritten public offering in July of 8,385,417 shares of common stock including the underwriter's exercise of their overallotment option.
- Amended our agreement with Astellas, whereby Cytokinetics obtained exclusive rights for the development and commercialization of *reldesemtiv*, CK-601 and other fast skeletal regulatory activator (FSRA) compounds. Astellas agreed to pay for certain costs associated with the conduct of a potential Phase 3 clinical trial of *reldesemtiv* in ALS in exchange for a low- to mid-single digit royalty on sales of *reldesemtiv* in ALS. Astellas and Cytokinetics also extended the joint research program through 2020.
- Announced the continuation of our partnership with The ALS Association in the fight against ALS.
- Supported the Patient Focused Drug Development Meeting hosted by the HCMA to shed light on the burden of disease and challenges faced by patients with HCM.

Financials

Revenues for the three and six months ended June 30, 2020 were \$3.6 million and \$7.4 million, respectively, compared to \$7.1 million and \$15.6 million for the corresponding periods in 2019. The decrease in revenues for the three and six month ended June 30, 2020 was due primarily to the completion of FORTITUDE-ALS in 2019.

Research and development expenses for the three and six months ended June 30, 2020 decreased to \$21.8 million and \$43.5 million, respectively, compared to \$24.0 million and \$47.6 million for the same periods in 2019, respectively, due to decreased spending primarily related to the completion of FORTITUDE-ALS in 2019 offset by an increase in spending for REDWOOD-HCM.

General and administrative expenses for the three and six months ended June 30, 2020 increased to \$14.2 million and \$26.6 million from \$9.8 million and \$19.3 million in 2019 due primarily to an increase in personnel related costs including stock-based compensation and higher outside spending for commercial readiness.

Financial Guidance

The company also updated financial guidance for 2020. The company still anticipates cash revenue will be in the range of \$18 to \$22 million and operating expenses will be in the range of \$120 to \$130 million. Guidance for net cash utilization has been narrowed to the range of \$110 to \$115 million for 2020.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's second quarter 2020 results via a webcast and conference call today at 4:30 PM Eastern Time. The webcast can be accessed through the Investors & Media section of the Cytokinetics website at www.cytokinetics.com. The live audio of the conference call can also be accessed by telephone by dialing either (866) 999-CYTK (2985) (United States and Canada) or +1 (706) 679-3078 (international) and typing in the passcode 5588711.

An archived replay of the webcast will be available via Cytokinetics' website until August 20, 2020. The replay will also be available via telephone by dialing (855) 859-2056 (United States and Canada) or +1 (404) 537-3406 (international) and typing in the passcode 5588711 from August 6, 2020 at 7:30 PM Eastern Time until August 20, 2020.

About Cytokinetics

Cytokinetics is a late-stage biopharmaceutical company focused on discovering, developing and commercializing first-in-class muscle activators and next-in-class muscle inhibitors as potential treatments for debilitating diseases in which muscle performance is compromised and/or declining. As a leader in muscle biology and the mechanics of muscle performance, the company is developing small molecule drug candidates specifically engineered to impact muscle function and contractility. Cytokinetics is collaborating with Amgen Inc. (Amgen) to develop *omecamtiv mecarbil*, a novel cardiac muscle activator. *Omecamtiv mecarbil* is the subject of an international clinical trials program in patients with heart failure including GALACTIC-HF and METEORIC-HF. Amgen holds an exclusive worldwide license to develop and commercialize *omecamtiv mecarbil* with a sublicense held by Servier for commercialization in Europe and certain other countries. Cytokinetics is developing *reldesemtiv*, a fast skeletal muscle troponin activator (FSTA) for the potential treatment of ALS and other neuromuscular indications following conduct of FORTITUDE-ALS and other Phase 2 clinical trials. The company is considering potential advancement of *reldesemtiv* to Phase 3. Cytokinetics is collaborating with Astellas Pharma Inc. (Astellas) to research, develop and commercialize other novel mechanism skeletal sarcomere activators (excluding FSTAs). Licenses

held by Amgen and Astellas are subject to specified co-development and co-commercialization rights of Cytokinetics. Cytokinetics is also developing CK-274, a novel cardiac myosin inhibitor that company scientists discovered independent of its collaborations, for the potential treatment of hypertrophic cardiomyopathies (HCM). Cytokinetics has granted Ji Xing Pharmaceuticals Limited an exclusive license to develop and commercialize CK-274 in China and Taiwan, in accordance with Cytokinetics' planned global registration programs. Cytokinetics is conducting REDWOOD-HCM, a Phase 2 clinical trial of CK-274 in patients with obstructive HCM. Cytokinetics continues its over 20-year history of pioneering innovation in muscle biology and related pharmacology focused to diseases of muscle dysfunction and conditions of muscle weakness.

For additional information about Cytokinetics, visit www.cytokinetics.com and follow us on [Twitter](#), [LinkedIn](#), [Facebook](#) and [YouTube](#).

Forward-Looking Statements

This press release contains forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995 (the "Act"). Cytokinetics claims the protection of the Act's Safe Harbor for forward-looking statements. Examples of such statements include, but are not limited to, statements related to the potential impact of the COVID-19 pandemic on our research and development activities and business operations, including our anticipated cash expenditures during the 2020 calendar year, statements relating to Cytokinetics' and its partners' research and development and commercial readiness activities, including the initiation, conduct, design, enrollment, progress, continuation, completion, timing and results of clinical trials, including the completion of GALACTIC-HF, Cytokinetics' ability to ensure commercial readiness and develop co-promotion plans in collaboration with Amgen; the significance and utility of pre-clinical study and clinical trial results; planned interactions with regulatory authorities and the outcomes of such interactions, including discussions in preparation for a potential Phase 3 clinical trial and registration program for *reldesemtiv* in patients with ALS; the expected timing of events and milestones; and the properties and potential benefits of Cytokinetics' drug candidates. Such statements are based on management's current expectations, but actual results may differ materially due to various risks and uncertainties, including, but not limited to Cytokinetics' need for additional funding and such additional funding may not be available on acceptable terms, if at all; potential difficulties or delays in the development, testing, regulatory approvals for trial commencement, progression or product sale or manufacturing, or production of Cytokinetics' drug candidates that could slow or prevent clinical development or product approval; patient enrollment for or conduct of clinical trials may be difficult or delayed; the FDA or foreign regulatory agencies may delay or limit Cytokinetics' or its partners' ability to conduct clinical trials; Amgen's decisions with respect to the design, initiation, conduct, timing and continuation of development activities for *omecamtiv mecarbil* and AMG 594; Cytokinetics may incur unanticipated research and development and other costs; standards of care may change, rendering Cytokinetics' drug candidates obsolete; and competitive products or alternative therapies may be developed by others for the treatment of indications Cytokinetics' drug candidates and potential drug candidates may target. For further information regarding these and other risks related to Cytokinetics' business, investors should consult Cytokinetics' filings with the Securities and Exchange Commission. Forward-looking statements are not guarantees of future performance, and Cytokinetics' actual results of operations, financial condition and liquidity, and the development of the industry in which it operates, may differ materially from the forward-looking statements contained in this press release. Any forward-looking statements that Cytokinetics makes in this press release speak only as of the date of this press release. Cytokinetics assumes no obligation to update its forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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Cytokinetics, Incorporated Condensed Consolidated Balance Sheets (in thousands)

	<u>June 30, 2020</u>	<u>December 31, 2019</u>
	<u>(unaudited)</u>	
ASSETS		
Current assets:		
Cash and short term investments	\$ 213,063	\$ 225,112
Other current assets	5,891	8,640
Total current assets	<u>218,954</u>	<u>233,752</u>
Long-term investments	—	42,650
Property and equipment, net	5,611	4,530
Operating lease right-of-use assets and other assets	7,930	8,882
Total assets	<u>\$ 232,495</u>	<u>\$ 289,814</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 16,608	\$ 20,283
Short-term lease liability	5,075	4,616
Other current liabilities	1,013	1,124
Total current liabilities	<u>22,696</u>	<u>26,023</u>
Term loan, net	45,631	45,052
Convertible notes, net	86,743	84,205
Liability related to the sale of future royalties, net	154,914	143,276
Long-term lease liability	591	2,195
Total liabilities	<u>310,575</u>	<u>300,751</u>

Commitments and contingencies

Stockholders' deficit:

Common stock	60	59
Additional paid-in capital	865,724	853,341
Accumulated other comprehensive income	1,337	679
Accumulated deficit	<u>(945,201)</u>	<u>(865,016)</u>
Total stockholders' deficit	<u>(78,080)</u>	<u>(10,937)</u>
Total liabilities and stockholders' deficit	<u>\$ 232,495</u>	<u>\$ 289,814</u>

Cytokinetics, Incorporated
Condensed Consolidated Statements of Operations
(in thousands except per share data)
(unaudited)

	<u>Three Months Ended</u>		<u>Six Months Ended</u>	
	<u>June 30, 2020</u>	<u>June 30, 2019</u>	<u>June 30, 2020</u>	<u>June 30, 2019</u>
Revenues:				
Research and development revenues	\$ 3,593	\$ 7,137	\$ 7,418	\$ 15,601
Total revenues	<u>3,593</u>	<u>7,137</u>	<u>7,418</u>	<u>15,601</u>
Operating expenses:				
Research and development	21,790	24,017	43,528	47,562
General and administrative	14,161	9,836	26,610	19,273
Total operating expenses	<u>35,951</u>	<u>33,853</u>	<u>70,138</u>	<u>66,835</u>
Operating loss	(32,358)	(26,716)	(62,720)	(51,234)
Interest expense	(3,892)	(1,377)	(7,969)	(2,547)
Non-cash interest expense on liability related to the sale of future royalties	(5,912)	(5,064)	(11,601)	(9,883)
Interest and other income	1,382	1,044	2,105	2,185
Net loss	<u>\$ (40,780)</u>	<u>\$ (32,113)</u>	<u>\$ (80,185)</u>	<u>\$ (61,479)</u>
Net loss per share — basic and diluted	<u>\$ (0.68)</u>	<u>\$ (0.56)</u>	<u>\$ (1.35)</u>	<u>\$ (1.09)</u>
Weighted-average number of shares used in computing net loss per share — basic and diluted	<u>59,605</u>	<u>57,648</u>	<u>59,438</u>	<u>56,242</u>



Source: Cytokinetics, Incorporated