Cytokinetics Reports Third Quarter 2020 Financial Results

November 4, 2020 9:00 PM EST

Topline Results From GALACTIC-HF Show Trial Met Primary Composite Endpoint of Reduction in Cardiovascular Death or Heart Failure Events; Trial Did Not Meet Secondary Endpoint of Reduction in Cardiovascular Death

Primary results from GALACTIC-HF to be presented as Late Breaking Clinical Trial Session at the American Heart Association Scientific Sessions 2020 on November 13, 2020

Enrollment Completed in Cohort 1 of REDWOOD-HCM

SOUTH SAN FRANCISCO, Calif., Nov. 04, 2020 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) reported financial results for the third quarter of 2020. Net loss for the third quarter was $3.2 million, or $0.05 per share, compared to net loss for the third quarter of 2019 of $29.6 million, or $0.50 per share. Cash, cash equivalents and investments totaled $451.2 million at September 30, 2020 and does not include $85 million expected upon the closing of RTW Investments' purchase of Cytokinetics' royalty rights on the future sales of *mavacamten*.

"We were pleased to recently announce positive topline results in GALACTIC-HF which demonstrated a reduction in the primary efficacy outcome endpoint with *omecamtiv mecarbil*." said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "We look forward to the presentation of the primary results at the AHA Scientific Sessions, including pre-specified subgroup analyses which will elaborate on patients that had differential effects with our cardiac myosin activator. During the third quarter, we continued to make progress on our pipeline, highlighted by the advancement of CK-274 in REDWOOD-HCM and our advancing a second cardiac myosin inhibitor into clinical development. With a strong balance sheet, fortified by business development and financing deals completed in July, we are well positioned to continue funding the progression of our muscle-directed drug candidates in clinical trials."

Recent Highlights

Cardiac Muscle Programs

omecamtiv mecarbil (cardiac myosin activator)

- Completed conduct of closeout activities for GALACTIC-HF (**G**lobal **A**pproach to **L**owering **A**dverse **C**ardiac Outcomes **T**hrough **I**mproving **C**ontractility in **H**eart **F**ailure), the Phase 3 cardiovascular outcomes clinical trial of *omecamtiv mecarbil*. Topline results from the trial were recently announced showing that treatment with *omecamtiv mecarbil* achieved the primary composite efficacy endpoint and demonstrated a statistically significant effect to reduce in cardiovascular (CV) death or heart failure events (heart failure hospitalization and other urgent treatment for heart failure), compared to placebo in patients treated with standard of care (HR: 0.92; 95% CI: 0.86, 0.99, p=0.0252). No reduction in the secondary endpoint of CV death was observed. Adverse events, including major ischemic cardiac events, were balanced between treatment arms.

- Primary results from GALACTIC-HF will be presented at the American Heart Association (AHA) Scientific Sessions 2020, as part of a virtual Late Breaking Clinical Trial session on Friday, November 13, 2020 from 10:35-10.45 a.m. CDT.

- Reviewing prespecified analyses and supplemental analyses of results of GALACTIC-HF in collaboration with Amgen. Discussions ongoing with Amgen on potential next steps.

- Continued conduct of METEORIC-HF (**M**ulticenter **E**xercise **T**olerance **E**valuation of ***O**mecamtiv Mecarbil* **R**elated to **I**ncreased **C**ontractility in **H**eart **F**ailure), the second Phase 3 trial of *omecamtiv mecarbil*. We expect enrollment to be completed in 1H 2021. METEORIC-HF is being conducted by Cytokinetics in collaboration with Amgen.

AMG 594 (cardiac troponin activator)

- Convened advisory board of consultants to discuss potential indications to inform Phase 2 trial planning. Continued discussions of potential next steps in the development program with

Amgen.

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**bstructive **O**utflow **D**isease in **HCM)**, the Phase 2 clinical trial designed to determine the safety and tolerability of CK-274 in patients with obstructive hypertrophic cardiomyopathy (HCM). Recently completed enrollment of first cohort of patients in REDWOOD-HCM, summary data from which will inform progression to the second cohort of the trial, expected by the end of 2020.

- Presented preclinical data at the American Association of Pharmaceutical Scientists (AAPS) 2020 PharmSci 360 showing that CK-274 demonstrated desirable pharmacokinetics *in vivo*, supporting the intended pharmacokinetic profile of once-daily oral dosing in humans and steady state plasma concentrations achieved within two weeks of initiation of dosing.

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

- Initiated a Phase 1 study of CK-271, our second cardiac myosin inhibitor. We expect to complete the study by the end of 2020.

Skeletal Muscle Program

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

- Convened meetings with ALS community stakeholders to obtain feedback on endpoints and other matters relating to the design of a potential Phase 3 trial of *reldesemtiv* in patients with ALS.

- Conducted readiness activities in preparation for the start of a potential Phase 3 clinical trial of *reldesemtiv* in patients with ALS.

Pre-Clinical Development and Ongoing Research

- Continued pre-clinical development of CK-3762601 (CK-601), a next-generation FSTA. We expect to continue conduct of IND-enabling studies of CK-601 in 2020.

- Published a manuscript on pre-clinical data in the *Journal of Cachexia, Sarcopenia and Muscle*, showing the fast skeletal muscle troponin activator CK-2066260 (CK-260) increases submaximal force in conditions with muscle weakness *in vitro*.

- 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

- Executed a series of transactions with affiliates of 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.

- Convened a virtual investor & analyst day to provide updates on the company's advancing cardiovascular pipeline and strategies to build a commercial franchise.

- 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.

- Provided $1 million grant and entered four-year partnership with the HCM Registry (HCMR), a global registry of patients with hypertrophic cardiomyopathy focused on improving predictive measures of risk for complications and identifying biomarkers associated with adverse clinical outcomes.

- Renewed our partnership with Cure SMA to increase education, awareness, public policy and fundraising for spinal muscular atrophy (SMA).

- Announced a call for proposals for the third annual Cytokinetics Communications Fellowship Grant program. The program provides $100,000 in grants to five selected patient advocacy organizations serving the ALS, heart failure, HCM, or SMA communities, and is intended to support increased capacity in communications, awareness building and community engagement.

Financials

Revenues for the three and nine months ended September 30, 2020 were $41.7 million and $49.1 million, respectively, compared to $6.1 million and $21.7 million for the corresponding periods in 2019. The increase in revenues for the three and nine month ended September 30, 2020 was primarily due to $36.5 million of license revenue recognized in the third quarter 2020 for the RTW transactions.

Research and development expenses for the three and nine months ended September 30, 2020 increased to $24.2 million and $67.7 million, respectively, compared to $20.2 million and $67.8 million for the same periods in 2019, respectively, due to increased spending on readiness for *reldesemtiv* and an increase in spending for our cardiac myosin inhibitor programs.

General and administrative expenses for the three and nine months ended September 30, 2020 increased to $12.3 million and $38.9 million from $9.8 million and $29.0 million in 2019 due primarily to an increase in personnel related costs including stock-based compensation and higher outside spending for commercial readiness.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's third 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 3979672.

An archived replay of the webcast will be available via Cytokinetics' website until November 18, 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 3979672 from November 4, 2020 at 7:30 PM Eastern Time until November 18, 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, of which topline results were recently reported, and METEORIC-HF, which is ongoing. 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 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 enrollment in METEORIC-HF and the availability of results from the first cohort of patients in REDWOOD-HCM, 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, including the results of GALACTIC-HF in respect of *omecamtiv mecarbil*; planned interactions with regulatory authorities in connection to any of Cytokinetics' drug candidates 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 and the prospects for FDA and other regulatory agency approval of *omecamtiv mecarbil*; the ability of Cytokinetics to fulfill applicable contractual conditions and receive a combination of committed capital, funding and sale proceeds of up to $250 million or any portion of such amount from affiliates of RTW Investments, LP, and/or Ji Xing Pharmaceuticals Limited; the ability of Cytokinetics to earn milestone payments and royalties from Ji Xing Pharmaceuticals Limited in connection to the development and commercialization of CK-274 in certain Asian countries; 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)

	September 30, 2020	December 31, 2019
	(unaudited)	
ASSETS		
Current assets:		
Cash and short term investments	$ 410,264	$ 225,112
Other current assets	8,148	8,640
Total current assets	418,412	233,752
Long-term investments	40,958	42,650
Property and equipment, net	7,667	4,530
Operating lease right-of-use assets and other assets	7,075	8,882
Total assets	$ 474,112	$ 289,814
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued liabilities	$ 21,224	$ 20,283
Short-term lease liability	3,943	4,616
Other current liabilities	2,406	1,124
Total current liabilities	27,573	26,023
Term loan, net	45,920	45,052
Convertible notes, net	88,102	84,205
Liability related to the sale of future royalties, net	160,395	143,276
Long-term lease and other non-current liabilities	2,517	2,195

Total liabilities	324,507	300,751
Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock	70	59
Additional paid-in capital	1,096,953	853,341
Accumulated other comprehensive income	958	679
Accumulated deficit	(948,376)	(865,016)
Total stockholders' equity (deficit)	149,605	(10,937)
Total liabilities and stockholders' equity (deficit)	$ 474,112	$ 289,814

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

	Three Months Ended		Nine Months Ended	
	September 30, 2020	**September 30, 2019**	**September 30, 2020**	**September 30, 2019**
Revenues:				
Research and development revenues	$ 5,187	$ 6,055	$ 12,605	$ 21,656
License revenues	36,501	—	36,501	—
Total revenues	41,688	6,055	49,106	21,656
Operating expenses:				
Research and development	24,202	20,229	67,730	67,791
General and administrative	12,302	9,753	38,912	29,026
Total operating expenses	36,504	29,982	106,642	96,817
Operating income (loss)	5,184	(23,927)	(57,536)	(75,161)
Interest expense	(3,976)	(1,345)	(11,945)	(3,892)
Non-cash interest expense on liability related to the sale of future royalties	(5,461)	(5,321)	(17,062)	(15,204)
Interest and other income	1,078	1,020	3,183	3,205
Net loss	$ (3,175)	$ (29,573)	$ (83,360)	$ (91,052)
Net loss per share — basic and diluted	$ (0.05)	$ (0.50)	$ (1.34)	$ (1.60)
Weighted-average number of shares used in computing net loss per share — basic and diluted	68,279	58,640	62,406	57,050

Cytokinetics

Source: Cytokinetics, Incorporated