Cytokinetics Reports Fourth Quarter 2019 Financial Results

March 3, 2020 9:00 PM EST

GALACTIC-HF Continuing Following Second Planned Interim Analysis;
Top-line Results for GALACTIC-HF Expected in Q4 2020

Company Provides 2020 Financial Guidance;
More Than Two Years of Cash Runway Based on 2020 Guidance

SOUTH SAN FRANCISCO, Calif., March 03, 2020 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq:CYTK) reported financial results for the fourth quarter and full year 2019. Net loss for the fourth quarter was $30.6 million or $0.52 per share and net loss for the year 2019 was $121.7 million, or $2.11 per share. Net loss for the fourth quarter of 2018 was $26.5 million, or $0.48 per share and net loss for the year 2018 was $106.3 million, or $1.95 per share. Cash, cash equivalents and investments totaled $267.7 million at December 31, 2019.

"We had a productive fourth quarter of 2019 which positions us well to deliver against our Vision 2025 that we recently announced pointing towards commercialization of our novel drug candidates, doubling our development pipeline and expanding the breadth of our muscle biology focused research," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "In 2020, we look forward to reaching several key milestones, including sharing top-line results of GALACTIC-HF and completing enrollment in METEORIC-HF, both alongside continued preparations for the potential commercialization of *omecamtiv mecarbil* and the development of a co-promotion plan in collaboration with Amgen. We are also advancing our pipeline of cardiac myosin inhibitors, including CK-274 in REDWOOD-HCM and CK-271 which we expect to enter Phase 1 soon. We began 2020 with a strong balance sheet enabling our continued execution on key objectives that we believe will empower us to deliver on the promise of our science for patients."

Recent Highlights

Cardiac Muscle Programs

omecamtiv mecarbil (cardiac myosin activator)

- Continued conduct of 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*, following the recently completed second and final planned interim analysis, which considered pre-specified criteria for futility and superiority. We expect top-line results in Q4 2020.

- Announced the publication of a manuscript relating to the design of GALACTIC-HF in the *Journal of American College of Cardiology: Heart Failure (JACC: HF).*

- Expect presentation of baseline characteristics from GALACTIC-HF at the American College of Cardiology meeting in March 2020.

- 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 to complete enrollment in METEORIC-HF in 2020.

- Presented results from COSMIC-HF (**C**hronic **O**ral **S**tudy of **M**yosin Activation to **I**ncrease **C**ontractility in **H**eart **F**ailure) at the American Heart Association's Scientific Sessions in Philadelphia. In this post-hoc analysis, patients with heart failure with reduced ejection fraction (HFrEF) treated with *omecamtiv mecarbil*, in addition to previously reported improvements in cardiac contractility measures (including systolic function, or pumping action of the heart), measures of diastolic function were not different from placebo and, for some measures, trended toward improvement.

AMG 594 (cardiac troponin activator)

- Continued conduct of the Phase 1 study of AMG 594 to assess its safety, tolerability, pharmacokinetics and potential to increase cardiac function in healthy volunteers. AMG 594 is

a novel, selective, oral, small molecule cardiac troponin activator, discovered under our joint research program with Amgen. This Phase 1 study is being conducted by Amgen in collaboration with Cytokinetics. We expect to complete the SAD/MAD cohorts of the study in 2H 2020.

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

- Prepared for and started 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). REDWOOD-HCM started in Q1 2020 and will continue through 2020. We expect data from the first cohort of patients enrolled in REDWOOD-HCM to be available in 2H 2020.

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

- We expect to file an IND and begin a Phase 1 study of CK-271 in 1H 2020.

Skeletal Muscle Program

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

- Presented subgroup analyses of FORTITUDE-ALS (**F**unctional **O**utcomes in a **R**andomized **T**rial of **I**nvestigational **T**reatment with CK-2127107 to **U**nderstand **D**ecline in **E**ndpoints – in **ALS**), the Phase 2 clinical trial of *reldesemtiv* in patients with amyotrophic lateral sclerosis (ALS) at the 30th International Symposium on ALS/MND in Perth, Australia, showing that the effect of *reldesemtiv* on patients with ALS was similar whether or not patients were also receiving *edaravone* and/or *riluzole*.

- Received Orphan Designation for *reldesemtiv* for the potential treatment of ALS by the U.S. Food and Drug Administration (FDA).

- Held regulatory interactions and conducted feasibility and other planning activities in preparation for the potential advancement of *reldesemtiv* to a Phase 3 trial in patients with ALS. We expect to continue to engage with regulatory and reimbursement authorities in 2020 in preparation for the potential trial.

Pre-Clinical Development and Ongoing Research

- Continued pre-clinical development of CK-3762601 (CK-601), a next-generation FSTA, under our collaboration with Astellas. 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

- We raised $120.5 million capital through a convertible note offering in November 2019. The convertible note carries a 4% coupon rate, a 27.5% convert premium, and matures in November 2026.

Financials

Revenues for the three and twelve months ended December 31, 2019 were $5.2 million and $26.9 million, respectively, compared to $9.4 million and $31.5 million for the corresponding periods in 2018. The decrease in revenues for the three and twelve months ended December 31, 2019 was due primarily to the winding down of FORTITUDE-ALS in addition to a lack of license revenue in 2019. License revenues in the fourth quarter and twelve months of 2018 were related to the Phase 2 trial of *reldesemtiv* in spinal muscular atrophy completed in 2018.

Research and development expenses for the three and twelve months ended December 31, 2019 were $18.3 million and $86.1 million, respectively compared to $23.3 million and $89.1 million for the same periods in 2018, respectively. The changes were primarily due to reduced spending for *reldesemtiv* as well as *tirasemtiv* following suspension of development of *tirasemtiv* in late 2017 offset by increased spending related to METEORIC-HF and the development of CK-274.

General and administrative expenses for the three and twelve months ended December 31, 2019 increased to $10.6 million and $39.6 million, respectively, from $7.6 million and $31.3 million for the same periods in 2018, respectively, due primarily to an increase in outside legal counsel and personnel related costs including stock-based compensation.

2020 Financial Guidance

The company also announced financial guidance for 2020. The company anticipates cash revenue will be in the range of $18 to $22 million, operating expenses will be in the range of $120 to $130 million, and net cash utilization will be approximately $105 to $115 million.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's fourth quarter 2019 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 (706) 679-3078 (international) and typing in the passcode 8698309.

An archived replay of the webcast will be available via Cytokinetics' website until March 17, 2020. The replay will also be available via telephone by dialing (855) 859-2056 (United States and Canada) or (404) 537-3406 (international) and typing in the passcode 8698309 from March 3, 2020 at 7:30 PM Eastern Time until March 17, 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 collaborating with Astellas Pharma Inc. (Astellas) to develop *reldesemtiv*, a fast skeletal muscle troponin activator (FSTA). Astellas currently holds an exclusive worldwide license to develop and commercialize *reldesemtiv*. 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 is conducting REDWOOD-HCM, a Phase 2 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, 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 and Astellas' decisions with respect to the design, initiation, conduct, timing and continuation of development activities for *omecamtiv mecarbil* and *reldesemtiv*, respectively; 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 Statements of Operations
(in thousands except per share data)
(unaudited)

	Three Months Ended December 31,		Years Ended December 31,	
	2019	2018	2019	2018
Revenues:				
Research and development revenues	$ 5,212	$ 9,377	$ 26,868	$ 26,368
License revenues	—	—	—	5,133
Total revenues	5,212	9,377	26,868	31,501
Operating expenses:				
Research and development	18,334	23,278	86,125	89,135
General and administrative	10,584	7,558	39,610	31,282
Total operating expenses	28,918	30,836	125,735	120,417
Operating loss	(23,706)	(21,459)	(98,867)	(88,916)
Interest expense	(2,731)	(1,170)	(6,623)	(3,797)
Non-cash interest expense on liability related to sale of future royalties	(5,533)	(4,740)	(20,737)	(17,767)
Interest and other income, net	1,330	900	4,535	4,191
Net loss before income taxes	(30,640)	(26,469)	(121,692)	(106,289)
Income tax benefit	—	—	—	—
Net loss	$ (30,640)	$ (26,469)	$ (121,692)	$ (106,289)
Net loss per share — basic and diluted	$ (0.52)	$ (0.48)	$ (2.11)	$ (1.95)
Weighted-average shares in net loss per share — basic and diluted	59,133	54,689	57,575	54,420

Cytokinetics, Incorporated
Condensed Consolidated Balance Sheets
(in thousands)

	December 31, 2019 (unaudited)	December 31, 2018[1]
ASSETS		
Current assets:		
Cash and short term investments	$ 225,112	$ 198,731
Other current assets	8,640	8,943
Total current assets	233,752	207,674
Long-term investments	42,650	—
Property and equipment, net	4,530	3,204
Operating lease right-of-use assets and other assets	8,882	300
Total assets	$ 289,814	$ 211,178
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued liabilities	$ 20,283	$ 19,521
Current portion of long-term debt	—	2,607
Short-term lease liability	4,616	—
Other current liabilities	1,124	66
Total current liabilities	26,023	22,194
Term loan, net	45,052	39,806
Convertible notes, net	84,205	—
Liability related to the sale of future royalties, net	143,276	122,473
Long-term lease liability	2,195	771
Total liabilities	300,751	185,244

Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock	59	55
Additional paid-in capital	853,341	768,703
Accumulated other comprehensive income	679	500
Accumulated deficit	(865,016)	(743,324)
Total stockholders' equity (deficit)	(10,937)	25,934
Total liabilities and stockholders' equity (deficit)	$ 289,814	$ 211,178

(1) Derived from the audited financial statements, included in the company's Annual Report on Form 10-K for the year ended December 31, 2018.

Source: Cytokinetics, Incorporated