



Cytokinetics, Inc. Reports Third Quarter 2018 Financial Results

November 1, 2018 8:00 PM EDT

METEORIC-HF Advancing to Trial Initiation

FORTITUDE-ALS on Track to Complete Enrollment by Year End

Phase 1 Clinical Studies of CK-274 and AMG 594 To Start in Q4

SOUTH SAN FRANCISCO, Calif., Nov. 01, 2018 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) reported financial results for the third quarter of 2018. Net loss for the third quarter was \$22.8 million, or \$0.40 per share, compared to a net loss for the third quarter of 2017 of \$32.4 million, or \$0.60 per share. Cash, cash equivalents and investments totaled \$210.3 million at September 30, 2018.

"With five programs advancing in development, we were pleased to report progress of our expanded pipeline of muscle biology directed potential medicines as recently outlined at our R&D Day," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "We look forward to beginning multiple trials across our cardiac muscle programs before year-end as well as soon completing enrollment in FORTITUDE-ALS, our Phase 2 clinical trial of *reldesemtiv* in patients with ALS, with results expected next year. I believe that the company has never been better positioned programmatically, operationally and financially to potentially deliver on the promise of our pioneering leadership in muscle biology."

Recent Highlights and Upcoming Milestones

Cardiac Muscle Programs

omecamtiv mecarbil (cardiac myosin activator)

- Continued patient enrollment in GALACTIC-HF (**G**lobal **A**pproach to **L**owering **A**dverse **C**ardiac **O**utcomes **T**hrough **I**mproving **C**ontractility in **H**eart **F**ailure), the Phase 3 cardiovascular outcomes clinical trial of *omecamtiv mecarbil*. Enrollment has surpassed 70 percent completion with over 5,800 patients randomized to date having the high-risk profile intended by the trial design. We expect completion of patient enrollment in GALACTIC-HF to occur during the first half of 2019. We also expect that GALACTIC-HF will have accrued a sufficient number of events to enable the Data Monitoring Committee to conduct a first interim analysis for the trial, the design of which is tied to the potential for futility, in the first half of 2019.
- Conducted readiness activities in advance of the initiation of METEORIC-HF (**M**ulticenter **E**xercise **T**olerance **E**valuation of **O**me**c**am**t**iv **M**ecar**b**il**R**elated to **I**ncreased **C**ontractility in **H**eart **F**ailure). METEORIC-HF is a Phase 3, randomized, placebo-controlled, double-blind, parallel group, multicenter clinical trial designed to evaluate the effect of treatment with *omecamtiv mecarbil* compared to placebo on exercise capacity as determined by cardiopulmonary exercise testing (CPET) following 20 weeks of treatment. Cytokinetics is working together with Amgen towards the objective of starting METEORIC-HF by the end of 2018.

AMG 594 (cardiac troponin activator)

- Continued pre-clinical development of AMG 594 and filed an IND in collaboration with Amgen. AMG 594 is a novel, first-in-class, selective, oral, small molecule cardiac troponin activator, discovered under a joint research program with Amgen. In preclinical models, AMG 594 increases myocardial contractility by binding to cardiac troponin through an allosteric mechanism that sensitizes the cardiac sarcomere to calcium. Based on preclinical data, AMG 594 may offer differentiated efficacy and dose-related convenience relative to *omecamtiv mecarbil*.
- We expect that Amgen will initiate a Phase 1 program for AMG 594 before the end of the year

to assess its safety, tolerability, pharmacokinetics and its potential to increase cardiac function in healthy volunteers.

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

- Continued pre-clinical development and filed an IND for CK-274. CK-274 is a novel, oral, small molecule cardiac myosin inhibitor that company scientists discovered independent of its collaborations. CK-274 arose from an extensive next-generation chemical optimization program conducted with careful attention to therapeutic index and pharmacokinetic properties and as may translate into best-in-class potential in clinical development. In preclinical models, CK-274 reduces myocardial contractility by binding directly to cardiac myosin at a distinct and selective allosteric binding site preventing myosin from entering a force producing state.
- We expect to initiate a Phase 1 program for CK-274 before the end of the year to assess its safety, tolerability, pharmacokinetics and its effect on cardiac function in healthy volunteers.

Skeletal Muscle Program

reldesemtiv (next-generation FSTA)

- Announced that additional results from the Phase 2 clinical study of *reldesemtiv* in patients with spinal muscular atrophy (SMA) were presented by John W. Day, M.D., Ph.D., Professor of Neurology and Pediatrics (Genetics), Stanford University at the 2018 Muscle Study Group Scientific Meeting in Oxford, UK, showing sustained increases in 6MWD and MEP four weeks after discontinuation of study drug.
- Continued site activation and patient enrollment in FORTITUDE-ALS (**F**unctional **O**utcomes in a **R**andomized **T**rial of Investigational **T**reatment with CK-2127107 to **U**nderstand **D**ecline in **E**ndpoints – in **ALS**), the Phase 2 clinical trial of *reldesemtiv* which is designed to assess the change from baseline in percent predicted slow vital capacity and other measures of skeletal muscle function after 12 weeks of treatment with *reldesemtiv* in patients with ALS. FORTITUDE-ALS has enrolled over 400 patients toward the objective of 445 patients in the trial and is being conducted by Cytokinetics in collaboration with Astellas. We expect to complete enrollment in FORTITUDE-ALS in Q4 2018 with results from this clinical trial expected in the first half of 2019.
- With Astellas, announced the Phase 2 clinical trial of *reldesemtiv* in patients with chronic obstructive pulmonary disease (COPD), which was designed to assess its effect on physical function, did not meet the primary endpoint and did not demonstrate a statistically significant treatment difference in any of the secondary endpoints. Adverse events were similar between groups receiving *reldesemtiv* and placebo.
- With Astellas, announced that an interim analysis of the Phase 1b clinical trial of *reldesemtiv* in elderly subjects with limited mobility, which was designed to assess its effect on measures of physical function, was recently conducted. The Data Monitoring Committee determined that the pre-defined criteria for lack of efficacy of *reldesemtiv* had been met; Astellas has proceeded to notify investigators to halt further enrollment in the trial.

Pre-Clinical Development and Ongoing Research

- Continued pre-clinical development of CK-3762601 (CK-601), a next-generation fast skeletal muscle troponin activator (FSTA) into IND-enabling studies under our collaboration with

Astellas.

- Continued research in collaboration with Astellas directed to the discovery of next-generation skeletal muscle activators. The companies are continuing their joint research program with Astellas providing sponsorship of Cytokinetics' activities through 2019.
- Continued independent research activities directed to our other muscle biology research programs.

Corporate

- Announced that The ALS Association Golden West Chapter is the inaugural recipient of the Cytokinetics Communications Fellowship, an annual grant from the company intended to support increased capacity and community engagement for nonprofit organizations.

Financials

Revenues for the three and nine months ended September 30, 2018 were \$10.6 million and \$22.1 million, respectively, compared to \$6.2 million and \$13.4 million for the corresponding periods in 2017. Revenues for the first nine months of 2018 stemmed from our strategic alliance with Astellas.

Research and development expenses for the third quarter of 2018 decreased to \$21.4 million from \$24.9 million for the third quarter of 2017, primarily due to cessation of development of *tirasemtiv* in late 2017, offset in part by increased spending in clinical trials of *reldesemtiv* and preclinical activities for CK-274 and other potential drug candidates. Research and development expenses for the first nine months of 2018 increased to \$65.9 million from \$64.0 million for the first nine months of 2017, primarily due to increased spending in clinical trials of *reldesemtiv* and preclinical activities for CK-274 as well as other potential drug candidates, offset in part by suspension of development of *tirasemtiv* in late 2017.

General and administrative expenses for the three and nine months ended September 30, 2018 decreased to \$7.2 million and \$23.7 million, respectively, from \$9.7 million and \$26.2 million for the same periods in 2017, respectively, primarily due to reduced pre-commercial activities for *tirasemtiv* and reduced other corporate activities.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's third quarter 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 9785146.

An archived replay of the webcast will be available via Cytokinetics' website until November 8, 2018. 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 9785146 from November 1, 2018 at 7:30 PM Eastern Time until November 8, 2018.

About Cytokinetics

Cytokinetics is a late-stage biopharmaceutical company focused on discovering, developing and commercializing first-in-class muscle activators and best-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. *Omeclamtiv mecarbil* is the subject of GALACTIC-HF, an international Phase 3 clinical trial in patients with heart failure. 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 also collaborating with Amgen to develop AMG 594, a first-in-class cardiac troponin activator, discovered under the companies' joint research program. Further development of AMG 594 is subject to the collaboration agreement between Amgen and Cytokinetics. Cytokinetics is collaborating with Astellas Pharma Inc. ("Astellas") to develop *reldesemtiv*, a fast skeletal muscle troponin activator (FSTA). *Reldesemtiv* has been granted orphan drug designation by the FDA for the potential treatment of spinal muscular atrophy. *Reldesemtiv* was the subject of a positive Phase 2 clinical study in patients with spinal muscular atrophy which showed increases in measures of endurance and stamina consistent with the mechanism of action. *Reldesemtiv* is currently the subject of a Phase 2 clinical trial in patients with amyotrophic lateral sclerosis. Cytokinetics is also advancing CK-601, a next-generation FSTA into IND-enabling studies under the collaboration with Astellas. Astellas 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 recently filed an IND for CK-274, a novel cardiac myosin inhibitor that company scientists discovered independent of its collaborations. Cytokinetics continues its 20-year history of innovation with three new muscle biology directed compounds advancing from research to development in 2018. For additional information about Cytokinetics, visit www.cytokinetics.com.

Forward-Looking Statements

This press release contains forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995 (the "Act"). Cytokinetics disclaims any intent or obligation to update these forward-looking statements, and 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 activities; the timing of enrollment of patients in Cytokinetics' and its partners' clinical trials; the design, timing, results, significance and utility of preclinical and clinical results; 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, 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, Cytokinetics' drug candidates may have adverse side effects or inadequate therapeutic efficacy, the FDA or foreign regulatory agencies may delay or limit Cytokinetics' or its partners' ability to conduct clinical trials, and Cytokinetics may be unable to obtain or

maintain patent or trade secret protection for its intellectual property; Astellas' decisions with respect to the design, initiation, conduct, timing and continuation of development activities for *reldesemtiv*; Amgen's decisions with respect to the design, initiation, conduct, timing and continuation of development activities for *omecamtiv mecarbil*; standards of care may change, rendering Cytokinetics' drug candidates obsolete; competitive products or alternative therapies may be developed by others for the treatment of indications Cytokinetics' drug candidates and potential drug candidates may target; and risks and uncertainties relating to the timing and receipt of payments from its partners, including milestones and royalties on future potential product sales under Cytokinetics' collaboration agreements with such partners. For further information regarding these and other risks related to Cytokinetics' business, investors should consult Cytokinetics' filings with the Securities and Exchange Commission.

Contact:

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

	<u>Three Months Ended</u>		<u>Nine Months Ended</u>	
	<u>September 30, 2018</u>	<u>September 30, 2017</u>	<u>September 30, 2018</u>	<u>September 30, 2017</u>
Revenues:				
Research and development, milestone, grant and other revenues, net	\$ 8,726	\$ 5,862	\$ 16,991	\$ 6,680
License revenues	1,915	318	5,133	6,706
Total revenues	<u>10,641</u>	<u>6,180</u>	<u>22,124</u>	<u>13,386</u>
Operating expenses:				
Research and development	21,391	24,947	65,858	64,045
General and administrative	7,164	9,657	23,724	26,210
Total operating expenses	<u>28,555</u>	<u>34,604</u>	<u>89,582</u>	<u>90,255</u>
Operating loss	(17,914)	(28,424)	(67,458)	(76,869)
Interest expense	(867)	(806)	(2,628)	(2,346)
Non-cash interest expense on liability related to sale of future royalties	(4,559)	(3,906)	(13,026)	(9,918)
Interest and other income, net	1,323	779	3,291	1,828
Net loss	<u>\$ (22,017)</u>	<u>\$ (32,357)</u>	<u>\$ (79,821)</u>	<u>\$ (87,305)</u>
Net loss per share — basic and diluted	<u>\$ (0.40)</u>	<u>\$ (0.60)</u>	<u>\$ (1.47)</u>	<u>\$ (1.82)</u>
Weighted-average shares in net loss per share — basic and diluted	<u>54,626</u>	<u>53,719</u>	<u>54,329</u>	<u>47,879</u>

Cytokinetics, Incorporated
Condensed Consolidated Balance Sheets
(in thousands)

	<u>September 30, 2018</u>	<u>December 31, 2017⁽¹⁾</u>
	<u>(unaudited)</u>	
ASSETS		
Current assets:		
Cash and short term investments	\$ 210,310	\$ 268,891
Other current assets	16,959	5,404
Total current assets	<u>227,269</u>	<u>274,295</u>
Long-term investments	—	16,518
Property and equipment, net	2,687	3,568
Other assets	323	429
Total assets	<u>\$ 230,279</u>	<u>\$ 294,810</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 17,676	\$ 22,645

Deferred revenue, current	—	9,572
Current portion of long-term debt	3,778	—
Other current liabilities	38	227
Total current liabilities	21,492	32,444
Long-term debt, net	38,127	31,777
Liability related to the sale of future royalties, net	117,718	104,650
Deferred revenue, non-current	—	15,000
Other long-term liabilities	874	1,097
Total liabilities	178,211	184,968
Stockholders' equity:		
Common stock	55	54
Additional paid-in capital	765,970	755,526
Accumulated other comprehensive income	447	343
Accumulated deficit	(714,404)	(646,081)
Total stockholders' equity	52,068	109,842
Total liabilities and stockholders' equity	\$ 230,279	\$ 294,810

(1) Derived from the audited financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017.



Source: Cytokinetics, Incorporated