



Cytokinetics Reports Second Quarter 2019 Financial Results

August 8, 2019 8:06 PM EDT

Completed Enrollment in GALACTIC-HF with More than 8,200 Heart Failure Patients

Results from Phase 1 Study of CK-274 to be Presented at HFSA in September 2019; Phase 2 Clinical Trial Expected to Begin in Q4

SOUTH SAN FRANCISCO, Calif., Aug. 08, 2019 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq:CYTK) reported financial results for the second quarter of 2019. Net loss for the second quarter was \$32.1 million, or \$0.56 per share, compared to net loss for the second quarter of 2018 of \$27.5 million, or \$0.51 per share. Cash, cash equivalents and investments totaled \$175.1 million at June 30, 2019.

"During the second quarter, we made progress across the breadth of our pipeline, with particular emphasis on our investigational medicines for cardiovascular diseases of muscle dysfunction," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "Our recently completing enrollment in GALACTIC-HF represents a significant milestone towards potentially bringing forward a novel therapy to address the high mortality and hospitalization rates in patients with heart failure. Additionally, we are pleased with encouraging data arising from the Phase 1 study of CK-274 and look forward to the planned initiation of a Phase 2 trial in patients with obstructive hypertrophic cardiomyopathy later this year. Our leadership in muscle biology affords us multiple opportunities to advance our drug candidates as our clinical trials generate clinical evidence to support the promise of potential new therapies."

Recent Highlights

Cardiac Muscle Programs

omecamtiv mecarbil (cardiac myosin activator)

- Continued conduct of 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*. In July 2019 we announced the completion of patient enrollment in GALACTIC-HF, having enrolled over 8,200 patients in 35 countries. We expect GALACTIC-HF to continue throughout 2019 and the next planned interim analysis in the first half of 2020.
- 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*. METEORIC-HF is a 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. We expect to continue enrollment of METEORIC-HF throughout 2019.

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 a joint research program with Amgen. This Phase 1 study is being conducted by Amgen in collaboration with Cytokinetics. We expect the conduct of this study to continue throughout 2019.

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

- Continued conduct of the Phase 1 double-blind, randomized, placebo-controlled, multi-part, single and multiple ascending dose clinical study of CK-274 in healthy adult subjects. CK-274 is a wholly-owned, novel cardiac myosin inhibitor, discovered by company scientists, in development for the potential treatment of hypertrophic cardiomyopathy (HCM). Results from the Phase 1 study have been accepted for presentation at the 23rd Annual Heart Failure

Society of America (HFSA) Scientific Meeting in Philadelphia in September 2019.

- Received feedback from FDA regarding the design of a planned Phase 2 clinical trial of CK-274 and made preparations for the start of that trial which we expect to begin in the fourth quarter of this year.
- Presented preclinical data at the American Heart Association's Basic Cardiovascular Sciences (BCVS) Scientific Sessions in Boston demonstrating that CK-274 produces exposure related effects on cardiac contractility in healthy animals and mouse models of HCM and support the therapeutic hypothesis relating to onset of action and reversibility.

Skeletal Muscle Program

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

- Presented results from 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 American Academy of Neurology 71st Annual Meeting in Philadelphia. FORTITUDE-ALS did not achieve statistical significance for a pre-specified dose-response relationship in its primary endpoint of change from baseline in slow vital capacity (SVC) after 12 weeks of dosing ($p=0.11$). Patients on all dose groups of *reldesemtiv* declined less than patients on placebo for SVC and ALSFRS-R, with larger and clinically meaningful differences emerging over time. While the dose-response analyses for the primary and secondary endpoints did not achieve statistical significance at the level of 0.05, in a post-hoc analysis pooling the doses together, the ALSFRS-R total score in patients who received *reldesemtiv* declined less than patients who received placebo ($p = 0.01$). The trial showed effects favoring *reldesemtiv* across dose levels and timepoints with clinically meaningful magnitudes of effect observed at 12 weeks for the primary and secondary endpoints.
- Continued to analyze results from FORTITUDE-ALS to inform the design of a potential Phase 3 trial and registration program that may begin in 2020.
- Concluded a Phase 1 study of *reldesemtiv* in healthy volunteers designed to assess higher doses and related plasma exposures than were evaluated in the prior Phase 2 study of patients with SMA. We are evaluating the data from the study to inform the design of potential future clinical trials.
- Presented data from two preclinical studies of *reldesemtiv* at the 2019 Annual Cure SMA Conference in Anaheim, CA, showing that the addition of *reldesemtiv* to treatment with SMN upregulators (nusinersen and SMN-C1, an analogue to risdiplam) significantly increased muscle force in a mouse model of spinal muscular atrophy (SMA).

Pre-Clinical Development and Ongoing Research

- Continued pre-clinical development of CK-3762601 (CK-601), a next-generation fast skeletal muscle troponin activator (FSTA), under our collaboration with Astellas.
- Continued research in collaboration with Astellas directed to the discovery of next-generation skeletal muscle activators; Astellas is sponsoring Cytokinetics' research activities through 2019.

- Continued independent research activities directed to our other muscle biology research programs.

Corporate

- We are currently in discussions with Astellas regarding amending the terms of our collaboration agreement, including, for *reldesemtiv*, the level of potential funding and share of commercial returns, as well as which company would be responsible for development and commercialization.
- Announced the continuation of our partnership with The ALS Association in the fight against ALS with renewal of Gold Level Sponsorship of the National Walks to Defeat ALS® and Premier Level National ALS Advocacy Conference Sponsorship as well as Platinum Level Sponsorship for initiatives led by The ALS Association Golden West Chapter, including grant funding for care services for people living with ALS in the San Francisco Bay Area.

Financials

Revenues for the three and six months ended June 30, 2019 were \$7.1 million and \$15.6 million, respectively, compared to \$6.2 million and \$11.5 million for the corresponding periods in 2018. The increase in revenues for the three and six month ended June 30, 2019 was due primarily to reimbursements for METEORIC-HF offset by no license revenue in 2019. License revenues in the second quarter and first half of 2018 were related to the Phase 2 study of *reldesemtiv* in spinal muscular atrophy completed in 2018.

Research and development expenses for the three and six months ended June 30, 2019 increased to \$24.0 million and \$47.6 million, respectively compared to \$21.6 million and \$43.7 million for the same periods in 2018, respectively due to increased spending related to METEORIC-HF and the development of CK-274, offset in part by reduced spending for *reldesemtiv* as well as for *tirasemtiv*, following suspension of development of *tirasemtiv* in late 2017.

General and administrative expenses for the three and six months ended June 30, 2019 increased to \$9.8 million and \$19.3 million from \$8.0 million and \$17.3 million in 2018 due primarily to an increase in outside legal counsel and personnel related costs.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's second 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 1778276.

An archived replay of the webcast will be available via Cytokinetics' website until August 15, 2019. 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 1778276 from August 8, 2019 at 7:30 PM Eastern Time until August 15, 2019.

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. *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) for diseases of neuromuscular dysfunction, including SMA and ALS. 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 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. 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 activities, including the initiation, conduct, design, enrollment, progress, continuation, completion, timing and results of clinical trials; the significance and utility of pre-clinical study and clinical trial results; planned interactions with regulatory authorities and the outcomes of such interactions; the expected timing of events and milestones, including the receipt of milestone payments; 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		Six Months Ended	
	June 30, 2019	June 30, 2018	June 30, 2019	June 30, 2018
Revenues:				
Research and development revenues	\$ 7,137	\$ 4,680	\$ 15,601	\$ 8,265
License revenues	—	1,535	—	3,218
Total revenues	7,137	6,215	15,601	11,483
Operating expenses:				
Research and development	24,017	21,582	47,562	43,717
General and administrative	9,836	8,046	19,273	17,310
Total operating expenses	33,853	29,628	66,835	61,027
Operating loss	(26,716)	(23,413)	(51,234)	(49,544)
Interest expense	(1,377)	(898)	(2,547)	(1,761)
Non-cash interest expense on liability related to the sale of future royalties	(5,064)	(4,338)	(9,883)	(8,467)
Interest and other income	1,044	1,126	2,185	1,968
Net loss	\$ (32,113)	\$ (27,523)	\$ (61,479)	\$ (57,804)
Net loss per share — basic and diluted	\$ (0.56)	\$ (0.51)	\$ (1.09)	\$ (1.07)
Weighted-average shares in net loss per share — basic and diluted	57,648	54,293	56,242	54,178

Cytokinetics, Incorporated
Condensed Consolidated Balance Sheets
(in thousands)

	June 30, 2019	December 31, 2018 ⁽¹⁾
	(unaudited)	
ASSETS		
Current assets:		
Cash and short term investments	\$ 172,868	\$ 198,731
Other current assets	12,083	8,943
Total current assets	184,951	207,674
Long-term investments	2,254	—
Property and equipment, net	2,945	3,204
Other assets	8,068	300
Total assets	\$ 198,218	\$ 211,178
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 17,022	\$ 19,521
Current portion of long-term debt	-	2,607
Short-term lease liability	4,538	—

Other current liabilities	399	66
Total current liabilities	21,959	22,194
Long-term debt, net	44,473	39,806
Liability related to the sale of future royalties, net	132,388	122,473
Long-term lease liability	4,294	—
Other long-term liabilities	—	771
Total liabilities	203,114	185,244
Stockholders' equity:		
Common stock	58	55
Additional paid-in capital	799,088	768,703
Accumulated other comprehensive income	761	500
Accumulated deficit	(804,803)	(743,324)
Total stockholders' equity	(4,896)	25,934
Total liabilities and stockholders' equity	\$ 198,218	\$ 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