Cytokinetics Reports Third Quarter 2021 Financial Results

November 3, 2021 8:00 PM EDT

Submission of NDA for Omecamtiv Mecarbil on Track to Occur in Q4 2021

Start-Up Activities Underway for SEQUOIA-HCM

Enrollment Complete in Cohort 3 of REDWOOD-HCM; Results Expected in Q1 2022

SOUTH SAN FRANCISCO, Calif., Nov. 03, 2021 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) reported financial results for the third quarter of 2021. Net loss for the third quarter was $76.1 million, or $0.95 per share, compared to net loss for the third quarter of 2020 of $3.2 million, or $0.05 per share. Cash, cash equivalents and investments totaled $668.9 million at September 30, 2021.

"During the third quarter we were pleased to deliver against several key milestones across our late-stage pipeline, including our sharing positive results from REDWOOD-HCM and conducting start-up activities for SEQUOIA-HCM, our Phase 3 trial of *aficamten*. In parallel, we were pleased to start COURAGE-ALS, our Phase 3 trial of *reldesemtiv* while also advancing towards our goal of submitting the NDA for *omecamtiv mecarbil*," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "Moreover, after recently outlining our go-to-market strategy for *omecamtiv mecarbil* in the U.S., we are forging ahead to execute on those plans, supported by a strong and growing commercial organization with focus to building a cardiovascular franchise. All of this is occurring alongside an expansion of our research programs with the objective to support a sustainable pipeline of innovation."

Q3 and Recent Highlights

Cardiac Muscle Programs

omecamtiv mecarbil (cardiac myosin activator)

- Continued activities supportive of our plans to submit a New Drug Application (NDA) for *omecamtiv mecarbil,* which remains on track to occur in Q4 2021.

- Results from additional analyses from 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) were presented at the Heart Failure Society of America (HFSA) Annual Scientific Meeting in Denver, CO, showing that the effect of treatment with *omecamtiv mecarbil* in Black patients was consistent with the overall population and with white patients.

- 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 METEORIC-HF by year end and report results in early 2022.

- Advanced our go-to-market-strategy and commercial readiness activities. We completed the hiring of our commercial senior leadership and payer account management teams and grew our U.S. marketing organization. In addition, we advanced key activities in preparation for potential commercial launch including refinement of product positioning, development of a product educational campaign, updating the sizing and deployment strategy for our U.S. sales team, U.S. pricing, and our product value proposition.

- Expanded our Medical Affairs organization with the hiring of therapeutic area lead Medical Directors and deployment of additional field-based Medical Scientists. We initiated vendor selection for the development of a Medical Contact Center and continued organizing the framework for the Investigator Sponsored Study Program.

- The manuscript entitled "Assessment of *Omecamtiv Mecarbil* for the Treatment of Patients with Severe Heart Failure" was published in *JAMA Cardiology.*

- The manuscript entitled “Characteristics and Outcomes of Patients with Heart Failure with Reduced Ejection Fraction After a Recent Worsening Heart Failure Event” was published in the *Journal of the American Heart Association*.

aficamten (cardiac myosin inhibitor)

- Announced positive results from Cohorts 1 and 2 of REDWOOD-HCM (**R**andomized **E**valuation of **D**osing **W**ith CK-274 in **O**bstructive **O**utflow **D**isease in **HCM**) demonstrating that treatment with *aficamten* for 10 weeks resulted in statistically significant reductions from baseline compared to placebo in the average resting left ventricular outflow tract pressure gradient (LVOT-G) and the average post-Valsalva LVOT-G. A large majority of patients treated with *aficamten* achieved the target goal of treatment, defined as resting gradient <30 mmHg and post-Valsalva gradient <50 mmHg at Week 10, compared to placebo. Patients treated with *aficamten* also saw improvements in heart failure symptoms and reductions in NT-proBNP, a biomarker of cardiac wall stress. Treatment with *aficamten* in REDWOOD-HCM was generally well tolerated. The incidence of adverse events on *aficamten* was similar to that of placebo. No serious adverse events were attributed to *aficamten,* and no treatment interruptions occurred on *aficamten*.

- Completed enrollment in Cohort 3 of REDWOOD-HCM for patients whose background therapy includes disopyramide. Continued enrolling patients in REDWOOD-HCM OLE, the open label extension clinical study designed to assess the long-term safety and tolerability of *aficamten* in patients with symptomatic obstructive HCM who have participated previously in REDWOOD-HCM. Results from Cohort 3 are expected in Q1 2022 and an update from REDWOOD-HCM OLE is expected in 2022.

- Conducted start-up activities, including regulatory filings and IRB submissions, for SEQUOIA-HCM (**S**afety, **E**fficacy, and **Q**uantitative **U**nderstanding of **O**bstruction **I**mpact of ***A****ficamten* in **HCM**), the Phase 3 clinical trial of *aficamten* in patients with obstructive HCM, with the first site initiations already completed. Drug product availability in early 2022 will enable the commencement of screening and enrollment of the first patients in this trial.

- Ji Xing Pharmaceuticals completed a Phase 1 study of *aficamten* in healthy subjects in China that showed favorable tolerability comparable to placebo and dose-proportional pharmacokinetics, similar to the results observed in the Phase 1 study of *aficamten* in healthy Caucasian subjects in the U.S.

- Published a manuscript entitled “Discovery of *Aficamten* (CK-274), a Next-Generation Cardiac Myosin Inhibitor for the Treatment of Hypertrophic Cardiomyopathy” in the *Journal of Medicinal Chemistry*.

- The manuscript entitled “Clinical Diagnosis of Hypertrophic Cardiomyopathy Over Time in the United States (A Population-Based Claims Analysis)” was published in *The American Journal of Cardiology*.

Skeletal Muscle Program

reldesemtiv (fast skeletal muscle troponin activator (FSTA))

- Started COURAGE-ALS (**C**linical **O**utcomes **U**sing ***R****eldesemtiv* on **A**LSFRS-R in a **G**lobal **E**valuation in **ALS**), the Phase 3 clinical trial of *reldesemtiv* in patients with ALS.

- Published a manuscript entitled “Prescription and Acceptance of Durable Medical Equipment in FORTITUDE-ALS, a Study of *Reldesemtiv* in ALS: Post Hoc Analyses of a Randomized, Double-Blind, Placebo-Controlled Clinical Trial” in *Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration.*

- Published a manuscript entitled “Discovery of *Reldesemtiv*, a Fast Skeletal Muscle Troponin Activator for the Treatment of Impaired Muscle Function” in *Journal of Medicinal Chemistry*.

Pre-Clinical Development and Ongoing Research

- Continued to advance new muscle directed compounds and conduct IND-enabling studies with the expectation of our potentially advancing 1-2 potential drug candidates into clinical development over the next year.

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

Corporate

- Raised approximately $296.9 million in net proceeds, after deducting underwriting discounts, commissions, and expenses from an underwritten public offering of 11,500,000 shares of common stock including the underwriters’ exercise of their overallotment option.

- Donated data from our completed clinical trials in ALS, including BENEFIT-ALS, VITALITY-ALS and FORTITUDE-ALS, to the Pooled Resource Open-Access ALS Clinical Trials (PRO-ACT) database, a resource for the research community that consists of thousands of anonymized clinical patient records from previously completed ALS clinical trials. PRO-ACT is sponsored by The ALS Association and managed by the Neurological Clinical Research Institute (NCRI) at Mass General Brigham.

- 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 awards five grants worth $20,000 each to patient advocacy organizations serving the ALS, heart failure, HCM, or SMA communities, and is intended to support increased capacity in communications and outreach.

Financials

Revenues for the three and nine months ended September 30, 2021 were $5.4 million and $14.8 million, respectively, compared to $41.7 million and $49.1 million for the corresponding periods in 2020. The changes in revenues are due to our recognizing a $5.0 million milestone from Ji Xing Pharmaceuticals in anticipation of the start of SEQUOIA-HCM, the absence of licensing revenue, the absence of revenue from our prior collaboration with Amgen, and changes in reimbursable collaborative activities with Astellas.

Research and development expenses for the three and nine months ended September 30, 2021 increased to $48.4 and $116.4 million, respectively, compared to $24.2 million and $67.7 million for the same periods in 2020. The changes were primarily due to increases in spending for our clinical development activities for our cardiac muscle inhibitor programs and COURAGE-ALS. In addition, for the three and nine months ended September 30, 2021, we incurred transition costs related to the termination of our collaboration with Amgen and our purchase from Amgen of approximately $7.3 million and $14.6 million, respectively, of materials including manufactured quantities of the active pharmaceutical ingredient for *omecamtiv mecarbil.*

General and administrative expenses for the three and nine months ended September 30, 2021 increased by $13.9 million and $24.1 million, from the three and nine months ended September 30, 2020, respectively, primarily due to higher outside service spend in anticipation of the potential commercial launch of *omecamtiv mecarbil*, an increase in personnel related costs including stock-based compensation and facilities expense due to the Oyster Point Lease recorded at the end of the first quarter of 2021.

Conference Call and Webcast Information

Members of Cytokinetics’ senior management team will review the company’s third quarter results on a conference call today at 4:30 PM Eastern Time. The call will be simultaneously webcast and can be accessed from the homepage and in the Investors & Media section of 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 5885725.

An archived replay of the webcast will be available via Cytokinetics' website until November 17, 2021. 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 5885725 from November 3, 2021 at 7:30 PM Eastern Time until November 17, 2021.

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. 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 preparing a U.S. NDA submission of *omecamtiv mecarbil*, its novel cardiac muscle activator, following positive results from GALACTIC-HF, a large, international Phase 3 clinical trial in patients with heart failure. Cytokinetics is conducting METEORIC-HF, a second Phase 3 clinical trial of *omecamtiv mecarbil*. Cytokinetics is also developing *aficamten*, a next-generation cardiac myosin inhibitor, for the potential treatment of hypertrophic cardiomyopathies (HCM). The company has announced positive results from Cohorts 1 and 2 in REDWOOD-HCM, a Phase 2 clinical trial of *aficamten* in patients with obstructive HCM. Cytokinetics expects to start SEQUOIA-HCM, the Phase 3 clinical trial of *aficamten* in patients with obstructive HCM in Q4 2021. Cytokinetics is also developing *reldesemtiv*, a fast skeletal muscle troponin activator, currently the subject of COURAGE-ALS, a Phase 3 clinical trial in patients with ALS. 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 the conduct of METEORIC-HF by the end of 2021 and the release of results of METEORIC-HF in early 2022, the availability of drug product in early 2022 to enable the commencement of screening and enrollment of patients in SEQUOIA-HCM, a Phase 3 clinical trial of *aficamten*, the release of results of Cohort 3 of REDWOOD-HCM in the first quarter of 2022; the timing of the release of interim results of COURAGE-ALS, the significance and utility of pre-clinical study and clinical trial results, including the results of GALACTIC-HF in respect of *omecamtiv mecarbil*; the timing of interactions with regulatory authorities in connection to any of Cytokinetics' drug candidates and the outcomes of such interactions, including the submission of an NDA for *omecamtiv mecarbil* in the fourth quarter of 2021, and the prospects of regulatory approval for, and if approved, potential commercialization of *omecamtiv mecarbil*; decisions by the FDA or other regulatory authorities to condition our approval of *omecamtiv mecarbil* on the need or approval of a dosage selection test for the personalized dose optimization of *omecamtiv mecarbil* in patients, our ability or the ability of any third party to develop or commercialize such a dosage selection test, or the timing, prospects, process or likelihood of the approval of such a dosage selection test; our decision to engage in or execute, and the cost and expenses to be incurred in connection with, any particular transition activities from Amgen related to *omecamtiv mecarbil* and any particular commercial launch readiness activities for *omecamtiv mecarbil*; 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; 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, particularly under the caption "Risk Factors" in Cytokinetics' latest Quarterly Report on Form 10- Q. 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, 2021 (unaudited)	December 31, 2020
ASSETS		
Current assets:		
Cash and short term investments	$ 477,636	$ 464,060
Other current assets	17,305	10,161
Total current assets	494,941	474,221
Long-term investments	191,295	36,954
Property and equipment, net	53,896	13,346
Operating lease right-of-use assets	80,725	2,924
Other assets	6,682	6,358
Total assets	$ 827,539	$ 533,803

LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued liabilities	$ 47,994	$ 27,365
Current portion of long-term debt	16,875	—
Short-term lease liabilities	13,586	2,785
Other current liabilities	2,413	1,049
Total current liabilities	80,868	31,199
Term loan, net	30,203	46,209
Convertible notes, net	93,885	89,504
Liability related to the sale of future royalties, net	174,775	166,068
Long-term deferred revenue	87,000	87,000
Long-term lease and other non-current liabilities	111,788	440
Total liabilities	578,519	420,420
Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock	84	70
Additional paid-in capital	1,426,051	1,105,470
Accumulated other comprehensive income	(65)	149
Accumulated deficit	(1,177,050)	(992,306)
Total stockholders' equity (deficit)	249,020	113,383
Total liabilities and stockholders' equity (deficit)	$ 827,539	$ 533,803

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

	Three Months Ended		Nine Months Ended	
	September 30, 2021	**September 30, 2020**	**September 30, 2021**	**September 30, 2020**
Revenues:				
Research and development revenues	$ 437	$ 5,187	$ 9,828	$ 12,605
License revenues	—	36,501	—	36,501
Milestone revenues	5,000	—	5,000	—
Total revenues	5,437	41,688	14,828	49,106
Operating expenses:				
Research and development	48,436	24,202	116,440	67,730
General and administrative	26,202	12,302	62,997	38,912
Total operating expenses	74,638	36,504	179,437	106,642
Operating (loss) income	(69,201)	5,184	(164,609)	(57,536)
Interest expense	(4,161)	(3,976)	(12,222)	(11,945)
Non-cash interest expense on liability related to the sale of future royalties	(2,955)	(5,461)	(8,621)	(17,062)
Interest and other income	231	1,078	708	3,183
Net loss	$ (76,086)	$ (3,175)	$ (184,744)	$ (83,360)
Net loss per share — basic and diluted	$ (0.95)	$ (0.05)	$ (2.48)	$ (1.34)
Weighted-average number of shares used in computing net loss per share — basic and diluted	80,329	68,279	74,460	62,406

Cytokinetics

Source: Cytokinetics, Incorporated