Cytokinetics Reports First Quarter 2022 Financial Results

May 4, 2022 8:00 PM EDT

Initial Data from REDWOOD-HCM OLE, the Open Label Extension Study of Aficamten, to be Presented at Heart Failure 2022 on May 23, 2022

Continued Launch Readiness Activities and Buildout of Commercial Infrastructure in Advance of PDUFA Date of November 30, 2022 for Omecamtiv Mecarbil

SOUTH SAN FRANCISCO, Calif., May 04, 2022 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) reported financial results for the first quarter of 2022. Net loss for the first quarter was $89.4 million, or $1.05 per share, compared to net loss for the first quarter of 2021 of $47.1 million, or $0.66 per share. Cash, cash equivalents and investments totaled $686.1 million at March 31, 2022.

"We achieved meaningful progress during the first quarter of 2022 with especially notable milestones relating to our cardiovascular pipeline, including the acceptance and filing of our NDA for *omecamtiv mecarbil* with FDA and the opening to enrollment in both SEQUOIA-HCM and Cohort 4 of REDWOOD-HCM. Additionally we shared positive data from Cohort 3 of REDWOOD-HCM demonstrating a substantial treatment effect with *aficamten* in patients taking *disopyramide*, and additional data from GALACTIC-HF reinforcing its safety, ease of initiation in the hospital setting and potential to reduce costs associated with fewer hospitalizations," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "Having secured long-term capital from Royalty Pharma also in the first quarter, our stronger balance sheet enables us to both accelerate our development of *aficamten* as well as to advance commercial readiness activities supportive of the potential approval of *omecamtiv mecarbil* this year."

Q1 and Recent Highlights

Cardiac Muscle Programs

omecamtiv mecarbil (cardiac myosin activator)

- The U.S. Food and Drug Administration (FDA) accepted and filed our New Drug Application (NDA) for *omecamtiv mecarbil* for the treatment of heart failure with reduced ejection fraction (HFrEF). The NDA was assigned standard review with a Prescription Drug User Fee Act (PDUFA) target action date of November 30, 2022.

- Continued building our commercial infrastructure and launch readiness capabilities for *omecamtiv mecarbil* in the U.S. including initiation of hiring first line field-based sales force leaders, selection of a patient services partner, and activities related to field force operations and market access.

- Doubled the size of our therapeutic Medical Scientist team, hired a Field Director, and began recruitment for our Managed Healthcare Medical Scientist team.

- Completed risk assessment of an end-to-end supply chain and advanced appropriate mitigating actions; initiated several major digital systems supportive of supply chain logistics.

- Presented additional data 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) at the American College of Cardiology 71st Annual Scientific Session (ACC.22) including:

    - An analysis showing that a subgroup of patients in GALACTIC-HF treated with *omecamtiv mecarbil* led to a reduction in resource intensity, with an estimated cost offset of $3,085, or 19% reduction per patient. The majority of these cost reductions were due to heart failure hospitalizations avoided by patients who were treated with *omecamtiv mecarbil*.

    - An analysis showing that the effect of treatment with *omecamtiv mecarbil* was associated with similar risk reduction in the primary composite endpoint in both hospitalized patients and in outpatients, indicating that initiation of *omecamtiv mecarbil*

was safe and well tolerated in both hospitalized patients and outpatients.

- Announced results 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), a Phase 3 clinical trial of *omecamtiv mecarbil* in patients with HFrEF that evaluated the effect of treatment with *omecamtiv mecarbil* compared to placebo on exercise capacity as determined by cardiopulmonary exercise testing (CPET). After 20 weeks of treatment, there was no change in peak oxygen uptake (pVO_2) in patients treated with *omecamtiv mecarbil* versus placebo. Adverse events, including major cardiac events, were similar between the treatment arms, and the safety profile of *omecamtiv mecarbil* was consistent with prior clinical trials, including GALACTIC-HF.

- Published a manuscript entitled “Influence of Atrial Fibrillation on Efficacy and Safety of *Omecamtiv Mecarbil* in Heart Failure: The GALACTIC-HF Trial” in the *European Heart Journal*.

- Published a manuscript entitled “Developments in Exercise Capacity Assessment in Heart Failure Clinical Trials and the Rationale for the Design of METEORIC-HF” in *Circulation: Heart Failure*.

aficamten (cardiac myosin inhibitor)

- Announced positive data from Cohort 3 of REDWOOD-HCM (**R**andomized **E**valuation of **D**osing **W**ith CK-274 in **O**bstructive **O**utflow **D**isease in **HCM**), which enrolled patients with symptomatic obstructive hypertrophic cardiomyopathy (HCM) and a resting left ventricular outflow tract gradient (LVOT-G) ≥50, or resting LVOT-G ≥30 mmHg and post-Valsalva LVOT-G ≥50 mmHg, whose background therapy included *disopyramide* and in the majority a beta-adrenergic blocker. Results showed that substantial reductions in the average resting LVOT-G as well as the post-Valsalva LVOT-G (defined as resting gradient <30 mmHg and post-Valsalva gradient <50 mmHg) were achieved. The safety and tolerability of *aficamten* were consistent with prior experience in REDWOOD-HCM with no treatment interruptions and no serious adverse events attributed to treatment reported by the investigators.

- Opened enrollment in Cohort 4 of REDWOOD-HCM (**R**andomized **E**valuation of **D**osing **W**ith CK-274 in **O**bstructive **O**utflow **D**isease in **HCM**), which will enroll, in an open label fashion, 30-40 patients with symptomatic non-obstructive hypertrophic cardiomyopathy receiving background medical therapy. The primary objective is to determine the safety and tolerability of *aficamten* in patients with non-obstructive hypertrophic cardiomyopathy.

- Opened enrollment in SEQUOIA-HCM (**S**afety, **E**fficacy, and **Q**uantitative **U**nderstanding of **O**bstruction **I**mpact of ***A****ficamten* in **HCM**), a Phase 3 randomized, placebo-controlled, double-blind, multi-center clinical trial designed to evaluate the effect of *aficamten* on exercise capacity, heart failure symptoms, and New York Heart Association (NYHA) Functional Class in patients with symptomatic obstructive HCM on background medical therapy for 24 weeks.

Skeletal Muscle Program

reldesemtiv (fast skeletal muscle troponin activator (FSTA))

- Continued conduct and enrollment of 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 amyotrophic lateral sclerosis (ALS).

Pre-Clinical Development and Ongoing Research

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

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

Corporate

- Secured long-term capital from entities affiliated with Royalty Pharma to support the potential commercialization of *omecamtiv mecarbil* and the further development of *aficamten*. Royalty Pharma will provide Cytokinetics long-term capital and debt financing of up to $300 million, subject to certain conditions, to support the potential commercialization of *omecamtiv mecarbil* and the further development of *aficamten*, and other general corporate purposes. Royalty Pharma also purchased a royalty on *aficamten* of 4.5% on sales up to $1 billion and 3.5% on sales above $1 billion, subject to certain potential step-downs, in exchange for payments of up to $150 million.

- Announced changes to the Board of Directors including the retirement of L. Patrick Gage, Ph.D., former Chairman of the Board, the appointment of John T. Henderson, M.B., Ch.B. as the company's new Chairman, and the appointment of Robert A. Harrington, M.D., Arthur L. Bloomfield Professor and Chair, Department of Medicine, Stanford University, to the Board.

- Joined with the European Organisation for Rare Diseases (EURORDIS) and the National Organization for Rare Disorders (NORD) to recognize Rare Disease Day®, an international campaign elevating the public understanding of rare diseases.

- Announced a three-year collaboration with the American Heart Association (AHA) Bay Area to accelerate education and awareness of heart disease, in which Cytokinetics will provide funding and support for several initiatives led by AHA Bay Area.

- Awarded Cytokinetics Communications Fellowship Grants to patient advocacy organizations serving the heart failure, HCM and ALS communities to support increased capacity in communications, awareness building and community engagement for nonprofit organizations serving the patient community.

2022 Corporate Milestones

Cardiac Muscle Programs

omecamtiv mecarbil (cardiac myosin activator)

- Launch *omecamtiv mecarbil* in the U.S. pending FDA approval in Q4 2022.

aficamten (cardiac myosin inhibitor)

- Continue enrolling patients with obstructive HCM in SEQUOIA-HCM through 2022.

- Continue enrolling patients with non-obstructive HCM in Cohort 4 of REDWOOD-HCM.

- Begin second Phase 3 clinical trial of *aficamten* in obstructive HCM in 2H 2022.

- Expect to share data from the open label extension study of *aficamten,* REDWOOD-HCM

OLE, at Heart Failure 2022 on May 23, 2022.

CK-3828136 (CK-136) (cardiac troponin activator)

- Reactivate development program for CK-136 in 2H 2022.

Skeletal Muscle Program

reldesemtiv (fast skeletal muscle troponin activator (FSTA))

- Expect the Data Monitoring committee to conduct the first interim analysis from COURAGE-ALS in 2H 2022, assessing for futility, 12 weeks after approximately one-third or more of the planned sample size is randomized.

Financials

Revenues for the first quarter 2022 were $1.1 million compared to $6.5 million for the corresponding period in 2021. The decrease in revenues was primarily due to the termination of the Amgen agreement effective May 20, 2021.

Research and development expenses for the first quarter 2022 increased to $45.9 million compared to $31.6 million for the same period in 2021, due primarily to increases in spending for clinical development activities for our cardiac muscle inhibitor programs, facility expenses, COURAGE-ALS, and early research programs.

General and administrative expenses for the first quarter 2022 increased to $33.1 million from $15.6 million for the same period in 2021 due primarily to higher outside services spending in anticipation of the potential commercial launch of *omecamtiv mecarbil*, an increase in personnel related costs including stock-based compensation and facilities expenses for our new headquarters.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's first 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 5771758.

An archived replay of the webcast will be available via Cytokinetics' website until May 18, 2022. 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 5771758 from May 4, 2022 at 8:00 PM Eastern Time until May 18, 2022.

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 readying for the potential commercialization of *omecamtiv mecarbil*, its cardiac muscle activator, following positive results from GALACTIC-HF, a large, international Phase 3 clinical trial in patients with heart failure. Cytokinetics is also developing *aficamten*, a next-generation cardiac myosin inhibitor, currently the subject of SEQUOIA-HCM, the Phase 3 clinical trial of *aficamten* in patients with symptomatic obstructive hypertrophic cardiomyopathy (HCM). *Aficamten* is also being evaluated in non-obstructive HCM in Cohort 4 of the Phase 2 clinical trial, REDWOOD-HCM. Cytokinetics is also developing *reldesemtiv*, an investigational fast skeletal muscle troponin activator, currently the subject of COURAGE-ALS, a Phase 3 clinical trial in patients with amyotrophic lateral sclerosis (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 not limited to, statements, express or implied, relating to our or our partners' research and development and commercial readiness activities, including the initiation, conduct, design, enrollment, progress, continuation, completion, timing and results of any of our clinical trials, or more specifically, our ability to commercially launch *omecamtiv mecarbil* by any particular date, if ever, our ability to fully enroll SEQUOIA-HCM, Cohort 4 of REDWOOD-HCM or COURAGE-ALS, our ability to conduct IND-enabling studies and to advance new muscle directed compounds into clinical development in the next year, if at all, our ability to initiate a second phase 3 clinical trial of *aficamten* in patients with obstructive HCM or to initiate a phase 1 clinical trial of CK-136 in 2022, if ever, the timing of the release of interim results of COURAGE-ALS, the timing of the release of any results of REDWOOD-HCM OLE, the significance and utility of pre-clinical study and clinical trial results, including, but not limited to, the results of GALACTIC-HF in respect of *omecamtiv mecarbil*, SEQUOIA-HCM and REDWOOD-HCM in respect of *aficamten*, or COURAGE-ALS in respect of *reldesemtiv*, the timing of interactions with FDA or any other regulatory authorities in connection to any of our drug candidates and the outcomes of such interactions, including, but not limited to, the likelihood of FDA's approval of the company's NDA for *omecamtiv mecarbil* by the PDUFA target action date of November 30, 2022 or at any other time, if ever; 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, statements relating to the potential patient population who could benefit from *omecamtiv mecarbil*, *aficamten*, *reldesemtiv* or any of our other drug candidates, and statements relating to our ability to receive additional capital or other funding, including, but not limited to, our ability to meet any of the conditions relating to or to otherwise secure additional sale proceeds or loan disbursements under any of our agreements with entities affiliated with Royalty Pharma or additional milestone payments from Ji Xing. 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' Annual Report on Form 10-K for the year-end December 31, 2021. 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)

	March 31, 2022 (unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and short term investments	$ 608,974	$ 471,638
Other current assets	14,552	64,034
Total current assets	623,526	535,672
Long-term investments	77,083	152,050
Property and equipment, net	75,740	73,271
Operating lease right-of-use assets	72,646	73,138
Other assets	7,258	7,188
Total assets	$ 856,253	$ 841,319
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued liabilities	$ 49,313	$ 55,457
Short-term lease liabilities	14,490	14,863
Other current liabilities	3,044	1,540
Total current liabilities	66,847	71,860
Term loan, net	61,165	47,367
Convertible notes, net	134,511	95,471
Liabilities related to revenue participation right purchase agreement, net	275,235	179,072
Long-term deferred revenue	87,000	87,000
Long-term operating lease liabilities	112,023	112,229
Other non-current liabilities	3,211	4,457
Total liabilities	739,992	597,456
Commitments and contingencies		
Stockholders' equity:		
Common stock	85	84
Additional paid-in capital	1,406,249	1,452,268
Accumulated other comprehensive income	(3,589)	(869)
Accumulated deficit	(1,286,484)	(1,207,620)
Total stockholders' equity	116,261	243,863
Total liabilities and stockholders' equity	$ 856,253	$ 841,319

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

	Three Months Ended	
	March 31, 2022	March 31, 2021

Revenues:		
Research and development revenues	$ 1,148	$ 6,548
Total revenues	1,148	6,548
Operating expenses:		
Research and development	45,935	31,561
General and administrative	33,070	15,598
Total operating expenses	79,005	47,159
Operating loss	(77,857)	(40,611)
Interest expense	(2,746)	(3,988)
Non-cash interest expense on liability related to the sale of future royalties	(6,564)	(2,795)
Loss on extinguishment of debt	(2,693)	—
Interest and other income	415	290
Net loss	$ (89,445)	$ (47,104)
Net loss per share — basic and diluted	$ (1.05)	$ (0.66)
Weighted-average number of shares used in computing net loss per share — basic and diluted	84,996	71,195

Source: Cytokinetics, Incorporated