Cytokinetics Reports Second Quarter 2022 Financial Results

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Advisory Committee Meeting to Review NDA for Omecamtiv Mecarbil Scheduled for December 13, 2022; PDUFA Target Action Date Set for February 28, 2023

Company Revises 2022 Financial Guidance; Reduces Projected Spending for 2022

SOUTH SAN FRANCISCO, Calif., Aug. 04, 2022 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) reported financial results for the second quarter of 2022. Net loss for the second quarter was $19.8 million, or $0.23 per share, compared to net loss for the second quarter of 2021 of $61.6 million, or $0.86 per share. Cash, cash equivalents and investments totaled $596.7 million at June 30, 2022.

In July, Cytokinetics raised $540 million netting approximately $383 million in proceeds through the offering of convertible senior notes, after deducting the purchasers' discounts and commissions and Cytokinetics' estimated offering expenses, as well as deducting $140.3 million to repurchase previously outstanding convertible senior notes. Cytokinetics expects to end 2022 with more than $800 million in cash.

"During the second quarter we made progress across regulatory, clinical and financial objectives. We engaged extensively with FDA in planning for its review of our NDA for *omecamtiv mecarbil* and advanced the enrollment and conduct of SEQUOIA-HCM and COURAGE-ALS while also planning for a second Phase 3 trial of *aficamten*," said Robert I Blum, Cytokinetics' President and Chief Executive Officer. "We also bolstered our balance sheet by executing on a fundraising of over $500 million while reducing our planned nearer-term spending in 2022. We believe that we are in a strong position to bring our potential therapies to patients while also executing well on late-stage clinical development programs."

Q2 and Recent Highlights

Cardiac Muscle Programs

omecamtiv mecarbil (cardiac myosin activator)

- Participated in a mid-cycle review meeting with the U.S. Food and Drug Administration (FDA) related to our New Drug Application (NDA) for *omecamtiv mecarbil.* Engaged extensively with FDA in other interactions related to its review of our NDA.

- Received notice that the FDA plans to convene an Advisory Committee meeting to review the NDA for *omecamtiv mecarbil*, and that the meeting is currently scheduled for December 13, 2022.

- Received notice that the FDA extended the Prescription Drug User Fee Act (PDUFA) date for *omecamtiv mecarbil* to February 28, 2023 due to additional pharmacokinetic analyses of *omecamtiv mecarbil* provided to the FDA upon request and that are deemed to constitute a major amendment to the NDA.

- Hired and deployed Managed Healthcare Medical Scientists and initiated medical support of our global value, access and distribution services. Continued building headquarters-based commercial infrastructure and engaging in launch readiness activities, including pre-approval information exchange discussions with key payers. Conducted Business Process inventory for enterprise resource planning implementation and strategic sourcing activities to mitigate supply chain risks.

- 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 Heart Failure 2022, an International Congress of the European Society of Cardiology, including:

    - An analysis showing that in patients with low blood pressure, there was a greater treatment effect from *omecamtiv mecarbil* on the primary composite endpoint of cardiovascular death or first heart failure event than in patients without low blood pressure such that there was an absolute risk reduction of 9.8 events per 100

patient-years (hazard ratio, 0.81; 95% confidence interval [CI] 0.70, 0.94; interaction p=0.051).

- An analysis showing that the treatment effect of *omecamtiv mecarbil* on the primary composite endpoint was consistent across patients with no tricuspid regurgitation (TR), mild TR and moderate/severe TR such that baseline TR did not modify the treatment effect (interaction p=0.91).

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

  - An analysis showing that treatment with *omecamtiv mecarbil* in a subgroup of patients in GALACTIC-HF led to a reduction in resource intensity, with an estimated cost offset of $3,085, or a 19% reduction in costs per patient. The majority of cost reductions were due to heart failure hospitalizations avoided by patients 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 “Effects of *Omecamtiv Mecarbil* in Heart Failure with Reduced Ejection Fraction According to Blood Pressure: The GALACTIC-HF Trial” in the *European Heart Journal*.

- Published a manuscript entitled “The Effect of *Omecamtiv Mecarbil* on Exercise Capacity in Chronic Heart Failure with Reduced Ejection Fraction: The METEORIC-HF Randomized Trial” in the *Journal of the American Medical Association.*

aficamten (cardiac myosin inhibitor)

- Presented the first long-term data from REDWOOD-HCM OLE (**R**andomized **E**valuation of **D**osing **W**ith CK-274 in **O**bstructive **O**utflow **D**isease in **HCM O**pen **L**abel **E**xtension) at Heart Failure 2022 from 38 patients treated for up to 24 weeks showing that treatment with *aficamten* was associated with substantial reductions in the average resting left ventricular outflow tract gradient (LVOT-G) and Valsalva LVOT-G. The reductions started to occur within two weeks of treatment, were sustained through 24 weeks of treatment, and were achieved with only modest decreases in the average LVEF. Improvements were also observed in New York Heart Association (NYHA) Functional Class and cardiac biomarkers including

NTpro-BNP and cardiac troponin. Treatment with *aficamten* was well-tolerated with one temporary discontinuation due to LVEF <50% and one temporary down-titration, neither related to drug. Both patients remain on treatment with *aficamten*.

- Presented additional data from REDWOOD-HCM at the American Society of Echocardiography (ASE) 33rd Annual Scientific Sessions showing that measures of cardiac structure, diastolic and mitral valve function improved in patients treated with *aficamten* after 10 weeks, including a significant reduction in left atrial volume index ($p<0.01$) and a trend towards a reduction in left ventricular hypertrophy (left ventricular mass index; $p=0.06$). Treatment with *aficamten* also resulted in improved ventricular relaxation and filling, as indicated by a reduction in lateral E/e' ($p<0.01$) and an increase in lateral e' ($p<0.05$).

- Announced positive data from Cohort 3 of REDWOOD-HCM, which enrolled patients with symptomatic obstructive hypertrophic cardiomyopathy (HCM) and a resting left 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.

- Began developing the go-to-market strategy for *aficamten* to support its potential future commercialization.

- Published a manuscript entitled "Characteristics of Patients with Obstructive Hypertrophic Cardiomyopathy in Real-World Community-Based Cardiovascular Practices" in *The American Journal of Cardiology.*

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).

- Started COURAGE-ALS OLE (**C**linical **O**utcomes **U**sing ***R**eldesemtiv* on **A**LSFRS-R in a **G**lobal **E**valuation in **ALS O**pen **L**abel **E**xtension), an open-label extension clinical study designed to assess the long-term safety and tolerability of *reldesemtiv* in people with ALS who have previously participated in COURAGE-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

- Raised $523.3 million in net proceeds, after deducting underwriters' discounts and transaction fees, and before repurchasing previously outstanding 2026 convertible senior notes.
- 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.
- Announced the continuation of our partnership with The ALS Association in the fight against ALS.

Upcoming Corporate Milestones

Cardiac Muscle Programs

omecamtiv mecarbil (cardiac myosin activator)

- Participate in Advisory Committee meeting to review the NDA for *omecamtiv mecarbil* on December 13, 2022.
- Launch *omecamtiv mecarbil* in the U.S. subject to FDA approval in Q1 2023.

aficamten (cardiac myosin inhibitor)

- Continue enrolling patients with obstructive HCM in SEQUOIA-HCM through 2022 with results expected in 2H 2023.
- Continue enrolling patients with non-obstructive HCM in Cohort 4 of REDWOOD-HCM with results expected in 1H 2023.
- Begin second Phase 3 clinical trial of *aficamten* in obstructive HCM in Q4 2022.
- Expect to share additional data from the open label extension study of *aficamten,* REDWOOD-HCM OLE in 2H 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 (assessing for futility) from COURAGE-ALS in Q4 2022.

Financials

Revenues for the three and six months ended June 30, 2022 were $89.0 million and $90.1 million, respectively, compared to $2.8 million and $9.4 million for the corresponding period in 2021. The increase in revenues was primarily due to the recognition of $87.0 million of deferred revenue for royalties on the net sales of products containing *mavacamten* as a result of the extinguishment of royalty obligations.

Research and development expenses for the three and six months ended June 30, 2022 increased to $57.1 million and $103.1 million, respectively, compared to $36.4 million and $68.0 million for the same period in 2021. The changes were primarily due to increases in spending for clinical development activities for COURAGE-ALS, for our cardiac muscle inhibitor programs, and early research programs.

General and administrative expenses for the three and six months ended June 30, 2022 increased to $42.7 million and $75.8 million, respectively, from $21.2 million and $36.8 for the same period in 2021 due primarily to higher outside services spending in anticipation of the potential commercial launch of *omecamtiv mecarbil*, and an increase in personnel related costs including stock-based compensation.

Revised 2022 Financial Guidance

The company today revised its financial guidance related to a reduction in expected operating expenses as a result of the three-month extension of the PDUFA date for *omecamtiv mecarbil* to February 28, 2023, which shifted certain hiring and activities previously planned to occur in 2022 to 2023. The company anticipates operating expenses for 2022 will be in the range of $375 to $385 million, and net cash utilization will be approximately $360 to $365 million. The company expects to end 2022 with more than $800 million, representing between two and three years of forward cash.

Conference Call and Webcast Information

The conference 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 registering in advance at the following link: Cytokinetics Q2 2022 Earnings Conference Call. Upon registration, participants will receive a dial-in number and a unique passcode to access the call. An archived replay of the webcast will be available via Cytokinetics' website for twelve months.

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 by the fourth quarter of 2022 or to reactivate CK-136 or to initiate a phase 1 clinical trial of CK-136 by any particular date, 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, our Advisory Committee for *omecamtiv mecarbil* scheduled for December 13, 2022, the likelihood of FDA's approval of the company's NDA for *omecamtiv mecarbil* by the PDUFA target action date of February 28, 2023 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; 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; and statements relating to our cash balance at any particular date or the amount of cash runway such cash balance represents at any particular time. 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)

	June 30, 2022 (unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and short term investments	$ 586,026	$ 471,638
Other current assets	16,224	64,034
Total current assets	602,250	535,672
Long-term investments	10,668	152,050
Property and equipment, net	78,586	73,271
Operating lease right-of-use assets	72,161	73,138
Other assets	8,052	7,188
Total assets	$ 771,717	$ 841,319
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued liabilities	$ 50,780	$ 55,457
Short-term operating lease liabilities	14,303	14,863
Other current liabilities	1,760	1,540
Total current liabilities	66,843	71,860
Term loan, net	62,344	47,367
Convertible notes, net	134,674	95,471
Liabilities related to revenue participation right purchase agreements, net	282,266	179,072
Long-term deferred revenue	—	87,000
Long-term operating lease liabilities	112,732	112,229
Other non-current liabilities	1,444	4,457
Total liabilities	660,303	597,456
Commitments and contingencies		
Stockholders' equity:		
Common stock	85	84
Additional paid-in capital	1,422,127	1,452,268
Accumulated other comprehensive income	(4,494)	(869)
Accumulated deficit	(1,306,304)	(1,207,620)
Total stockholders' equity	111,414	243,863
Total liabilities and stockholders' equity	$ 771,717	$ 841,319

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

	Three Months Ended		Six Months Ended	
	June 30, 2022	June 30, 2021	June 30, 2022	June 30, 2021
Revenues:				
Research and development revenues	$ 968	$ 2,843	$ 2,116	$ 9,391
Milestone revenues	1,000	—	1,000	—
Realization of revenue participation right purchase agreement	87,000	—	87,000	—
Total revenues	88,968	2,843	90,116	9,391
Operating expenses:				
Research and development	57,126	36,443	103,061	68,004
General and administrative	42,716	21,197	75,786	36,795
Total operating expenses	99,842	57,640	178,847	104,799
Operating loss	(10,874)	(54,797)	(88,731)	(95,408)
Interest expense	(2,807)	(4,073)	(5,553)	(8,061)
Loss on extinguishment of debt	—	—	(2,693)	—
Non-cash interest expense on liabilities related to revenue participation right purchase agreements	(7,003)	(2,871)	(13,567)	(5,666)
Interest and other income	864	187	1,279	477
Net loss	$ (19,820)	$ (61,554)	$ (109,265)	$ (108,658)
Net loss per share — basic and diluted	$ (0.23)	$ (0.86)	$ (1.28)	$ (1.52)

Weighted-average number of shares used in computing net loss per share — basic and diluted	85,731	71,754	85,366	71,476

Source: Cytokinetics, Incorporated