Cytokinetics Reports Second Quarter 2021 Financial Results

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Submission of NDA for Omecamtiv Mecarbil on Track to Occur in 2H 2021

Positive Results from REDWOOD-HCM Support Progression of Aficamten (CK-274) to Pivotal Phase 3 Trial in Patients with Obstructive Hypertrophic Cardiomyopathy Expected to Start in Q4

Pivotal Phase 3 Trial of Reldesemtiv in Patients with ALS Now Enrolling

More than Three Years of Cash Runway Following Recent Financing and Updated 2021 Guidance

SOUTH SAN FRANCISCO, Calif., Aug. 05, 2021 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) reported financial results for the second quarter of 2021. Net loss for the second quarter was $61.6 million, or $0.86 per share, compared to net loss for the second quarter of 2020 of $40.8 million, or $0.68 per share. Cash, cash equivalents and investments totaled $424.0 million at June 30, 2021. After the quarter, Cytokinetics raised approximately $297.3 million in net proceeds after deducting the applicable underwriting discounts and commissions through a public offering of common stock. Cytokinetics expects to end 2021 with more than $600 million in cash.

"During the second quarter, we made progress in advancing our late-stage muscle biology-directed pipeline and are now preparing for our first NDA submission while two other programs are expected to proceed in pivotal Phase 3 trials this year," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "Results from REDWOOD-HCM and GALACTIC-HF demonstrate the potential of modulating cardiac myosin to improve outcomes in patients with HCM and heart failure for which there are no medical treatments that address underlying impaired contractility. Following our recent financing, we are also taking steps to build our commercial organization in anticipation of our first potential product launch next year in parallel with our continued clinical progress."

Q2 and Recent Highlights

Cardiac Muscle Programs

omecamtiv mecarbil (cardiac myosin activator)

- Engaged with the U.S. Food and Drug Administration (FDA) in both a Type C meeting and a pre-NDA meeting to inform our plans to submit a New Drug Application (NDA) for *omecamtiv mecarbil* in 2H 2021. The submission will be based on GALACTIC-HF which demonstrated a positive effect on the primary composite endpoint of cardiovascular death or heart failure events in patients with heart failure and reduced ejection fraction who were receiving standard of care plus *omecamtiv mecarbil*.

- Results from a secondary analysis of 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 American College of Cardiology 70th Annual Scientific Session & Expo (ACC.21) showing that the treatment effect of *omecamtiv mecarbil* increased progressively as baseline ejection fraction decreased. The results were also published in the *Journal of the American College of Cardiology*.

- Additional results from GALACTIC-HF were presented at Heart Failure 2021, an International Congress of the European Society of Cardiology demonstrating that the patients who derived greater treatment benefit from *omecamtiv mecarbil* included patients without atrial fibrillation or flutter, patients with higher baseline NT-proBNP and patients with severe heart failure based on modified criteria from the Heart Failure Association of the European Society of Cardiology (ESC-HFA) advanced heart failure position statement.

- Completed enrollment in 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 conduct of METEORIC-HF by year end and report results in early 2022.

- Expanded Medical Affairs team and activities. Hired medical directors and deployed Medical Science Liaisons in key U.S. locations. Organized framework for the Investigator Sponsored Study Program.

- Established Go-to-Market-strategy and conducted commercial readiness activities, including organizational design, market research, forecasting, market access preparations and supply chain and logistics planning.

aficamten (CK-3773274**,** cardiac myosin inhibitor)

- Received approval from the World Health Organization and the United States Adopted Name Council for *aficamten* to be used as the International Nonproprietary Name for CK-3773274.

- Announced positive topline 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) ($p=0.0003$, $p=0.0004$, Cohort 1 and Cohort 2, respectively) and the average post-Valsalva LVOT-G ($p=0.001$, $p<0.0001$, Cohort 1 and Cohort 2, respectively). The majority of patients treated with *aficamten* (78.6% in Cohort 1 and 92.9% in Cohort 2) achieved the target goal of treatment, defined as resting gradient <30 mmHg and post-Valsalva gradient <50 mmHg at Week 10 compared to placebo (7.7%). Treatment with *aficamten* in REDWOOD-HCM was generally well tolerated. The incidence of adverse events was similar between treatment arms. No serious adverse events were attributed to *aficamten* and no treatment interruptions occurred on *aficamten,* and no new cases of atrial fibrillation in patients treated with *aficamten* were reported.

- Opened enrollment in Cohort 3 of REDWOOD-HCM for patients whose background therapy includes *disopyramide*. Activated the first site for enrollment 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.

- Engaged FDA in a Type C meeting and subsequent end-of Phase 2 interaction to review the design of the planned Phase 3 clinical trial of *aficamten* in patients with obstructive HCM as well as the intended dosing strategy. Feedback was supportive of our objectives and progression.

- Conducted preparations for a pivotal Phase 3 clinical trial of *aficamten* in patients with obstructive HCM, expected to begin in Q4 2021.

- Ji Xing Pharmaceuticals continued enrolling patients in a Phase 1 study of *aficamten* in China and is preparing to participate in the planned Phase 3 clinical trial of *aficamten* in patients with obstructive HCM.

- Presented scientific data related to the optimization of *aficamten*, including the first disclosure of its chemical structure, at the American Chemical Society Spring 2021 Virtual Meeting.

Skeletal Muscle Program

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

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

Pre-Clinical Development and Ongoing Research

- Continued to advance new chemical entities and to conduct IND-enabling studies with 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 $297.3 million in net proceeds, after deducting underwriting discounts and commissions from an underwritten public offering of 11,500,000 shares of common stock including the underwriter's exercise of their overallotment option.

- Executed agreements related to the termination of our Collaboration Agreement with Amgen and the transition to Cytokinetics of the development and commercialization rights for *omecamtiv mecarbil* and CK-136.

- Announced the continuation of our partnership with The ALS Association in the fight against ALS.

Financials

Revenues for the three and six months ended June 30, 2021 were $2.8 million and $9.4 million, respectively, compared to $3.6 million and $7.4 million for the corresponding periods in 2020. The changes in revenues are due to changes in reimbursable collaborative activities with Amgen and Astellas.

Research and development expenses for the three and six months ended June 30, 2021 increased to $36.4 and $68.0 million, respectively, compared to $21.8 million and $43.5 million for the same periods in 2020. The changes were primarily due to increases in spending for COURAGE-ALS and our clinical development activities for our cardiac muscle inhibitor programs. In addition, this quarter, we incurred transition costs related to the termination of our collaboration with Amgen and the purchase from Amgen of approximately $7.3 million of materials including manufactured quantities of the active pharmaceutical ingredient for *omecamtiv mecarbil.*

General and administrative expenses for the three and six months ended June 30, 2021 increased to $21.2 million and $36.8 million from $14.2 million and $26.6 million in 2020 due primarily to an increase in personnel related costs including stock-based compensation and higher outside spending for commercial readiness.

Financial Guidance and Cash Runway

The company recently updated its financial guidance for 2021. We expect our revenues for 2021 will be in the range of $23 million to $28 million, our operating expenses will be in the range of $230 million to $250 million, and our net cash utilization will be in the range of $195 million to $215 million. This new guidance includes non-recurring new building construction costs of approximately $35 million and assumes receipt of $45 million under our funding agreement with RTW Investments, LP.

The company ended the second quarter with $424 million cash. With the common stock offering in July and our having raised approximately $297 million in net proceeds, we believe that we have more than three years of cash runway based on our revised 2021 cash utilization guidance.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's second 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 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 7387377.

An archived replay of the webcast will be available via Cytokinetics' website until August 19, 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 7387377 from August 5, 2021 at 7:30 PM Eastern Time until August 19, 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 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 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 topline 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 a 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 enrollment in METEORIC-HF in Q2 2021 and the release of results of METEORIC-HF in early 2022, the commencement of a Phase 3 clinical trial of *aficamten* by year-end 2021, 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 end of 2021, and the prospects of regulatory approval for, and if approved, potential commercialization of *omecamtiv mecarbil*; 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* ; the properties and potential benefits of Cytokinetics' drug candidates; and our ability to satisfy the conditions to disbursement under our financing agreement with, and our ability to obtain $45 million from, RTW. 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)

	June 30, 2021 (unaudited)	December 31, 2020
ASSETS		
Current assets:		
Cash and short term investments	$ 350,301	$ 464,060
Other current assets	13,928	10,161
Total current assets	364,229	474,221
Long-term investments	73,672	36,954
Property and equipment, net	36,942	13,346
Operating lease right-of-use assets	83,006	2,924
Other assets	6,453	6,358
Total assets	$ 564,302	$ 533,803
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued liabilities	$ 37,322	$ 27,365
Current portion of long-term debt	11,250	—
Short-term lease liabilities	12,190	2,785
Other current liabilities	1,004	1,049
Total current liabilities	61,766	31,199
Term loan, net	35,538	46,209
Convertible notes, net	92,348	89,504
Liability related to the sale of future royalties, net	171,790	166,068
Long-term deferred revenue	87,000	87,000
Long-term lease liability	99,371	440
Total liabilities	547,813	420,420

Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock	72	70
Additional paid-in capital	1,117,403	1,105,470
Accumulated other comprehensive income	(22)	149
Accumulated deficit	(1,100,964)	(992,306)
Total stockholders' equity (deficit)	16,489	113,383
Total liabilities and stockholders' equity (deficit)	$ 564,302	$ 533,803

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

	Three Months Ended		Six Months Ended	
	June 30, 2021	June 30, 2020	June 30, 2021	June 30, 2020
Revenues:				
Research and development revenues	$ 2,843	$ 3,593	$ 9,391	$ 7,418
Total revenues	2,843	3,593	9,391	7,418
Operating expenses:				
Research and development	36,443	21,790	68,004	43,528
General and administrative	21,197	14,161	36,795	26,610
Total operating expenses	57,640	35,951	104,799	70,138
Operating loss	(54,797)	(32,358)	(95,408)	(62,720)
Interest expense	(4,073)	(3,892)	(8,061)	(7,969)
Non-cash interest expense on liability related to the sale of future royalties	(2,871)	(5,912)	(5,666)	(11,601)
Interest and other income	187	1,382	477	2,105
Net loss	$ (61,554)	$ (40,780)	$ (108,658)	$ (80,185)
Net loss per share — basic and diluted	$ (0.86)	$ (0.68)	$ (1.52)	$ (1.35)
Weighted-average number of shares used in computing net loss per share — basic and diluted	71,754	59,605	71,476	59,438

Source: Cytokinetics, Incorporated