Cytokinetics Reports Fourth Quarter 2021 Financial Results

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Commercial Launch Readiness Activities Underway for Omecamtiv Mecarbil in Advance of PDUFA Date of November 30, 2022

SEQUOIA-HCM Open to Enrollment;
Development Program for Aficamten Expanding in 2022

Company Provides 2022 Financial Guidance;
More Than 2 Years of Cash Runway

SOUTH SAN FRANCISCO, Calif., Feb. 24, 2022 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) reported financial results for the fourth quarter and full year 2021. Net loss for the fourth quarter was $30.6 million or $0.36 per share and the net loss for the year 2021 was $215.3 million or $2.80 per share. Net loss for the fourth quarter of 2020 was $43.9 million or $0.62 per share and net loss for the year 2020 was $127.3 million or $1.97 per share. Cash, cash equivalents and investments totaled $623.7 million at December 31, 2021. This cash balance does not include $150 million in proceeds received from transactions executed in late 2021 and early 2022.

"In the fourth quarter of last year and in early January we were pleased to execute two important transactions, comprising the licensing of *omecamtiv mecarbil* in China as well as funding for long-term capital supportive of the commercial launch of *omecamtiv mecarbil* and the further development of *aficamten*. In the fourth quarter we also continued to build our commercial infrastructure remaining prudent to spending gated to key de-risking events, such as the recent acceptance of the New Drug Application for *omecamtiv mecarbil* by the U.S. Food and Drug Administration," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "As we look ahead to what may be a pivotal year for our company, we believe that we are in a strong financial position to expand the development program for *aficamten* and advance our pipeline of early drug candidates while we also deliver on the promise of muscle biology by responsibly transforming from a R&D focused company to one that is also commercial."

Q4 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 capabilities and engaged in product launch readiness activities for *omecamtiv mecarbil* in the U.S. Key launch readiness activities in Q4 focused to market access, distribution strategy, campaign development, pricing, field force size, structure and territory boundaries. Furthermore, the recent NDA filing has triggered additional investments in systems, training programs, supply chain and logistics as we continue to plan for a potential launch.

- Continued to expand our therapeutic Medical Scientists team and began development of our Managed Healthcare Medical Science Liaison team. We completed vendor selection for the Medical Contact Center and finalized design of our Investigator Sponsored Study Program.

- Announced topline 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. METEORIC-HF evaluated the effect of treatment with *omecamtiv mecarbil* compared to placebo on exercise capacity as determined by cardiopulmonary exercise testing (CPET). There was no effect on the primary endpoint of change in peak oxygen uptake (pVO_2) on CPET from baseline to Week 20 in patients treated with *omecamtiv mecarbil* compared to 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. The results from METEORIC-HF will be presented at the American College of Cardiology 71st Annual Scientific

Session & Expo in Washington, D.C., as part of a Late Breaking Clinical Trial session on Sunday, April 3, 2022.

- Presented 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) at the American Heart Association (AHA) Scientific Sessions 2021 showing that treatment with *omecamtiv mecarbil* was associated with a significant reduction in the risk of stroke.

aficamten (cardiac myosin inhibitor)

- Opened enrollment in SEQUOIA-HCM (**S**afety, **E**fficacy, and **Q**uantitative **U**nderstanding of **O**bstruction **I**mpact of ***A****ficamten* in **HCM**). SEQUOIA-HCM is a Phase 3 randomized, placebo-controlled, double-blind, multi-center clinical trial designed to evaluate *aficamten* in patients with symptomatic obstructive HCM on background medical therapy for 24 weeks. The primary endpoint is the change in pVO_2 measured by CPET from baseline to week 24. SEQUOIA-HCM is expected to enroll 270 patients, randomized on a 1:1 basis to receive *aficamten* or placebo in addition to standard-of-care treatment. Each patient will receive up to four escalating doses of *aficamten* or placebo based on echocardiographic guidance alone.

- Announced positive topline results 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 HCM and a resting or post-Valsalva left ventricular outflow tract gradient (LVOT-G) of ≥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. In addition, 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. The results from Cohort 3 of REDWOOD-HCM will be presented at the American College of Cardiology 71st Annual Scientific Session & Expo in Washington, D.C., on Saturday, April 2, 2022.

- Received Breakthrough Therapy Designation for *aficamten* for the treatment of symptomatic obstructive HCM from the (FDA).

- The Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) granted Breakthrough Therapy Designation for *aficamten* for the treatment of symptomatic obstructive HCM in China.

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

- Presented preclinical data relating to the discovery and optimization of CK-136 at the 2021 Medicinal Chemistry Gordon Research Conference in West Dover, VT, and presented preclinical data on a closely related analog to CK-136 related to its effect on cardiac contractility and energetics at the American Heart Association (AHA) Scientific Sessions 2021.

Skeletal Muscle Program

reldesemtiv (fast skeletal muscle troponin activator (FSTA))

- Continued conduct 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).

- Presented data from our ALS program at the 32nd International Symposium on ALS/MND, including an analysis of baseline characteristics from the initial 27 patients enrolled in COURAGE-ALS indicating that the majority of patients enrolled to date were categorized as middle or fast progressors. Supplemental analyses presented from FORTITUDE-ALS showed that declining grip strength was strongly correlated with declining fine motor function and declining arm function, and that extremity muscle strength was correlated with physical function and quality of life. Results were also presented from IMPACT ALS, a self-reported online survey of ALS patients and caregivers in Europe exploring perspectives on burden of disease and treatment.

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 of up to $300 million 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.

- Expanded collaboration with Ji Xing Pharmaceuticals Limited (Ji Xing), a biopharmaceutical company backed by investment funds affiliated with RTW Investments, LP (RTW), by entering into an exclusive license and collaboration agreement to develop and commercialize *omecamtiv mecarbil* for the proposed treatment of HFrEF in Greater China. The company also entered into Common Stock Purchase Agreements with investment funds affiliated with RTW. Cytokinetics has received committed capital of $70 million, and will receive up to $330 million from Ji Xing in additional milestone payments plus tiered royalties on the net sales of *omecamtiv mecarbil* in Greater China, subject to certain reductions.

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 enrollment in SEQUOIA-HCM through 2022.

- Begin enrolling patients with non-obstructive HCM in Cohort 4 of REDWOOD-HCM in Q1 2022.

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

- Expect to share data from the open label extension study, REDWOOD-HCM OLE, for patients who complete REDWOOD-HCM, in 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 three and twelve months ended December 31, 2021 were $55.6 million and $70.4 million, respectively, compared to $6.7 million and $55.8 million for the corresponding periods in 2020. The increase in revenues for the year ended December 31, 2021 was primarily due to $54.9 million of license revenue recognized for the transaction with Ji Xing.

Research and development expenses for the three and twelve months ended December 31, 2021 increased to $43.5 million and $159.9 million, respectively, compared to $29.2 million and $97.0 million for the same periods in 2020, respectively, due primarily to increases in spending for clinical development activities for our cardiac muscle inhibitor programs, COURAGE-ALS, facility expenses and for regulatory filing costs. In addition, we incurred transition costs related to the termination of our collaboration with Amgen and our purchase of approximately $14.6 million of material including manufactured quantities of the active pharmaceutical ingredients for *omecamtiv mecarbil*.

General and administrative expenses for the three and twelve months ended December 31, 2021 increased to $33.8 million and $96.8 million from $13.9 million and $52.8 million in 2020 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.

2022 Financial Guidance

The company today announced financial guidance for 2022. The company anticipates revenue will be in the range of $20 to $25 million, operating expenses will be in the range of $380 to $400 million, and net cash utilization will be approximately $365 to $385 million. Our current cash balance of $724 million, in addition to committed capital expected to be earned upon dosing of the first patient in SEQUOIA-HCM, represents more than two years of forward cash based on our projected operating expenses and net cash utilization.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's fourth 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 2895984.

An archived replay of the webcast will be available via Cytokinetics' website until March 10, 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 2895984 from February 24, 2022 at 7:30 PM Eastern Time until March 10, 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 novel 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 hypertrophic cardiomyopathy (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 the Q4 2022 or Q1 2023, our ability to fully enroll SEQUOIA-HCM or COURAGE-ALS, our ability to conduct IND-enabling studies and to advance new muscle directed compounds into clinical development in 2022, 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 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 respective 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' Quarterly Report on Form 10-Q for the third quarter 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)

	December 31, 2021 (unaudited)	December 31, 2020
ASSETS		
Current assets:		
Cash and short term investments	$ 471,638	$ 464,060
Other current assets	64,034	10,161
Total current assets	535,672	474,221
Long-term investments	152,050	36,954
Property and equipment, net	73,271	13,346
Operating lease right-of-use assets	73,138	2,924
Other assets	7,188	6,358
Total assets	$ 841,319	$ 533,803
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 55,457	$ 27,365
Short-term lease liability	14,863	2,785
Other current liabilities	1,540	1,049
Total current liabilities	71,860	31,199
Term loan, net	47,367	46,209
Convertible notes, net	95,471	89,504
Liabilities related to revenue participation right purchase agreement, net	179,072	166,068
Long-term deferred revenue	87,000	87,000
Long-term operating lease liabilities	112,229	440
Other non-current liabilities	4,457	—
Total liabilities	597,456	420,420
Commitments and contingencies		
Stockholders' equity:		
Common stock	84	70
Additional paid-in capital	1,452,268	1,105,470
Accumulated other comprehensive income	(869)	149
Accumulated deficit	(1,207,620)	(992,306)
Total stockholders' equity	243,863	113,383
Total liabilities and stockholders' equity	$ 841,319	$ 533,803

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

	Three Months Ended December 31,		Years Ended December 31,	
	2021	**2020**	**2021**	**2020**
Revenues:				
Research and development revenues	$ 744	$ 4,222	$ 10,572	$ 16,527
License revenues	54,856	—	54,856	36,501
Milestone revenues	—	2,500	5,000	2,800
Total revenues	55,600	6,722	70,428	55,828
Operating expenses:				
Research and development	43,498	29,221	159,938	96,951
General and administrative	33,806	13,908	96,803	52,820
Total operating expenses	77,304	43,129	256,741	149,771
Operating loss	(21,704)	(36,407)	(186,313)	(93,943)
Interest expense	(4,218)	(4,018)	(16,440)	(15,963)
Non-cash interest expense on liability related to sale of future royalties	(4,271)	(5,651)	(12,892)	(22,713)
Interest and other income, net	(377)	2,146	331	5,329
Net loss before income taxes	(30,570)	(43,930)	(215,314)	(127,290)
Income tax benefit	—	—	—	—
Net loss	$ (30,570)	$ (43,930)	$ (215,314)	$ (127,290)
Net loss per share — basic and diluted	$ (0.36)	$ (0.62)	$ (2.80)	$ (1.97)
Weighted-average shares in net loss per share — basic and diluted	84,087	70,833	76,886	64,524

Cytokinetics

Source: Cytokinetics, Incorporated