UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event Reported): October 31, 2019

Cytokinetics, Incorporated
(Exact Name of Registrant as Specified in Charter)

Delaware	**000-50633**	**94-3291317**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

280 East Grand Avenue, South San Francisco, California 94080
(Address of Principal Executive Offices) (Zip Code)

(650) 624-3000
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

[ ] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
[ ] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
[ ] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
[ ] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company [ ]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	**CYTK**	**The Nasdaq Global Select Market**

Item 2.02. Results of Operations and Financial Condition.

On October 31, 2019, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

Exhibit 99.1. Press release dated October 31, 2019

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Cytokinetics, Incorporated

Date: October 31, 2019

By: /s/ Robert Wong
Robert Wong
VP, Chief Accounting Officer

EXHIBIT 99.1

Cytokinetics Reports Third Quarter 2019 Financial Results

Enrollment Completed in GALACTIC-HF with More than 8,200 Heart Failure Patients;
Second Interim Analysis Expected in Q1 2020

Data from Phase 1 Study of CK-274 Support Progression;
Phase 2 Clinical Trial in Patients with Obstructive Hypertrophic Cardiomyopathy to Begin in Q4 2019

Faster Progressing Patients Receiving Reldesemtiv in FORTITUDE-ALS Experienced Slower Decline in ALSFRS-R and Greater Difference from Placebo than Slower Progressing Patients

SOUTH SAN FRANCISCO, Calif., Oct. 31, 2019 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq:CYTK) reported financial results for the third quarter of 2019. Net loss for the third quarter was $29.6 million, or $0.50 per share, compared to net loss for the third quarter of 2018 of $22.0 million, or $0.40 per share. Cash, cash equivalents and investments totaled $166.0 million at September 30, 2019.

“In the third quarter of 2019, we achieved major milestones in both our cardiovascular and neuromuscular programs representing progress on key priorities across our pipeline of muscle-directed therapies,” said Robert I. Blum, Cytokinetics’ President and Chief Executive Officer. “Completion of enrollment of GALACTIC-HF represents a significant step forward towards the completion of this important trial which holds promise for advancing the treatment of millions of patients suffering from heart failure. Additionally, recently presented Phase 1 data for CK-274 reaffirms its next-generation profile and supports advancing this program into a Phase 2 trial in patients with obstructive hypertrophic cardiomyopathy this year. Furthermore, additional analyses of results from FORTITUDE-ALS, as well as ongoing regulatory interactions, provide support for a potential Phase 3 trial of *reldesemtiv* in patients with ALS next year. We believe this progress positions us well to leverage our leadership in muscle pharmacology to benefit a wide array of patients suffering from varied diseases of muscle dysfunction.”

Recent Highlights

Cardiac Muscle Programs

omecamtiv mecarbil (cardiac myosin activator)

- Completed patient enrollment in 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), the Phase 3 cardiovascular outcomes clinical trial of *omecamtiv mecarbil*. GALACTIC-HF enrolled over 8,200 patients in 35 countries. We expect GALACTIC-HF to continue throughout 2019 and the second planned interim analysis of GALACTIC-HF to occur in the first quarter of 2020.

- 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.* METEORIC-HF is a randomized, placebo-controlled, double-blind, parallel group, multicenter clinical trial designed to evaluate the effect of treatment with *omecamtiv mecarbil* compared to placebo on exercise capacity as determined by cardiopulmonary exercise testing (CPET) following 20 weeks of treatment. We expect to continue enrollment of METEORIC-HF throughout 2019.

AMG 594 (cardiac troponin activator)

- Continued conduct of the Phase 1 study of AMG 594 to assess its safety, tolerability, pharmacokinetics and potential to increase cardiac function in healthy volunteers. AMG 594 is a novel, selective, oral, small molecule cardiac troponin activator, discovered under our joint research program with Amgen. This Phase 1 study is being conducted by Amgen in collaboration with Cytokinetics. We expect the conduct of this study to continue throughout 2019.

CK-3773274 (CK-274, cardiac myosin inhibitor)

- Presented data from the Phase 1 study of CK-274 at the Heart Failure Society of America’s 23 rd Annual Scientific Meeting in Philadelphia. The study met its primary and secondary objectives to assess the safety and tolerability of single and multiple oral doses of CK-274, describe the pharmacokinetics of CK-274 and its pharmacodynamic effects as measured by echocardiography, as well as to characterize the PK/PD relationship with regards to cardiac function. These data support the advancement of CK-274 into a Phase 2 clinical trial in patients with obstructive hypertrophic cardiomyopathy (HCM) which is expected to begin in Q4 2019.

- Presented preclinical data at the American Heart Association’s Basic Cardiovascular Sciences Scientific Sessions in Boston demonstrating that CK-274 produces exposure related effects on cardiac contractility in healthy animals and mouse models of HCM and support the therapeutic hypothesis relating to onset of action and reversibility.

Skeletal Muscle Program

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

- Presented post-hoc analyses from FORTITUDE-ALS (**F**unctional **O**utcomes in a **R**andomized **T**rial of **I**nvestigational **T**reatment with CK-2127107 to **U**nderstand **D**ecline in **E**ndpoints – in **ALS**), at the 2019 Northeast Amyotrophic Lateral Sclerosis (NEALS) Meeting in Clearwater Beach, FL. The analyses demonstrated that, in the combined middle and faster progressing tertiles of patients, the decline in the ALSFRS-R total score from baseline to week 12 in patients who received any dose of *reldesemtiv* was significantly smaller than the decline on placebo, while no significant difference between *reldesemtiv* and placebo was observed in slower progressing patients.

- Held regulatory interactions and conducted feasibility and other planning activities in preparation for the potential advancement of *reldesemtiv* to a Phase 3 trial in patients in ALS in 2020.

- Received European Orphan Designation for *reldesemtiv* for the potential treatment of spinal muscular atrophy (SMA) by the European Medicines Agency (EMA).

Pre-Clinical Development and Ongoing Research

- Announced the publication of "Fast Skeletal Muscle Troponin Activator CK-2066260 Increases Fatigue Resistance by Reducing the Energetic Cost of Muscle Contraction," in *The Journal of Physiology,* demonstrating that a FSTA can decrease skeletal muscle fatigue by increasing the metabolic efficiency of muscle contraction. CK-2066260 is a preclinical FSTA tool compound.

- Continued pre-clinical development of CK-3762601 (CK-601), a next-generation FSTA, under our collaboration with Astellas.

- Continued research in collaboration with Astellas directed to the discovery of next-generation skeletal muscle activators; Astellas is sponsoring Cytokinetics' research activities through 2019.

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

Corporate

- We and Astellas have agreed in principle to revise the terms of our collaboration agreement so that Cytokinetics would have the exclusive right to develop and commercialize all FSTAs, including *reldesemtiv* and CK-601. Astellas' future contributions would be to provide partial co-funding for certain Phase 3 clinical trial costs for *reldesemtiv* in ALS and to provide other in-kind support. In exchange, Astellas would receive a low- to mid- single digit royalty on *reldesemtiv* to be payable by Cytokinetics. We have also agreed in principle to extend our joint research program for another year with Astellas sponsoring research at Cytokinetics through 2020.

- The above agreements in principle are non-binding and contingent upon our finalizing amendments to our collaboration agreement and, absent such agreement, the terms of the existing agreement remain in place.

- Announced the continuation of our partnership with Cure SMA to increase education, awareness, public policy and fundraising for SMA. The partnership includes support for several of Cure SMA's national initiatives as well as local community events.

- Announced a call for proposals for the second annual Cytokinetics Communications Fellowship Grant program. The program provides $100,000 in grants to five selected patient advocacy organizations serving the ALS, heart failure, HCM, or SMA communities, and is intended to support increased capacity in communications, awareness building and community engagement.

Financials

Revenues for the three and nine months ended September 30, 2019 were $6.1 million and $21.7 million, respectively, compared to $10.6 million and $22.1 million for the corresponding periods in 2018. The decrease in revenues for the three and nine months ended September 30, 2019 was due primarily to the winding down of FORTITUDE-ALS in addition to a lack of license revenue in 2019. License revenues in the third quarter and first nine months of 2018 were related to the Phase 2 trial of *reldesemtiv* in spinal muscular atrophy completed in 2018.

Research and development expenses for the three and nine months ended September 30, 2019 were $20.2 million and $67.8 million, respectively compared to $21.4 million and $65.9 million for the same periods in 2018, respectively. The changes were primarily due to reduced spending for *reldesemtiv* as well as *tirasemtiv* following suspension of development of *tirasemtiv* in late 2017 offset by increased spending related to METEORIC-HF and the development of CK-274.

General and administrative expenses for the three and nine months ended September 30, 2019 increased to $9.8 million and $29.0 million, respectively, from $7.2 million and $23.7 million for the same periods in 2018, respectively, due primarily to an increase in outside legal counsel and personnel related costs including stock-based compensation.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's third quarter 2019 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 the 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 9440838.

An archived replay of the webcast will be available via Cytokinetics' website until November 7, 2019. 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 9440838 from October 31, 2019 at 7:30 PM Eastern Time until November 7, 2019.

About Cytokinetics

Cytokinetics is a late-stage biopharmaceutical company focused on discovering, developing and commercializing first-in-class muscle activators and best-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 collaborating with Amgen Inc. (Amgen) to develop *omecamtiv mecarbil*, a novel cardiac muscle activator. *Omecamtiv mecarbil* is the subject of an international clinical trials program in patients with heart failure including GALACTIC-HF and METEORIC-HF. Amgen holds an exclusive worldwide license to develop and commercialize *omecamtiv mecarbil* with a sublicense held by Servier for commercialization in Europe and certain other countries. Cytokinetics is collaborating with Astellas Pharma Inc. (Astellas) to develop *reldesemtiv*, a fast skeletal muscle troponin activator (FSTA) for diseases of neuromuscular dysfunction, including SMA and ALS. Astellas holds an exclusive worldwide license to develop and commercialize *reldesemtiv*. Licenses held by Amgen and Astellas are subject to specified co-development and co-commercialization rights of Cytokinetics. Cytokinetics is also developing CK-274, a novel cardiac myosin inhibitor that company scientists discovered independent of its collaborations, for the potential treatment of hypertrophic cardiomyopathies. 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 activities, including the initiation, conduct, design, enrollment, progress, continuation, completion, timing and results of clinical trials; the significance and utility of pre-clinical study and clinical trial results; planned interactions with regulatory authorities and the outcomes of such interactions; the expected timing of events and milestones, including the receipt of milestone payments; the agreement in principle to revise the terms of the collaboration agreement between Astellas and Cytokinetics; 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; Amgen's and Astellas' decisions with respect to the design, initiation, conduct, timing and continuation of development activities for *omecamtiv mecarbil* and *reldesemtiv*, respectively; 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. 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 Statements of Operations
(in thousands, except per share data)
(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30, 2019	September 30, 2018	September 30, 2019	September 30, 2018
Revenues:				
Research and development revenues	$ 6,055	$ 8,726	$ 21,656	$ 16,991
License revenues	—	1,915	—	5,133
Total revenues	6,055	10,641	21,656	22,124
Operating expenses:				
Research and development	20,229	21,391	67,791	65,858
General and administrative	9,753	7,164	29,026	23,724
Total operating expenses	29,982	28,555	96,817	89,582
Operating loss	(23,927)	(17,914)	(75,161)	(67,458)
Interest expense	(1,345)	(867)	(3,892)	(2,628)
Non-cash interest expense on liability related to the sale of future royalties	(5,321)	(4,559)	(15,204)	(13,026)
Interest and other income	1,020	1,323	3,205	3,291
Net (loss) income before income taxes	(29,573)	(22,017)	(91,052)	(79,821)
Income tax benefit	-	-	-	-
Net loss	$ (29,573)	$ (22,017)	$ (91,052)	$ (79,821)
Net loss per share — basic and diluted	$ (0.50)	$ (0.40)	$ (1.60)	$ (1.47)
Weighted-average shares in net loss per share — basic and diluted	58,640	54,626	57,050	54,329

Cytokinetics, Incorporated
Condensed Consolidated Balance Sheets
(in thousands)

	September 30, 2019 (unaudited)	December 31, 2018[1]
ASSETS		
Current assets:		
Cash and short term investments	$ 166,039	$ 198,731
Other current assets	10,496	8,943
Total current assets	176,535	207,674
Property and equipment, net	3,615	3,204
Other assets	7,243	300
Total assets	$ 187,393	$ 211,178
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 16,551	$ 19,521
Current portion of long-term debt	-	2,607
Short-term lease liability	4,577	—
Other current liabilities	389	66
Total current liabilities	21,517	22,194
Long-term debt, net	44,762	39,806
Liability related to the sale of future royalties, net	137,726	122,473
Long-term lease liability	3,257	—
Other long-term liabilities	—	771
Total liabilities	207,262	185,244
Stockholders' equity:		
Common stock	59	55
Additional paid-in capital	813,729	768,703
Accumulated other comprehensive income	719	500
Accumulated deficit	(834,376)	(743,324)
Total stockholders' equity	(19,869)	25,934
Total liabilities and stockholders' equity	$ 187,393	$ 211,178

[1] Derived from the audited financial statements, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018.