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): February 21, 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. [ ]

Item 2.02. Results of Operations and Financial Condition.

On February 21, 2019, Cytokinetics, Incorporated issued a press release announcing its results for the fourth quarter ended December 31, 2018. A copy of the press release is being filed as Exhibit 99.1 to this Current Report and is hereby incorporated by reference into this item 2.02.

Item 9.01. Financial Statements and Exhibits.

Exhibit 99.1. Press release dated February 21, 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: February 21, 2019

By: /s/ Peter S. Roddy
Peter S. Roddy
Senior Vice President, Chief Accounting Officer

EXHIBIT 99.1

Cytokinetics Reports Fourth Quarter 2018 Financial Results

Company Provides 2019 Financial Guidance and Expected Milestones

Reduced Operating Expenses vs. 2018; Over Two Years of Cash Based on Current Burn Rate

Interim Analysis for GALACTIC-HF on Track for 1H 2019

Results from FORTITUDE-ALS Expected in Q2 2019

SOUTH SAN FRANCISCO, Calif., Feb. 21, 2019 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) reported financial results for 2018. Net loss for 2018 was $106 million, or $1.95 per share, compared to net loss for 2017 of $128 million, or $2.59 per share. Cash, cash equivalents and investments totaled $199 million at December 31, 2018.

“We had a productive fourth quarter 2018 highlighted by the expansion of our clinical pipeline of muscle-directed investigational medicines and the advancement of our wholly-owned cardiac myosin inhibitor which we are developing for the potential treatment of patients with hypertrophic cardiomyopathies,” said Robert I. Blum, Cytokinetics’ President and Chief Executive Officer. “Our progress is continuing with the achievement of key milestones under our partnered programs. Under our collaboration with Amgen, we recently opened METEORIC-HF to enrollment and expect GALACTIC-HF to complete enrollment in the next few months. In that same timeframe, we are also looking forward to results from FORTITUDE-ALS under our collaboration with Astellas. We believe that our pioneering leadership in muscle biology, alongside our partnerships and current financials, position us well for upcoming company milestones.”

Recent Highlights

Cardiac Muscle Programs

omecamtiv mecarbil (cardiac myosin activator)

- Continued 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*. Enrollment is nearing 90 percent completion with over 7,000 patients randomized to date having the high-risk profile intended by the trial design. GALACTIC-HF is being conducted by Amgen in collaboration with Cytokinetics.

- Opened 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. METEORIC-HF is being conducted by Cytokinetics in collaboration with Amgen.

AMG 594 (cardiac troponin activator)

- Began dosing in 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 a joint research program with Amgen. This Phase 1 study is being conducted by Amgen in collaboration with Cytokinetics.

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

- Continued enrollment in a Phase 1 double-blind, randomized, placebo-controlled, multi-part, single and multiple ascending dose clinical study of CK-274 in healthy adult subjects. CK-274 is a wholly-owned, novel cardiac myosin inhibitor, discovered by company scientists, in development for the potential treatment of hypertrophic cardiomyopathy (HCM).

Skeletal Muscle Program

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

- Received feedback from the U.S. Food and Drug Administration that the Six Minute Walk Test is an acceptable primary endpoint for a potential registration program for *reldesemtiv* in ambulatory patients with SMA.

- Completed patient enrollment in 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**), the Phase 2 clinical trial designed to assess the change from baseline in the percent predicted slow vital capacity and other measures of skeletal muscle function after 12 weeks of treatment with *reldesemtiv* in patients with ALS. This Phase 2 trial is being conducted by Cytokinetics in collaboration with Astellas.

- Announced data from FORTITUDE-ALS at the 29th International Symposium on ALS/MND in Glasgow, Scotland, UK, including patient baseline characteristics and demographics. Baseline characteristics of patients enrolled in FORTITUDE-ALS are similar to those of other recent large clinical trials in ALS, including BENEFIT-ALS and VITALITY-ALS.

Pre-Clinical Development and Ongoing Research

- 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; The companies are continuing their joint research program with Astellas providing sponsorship of Cytokinetics' activities through 2019.

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

Corporate

- Convened an R&D Day to provide an update on our expanded pipeline of muscle-directed drug candidates.

Financials

Revenues for 2018 included $29.4 million in revenue from our collaboration with Astellas and $1.9 million from our collaboration with Amgen. Revenues from Astellas in 2018 included $22.3 million for reimbursement of research and development expenses, $5.1 million in license revenue and $2.0 million in a milestone payment. Revenues from Amgen in 2018 include $1.9 million for reimbursement of research and development expenses. Revenues for 2017 were offset by $20.0 million for payments to Amgen related to our option to co-fund the Phase 3 development program of *omecamtiv mecarbil* in exchange for an increased royalty upon potential commercialization.

Research and development expenses decreased to $89.1 million in 2018 from $90.3 million in 2017, primarily due to the suspension of development of *tirasemtiv* in late 2017, offset in part by increased development activities for *reldesemtiv* and CK-274.

General and administrative expenses decreased to $31.3 million in 2018 from $36.5 million in 2017, primarily due to decreased commercial readiness activities.

2019 Financial Guidance

The company also announced financial guidance for 2019. The company anticipates cash revenue will be in the range of $28 to $32 million, operating expenses will be in the range of $110 to $115 million, and net cash utilization will be approximately $85 to $90 million.

2019 Corporate Milestones

Cardiac Muscle Programs

omecamtiv mecarbil (cardiac myosin activator)

- Expect to complete patient enrollment in GALACTIC-HF in the first half of 2019.

- Expect the Data Monitoring Committee to conduct a first interim analysis for GALACTIC-HF, the design of which is tied to the potential for futility, in the first half of 2019.

- Expect to continue patient enrollment in METEORIC-HF through 2019.

AMG 594 (cardiac troponin activator)

- Expect the continued conduct of the Phase 1 study of AMG 594 through 2019.

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

- Expect data from a Phase 1 study of CK-274 in the second half of 2019.

Skeletal Muscle Program

reldesemtiv (next-generation FSTA)

- Expect results from FORTITUDE-ALS in Q2 2019.

Pre-Clinical Research

- Expect to continue joint research program with Astellas through 2019.

- Expect to continue independent research activities directed to our other muscle biology research programs through 2019.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's fourth quarter 2018 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 9798766.

An archived replay of the webcast will be available via Cytokinetics' website until February 28, 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 9798766 from February 21, 2019 at 7:30 PM Eastern Time until February 28, 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 also collaborating with Amgen to develop AMG 594, a first-in-class cardiac troponin activator, discovered under the companies' joint research program. Further development of AMG 594 is subject to the collaboration agreement between Amgen and Cytokinetics. Cytokinetics is collaborating with Astellas Pharma Inc. (Astellas) to develop *reldesemtiv*, a fast skeletal muscle troponin activator (FSTA). *Reldesemtiv* has been granted orphan drug designation by the FDA for the potential treatment of spinal muscular atrophy. *Reldesemtiv* was the subject of a positive Phase 2 clinical study in patients with spinal muscular atrophy which showed increases in measures of endurance and stamina consistent with the mechanism of action. *Reldesemtiv* is currently the subject of FORTITUDE-ALS, a Phase 2 clinical trial in patients with amyotrophic lateral sclerosis. Cytokinetics is also advancing CK-601, a next-generation FSTA, under the collaboration with Astellas. 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.

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; 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.

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

	Three Months Ended December 31,		Years Ended December 31,	
	2018	**2017**	**2018**	**2017**
Revenues:				
Research and development, milestone, grant and other revenues, net	$ 9,377	$ (5,234)	$ 26,368	$ 4,569
License revenues	—	5,216	5,133	8,799
Total revenues	9,377	(18)	31,501	13,368
Operating expenses:				
Research and development	23,278	26,250	89,135	90,296
General and administrative	7,558	10,259	31,282	36,468
Total operating expenses	30,836	36,509	120,417	126,764
Operating loss	(21,459)	(36,527)	(88,916)	(113,396)
Interest expense	(1,170)	(670)	(3,797)	(3,016)
Non-cash interest expense on liability related to sale of future royalties	(4,740)	(4,061)	(17,767)	(13,980)
Interest and other income, net	900	774	4,191	2,602
Net loss	$ (26,469)	$ (40,484)	$ (106,289)	$ (127,790)
Net loss per share	$ (0.48)	$ (0.75)	$ (1.95)	$ (2.59)
Weighted-average shares in net loss per share	54,689	53,929	54,420	49,404

Cytokinetics, Incorporated
Condensed Consolidated Balance Sheets
(in thousands)

	December 31, 2018 (unaudited)	December 31, 2017[(1)]
ASSETS		
Current assets:		
Cash and short term investments	$ 198,731	$ 268,891
Other current assets	8,943	5,404
Total current assets	207,674	274,295
Long-term investments	—	16,518
Property and equipment, net	3,204	3,568
Other assets	300	429
Total assets	$ 211,178	$ 294,810
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 19,521	$ 22,645
Deferred revenue, current	—	9,572
Current portion of long-term debt	2,607	—
Other current liabilities	66	227
Total current liabilities	22,194	32,444
Long-term debt, net	39,806	31,777
Liability related to the sale of future royalties, net	122,473	104,650
Deferred revenue, non-current	—	15,000
Other long-term liabilities	771	1,097
Total liabilities	185,244	184,968
Stockholders' equity:		
Common stock and additional paid-in capital	768,758	755,580

Accumulated other comprehensive income	500	343
Accumulated deficit	(743,324)	(646,081)
Total stockholders' equity	25,934	109,842
Total liabilities and stockholders' equity	$ 211,178	$ 294,810

(1) Derived from the audited financial statements, included in the company's Annual Report on Form 10-K for the year ended December 31, 2017.