
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):

July 31, 2013

Cytokinetics, Incorporated

(Exact name of registrant as specified in its charter)

Delaware

000-50633

94-3291317

(State or other jurisdiction
of incorporation)

(Commission
File Number)

(I.R.S. Employer
Identification No.)

280 East Grand Avenue, South San Francisco,
California

94080

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code:

(650) 624 - 3000

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))
-

[Top of the Form](#)

Item 2.02 Results of Operations and Financial Condition.

On July 31, 2013, Cytokinetics, Incorporated issued a press release announcing its results for the second quarter ended June 30, 2013. 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.

(d) Exhibits.

The following Exhibits are filed as part of this Current Report on Form 8-K:

Exhibit No. Description

99.1 Press Release, dated July 31, 2013.

[Top of the Form](#)

SIGNATURES

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.

July 31, 2013

Cytokinetics, Incorporated

By: /s/ Sharon Barbari

*Name: Sharon Barbari
Title: Executive Vice President, Finance and Chief Financial Officer*

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated July 31, 2013

CYTOKINETICS, INCORPORATED REPORTS SECOND QUARTER 2013 FINANCIAL RESULTS

Company Provides Updated Financial and Milestone Guidance in Connection with Recent Strategic Transactions and Clinical Trials Progress

SOUTH SAN FRANCISCO, CA, July 31, 2013 – Cytokinetics, Incorporated (Nasdaq: CYTK) reported total research and development revenues for the second quarter of 2013 were \$1.0 million, compared to \$1.8 million during the same period in 2012. The second quarter revenue does not include \$33.5 million in deferred revenue related to the agreements entered into with Amgen Inc. and Astellas Pharma Inc. in June 2013. The net loss for the second quarter was \$15.0 million, or \$0.58 per basic and diluted share. This is compared to a net loss allocated to common stockholders for the same period in 2012, of \$10.3 million, or \$0.76 per basic and diluted share, which included a one-time, non-cash dividend of \$1.3 million related to the beneficial conversion feature of the Series B convertible preferred stock. As of June 30, 2013, cash, cash equivalents and investments totaled \$75.7 million, which includes the receipt of \$15 million from the expansion of our strategic collaboration with Amgen for *omecamtiv mecarbil* and \$10 million for the sale of common stock to Amgen, but does not include \$16.0 million received from Astellas in July 2013.

“In the second quarter, Cytokinetics announced important strategic transactions and progress in our lead development-stage programs,” stated Robert I. Blum, Cytokinetics’ President and Chief Executive Officer. “A new collaboration with Astellas and an expanded alliance with Amgen afford us increased resources and opportunities to take key steps forward as we are advancing multiple drug candidates from our leading muscle biology directed research. We believe that Cytokinetics is well-positioned in both our cardiac and skeletal muscle activator programs to deliver on the promise they may represent for patients suffering from grievous illnesses and we are looking forward to the results from our Phase II clinical trials.”

Updated Financial Guidance for 2013

Cytokinetics also announced its updated financial guidance for 2013. The company anticipates cash revenue will be approximately \$40 to \$42 million, cash R&D expenses will be in the range of \$52 to \$55 million, and cash G&A expenses will be in the range of \$15 to \$16 million. This financial guidance is on a cash basis and does not include the deferral of approximately \$10 million in revenue to future calendar years and an estimated \$5.6 million in non-cash related operating expenses primarily related to stock compensation expense.

Company Highlights

Cardiac Muscle Contractility

omecamtiv mecarbil

- During the quarter, Cytokinetics announced that results from ATOMIC-AHF (**A**cute **T**reatment with **O**me**c**am**t**iv **M**ecar**b**il to **I**ncrease **C**ontractility in **A**cute **H**eart **F**ailure) have been accepted for presentation during a Hot Line Late Breaking Trials Session at the European Society of Cardiology (ESC) Congress. ATOMIC-AHF is a Phase IIb clinical trial designed to evaluate the safety, tolerability and efficacy of an intravenous formulation of *omecamtiv mecarbil* compared to placebo in patients with left ventricular systolic dysfunction who are hospitalized with acute heart failure.
- Recently, cohort 2 of COSMIC-HF (**C**hronic **O**ral Study of **M**yo**s**in **A**ctivation to **I**ncrease **C**ontractility in **H**eart **F**ailure) opened to enrollment. This Phase II, double-blind, randomized, placebo-controlled, multicenter, dose escalation study is designed to evaluate three modified-release oral formulations of *omecamtiv mecarbil* in patients with heart failure and left ventricular systolic dysfunction. COSMIC-HF is expected to inform the selection of an oral formulation of *omecamtiv mecarbil* for potential advancement into the Phase III clinical development program.
- During the quarter, Cytokinetics and Amgen reviewed results from a recently completed Phase I, open-label, single-dose clinical trial designed to compare the pharmacokinetics of *omecamtiv mecarbil* in patients undergoing hemodialysis versus healthy volunteers. No clinically meaningful differences were observed in this study in the pharmacokinetics of *omecamtiv mecarbil* administered to patients undergoing hemodialysis versus healthy volunteers.

The trials described above were or are being conducted by Amgen in collaboration with Cytokinetics. Additional information on these and other clinical trials of *omecamtiv mecarbil* can be found at www.clinicaltrials.gov.

Skeletal Muscle Contractility

tirasemtiv

- We are conducting BENEFIT-ALS (**B**linded **E**valuation of **N**euro**m**uscular **E**ffects and **F**unctional **I**mprovement with **T**irase**m**tiv in **A**LS) at over 70 sites across the United States, Canada and several European countries. To date, we have enrolled over 500 patients in BENEFIT-ALS. Cytokinetics recently announced that it had been informed by its data management vendor that a programming error in the electronic data capture system controlling study drug assignment for the on-going BENEFIT-ALS clinical trial caused 58 patients initially randomized to and treated with *tirasemtiv* to receive placebo instead at a certain study visit and for the remainder of the study. No patients randomized to placebo were dispensed incorrect treatment. Cytokinetics and all clinical trial personnel remain blinded to the specific patients affected by the error. Following detection of the error, the company took steps to ensure that no further incorrect study drug assignments occurred and to correct the programming error in the electronic data capture system controlling study drug assignment. In addition, we convened an ad hoc meeting of the study’s Data Safety Monitoring Board (DSMB) to assess whether the error in dispensing study drug had impacted the safety of the 58 affected patients. After review of the relevant safety data from BENEFIT-ALS, the DSMB reported no concerns regarding patient safety.
- Following interactions with regulatory authorities, Cytokinetics amended the protocol for BENEFIT-ALS to enable increased enrollment to approximately 680 patients and to update the statistical methods section, in both cases with the objective to maintain the originally intended statistical power of the trial.

CK-2127107

- During the quarter, Cytokinetics continued to enroll patients in CY 5011, a first-time-in-humans, Phase I clinical trial of CK-2127107, a novel small molecule activator of the fast skeletal muscle troponin complex, in healthy male volunteers. CY 5011 is a double-blind, randomized, placebo-controlled study designed to assess the safety, tolerability, and pharmacokinetics of single ascending oral doses of CK-2127107 administered in a three-period crossover design.

Pre-Clinical Research

- During the quarter, Cytokinetics continued to conduct research under our joint research program with Amgen directed to the discovery of next-generation cardiac sarcomere activators. In addition, the company continued research activities directed to other muscle biology programs.
- In June, Cytokinetics announced the publication of three peer-reviewed manuscripts co-authored by company scientists and a group led by Dr. Henk Granzier, Professor of Physiology, and Norville Endowed Chair, Molecular Cardiovascular Research Program, University of Arizona. These publications describe translational research conducted by Dr. Granzier's laboratory in collaboration with Cytokinetics in which the effects of fast skeletal muscle troponin activation were explored in nemaline myopathy, a rare, sarcomere-based disease.

Corporate

- In June, Cytokinetics announced an expansion of our strategic collaboration with Amgen to include Japan. In consideration of this expansion, Cytokinetics received \$25 million from Amgen comprised of a \$15 million non-refundable license fee and \$10 million for Amgen's purchase of 1.4 million shares of Cytokinetics' common stock. Cytokinetics is also eligible to receive additional pre-commercialization milestone payments for the development of *omecamtiv mecarbil* in Japan of up to \$50 million, as well as royalties on sales of *omecamtiv mecarbil* in Japan. As of June 30, 2013, the Company determined that all conditions necessary for revenue recognition under the accounting guidelines had not been met. The Company will defer the recognition of the \$15.0 million license fee under this amendment to the collaboration agreement until these criteria have been satisfied, which we anticipate will be in the third quarter 2013.
- In June, Cytokinetics and Astellas Pharma Inc. announced a collaboration focused on the research, development and commercialization of skeletal muscle activators. The primary objective of the collaboration is to advance novel therapies for diseases and medical conditions associated with muscle weakness. The parties will jointly conduct research in the area of skeletal muscle activation. Astellas will have exclusive rights to develop and commercialize drug candidates that may arise from these activities, subject to certain Cytokinetics' development and commercialization rights. As part of this collaboration, Cytokinetics has exclusively licensed to Astellas the rights to co-develop and commercialize CK-2127107, for potential applications in non-neuromuscular indications. CK-2127107 will be developed jointly by Cytokinetics and Astellas. Under the agreement, Cytokinetics will be primarily responsible for the conduct of Phase I clinical trials and certain Phase II readiness activities for CK-2127107 and Astellas will be primarily responsible for the conduct of subsequent development and commercialization activities for CK-2127107. Astellas will have exclusive rights to develop and commercialize other fast skeletal troponin activators in non-neuromuscular indications and to develop and commercialize other novel mechanism skeletal muscle activators in all indications, subject to certain Cytokinetics' development and commercialization rights. Astellas will have the exclusive right to commercialize collaboration products worldwide, subject to Cytokinetics' option to co-promote collaboration products in the United States and Canada. In July, Cytokinetics received a \$16.0M non-refundable upfront payment and is eligible to potentially receive over \$24.0M in reimbursement of sponsored research and development activities during the initial two years of the collaboration. In addition, Cytokinetics is eligible to receive over \$450 million in pre-commercialization and commercialization milestones plus royalties. The Company will recognize the \$16.0 million upfront license fee ratably over the 24 month period of the research plan with Astellas.
- In June, Cytokinetics filed a Certificate of Amendment to its Amended and Restated Certificate of Incorporation to effect a one-for-six reverse stock split of its common stock. As of June 30, 2013, there were 28,685,215 basic shares outstanding and 41,495,272 fully diluted shares outstanding.
- In June, Cytokinetics was added as a member of the Russell Global, Russell 3000, Russell 2000 and Russell Microcap Indexes as Russell Investments reconstituted its comprehensive family of global indexes.

Financials

Revenues for the second quarter of 2013 were \$1.0 million, compared to \$1.8 million during the same period in 2012. Revenues for the second quarter of 2013 included \$0.4 million of revenue from our collaboration with MyoKardia, Inc., \$0.6 million of revenue from our collaboration with Amgen, and \$36,000 of grant revenue. Revenues for the same period in 2012 included \$1.1 million of revenue from our collaboration with Amgen, \$0.3 million in grant revenue, and \$0.4 million of revenue from our collaboration with Global Blood Therapeutics, Inc.

Total research and development (R&D) expenses in the second quarter of 2013 were \$12.3 million, compared with \$8.2 million for the same period in 2012. The \$4.1 million increase in R&D expenses for the second quarter of 2013, compared with the same period in 2012, was primarily due to increased spending for outsourced clinical and personnel-related costs, partially offset by decreased spending for outsourced preclinical expenses.

Total general and administrative (G&A) expenses for the second quarter of 2013 were \$3.7 million, compared with \$2.6 million for the same period in 2012. The \$1.1 million increase in G&A expenses in the second quarter of 2013, compared with the same period in 2012, was primarily due to increased spending for personnel-related costs and legal expenses.

Revenues for the six months ended June 30, 2013 were \$1.8 million, compared to \$3.7 million for the same period in 2012. Revenues for the first six months of 2013 included \$0.9 million of reimbursements in program expenses under the Amgen collaboration, \$0.8 million revenue from our collaboration with MyoKardia and \$0.1 million of grant revenue. Revenues for the same period in 2012 included \$2.3 million of revenue from our collaboration with Amgen, \$0.6 million in grant revenue, and \$0.8 million of revenue from our collaboration with Global Blood Therapeutics.

Total R&D expenses for the six months ended June 30, 2013 were \$22.2 million, compared to \$17.0 million for the same period in 2012. The \$5.2 million increase in R&D expenses in the first six months of 2013, over the same period in 2012, was primarily due to increased spending for outsourced clinical and personnel-related costs, partially offset by decreased spending for outsourced preclinical expenses.

Total G&A expenses for the six months ended June 30, 2013 were \$7.4 million, compared to \$5.6 million for the same period in 2012. The \$1.8 million increase in G&A spending in the first six months of 2013 compared to the same period in 2012, was primarily due to increased spending for personnel-related costs, legal expenses and outside services.

The net loss allocable to common stockholders for the six months ended June 30, 2013, was \$27.7 million, or \$1.11 per basic and diluted share, compared to a net loss allocable to common stockholders of \$20.2 million, or \$1.54 per basic and diluted share, for the same period in 2012, which includes a one-time, non-cash dividend of \$1.3 million related to the beneficial conversion feature of the Series B convertible preferred stock.

Company Milestones

Cardiac Muscle Contractility

omecamtiv mecarbil

- Results from ATOMIC-AHF are planned to be presented at the Hot Line Late Breaking Clinical Trials Session at the ESC Congress in Amsterdam, Netherlands on September 3, 2013 at 11:18 AM Central European Time. In addition, results from ATOMIC-AHF are planned to be presented at the Late Breaking Clinical Trial Session at the Heart Failure Society of America Conference in Orlando, FL on September 23, 2013 at 4:00 PM Eastern Time.
- By the end of 2013, Cytokinetics expects the opening to enrollment of the expansion phase of COSMIC-HF.

Skeletal Muscle Contractility

tirasemtiv

- In the second half of 2013, Cytokinetics anticipates completion of enrollment in BENEFIT-ALS.

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 Homepage and Investor Relations 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 92572524.

An archived replay of the webcast will be available via Cytokinetics' website until August 7, 2013. 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 92572524 from July 31, 2013 at 5:30 PM Eastern Time until August 7, 2013.

About Cytokinetics

Cytokinetics is a clinical-stage biopharmaceutical company focused on the discovery and development of novel small molecule therapeutics that modulate muscle function for the potential treatment of serious diseases and medical conditions. Cytokinetics' lead drug candidate from its cardiac muscle contractility program, *omecamtiv mecarbil*, is in Phase II clinical development for the potential treatment of heart failure. Amgen Inc. holds an exclusive license worldwide to develop and commercialize *omecamtiv mecarbil* and related compounds, subject to Cytokinetics' specified development and commercialization participation rights. Cytokinetics is independently developing *tirasemtiv*, a fast skeletal muscle activator, as a potential treatment for diseases and medical conditions associated with neuromuscular dysfunction. *Tirasemtiv* is currently the subject of a Phase II clinical trials program and has been granted orphan drug designation and fast track status by the U.S. Food and Drug Administration and orphan medicinal product designation by the European Medicines Agency for the potential treatment of amyotrophic lateral sclerosis, a debilitating disease of neuromuscular impairment. Cytokinetics is collaborating with Astellas Pharma Inc. to develop CK-2127107, a skeletal muscle activator structurally distinct from *tirasemtiv*, for non-neuromuscular indications. All of these drug candidates have arisen from Cytokinetics' muscle biology focused research activities and are directed towards the cytoskeleton. The cytoskeleton is a complex biological infrastructure that plays a fundamental role within every human cell. Additional information about Cytokinetics can be obtained at www.cytokinetics.com.

Forward-Looking Statements

*This press release contains forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995 (the "Act"). Cytokinetics disclaims any intent or obligation to update these forward-looking statements, and 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' financial guidance, including expected revenue and R&D and G&A expenses for 2013; Cytokinetics' and its partners' research and development activities, including the initiation, conduct, design, enrollment, progress, completion and results of clinical trials, the anticipated timing for the availability of clinical trial results, planned presentations of clinical trial results, and the significance and utility of clinical trial results; the effectiveness of steps taken to prevent further occurrences of incorrect study drug assignment; the objective of the protocol amendment for the BENEFIT-ALS trial to maintain the originally intended statistical power of the trial; potential milestone payments, royalties and other payments under Cytokinetics' collaborations; the expected roles of Cytokinetics and Astellas under their collaboration and in developing or commercializing drug candidates or products subject to the collaboration; 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 may not be able to enroll additional patients in BENEFIT-ALS until the protocol amendment is implemented; Cytokinetics anticipates that it will be required to conduct at least one confirmatory Phase III clinical trial of *tirasemtiv* in ALS patients which will require significant additional funding, and it may be unable to obtain such additional funding 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, including risks that current and past results of clinical trials or preclinical studies may not be indicative of future clinical trials results, patient enrollment for or conduct of clinical trials may be difficult or delayed, Cytokinetics' drug candidates may have adverse side effects or inadequate therapeutic efficacy, the U.S. Food and Drug Administration or foreign regulatory agencies may delay or limit Cytokinetics' or its partners' ability to conduct clinical trials, and Cytokinetics may be unable to obtain or maintain patent or trade secret protection for its intellectual property; Amgen's and Astellas' decisions with respect to the design, initiation, conduct, timing and continuation of development activities for *omecamtiv mecarbil* and CK-2127107, respectively; Cytokinetics may incur unanticipated research and development and other costs or be unable to obtain additional financing necessary to conduct development of its products; Cytokinetics may be unable to enter into future collaboration agreements for its drug candidates and programs on acceptable terms, if at all; standards of care may change, rendering Cytokinetics' drug candidates obsolete; competitive products or alternative therapies may be developed by others for the treatment of indications Cytokinetics' drug candidates and potential drug candidates may target; and risks and uncertainties relating to the timing and receipt of payments from its partners, including milestones and royalties on future potential product sales under Cytokinetics' collaboration agreements with such partners. For further information regarding these and other risks related to Cytokinetics' business, investors should consult Cytokinetics' filings with the Securities and Exchange Commission.*

Contact:

Joanna L. Goldstein
 Manager, Investor Relations & Corporate Communications
 (650) 624-3000

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

	Three Months Ended		Six Months Ended	
	June 30, 2013	June 30, 2012	June 30, 2013	June 30, 2012
Revenues:				
Research and development	\$ 1,009	\$ 1,841	\$ 1,830	\$ 3,661
Total revenues	<u>1,009</u>	<u>1,841</u>	<u>1,830</u>	<u>3,661</u>
Operating Expenses:				
Research and development	12,347	8,242	22,181	16,987
General and administrative	3,730	2,568	7,364	5,624
Restructuring	—	(13)	—	(54)
Total operating expenses	<u>16,077</u>	<u>10,797</u>	<u>29,545</u>	<u>22,557</u>
Operating loss	(15,068)	(8,956)	(27,715)	(18,896)
Interest and other, net	27	13	55	26
Net loss	<u>(15,041)</u>	<u>(8,943)</u>	<u>(27,660)</u>	<u>(18,870)</u>
Deemed dividend related to beneficial conversion feature of convertible preferred stock	—	(1,307)	—	(1,307)
Net loss allocable to common stockholders	<u>\$ (15,041)</u>	<u>\$ (10,250)</u>	<u>\$ (27,660)</u>	<u>\$ (20,177)</u>
Net loss per share allocable to common stockholders – basic and diluted	\$ (0.58)	\$ (0.76)	\$ (1.11)	\$ (1.54)
Weighted average shares used in computing net loss per share allocable to common stockholders - basic and diluted	25,773	13,538	24,896	13,109

Cytokinetics, Incorporated
Condensed Balance Sheets
(in thousands)
(unaudited)

	June 30, 2013	December 31, 2012
Assets		
Cash and cash equivalents	\$17,057	\$ 14,907
Short term investments	58,596	59,093
License fee receivable	16,000	—
Related party receivables	—	4
Other current assets	<u>1,967</u>	<u>2,423</u>
Total current assets	93,620	76,427
Property and equipment, net	809	997
Other assets	<u>126</u>	<u>127</u>
Total assets	<u>\$94,555</u>	<u>\$ 77,551</u>
Liabilities and stockholders' equity		
Deferred revenue, current	\$25,529	\$ —
Other current liabilities	8,517	7,105
Total current liabilities	34,046	7,105
Deferred revenue, non-current	8,000	—
Other non-current liabilities	520	361
Stockholders' equity	<u>51,989</u>	<u>70,085</u>
Total liabilities and stockholders' equity	<u>\$94,555</u>	<u>\$ 77,551</u>