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): September 8, 2008

# 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))

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**Item 8.01 Other Events.**

On September 8, 2008, Cytokinetics, Incorporated issued a press release announcing that data from its ongoing Phase I/II clinical trial of ispinesib were presented in a poster at the 2008 American Society of Clinical Oncology (ASCO) Breast Cancer Symposium held on September 5-7, 2008 in Washington, DC.

A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K, and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

The following Exhibit is filed as part of this Current Report on Form 8-K:

Exhibit No. Description
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99.1 Press Release, dated September 8, 2008.

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**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.

Cytokinetics, Incorporated

*September 8, 2008*

*By: /s/ Sharon Barbari*

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

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Exhibit Index

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Press release, dated September 8, 2008 |

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*Director, Corporate Development*
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*Director, Investor Relations*
*(650) 624-3000*

**CYTOKINETICS ANNOUNCES INTERIM CLINICAL TRIAL DATA RELATING TO *ISPINESIB* PRESENTED AT THE 2008 ASCO BREAST CANCER SYMPOSIUM**

*Clinical Activity Observed in the Phase I Portion of Clinical Trial*
*Evaluating Ispinesib as First-Line Monotherapy on Alternative Dosing Schedule*

***South San Francisco, CA, September 8, 2008*** – Cytokinetics, Incorporated (Nasdaq: CYTK) announced that data from its ongoing Phase I/II clinical trial of *ispinesib* were presented in a poster at the 2008 American Society of Clinical Oncology (ASCO) Breast Cancer Symposium held on September 5-7, 2008 in Washington, DC.

A poster entitled, "A Phase I-II Trial of *Ispinesib*, a Kinesin Spindle Protein (KSP) Inhibitor, Dosed Every Two Weeks in Patients (pts) with Locally Advanced (LA) or Metastatic Breast Cancer (MBC) Previously Untreated with Chemotherapy (CT) for Metastatic Disease or Recurrence," was presented by Henry Gomez, MD, Attending Physician and Chief of Medical Oncology, Departamento de Investigacion, Instituto Nacional de Enfermedades Neoplasicas (INEN) in Lima, Peru on September 5, 2008. The primary objectives of the Phase I portion of this clinical trial are to determine the dose limiting toxicities (DLTs) and maximum tolerated dose and to assess the safety and tolerability of *ispinesib* administered as a 1-hour intravenous infusion on days 1 and 15 of a 28-day cycle. The secondary objectives are to characterize the pharmacokinetics of *ispinesib* on this schedule and to evaluate the effect of *ispinesib* on biomarkers of cell proliferation in patients with accessible tumors.

Interim results were provided for 15 patients who had been enrolled at one of three dose levels of *ispinesib* (10 mg/m$^2$, 12 mg/m$^2$ and 14 mg/m$^2$) and had completed at least one cycle of treatment. At the time of data analysis, thirteen patients were evaluable for safety and efficacy. Tumor response was assessed for an additional two patients subsequently treated at 12 mg/m$^2$. Two of 7 patients treated at the 14 mg/m$^2$ dose level had protocol-defined DLTs of transient Grade 3 increases in the liver enzymes ALT and AST following cycle 1, day 15 dosing. As a result of these DLTs at 14 mg/m$^2$, the 12 mg/m$^2$ cohort was expanded to 6 patients, and no DLTs were observed at the latter dose level. Because the 12 mg/m$^2$ dose level was thus demonstrated to be tolerable, and because the authors concluded that the DLTs of Grade 3 ALT/AST increases at 14 mg/m$^2$ dose level had a questionable temporal relationship to the administration of *ispinesib,* plans are underway to further evaluate the 14 mg/m$^2$ dose level. The most frequent adverse event was neutropenia, reported in 85% of patients, with 69% of patients experiencing Grade 3 or 4 neutropenia. Other than neutropenia and the Grade 3 ALT/AST increases described above, there were no other Grade 3 or 4 adverse events; no alopecia or neurotoxicity was reported.

The best responses observed to date in the Phase I portion of this ongoing Phase I/II clinical trial were investigator-reported reductions of 30% or greater in the sum of the target lesion diameters, reported in 3 patients. One of these patients had an investigator-reported partial response according to the Response Evaluation Criteria in Solid Tumors (RECIST). Three patients had investigator-reported stable disease of 4 months or longer according to RECIST.

"These data are encouraging and support the ongoing development of this novel mechanism anti-mitotic chemotherapeutic," stated Dr. Gomez. "*Ispinesib* has been well-characterized in prior studies and has shown a favorable tolerability profile. These data support the safety and tolerability of this drug candidate on a more dose-dense schedule and suggest the potential for amplified clinical activity."

"We are pleased with the progress of this clinical trial evaluating *ispinesib* monotherapy in chemotherapy-naïve women with locally advanced or metastatic breast cancer," stated Dr. Andrew A. Wolff, Cytokinetics' Senior Vice President of Clinical Research and Development and Chief Medical Officer. "We look forward to sharing more data with the medical community as this trial continues."

***Ispinesib* in Breast Cancer**

In June 2008, as part of a poster session at the ASCO Annual Meeting, Cytokinetics announced interim data from the Phase I portion of this ongoing Phase I/II clinical trial. At that time, the authors concluded that preliminary data suggest that *ispinesib* is well-tolerated when dosed on days 1 and 15 every 28 days at doses up to 12 mg/m$^2$.

In June 2007, Cytokinetics reported final results of a Phase II clinical trial conducted by GlaxoSmithKline (GSK) designed to evaluate the safety and efficacy of *ispinesib* in the second- or third-line treatment of patients with locally advanced or metastatic breast cancer whose disease had recurred or progressed despite treatment with anthracyclines and taxanes. In that trial, patients received *ispinesib* as monotherapy at 18 mg/m$^2$ as a 1-hour intravenous infusion every 21 days. The primary endpoint of the trial was objective response by RECIST. Partial responses, observed in 4 of 45 evaluable patients, were confirmed by independent radiology review and were seen in liver, lung and lymph node metastases. The duration of these responses, also independently reviewed, ranged from 7.1 weeks to 30.0 weeks. The median time to progression in the treated population was 5.9 weeks. The adverse events were manageable, predictable and consistent with those seen in the Phase I trials of *ispinesib*. The most common grade 3/4 adverse events observed in the 50 patients evaluable for safety were neutropenia (21 patients), febrile neutropenia (4 patients) and neutropenic sepsis (1 patient).

**Clinical Trials of *Ispinesib***

*Ispinesib* has been the subject of a broad Phase II clinical trials program under the sponsorship of GSK and of the National Cancer Institute (NCI). GSK sponsored three Phase II clinical trials, one evaluating *ispinesib* as second- or third-line treatment for patients with locally advanced or metastatic breast cancer, one evaluating *ispinesib* as second-line treatment for patients with non-small cell lung cancer, and one evaluating *ispinesib* as second-line treatment for patients with advanced ovarian cancer. Enrollment in all of these studies has been closed. To date, Cytokinetics believes clinical activity with *ispinesib* has been observed in breast, ovarian and non-small cell lung cancer, with the most robust clinical activity observed in GSK's Phase II clinical trial evaluating *ispinesib* in the treatment of patients with locally advanced or metastatic breast cancer that failed to respond or recurred after treatment with taxanes and anthracyclines.

In addition, GSK sponsored three dose-escalating Phase Ib clinical trials. Each of these trials was designed to evaluate the safety, tolerability and pharmacokinetics of *ispinesib* in combination with a leading anti-cancer therapeutic, one in combination with *carboplatin*, the second in combination with *capecitabine*, and the third in combination with *docetaxel*. The Phase Ib clinical trials of *ispinesib* in combination with *carboplatin* and *docetaxel* were completed in 2006 and demonstrated that *ispinesib* has an acceptable tolerability profile in combination with these standard chemotherapeutic agents. The

results of the Phase Ib clinical trial evaluating *ispinesib* in combination with *capecitabine* were announced in June 2008. The combination of *ispinesib* with *capecitabine* was found to have had an acceptable tolerability profile on the 21-day schedule investigated in the trial. The dose limiting toxicity in this combination regimen was consistent with the monotherapy toxicities of *ispinesib* (prolonged neutropenia) and *capecitabine* (rash). In this combination trial, the best response observed by RECIST was a partial response in a patient with advanced breast cancer and 11 patients had a response of stable disease.

Cytokinetics is conducting, at its expense, a focused development program for *ispinesib* in breast cancer specifically designed to supplement the Phase I and Phase II clinical trials sponsored by GSK that demonstrated clinical activity in the treatment of patients with metastatic breast cancer and an acceptable tolerability profile for *ispinesib* in combination with *capecitabine*. The Phase I/II clinical trial from which interim results were announced today is an integral part of this development program, the objective of which is to evaluate the possibility that *ispinesib* administered as monotherapy on days 1 and 15 of a 28-day cycle may demonstrate an amplified signal of clinical activity in chemotherapy-naïve breast cancer patients.

**Background on Cytokinetics and GlaxoSmithKline Strategic Alliance**

In June 2001, Cytokinetics and GSK entered into a broad strategic alliance to discover, develop and commercialize novel small molecule therapeutics targeting mitotic kinesins for applications in the treatment of cancer and other diseases. The strategic alliance has generated three drug candidates in clinical development, *ispinesib* and SB-743921, both inhibitors of KSP, and GSK-923295, an inhibitor of centromere-associated protein E (CENP-E). Under a November 2006 amendment to its collaboration and license agreement with GSK, Cytokinetics assumed responsibility for the costs and activities associated with the continued development of *ispinesib* and SB-743921, subject to GSK's option to resume responsibility for some or all development and commercialization activities associated with each of these novel drug candidates, exercisable during a defined period. GSK-923295, now in a Phase I clinical trial in advanced cancers, is being developed under the strategic alliance by GSK. In June 2008, Cytokinetics announced a further one-year extension of the strategic alliance's research term, which began in June 2001, to continue activities focused towards translational research directed to CENP-E. Cytokinetics will receive royalties from the sale of any products arising from the strategic alliance that GSK progresses to commercialization. For products that GSK progresses in development, Cytokinetics retains a product-by-product option to co-fund certain later-stage development activities, thereby providing Cytokinetics an opportunity to increase its potential royalties and obtain co-promotion rights in North America.

**About Cytokinetics**

Cytokinetics is a biopharmaceutical company focused on the discovery, development and commercialization of novel small molecule drugs that may address areas of significant unmet clinical needs. Cytokinetics' cardiovascular disease program is focused to cardiac myosin, a motor protein essential to cardiac muscle contraction. Cytokinetics' lead compound from this program, CK-1827452, a novel small molecule cardiac myosin activator, entered Phase II clinical trials for the treatment of heart failure in 2007. Under a strategic alliance established in 2006, Cytokinetics and Amgen Inc. are performing joint research focused on identifying and characterizing activators of cardiac myosin as back-up and follow-on potential drug candidates to CK-1827452. Amgen has obtained an option for an exclusive license to develop and commercialize CK-1827452, subject to Cytokinetics' development and commercial participation rights. Cytokinetics' cancer program is focused on mitotic kinesins, a family of motor proteins essential to cell division. Under a strategic alliance established in 2001, Cytokinetics and GlaxoSmithKline (GSK) are conducting research and development activities focused on the potential treatment of cancer. Cytokinetics is developing two novel drug candidates that have arisen from this program, *ispinesib* and SB-743921, each a novel inhibitor of kinesin spindle protein (KSP), a mitotic kinesin. Cytokinetics is sponsoring a Phase I/II clinical trial of *ispinesib* as monotherapy as a first-line treatment in chemotherapy-naïve patients with locally advanced or metastatic breast cancer. In addition, Cytokinetics is conducting a Phase I/II trial of SB-743921 in patients with non-Hodgkin or Hodgkin lymphoma. GSK has obtained an option for the joint development and commercialization of *ispinesib* and SB-743921. Cytokinetics and GSK are conducting collaborative research activities directed to the mitotic kinesin centromere-associated protein E (CENP-E). GSK-923295, a CENP-E inhibitor, is being developed under the strategic alliance by GSK; GSK began a Phase I clinical trial with GSK-923295 in 2007. In April 2008, Cytokinetics announced the selection of a potential drug candidate directed towards skeletal muscle contractility which may be developed as a potential treatment for skeletal muscle weakness associated with neuromuscular diseases or other conditions. All of these drug candidates and potential drug candidates have arisen from Cytokinetics' 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.

*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 Safe Harbor for forward-looking statements contained in the Act. Examples of such statements include, but are not limited to, statements relating to Cytokinetics' research and development programs, including the design, conduct and results of clinical trials and the availability of clinical trial results; the properties and potential benefits of Cytokinetics' drug candidates and potential drug candidates; and Cytokinetics' potential receipt of funds and anticipated role in development and commercialization activities under its collaboration and license agreement with GSK. 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, potential difficulties or delays in the development, testing, regulatory approval 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; GSK may decide to postpone or discontinue development activities for GSK-923295; Cytokinetics may incur unanticipated research and development and other costs or be unable to obtain additional financing necessary to conduct development of its products; standards of care may change and others may introduce products or alternative therapies 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 Cytokinetics' partners, including milestones and royalties on future potential product sales under its 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.*

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