

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549

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**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 27, 2005 (September 26, 2005)**

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**CYTOKINETICS, INCORPORATED**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation)

**000-50633**  
(Commission File Number)

**94-3291317**  
(IRS Employer  
Identification No.)

**280 East Grand Avenue**  
**South San Francisco, California 94080**  
(Address of principal executive offices, including zip code)

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

(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 (see General Instruction A.2. below):

- 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 1.01. Entry into a Material Definitive Agreement.**

On September 26, 2005, Cytokinetics, Incorporated (the “Company”) and GlaxoSmithKline (“GSK”) executed an Amendment to the Collaboration and License Agreement (the “Amendment”), with such Amendment effective as of September 21, 2005, which amends certain provisions of the Collaboration and License Agreement, by and among the Company and GSK, dated as of June 20, 2001 (the “Collaboration Agreement”).

Pursuant to the Collaboration Agreement, the Company formed a strategic alliance with GSK to discover, develop and commercialize novel small molecule drugs targeting kinesin spindle protein, also known as KSP, and certain other cytoskeletal proteins involved in cell proliferation for applications in the treatment of cancer and other diseases. A further description of the material terms of the Collaboration Agreement are set forth in our Annual Report on Form 10-K for the year ended December 31, 2004, as filed with the Securities and Exchange Commission on March 11, 2005.

Under the terms of the Collaboration Agreement, as modified by the Amendment, the Company will lead and fund activities for the development of its second cancer drug candidate, SB-743921, in the treatment of non-Hodgkin’s lymphoma, Hodgkin’s lymphoma and multiple myeloma, subject to the option for GSK to resume responsibility for development and commercialization activities for SB-743921 in these indications during a defined period. The Company’s development activities will be conducted in parallel with GSK’s conduct of development activities for SB-743921 in other indications.

The Amendment also modifies the Collaboration Agreement to provide for the early formation of a Joint Development Committee to oversee the conduct of all development activities conducted by the Company and GSK for SB-743921 and for the Company to co-fund certain later stage development costs for this drug candidate. It further provides for the Company to receive pre-commercialization payments from GSK, in addition to those previously set forth in the Collaboration Agreement, based on the achievement of certain milestones for SB-743921 for the additional indications described above and increased royalties from GSK on net sales of products containing SB-743921 under certain scenarios.

**Item 7.01. Regulation FD Disclosure.**

The Company is issuing press releases, and holding a conference call and webcast, in connection with the Amendment and in connection with the announcement of certain results from the clinical trials of its drug candidate *ispinesib*. A copy of the press release regarding the Amendment is being furnished with this Current Report on Form 8-K as Exhibit 99.1, and is hereby incorporated by reference under this Item 7.01. A copy of the press release regarding the announcement of certain clinical trial results is being furnished with this Current Report on Form 8-K as Exhibit 99.2, and is hereby incorporated by reference under this Item 7.01. Both press releases contain information regarding access to the conference call and webcast concerning the subject matter of such releases, which is scheduled to take place at 6:00 PM (Eastern Time) on September 27, 2005.

**Item 9.01. Financial Statements and Exhibits.**

(c) Exhibits.

The following exhibits are furnished as part of this Current Report on Form 8-K.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Amendment to the Collaboration and License Agreement Press Release, dated September 27, 2005
99.2	Clinical Trials Announcement Press Release, dated September 27, 2005

**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**

*/s/ James H. Sabry*

James H. Sabry

*President and Chief Executive Officer*

Dated: September 27, 2005

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## Contacts:

*Cytokinetics, Incorporated*  
 Robert I. Blum  
 EVP, Corporate Development and Commercial Operations & CBO  
 (650) 624-3000

*Burns McClellan, Inc.*  
 Clay Kramer (investors)  
 Justin Jackson (media)  
 (212) 213-0006

**CYTOKINETICS AND GLAXOSMITHKLINE AMEND COLLABORATION AGREEMENT FOR SB-743921**

***Maturation of Cytokinetics' Capabilities Enables Increased Responsibility  
 for Clinical Development under Augmented Development Program for KSP Inhibitors***

**South San Francisco, CA, September 27, 2005** — Cytokinetics, Incorporated (Nasdaq: CYTK) announced the amendment of the company's strategic alliance with GlaxoSmithKline (GSK), which will provide Cytokinetics an expanded role in clinical research and development for SB-743921, a novel, small molecule inhibitor of kinesin spindle protein (KSP). This drug candidate is being developed under an alliance focused on novel small molecule therapeutics targeting human mitotic kinesins for applications in the treatment of cancer and other diseases.

Under the terms of the amendment, Cytokinetics will lead and fund development activities to explore the potential application of SB-743921 for the treatment of non-Hodgkin's lymphoma, Hodgkin's lymphoma and multiple myeloma, subject to the option for GSK to resume responsibility for development and commercialization activities for SB-743921 for these indications during a defined period. Cytokinetics' development activities will be conducted in parallel with GSK's conduct of development activities for SB-743921 in other indications and for *ispinesib* (SB-715992). *Ispinesib* is the first drug candidate to emerge from the strategic alliance and is currently the subject of a broad clinical trials program pursuant to the alliance.

The amendment provides for acceleration of the formation of a Joint Development Committee to oversee the conduct of all development activities conducted by Cytokinetics and GSK for SB-743921 and for the exercise of Cytokinetics' option to co-fund certain later stage development costs for this drug candidate. In addition to the payments that GSK may make to Cytokinetics under the original terms of the collaboration agreement, based on Cytokinetics' expanded role under the amendment in the development of SB-743921, Cytokinetics may receive additional pre-commercialization payments from GSK based on the achievement of certain milestones for SB-743921 for the additional indications described above and increased royalties from GSK on net sales of products containing SB-743921 under certain scenarios.

"The expanded role to be played by Cytokinetics in the joint development of SB-743921 with GSK reflects the maturation of Cytokinetics' capabilities in the area of clinical research and development since the initiation of the collaboration in June 2001," stated Robert I. Blum, Executive Vice President, Corporate Development and Commercial Operations and Chief Business Officer. "We have evolved as a company, increasing the resources that we can bring to bear on development activities now being directed to this program. We look forward to the initiation of a clinical trial for SB-743921 in non-Hodgkin's lymphoma in the coming months."

SB-743921 entered a Phase I clinical trial conducted by GSK in the United States in May 2004 to evaluate its tolerability and pharmacokinetics in advanced cancer patients. Data relating to SB-743921 were presented at the 2005 Annual Meeting of the American Society of Clinical Oncology in May 2005. The data presented were from 20 patients that collectively had a variety of advanced solid tumors and received doses of SB-743921 intravenously once every 21 days. SB-743921 appears to have an acceptable tolerability profile for patients suffering from advanced solid tumors. The dose-limiting toxicities observed to date are prolonged neutropenia, febrile neutropenia (with or without infection), elevated transaminases, hyperbilirubinemia and hyponatremia. Notably, neurotoxicities, mucositis, thrombocytopenia, alopecia and nausea/vomiting requiring pre-medication have not been observed to date.

"We are excited about investigating new potential therapeutic indications for SB-743921, augmenting the efforts of our partner in evaluating KSP inhibitors for their potential in the treatment of patients with various cancers," stated Andrew A. Wolff, M.D., F.A.C.C., Senior Vice President, Clinical Research and Development and Chief Medical Officer. "Our working in parallel with GSK in development of SB-743921 is consistent with the original intent of our alliance to explore the full breadth of the therapeutic potential of our drug candidates. SB-743921 is the second KSP inhibitor to enter clinical trials under our collaboration and has distinct clinical potential that we believe warrants exploration in additional tumor types."

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### Research & Development Expense Guidance for 2005

The financial impact of this amendment will not result in an increase in Cytokinetics' research and development expense guidance for 2005. The guidance previously provided for research and development expenses for 2005 is \$45 to \$49 million.

### Conference Call / Webcast

Cytokinetics will host a conference call on Tuesday, September 27, 2005 at 6:00 p.m. Eastern Time. The conference call will be simultaneously webcast and will be accessible in the Investor Relations section of Cytokinetics' website at [www.cytokinetics.com](http://www.cytokinetics.com). The live audio of the conference call will also be accessible via telephone to investors, members of the news media and the general public by dialing either (866) 999-CYTK (2985) (United States and Canada) or (706) 679-3078 (International) and typing in the passcode 9953889. An archived replay of the webcast will be available via Cytokinetics' website until October 4, 2005. The replay will also be available via telephone by dialing (800) 642-1687 (United States and Canada) or (706) 645-9291 (International) and typing in the passcode 9953889 from September 27, 2005 at 7:00 p.m. Eastern Time until October 4, 2005.

### Background on KSP Inhibitors

Since their introduction over 40 years ago, anti-mitotic drugs (taxanes and vinca alkaloids) have advanced the treatment of cancer and are commonly used for the treatment of several tumor types. However, these drugs have demonstrated limited treatment benefit against certain cancers. In addition, these drugs target tubulin, a cytoskeletal protein involved not only in mitosis and cell proliferation, but also in other important cellular functions. Inhibition of these other cellular functions produces dose-limiting toxicities such as peripheral neuropathy, an impairment of the peripheral nervous system. Neuropathies result when these drugs interfere with the dynamics of microtubule filaments that are responsible for the long-distance transport of important cellular components within nerve cells.

The strategic alliance between Cytokinetics and GSK has yielded two novel drug candidates, *ispinesib* (SB-715992) and SB-743921. *Ispinesib* and SB-743921 are structurally distinct small molecules that modulate cell proliferation and promote cancer cell death by specifically inhibiting kinesin spindle protein (KSP). KSP is a mitotic kinesin that is essential for cell proliferation, a process which when unregulated, results in tumor growth. Mitotic kinesins are essential to mitosis, and, unlike tubulin, appear to have no role in unrelated cellular functions. We believe drugs that inhibit KSP and other mitotic kinesins may represent the next generation of anti-mitotic cancer drugs by arresting mitosis and cell proliferation without impacting unrelated, normal cellular functions, avoiding many of the toxicities commonly experienced by patients treated with existing anti-mitotic drugs.

### Clinical Trials Status for *Ispinesib*

*Ispinesib* is the subject of a broad clinical trials program under the sponsorship of GSK and the National Cancer Institute (NCI). GSK is conducting 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 platinum-sensitive non-small cell lung cancer and one evaluating *ispinesib* as second-line treatment for patients with advanced ovarian cancer. In addition, GSK is continuing three dose-escalating Phase Ib clinical trials. Each of these clinical trials is 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 NCI, in collaboration with GSK, continues patient enrollment in five additional Phase II clinical trials evaluating the potential efficacy of *ispinesib* in the second-line treatment of patients with colorectal cancer, in the first-line treatment of patients with hepatocellular cancer, in the first-line treatment of patients with melanoma, in the first-line or second-line treatment of patients with head and neck cancers, and in the second-line treatment of patients with hormone-refractory prostate cancer. In addition, the NCI plans to initiate an additional Phase II clinical trial to evaluate the potential efficacy of *ispinesib* as second-line treatment of patients with renal cell cancer. The NCI also continues patient enrollment in two additional Phase I clinical trials designed to evaluate the safety, tolerability and pharmacokinetics of *ispinesib* on an alternative dosing schedule. One clinical trial is enrolling patients with advanced solid tumors that have failed to respond to all standard therapies and the other clinical trial is enrolling patients with acute leukemia, chronic myelogenous leukemia or advanced myelodysplastic syndromes.

### About Cytokinetics

Cytokinetics is a leading biopharmaceutical company focused on the discovery, development and commercialization of novel small molecule drugs that specifically target the cytoskeleton. The cytoskeleton is a complex biological infrastructure that plays a fundamental role within every human cell. Cytokinetics' focus on the cytoskeleton enables it to develop novel and potentially safer and more effective classes of drugs directed at treatments for cancer, cardiovascular disease and other

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diseases. Cytokinetics has developed a cell biology driven approach and proprietary technologies to evaluate the function of many interacting proteins in the complex environment of the intact human cell. Cytokinetics employs the PUMA™ system and Cytometrix™ technologies to enable early identification and automated prioritization of compounds that are highly selective for their intended protein targets without other cellular effects, and may therefore be less likely to give rise to clinical side effects. Cytokinetics and GlaxoSmithKline have entered into a strategic alliance to discover, develop and commercialize small molecule therapeutics targeting human mitotic kinesins for applications in the treatment of cancer and other diseases. GlaxoSmithKline is conducting Phase II and Phase Ib clinical trials for *ispinesib* (SB-715992) and a Phase I clinical trial for SB-743921, each a drug candidate that has emerged from the strategic alliance. Cytokinetics' heart failure program is the second program to leverage the company's expertise in cytoskeletal pharmacology. Cytokinetics recently initiated a Phase I clinical trial with CK-1827452, a novel small molecule cardiac myosin activator, for the treatment of heart failure. Additional information about Cytokinetics can be obtained at [www.cytokinetics.com](http://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 our and our partners' clinical research and development programs, including expected future clinical trials, statements regarding the reaffirmation of our previous guidance for research and development expenses for 2005, and statements regarding the potential benefits of our drug candidates and potential drug candidates and the enabling capabilities of our proprietary technologies. Such statements are based on management's current expectations, but actual results may differ materially due to various factors. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to difficulties or delays in development, testing, regulatory approval, production and marketing of Cytokinetics' drug candidates that could slow or prevent clinical development or product approval (including the risks relating to uncertainty of patent protection for Cytokinetics' intellectual property or trade secrets, Cytokinetics' ability to obtain additional financing if necessary and unanticipated research and development and other costs), the receipt of funds under our collaborations, and the timing of initiation of additional clinical development activities for SB-743921. 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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## Contacts:

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**CYTOKINETICS PROVIDES CLINICAL TRIALS UPDATE FOR *ISPINESIB* (SB-715992)**

***Drug Candidate Demonstrates Sufficient Anti-Tumor Activity to Proceed  
 in its Phase II Locally Advanced or Metastatic Breast Cancer Clinical Trial***

***Drug Candidate Does Not Demonstrate Sufficient Anti-Tumor Activity to Proceed  
 in the Platinum-Refractory Arm of its Phase II Non-Small Cell Lung Cancer Clinical Trial***

**South San Francisco, CA, September 27, 2005** — Cytokinetics, Incorporated (Nasdaq: CYTK) announced the results from planned interim analyses of two Phase II clinical trials of *ispinesib* administered as monotherapy in the treatment of patients with locally advanced or metastatic breast cancer and the treatment of patients with platinum-refractory non-small cell lung cancer, both Phase II clinical trials being conducted by its alliance partner, GlaxoSmithKline (GSK).

In the treatment of locally advanced or metastatic breast cancer patients, *ispinesib* has demonstrated sufficient clinical activity to proceed to the next stage of the Phase II clinical trial. In the platinum-refractory treatment arm of the non-small cell lung cancer trial, *ispinesib* did not demonstrate sufficient clinical activity to proceed to the next stage of the Phase II clinical trial for this stratum. A second platinum-sensitive patient treatment arm in that trial continues. Both clinical trials employ a conventional Green-Dahlberg design which specifies that the advancement to the second stage requires the satisfaction of pre-defined efficacy criteria. These clinical trials are the first to reach the stage of interim data analysis from a broad Phase II program of *ispinesib* that is designed to determine potential anti-cancer activity and relevant clinical effect in nine Phase II clinical trials encompassing multiple tumor types under the sponsorship of GSK or the National Cancer Institute (NCI).

In an ongoing Phase II clinical trial 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 has recurred or progressed despite treatment with anthracyclines and taxanes, the drug candidate has satisfied the criteria for advancement to the next stage. This clinical trial is now planned to proceed to full enrollment of 55 evaluable patients. This clinical trial is designed to require a minimum of 3 confirmed partial or complete responses out of 30 evaluable patients to proceed to stage 2. The trial's primary endpoint is response rate as determined using RECIST criteria. The best overall responses observed to date have been partial responses observed in 3 patients. All patients enrolled to date in this clinical trial have had metastatic disease. Interim results from this clinical trial have been accepted for presentation at the 28th San Antonio Breast Cancer Symposium to be held from December 7-10, 2005.

In a Phase II clinical trial designed to evaluate the safety and efficacy of *ispinesib* in the second-line treatment of patients with either platinum-sensitive or platinum-refractory non-small cell lung cancer, the drug candidate has not satisfied the criteria for advancement to the next stage in the platinum-refractory treatment arm. The platinum-sensitive treatment arm continues to treat patients but has not yet reached the interim analysis stage. This clinical trial is designed to require a minimum of 1 confirmed partial or complete response out of 20 evaluable patients in a treatment arm to proceed to stage 2 in that treatment arm. The trial's primary endpoint is response rate as determined using RECIST criteria. The best overall responses observed to date in the platinum-refractory treatment arm of this clinical trial have been disease stabilization observed in 5 of 20 evaluable patients. Overall, median time to disease progression was 6 weeks; in the 5 patients whose best response was stable disease, median time to progression was 12 weeks. The safety and pharmacokinetics of *ispinesib* in the platinum-refractory arm of this clinical trial appear comparable to that observed from its Phase I clinical trial at equivalent doses. Data from the platinum-sensitive treatment arm of this clinical trial are expected to be announced by the end of 2005.

"We are pleased to share the data recently emerging from our ongoing Phase II clinical trials program with *ispinesib*," stated James Sabry, M.D., Ph.D., President and Chief Executive Officer. "Today's announcements are encouraging as we have now observed measurable anti-cancer activity with this mechanism in the second-line and third-line treatment of locally advanced or metastatic breast cancer patients and the first evidence of confirmed tumor shrinkage due to treatment of cancer patients with *ispinesib*."

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“We are now seeing evidence of potential clinical benefit of *ispinesib* demonstrated in the form of tumor shrinkage in locally advanced or metastatic breast cancer patients,” said Dr Allen Oliff, Senior Vice President of the Microbial, Musculoskeletal and Proliferative Diseases Center for Excellence in Drug Discovery at GlaxoSmithKline. “We look forward to further data arising out of our broad clinical trials program designed to evaluate the full potential of this novel drug candidate.”

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