

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): April 23, 2020

Cytokinetics, Incorporated

(Exact Name of Registrant as Specified in Charter)

Delaware

(State or Other Jurisdiction of Incorporation)

000-50633

(Commission File Number)

94-3291317

(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))

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, par value \$0.001	CYTK	The Nasdaq Stock Market LLC

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

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 1.01 Entry into a Material Definitive Agreement.

Amended and Restated Astellas Collaboration Agreement

On April 23, 2020, Cytokinetics, Incorporated (the “Company” or “Cytokinetics”) and Astellas Pharma Inc. (“Astellas”) entered into two agreements, which, taken together, amend and restate the Company’s research, development and commercialization collaboration with Astellas, under their License and Collaboration Agreement dated June 21, 2013, as amended, (the “Original Collaboration Agreement”), in follow up to the previously disclosed agreement in principle to revise the terms of such Original Collaboration Agreement.

Fast Skeletal Regulatory Activator Agreement

The Company and Astellas signed a Fast Skeletal Regulatory Activator Agreement dated April 23, 2020 (the “FSRA Agreement”). As a result of the FSRA Agreement, the Company will now have exclusive control and responsibility for the Company’s future development and commercialization of reldesemtiv, CK-601 and other fast skeletal regulatory activator (collectively “FSRA”) compounds and products that were subject to the Original Collaboration Agreement, and accordingly, Astellas has agreed to terminate its license to all FSRA compounds and related products.

Astellas has agreed to pay one-third of the out-of-pocket clinical development costs which may be incurred in connection with the Company’s potential Phase 3 clinical trial of reldesemtiv in amyotrophic lateral sclerosis up to a maximum contribution by Astellas of \$12 million. In addition, Astellas has agreed to non-cash contributions to the Company, which include the transfer of its existing inventories of active pharmaceutical ingredient of reldesemtiv and CK-601. Astellas has also agreed to the continued conduct of ongoing stability studies pertaining to such existing inventories of active pharmaceutical ingredient, at its cost.

In exchange, the Company will pay Astellas a low- to mid- single digit royalty on sales of reldesemtiv in the United States, Canada, United Kingdom and the European Union until the later of (i) ten years following the first commercial sale of such product in a major market country, or (ii) December 31, 2034, subject to certain royalty reduction provisions. The Company would not owe Astellas royalties on sales of reldesemtiv in any other country, or on the sale of any FSRA compounds or related products other than reldesemtiv.

Astellas has assigned to the Company all of Astellas’ interest in intellectual property generated by any of the parties under the Original Collaboration Agreement that solely relates to FSRA compounds and products. In addition, Astellas has granted an exclusive license to the Company under any other intellectual property generated by any of the parties under the Original Collaboration Agreement and any intellectual property owned or controlled by Astellas or its affiliates as of the effective date of the FSRA Agreement that is reasonably necessary or useful to the development, manufacture or commercialization of FSRA compounds and products for such purposes. Finally, Astellas has agreed to transfer to the Company related regulatory materials and provide the Company with technical assistance during the transition of the program to the Company.

For a period of four years, Astellas has agreed not to engage in any research and development activities on FSRA compounds and products with a carve-out mechanism for certain of Astellas’ mergers and acquisitions activities. The parties also agreed that the option previously granted to Astellas to receive a license to tirasemtiv, a FSRA compound for which the Company suspended clinical development in 2018, has expired without exercise and has no further force or effect.

License and Collaboration Agreement for Other Skeletal Sarcomere Activators

The Company and Astellas also signed a License and Collaboration Agreement for Other Skeletal Sarcomere Activators, dated April 23, 2020 (the “2020 Collaboration Agreement”). The 2020 Collaboration Agreement is an amendment and restatement of the Original Collaboration Agreement between the Company and Astellas, and removes the FSRA compounds and products from the collaboration.

Under the 2020 Collaboration Agreement, Astellas has extended the joint research program at the Company through December 31, 2020, with a minimum of fifteen (15) research FTE’s being supported by Astellas. Astellas has exclusive rights to co-develop and commercialize skeletal sarcomere activators (other than FSRA compounds and products) in all indications, subject to certain Cytokinetics’ development and commercialization rights; Cytokinetics may co-promote and conduct certain commercial activities in the U.S., Canada and/or Europe under agreed scenarios. Astellas will be responsible for the costs associated with the development of all collaboration products under the 2020 Collaboration Agreement, subject to Cytokinetics’ option to co-fund certain development costs as described below. Cytokinetics retains an option to conduct early-stage development for certain agreed indications at its initial expense, subject to reimbursement if development continues under the collaboration. Astellas will reimburse Cytokinetics for certain expenses associated with its co-promotion activities. The 2020 Collaboration Agreement also provides for Cytokinetics to lead certain activities relating to the commercialization of collaboration products for neuromuscular indications in the U.S., Canada and Europe under particular scenarios. The research term may be extended beyond December 31, 2020 by mutual consent.

If development candidates are identified and advance in clinical research, the 2020 Collaboration Agreement contains provisions related to shared development roles between the Company and Astellas, and opportunities for the Company to co-invest and/or co-promote under certain conditions. In the case of molecules taken forward solely by Astellas, the Company would receive development and regulatory milestones of \$25 to \$35 million per product, up to \$250 million for all products, except under certain scenarios, commercial milestones of up to \$200 million, and royalties that range from a mid-single digit level to low double-digits. In the event of co-investment by the Company and approvals in certain indications, the Company would receive royalties ranging from mid-to-high double digits (not to exceed an incremental rate in the mid-twenties).

Astellas may terminate the 2020 Collaboration Agreement as to any particular product or territory, or in its entirety, upon 180 days advance written notice following expiration of the research term.

The above description of the FSRA Agreement and the 2020 Collaboration Agreement is a summary of their material terms, does not purport to be complete and is qualified in its entirety by reference to the FSRA Agreement and the 2020 Collaboration Agreement, which will be filed as exhibits to the Company's Quarterly Report on Form 10-Q for the quarter ending June 30, 2020.

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: April 23, 2020

By: /s/ Ching Jaw
Ching Jaw
Senior Vice President, Chief Financial Officer