

ACADIA PHARMACEUTICALS INC

Form 8-K

October 06, 2009

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): October 6, 2009 (October 5, 2009)

ACADIA PHARMACEUTICALS INC.

(Exact Name of Registrant as Specified in Charter)

DELAWARE
(State or Other Jurisdiction

of Incorporation)

000-50768
(Commission File Number)

06-1376651
(I.R.S. Employer

Identification No.)

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3911 SORRENTO VALLEY BOULEVARD

SAN DIEGO, CALIFORNIA
(Address of Principal Executive Offices)

(858) 558-2871

92121
(Zip Code)

(Registrant's telephone number, including area code)

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K 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))

Item 1.01. Entry into a Material Definitive Agreement.

On October 5, 2009, ACADIA Pharmaceuticals Inc. and Biovail Laboratories International SRL, a subsidiary of Biovail Corporation, entered into an amendment (the "Amendment") to their existing Collaboration and License Agreement, dated as of May 1, 2009 (the "Agreement"), related to the development of pimavanserin, ACADIA's proprietary and selective 5-HT_{2A} inverse agonist, in the United States and Canada.

Pursuant to the Amendment, and in connection with the announcement of the early conclusion of the ACP-103-014 trial (the "-014 Trial") for pimavanserin in Parkinson's disease psychosis ("PDP") being conducted pursuant to the Agreement, ACADIA and Biovail are planning a new Phase III trial for pimavanserin in PDP, which is expected to start in the first half of 2010 (the "New PDP Trial"). The Amendment provides that the New PDP Trial will be funded by Biovail, in accordance with the Agreement, provided however, that if the trial does not meet its primary endpoint, then ACADIA would reimburse Biovail 50% of the costs of the New PDP Trial. ACADIA estimates that the amount of the potential reimbursement would approximate the savings to ACADIA from the early conclusion of the -014 Trial. If the New PDP Trial or a subsequent pivotal trial in PDP meets its primary endpoint, Biovail may credit 50% of the costs of the applicable trial against the potential milestone payment triggered by such trial.

The Amendment also provides that ACADIA may elect to pursue an initial clinical trial in Alzheimer's disease psychosis (the "New ADP Trial") at its own expense. However, if the New ADP Trial meets its primary endpoint, then Biovail would reimburse ACADIA 100% of the costs of the New ADP Trial.

Forward-Looking Statements

Certain statements in this report that are not historical facts are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements relating to ACADIA's and Biovail's plans with respect to pimavanserin, including potential future trials, the funding obligations therefore and estimated savings from the early conclusion of the -014 Trial. These statements are only predictions based on current information and expectations and involve a number of risks and uncertainties. Actual events or results may differ materially from those projected in any of such statements due to various factors, including the completion of analysis of results from the initial Phase III trial with pimavanserin and the -014 Trial, the risks and uncertainties inherent in drug discovery, development and commercialization, the uncertainty inherent in estimating the expenses of clinical trials, and the fact that past results of clinical trials may not be indicative of future trial results. For a discussion of these and other factors, please refer to ACADIA's annual report on Form 10-K for the year ended December 31, 2008 as well as other subsequent filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All forward-looking statements are qualified in their entirety by this cautionary statement and ACADIA undertakes no obligation to revise or update this report to reflect events or circumstances after the date hereof.

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.

ACADIA Pharmaceuticals Inc.

By: /s/ GLENN F. BAITY
Glenn F. Baity
Vice President, General Counsel and Assistant Secretary

Date: October 6, 2009