

SECURITIES AND EXCHANGE COMMISSION

FORM 8-K

Current report filing

Filing Date: **2010-06-01** | Period of Report: **2010-06-01**
SEC Accession No. **0000950130-10-002112**

([HTML Version](#) on secdatabase.com)

FILER

ACCENTIA BIOPHARMACEUTICALS INC

CIK: **1310094** | IRS No.: **000000000**
Type: **8-K** | Act: **34** | File No.: **000-51383** | Film No.: **10868361**
SIC: **2834** Pharmaceutical preparations

Mailing Address	Business Address
324 SOUTH HYDE PARK AVE SUITE 350 TAMPA FL 33606	324 SOUTH HYDE PARK AVE SUITE 350 TAMPA FL 33606 8138642562

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): June 1, 2010

ACCENTIA BIOPHARMACEUTICALS, INC.

(Exact name of Registrant as Specified in its Charter)

Florida
(State or other jurisdiction of
incorporation or organization)

000-51383
(Commission
File Number)

04-3639490
(I.R.S. Employer
Identification No.)

324 South Hyde Park Ave., Suite 350
Tampa, Florida 33606
(Address of Principal Executive Offices; Zip Code)

Registrant's telephone number, including area code: **(813) 864-2554**

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))
-
-

FORM 8-K

Item 7.01. Regulation FD Disclosure.

The following information is being furnished under Item 7.01 of Form 8-K: Press release dated June 1, 2010, by the Company, titled "Accentia Files Plan of Reorganization". A copy of this press release is attached as Exhibit 99.1 to this Form 8-K.

This Current Report on Form 8-K sets forth statements that are not strictly historical in nature constitute "forward-looking statements." Such statements include, but are not limited to, statements about Revimmune(TM) and BiovaxID(R) and any other statements relating to products, product candidates, product development programs, the FDA or clinical study process including the commencement, process, or completion of clinical trials, the intent to treat analysis, accelerated approval and all aspects of the regulatory process. Such statements may include, without limitation, statements with respect to the Company's plans, objectives, expectations and intentions, and other statements identified by words such as "may," "could," "would," "should," "believes," "expects," "anticipates," "estimates," "intends," "plans," or similar expressions. Such forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause the actual results of Accentia to be materially different from historical results or from any results expressed or implied by such forward-looking statements. These factors include, but are not limited to, risks and uncertainties related to the progress, timing, cost, and results of clinical trials and product development programs; difficulties or delays in obtaining regulatory approval for product candidates; competition from other pharmaceutical or biotechnology companies; and the additional risks discussed in filings with the Securities and Exchange Commission. All forward-looking statements in this Form 8-K are qualified in their entirety by this cautionary statement, and Accentia undertakes no obligation to revise or update this Current Report on Form 8-K to reflect events or circumstances after the date hereof. The product names used in this statement are for identification purposes only. All trademarks and registered trademarks are the property of their respective owners.

Item 9.01. Financial Statements and Exhibits.

See the Exhibit Index set forth below for a list of exhibits included with this Form 8-K.

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 thereunder duly authorized.

ACCENTIA BIOPHARMACEUTICALS, INC.

By: /s/ Samuel S. Duffey

Samuel S. Duffey

President & General Counsel

Date: June 1, 2010

EXHIBIT INDEX

Exhibit Number

Description

99.1

Press Release dated June 1, 2010 titled, "Accentia Files Plan of Reorganization".



Accentia Files Plan of Reorganization

Restructuring supports plans to advance promising multiple sclerosis therapy into late-stage clinical trial while preserving common shares

TAMPA, FLORIDA - June 1, 2010 - Accentia Biopharmaceuticals, Inc. (Other OTC: "ABPIQ") today announced that the Company filed its proposed Plan of Reorganization (Plan) with the U.S. Bankruptcy Court for the Middle District of Florida, Tampa Division. With this filing, Accentia is positioned to emerge from Chapter 11 protection this summer as a fully restructured company. Upon Court-ordered confirmation, the Plan is expected to support the regulatory advancement of the autoimmune disease therapy, Revimmune(TM), a comprehensive system of care and drug regimen designed to "reboot" the immune system to potentially eliminate multiple sclerosis and significantly reduce disability. Accentia is preparing to advance a regulatory strategy in order to proceed with a planned late-stage clinical trial for Revimmune.

"We are very proud to report that the Accentia Plan of Reorganization achieves our priority goal of preserving the interests of all stakeholders. The Plan will strengthen the Company's financial position and balance sheet with favorably restructured terms allowing us to service our long-term debt obligations while importantly preserving the common shares without significantly increasing the fully diluted share count," stated Accentia's President, Mr. Samuel S. Duffey. "Our foremost priority in emerging from Chapter 11 is to devote our resources towards the advancement of Revimmune, which offers the unprecedented potential to change the way multiple sclerosis and other autoimmune diseases are treated. Revimmune has been shown to eliminate the peripheral immune cells, including the cells perpetuating the autoimmunity, as opposed to current standard of care treatments that only delay disease progression."

Through an Accentia-managed Revimmune patient registration program, a Revimmune therapy candidate would be pre-qualified to determine eligibility to receive a comprehensive system of care which includes an ultra-high dose, pulsed regimen of cyclophosphamide (HyCy) designed to "reboot" the patient's immune system. Revimmune therapy is believed to act by completely eliminating mature lymphocytes throughout the body while selectively sparing immune stem cells in the bone marrow. Shortly following a course of Revimmune, the bone marrow stem cells repopulate the immune system with new cells that lack the traits of autoimmunity, offering the potential for sustained remissions.

Accentia is also a majority stakeholder in Biovest International, Inc. (Other OTC: "BVTI"), and this investment may represent significant value as Biovest has completed a Phase 3 clinical trial and plans to seek approvals for BiovaxID(R), a personalized cancer vaccine, to treat certain B-cell lymphomas.

About Accentia Biopharmaceuticals, Inc.

Headquartered in Tampa, Florida, Accentia Biopharmaceuticals, Inc. (Other OTC: "ABPIQ") is committed to making the autoimmune disease therapy, Revimmune(TM), available to patients as a comprehensive system of care and drug regimen designed to result in a pronounced reduction in disease activity while potentially restoring neurologic and physical functions for patients suffering from multiple sclerosis (MS). A late-stage MS clinical trial for Revimmune is being planned.

Accentia also holds a majority-ownership stake in Biovest International, Inc. (Other OTC: "BVTI"). Biovest, in collaboration with the National Cancer Institute, has developed a patient-specific cancer vaccine, BiovaxID(R), which has demonstrated statistically significant Phase III clinical benefit in follicular non-Hodgkin's lymphoma by prolonging disease-free survival in patients treated with BiovaxID as compared to a control group. Based on positive Phase II and Phase III results, Biovest is currently preparing to seek U.S. and international approvals.

Additionally, Accentia's wholly-owned subsidiary, Analytica International, based in New York City, is a global research and strategy consulting firm that provides professional services to the pharmaceutical and biotechnology industries. Since 1997, Analytica has expertly directed research studies and projects, including traditional health economic modeling projects, database studies, structured reviews, health technology assessments, reimbursement analyses, and value dossiers.

For further information, please visit: <http://www.Accentia.net>

Accentia Biopharmaceuticals, Inc. Corporate Contact:

Douglas Calder, Director of Investor Relations & Public Relations,
Phone: (813) 864-2554, ext.258 / Email: dwcald@accentia.net

Forward-Looking Statements:

Statements in this release that are not strictly historical in nature constitute "forward-looking statements." Such statements include, but are not limited to, statements about Revimmune(TM), BiovaxID(R) and any other statements relating to products, product candidates, product development programs, the FDA or clinical study process including the commencement, process, or completion of clinical trials or the regulatory process. Such statements may include, without limitation, statements with respect to the Company's plans, objectives, expectations and intentions, and other statements identified by words such as "may," "could," "would," "should," "believes," "expects," "anticipates," "estimates," "intends," "plans," or similar expressions. Such forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause the actual results of Accentia to be materially different from historical results or from any results expressed or implied by such forward-looking statements. These factors include, but are not limited to, risks and uncertainties related to the progress, timing, cost, and results of clinical trials and product development programs; difficulties or delays in obtaining regulatory approval for product candidates; competition from other pharmaceutical or biotechnology companies; and the additional risks discussed in filings with the Securities and Exchange Commission. All forward-looking statements are qualified in their entirety by this cautionary statement, and Accentia undertakes no obligation to revise or update this news release to reflect events or circumstances after the date hereof. The product names used in this statement are for identification purposes only. All trademarks and registered trademarks are the property of their respective owners.