BIOSPECIFICS TECHNOLOGIES CORP
Form 8-K
September 01, 2011

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): **August 31, 2011**

BIOSPECIFICS TECHNOLOGIES CORP.

(Exact name of registrant as specified in its charter)

Delaware	**001-34236**	**11-3054851**
(State or Other Jurisdiction Of Incorporation)	*(Commission File Number)*	*(I.R.S. Employer Identification No.)*

35 Wilbur Street
Lynbrook, NY 11563
(Address of Principal Executive Office) (Zip Code)

516.593.7000
(Registrant s telephone number, including area code)

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)) the Exchange Act (17 CFR 240.13e-4(c))

INTRODUCTORY COMMENT

Throughout this Current Report on Form 8-K, the terms we, us, our and Company refer to BioSpecifics Technolo Corp.

ITEM 1.01 ENTRY INTO A MATERIAL DEFINITIVE AGREEMENT.

Second Amended and Restated Development and License Agreement with Auxilium Pharmaceuticals, Inc.

As previously reported, on June 3, 2004 the Company and Auxilium Pharmaceuticals, Inc. (Auxilium) entered into a development and license agreement (the Original Agreement). Also as previously reported, the Company and Auxilium amended the Original Agreement on May 10, 2005 and December 15, 2005 and subsequently, on December 11, 2008, amended and restated the Original Agreement by entering into an amended and restated development and license agreement (the Amended and Restated Agreement), which became effective December 17, 2008.

Under the Amended and Restated Agreement, the Company granted to Auxilium exclusive worldwide rights under certain licensed technology to develop, market and sell certain products containing the Company s injectable collagenase enzyme (the Enzyme), which Auxilium refers to as XIAFLEX® (collagenase Clostridium histolyticum), other than dermal formulations labeled for topical administration (such pharmaceutical product, the Product) for clinical indications in Dupuytren s contracture, Peyronie s disease and Frozen Shoulder syndrome (collectively, the Licensed Indications). The Company also granted Auxilium an exclusive option to license additional indications. In partial consideration of the rights granted to Auxilium under the Amended and Restated Agreement, the Company received 8.5% of the sublicense income paid to Auxilium by Pfizer, Inc. (Pfizer) in connection with a development, commercialization and supply agreement, dated December 17, 2008, as well as certain milestone payments.

On August 31, 2011, the Company and Auxilium entered into a second amended and restated development and license agreement (the Second Amended and Restated Agreement) under which the Company and Auxilium clarified and changed certain rights and obligations of the parties, including, but not limited to, the following:

- We retain the right to conduct trials, studies or development work:
  - ♦ for indications in canine lipomas and human lipomas;
  - ♦ for additional indications upon approval by the parties joint development committee;
  - ♦ for tissue disassociation research and development; and
  - ♦ for *in vitro* research and development.
- We also retain the right to manufacture:
  - ♦ the Enzyme for use as a reagent for tissue disassociation;
  - ♦ the Enzyme for performing *in vitro* research and development, unless the Product is supplied by Auxilium for such purposes;
  - ♦ the Product for purposes of development and commercialization of any indications outside the Licensed Indications (together with any indications added pursuant to the terms of the Second Amended and Restated Agreement, the Field), and which Auxilium has failed to exercise its option to license; and

- the Product for any early-stage development activities conducted by the Company through Phase II clinical trials for any indications outside the Field, and which Auxilium has failed to supply Product, diluent or placebo for such purpose.

- In the United States, Japan and the Pfizer Territory, the Company will continue to receive low double-digit royalties as a percentage of net sales by Auxilium, Asahi Kasei Pharma Corporation or Pfizer, independent of clinical indication or sales volume. In other territories (the Partner II Territories), this royalty may be adjusted to reflect a specified percentage of what royalty Auxilium receives from a future sublicensee who is sublicensed in the Partner II Territory.

- The Company will also continue to receive an additional mark-up of cost of goods sold, which may be adjusted in the Partner II Territory to a specified percentage of what cost of goods payment Auxilium receives from a future sublicensee.

- The Company will also continue to receive modest milestones for additional indications and regulatory submissions in the United States and major markets in Europe.

- The Company will receive a certain percentage of any sublicense payments paid to Auxilium, as determined by the country in which the sublicense is granted, the specific indication and the stage of development of the Product at the time of sublicensing in such country.

- Auxilium and BioSpecifics have formalized the process by which the parties will identify, discuss and prioritize potential new indications for the Product; moreover, the parties have clarified the rights and responsibilities of the joint development committee.

- Auxilium will have, at its sole cost, responsibility for performing early stage development activities for the treatment of Edematous Fibrosclerotic Panniculopathy, more commonly known as cellulite. The Company has granted Auxilium an exclusive license to research, develop, manufacture and use the Product in connection with this development, and Auxilium has the option, upon completion of such early stage development and upon its payment to the Company of a one-time $500,000 license fee, to add the treatment of cellulite to the Field. All of the cellulite work will be performed by Auxilium at its own cost. If cellulite is added to the Field, the Company will receive milestone payments and royalties for further cellulite development as noted above.

The foregoing is a summary description of certain terms of the Second Amended and Restated Agreement and, by its nature, is incomplete. It is qualified in its entirety by the text of the Second Amended and Restated Agreement, attached as Exhibit 10.1 to this Current Report on Form 8-K. All readers are encouraged to read the entire text of the Second Amended and Restated Agreement. Certain terms of the Second Amended and Restated Agreement have been omitted from this Current Report on Form 8-K and the version of the Second Amended and Restated Agreement attached as Exhibit 10.1 hereto pursuant to a Confidential Treatment Request that the Company filed with the Securities and Exchange Commission at the time of the filing this Current Report on Form 8-K.

Settlement Agreement with Auxilium Pharmaceuticals, Inc.

As previously reported, on February 15, 2011, Auxilium filed a complaint against the Company in the Court of Common Pleas in Chester County, Pennsylvania concerning the Company s right to conduct clinical trials without prior approval of the parties joint development committee. Also, as previously reported, on May 2, 2011, the Company filed a complaint against Recipharm AB, RecipharmCobra Holdings Limited (the Recipharm entities, collectively Cobra) and Auxilium in the Supreme Court of the State of New York in Nassau County, New York alleging that Auxilium had wrongfully, and in breach of its agreement with the Company, interfered with our rights under a material transfer agreement between the Company and Cobra. On August 31, 2011, the Company and Auxilium entered into a settlement agreement (the Settlement Agreement), pursuant to which the parties settled all pending litigation and resolved other outstanding disputes between them.

Pursuant to the Settlement Agreement and certain assignment agreements executed in connection therewith, the Company became a co-owner with Auxilium of the 560 Patent and any continuations and divisionals thereof. The parties also agreed to certain clarifications as to intellectual property matters and amounts owed between the parties. The effectiveness of the Settlement Agreement was conditioned, in part, upon the execution by the parties of the Second Amended and Restated Agreement.

The foregoing is a summary description of certain terms of the Settlement Agreement and, by its nature, is incomplete. It is qualified in its entirety by the text of the Settlement Agreement, attached as Exhibit 10.2 to this Current Report on Form 8-K. All readers are encouraged to read the entire text of the Settlement Agreement. Certain terms of the Settlement Agreement have been omitted from this Current Report on Form 8-K and the version of the Settlement Agreement attached as Exhibit 10.2 hereto pursuant to a Confidential Treatment Request that the Company filed with the Securities and Exchange Commission at the time of the filing this Current Report on Form 8-K.

ITEM 7.01 REGULATION FD DISCLOSURE.

On August 31, 2011, the Company issued a press release announcing:

- The Company s plans to develop XIAFLEX for the treatment of human and canine lipomas;
- The Company s and Auxilium s agreement to dismiss all pending litigation and resolve other outstanding disputes between the parties; and
- The Company s entry into the Second Amended and Restated Agreement with Auxilium.

The full text of such press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description of Exhibit
10.1#	Second Amended and Restated Development and License Agreement, dated as of August 31, 2011, by and between BioSpecifics Technologies Corp. and Auxilium Pharmaceuticals, Inc.
10.2#	Settlement Agreement, dated as of August 31, 2011, by and between BioSpecifics Technologies Corp. and Auxilium Pharmaceuticals, Inc.
99.1	Press Release, dated August 31, 2011, issued by BioSpecifics Technologies Corp.

#Confidential treatment requested under 17 C.F.R. §§ 200.80(b)(4) and 240.24b -2. The confidential portions of this exhibit have been omitted and are marked accordingly. The confidential portions have been filed separately with the Securities and Exchange Commission.

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.

Date: September 1, 2011

BIOSPECIFICS TECHNOLOGIES CORP.
(Registrant)

/s/ Thomas L. Wegman
Thomas L. Wegman
President

EXHIBIT INDEX

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