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 13, 2018**

Stemline Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-35619**	**45-0522567**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

750 Lexington Avenue
Eleventh Floor
New York, New York 10022
(Address of Principal Executive Offices)

(646) 502-2311
(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.

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act.

☐ Pre-commencement communications pursuant to Rule 14d-2b under the Exchange Act.

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act.

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 8.01 Other Events.

On August 13, 2018, Stemline Therapeutics, Inc. announced that the U.S. Food and Drug Administration (FDA) has accepted for filing the Company's Biologics License Application (BLA) for ELZONRIS™ (tagraxofusp; SL-401) for the treatment of patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN). The FDA also granted Priority Review for the BLA and has set a target action date of February 21, 2019, under the Prescription Drug User Fee Act (PDUFA).

A copy of the press release is being furnished as Exhibit 99.1 to this report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished herewith:

Exhibit Number	Description
99.1	Press release issued by Stemline Therapeutics, Inc., dated August 13, 2018.

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.

Date: August 13, 2018

Stemline Therapeutics, Inc.
(Registrant)

By /s/ Kenneth Hoberman
Kenneth Hoberman
Chief Operating Officer

Exhibit 99.1

Stemline Therapeutics Announces that FDA Accepts ELZONRIS™ Biologics License Application (BLA) and Grants Priority Review

- **Conference call on BLA acceptance and commercial readiness scheduled for Monday, August 13, 2018 at 8:30 AM ET**

NEW YORK, August 13, 2018 (GLOBE NEWSWIRE) — Stemline Therapeutics, Inc. (Nasdaq: STML), a clinical-stage biopharmaceutical company developing novel oncology therapeutics, announced today that the U.S. Food and Drug Administration (FDA) has accepted for filing the Company's Biologics License Application (BLA) for ELZONRIS™ (tagraxofusp; SL-401) for the treatment of patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN). The FDA also granted Priority Review for the BLA and has set a target action date of February 21, 2019, under the Prescription Drug User Fee Act (PDUFA).

The FDA grants Priority Review to product applications that, if approved, would provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications.

ELZONRIS has also been granted Breakthrough Therapy Designation (BTD) and Orphan Drug Designation (ODD) by the FDA.

Ivan Bergstein, M.D., Stemline's CEO, commented, "The acceptance of our BLA for filing and grant of Priority Review represent tremendous milestones for Stemline and the BPDCN patient community. We would like to thank the patients and their families who participated in our clinical trials, as well as recognize the tireless work of our investigators and entire Stemline team. Given both Priority and Breakthrough status, our commercial organization is positioning itself to rapidly launch ELZONRIS, if approved, to ensure this important new treatment reaches patients as quickly as possible."

Conference Call and Webcast

Stemline Therapeutics will host a conference call and audio webcast on Monday, August 13, 2018 at 8:30 AM ET. Interested participants and investors may access the conference call by dialing 844-389-8660 (U.S./Canada) or 478-219-0408 (International) and referencing conference ID: 4762319. An audio webcast can also be accessed via the Investor Relations tab of the Stemline Therapeutics website at http://ir.stemline.com.

About ELZONRIS™ (tagraxofusp; SL-401)

ELZONRIS™ (tagraxofusp; SL-401) is a novel targeted investigational therapy directed to CD123, a cell surface receptor expressed on a range of malignancies. ELZONRIS successfully completed a pivotal trial in patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN), and a Biologics License Application (BLA) in this indication has been accepted for filing and been granted Priority Review by the U.S. Food and Drug Administration (FDA). ELZONRIS has also been granted Breakthrough Therapy Designation (BTD) and Orphan Drug Designation by the FDA. ELZONRIS is also being evaluated in clinical trials in additional indications including chronic myelomonocytic leukemia (CMML), myelofibrosis (MF), and others.

About BPDCN

Please visit the BPDCN disease awareness website: www.bpdcninfo.com.

About Stemline Therapeutics

Stemline Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing novel oncology therapeutics. Stemline is developing three clinical stage product candidates, ELZONRIS™ (tagraxofusp;

SL-401), SL-801, and SL-701. ELZONRIS is a targeted therapy directed to the interleukin-3 receptor (CD123) present on a range of malignancies. ELZONRIS has completed a pivotal trial in blastic plasmacytoid dendritic cell neoplasm (BPDCN), for which it was granted breakthrough therapy designation (BTD). The pivotal trial met its primary endpoint, and a Biologics License Application (BLA) has been accepted for filing and granted Priority Review by the FDA. ELZONRIS is also being evaluated in clinical trials in additional indications including chronic myelomonocytic leukemia (CMML), myelofibrosis (MF), and others. SL-801 is a novel oral small molecule reversible inhibitor of XPO1 that is currently in a Phase 1 trial of patients with advanced solid tumors; dose escalation is ongoing. SL-701, an immunotherapeutic, has completed a Phase 2 trial in patients with second-line glioblastoma; data and next steps for the program are being evaluated.

Forward-Looking Statements

Some of the statements included in this press release may be forward-looking statements that involve a number of risks and uncertainties. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. The factors that could cause our actual results to differ materially include: the success and timing of our BLA submission to the FDA; the success and timing of our clinical trials and preclinical studies for our product candidates, including site initiation, institutional review board approval, scientific review committee approval, patient accrual, safety, tolerability and efficacy data observed, and input from regulatory authorities including the risk that the FDA or other ex-U.S. national drug authority ultimately does not agree with our data, find our data supportive of approval, or approve any of our product candidates; our plans to develop and commercialize our product candidates; market acceptance of our products; reimbursement available for our products; our available cash and investments; our ability to obtain and maintain intellectual property protection for our product candidates; our ability to obtain and maintain intellectual property protection for our product candidates; our ability to manufacture; the performance of third-party manufacturers, clinical research organizations, clinical trial sponsors and clinical trial investigators; and other risk factors identified from time to time in our reports filed with the SEC. Any forward-looking statements set forth in this press release speak only as of the date of this press release. We do not intend to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof.

Contact

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