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 25, 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 June 25, 2018, Stemline Therapeutics, Inc. announced it completed the submission of its Biologics License Application (BLA) for ELZONRIS (tagraxofusp; SL-401), a targeted therapy directed to the interleukin-3 receptor (CD123), to the U.S. Food and Drug Administration (FDA).

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 June 25, 2018.

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.

Stemline Therapeutics, Inc.
(Registrant)

By /s/ Kenneth Hoberman
Kenneth Hoberman
Chief Operating Officer

Date: June 26, 2018

Exhibit 99.1

Stemline Therapeutics Announces Completion of Rolling BLA Submission for ELZONRIS™ (tagraxofusp; SL-401) for the Treatment of BPDCN

NEW YORK, June 25, 2018 (GLOBE NEWSWIRE) — Stemline Therapeutics, Inc. (Nasdaq: STML), a clinical-stage biopharmaceutical company developing novel oncology therapeutics, announced today that it has completed submission of a rolling Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for ELZONRIS™ (tagraxofusp; SL-401), a potential treatment for patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN), a CD123+ malignancy of unmet medical need for which the agent was awarded Breakthrough Therapy Designation (BTD).

Ivan Bergstein, M.D., Stemline's CEO, commented, "The completion of our rolling BLA submission is a major milestone for Stemline and the overall BPDCN patient community. We want to recognize the hard work of our dedicated investigators as well as the entire Stemline team in completing this submission. We also want to especially thank all of the patients and their families who participated in the clinical development program. We are committed to bringing this promising agent to BPDCN patients as rapidly as possible."

BPDCN Efficacy — Stages 1, 2, and 3, ELZONRIS (12µg/kg/day) (n=42)

The trial of investigational agent, ELZONRIS, in patients with BPDCN was comprised of 3 stages, with Stage 3 serving as the pivotal cohort for confirmation of efficacy. To ensure ongoing access to ELZONRIS, patients with BPDCN are being enrolled in an additional cohort, Stage 4. Stage 3 met its primary endpoint with a CR+CRc (complete response + clinical complete response) rate of 54% (95% CI: 25.1, 80.8). A summary of efficacy results is shown below.

Summary table: Efficacy of ELZONRIS (12µg/kg/day) in patients with BPDCN (Stages 1, 2 and 3 [n=42])

Line of Therapy	First-line	Relapsed / Refractory
n	29	13
ORR, n (%)	26 (90%)	9 (69%)
CR+CRc+CRi, n (%)	21 (72%)	5 (38%)
CR	12	1
CRc	7	3
CRi	2	1
PR, n (%)	5 (17%)	4 (31%)
Bridged to SCT, n (%)	13 (45%)	1 (8%)

Abbreviations: ORR=overall response rate; CR=complete response; CRc=clinical CR (CR with minimal residual skin abnormality); CRi=CR with incomplete hematologic recovery; PR=partial response; SCT=stem cell transplant.

Overall Safety

148 patients received ELZONRIS (12µg/kg/day) across all Stemline-sponsored trials, including in BPDCN, myeloproliferative neoplasms, and acute myeloid leukemia. A summary of safety results is shown below.

Summary table: Safety and tolerability of ELZONRIS (12µg/kg/day) in all Stemline-sponsored clinical trials (n=148)

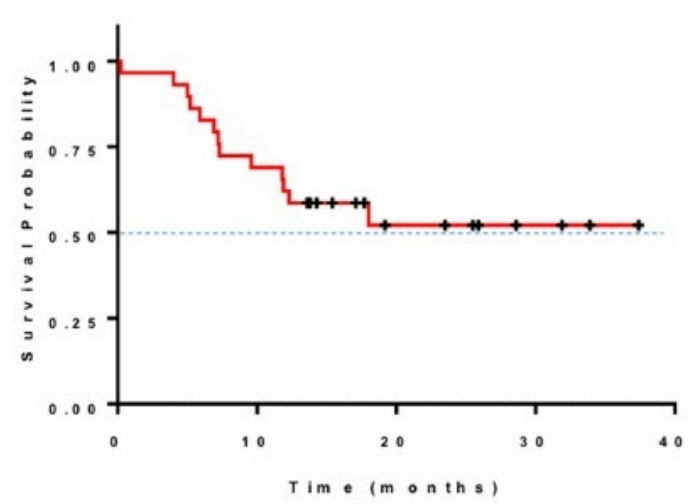
Most Common Adverse Events (AEs) (>15% treatment-related AEs, TRAEs)

	All Grades, n (%)		TRAEs, n (%)			
Preferred Term	**TRAEs**	**All AEs**	**Gr 1-2**	**Gr 3**	**Gr 4**	**Gr 5**
ALT increased	65 (43.9%)	80 (54.1%)	31 (20.9%)	34 (23.0%)	0 (0.0%)	0 (0.0%)
AST increased	65 (43.9%)	74 (50.0%)	30 (20.3%)	31 (20.9%)	4 (2.7%)	0 (0.0%)
Hypoalbuminaemia	65 (43.9%)	73 (49.3%)	64 (43.2%)	1 (0.7%)	0 (0.0%)	0 (0.0%)
Thrombocytopenia	39 (26.4%)	48 (32.4%)	7 (4.7%)	8 (5.4%)	24 (16.2%)	0 (0.0%)
Nausea	38 (25.7%)	70 (47.3%)	37 (25.0%)	1 (0.7%)	0 (0.0%)	0 (0.0%)
Pyrexia	33 (22.3%)	60 (40.5%)	33 (22.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Fatigue	30 (20.3%)	67 (45.3%)	26 (17.6%)	4 (2.7%)	0 (0.0%)	0 (0.0%)
Weight increased	28 (18.9%)	42 (28.4%)	28 (18.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Chills	26 (17.6%)	40 (27.0%)	25 (16.9%)	1 (0.7%)	0 (0.0%)	0 (0.0%)
Capillary leak syndrome (CLS)(a)	25 (16.9%)	25 (16.9%)	16 (10.8%)	5 (3.4%)	3 (2.0%)	1 (0.7%)
Hypotension	23 (15.5%)	36 (24.3%)	17 (11.5%)	5 (3.4%)	1 (0.7%)	0 (0.0%)
Oedema peripheral	22 (14.9%)	57 (38.5%)	21 (14.2%)	1 (0.7%)	0 (0.0%)	0 (0.0%)

(a)0.7% (1/148) for all trials (12µg/kg/day) and 1.6% (3/182) for all trials (all doses) were grade 5. A myocardial infarction, grade 5, was also reported in a patient who experienced a grade 4 CLS.

Overall Survival (OS)

In first-line BPDCN patients who received ELZONRIS (12µg/kg/day) in Stages 1, 2 and 3, the median OS has not been reached. Median follow up was 13.8 months (range: 0.2-37.4+ months).



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 has successfully completed a pivotal trial in patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN), an indication for which it was granted Breakthrough Therapy Designation (BTD). A rolling Biologics License Application (BLA) submission has been completed. ELZONRIS is also being evaluated in clinical trials in additional indications including chronic myelomonocytic leukemia (CMML), myelofibrosis (MF), acute myeloid leukemia (AML), and myeloma.

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 rolling Biologics License Application (BLA) submission has been completed. ELZONRIS is also being evaluated in clinical trials in additional indications including chronic myelomonocytic leukemia (CMML), myelofibrosis (MF), acute myeloid leukemia (AML), and myeloma. 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.

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