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 9, 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 2.02. Results of Operations and Financial Condition.

On August 9, 2018, Stemline Therapeutics, Inc. issued a press release to provide a corporate update and to announce its financial results for the second quarter ended June 30, 2018. A copy of such 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 9, 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 9, 2018

Stemline Therapeutics, Inc.
(Registrant)

By /s/ Kenneth Hoberman
Kenneth Hoberman
Chief Operating Officer

Exhibit 99.1

Stemline Therapeutics Reports Second Quarter 2018 Financial Results

NEW YORK, August 9, 2018 (GLOBE NEWSWIRE) — Stemline Therapeutics, Inc. (Nasdaq: STML), a clinical-stage biopharmaceutical company developing novel oncology therapeutics, announced today its financial results for the quarter ended June 30, 2018. The Company also reviewed recent clinical and regulatory events, and outlined key upcoming milestones:

ELZONRIS™ (SL-401, tagraxofusp) — BLA submission completed

- We completed submission of a rolling Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for ELZONRIS, which has been granted breakthrough therapy designation (BTD), for the treatment of patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN). If successful, we anticipate acceptance of our BLA within 60 days of submission (i.e. in the coming weeks) and potential U.S. marketing approval by 1Q19, or possibly sooner.

- Data from our pivotal trial in patients with BPDCN was the subject of an oral presentation at the 23rd Congress of the European Hematology Association (EHA) in Stockholm, Sweden.

- We anticipate feedback from the European Medicines Agency (EMA) later this year regarding a potential ELZONRIS regulatory filing in Europe.

- In preparation for potential marketing approval, we continue to build out our pre-launch and commercial activities, including our disease awareness campaign targeting key stakeholders including hematologist-oncologists, dermatologists, and pathologists.

ELZONRIS — Other potential indications

- ELZONRIS is also being evaluated in clinical trials in additional indications including chronic myelomonocytic leukemia (CMML) and myelofibrosis (MF).

- Clinical data from ongoing trials in patients with CMML and MF were selected for presentation at EHA in June.

    - In relapsed/refractory CMML (n=16 patients), ELZONRIS demonstrated 100% (8/8) spleen responses in evaluable patients with baseline splenomegaly by physical exam and 2 bone marrow complete responses (BMCRs), coupled with a tolerable safety profile. Given the results observed to date, we are currently formulating registrational trial designs.

    - In relapsed/refractory MF (n=15 patients), ELZONRIS demonstrated 50% (6/12) spleen responses in evaluable patients with baseline splenomegaly (≥5 cm palpable below the costal margin by physical exam), coupled with a tolerable safety profile. Given the results observed to date, we are currently evaluating next steps including possible registrational trial designs.

SL-801

- Data from the ongoing Phase 1 trial of SL-801 in patients with advanced solid tumors were presented at the 2018 American Society of Clinical Oncology (ASCO) annual meeting in June. Patient enrollment and dose escalation continues.

SL-701

- Data from the Phase 2 trial of SL-701 in patients with second-line glioblastoma (GBM) were presented at the 2018 ASCO meeting in June. Notably, there were long-term (>12 month) overall survivors in the SL-701+bevacizumab cohort which consisted primarily of patients who demonstrated an elevated immune response (i.e. potentially representing an "immunocompetent" population). Further analyses, including registration-directed designs are ongoing.

Ivan Bergstein, MD, CEO of Stemline, commented, "We have completed our rolling BLA submission and are quickly approaching the very important milestone of a potential BLA acceptance for filing by the FDA. We continue to advance closer to our ultimate goal of potentially making ELZONRIS widely available to patients with BPDCN. In parallel, ELZONRIS continues to generate very promising clinical data in additional indications including CMML and MF, two settings of unmet medical need for which we are actively evaluating registration pathways. Additionally, we continue to expand our commercial infrastructure including the build out of our sales and marketing teams ahead of our potential approval."

Second Quarter 2018 Financial Results Review

Stemline ended the second quarter of 2018 with $97.1 million in cash, cash equivalents and investments, with a cash burn of $17.6 million in the second quarter. The Company ended the second quarter of 2018 with 30.9 million shares outstanding. For the second quarter of 2018, Stemline had a net loss of $18.9 million, or $0.66 per share, compared with a net loss of $15.5 million, or $0.66 per share, for the same period in 2017.

Research and development expense was $11.2 million for the quarter ended June 30, 2018, compared with $11.5 million for the quarter ended June 30, 2017, representing a decrease of $0.3 million.

General and administrative expense was $8.6 million for the quarter ended June 30, 2018, compared with $4.5 million for the quarter ended June 30, 2017, representing an increase of $4.1 million. The increase in expense was primarily attributed to a $3.0 million increase in pre-launch expenses in support of our potential commercialization of ELZONRIS in BPDCN, if marketing approval from the FDA is received. Additionally, the higher expense was also due to an increase of non-cash stock-based compensation expense and increased headcount.

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), and other indications. 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

Investor Relations
Stemline Therapeutics, Inc.
750 Lexington Avenue
Eleventh Floor
New York, NY 10022
Tel: 646-502-2307
Email: investorrelations@stemline.com

Table 1. Stemline Therapeutics, Inc. - Balance Sheets

	June 30, 2018 (Unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 16,909,400	$ 4,795,098
Short-term investments	79,232,550	46,924,612
Prepaid expenses and other current assets	2,221,982	469,067
Total current assets	98,363,932	52,188,777
Property and equipment, net	142,137	136,672
Long-term investments	992,317	14,468,414
Other Assets	212,305	212,305
Total assets	$ 99,710,691	$ 67,006,168
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 18,179,418	$ 19,742,087
Other current liabilities	106,222	96,826
Total current liabilities	18,285,640	19,838,913
Other liabilities	67,785	96,826
Total liabilities	18,353,425	19,935,739
Stockholders' equity:		
Preferred stock $0.0001 par value, 5,000,000 shares authorized, none issued and outstanding at June 30, 2018 and December 31, 2017	—	—
Common stock $0.0001 par value, 53,750,000 shares authorized at June 30, 2018 and December 31, 2017. 30,917,705 shares issued and outstanding at June 30, 2018 and 25,313,595 shares issued and outstanding at December 31, 2017	3,092	2,531
Additional paid-in capital	322,886,302	251,489,546
Accumulated other comprehensive loss	(122,973)	(145,958)
Accumulated deficit	(241,409,155)	(204,275,690)
Total stockholders' equity	81,357,266	47,070,429
Total liabilities and stockholders' equity	$ 99,710,691	$ 67,006,168

Table 2. Stemline Therapeutics, Inc. - Statements of Operations (Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenues:				
Grant income	$ 500,000	$ 299,401	$ 500,000	$ 598,802
Operating expenses:				
Research and development	11,184,064	11,479,030	23,892,122	21,099,354
General and administrative	8,622,616	4,480,630	14,561,216	9,848,406
Total operating expenses	19,806,680	15,959,660	38,453,338	30,947,760
Loss from operations	(19,306,680)	(15,660,259)	(37,953,338)	(30,348,958)
Other expense	—	—	(3,897)	—
Interest expense	(123)	—	(123)	—
Interest income	378,100	203,323	611,902	326,012
Net loss	$ (18,928,703)	$ (15,456,936)	$ (37,345,456)	$ (30,022,946)
Net loss per common share:				
Basic and Diluted	$ (0.66)	$ (0.66)	$ (1.34)	$ (1.33)
Weighted-average shares outstanding:				
Basic and Diluted	28,567,982	23,412,409	27,851,707	22,615,909