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): **November 8, 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 November 8, 2018, Stemline Therapeutics, Inc. issued a press release to provide a corporate update and to announce its financial results for the third quarter ended September 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 November 8, 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: November 8, 2018

Stemline Therapeutics, Inc.
(Registrant)

By: /s/ Kenneth Hoberman
Kenneth Hoberman
Chief Operating Officer

Exhibit 99.1

Stemline Therapeutics Reports Third Quarter 2018 Financial Results

NEW YORK, November 8, 2018 (GLOBE NEWSWIRE) — Stemline Therapeutics, Inc. (Nasdaq: STML), a biopharmaceutical company focused on the development and potential commercialization of novel oncology therapeutics, announced today financial results for the quarter ended September 30, 2018. The Company also reviewed recent clinical and regulatory events, and outlined key upcoming milestones:

ELZONRIS — Potential Approval and Pre-Commercial Activities

- The FDA 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 set a target action date of February 21, 2019, under the Prescription Drug User Fee Act (PDUFA).

- In preparation for potential US approval, we continue to build out our pre-launch activities. These efforts include ramping up our disease awareness campaign targeting key stakeholders including hematologist-oncologists, dermatologists, and pathologists.

- During the quarter, we conducted meetings with our assigned Rapporteurs and the European Medicines Agency (EMA). Based on feedback from these meetings, we plan to submit a Marketing Authorization Application (MAA) to the EMA for ELZONRIS in the first quarter of 2019 seeking marketing approval in Europe.

ELZONRIS — Market Expansion Efforts

- ELZONRIS is being evaluated in clinical trials in additional indications, with a focus on chronic myelomonocytic leukemia (CMML) and myelofibrosis (MF).

- Based on the clinical results observed in CMML and MF thus far, we are finalizing registrational plans in these indications. We plan to seek regulatory advice in early 2019 with the goal of initiating pivotal trials, or cohorts, to follow. Ahead of this, the ongoing trial continues to enroll CMML and MF patients, and periodic updates at upcoming conferences will be provided.

ASH Conference

- At the upcoming American Society of Hematology (ASH) conference in December, ELZONRIS data were selected for four presentations, including an oral presentation. Presentations include results of the BPDCN pivotal trial and updated clinical trial data in patients with chronic myelomonocytic leukemia (CMML) and myelofibrosis (MF).

- Additionally, we expect to have a robust clinical, medical affairs and pre-commercial presence at ASH, including hosting an investor/analyst event on December 3rd.

SL-801

- In October, data from the ongoing Phase 1 trial of SL-801 in patients with advanced solid tumors were presented at the European Society of Medical Oncology (ESMO) Annual Congress 2018.

- Patient enrollment and dose escalation continues. We expect to provide further updates at upcoming conferences.

SL-701

- In October, data from the Phase 2 trial of SL-701 in patients with second-line glioblastoma (GBM) were delivered via oral presentation at the European Society of Medical Oncology (ESMO) Annual Congress 2018.

- Discussions around next steps to unlock potential value from the program are ongoing, and we expect to provide further updates at upcoming conferences.

Ivan Bergstein, M.D., CEO of Stemline Therapeutics, commented "This is an extremely exciting time for Stemline, as we gear up for the possible approval and near-term launch of ELZONRIS for BPDCN. We have nearly completed the full build-out of our U.S. sales force and commercial infrastructure in preparation for potential launch of ELZONRIS. In parallel, we continue to generate very promising clinical data in CMML and MF, additional areas of unmet medical need. Overall, the ability to effectively target CD123 with an acceptable safety profile we believe opens up significant developmental and commercial opportunities for Stemline."

Third Quarter 2018 Financial Results Review

Stemline ended the third quarter of 2018 with $78.5 million in cash, cash equivalents and investments, representing cash use of $18.6 million in the third quarter. The Company ended the third quarter of 2018 with 31.7 million shares outstanding. For the third quarter of 2018, Stemline had a net loss of $21.0 million, or $0.73 per share, compared with a net loss of $16.1 million, or $0.68 per share, for the same period in 2017.

Research and development expenses were $11.8 million for the quarter ended September 30, 2018, compared with $12.4 million for the quarter ended September 30, 2017.

General and administrative expenses were $9.6 million for the quarter ended September 30, 2018, compared with $4.2 million for the quarter ended September 30, 2017, representing an increase of $5.4 million. The higher expenses were primarily attributed to a $4.6 million increase in pre-launch expenses to support a potential commercialization of ELZONRIS in BPDCN, if marketing approval from the FDA is obtained. Additionally, the higher expense was also due to an increase in non-cash stock-based compensation and increased headcount.

About BPDCN

Please visit the BPDCN disease awareness booth (#205) at ASH 2018, and the BPDCN disease awareness website at www.bpdcninfo.com.

About Stemline Therapeutics

Stemline Therapeutics, Inc. is a biopharmaceutical company focused on the development and potential commercialization of 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 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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Table 1. Stemline Therapeutics, Inc. - Balance Sheets

	September 30, 2018 (Unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 11,677,741	$ 4,795,098
Short-term investments	66,856,499	46,924,612
Prepaid expenses and other current assets	1,996,235	469,067
Total current assets	80,530,475	52,188,777
Property and equipment, net	221,820	136,672
Long-term investments	—	14,468,414
Other Assets	212,305	212,305
Total assets	$ 80,964,600	$ 67,006,168
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses.	$ 17,202,090	$ 19,742,087
Other current liabilities	133,170	96,826
Total current liabilities	17,335,260	19,838,913
Other liabilities	91,174	96,826
Total liabilities	17,426,434	19,935,739
Commitments and Contingencies Stockholders' equity:		
Preferred stock $0.0001 par value, 5,000,000 shares authorized, none issued and outstanding at September 30, 2018 and December 31, 2017	—	—
Common stock $0.0001 par value, 53,750,000 shares authorized at September 30, 2018 and December 31, 2017. 31,671,552 shares issued and outstanding at September 30, 2018 and 25,313,595 shares issued and outstanding at December 31, 2017	3,167	2,531
Additional paid-in capital	326,084,695	251,489,546
Accumulated other comprehensive loss	(96,546)	(145,958)
Accumulated deficit	(262,453,150)	(204,275,690)
Total stockholders' equity	63,538,166	47,070,429
Total liabilities and stockholders' equity	$ 80,964,600	$ 67,006,168

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Income:				
Grant income	$ —	$ 299,397	$ 500,000	$ 898,199
Operating expenses:				
Research and development	11,758,025	12,417,652	35,650,147	33,517,006
General and administrative	9,647,336	4,152,449	24,208,551	14,000,854
Total operating expenses	21,405,361	16,570,101	59,858,698	47,517,860
Loss from operations	(21,405,361)	(16,270,704)	(59,358,698)	(46,619,661)
Other income	—	381	—	381
Other expense	—	(3,566)	(3,897)	(3,566)
Interest expense	(350)	—	(473)	—
Interest income	361,715	217,742	973,617	543,753
Net loss	$ (21,043,996)	$ (16,056,147)	$ (58,389,451)	$ (46,079,093)
Net loss per common share:				
Basic and Diluted	$ (0.73)	$ (0.68)	$ (2.07)	$ (2.01)
Weighted-average shares outstanding:				
Basic and Diluted	29,018,507	23,464,505	28,253,750	22,901,883