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): **March 16, 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 March 16, 2018, Stemline Therapeutics, Inc. issued a press release to provide a corporate update and to announce its financial results for the fourth quarter ended December 31, 2017. 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 March 16, 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: March 16, 2018

Stemline Therapeutics, Inc.
(Registrant)

By /s/ Kenneth Hoberman
Kenneth Hoberman
Chief Operating Officer

Exhibit 99.1

Stemline Therapeutics Reports Fourth Quarter 2017 Financial Results

NEW YORK, March 16, 2018 (GLOBE NEWSWIRE) — Stemline Therapeutics, Inc. (Nasdaq: STML), a clinical-stage biopharmaceutical company developing novel oncology therapeutics, announced today financial results for the quarter ended December 31, 2017. The Company also reviewed recent clinical and regulatory events, and outlined key upcoming milestones:

SL-401 in Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)

- In December 2017, we presented detailed data from the pivotal trial at the 2017 American Society of Hematology (ASH) Annual Meeting in Atlanta, GA.
- Based on these trial results and other data, we expect to complete submission of a rolling Biologics License Application (BLA) in the first half of 2018.
- Also at ASH, we launched our BPDCN disease awareness campaign which is designed to build awareness of BPDCN and CD123.
- Later this year, we anticipate feedback from the European Medicines Agency (EMA) regarding a potential regulatory filing.

Additional Clinical Trials

- SL-401 is also being evaluated in clinical trials in additional indications including myeloproliferative neoplasms (MPN) focused on chronic myelomonocytic leukemia (CMML) and myelofibrosis (MF), acute myeloid leukemia (AML), and multiple myeloma.
- We presented data from the ongoing SL-401 MPN trial at ASH:
    - In relapsed/refractory CMML (n=11), 71% (5/7) of patients with baseline splenomegaly had a ≥50% reduction in spleen size by physical examination. One relapsed/refractory CMML patient had a complete response (CR), comprised of a bone marrow complete response (BMCR) and a 100% spleen reduction (5 to 0 cm, or not palpable).
    - In relapsed/refractory MF (n=12), 50% (5/10) of patients with baseline splenomegaly had spleen reductions of ≥25% (range: 29-100%) by physical exam, including 3 patients (30%) with spleen reductions >35%. Notably, 2 of these 3 patients had baseline thrombocytopenia prior to administration of SL-401: 1 patient with platelets <100K/microliter and 1 patient with platelets <50K/microliter.
    - Most common treatment-related adverse events (TRAEs) included hypoalbuminemia (33%), thrombocytopenia (33%), and fatigue (29%). Capillary leak was reported in 24% (5/21) evaluable patients: 4 cases were grades 1-2 and 1 case was grade 3. Most common TRAEs (grade 3 or higher) included thrombocytopenia (24%) and anemia (19%).
    - Patient enrollment and follow-up is ongoing in this trial. We believe SL-401's favorable tolerability and preliminary signs of activity support continued development and evaluation of possible registration-directed trial designs. Updates relating to this trial, and further plans for these indications, are expected later this year.
- SL-801: the Phase 1 trial in patients with advanced solid tumors is ongoing. Preliminary data were presented at the European Society of Medical Oncology (ESMO) Annual Congress in 2017.

No dose limiting toxicity or maximum tolerated dose has been reached. Dose escalation is ongoing and we are currently enrolling patients in the ninth dosing cohort.

- SL-701: the Phase 2 trial in patients with second-line glioblastoma has been completed. Data were presented at the Society for Neuro-Oncology (SNO) annual meeting in November 2017. SL-701 was well-tolerated and demonstrated evidence of activity, with immunostimulants, as a single agent and in combination with bevacizumab including several major responses and long-term survivors. Data are being analyzed and we expect to provide next steps for the program later this year.

Fourth Quarter 2017 Financial Results Review

Stemline ended the fourth quarter of 2017 with $66.2 million in cash, cash equivalents and investments, as compared to $79.9 million as of September 30, 2017, which reflects cash expenditures of $13.7 million for the quarter. Subsequent to year-end 2017, Stemline completed a follow-on public offering during January 2018 raising $55.5 million in net cash proceeds bringing total cash, cash equivalents and investments as of March 16, 2018 to approximately $106.8 million.

For the fourth quarter of 2017, Stemline had a net loss of $21.7 million, or $0.93 per share, compared with a net loss of $10.0 million, or $0.56 per share, for the same period in 2016.

Research and development expenses were $16.7 million for the fourth quarter of 2017, which reflects an increase of $9.4 million compared with $7.3 million for the fourth quarter of 2016. The higher costs are primarily due to an increase in manufacturing and regulatory expenses in support of our BLA filing and potential commercialization of SL-401. In addition, the higher costs are attributable to increased headcount relating to the build out of various functions, including regulatory and commercial, in support of our BLA filing and potential launch.

General and administrative expenses were $5.2 million for the fourth quarter of 2017, which reflects an increase of $2.1 million compared with $3.1 million for the fourth quarter of 2016. The increase in costs was primarily attributable to pre-launch expenses in support of the potential commercialization of SL-401, if marketing approval from the FDA is obtained, legal expenses, and compensation costs.

About Stemline Therapeutics

Stemline Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing novel oncology therapeutics. Stemline is developing three clinical stage product candidates, SL-401, SL-801, and SL-701. SL-401 is a targeted therapy directed to the interleukin-3 receptor (CD123) present on a range of malignancies. SL-401 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 BLA filing is in preparation. SL-401 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 intended use of proceeds from the offering; 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

	December 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 4,795,098	$ 10,316,064
Short-term investments	46,924,612	36,562,900
Prepaid expenses and other current assets	469,067	290,747
Total current assets	52,188,777	47,169,711
Property and equipment, net	136,672	22,531
Long-term investments	14,468,414	20,714,551
Other assets	212,305	212,305
Total assets	$ 67,006,168	$ 68,119,098
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 19,742,087	$ 9,284,514
Current portion of deferred grant revenue	—	898,199
Other current liabilities	96,826	71,100
Total current liabilities	19,838,913	10,253,813
Other liabilities	96,826	142,200
Total liabilities	19,935,739	10,396,013
Commitments and contingencies		
Stockholders' equity:		
Preferred stock $0.0001 par value, 5,000,000 shares authorized, none issued and outstanding at December 31, 2017 and 2016	—	—
Common stock $0.0001 par value, 53,750,000 shares authorized at December 31, 2017 and 33,750,000 shares authorized at December 31, 2016. 25,313,595 shares issued and outstanding at December 31, 2017 and 19,219,223 shares issued and outstanding at December 31, 2016	2,531	1,922
Additional paid-in capital	251,489,546	193,563,572
Accumulated other comprehensive loss	(145,958)	(99,802)
Accumulated deficit	(204,275,690)	(135,742,607)
Total stockholders' equity	47,070,429	57,723,085
Total liabilities and stockholders' equity	$ 67,006,168	$ 68,119,098

Table 2. Stemline Therapeutics, Inc. - Statements of Operations

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2017	2016	2017	2016
Revenues:				
Grant revenue	$ —	$ 299,401	$ 898,199	$ 1,041,354
Operating expenses:				
Research and development	16,725,380	7,284,262	50,242,386	27,869,921
General and administrative	5,213,353	3,142,260	19,214,207	12,056,890
Total operating expenses	21,938,733	10,426,522	69,456,593	39,926,811
Loss from operations	(21,938,733)	(10,127,121)	(68,558,394)	(38,885,457)
Other (expense) income	(3,145)	(299)	(6,330)	11,438
Interest income	192,577	128,606	736,330	545,718
Net loss before income taxes	$ (21,749,301)	$ (9,998,814)	$ (67,828,394)	$ (38,328,301)
Income tax (expense) benefit	—	(10,282)	—	25,296
Net loss	$ (21,749,301)	$ (10,009,096)	$ (67,828,394)	$ (38,303,005)
Net loss per common share:				
Basic and Diluted	$ (0.93)	$ (0.56)	$ (2.94)	$ (2.15)
Weighted-average shares outstanding:				
Basic and Diluted	23,517,007	17,885,113	23,056,928	17,804,681