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 15, 2019**

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 15, 2019, 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, 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 March 15, 2019.

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 15, 2019

Stemline Therapeutics, Inc.
(Registrant)

By /s/ Kenneth Hoberman
Kenneth Hoberman
Chief Operating Officer

Exhibit 99.1

Stemline Therapeutics Reports Fourth Quarter 2018 Financial Results

NEW YORK, Mar. 15, 2019 (GLOBE NEWSWIRE) — Stemline Therapeutics, Inc. (Nasdaq: STML), a commercial-stage biopharmaceutical company focused on the development and commercialization of novel oncology therapeutics, announced today financial results for the quarter ended December 31, 2018. The Company also reviewed recent milestones:

ELZONRIS™ (tagraxofusp) — US Approval and Commercial Launch

- ELZONRIS was FDA-approved on December 21, 2018 for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and in pediatric patients, two years and older.
- ELZONRIS has been commercially available in the U.S. since the end of January 2019, and patients are currently being treated with ELZONRIS in the commercial setting.
- A Marketing Authorization Application (MAA) for ELZONRIS seeking marketing approval in Europe was submitted to, and subsequently validated by, the European Medicines Agency (EMA) in January 2019. The MAA has been granted accelerated assessment and is currently under review.

ELZONRIS — Market Expansion Efforts

- ELZONRIS is being evaluated in clinical trials in additional indications, including chronic myelomonocytic leukemia (CMML), myelofibrosis (MF), and acute myeloid leukemia (AML).
- Based on the clinical results observed in CMML and MF thus far, we are evaluating potential registrational pathways in these indications. For CMML, we intend to discuss registration-directed plans with the FDA mid-year.
- We are also working towards expansion opportunities within the BPDCN universe, including maintenance therapy after stem cell transplant.
- In parallel, we plan to expand our clinical efforts later this year and next into subsets of AML patients enriched for $CD123^{+}$ expression.
- We expect to provide periodic updates on these initiatives throughout this year and next at scientific conferences.

ASH Conference

- In December 2018, ELZONRIS data were selected for four presentations at the 2018 American Society of Hematology (ASH) conference. Presentations included results of the BPDCN pivotal trial, delivered via oral presentation, and updated clinical trial data in patients with CMML and MF.
- Additionally, we had an active clinical, medical affairs and pre-commercial presence at ASH focused on BPDCN disease awareness.

SL-801

- In October 2018, 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. We expect to provide further updates at upcoming conferences.

SL-701

- In November 2018, data from the Phase 2 trial of SL-701 in patients with second-line glioblastoma (GBM) were delivered via oral presentation at the 23rd Annual Meeting of the Society of Neuro-Oncology (SNO). We expect to provide further updates on this program later this year.

SL-901

- SL-901 is a novel kinase inhibitor that was evaluated in an abbreviated Phase 1 trial of solid tumor patients in Europe. Neither a dose limiting toxicity nor maximum tolerated dose was identified, and there was one partial response (PR) in a patient with advanced non-small cell lung cancer. We plan to re-initiate a Phase 1 study by early 2020.

SL-1001

- In March 2019, we announced the in-licensing of SL-1001, a novel, selective RET kinase inhibitor that demonstrated potent preclinical in vitro and in vivo activity. We expect to begin IND-enabling studies this year, with a Phase 1 clinical trial targeted for 2020.

Robert Francomano, SVP and Global Head of Commercial, commented, "2018 was a transformational year for Stemline as we invested in building out a focused, world class, commercial organization ahead of the FDA approval of ELZONRIS. We are excited to bring this important new treatment to patients, and our highly talented team is in the field, excited, engaged, and poised for success in 2019."

Ivan Bergstein, M.D., CEO of Stemline Therapeutics, commented "We have built a solid foundation for growth in 2019 and beyond, driven by the launch of ELZONRIS in BPDCN. ELZONRIS is the first drug ever approved for BPDCN and brings to patients with BPDCN a new treatment option and hope. In parallel, our team is working diligently with the EMA in an effort to make ELZONRIS potentially available to patients in Europe. We continue to aggressively pursue market expansion efforts with ELZONRIS, while also building out our overall pipeline, with the goal of improving the lives of patients with cancer."

Fourth Quarter 2018 Financial Results Review

Stemline ended the fourth quarter of 2018 with $60.1 million in cash, cash equivalents and investments, as compared to $78.5 million as of September 30, 2018, which reflects cash expenditures of $18.4 million for the quarter. Subsequent to year-end 2018, Stemline completed a follow-on public offering during January 2019 raising $86.1 million in net cash proceeds bringing total cash, cash equivalents and investments to $125.2 million as of March 15, 2019.

For the fourth quarter of 2018, Stemline had a net loss of $26.6 million, or $0.92 per share, compared with a net loss of $21.7 million, or $0.93 per share, for the same period in 2017.

Research and development expenses were $12.1 million for the fourth quarter of 2018, which reflects a decrease of $4.6 million compared with $16.7 million for the fourth quarter of 2017. The higher costs in 2017 were primarily due to manufacturing and regulatory expenses in support of our BLA filing for ELZONRIS.

General and administrative expenses were $14.9 million for the fourth quarter of 2018, which reflects an increase of $9.7 million compared with $5.2 million for the fourth quarter of 2017. The increase in costs were primarily attributable to pre-launch expenses in support of the commercialization of ELZONRIS and compensation costs related to an increase in headcount to support the commercial launch.

About BPDCN

BPDCN is an aggressive hematologic malignancy with historically poor outcomes and an area of unmet medical need. BPDCN typically presents in the bone marrow and/or skin and may also involve lymph nodes and viscera. The BPDCN cell of origin is the plasmacytoid dendritic cell (pDC) precursor. The diagnosis of BPDCN is based on the immunophenotypic diagnostic triad of CD123, CD4, and CD56, and

other markers. For more information, please visit the BPDCN disease awareness website at www.bpdcninfo.com.

About ELZONRIS™

ELZONRIS (tagraxofusp), a CD123-directed cytotoxin, was approved by the Food and Drug Administration (FDA) on December 21, 2018 for the treatment of adult and pediatric patients, two years and older, with blastic plasmacytoid dendritic cell neoplasm (BPDCN). For full prescribing information in the U.S., visit www.ELZONRIS.com. In November 2018, the European Medicines Agency (EMA) granted ELZONRIS accelerated assessment to the marketing authorization application (MAA), which was submitted to, and validated by, the EMA in January 2019. ELZONRIS is also being evaluated in additional clinical trials in other indications including chronic myelomonocytic leukemia (CMML), myelofibrosis (MF) and acute myeloid leukemia (AML).

About Stemline Therapeutics

Stemline Therapeutics, Inc. is a biopharmaceutical company focused on the development and commercialization of novel oncology therapeutics. In December 2018, the FDA approved ELZONRIS, a targeted therapy directed to CD123, for the treatment of adult and pediatric patients, two years or older, with blastic plasmacytoid dendritic cell neoplasm (BPDCN). In November 2018, the European Medicines Agency (EMA) granted accelerated assessment to the marketing authorization application (MAA) of ELZONRIS for the treatment of patients with BPDCN, which was submitted to, and validated by, the EMA in January 2019. ELZONRIS is also being evaluated in clinical trials in additional indications including chronic myelomonocytic leukemia (CMML), myelofibrosis (MF) and acute myeloid leukemia (AML). Additional pipeline candidates include: SL-701 (immunotherapeutic; Phase 2 in glioblastoma patients completed), SL-801 (XPO1 inhibitor; Phase 1 in advanced solid tumor patients ongoing), SL-901 (novel kinase inhibitor; prior abbreviated European Phase 1, IND-enabling studies ongoing), and SL-1001 (novel RET kinase inhibitor, IND-enabling studies pending).

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 of our MAA submission to the EMA; 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, EMA, 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; the possibility that results of clinical trials are not predictive of safety and efficacy results of our product candidates in broader patient populations or of our products if approved; our plans to develop and commercialize our product candidates, including, but not limited to delays in arranging satisfactory manufacturing capabilities and establishing commercial infrastructure for ELZONRIS; product efficacy or safety concerns resulting in product recalls or regulatory action; the risk that estimates regarding the number of patients with the diseases that our products and product candidates may treat are inaccurate; inadequate market penetration of our products; our products not gaining acceptance among patients (and providers or third party payers) for certain indications (due to cost or otherwise); the risk that third party payors (including governmental agencies) will not reimburse for the use of ELZONRIS at acceptable rates or at all; the company's ability to produce, maintain or increase sales of ELZONRIS; the company's ability to develop and/or commercialize ELZONRIS; the adequacy of our pharmacovigilance and drug safety reporting processes; our available cash and investments; our ability to obtain and maintain intellectual property protection for our products and product candidates; delays, interruptions, or failures in the manufacture and supply of our products and product candidates; the performance of third-party businesses, including, but not limited to, 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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Table 1. Stemline Therapeutics, Inc. - Balance Sheets

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 9,443,667	$ 4,795,098
Short-term investments	50,662,189	46,924,612
Prepaid expenses and other current assets	2,952,996	469,067
Total current assets	63,058,852	52,188,777
Property and equipment, net	222,413	136,672
Long-term investments	—	14,468,414
Other Assets	212,305	212,305
Total assets	$ 63,493,570	$ 67,006,168
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 21,153,062	$ 19,742,087
Other current liabilities	65,862	96,826
Total current liabilities	21,218,924	19,838,913
Other liabilities	72,591	96,826
Total liabilities	21,291,515	19,935,739
Commitments and contingencies		
Stockholders' equity:		
Preferred stock $0.0001 par value, 5,000,000 shares authorized, none issued and outstanding at December 31, 2018 and 2017	—	—
Common stock $0.0001 par value, 53,750,000 shares authorized at December 31, 2018 and December 31, 2017. 31,943,186 shares issued and outstanding at December 31, 2018 and 25,313,595 shares issued and outstanding at December 31, 2017	3,194	2,531
Additional paid-in capital	331,343,484	251,489,546
Accumulated other comprehensive loss	(56,559)	(145,958)
Accumulated deficit	(289,088,064)	(204,275,690)
Total stockholders' equity	42,202,055	47,070,429
Total liabilities and stockholders' equity	$ 63,493,570	$ 67,006,168

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
Income:				
Grant income	$ —	$ —	$ 500,000	$ 898,199
Operating expenses:				
Research and development	12,074,872	16,725,380	47,725,019	50,242,386
General and administrative	14,853,116	5,213,353	39,061,667	19,214,207
Total operating expenses	26,927,988	21,938,733	86,786,686	69,456,593
Loss from operations	(26,927,988)	(21,938,733)	(86,286,686)	(68,558,394)
Other expense	(3,608)	(3,145)	(7,505)	(6,330)
Interest expense	(321)	—	**(794)**	—
Interest income	297,003	192,577	1,270,620	736,330
Net loss	$ (26,634,914)	$ (21,749,301)	$ (85,024,365)	$ (67,828,394)
Net loss per common share:				
Basic and Diluted	$ (0.92)	$ (0.93)	$ (2.99)	$ (2.94)
Weighted-average shares outstanding:				
Basic and Diluted	29,085,767	23,517,007	28,388,901	23,056,928