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): **May 10, 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. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	**Trading Symbol(s)**	**Name of each exchange on which registered:**
Common Stock	STML	Nasdaq Capital Market

Item 2.02. Results of Operations and Financial Condition.

On May 10, 2019, Stemline Therapeutics, Inc. (the "Company") issued a press release to provide a corporate update and to announce its financial results for the first quarter ended March 31, 2019. A copy of such press release is being furnished as Exhibit 99.1 to this report.

The Company's senior management will host a conference call and live webcast on Friday, May 10, 2019 at 8:00 a.m. ET. The conference call can be accessed by dialing 1-800-667-5617 (domestic) or 1-334-323-0509 (international) and referring to conference ID 2090827. The live webcast can be accessed via the Company's website (www.stemline.com) at the bottom of the "Investors & Media" section in the "News & Events" page. The webcast will be archived and made available for replay on the Company's website shortly after the call.

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 May 10, 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: May 10, 2019

Stemline Therapeutics, Inc.
(Registrant)

By /s/ Kenneth Hoberman
Kenneth Hoberman
Chief Operating Officer

Exhibit 99.1

Stemline Therapeutics Reports First Quarter 2019 Financial Results

- *Net revenue for ELZONRIS was $5.05 million for the first quarter*
- *Conference call and live webcast scheduled for today at 8:00 AM ET*

NEW YORK, May 10, 2019 (GLOBE NEWSWIRE) — Stemline Therapeutics, Inc. (Nasdaq: STML), a commercial-stage biopharmaceutical company focused on the development and commercialization of novel oncology therapeutics, today reported financial results and business highlights for the first quarter ended March 31, 2019.

"Since ELZONRIS became commercially available in January, we have been very pleased with the progress we have made executing our launch plan," stated Robert Francomano, SVP and Global Head of Commercial. "Our entire organization is working hard to ensure patients with BPDCN have access to ELZONRIS. Although still early, we believe the launch is progressing extremely well and remain poised for a very successful 2019 and beyond."

Ivan Bergstein, M.D., CEO of Stemline Therapeutics, commented "We have built a solid foundation for growth, driven by our launch of ELZONRIS for patients with BPDCN. We are executing our commercial plan, including pursuing ongoing efforts to unlock additional value from ELZONRIS in other indications as well as from our entire pipeline, all with the goal of improving the lives of patients with cancer around the world."

First Quarter 2019 Financial Results Review
Net revenue for ELZONRIS was $5.05 million for the quarter ended March 31, 2019. Stemline began commercial sales of ELZONRIS within the United States in January 2019.

Stemline ended the first quarter with $124.4 million in cash, cash equivalents and investments. For the first quarter, Stemline had a net loss of $27.4 million. Cash expenditures for the first quarter of 2019 was $21.9 million.

Research and development expenses were $17.0 million for the first quarter of 2019, which reflects an increase of $4.3 million compared with $12.7 million for the first quarter of 2018. The higher cost was primarily driven by expense recorded related to repayment of research funding as a result of the first commercial sale of ELZONRIS.

Selling, general and administrative expenses were $16.0 million for the first quarter of 2019, which reflects an increase of $10.1 million compared with $5.9 million for the first quarter of 2018. The increase in costs were primarily attributable to launch expenses in support of the commercialization of ELZONRIS.

Recent Corporate Developments and Program Highlights

ELZONRIS™ (tagraxofusp) — Blastic plasmacytoid dendritic cell neoplasm (BPDCN)

- ELZONRIS was approved by the FDA on December 21, 2018 and commercially available for patients with BPDCN in the U.S. in January 2019.
- The *New England Journal of Medicine* published the pivotal trial results in its April 25th edition.
- We submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in January 2019 seeking marketing approval in Europe. The MAA was granted accelerated assessment and is currently under review.

ELZONRIS — Market Expansion Efforts

- We are conducting clinical trials to evaluate ELZONRIS in additional indications, including chronic myelomonocytic leukemia (CMML), myelofibrosis (MF), and acute myeloid leukemia (AML).
- Based on clinical results observed in patients with CMML and MF, we are evaluating next steps, including potential registrational pathways. For CMML, we intend to provide our registration-directed plans mid-year.
- We are also evaluating additional expansion opportunities, including maintenance therapy after stem cell transplant in patients with BPDCN.
- In parallel, we plan to expand our clinical efforts later this year and next into subsets of AML patients, including those enriched for CD123+ expression.
- We expect to provide periodic updates on these programs throughout this year and next at scientific conferences.

ASCO Conference

- ELZONRIS clinical trial data in CMML and MF have been selected for two poster presentations at the 2019 American Society of Clinical Oncology (ASCO) conference in June.

Other pipeline candidates

- We expect to provide periodic updates on our other product candidates, SL-701, SL-801, SL-901, and SL-1001, later this year.

Conference Call Information
Stemline will host a conference call and live webcast today at 8:00 a.m. ET to discuss first quarter 2019 financial results and recent business activities. The conference call can be accessed by dialing 1-800-667-5617 (domestic) or 1-334-323-0509 (international) and referring to conference ID 2090827.

The live webcast can be accessed via the company's website (www.stemline.com), at the bottom of the "Investors & Media" section in the "News & Events" page. The webcast will be archived and made available for replay on the company's website shortly after the event.

About ELZONRIS™
ELZONRIS (tagraxofusp-erzs), a CD123-directed cytotoxin, is approved by the U.S. Food and Drug Administration (FDA) and commercially available in the U.S. for the treatment of adult and pediatric patients, two years or older, with blastic plasmacytoid dendritic cell neoplasm (BPDCN). For full prescribing information in the U.S., visit www.ELZONRIS.com. In Europe, a marketing authorization application (MAA) is under review by the European Medicines Agency (EMA). 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 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, as well as other markers. For more information, please visit the BPDCN disease awareness website at www.bpdcninfo.com.

About CD123
CD123 is a cell surface target expressed on a wide range of myeloid tumors including blastic plasmacytoid dendritic cell neoplasm (BPDCN), certain myeloproliferative neoplasms (MPNs) including chronic myelomonocytic leukemia (CMML) and myelofibrosis (MF), acute myeloid leukemia (AML) (and potentially enriched in certain AML subsets), myelodysplastic syndrome (MDS), and chronic myeloid leukemia (CML). CD123 has also been reported on certain lymphoid malignancies including multiple

myeloma (MM), acute lymphoid leukemia (ALL), hairy cell leukemia (HCL), Hodgkin's lymphoma (HL), and certain Non-Hodgkin's lymphomas (NHL). In addition, CD123 has been detected on some solid tumors as well as autoimmune disorders including cutaneous lupus and scleroderma.

About Stemline Therapeutics
Stemline Therapeutics, Inc. is a commercial-stage biopharmaceutical company focused on the development and commercialization of novel oncology therapeutics. ELZONRIS™ (tagraxofusp), a targeted therapy directed to CD123, is FDA-approved and commercially available in the U.S. for the treatment of adult and pediatric patients, two years or older, with blastic plasmacytoid dendritic cell neoplasm (BPDCN). In Europe, a marketing authorization application (MAA) is under review by the European Medicines Agency (EMA). 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). For more information, please visit the company's website at www.stemline.com.

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 U.S. launch and commercialization; the success of our MAA submission to the EMA and potential launch in Europe; the success and timing of our clinical trials and preclinical studies for our product and product candidates, including ELZONRIS in additional indications and our other pipeline 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 product 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 payors) 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 product and product candidates; delays, interruptions, or failures in the manufacture and supply of our product 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.

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

	March 31, 2019 (Unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 24,014,510	$ 9,443,667
Short-term investments	100,337,983	50,662,189
Accounts receivable	5,618,900	—
Inventories	848,493	—
Prepaid expenses and other current assets	3,120,926	2,952,996
Total current assets	133,940,812	63,058,852
Property and equipment, net	273,399	222,413
Right-of-use asset, net	1,738,680	—
Other Assets	212,305	212,305
Total assets	$ 136,165,196	$ 63,493,570
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 25,413,021	$ 21,153,062
Right-of-use liability — current portion	1,023,678	—
Other current liabilities	6,021	65,862
Total current liabilities	26,442,720	21,218,924
Right-of-use liability	818,303	—
Other liabilities	12,011	72,591
Total liabilities	27,273,034	21,291,515
Stockholders' equity:		
Preferred stock $0.0001 par value, 5,000,000 shares authorized, none issued and outstanding at March 31, 2019 and December 31, 2018	—	—
Common stock $0.0001 par value, 53,750,000 shares authorized at March 31, 2019 and December 31, 2018. 43,576,081 shares issued and outstanding at March 31, 2019 and 31,943,186 shares issued and outstanding at December 31, 2018	4,358	3,194
Additional paid-in capital	425,410,295	331,343,484
Accumulated other comprehensive loss	(27,161)	(56,559)
Accumulated deficit	(316,495,330)	(289,088,064)
Total stockholders' equity	108,892,162	42,202,055
Total liabilities and stockholders' equity	$ 136,165,196	$ 63,493,570

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

	Three Months Ended March 31,	
	2019	2018
Revenues:		
Product revenue, net	$ 5,048,590	$ —
Operating expenses: Cost of goods sold	85,728	—
Research and development	16,953,822	12,708,058
Selling, general and administrative	15,953,968	5,938,600
Total operating expenses	32,993,518	18,646,658
Loss from operations	(27,944,928)	(18,646,658)
Other expense	(4,616)	(3,897)
Interest income	538,584	233,802
Net loss before income taxes	(27,410,960)	(18,416,753)
Income tax benefit	3,694	—
Net loss	$ (27,407,266)	$ (18,416,753)
Net loss per common share:		
Basic and Diluted	$ (0.73)	$ (0.69)
Weighted-average shares outstanding: Basic and Diluted	37,550,931	26,845,983