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 13, 2020**

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.

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

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 13, 2020, Stemline Therapeutics, Inc. (the "Company") issued a press release to provide a corporate update and to announce its financial results for the fourth quarter ended December 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 Monday, March 16, 2020 at 8:00 a.m. ET. The conference call can be accessed by dialing 1-800-367-2403 (domestic) or 1-334-777-6978 (international) and referring to conference ID 7728185. 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.

The information, including Exhibit 99.1, in this Form 8-K is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Form 8-K shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended, except as shall otherwise be expressly set forth by specific reference in such filing.

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 13, 2020.

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 13, 2020

Stemline Therapeutics, Inc.
(Registrant)

By /s/ Kenneth Hoberman
Kenneth Hoberman
Chief Operating Officer

Exhibit 99.1

Stemline Therapeutics Reports Fourth Quarter 2019 Financial Results

- *Net revenue for ELZONRIS® was $11.8 million for the fourth quarter*
- *Conference call and live webcast scheduled for Monday, March 16th, at 8:00 AM ET*

NEW YORK, March 13, 2020 (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 fourth quarter ended December 31, 2019.

Robert Francomano, Chief Commercial Officer of Stemline, stated, “Overall, we are very pleased with the solid demand we generated for ELZONRIS in the first year of launch and look to expand our reach in the market as we continue to build a strong commercial foundation. Importantly, new medical claims data align with our independent analyses which support our market size estimates of the BPDCN U.S. patient population. We believe there is significant growth potential ahead and are poised to capture greater market penetration. Based on market assessments, we have already started to implement a new host of tactics to better situate ELZONRIS in this dynamic and emerging market – all of which should benefit growth later this year.”

Ivan Bergstein, CEO of Stemline, commented, “Our first year of launch has created a strong foundation for the future growth of the company. We are investing in multiple label expansion opportunities for ELZONRIS in such indications as CMML, MF, and AML, as well as advancing our other pipeline products including felezonexor, our XPO1 inhibitor and SL-1001, our RET kinase inhibitor, toward key inflection points over the coming year and beyond.”

Fourth Quarter 2019 Financial Results Review
Net product revenue for ELZONRIS was $11.8 million for the quarter ended December 31, 2019. Stemline began commercial sales of ELZONRIS within the United States in January 2019.

Stemline ended the fourth quarter with $164.4 million in cash, cash equivalents and short-term investments. For the fourth quarter, Stemline reported a net loss of $17.7 million, with net cash expenditures of $10.1 million.

Research and development expenses were $10.5 million for the fourth quarter of 2019, which reflects decrease of $1.6 million compared with $12.1 million for the fourth quarter of 2018. The lower expenses are primarily attributable to higher costs incurred during 4Q18 related to the ELZONRIS BLA filing and manufacturing of ELZONRIS prior to FDA approval.

Selling, general and administrative expenses were $16.5 million for the fourth quarter of 2019, which reflects an increase of $1.6 million compared with $14.9 million for the fourth quarter of 2018. The increase in costs were primarily attributable to ongoing U.S. launch expenses for ELZONRIS and pre-launch ELZONRIS-related costs in support of a potential regulatory approval and launch in the EU.

Corporate Highlights and Key Commercial and Clinical Milestones

BPDCN

- $43.2 million in net revenues for ELZONRIS in 2019
- IQVIA medical claims data identified approximately 534 unique patients in the U.S. in 2018 with at least one claim of Blastic NK-Cell Lymphoma, a former name of BPDCN
- Marketing Authorization Application (MAA) under review by European Medicines Agency (EMA) for potential approval in the EU
- Phase 1/2 trial of ELZONRIS in patients with BPDCN in the maintenance setting, post-stem cell transplant (SCT), open for enrollment

Chronic Myelomonocytic Leukemia (CMML)

- The CMML expansion cohort, Stage 3a, is open for enrollment of two patient populations: relapsed/refractory patients, and first-line, poor prognosis patients not expected to benefit from first line cytoreductive treatment
- Results from Stage 3a are expected to inform the design of the subsequent Stage 3b confirmatory cohort for potential registration
- We expect to provide updates from this trial in ~4Q20/1Q21

Myelofibrosis (MF)

- At ASH 2019, ELZONRIS data in patients with relapsed/refractory MF was the subject of an oral presentation.
- In the MF clinical trial, ELZONRIS demonstrated efficacy (spleen size reductions and total symptom score [TSS] reductions) with a predictable and manageable safety profile, including in patients with poor prognostic factors, such as thrombocytopenia, CMML-type features/monocytosis, and clonal evolution
- The MF cohort of the ongoing trial has been expanded to include 20-25 additional patients
- We are evaluating relapsed/refractory patients and specific subsets of patients, including patients with monocytosis, thrombocytopenia, and CD123 positivity.
- We expect to provide updates from this trial in ~4Q20/1Q21

Acute Myeloid Leukemia (AML)

- A Phase 1/2 trial of ELZONRIS in combination with other agents in patients with relapsed/refractory AML, treatment-naive AML unfit for chemotherapy, and high-risk myelodysplastic syndrome (MDS) is currently enrolling patients. CD123 expression levels are also being evaluated. We expect to provide updates later this year.

Conference Call Information
The company will host a conference call and webcast on Monday, March 16, 2020 at 8:00 a.m. ET. The conference call can be accessed by dialing 1-800-367-2403 (domestic) or 1-334-777-6978 (international) and referring to conference ID 7728185.

The 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, and will be available live and for replay shortly after the event.

About ELZONRIS®
ELZONRIS® (tagraxofusp), a targeted therapy directed to CD123, 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 $CD123^+$ indications, including chronic myelomonocytic leukemia (CMML), myelofibrosis (MF), acute myeloid leukemia (AML), and others are planned, including a $CD123^+$ all-comers trial.

About BPDCN
BPDCN, formerly blastic NK-cell lymphoma, is an aggressive hematologic malignancy, often with cutaneous manifestations, with historically poor outcomes. 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. The World Health Organization (WHO) termed this disease "BPDCN" in 2008; previous names included blastic NK cell lymphoma and agranular CD4+/CD56+ hematodermic neoplasm. 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 malignancies 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 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+ cells have been detected in the tumor microenvironment of several solid tumors as well as in certain 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 and 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) acute myeloid leukemia (AML), and additional trials and indications are planned. Additional pipeline candidates include: felezonexor (SL-801) (XPO1 inhibitor; Phase 1 in advanced solid tumor patients ongoing) and SL-1001 (RET kinase inhibitor, IND-enabling studies ongoing). 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.

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Table 1. Stemline Therapeutics, Inc. - Balance Sheets

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 13,561,712	$ 9,443,667
Short-term investments	150,869,056	50,662,189
Accounts receivable, net	15,120,229	—
Inventories, net	1,151,373	—
Prepaid expenses and other current assets	4,459,127	2,952,996
Total current assets	185,161,497	63,058,852
Property and equipment, net	191,158	222,413
Operating lease right-of-use assets	1,317,598	—
Other assets	308,751	212,305
Total assets	$ 186,979,004	$ 63,493,570
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 21,952,048	$ 21,153,062
Operating lease liabilities – current portion	1,169,764	—
Other current liabilities	10,125	65,862
Total current liabilities	23,131,937	21,218,924
Operating lease liabilities	226,306	—
Other liabilities	4,370	72,591
Total liabilities	23,362,613	21,291,515
Commitments and contingencies		
Stockholders' equity:		
Preferred stock $0.0001 par value, 5,000,000 shares authorized, none issued and outstanding at December 31, 2019 and December 31, 2018	—	—
Common stock $0.0001 par value, 83,750,000 shares authorized at December 31, 2019 and 53,750,000 shares authorized at December 31, 2018. 50,349,150 shares issued and outstanding at December 31, 2019 and 31,943,186 shares issued and outstanding at December 31, 2018	5,035	3,194
Additional paid-in capital	529,488,474	331,343,484
Accumulated other comprehensive income (loss)	28,171	(56,559)
Accumulated deficit	(365,905,289)	(289,088,064)
Total stockholders' equity	163,616,391	42,202,055
Total liabilities and stockholders' equity	$ 186,979,004	$ 63,493,570

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	2018	2019	2018
Revenues:				
Product revenue, net	$ 11,828,984	$ —	$ 43,216,862	$ —
Income:				
Grant income	—	—	—	500,000
Operating expenses:				
Cost of goods sold	3,152,779	—	4,893,339	—
Research and development	10,546,987	12,074,872	50,724,411	47,725,019
Selling, general and administrative	16,476,470	14,853,116	66,846,633	39,061,667
Total operating expenses	30,176,236	26,927,988	122,464,383	86,786,686
Loss from operations	(18,347,252)	(26,927,988)	(79,247,521)	(86,286,686)
Other expense, net	(44,087)	(3,608)	(47,697)	(7,505)
Interest expense	(33,920)	(321)	(34,706)	(794)
Interest income	784,255	297,003	2,538,273	1,270,620
Net loss before income taxes	$ (17,641,004)	$ (26,634,914)	$ (76,791,651)	$ (85,024,365)
Income tax expense	(39,021)	—	(25,574)	—
Net loss	$ (17,680,025)	$ (26,634,914)	$ (76,817,225)	$ (85,024,365)
Net loss per common share:Basic and Diluted	$ (0.38)	$ (0.92)	$ (1.83)	$ (2.99)
Weighted-average shares outstanding:Basic and Diluted	46,851,498	29,085,767	42,091,027	28,388,901