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 7, 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.

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 November 7, 2019, Stemline Therapeutics, Inc. (the "Company") issued a press releaseto provide a corporate update and to announce its financial results for the third quarter ended September 30, 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, November 8, 2019 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 9176352. 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.

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 November 7, 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: November 7, 2019

Stemline Therapeutics, Inc.
(Registrant)

By /s/ Kenneth Hoberman
Kenneth Hoberman
Chief Operating Officer

Exhibit 99.1

Stemline Therapeutics Reports Third Quarter 2019 Financial Results

- *Net revenue for ELZONRIS® was $13.3 million for the third quarter*
- *New patient starts estimated to have increased greater than 20% from last quarter*
- *Conference call and live webcast scheduled for tomorrow, Friday November 8th, at 8:00 AM ET*

NEW YORK, November 7, 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 third quarter ended September 30, 2019.

Robert Francomano, SVP and Global Head of Commercial, stated, "We are very pleased with thesustained revenue generation and significant progress we continue to make on the ELZONRIS launch. Notably, we observed a greater than 20% increase in estimated new patient starts quarter over quarter, which is a testament to our execution and bodes very well for the future of the brand. Additionally, we implemented a number of strategies designed to increase the speed and accuracy of BPDCN diagnoses, not only in hematology and hematopathology but also within the dermatology and dermatopathology segments - where our data indicate the preponderance of misdiagnoses occurs. Our entire organization is focused on ensuring that patients with BPDCN gain access to ELZONRIS, and we look to capitalize on the positive trends we are seeing to ensure continued performance through 2020 and beyond."

Ivan Bergstein, M.D., CEO of Stemline Therapeutics, commented, "We are very pleased with the continued commercial performance and our efforts to realize additional value from ELZONRIS in other indications. Based on encouraging clinical data observed in the first stages of our clinical trial in chronic myelomonocytic leukemia (CMML), combined with a strong rationale for targeting CD123 in this disease setting, we view CMML as our next key indication. We anticipate opening enrollment of the registration-directed stage of the trial in the next few months. We look forward to data and regulatory updates around this program, including in both relapsed/refractory and first-line patients, by the second half of 2020."

Third Quarter 2019 Financial Results Review

Net revenue for ELZONRIS increased to $13.3 million for the quarter ended September 30, 2019.

Stemline ended the third quarter with $174.5 million in cash, cash equivalents and short-term investments. For the third quarter, Stemline reported a net loss of $14.9 million, with net cash expenditures of $11.8 million.

Research and development expenses were $12.3 million for the third quarter of 2019, which reflects an increase of $0.5 million compared with $11.8 million for the third quarter of 2018. The higher costs were primarily due to increased investment as we continue to explore new indications for ELZONRIS.

Selling, general and administrative expenses were $15.4 million for the third quarter of 2019, which reflects an increase of $5.8 million compared with $9.6 million for the third quarter of 2018. The increase in costs were primarily attributable to ongoing commercial launch expenses for ELZONRIS.

Recent Business Highlights

Commercial

- We continue to create a positive reimbursement environment for ELZONRIS that we expect will further enhance the value proposition of the brand and generate more patient starts for the foreseeable future. In particular,
    - Awarding by the CMS (the Centers for Medicare and Medicaid Services) of NTAP (New Technology Add-On Payment), granted to therapies that are deemed to deliver a substantial clinical improvement over existing therapies, for ELZONRIS went into effect on October 1, 2019.
    - Assignment of an ELZONRIS specific J-Code which makes billing for treatment easier and speeds up claims processing time, also in effect October 1st.
    - With regard to private payers, ELZONRIS now has favorable coverage for over 170 million lives, with policy decisions to the label for key large commercial payers.
- We continue to execute on our brand and disease awareness efforts which are designed to raise the profile of BPDCN and underscore the importance of testing patients for CD123, particularly within the dermatology and dermatopathology segment.

ELZONRIS Product Line Extension Efforts

- In an ongoing effort to pursue market expansion opportunities, ELZONRIS is being investigated in a variety of clinical trials and indications, with a number of others planned. By the end of 2020, we expect substantial data and regulatory updates, including in the following programs:

Chronic myelomonocytic leukemia (CMML)

- We plan to open an additional single-arm cohort, Stage 3, of patients with relapsed/refractory CMML to the currently enrolling trial in the next few months. In the first part of Stage 3 (Stage 3a), enrichment strategies (e.g. high CD123 expression levels) and certain potential efficacy endpoints, including spleen size reduction, symptom score improvement, and bone marrow complete response with partial hematologic recovery will be evaluated. First-line CMML patients not expected to benefit from available therapies will also be enrolled.
- Stage 3a endpoints will be assessed for potential inclusion in the confirmatory cohort (Stage 3b), that will aim to provide the primary evidence of efficacy to support potential registration.
- We expect to provide data from Stage 3a, in both relapsed/refractory and first-line patients, as well as further regulatory updates by the end of 2020.

Myelofibrosis (MF)

- ELZONRIS clinical data from the ongoing Phase 1/2 trial in patients with relapsed/refractory MF were selected for oral presentation at the upcoming American Society of Hematology (ASH) conference.
- We are encouraged by the clinical data thus far and are expanding the Stage 2 cohort of the currently enrolling Phase 2 trial of ELZONRIS in patients with relapsed/refractory MF.
    - We will continue to assess ELZONRIS in relapsed/refractory MF patients as a whole as well as in certain patient subsets of interest including patients with baseline thrombocytopenia (a setting where other agents in this area may require dose interruption or reduction), monocytosis (a potential poor prognostic feature), and high CD123 expression levels.

- We expect to provide additional data, including in various subsets of interest, by the end of 2020, and possibly before.

Maintenance therapy post-stem cell transplant (SCT) in BPDCN

- The Phase 2 investigator-sponsored clinical trial of ELZONRIS in patients with BPDCN as maintenance therapy post- SCT has been granted regulatory authorization to proceed. The trial will evaluate the safety and feasibility of ELZONRIS in the maintenance setting for patients with BPDCN after SCT.

- We expect to provide updates by the end of 2020, and possibly before.

Acute myeloid leukemia (AML)

- A Phase 1/2 investigator-sponsored trial is currently ongoing with ELZONRIS in combination with azacitidine and venetoclax in patients with relapsed/refractory AML, elderly AML unfit for chemotherapy, and high-risk myelodysplastic syndrome (MDS).

- Phase 1/2 investigator-sponsored trials are currently planned with ELZONRIS in combination with other agents in patients with relapsed/refractory AML and elderly AML unfit for chemotherapy, with high CD123 expression levels and/or BPDCN-like features.

- We expect to provide updates by the end of 2020, and possibly before.

Ex-U.S.

- In January 2019, Stemline submitted a Marketing Authorization Application to the European Medicines Agency (EMA), seeking approval of ELZONRIS for the treatment of adult patients with BPDCN. We continue to interact with the EMA regarding the application and a scientific advisory group meeting is expected to occur in the first quarter of 2020. Based on this timeline, we expect an opinion or further questions from the Committee for Medicinal Products for Human Use (CHMP) in the first quarter 2020.

- ELZONRIS clinical trial data in BPDCN was presented via oral presentation on October 13^{h} at the Japanese Society of Hematology (JSH) meeting in Tokyo, Japan.

Additional Pipeline Candidates

- Felezonexor (SL-801) is a reversible inhibitor of XPO1. Updated Phase 1 data were presented at the European Society for Medical Oncology (ESMO) meeting. The trial is ongoing, and we intend to provide further updates as the Phase 1 trial continues.

- Stemline is also developing its preclinical assets, SL-1001 (RET kinase inhibitor) and SL-901 (kinase inhibitor), which are both in IND-enabling studies and are expected to enter the clinic next year.

Conference Call Information

The conference call can be accessed by dialing 1-800-367-2403 (domestic) or 1-334-777-6978 (international) and referring to conference ID 9176352. 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-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 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) and acute myeloid leukemia (AML). Additional pipeline candidates include: felezonexor (SL-801) (XPO1 inhibitor; Phase 1 in advanced solid tumor patients ongoing), SL-1001 (novel RET kinase inhibitor, IND-enabling studies ongoing), SL-701 (immunotherapeutic; Phase 2 in glioblastoma patients completed), and SL-901 (novel kinase inhibitor; prior abbreviated European Phase 1, 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 (Unaudited)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 27,378,573	$ 9,443,667
Short-term investments	147,152,571	50,662,189
Accounts receivable	16,566,838	—
Inventories	2,856,876	—
Prepaid expenses and other current assets	2,547,101	2,952,996
Total current assets	196,501,959	63,058,852
Property and equipment, net	213,036	222,413
Operating lease right-of-use assets	1,240,455	—
Other assets	212,305	212,305
Total assets	$ 198,167,755	$ 63,493,570
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 21,376,369	$ 21,153,062
Operating lease liabilities — current portion	1,061,721	—
Other current liabilities	10,000	65,862
Total current liabilities	22,448,090	21,218,924
Operating lease liabilities	277,758	—
Other liabilities	6,949	72,591
Total liabilities	22,732,797	21,291,515
Stockholders' equity:		
Preferred stock $0.0001 par value, 5,000,000 shares authorized, none issued and outstanding at September 30, 2019 and December 31, 2018	—	—
Common stock $0.0001 par value, 83,750,000 shares authorized at September 30, 2019 and 53,750,000 shares authorized at December 31, 2018. 50,010,233 shares issued and outstanding at September 30, 2019 and 31,943,186 shares issued and outstanding at December 31, 2018	5,001	3,194
Additional paid-in capital	523,656,945	331,343,484
Accumulated other comprehensive loss	(1,724)	(56,559)
Accumulated deficit	(348,225,264)	(289,088,064)
Total stockholders' equity	175,434,958	42,202,055
Total liabilities and stockholders' equity	$ 198,167,755	$ 63,493,570

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues:				
Product revenue, net	$ 13,332,580	$ —	$ 31,387,878	$ —
Income:				
Grant income	—	—	—	500,000
Operating expenses:				
Cost of goods sold	1,071,673	—	1,740,560	—
Research and development	12,332,208	11,758,025	40,177,424	35,650,147
Selling, general and administrative	15,413,688	9,647,336	50,370,163	24,208,551
Total operating expenses	28,817,569	21,405,361	92,288,147	59,858,698
Loss from operations	(15,484,989)	(21,405,361)	(60,900,269)	(59,358,698)
Other income (expense)	714	—	(3,610)	(3,897)
Interest income	604,510	361,365	1,753,232	973,144
Net loss before income taxes	$ (14,879,765)	$ (21,043,996)	$ (59,150,647)	$ (58,389,451)
Income tax (expense) benefit	(8,747)	—	13,447	—
Net loss	$ (14,888,512)	$ (21,043,996)	$ (59,137,200)	$ (58,389,451)
Net loss per common share:				
Basic and Diluted	$ (0.34)	$ (0.73)	$ (1.46)	$ (2.07)
Weighted-average shares outstanding:				
Basic and Diluted	43,733,163	29,018,507	40,486,766	28,253,750