Stemline Therapeutics Inc Logo

Stemline Therapeutics Reports Second Quarter 2019 Financial Results

August 2, 2019

- *Net revenue for ELZONRIS® was $13.0 million for the second quarter*
- *Conference call and live webcast scheduled for today at 8:00 AM ET*

NEW YORK, Aug. 02, 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 second quarter ended June 30, 2019.

"We are very excited with the progress we continue to make on the ELZONRIS U.S. launch. Our commercial team continues to generate strong momentum, as evidenced by robust sales, steady increases in new patient starts and a broadening prescriber base," stated Robert Francomano, SVP and Global Head of Commercial. "Our entire organization is focused on ensuring patients with BPDCN gain access to ELZONRIS, and given the trends we are seeing, we remain poised for a successful 2019 and beyond."

Ivan Bergstein, M.D., CEO of Stemline Therapeutics, commented: "We are very pleased with the continued strong commercial performance and the rapid, broad-based adoption of ELZONRIS in the marketplace. 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 building a leading biopharmaceutical company and improving the lives of patients with cancer around the world."

Second Quarter 2019 Financial Results Review
Net revenue for ELZONRIS was $13.0 million for the quarter ended June 30, 2019. Stemline began commercial sales of ELZONRIS within the United States in January 2019.

Stemline ended the second quarter with $103.9 million in cash, cash equivalents and investments. For the second quarter, Stemline had a net loss of $16.8 million. The net cash expenditures for the second quarter of 2019 was $20.5 million.

Research and development expenses were $10.9 million for the second quarter of 2019, which reflects a decrease of $0.3 million compared with $11.2 million for the second quarter of 2018. The lower costs in the current period were primarily due to expenses in the prior year related to our biologics license application (BLA) filing for ELZONRIS with the FDA.

Selling, general and administrative expenses were $19.0 million for the second quarter of 2019, which reflects an increase of $10.4 million compared with $8.6 million for the second quarter of 2018. The increase in costs were primarily attributable to pre-launch and launch expenses in support of the commercialization of ELZONRIS in the U.S. and potential launch in the European Union.

Recent Business Highlights

Commercial

- Net revenue of ELZONRIS were $13.0 million during the second quarter, representing a 157% increase over last quarter.
- The Centers for Medicare and Medicaid Services (CMS) recently assigned a J-Code for ELZONRIS, which happened one quarter earlier than we expected. The J-Code is a permanent code assigned to ELZONRIS by CMS and used by Medicare, Medicaid, and commercial payers for billing and claims processing. With a permanent J-code, ELZONRIS billing becomes more efficient, particularly in the outpatient setting.
- On the private payer side, ELZONRIS now has favorable coverage for over 100 million lives, with coverage policy decisions to the label for key commercial payers.
- We continue to execute on our disease awareness efforts which are designed to raise the profile of BPDCN and underscore the importance of CD123 testing.

Market Expansion Efforts

- Blastic plasmacytoid dendritic cell neoplasm (BPDCN)

  • Stemline announced today that the Phase 2 investigator-sponsored clinical trial of ELZONRIS in patients with BPDCN as maintenance therapy post-stem cell transplant (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 further program updates later this year.

- Chronic myelomonocytic leukemia (CMML)

  • ELZONRIS clinical data from its ongoing Phase 2 clinical trial in patients with CMML were presented at the 2019 American Society of Clinical Oncology (ASCO) annual meeting in Chicago, Illinois and at the 24thCongress of the

European Hematology Association (EHA) in Amsterdam, Netherlands.

• We plan to open an additional single-arm cohort, Stage 3, of patients with previously-treated CMML to the currently enrolling trial later this year. In the first part of Stage 3 (Stage 3a), enrichment strategies and certain efficacy endpoints, including spleen size reduction and bone marrow complete response with partial hematologic recovery, 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.

- Myelofibrosis (MF)

• ELZONRIS clinical data from its ongoing Phase 2 clinical trial in patients with MF were presented at the 2019 American Society of Clinical Oncology (ASCO) annual meeting in Chicago, Illinois and at the 24thCongress of the European Hematology Association (EHA) in Amsterdam, Netherlands.

• The trial continues to enroll and we expect to provide further program updates later this year.

- Systemic sclerosis

• ELZONRIS preclinical results in systemic sclerosis, an autoimmune disorder in which CD123^{+} plasmacytoid dendritic cells (pDCs) play a role in disease pathogenesis, were presented at the Annual European Congress of Rheumatology (EULAR) in Madrid, Spain.

- Acute myeloid leukemia (AML) and others

• ELZONRIS in combination with other agents is currently being evaluated in an investigator-sponsored Phase 1/2 trial of patients with AML and high-risk myelodysplastic syndrome (MDS). Additional investigator-sponsored trials of ELZONRIS in combination with other agents in patients with subsets of AML that are enriched for CD123^{+} and/or BPDCN-like features are targeted to open in the 4Q19/1H20 timeframe. Other indications are also under consideration.

Ex-U.S.

- Stemline continues to build out a European commercial infrastructure in advance of potential approval by the European Medicines Agency (EMA). The ELZONRIS marketing authorization application (MAA) is under review on a standard timeline. In June 2019, we received the day 120 list of questions relating to chemistry, manufacturing and controls (CMC), quality, non-clinical, and all stages of the clinical trial, including stage 4 largely involving lyophilized drug product. We have requested, and received, a clock stop extension. A scientific advisory group meeting is being planned. Based on this timeline, we expect an opinion from the Committee for Medicinal Products for Human Use (CHMP) in 1H20. In anticipation of potential regulatory success, we have started to hire personnel to meet the needs of a possible mid-2020 European commercial launch.

- Stemline has instituted a global Early Access Program (EAP) whereby physicians may seek access to ELZONRIS outside of a clinical trial and/or before it is commercially available.

- ELZONRIS clinical trial data in patients with BPDCN continue to be featured at prominent international hematological conferences with recent presentations in Europe and an upcoming oral presentation at a major medical meeting in Asia.

Additional Pipeline Candidates

- Stemline continues to advance its clinical stage assets, including SL-801 (felezonexor), a reversible inhibitor of XPO1. Updated Phase 1 data were selected for presentation at the upcoming European Society for Medical Oncology (ESMO) meeting. Stemline is also developing its preclinical assets SL-1001 (RET kinase inhibitor) and SL-901 (kinase inhibitor), both of which are in IND-enabling studies and are expected to enter the clinic next year.

Conference Call Information

Stemline will host a conference call and live webcast today at 8:00 a.m. ET to discuss second quarter 2019 financial results and recent business activities. The conference call can be accessed by dialing 1-888-220-8451 (domestic) or 1-323-794-2588 (international) and referring to conference ID 7887580.

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 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.

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Table 1. Stemline Therapeutics, Inc. - Balance Sheets

	June 30, 2019 (Unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 16,965,619	$ 9,443,667
Short-term investments	86,918,164	50,662,189
Accounts receivable	15,093,121	—
Inventories	3,655,017	—
Prepaid expenses and other current assets	3,596,436	2,952,996

Total current assets	126,228,357	63,058,852
Property and equipment, net	238,729	222,413
Right-of-use asset, net	1,469,714	—
Other assets	212,305	212,305
Total assets	$ 128,149,105	$ 63,493,570
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 25,748,958	$ 21,153,062
Right-of-use liability – current portion	1,042,526	—
Other current liabilities	6,142	65,862
Total current liabilities	26,797,626	21,218,924
Right-of-use liability	550,496	—
Other liabilities	9,496	72,591
Total liabilities	27,357,618	21,291,515
Stockholders' equity:		
Preferred stock $0.0001 par value, 5,000,000 shares authorized, none issued and outstanding at June 30, 2019 and December 31, 2018	—	—
Common stock $0.0001 par value, 83,750,000 shares authorized at June 30, 2019 and 53,750,000 shares authorized at December 31, 2018. 43,875,679 shares issued and outstanding at June 30, 2019 and 31,943,186 shares issued and outstanding at December 31, 2018	4,388	3,194
Additional paid-in capital	434,071,363	331,343,484
Accumulated other comprehensive income (loss)	52,488	(56,559)
Accumulated deficit	(333,336,752)	(289,088,064)
Total stockholders' equity	100,791,487	42,202,055
Total liabilities and stockholders' equity	$ 128,149,105	$ 63,493,570

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Revenues:				
Product revenue, net	$ 13,006,709	—	$ 18,055,299	—
Income:				
Grant income	—	$ 500,000	—	$ 500,000
Operating expenses:				
Cost of goods sold	583,159	—	668,888	—
Research and development	10,891,394	11,184,064	27,845,216	23,892,122
Selling, general and administrative	19,002,508	8,622,616	34,956,475	14,561,216
Total operating expenses	30,477,061	19,806,680	63,470,579	38,453,338
Loss from operations	(17,470,352)	(19,306,680)	(45,415,280)	(37,953,338)
Other expense	(262)	(123)	(4,878)	(4,020)
Interest income	610,692	378,100	1,149,276	611,902
Net loss before income taxes	$ (16,859,922)	$ (18,928,703)	$ (44,270,882)	$ (37,345,456)
Income tax benefit	18,500	—	22,194	—
Net loss	$ (16,841,422)	$ (18,928,703)	$ (44,248,688)	$ (37,345,456)
Net loss per common share: Basic and Diluted	$ (0.42)	$ (0.66)	$ (1.14)	$ (1.34)

Weighted-average shares outstanding: Basic and Diluted	40,108,267	28,567,982	38,836,664	27,851,707

Source: Stemline Therapeutics, Inc.