Stemline Therapeutics Reports First Quarter 2018 Financial Results

May 9, 2018

NEW YORK, May 09, 2018 (GLOBE NEWSWIRE) -- Stemline Therapeutics, Inc. (Nasdaq:STML), a clinical-stage biopharmaceutical company developing novel oncology therapeutics, announced today financial results for the quarter ended March 31, 2018. The Company also reviewed recent clinical and regulatory events, and outlined key upcoming milestones:

SL-401 in Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)

- In April, we announced initiation of a rolling Biologics License Application (BLA) submission for SL-401, and expect to complete the rolling submission in 2Q18.
- If our BLA is successful, we anticipate possible U.S. approval of SL-401 in the 4Q18/1Q19 timeframe.
- In preparation for possible approval, we continue to build out our pre-launch and commercial activities.
- At the upcoming American Society of Clinical Oncology (ASCO) annual meeting, we are sponsoring a BPDCN disease awareness booth designed to continue to build awareness around BPDCN and CD123.
- We anticipate feedback from the European Medicines Agency (EMA) regarding a potential regulatory filing in Europe, later this year.

Additional Clinical Trials

- SL-401 is also being evaluated in clinical trials in additional indications including myeloproliferative neoplasms (MPN) [focused on chronic myelomonocytic leukemia (CMML) and myelofibrosis (MF)], acute myeloid leukemia (AML), and multiple myeloma.
- We are evaluating possible registration-directed trial designs in CMML and MF given the results observed to date. Updates relating to these programs are expected later this year.
- SL-801: the Phase 1 trial in patients with advanced solid tumors is ongoing, and dose escalation continues. Data from the SL-801 trial were selected for presentation at the upcoming ASCO meeting in June.
- SL-701: the Phase 2 trial in patients with second-line glioblastoma has completed. Data from the SL-701 trial were selected for presentation at the upcoming ASCO meeting in June.

Ivan Bergstein, MD, CEO of Stemline, commented “The initiation of our rolling BLA submission advances us ever closer to potential approval and commercialization of SL-401. We continue to build out our commercial infrastructure, including accelerating efforts to raise awareness around BPDCN and CD123. In parallel, we continue to pursue SL-401 in other CD123 positive malignancies and look forward to forging additional registrational opportunities. We expect clinical updates from each of our pipeline candidates this year - all with an eye towards achieving our goal of improving the lives of patients with cancer and building a leading biopharmaceutical company.”

First Quarter 2018 Financial Results Review
Stemline ended the first quarter of 2018 with $106.2 million in cash, cash equivalents and investments, as compared to $66.2 million as of December 31, 2017, which reflects a cash increase of $40.0 million for the quarter. The $40.0 million increase in cash represents the $55.7 million in net cash proceeds received from the Company’s follow-on public offering during January 2018 offset by $15.7 million of net cash expenditures during the first quarter 2018. The Company ended the first quarter of 2018 with 30.2 million shares outstanding.

For the first quarter of 2018, Stemline had a net loss of $18.4 million, or $0.69 per share, compared with a net loss of $14.6 million, or $0.67 per share, for the same period in 2017.

Research and development expense was $12.7 million for the quarter ended March 31, 2018, compared with $9.6 million for the quarter ended March 31, 2017, representing an increase of $3.1 million. The higher costs are primarily driven by an increase in regulatory and manufacturing expenses in support of our BLA filing and potential commercialization of SL-401.

General and administrative expense was $5.9 million for the quarter ended March 31, 2018, compared with $5.4 million for the quarter ended March 31, 2017, representing an increase of $0.5 million. The increase in expense was due to $0.9 million in higher pre-launch expenses in support of preparing for a potential commercialization of SL-401 in BPDCN, if marketing approval from the FDA is received. Additionally, the higher costs also resulted from a $0.9 million increase in non-cash stock-based compensation expense and increased headcount. Partially offsetting the higher costs was a decrease in legal expenses of $1.3 million.

About BPDCN
Please visit the BPDCN disease awareness booth (#4125) at ASCO 2018 and www.bpdcninfo.com.

About Stemline Therapeutics
Stemline Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing novel oncology therapeutics. Stemline is developing three clinical stage product candidates, SL-401, SL-801, and SL-701. SL-401 is a targeted therapy directed to the interleukin-3 receptor (CD123) present on a range of malignancies. SL-401 has completed a pivotal trial in blastic plasmacytoid dendritic cell neoplasm (BPDCN), for which it was granted breakthrough therapy designation (BTD). The pivotal trial met its primary endpoint, and a rolling Biologics License Application (BLA) submission has been initiated. SL-401 is also being evaluated in clinical trials in additional indications including chronic myelomonocytic leukemia (CMML), myelofibrosis (MF), acute myeloid leukemia (AML), and myeloma. SL-801 is a novel oral small molecule reversible inhibitor of XPO1 that is currently in a Phase 1 trial of patients with advanced solid tumors; dose escalation is ongoing. SL-701, an immunotherapeutic, has completed a Phase 2 trial in patients with second-line glioblastoma; data and next steps for the program are being evaluated.

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 and timing of our BLA submission to the FDA; 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 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; our plans to develop and commercialize our product candidates; market acceptance of our products; reimbursement available for our products; our available cash and investments; our ability to obtain and maintain intellectual property protection for our product candidates; our ability to obtain and maintain intellectual property protection for our product candidates; our ability to manufacture; the performance of third-party 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

	March 31, 2018 (Unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 15,230,838	$ 4,795,098
Short-term investments	84,276,796	46,924,612
Prepaid expenses and other current assets	1,097,642	469,067
Total current assets	100,605,276	52,188,777
Property and equipment, net	124,886	136,672
Long-term investments	6,733,137	14,468,414
Other Assets	212,305	212,305
Total assets	$ 107,675,604	$ 67,006,168
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 19,488,507	$ 19,742,087
Other current liabilities	96,827	96,826
Total current liabilities	19,585,334	19,838,913
Other liabilities	72,620	96,826
Total liabilities	19,657,954	19,935,739
Stockholders' equity:		
Preferred stock $0.0001 par value, 5,000,000 shares authorized, none issued and outstanding at March 31, 2018 and December 31, 2017	—	—
Common stock $0.0001 par value, 53,750,000 shares authorized at March 31, 2018 and December 31, 2017. 30,216,530 shares issued and outstanding at March 31, 2018 and 25,313,595 shares issued and outstanding at December 31, 2017	3,022	2,531
Additional paid-in capital	310,857,448	251,489,546
Accumulated other comprehensive loss	(150,377)	(145,958)
Accumulated deficit	(222,692,443)	(204,275,690)
Total stockholders' equity	88,017,650	47,070,429
Total liabilities and stockholders' equity	$ 107,675,604	$ 67,006,168

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

	Three Months Ended March 31,	
	2018	2017
Income:		

Grant Income	$ —	$ 299,401
Operating expenses:		
Research and development	12,708,058	9,620,324
General and administrative	5,938,600	5,367,775
Total operating expenses	18,646,658	14,988,099
Loss from operations	(18,646,658)	(14,688,698)
Other expense	(3,897)	—
Interest income	233,802	122,688
Net loss	$ (18,416,753)	$ (14,566,010)
Net loss per common share:		
Basic and Diluted	$ (0.69)	$ (0.67)
Weighted-average shares outstanding: Basic and Diluted	26,845,983	21,810,559

Primary Logo

Source: Stemline Therapeutics, Inc.