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Stemline Therapeutics Provides Second Quarter 2014 Financial Results and Corporate Update

NEW YORK, Aug. 14, 2014 (GLOBE NEWSWIRE) -- Stemline Therapeutics, Inc. (Nasdaq:STML), a clinical stage biopharmaceutical company developing novel drugs targeting cancer stem cells (CSCs) and tumor bulk, today provided a corporate update and reported financial results for the quarter ended June 30, 2014.

"2014 has been a very productive year for Stemline thus far, as we continue to execute on our corporate plan. We have manufactured both SL-401 and SL-701 at commercial scale and are implementing broad clinical development programs with both agents", said Ivan Bergstein, M.D., CEO of Stemline. He continued, "Our experienced team has designed clinical studies and regulatory strategies that we believe are cost-effective and targeted, largely in malignancies that are underserved by available therapies, and designed to provide potential data points this year and throughout next year. We will continue to pursue our plan to create near-term value while also investing in our longer term vision to build a leading commercial-stage biopharmaceutical company with a deep pipeline of innovative products."

Business Highlights

- **Opened corporate-sponsored IND for SL-401.** Following the recently completed investigator-sponsored Phase 1/2 trial, Stemline has opened a corporate-sponsored investigational new drug (IND) with SL-401, which has been manufactured at commercial scale.
- **Opened multicenter trial with SL-401 in advanced blastic plasmacytoid dendritic cell neoplasm (BPDCN) and acute myeloid leukemia (AML).** Stemline has opened a multicenter, open-label study in BPDCN and AML. The trial will include a brief lead-in that transitions into a larger expansion stage in these indications. Stemline plans to evaluate SL-401 in relapsed/refractory BPDCN, an IL-3R-expressing malignancy, which is an unmet medical need and for which Stemline has secured Orphan Drug designation. Stemline will also evaluate IL-3R expression, and other factors potentially related to clinical responsiveness, in relapsed/refractory AML.
- **Published BPDCN clinical results of SL-401 in the journal *Blood*.** Clinical data from the completed Phase 1/2 investigator-sponsored trial of SL-401 in over 80 patients with advanced hematologic cancers were published in the July 17, 2014 issue of *Blood* (*Blood* 124: 385-392, 2014), with an accompanying editorial (*Blood* 124: 310-312, 2014). Seven of nine evaluable BPDCN patients treated with a single cycle of SL-401 had major responses (78% overall response rate), including 5 complete responses (CRs). Median CR duration was over 5 months (and still ongoing) with a single cycle of SL-401. Four patients were still in remission, with one patient still in remission for over 20 months.
- **Opened corporate-sponsored IND and multicenter trial in adult second-line glioblastoma with SL-701.** Stemline has opened a corporate-sponsored investigational new drug (IND) with SL-701, which has been manufactured at commercial scale. Stemline has opened a multicenter, open-label trial in adults with glioblastoma (GBM) in early first recurrence.
- **Additional SL-401 trials being planned in other IL-3R+ cancers.** Stemline is planning additional SL-401 trials in other cancers including several rare IL-3R+ myeloproliferative disorders.
- **Advanced preclinical pipeline and discovery platform.** Stemline has continued to develop its next generation IL-3R-targeted agents, SL-501 and SL-101, as well as naked monoclonal antibodies directed to this target. SL-501 preclinical efficacy data in tyrosine kinase inhibitor (TKI)-resistant chronic myeloid leukemia (CML) were presented at the 2014 American Association for Cancer Research (AACR) annual meeting.
- **Fortified intellectual property portfolio.** Stemline has had seven additional patent allowances/issuances this year. This includes patents derived from our early and broad filings around CSC-directed therapeutics, diagnostics, and drug screening, as well as our tenth patent around the therapeutic targeting of IL-3R.

Second Quarter 2014 Financial Results Review

We ended the June quarter with \$69.5 million in cash, cash equivalents and investments as compared to \$75.6 million as of March 31, 2014, a cash burn of \$6.1 million. Our existing cash, cash equivalents and investments are expected to enable us to fund forecasted operations for at least the next two years. We ended the June quarter with 13.3 million shares outstanding.

For the second quarter of 2014, we had a net loss of \$6.0 million, or \$0.47 per share, compared with a net loss of \$5.5 million, or \$0.55 per share, for the same period in 2013. The net loss for the first six months of 2014 was \$15.0 million, or \$1.16 per share, as compared with a net loss of \$11.0 million, or \$1.37 per share, for the six-month period ended June 30, 2013.

Research and development expense was flat year over year at \$4.1 million for the quarters ended June 30, 2014 and June 30, 2013, respectively. We experienced \$2.0 million of higher clinical and manufacturing development costs during the current quarter as compared to the prior year. The increase in expenses is primarily related to clinical trial preparation and recruitment activities in support of clinical development programs for SL-401 and SL-701. Offsetting higher costs for the quarter was a one-time \$2.0 million in-process research and development expense recorded in the prior year related to intellectual property rights.

General and administrative expense increased \$0.9 million, or 89%, to \$2.0 million for the quarter ended June 30, 2014, from \$1.1 million for the quarter ended June 30, 2013. The increase in costs was primarily attributable to higher compensation expense as a result of increased headcount and an increase in other general and administrative expenses relating to the regulatory requirements in support of becoming a public company.

About Stemline Therapeutics

Stemline Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing novel oncology therapeutics that target both cancer stem cells (CSCs) and tumor bulk in a variety of cancer types. Stemline is currently developing two clinical-stage product candidates, SL-401 and SL-701. SL-401 is a targeted therapy directed to the interleukin-3 receptor (IL-3R). SL-401 has demonstrated single-agent activity, including durable complete responses (CRs), in a Phase 1/2 trial in several indications including blastic plasmacytoid dendritic cell neoplasm (BPDCN) and relapsed or refractory acute myeloid leukemia (AML). SL-401 is being advanced into programs for BPDCN and other rare IL-3R+ malignancies, as well as additional hematologic cancers including AML and myeloma. SL-701 is an enhanced immunotherapy that activates the immune system to attack tumors. An earlier version of this therapy demonstrated clinical activity, including durable CRs and partial responses (PRs), in Phase 1/2 trials in advanced adult and pediatric brain cancers. SL-701 is being advanced into trials of adults with glioblastoma multiforme (GBM) at first recurrence, and children with non-brainstem and brainstem glioma. For more information about Stemline Therapeutics, visit 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 and timing of our preclinical studies and clinical trials, including site initiation, internal review board approval, scientific review committee approval, and patient accrual; our plans to develop and commercialize our product candidates; our available cash; our ability to obtain and maintain intellectual property protection for our product candidates; the ability of our product candidates to successfully perform in clinical trials; 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 Securities and Exchange Commission. 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.

Table 1. Stemline Therapeutics, Inc. - Balance Sheets

	June 30, 2014	December 31, 2013
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 21,160,428	\$ 44,200,420
Short-term investments	1,042,378	—
Related party receivable	—	199,615
Prepaid expenses and other current assets	1,660,812	292,916
Total current assets	23,863,618	44,692,951
Furniture and fixtures, net	306,667	383,333
Long-term investments	47,318,347	40,204,912
Total assets	<u>\$ 71,488,632</u>	<u>\$ 85,281,196</u>

Liabilities and stockholders' equity

Current liabilities:

Accounts payable and accrued expenses	\$ 4,233,072	\$ 5,013,808
Total current liabilities	4,233,072	5,013,808

Deferred grant revenue

	500,857	643,000
Total liabilities	4,733,929	5,656,808

Stockholders' equity:

Preferred stock \$0.0001 par value, 5,000,000 shares authorized, none issued and outstanding at December 31, 2013 and June 30, 2014

Common stock \$0.0001 par value, 33,750,000 shares authorized at June 30, 2014 and December 31, 2013, 13,258,168 shares issued and outstanding at June 30, 2014 and 13,095,726 shares issued and outstanding at **December 31, 2013**

	—	—
	1,326	1,310
Additional paid-in capital	113,123,849	111,032,619
Accumulated other comprehensive gain (loss)	7,919	(43,775)
Accumulated deficit	(46,378,391)	(31,365,766)
Total stockholders' equity	66,754,703	79,624,388
Total liabilities and stockholders' equity	\$ 71,488,632	\$ 85,281,196

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Revenues:				
Grant revenue	\$ 71,429	—	\$ 142,429	—
Operating expenses:				
Research and development	4,090,590	\$ 4,084,521	11,207,446	\$ 7,246,247
General and administrative	2,026,865	1,071,426	4,015,225	3,238,893
Total operating expenses	6,117,455	5,155,947	15,222,671	10,485,140
Loss from operations	(6,046,026)	(5,155,947)	(15,080,242)	(10,485,140)
Other income	632	—	632	30,649
Other expense	(11,146)	—	(19,069)	—
Interest expense	—	(297,935)	—	(505,037)
Interest income	43,842	3,244	86,054	3,244
Net loss from operations	(6,012,698)	(5,450,638)	(15,012,625)	(10,956,284)
Net loss attributable to common stockholders	\$ (6,012,698)	\$ (5,450,638)	\$ (15,012,625)	\$ (10,956,284)
Net loss attributable to common stockholders per common share:				
Basic and Diluted	\$ (0.47)	\$ (0.55)	\$ (1.16)	\$ (1.37)
Weighted-average shares outstanding: Basic and Diluted	12,921,898	9,837,062	12,907,931	8,014,529

CONTACT: Investor Relations

Stemline Therapeutics, Inc.

750 Lexington Avenue

Eleventh Floor

New York, NY 10022

Tel: 646-502-2307

Email: investorrelations@stemline.com

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