

# SECURITIES AND EXCHANGE COMMISSION

## FORM FWP

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### SUBJECT COMPANY

#### STEMLINE THERAPEUTICS INC

CIK: [1264587](#) | IRS No.: **450522567** | State of Incorporation: **DE** | Fiscal Year End: **1231**  
Type: **FWP** | Act: **34** | File No.: **333-180515** | Film No.: **13521359**  
SIC: **2834** Pharmaceutical preparations

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**Issuer Free Writing Prospectus**

**Dated January 9, 2013**

**Filed Pursuant to Rule 433**

**Registration No. 333-180515**

**Stemline Therapeutics, Inc.**

**Free Writing Prospectus**

**We have filed a registration statement (including a prospectus) with the Securities and Exchange Commission (“SEC”) for the offering to which this communication relates. The registration statement has not yet become effective. Before you invest, you should read the prospectus in that registration statement (including the risk factors described therein) and other documents we have filed with the SEC for more complete information about us and the offering. You may get these documents for free by visiting EDGAR on the SEC Web site at [www.sec.gov](http://www.sec.gov).**

**The preliminary prospectus, dated January 8, 2013, is available on the SEC Web site at:  
<http://www.sec.gov/Archives/edgar/data/1264587/000104746913000116/a2210473zs-1a.htm>**

**Alternatively, we or any underwriter participating in the offering will arrange to send you the prospectus if you contact Aegis Capital Corp., Prospectus Department, 810 Seventh Avenue, 11th Floor, New York, NY 10019, telephone: 212-813-1010, e-mail: [prospectus@aegiscap.com](mailto:prospectus@aegiscap.com); Feltl and Company, Inc., Prospectus Department, 800 LaSalle Avenue, Suite 2100, Minneapolis, MN 55402, telephone: 612-492-8800, e-mail: [prospectus@feltrl.com](mailto:prospectus@feltrl.com); or Sunrise Securities Corp., 600 Lexington Avenue, 23rd Floor, New York, NY 10022, telephone: 212-421-1616, email: [prospectus@sunrisecorp.com](mailto:prospectus@sunrisecorp.com).**

On November 8, 2012, we issued the following press release.



**Stemline Therapeutics, Inc.**

**Press Release**

**Stemline Therapeutics’ Lead Clinical Candidate SL-401 Induces a Complete Response in a Patient with a Drug-Refractory Plasmacytoid Dendritic Cell Neoplasm**

NEW YORK, Nov. 8, 2012 /PRNewswire/ – Stemline Therapeutics, Inc., a clinical-stage biopharmaceutical company developing oncology therapeutics that target both cancer stem cells (CSCs) and tumor bulk, announced today that a heavily pre-treated patient with a drug-refractory and recurrent blastic plasmacytoid dendritic cell neoplasm (BPDCN) achieved a complete response (CR) following treatment with Stemline’s SL-401. BPDCN is a rare and aggressive hematologic cancer which is generally unresponsive to standard treatment regimens. SL-401 is Stemline’s lead therapeutic being developed to treat acute myeloid leukemia (AML) and other hematologic cancers.

The patient, a 40-year-old male, developed progressive BPDCN with malignant cells in his blood and bone marrow, which resulted in low blood cell counts despite receiving several intensive high-dose chemotherapy regimens, including bone marrow transplantation. After developing progressively worsening BPDCN following failure of multiple standard drug regimens, his physicians referred him to the MD Anderson Cancer Center in Houston, Texas and the Texas A&M Health Science Center College of Medicine at Scott and White Cancer Research Institute in Temple, Texas, to receive treatment with Stemline’s SL-401 in a Phase 1/2 clinical trial. The patient was

treated with five daily doses of SL-401, a targeted therapy directed specifically to cells that overexpress the interleukin-3 receptor (IL-3R) on their cell surface. BPDCN is known to overexpress IL-3R. SL-401 has previously been shown to possess potent anti-BPDCN activity in preclinical models. Thirty days after SL-401 treatment, the patient achieved a CR, with no evidence of malignant BPDCN cells in his bone marrow or bloodstream and his blood cell counts; in particular, his absolute neutrophil and platelet counts returned to normal levels. Furthermore, he did not

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experience any serious side effects from SL-401 treatment. “It is always very gratifying to observe a CR and negligible side effects following use of a new agent in patients with cancers, in which approved treatments are of little to no value,” said Dr. Eric Rowinsky, Chief Medical Officer and Head of Research and Development at Stemline Therapeutics. “Since we believe the explanation for this prominent clinical response and lack of side effects is SL-401’s specific targeting of IL-3R, which is overexpressed on BPDCN and other hematologic malignancies, Stemline will continue to evaluate and potentially register SL-401 in BPDCN.”

BPDCN is a relatively uncommon hematologic cancer of plasmacytoid dendritic cells, which are specialized immune cells that circulate throughout the bloodstream, bone marrow, and many other organs. In BPDCN, the cancer cells typically reside and grow in the skin and bone marrow. Their growth in the bone marrow results in decreased blood cell counts, thereby causing serious infections, bleeding, and invariably death. Although BPDCN can be controlled for brief periods with standard chemotherapy that is used to treat other hematologic cancers, meaningful clinical responses are rare and such treatment often produces serious side effects. There are no therapies approved to treat BPDCN. BPDCN cells express high levels of IL-3R on their cell surface, which served as the rationale for treating the patient with SL-401, which specifically targets the IL-3R. SL-401 has also demonstrated clinical activity in other hematologic malignancies that overexpress IL-3R, including AML and myelodysplastic syndrome (MDS). Other malignancies in which high levels of the IL-3R are expressed include Hodgkin’s and non-Hodgkin’s lymphoma, chronic myeloid leukemia (CML), and multiple myeloma. Preclinical studies of SL-401 in these cancers have demonstrated favorable anticancer activity. SL-401 is currently being advanced into a registration-directed Phase 2b study in advanced stage AML.

### **About Stemline Therapeutics, Inc.**

Stemline Therapeutics, Inc. is a clinical stage biopharmaceutical company developing novel oncology therapeutics that target both cancer stem cells (CSCs) as well as the tumor bulk. Among Stemline’s drug candidates are SL-401 and SL-701, both of which have demonstrated single agent clinical activity in Phase 1/2 studies of advanced cancer patients. In a multicenter Phase 1/2 trial in patients with advanced acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS), SL-401 demonstrated single agent activity, including durable complete responses (CRs), and an overall survival (OS) improvement relative to historical data in the most heavily pretreated AML patients. In addition, SL-401 was well-tolerated and was not toxic to the bone marrow. SL-401 is being advanced into later stage trials in advanced AML. In Phase 1/2 trials, Stemline’s second clinical stage therapeutic, SL-701, has demonstrated single agent activity including durable CRs and partial responses (PRs) in adult patients with refractory or recurrent glioblastoma and pediatric patients with malignant glioma, as well as an OS benefit in adult patients with refractory or recurrent glioblastoma compared with historical data. SL-701 is now poised for later stage trials in pediatric and adult patients with advanced brain cancer. Stemline is also developing a broad portfolio of preclinical small molecules and antibodies for a variety of solid and hematological cancer types. Many of these compounds have derived from the Company’s proprietary discovery platform, StemScreen®. For more information, please visit the Company’s website at [www.stemline.com](http://www.stemline.com).

### **Stemline Contact:**

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