# FORM FWP

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## SUBJECT COMPANY

**STEMLINE THERAPEUTICS INC**

CIK:**1264587**| IRS No.: **450522567** | State of Incorp.:**DE** | Fiscal Year End: **1231**
Type: **FWP** | Act: **34** | File No.: **333-180515** | Film No.: **13521361**
SIC: **2834** Pharmaceutical preparations

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## FILED BY

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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.**

**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; Feltl and Company, Inc., Prospectus Department, 800 LaSalle Avenue, Suite 2100, Minneapolis, MN 55402, telephone: 612-492-8800, e-mail: prospectus@feltl.com; or Sunrise Securities Corp., 600 Lexington Avenue, 23rd Floor, New York, NY 10022, telephone: 212-421-1616, email: prospectus@sunrisecorp.com.**

On January 7, 2013, we issued the following press release.

**Stemline Therapeutics, Inc.**

**Press Release**

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

NEW YORK, Monday, January 7, 2013 /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 second heavily pre-treated patient with a drug-refractory and recurrent blastic plasmacytoid dendritic cell neoplasm (BPDCN) achieved a complete response (CR) following treatment with a single cycle of Stemline' s lead therapeutic, SL-401. BPDCN is a highly aggressive hematologic cancer that is not effectively treated with available cancer therapies. SL-401 is being developed to treat BPDCN, acute myeloid leukemia (AML) and other hematologic cancers. To date, two of three patients with drug-refractory BPDCN experienced CRs following treatment with SL-401.

The most recent complete responder, a 72-year-old male, had a history of recurrent and progressive BPDCN with malignant disease involving his skin and bone marrow, resulting in multiple skin lesions and low blood counts. He had previously been treated with three intensive regimens of chemotherapy, including bone marrow transplantation. After the progressive worsening of his cancer following the failure of his third intensive chemotherapy regimen, the patient was treated with SL-401 at the Texas A&M Health Science Center

College of Medicine at Scott and White Cancer Research Institute in Temple, Texas. Approximately 30 days after SL-401 treatment, this patient achieved a CR, with no evidence of BPDCN in the skin, bone marrow, or bloodstream. In addition, this patient' s blood cell counts returned to normal levels and no serious side effects were observed.

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"These complete responses are meaningful, unprecedented, and consistent with the mechanism of SL-401, a targeted therapy directed to the interleukin-3 receptor, or IL-3R. IL-3R is overexpressed on BPDCN, AML, myelodysplastic syndrome, lymphoma, myeloma, and many other hematologic malignancies," said Dr. Eric Rowinsky, Chief Medical Officer and Head of Research and Development at Stemline Therapeutics. "Based on these additional positive data, we are planning to initiate a pivotal Phase 2b trial in BPDCN, an unmet medical need, in parallel with advancing SL-401 into a registration-directed trial in advanced AML."

BPDCN is an uncommon and highly aggressive hematologic cancer. 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 treatment with SL-401, a targeted therapy directed to IL-3R. Moreover, SL-401 has demonstrated potent anti-BPDCN activity in preclinical models, and has now shown clinical activity, in the form of two complete responses, in patients with heavily pre-treated BPDCN.

**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 hematologic cancer, SL-401 demonstrated single agent activity in multiple indications, including durable complete responses (CRs) in relapsed or refractory acute myeloid leukemia (AML) and blastic plasmacytoid dendritic cell neoplasm (BPDCN), and an overall survival (OS) improvement relative to historical data in the most heavily pre-treated patients. In addition, SL-401 was well-tolerated and was not toxic to the bone marrow. SL-401 is being advanced into a pivotal Phase 2b trial in patients with BPDCN and a registration-directed Phase 2b study in patients with 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.

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