

# STEMLINE THERAPEUTICS, INC. (NASDAQ: STML)

Updated SL-401 BPDCN Clinical Data Presented at ASH; Second BPDCN Retreated with SL-401 Showing Drug was Well Tolerated with No Significant Side Effects. Reiterate Our BUY Rating and \$44 Price Target.

## Investment Rating

**BUY**

Price Target \$44.00

Price (December 11, 2013) \$19.26  
52 Week Range \$10.33 - \$47.25  
Shares Outstanding 12.5 MM  
Market Capitalization \$240 MM  
Cash (September 30, 2013) \$88 MM

## Fiscal Year End

December

## Revenue (MM's):

	<u>Current</u>	<u>Prior</u>
2014E	\$0.0	
2013E	\$0.0	
2012A	\$0.0	

## EPS GAAP:

	<u>Current</u>	<u>Prior</u>
2014E	(\$2.32)	
2013E	(\$2.27)	
2012A	(\$1.82)	

## Quarterly EPS GAAP:

	<u>Current</u>	<u>Prior</u>
2014E		
Mar	(\$0.55)	
Jun	(\$0.56)	
Sep	(\$0.59)	
Dec	(\$0.62)	
2013E		
Mar (A)	(\$0.90)	
Jun (A)	(\$0.55)	
Sep (A)	(\$0.45)	
Dec	(\$0.54)	

## Highlights

**Updated SL-401 BPDCN early clinical trial data presented at ASH demonstrating SL-401 continues to show clear activity in the treatment of BPDCN.** Two additional BPDCN patients have been treated with one achieving a CR and the second was a non-responder (currently 8 BPDCN patients have been treated (7 are evaluable for response)). SL-401 with just a single cycle of therapy has shown a solid signal of tumor shrinkage now in 6 out of 7 evaluable patients (86% ORR) with BPDCN, of which 5 (71%) of the responders were able to obtain a CR, one of which is durable for 9+ months and another for 5 months. In addition, Dr. Frankel who is the lead investigator for the study, indicated he retreated a second BPDCN patient who had achieved a CR following a relapse of their disease. Similar to the first retreated patient, the second retreated patient was also not an optimal treatment as the patient received another cycle of SL-401 after relapsing following a "drug holiday" and was not treated continuously with SL-401. Despite the non-ideal treatment the first retreated patient did show clearance of skin lesions but subsequently had progression in the bone marrow following the completion of therapy. The second retreated patient did show some symptom improvement but no objective response was achieved. Again, both retreated patients had relapsed while off therapy following one treatment cycle, a non-ideal treatment paradigm. Importantly, Dr. Frankel noted, for both patients, the re-treatment with SL-401 was safe and well tolerated with no significant side effects observed based on the retreatment. Notably, there currently is nothing approved or thought to be meaningfully efficacious for the treatment of BPDCN, and the prognosis of BPDCN is dire with a median overall survival of 12 months. Therefore, we believe FDA approval via the BPDCN indication is potentially the most direct regulatory pathway for SL-401. Moreover, the FDA has granted SL-401 Orphan Drug status for the BPDCN indication. Additionally, we are impressed with SL-401's activity observed with only a single cycle of therapy and we look forward to additional data following multiple cycles of treatment which could enhance to the ORR and further extend the durability of the effects observed.

**SL-401 and SL-701 clinical development update.** Stemline plans to initiate a pivotal Phase 2b program with SL-401 for the BPDCN indication in 1H14 (we believe the BPDCN trial should take approximately 15 to 18 months to complete with pivotal data expected by 2H15. An NDA submission in 1H16 is expected, although an earlier submission date is also plausible if data are approval-worthy prior to full accrual, given that the trial is open-label) along with a pivotal Phase 2b trial for AML in 2H14. Additionally, Stemline anticipates initiating two Phase 2b trials for SL-701 in 2014 as well, to consist of one pediatric brainstem and non-brainstem glioma trial and one adult second-line GBM trial.

**We believe STML's current value is primarily driven by SL-401.** Our STML valuation and price target are primarily generated from our forecasted sales of SL-401. We believe Stemline's current valuation offers significant upside potential, particularly if the products are efficacious in the other indications Stemline plans to pursue, beyond BPDCN and AML. Specifically, we employed a sum-of-the-parts analysis based on the cash flow generated by SL-401. Our analysis employs only the U.S. revenue generated from SL-401 in relapsed and refractory AML and BPDCN patient populations, as well as the cash position at the projected price target date. We view STML, at current prices, as an attractive investment opportunity with significant upside potential.

**We reiterate our BUY rating and \$44 price target.**

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Disclosures and Analyst Certifications can be found in Appendix A.

NEW YORK, NY      MELVILLE, NY      MIAMI, FL      BOCA RATON, FL      NAPLES, FL      HOUSTON, TX      BOSTON, MA

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**Five presentations at ASH.** The presentations at ASH included:

Sunday, December 8<sup>th</sup>

**Abstract #: 2682:** An Update on the Robust Clinical Activity of SL-401, a Targeted Therapy Directed to the Interleukin-3 Receptor on Cancer Stem Cells and Tumor Bulk, in Patients with Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN).

**Abstract #: 3170:** SL-401, A Novel Targeted Therapy Directed to the Interleukin-3 Receptor (IL-3R), Inhibits Plasmacytoid Dendritic Cell (pDC)-induced Myeloma Cell Growth and Overcomes Drug Resistance.

Monday, December 9<sup>th</sup>

**Abstract #: 359:** Leukemia Stem Cell Marker CD123 (IL-3R alpha) Predicts Minimal Residual Disease and Relapse, Providing a Valid Target for SL-101 in Acute Myeloid Leukemia with FLT3-ITD Mutations (Oral Presentation).

**Abstract #: 3942:** Preclinical Studies of SL-401, a Targeted Therapy Directed to the Interleukin-3 Receptor (IL-3R), in Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN): Potent Activity in BPDCN Cell Lines, Primary Tumor, and in an In Vivo Model.

**Abstract #: 4104:** SL-401, a Targeted Therapy Directed to the Interleukin-3 Receptor (IL-3R), Possesses Preclinical Cytotoxic Activity against Chronic Eosinophilic Leukemia.

**Stemline's lead product SL-401:** SL-401 is a targeted therapy directed to IL-3R present on tumor bulk and cancer stem cells (CSCs). SL-401 is a biologic recombinant protein comprised of human IL-3 fused to truncated diphtheria toxin (which inhibits protein synthesis). We believe SL-401 has the potential to be a best in class product for the treatment of BPDCN. The human IL-3 of SL-401 is able to target IL-3R, which is overexpressed on CSCs, which are responsible for re-population of the tumor and on leukemia blasts, which are responsible for the tumor bulk of AML, BPDCN, MDS, CML, ALL, Hodgkin's disease, multiple myeloma, and certain NHL's. Furthermore, SL-401 selectively targets cancer cells since IL-3R is only minimally expressed on non-cancer cells. Thus, we believe this explains why SL-401 is more tolerable and potentially has fewer adverse events and side effects (for example no evidence of hematologic toxicity) than the chemotherapies currently used to treat hematologic cancers.

#### **Currently planned SL-401 Phase 2b trials:**

**AML registration-directed Phase 2b trial:** A total of approximately 240 third-line AML patients are anticipated to be randomized 2:1 to either multiple cycles of SL-401 or physician's choice. Overall survival is the primary endpoint. We are anticipating this trial to be initiated in 2H14 with interim data in 2015-16. Enrollment could take approximately 1.5 years with final data expected by 2H16 (if the trial is not stopped earlier at an interim analysis), and an NDA filing in early- to mid- 2017 and potential market launch by late 2017/early 2018. Additionally, with interim analyses an earlier filing and approval is possible based on positive interim data, given the strong overall survival seen to date. We would anticipate such a trial to cost about \$25 - \$30 million in total and to fulfill both the U.S. and E.U. requirements.

**Pivotal BPDCN Phase 2b trial:** The pivotal single-arm BPDCN program, which will enroll up to approximately 40 to 50 patients in total with ORR (CR+PR) as the primary endpoint, is on track to start in 1H14. Given the orphan indication and the data from the previous 83 patient Phase 1/2 trial, we anticipate that this trial will satisfy the U.S. and E.U. requirements for marketing approval for the BPDCN indication. Due to the lack of therapeutic alternatives we anticipate a relatively rapid enrollment, which is more dependent on the incidence rate than patient choice. Thus we believe the trial should take approximately 15 to 18 months to complete with pivotal data expected by 2H15. An NDA submission in 1H16 is expected, although an earlier submission date is also plausible if data are approval-worthy prior to full accrual, given that the trial is open-label. Moreover, we believe that an accelerated FDA review is probable due to the stark unmet medical need in this patient population, which could enable approval by mid-2016, with a market launch in 2016 as well.

**Phase 2b studies planned in other IL-3R over-expressing rare tumors:** Stemline also plans to launch other SL-401 Phase 2 trials to examine the compound in other IL-3R over-expressing tumors including multiple myeloma, myelodysplastic syndrome (MDS) and certain rare disorders including hairy cell leukemia, mastocytosis, and basophilic leukemias. We expect these studies to start throughout 2014. We expect data from these open-label studies by end of 2014 and throughout 2015.

**Future development:** Future development may consist of combination trials of SL-401 with traditional chemotherapy for AML, earlier lines (i.e. second and first-line) of AML and the expansion into other indications such as MDS, multiple myeloma, CML, Hodgkin's, and NHLs. Development will also continue through independent investigator sponsored studies.

**Impressive SL-401 Phase 1/2 data already presented.** In a multi-center Phase 1/2 trial, patients with advanced hematologic malignancies were dosed with SL-401 using two different regimens to determine MTD. In regimen A, 45 patients were dosed with up to six intravenous (IV) infusions ranging from 4 to 12.5 µg/kg every other day, and in

regimen B 35 patients were dosed with up to five IV infusions ranging from 7.1 to 22.1 µg/kg daily. Of the 85 patients enrolled 59 were relapsed or refractory AML patients, 11 were de-novo AML patients unfit for chemotherapy. Additionally, there were 7 patients with high-risk myelodysplastic syndrome (MDS), and 8 patients with relapsed or refractory BPDCN. The majority of the patients treated had greater than 3 prior lines of therapy.

The primary intent of the SL-401 Phase 1/2 trial was to determine the safety and tolerability of SL-401, but the trial also gave a clear efficacy signal. Given the intent to determine the maximum tolerable dose (MTD), this trial only dosed patients with one cycle of therapy, many of whom were dosed with below the therapeutically optimal doses of SL-401. Notwithstanding this fact, SL-401 was able to achieve responses of stable disease or tumor shrinkage in 46% of patients with relapsed or refractory AML and 86% of patients with relapsed or refractory BPDCN, which included 7 CRs, 2 in AML and 5 in BPDCN. Thus, with more than one cycle of treatment (which could convert patients who did not respond to responders, patients with SD to responders, patients with PRs to CRs, and/or responders to more durable responders) we hope to see an even greater response rate and an increase in the number of CRs and durable CRs achieved. We are impressed with the activity observed in this Phase 1/2 study. The overall survival (OS) of patients with third-line or greater AML receiving therapeutically relevant doses was improved to a median OS of 5.6 months (95% CI: 2.5, 10.8 months) versus the historical median OS of 1.5 months for patients with third-line AML treated with chemotherapy. This is promising as we anticipate a third-line AML pivotal trial to utilize OS as the primary endpoint. Perhaps the most striking SL-401 efficacy data were shown in relapsed or refractory BPDCN patients, where 86% (6 out of 7 evaluable patient) of patients responded, and 5 out of the 6 responders achieved CRs (one achieved a PR). One of the BPDCN CRs occurred in a third-line patient who had malignant blasts in the bone marrow and blood at baseline, all of which resolved after a single-cycle of SL-401 and lasted for 5 months. Another BPDCN CR occurred in a 4th line patient who, after a single-cycle of SL-401, has maintained a CR for 9+ months. SL-401 has also been well tolerated, with no DLTs in the eight BPDCN patients. Although these very early data are not yet statistically robust, the results are very encouraging given that lack of efficacy and the toxicity that BPDCN patients have experienced with existing therapies in the relapsed or refractory setting.

**Table 1: Efficacy of single agent SL-401 with one cycle of therapy**

Efficacy measures	BPDCN (n=8)	AML Relapsed, refractory (n=59)	AML 3rd line (n=35)	AML Not chemo candidate (n=11)	MDS Refractory, High risk (n=7)
Tumor shrinkages/SD	86%	46%	43%	55%	43%
Tumor shrinkages	86%	25%	23%	27%	29%

Source: Company documents & Ladenburg Thalmann & Co.

**Solid cash position.** As of September 30, 2013 STML had \$87.7 million in cash. We believe STML's current cash position is sufficient to generate significant SL-401 BPDCN and AML data and to reach into early 2016.

**Table 2: STML Sum-of-the-Parts Valuation**

Per share value of assets		Weighted ave. product discount rate	35.0%
SL-401 in the US	33.06		
SL-401 in the EU	3.64		
SL-701 in the US	-		
SL-701 in the EU	-		
Other			
Value of net cash	7.20		
TP	\$ 43.90		

Source: Ladenburg Thalmann & Co. Inc. Estimates

**Valuation.** Our \$44.00 price target is based on a sum-of-the-parts (SOP) analysis employs the revenue and generated from SL-401 in the relapsed and refractory AML, BPDCN and MDS patient populations, as well as the current cash position. The SOP analysis utilizes a 35% discount rate for SL-401 revenue from the U.S. and a 35% rate from the ex-U.S. royalties. The first line patients for AML and all royalty revenue for SL-701 are left as upside potential.

Table 3: Stemline Therapeutics – Upcoming Milestones

Timing	Compound	Event	Indication
1H14	SL-401	Initiate Pivotal program in BPDCN trial	BPDCN
mid-2014	SL-401	Initiate Phase 2 trial of other IL-3R+ indications	other
mid-2014	SL-701	Initiate Phase 2b adult second-line GBM trial	GBM
2H14	SL-701	Initiate Phase 2b pediatric malignant glioma trial	GBM
2H14	SL-401	Initiate Phase 2b of AML trial	AML
mid-15	SL-401	Phase 2b data	BPDCN
2H15	SL-401	Interim Phase 2b data	AML
mid-2015	SL-701	Phase 2b data from adult second-line GBM trial	GBM
Late-2015	SL-701	Phase 2b data from pediatric malignant glioma trial	GBM

Table 4: Stemline Therapeutics Pipeline

	Preclinical	Phase I	Phase II	Pivotal	Approved
<b>SL-401:</b>					
BPDCN					
Relapsed or refractory AML					
Other IL-3R <sup>+</sup> cancers					
<b>SL-701:</b>					
Pediatric glioma					
Adult high-grade glioma					

**COMPANY SPECIFIC RISKS**

On top of normal economic and market risk factors that impact most all equities, STML is uniquely subject to risks typical for small- to mid- cap biotech companies: The products the Company is developing may not work, may prove to be unsafe, may never win approval and may never generate meaningful revenues. Changing medical practices, a changing reimbursement environment and/or products introduced by others could shrink the market for the Company's products. The Company may not be able to enforce its own patents or may find itself infringing on patents held by others.

Risks include but are not limited to:

**If STML does not receive regulatory approvals to market SL-401 and/or SL-701 in a timely manner, or at all, their business will be materially harmed and their stock price may be adversely affected.**

**Even if STML obtains regulatory approval to market SL-401 and/or SL-701, if it fails to achieve market acceptance, STML may never record meaningful revenues.**

**If STML's competitors develop and market products that are less expensive, more effective or safer than SL-401 and/or SL-701, or SL-401 and/or SL-701 does not achieve market acceptance versus existing treatments, STML commercial opportunities may be reduced or eliminated.**

**STML relies on third parties to manufacture and analytically test SL-401 and SL-701. If these third parties do not successfully manufacture and test SL-401 and SL-701, their business will be harmed.**

The status of reimbursement from third-party payors for newly approved health care drugs is uncertain and failure to obtain adequate reimbursement could limit their ability to generate revenue.

Health care reform measures could adversely affect their business.

The intellectual property that STML owns or has licensed relating to their drug candidates, SL-401 and SL-701, is limited, which could adversely affect their ability to compete in the market and adversely affect the value of SL-401 and/or SL-701.

Future sales or other issuances of STML common stock could depress the market for their stock.

## GENERAL RISKS

In addition, equity markets in general, and the market for biotechnology and life sciences companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies traded in those markets. These broad market and industry factors may materially affect the market price of our common stock, regardless of the company's development and operating performance. Factors influencing a company's stock price include:

Developments concerning a company's drug candidate(s), including the safety and efficacy results from clinical trials and regulatory filings and approvals;

Announcements of technological innovations by them or their competitors including new products;

Developments relating to their intellectual property and those of their competitors, including but not limited to, the commercialization of generic products;

Expectations regarding their financial condition including actual or anticipated operating results;

Expiration or termination of licenses, research contracts or other collaboration agreements.

Table 5: STML– Quarterly Financial Model

### STEMLINE THERAPEUTICS Income Statement (December Fiscal Year; All amounts in '000s except per share items)

	2011A	2012A	1Q13A	2Q13A	3Q13A	4Q13E	2013E	1Q14E	2Q14E	3Q14E	4Q14E	2014E	2015E
<b>Sales/Royalties:</b>													
SL-401 Revenue & Royalties	-	-	-	-	-	-	-	-	-	-	-	-	-
SL-701 Royalties	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Total product revenue and royalties</b>	-	-	-	-	-	-	-	-	-	-	-	-	-
COGS	-	-	-	-	-	-	-	-	-	-	-	-	-
R&D	1,629	3,377	3,162	4,085	3,324	5,650	16,220	5,763	5,936	6,292	6,670	24,661	30,165
G&A	1,088	3,091	2,167	1,071	2,254	1,352	6,845	1,420	1,505	1,610	1,739	6,274	7,871
<b>Total operating expenses</b>	<b>2,717</b>	<b>6,468</b>	<b>5,329</b>	<b>5,156</b>	<b>5,577</b>	<b>7,002</b>	<b>23,065</b>	<b>7,183</b>	<b>7,441</b>	<b>7,903</b>	<b>8,409</b>	<b>30,936</b>	<b>38,036</b>
<b>Operating income (EBIT)</b>	<b>(2,717)</b>	<b>(6,468)</b>	<b>(5,329)</b>	<b>(5,156)</b>	<b>(5,577)</b>	<b>(7,002)</b>	<b>(23,065)</b>	<b>(7,183)</b>	<b>(7,441)</b>	<b>(7,903)</b>	<b>(8,409)</b>	<b>(30,936)</b>	<b>(38,036)</b>
<b>Other expenses</b>													
Other income	47	302	31	-	-	-	31	-	-	-	-	-	-
Other expense	(10)	(0)	(125)	-	-	-	(125)	-	-	-	-	-	-
Interest expense	(99)	(119)	(82)	(298)	-	-	(380)	-	-	-	-	-	-
Interest income	24	10	-	3	4	203	210	187	232	212	192	823	1,030
Total other income (expense), net	(38)	193	(176)	(295)	4	203	(262)	187	232	212	192	822	1,030
<b>Pretax income</b>	<b>(2,755)</b>	<b>(6,275)</b>	<b>(5,506)</b>	<b>(5,451)</b>	<b>(5,574)</b>	<b>(6,799)</b>	<b>(23,327)</b>	<b>(6,996)</b>	<b>(7,209)</b>	<b>(7,690)</b>	<b>(8,217)</b>	<b>(30,113)</b>	<b>(37,005)</b>
Benefit or (Provision for) income taxes	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Net income</b>	<b>(2,755)</b>	<b>(6,275)</b>	<b>(5,506)</b>	<b>(5,451)</b>	<b>(5,574)</b>	<b>(6,799)</b>	<b>(23,327)</b>	<b>(6,996)</b>	<b>(7,209)</b>	<b>(7,690)</b>	<b>(8,217)</b>	<b>(30,113)</b>	<b>(37,005)</b>
<b>EPS basic</b>	\$ (0.80)	\$ (1.82)	\$ (0.90)	\$ (0.55)	\$ (0.45)	\$ (0.54)	\$ (2.27)	\$ (0.55)	\$ (0.56)	\$ (0.59)	\$ (0.62)	\$ (2.32)	\$ (2.20)
<b>EPS diluted, GAAP</b>	\$ (0.80)	\$ (1.82)	\$ (0.90)	\$ (0.55)	\$ (0.45)	\$ (0.54)	\$ (2.27)	\$ (0.55)	\$ (0.56)	\$ (0.59)	\$ (0.62)	\$ (2.32)	\$ (2.20)
Basic shares outstanding	3,442	3,442	6,148	9,837	12,471	12,696	10,288	12,811	12,926	13,042	13,160	12,985	16,837
Diluted shares outstanding	3,442	3,442	6,148	9,837	12,471	12,696	10,288	12,811	12,926	13,042	13,160	12,985	16,837

Source: Company documents and Ladenburg Thalmann & Co. estimates



## APPENDIX A: IMPORTANT RESEARCH DISCLOSURES

### ANALYST CERTIFICATION

I, Matt Kaplan, attest that the views expressed in this research report accurately reflect my personal views about the subject security and issuer. Furthermore, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report, provided, however, that:

The research analyst primarily responsible for the preparation of this research report has or will receive compensation based upon various factors, including the volume of trading at the firm in the subject security, as well as the firm's total revenues, a portion of which is generated by investment banking activities.

Additional information regarding the contents of this publication will be furnished upon request. Please contact Ladenburg Thalmann, Compliance Department, 570 Lexington Avenue, 11<sup>th</sup> floor, New York, New York 10022 (or call 212-409-2000) for any information regarding current disclosures, and where applicable, relevant price charts, in regard to companies that are the subject of this research report.

### COMPANY BACKGROUND

Stemline Therapeutics is a biopharmaceutical company focused on the acquisition and development of oncology products that target cancer stem cells. STML's comparative advantage is to identify quality assets to develop. Lead product candidates are SL-401 and SL-701. SL-401 is indicated for AML, BPDCN and possibly other cancers that overexpress IL-3R. SL-701 is indicated for GBM, and is in line with the company's focus to target cancer stem cells. Stemline's management is a significant shareholder and strongly incentivized to achieve share price growth. Stemline operations are headquartered in New York, NY.

### VALUATION METHODOLOGY

Our \$44.00 price target is based on a sum-of-the-parts (SOP) analysis employs the revenue and generated from SL-401 in the relapsed and refractory AML, BPDCN and MDS patient populations, as well as the current cash position. The SOP analysis utilizes a 35% discount rate for SL-401 revenue from the U.S. and a 35% rate from the ex-U.S. royalties.

### RISKS

**Revenue.** There is no assurance that Stemline will be able to execute its development strategy, and generate the forecasted revenues. Moreover, there is no assurance that competitive products will not out compete Stemline's products, or that products not yet in existence or in the public space will be developed that may be superior to Stemline's products. Stemline is a development-stage biopharmaceutical company, and does not have any commercial products that generate revenues or any other sources of revenue. Stemline may never be able to successfully develop marketable products. Stemline's pharmaceutical development methods are unproven and may not lead to commercially viable products for any of several reasons. Stemline currently has no marketing and sales organization and no experience in marketing pharmaceutical products. If Stemline is unable to establish sales and marketing capabilities or fails to enter into agreements with third parties to market and sell any products it may develop, Stemline may not be able to effectively market and sell its products and generate product revenue. Stemline also faces product reimbursement risk. Thus, there is risk that our revenue forecasts are not met. Stemline has incurred net operating losses since its inception and we anticipate that they will continue to incur substantial operating losses for the foreseeable future. Stemline may never achieve or sustain profitability, which would depress the market price of its common stock, and could cause an investor to lose all or a part of their investment.

**Commercial Partnerships.** There is no assurance Stemline will be able to find a partner for products in its existing portfolio or if they are able to find a partner that the financial terms will be attractive to Stemline. Stemline focuses on in-licensing and developing products as its business strategy, and plans to continue to in-license products. There is no assurance that competitors will not be able to more effectively gain access to additional attractive product opportunities than Stemline. Stemline could face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully, than Stemline.

**Regulatory.** There can be no assurance that the FDA or other regulatory boards approve Stemline's current or future products. The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if Stemline is ultimately unable to obtain regulatory approval for its product candidates, Stemline's business will be substantially harmed. Furthermore if Stemline initiates a clinical trial with SL-401 or other future product there can be no assurance these studies will be completed in a timely manner, that results will support the intended regulatory or commercial purpose or that results will favorably impact either regulatory reviews or adoption by clinicians. Delays in the commencement of clinical trials and delays in the receipt of data from preclinical or clinical trials conducted by third parties could significantly impact Stemline's product development costs. Results of earlier clinical trials may not be predictive of the results of later-stage clinical trials. Third parties have conducted all clinical trials of SL-401 and SL-701 so far, and Stemline's ability to influence the design and conduct of such trials has been limited. Stemline plans to assume control over the future clinical and regulatory development of such product candidates will entail additional expenses and require Stemline to rely on additional third parties. Any failure by a third party to meet its obligations with respect to the clinical and regulatory development of Stemline's product candidates may delay or impair their ability to obtain regulatory approval for their products.

**Financing.** The company's current financial resources should fund the company to 2H15. However, the commercial development of the company's products will require substantial direct funding from Stemline. There can be no assurance that revenue will materialize or adequately fund the company. Additionally, should Stemline require additional financial resources, there is no guarantee the company will have access to capital in the future on adequate terms, or at all.

**Manufacturing.** Stemline relies completely on third parties to manufacture preclinical and clinical pharmaceutical supplies and intends to rely on third parties to produce commercial supplies of any approved product candidate, and Stemline's commercialization of any of its product candidates could be stopped, delayed or made less profitable if those third parties fail to obtain approval of the FDA, fail to provide Stemline with sufficient quantities of pharmaceutical product or fail to do so at acceptable quality levels or prices. Any quality control, manufacturing or stability concerns could negatively impact revenues.

**Intellectual Property.** Stemline's ability to generate revenue is dependent on market exclusivity of its products, such as SL-401 and SL-701. There is no guarantee that Stemline will be able to successfully defend its patents. Should Stemline's patents fail to provide market exclusivity, and should orphan drug designation also fail to provide market exclusivity, there is no assurance that the company will be able to generate revenue sufficient enough to fund operations. Changes in U.S. patent law could diminish the value of patents in general, thereby impairing Stemline's ability to protect their products.

For a full review of Stemline specific risk factors investors should refer to the Company's most recent forms 10K and 10Q on file with the SEC.

## STOCK RATING DEFINITIONS

**Buy:** The stock's return is expected to exceed 12.5% over the next twelve months.

**Neutral:** The stock's return is expected to be plus or minus 12.5% over the next twelve months.

**Sell:** The stock's return is expected to be negative 12.5% or more over the next twelve months.

Investment Ratings are determined by the ranges described above at the time of initiation of coverage, a change in risk, or a change in target price. At other times, the expected returns may fall outside of these ranges because of price movement and/or volatility. Such interim deviations from specified ranges will be permitted but will become subject to review.

## RATINGS DISPERSION AND BANKING RELATIONSHIPS (AS OF 11/30/13)

**Buy:** 76% (49% are banking clients)

**Neutral:** 24% ( 8% are banking clients)

**Sell:** 0% ( 0% are banking clients)

**BIOTECHNOLOGY & HEALTHCARE SECTOR STOCKS UNDER AUTHOR ANALYST COVERAGE ("The Universe")**

Antares Pharma (ATRS)  
 Aradigm (ARDM)  
 Bidel, Inc. (BIOD)  
 BioDelivery Sciences International (BDSI)  
 Cornerstone Therapeutics (CRTX)  
 Dara Biosciences, Inc. (DARA)  
 Flamel Technologies S.A. (FLML)  
 Furiex Pharmaceuticals, Inc. (FURX)  
 IsoRay (ISR)  
 Keryx Biopharmaceuticals (KERX)  
 MediciNova (MNOV)  
 Prolor Biotech (PBTH)  
 Repros Therapeutics (RPRX)  
 Stemline Therapeutics (STML)  
 TG Biosciences Inc. (TGTX)  
 United Therapeutics (UTHR)  
 XOMA Corp. (XOMA)

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**INVESTMENT RATING AND PRICE TARGET HISTORY**



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