ROTH Capital Partners

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Healthcare: Biotechnology

Stemline Therapeutics, Inc. | STML - $29.30 - NASDAQ | *Buy*

Company Update

Stock Data	
52-Week Low - High	$10.00 - $47.25
Shares Out. (mil)	12.54
Mkt. Cap.(mil)	$367.4
3-Mo. Avg. Vol.	190,377
12-Mo.Price Target	$50.00
Cash (mil)	$90.0
Tot. Debt (mil)	$0.6

Cash (mil): Proforma cash includes May 2013 $60 million equity raise

EPS $

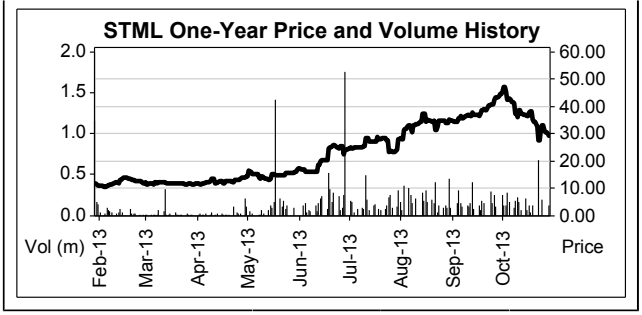
Yr Dec	—2012—	—2013E—	—2014E—
		Curr	Curr
1Q	-	(0.90)A	(0.53)E
2Q	-	(0.47)E	(0.55)E
3Q	-	(0.49)E	(0.56)E
4Q	-	(0.54)E	(0.58)E
YEAR	(1.82)A	(1.96)E	(2.22)E
P/E	NM	NM	NM

January 2013 IPO

Quarterly EPS may not add to full year due to increases in share count and rounding

Revenue ($ millions)

Yr Dec	—2012—	—2013E—	—2014E—
		Curr	Curr
1Q	-	0.0A	0.0E
2Q	-	0.0E	0.0E
3Q	-	0.0E	0.0E
4Q	-	0.0E	0.0E
YEAR	0.0A	0.0E	0.0E



STML: Pressing the Accelerator for SL-401; LLS On Board; Reiterate Buy

Lead product, SL-401, gets an important nod with a new collaboration with LLS. LLS will provide >$3 million to support both clinical studies and increasing physician awareness for orphan indication, BPDCN. The drug is poised to enter pivotal studies in 2014 for BPDCN and AML. STML shares are off their recent highs and we believe are at a compelling valuation. Reiterate Buy and $50 target.

Event

Stemline announced a collaboration with The Leukemia & Lymphoma Society (LLS) to provide additional funding and physician education efforts for lead product, SL-401. LLS will provide >$3 million to support both clinical studies as well as a concerted effort to increase physician awareness of the orphan indication, BPDCN. In 2014, SL-401 is expected to enter pivotal studies for both BPDCN and AML patients.

Impact

LLS joining the SL-401 effort is a positive increment and important validation, in our belief, as to the drug's potential. Clinical data to date (discussed below) indicate to us that SL-401 has yielded significant activity in advanced hematological cancers. The company will be looking to move quickly into two pivotal studies in 2014 based on 1) the unmet medical need and 2) high expression of the drug's IL-3R target. The two studies will be in blastic plasmacytoid dendritic cell neoplasm (BPDCN) for which there is currently no standard of care and 3rd line AML, again for which there is no standard of care. Our enthusiasm for the SL-401 program comes from the recent clinical update at ASCO 2013 from a Phase I/II study. The company's second product, SL-701 is a cancer vaccine designed to go after glioblastoma in both children and adults. Clinical data to date are quite encouraging to us and the company is also moving forward relatively quickly in additional Phase II studies. We believe the company's strong cash balance will allow them to move past critical data inflection points over the next couple of years and the attractiveness of any potential business development activity will likely increase.

Action

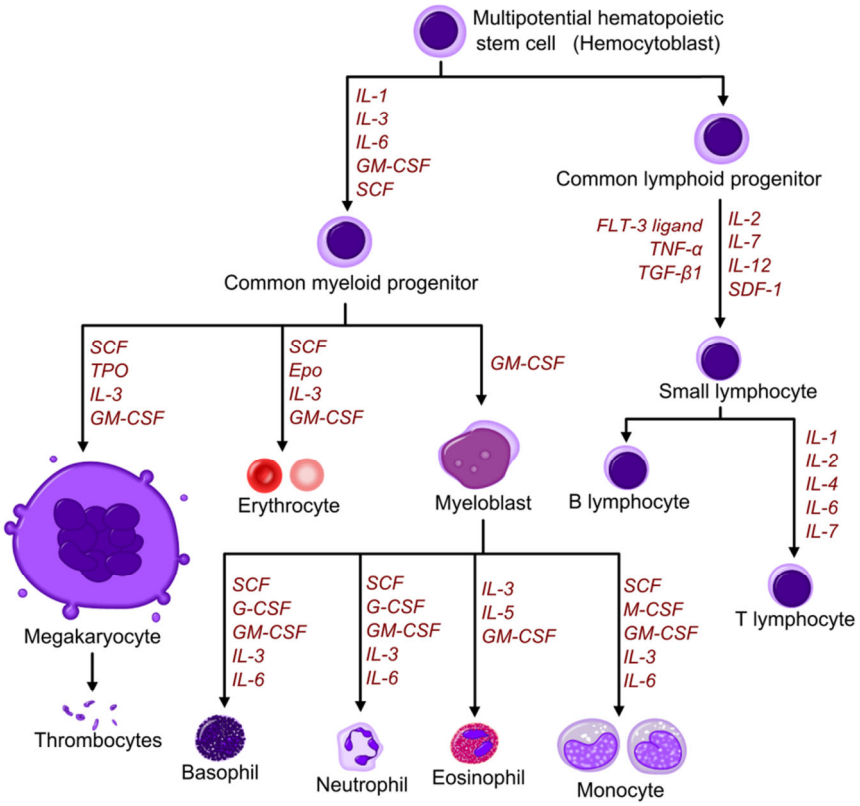
We reiterate our Buy rating and a $50 price target on STML shares. We believe that Stemline is poised for significant growth as it looks to begin pivotal studies with SL-401 as well as the potential of having a leading cancer immunotherapy product in SL-701.

SL-401 – Dual Targeting of Both Cancer Stem Cells and Tumor Bulk with a Single Agent

What is it?
SL-401 is the most advanced product in Stemline's pipeline. It is a targeted therapy directed to the interleukin-3 receptor (IL-3R). It is comprised of a recombinant human interleukin-3 (IL-3) coupled to a truncated diphtheria toxin payload. The recombinant protein is made in *E. coli*. SL-401 has received Orphan Drug Product designation for acute myeloid leukemia (AML) and blastic plasmacytoid dendritic cell neoplasm (BPDCN) in the United States.

Interleukin-3 signaling – "normal circumstances"
Interleukins are a class of soluble cell signaling molecules called cytokines that bind to cell surface receptors. Interleukin-3 (IL-3) belongs to a family of cytokines that involved in blood cell production (hematapoiesis) by regulating differentiation, migration, and proliferation of blood lineage precursor cells.

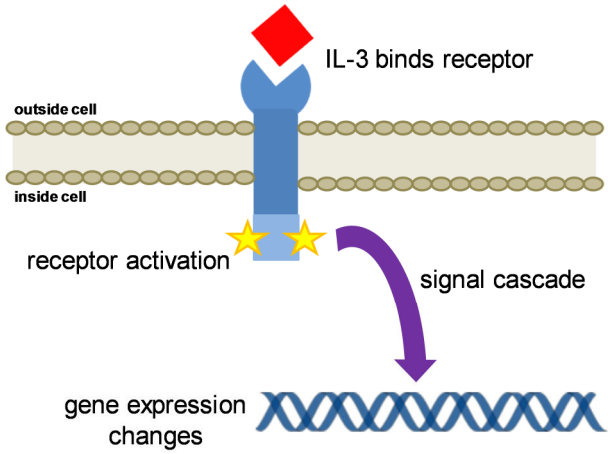
Interleukin-3 and other signaling molecules in blood cell production



Source: University of Minnesota Duluth, Dr. Janet Fitzakerley wesite May 2013

IL-3 acts by binding to interleukin-3 receptor (IL-3R), which is found normally on the surface of certain hematopoietic cells including dendritic cells, basophils, mast cells and certain maturing cells of the B cell and myeloid lineage. IL-3R is relatively rarely expressed on the bone marrow as a whole. Moreover, IL-3R is not expressed on normal hematopoietic stem cells. Notably, knock-out mice with the IL-3R gene deleted develop normal hematopoietic systems indicating that the gene product may not be essential. The IL-3 receptor is composed of a two subunits: the α subunit, which is highly specific for the cytokine, and a βc subunit which increases the affinity of the cytokine-receptor binding.

Intereukin-3 receptor activation causes gene expression change that drive growth and proliferation under normal circumstances

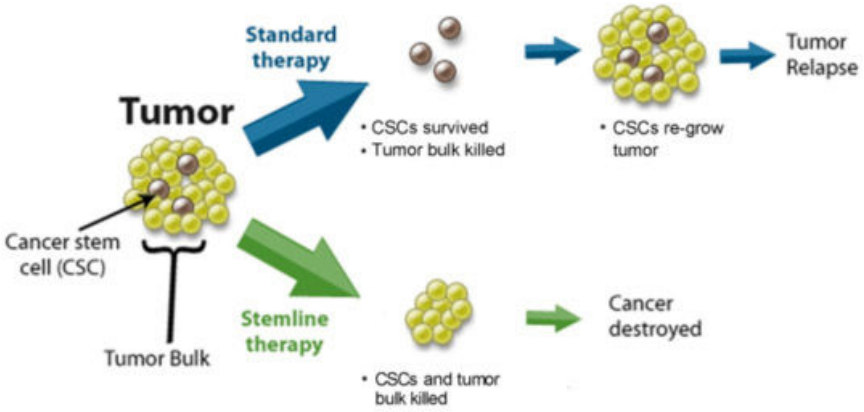


Source: ROTH Capital Partners

Interleukin-3 Receptor; The "mailbox for the SL-401 delivery"

IL-3 receptor (IL-3R) is known to be strongly upregulated in various hematologic malignancies. IL-3R upregulation is seen in most heme cancers, including acute myeloid leukemia (AML), blastic plasmacytoid dendritic cell neoplasm (BPDCN), multiple myeloma, chronic myeloid leukemia (CML), high-risk myelodysplastic syndrome (MDS), and Hodgkin's and certain Non-Hodgkin's lymphomas. IL-3R overexpresion is also seen on AML CSCs versus normal hematopoietic stem cells. Furthermore, IL-3R upregulation is seen on both tumor bulk cells and on CSCs (discussed below).

The first advantage of IL-3R targeted therapy is that IL-3R is expressed more frequently and at higher levels on malignant cells than on normal bone marrow cells or normal hematopoietic stem cells.



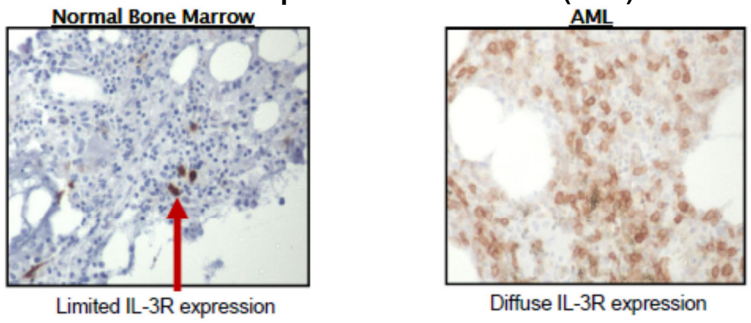
Source: Stemline company presentation June 2013

The second advantage of IL-3R directed therapies, is dual targeting of both cancer stem cells and tumor bulk with a single agent. Traditional chemotherapeutics and radiation target rapidly growing tumor bulk cells, but are ineffective against slow growing cancer stem cells. Cancer stem cells have the ability to seed new tumors, and their persistence leaves patients vulnerable to tumor recurrence, a major problem with current AML therapies. Dual targeting can be expected to increase survival rates by destroying cancer stem cells that are associated with recurrence.

The IL-3R Target of SL-401; "Special Delivery"

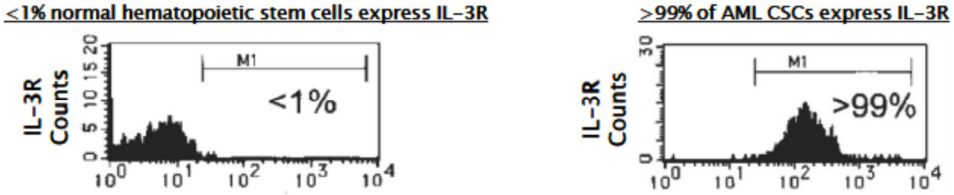
One of the key differentiating factors of targeting IL-3R is that this target is expressed on both bulk tumor cells as well as the smaller CSC population. The first figure below showed histological staining for the IL-3R target. The top left panel contains normal bone marrow cells with very little expression of the target (red arrow pointing to few brown-staining cells) versus high expression of IL-3R on the bone marrow of an AML patient (top right panel, diffuse brown-staining), which we also believe talks to the potentially more benign safety profile compared to other leukemia drugs. The lower panels contain data from flow cytometry studies comparing normal hematopoetic stem cells expressing only <1% of IL-3R whereas AML CSCs contain >99% of IL-3R expressing cells. In short, having a target expressed on both tumor cell populations makes it an attractive target.

IL-3R Overexpression in AML cells (bulk)



Source: Stemline company presentation June 2013

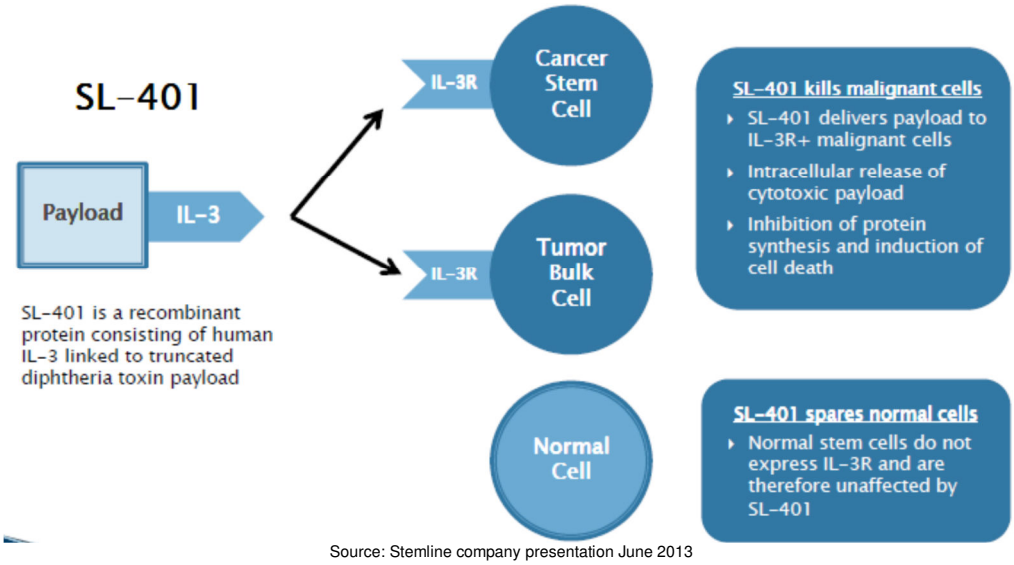
IL-3R Overexpression in AML Cancer Stem Cells



Source: Stemline company presentation June 2013

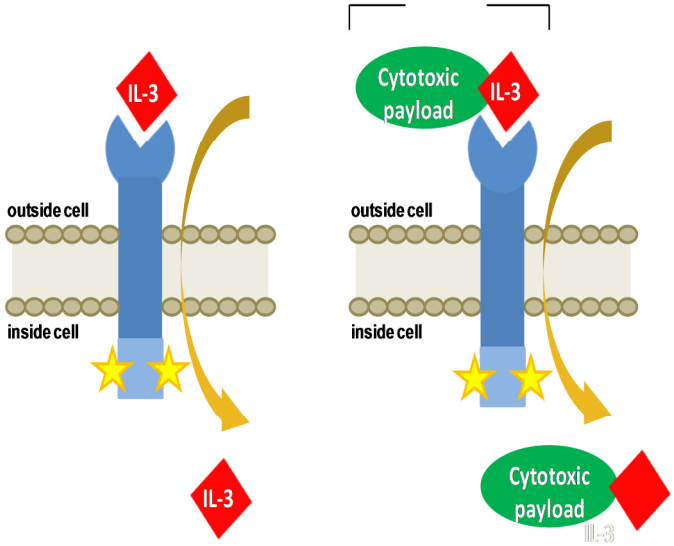
With the data above in mind, the figure below highlights the overall mechanism of action for SL-401.

SL-401 Mechanism of Action



Source: Stemline company presentation June 2013

Stemline's SL-401 product is a targeted therapy directed to IL-3R. SL-401 is comprised of recombinant IL-3 fused to a diphtheria toxin payload that is truncated such that IL-3 replaces is binding domain but its catalytic and translocation domains are left intact. The IL-3 portion of SL-401 binds to IL-3R and the entire SL-401 molecule undergoes receptor internalization. When inside the cell, the payload of SL-401 is cleaved from IL-3 and activated at which point it inhibits protein synthesis which causes cell death.



Source: ROTH Capital Partners

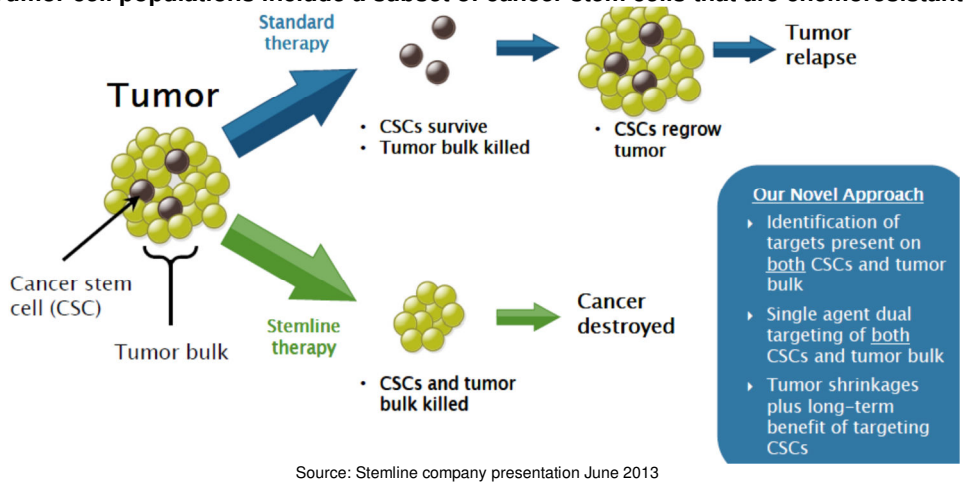
The Cancer Stem Cell (CSC) paradigm

Cancer stem cells (CSCs) represent a small but extremely important portion of tumors. CSCs are highly tumorigenic and resistant to traditional therapies and are key contributors to treatment failure and recurrence of cancers following cytotoxic treatments (e.g. chemotherapy and radiation). An increasing body of evidence suggests that each tumor has two cell populations:

- a small subpopulation of malignant, slow dividing, stem-like, progenitor cell population (CSCs), and
- a larger population of fast dividing population of cells that makes up the bulk of the tumor

Fast dividing cells are generally more susceptible to chemotherapy, whereas the CSCs are resistant to chemotherapeutic agents, and can "seed" a recurrent tumor as shown in the diagram below:

Tumor cell populations include a subset of cancer stem cells that are chemoresistant



Source: Stemline company presentation June 2013

Chemotherapy agents typically interfere with DNA repair mechanisms, which are heavily employed by dividing cells. Therefore, the fast dividing tumor cells are highly susceptible to chemo agents and become quickly depleted as the tumor is debulked. In contrast, the tumor "seeds" or the CSCs rarely divide, thereby potentially explaining their resistance to chemo and ability to induce cancer recurrence. As a result, it is often the case that the tumor volume is reduced with chemoradiation and the patient achieves a response as measured by RECIST criteria. While CSCs are not typically detected by regular scans, they can regenerate large tumors, with the patient experiencing disease recurrence.

Proliferative characteristics of CSCs are consistent with functions performed by stem cells in normal development, where the pluripotent progenitor can migrate and give rise (differentiate) to all different cell types that make up a specific tissue. Experimental evidence from virtually all cancer types indicates that CSC tumor subpopulations, once isolated from a tumor and transplanted in recipient tissue, can re-grow the primary tumor. In conclusion, CSCs play a key role in tumor initiation, maintenance, metastasis, and chemoresistance.

Several cellular pathways are critical for CSC maintenance

Similar to their "normal" counterparts, CSCs reactivate signaling pathways that are typically employed in early development and which result in sustained growth and cell proliferation. Therefore, identifying and targeting CSC-specific signaling pathways may help circumvent mechanisms of CSC chemoresistance and provide an attractive therapeutic approach.

SL-401 Clinical Data and Plans – The Key Driver

A key takeaway for us is how much the pilot Phase I/II study for SL-401 has generated with regard to efficacy and safety data as well as driving direction for pivotal plans now. What is most intriguing to us is that these promising clinical data have all been generated after only a single treatment cycle with SL-401. Going forward with the pivotal studies planned, multiple cycles will be administered, which we believe could further enhance efficacy of the product (discussed below).

The Phase I/II study (the "401 AHC Study) was conducted in 83 patients with advanced hematological cancers (59 r/r AML, 11 AML poor risk/non-chemo candidates, 7 high risk MDS patients and 6 BPDCN patients). Patients received a single cycle of SL-401 in this dose ranging study (4.0 to 22.1 ug/kg/day) delivered as a 15-minute intravenous infusion using either an every-other-day schedule from up to six treatments or daily on a five-day schedule. Each of those two regimens represented "one cycle".

Clinical results to date – Just a Single Cycle

The meaningful amount of data from the 401 study started to flow at ASH 2012 and the latest update with more mature data came at ASCO in June 2013. We describe the data and patient characteristics below.

ASCO 2013 Data Breakdown

The patient characteristics are found in the table below highlighting a couple of key points. First the median age in the study was 65 years old, which at this age, represents a good proxy for helping to delineate the safety of drug. The second point is the advanced level of these patients' disease and the number of prior treatments. As we discuss the clinical data below, we believe the ability of SL-401 to show meaningful clinical activity after only a single cycle makes the story more compelling.

Phase I/II Patient Characteristics

Patient Characteristics	All Patients (N=85)
Median Age, years (range)	65 (7, 84)
Gender, n (%)	
Male	51 (60.0)
Female	34 (40.0)
Disease, n (%)	
AML	70 (82.4)
relapsed/refractory disease	59 (69.4)
de novo unfit for chemotherapy	11 (12.9)
MDS (high risk)	7 (8.2)
CML (accelerated/blast phase)	3 (3.5)
BPDCN (relapsed/refractory)	5 (5.9)
Therapy Line for Disease in Study, n (%)	
de novo AML unfit for chemotherapy	11 (12.9)
2nd Line for AML	24 (28.2)
3rd Line for AML	16 (18.8)
>3rd Line for AML	19 (22.4)
2nd Line for BPDCN	1 (1.2)
3rd Line for BPDCN	2 (2.4)
>3rd Line for BPDCN	2 (2.4)
MDS; various prior lines of therapy	7 (8.2)
CML; various prior lines of therapy	3 (3.5)
AML Cytogenetic Risk, n (%)	
Intermediate	43 (61.4)
Poor	25 (35.7)
Unknown	2 (2.9)

Source: ASCO 2013 presentation

Safety and tolerability

As mentioned above, a key consideration is the safety and tolerability of a treatment, especially when treating older patients and patients who have essentially gone "through the ringer" with regard to prior treatments. The table below contains the dose limiting toxicities (DLTs) and clinical responses per dose. In order to compare, the safety profile is much more benign compared to chemotherapy regimens used was generally similar to that of Ontak (denileukin diftitox). The side effect profile consisted primarily of mild to moderate fever/chills which were managed and not dose limiting. Moderate to severe adverse events included liver enzyme elevations (mostly transient and not dose limiting) and some manifestations of capillary leak syndrome (e.g. reduced albumin, edema and weight gain) were also reported. It has been observed that successive treatments with Ontak results in lessened side effects and we have no reason to believe that when SL-401 moves to multiple cycles in upcoming studies, that we will not observe the same.

Treatment Regimen, DLTs and Responses

Dose, µg/kg/day	Patients Treated (Received All Doses)	Patients with DLT	Responses
Regimen A:			
4.00	7 (5)	0	1 PR
5.32	8 (6)	0	1 PR
7.07	13 (8)	0	2 PR, 1 CR
9.40	7 (3)	0	–
12.50	10 (3)	0	2 PR
Regimen B:			
7.07	5 (3)	0	1 PR
9.40	8 (8)	1[a]	–
12.50	17 (12)	1[b]	2 PR, 4 CR
16.60*	8 (7)	1[c]	–
22.12	2 (0)	2[c]	–

[a]GI bleed; [b]transaminase and creatine kinase elevations; [c]capillary leak syndrome; *Maximum tolerated dose for Regimen B

Source: ASCO 2013 presentation

The Data Speak for Itself

The clinical efficacy data are discussed below on two fronts, clinical responses and observations of survival benefit. Additionally, the BPDCN data are broken out further. The first table below highlights the updated clinical responses reported at ASCO 2013. Recall that these patients were highly advanced and the data below come from only a single cycle of treatment with SL-401.

SL-401 Phase I/II Response Data Summary

	BPDCN (n=6)	AML *Relapsed, refractory* (n=59)	AML *≥3rd line* (n=35*)	AML *Not chemo candidate* (n=11)	MDS *Refractory, High risk* (n=7)
Tumor shrinkages / disease stabilization	83%	46%	43%	55%	43%
Tumor shrinkages	83% 3 CRs	25% 2 CRs	23% 1 CR	27%	29%

AML=Acute myeloid leukemia; MDS=Myelodysplastic syndrome; BPDCN=Blastic plasmacytoid dendritic cell neoplasm
CR = Complete response
*Subpopulation of relapsed, refractory

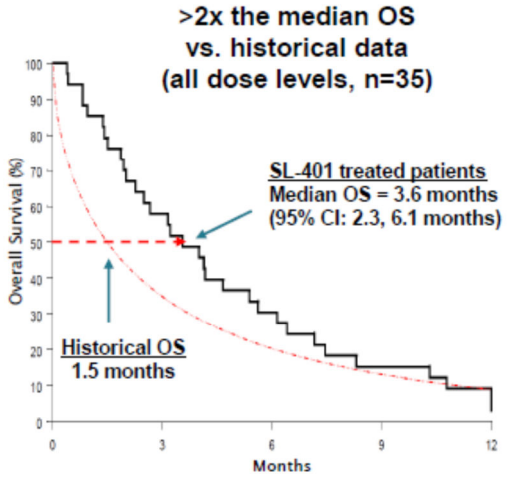
Source: ASCO 2013 presentation

Things are pointing in the right direction for the "gold standard" of survival

In AML patients who were third line or greater, overall survival was assessed and we believe the outcomes are encouraging. While the survival data is compared to historical controls, we believe the data remain positive based on the perspective of the indications. Once patients reach these stages of disease, there are very few to no options available to them so clinical benefit is relatively easy to measure especially from a survival standpoint.

A single cycle of SL-401 resulted in a >2-fold improvement in the median OS of patients with third or greater line AML compared to historical data.

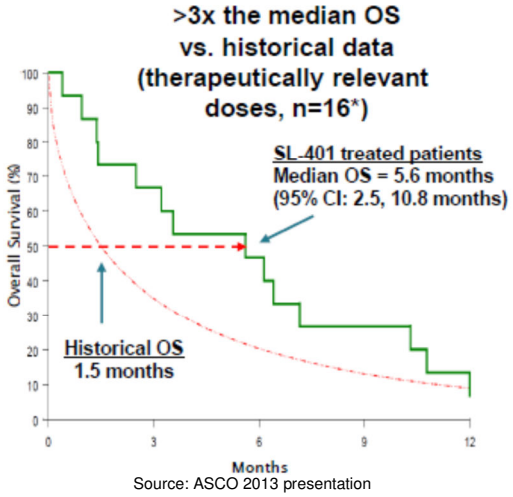
Overall Survival in >3rd line AML patients treated with single cycle (all doses; n=35)



Source: ASCO 2013 presentation

Recall that the Phase I/II was a dose escalation study. A single cycle of SL-401 at therapeutically relevant doses (the MTD and one to two dose levels below – 16.6 ug/kg/d, 12.5 ug/kg/d and 9.4 ug/kg/d) resulted in a >3-fold improvement in the median OS of patients with third or greater line AML compared to historical data.

Overall Survival in >3rd line AML patients treated with single cycle at therapeutically relevant doses (all doses; n=35)



Source: ASCO 2013 presentation

Study conclusions:

- SL-401 is a novel targeted therapy directed to the interleukin-3 receptor (IL-3R).
- IL-3R is overexpressed on CSCs and tumor bulk of multiple hematologic cancers, including AML, BPDCN, MDS, myeloma and CML. IL-3R is also overexpressed on acute lymphoid leukemia (ALL), Hodgkin's and certain NHLs.
- SL-401 has demonstrated single agent activity, including durable CRs and a survival benefit in heavily pretreated patients.
- No evidence of treatment-related hematologic toxicity, which appears to differentiate SL-401 from other therapies for hematologic malignancies.
- Registration-directed trials planed of single agent SL-401, administered in multiple cycles.
    - Single-arm Phase IIb in relapsed/refractory BPDCN
    - Randomized Phase IIb trial in 3rd line AML

ASCO 2013 BPDCN data breakdown

In a separate poster at ASCO 2013, the BPDCN data from the Phase I/II study were separated out. The patient characteristics are found in the table below which shows the majority of patients seeing high levels of prior treatments as well as almost all patients completing the entire single cycle of treatment.

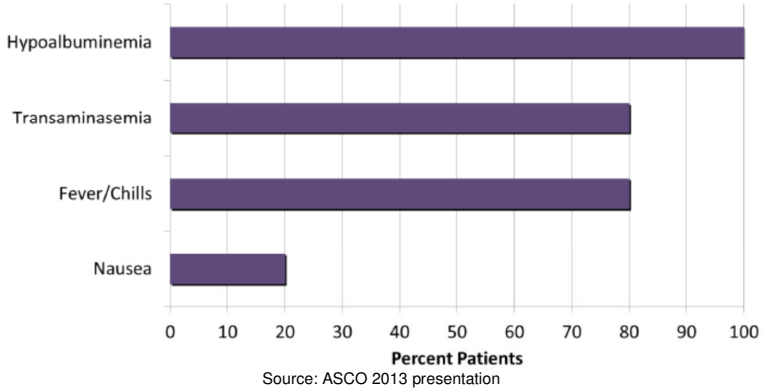
Phase I/II BPDCN Patient Characteristics

Subject No.	Age/ Gender	Previous Treatment	Sites of Disease	No. of Doses Received of 5 Daily Doses (1 cycle)
1	35/F	Two intensive combination chemotherapy regimens	Bone Marrow	5/5
2	40/M	Cytarabine/Daunorubicin/Etoposide, BMT, DLI	Bone Marrow, Nodes	5/5
3	72/M	Cytarabine/Idarubicin, Gemcitabine, BMTx2	Skin, Bone Marrow	3/5
4	65/M	Etoposide/Doxorubicin/Vincristine/Prednisone/Cyclophosphamide, Fludarabine, BMT	Skin, Bone Marrow	5/5
5	70/M	Decitabine	Skin,Bone Marrow	5/5
6	70/M	0	skin	5/5

Source: ASCO 2013 presentation

The safety is highlighted below and match with those discussed above. Importantly again, there appears to be much less to no bone marrow toxicity, which the patients had experienced based on their prior therapies.

Grade 2 Toxicities



Source: ASCO 2013 presentation

The clinical responses as well the pharmacokinetic and immune response data are found in the table below. The immune response data show that antibodies against SL-401 do not appear to correlate with clinical outcome.

PK/Immune Response and Clinical Activity

Subject No	Cmax days 1/5 (ng/mL)	Half-lives days1/5 (min)	Antibody pre/day 15-30 (µg/mL)*	Objective Response*	Response Duration (mo)
1	ND	ND	ND	ND	ND
2	0/7	-/50	6/34	CR	5
3	0/-	-/-	8/4590	CR	9+ (ongoing)
4	22/2	40/10	0.5/35	CR	1
5	8/18	30/30	1/ND	PR	1
6	0/-	-/ND	4/ND	PR	0.5+ (ongoing)

*Antibody levels day 15 except #1 was day 39, CR, complete remission; PR, partial remission; ND, not determined.

Source: ASCO 2013 presentation

Study conclusions:

- SL-401 demonstrates an excellent safety profile in patients with BPDCN
- A single cycle of SL-401 demonstrates prominent anti-tumor activity in heavily pretreated patients with advanced BPDCN
- To date, 83% (5 of 6) BPDCN patients treated with a single cycle of SL-401 had objective responses with 3 CRs, 2 of which have lasted > 3 months (1 ongoing at 9+ months)
- Methods to increase response rate and duration of response may include administering multiple cycles of SL-401.
- A pivotal program is planned in which SL-401 will be administered in a multiple cycle regimen to patients with advanced BPDCN

Clinical development plan for SL-401

The data to date are robust enough, in our's and the company's belief, to move into a pivotal study in select populations based on niche and unmet medical need opportunities. 2014 will be a busy year with trial initiations.

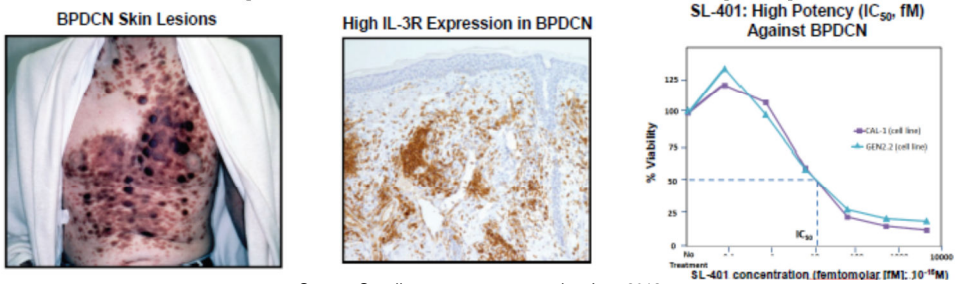
First up in 1H14 will be pivotal program for BPDCN patients (following 2H13 discussions with the FDA). The pivotal Phase IIb study will be single arm with target enrollment of 40-50 patients at 15-20 sites in North America and Europe. Based on how robust the data are in this study and since it is an open label trial, the potential exists to seek approval on fewer patients than the targeted 40-50. From a benchmarking standpoint, front-line BPDCN patients have an approximate 12 month survival. In chemotherapy naïve patients a response rate of approximately 50% or greater is seen however the responses are not durable followed by under 20% response rates after relapse. In the second-line setting a 20% response rate would be considered encouraging. Physicians are currently in the "see what sticks" mode regarding treatments and are trying various chemotherapies for both AML and lymphomas as well as bone marrow transplantation.

In 2H14, a pivotal study is planned in 3rd line AML patients. This study will be a randomized study comparing SL-401 vs. physician's choice (little to no options at this point). ~240 patients will be randomized 2:1 at 30-40 sites in North America. The primary endpoint of the study will be overall survival. Two interim analyses will be planned at one-third and one-half the events and the company is projecting ~18 months for full enrollment.

In mid-2014 the company will also begin a Phase II open label program in tumor cell types known to be both rare as well as overexpressing the IL-3R target. These include hairy cell leukemia, systemic mastocytosis, as well as basophilic and eosiniophilic leukemias. In addition to these more rare cancers, the company will also be initiating Phase II studies in relapsed/refractory multiple myeloma and high risk MDS patients. These latter two studies could be structured in such a way that, depending on the activity, could be expanded to potentially represent registration studies. We also look forward to potential combination studies over the long term.

Initial market opportunities (BPDCN and 3rd line AML)
As the company looks to move into its planned pivotal studies discussed above, we believe it is important to highlight the initial market opportunity for SL-401. From a pricing standpoint, we believe the drug can be priced conservatively in the $150,000 to $200,000 range. The projected peak sales in our clinical NPV valuation model above assume worldwide peak sales estimates. While the Phase I/II study for SL-401 only contained a small number of BPDCN patients, we believe the evidence is clear as to its validity as a target based on the high expression levels of IL-3R. The figure below (from left to right) indicates the severity of skin lesions in patients, histological evidence of the IL-3R target and femtomolar potency against BPDCN cell lines.

Linking BPDCN, Pivotal Plans and IL-3R Targeting



Source: Stemline company presentation June 2013

The table below indicates the unmet medical need for both BPDCN and 3rd line AML based on current treatment paradigms.

Treatment Paradigms for AML and BPDCN

	AML Treatment	BPDCN Treatment
1st Line	• "7+3" (Ara-C +anthracycline) approved • Bone marrow transplant when indicated	• No approved treatment • No standard of care
2nd Line	• No approved treatment • Standard of care: additional chemotherapy	• No approved treatment • No standard of care
3rd Line	• No approved treatment • No standard of care; patients typically not candidates for added chemo	• No approved treatment • No standard of care

Source: NCCN Guidelines, Stemline corporate presentation June 2013 and ROTH Capital Partners

Market sizes and potential for SL-401

SL-401 has the potential to treat multiple tumor indications which could lead to significant market expansion, in our belief. The relative sizes of these markets are found below:

- BPDCN - ~2,000 new cases annually in the U.S. and Europe
- AML - ~14,000 new cases annually in the U.S. and ~19,000 new cases annually in Europe
- "Other" rare IL-3R+ cancers (hairy cell leukemia, mastocytosis, basophilic leukemias) - ~4,000 new cases annually in the U.S. and ~5,000 new cases in Europe
- Multiple myeloma - ~22,000 new cases in the U.S. annually and ~28,000 cases in Europe
- MDS - ~16,000 new cases in the U.S. annually and ~20,000 new cases in Europe
- Other IL-3R+ heme cancers (CML, ALL, NHL, Hodgkin's) - ~87,000 new cases in the U.S. and ~113,500 new cases in Europe

VALUATION

We reiterate our Buy rating and $50 price target. Our valuation of Stemline is based on our probability weighted clinical net present value (NPV) valuation model. We believe this method is appropriate in capturing the value of the clinical stage pipeline. Factors that could impact the shares of Stemline from reaching our price target are negative data readouts from the ongoing clinical studies, any perceived delays with the regulatory progress, as well as Stemline's ability to continue to fund its operations.

RISKS

Novel mechanism and small patient numbers. While SL-401 is a novel mechanism, we believe the approach has already been validated by Ontak. Ontak uses a similar fusion approach, but uses the IL-2 receptor to deliver the diphtheria toxin. Additionally, the patient numbers in the clinical studies to date for SL-401 and SL-701 are relatively small. However, in oncology perspective is always important, in our belief, regarding the ability of these two drugs to show meaningful clinical benefit in patient populations where this would generally not be expected.

Cancer immunotherapy remains exciting, but skeptics remain. Our perception of cancer immunotherapy is excitement for the approach continues though the space has been fraught with volatility, especially with Dendreon’s trials and tribulations. We believe skepticism will remain until we see another “win” in the space, with several Phase III vaccine studies expected to read out within the next 12 months.

Clinical and financing risk. As with all development stage biotechnology companies, clinical risk and financing risk always remain front and center. Any negative clinical data news flow could have a negative impact on Stemline’s valuation. To this end, the ability of Stemline’s products to potentially address multiple therapeutic indications helps to mitigate this risk. Regarding financing risk, any indications that Stemline is not able to raise sufficient funds to continue its products’ development could negatively impact the stock. Currently, we project Peregrine has cash resources to fund operations for three years or more, beyond meaningful catalysts.

COMPANY DESCRIPTION

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. 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. Stemline also possesses a landmark portfolio of intellectual property that includes the earliest filings in the CSC field covering CSC-directed therapeutics, diagnostics, and drug discovery.

($ in millions except per share data)

Profit & Loss	2011A	2012A	2013E	2014E	2015E	2016E
Licensing	0.0	0.0	0.0	0.0	0.0	0.0
R&D collaborations	0.0	0.0	0.0	0.0	0.0	0.0
Product and Royalties	0.0	0.0	0.0	0.0	0.0	4.5
Other revenues	0.0	0.0	0.0	0.0	0.0	0.0
Revenues	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**4.5**
CoGS	0.0	0.0	0.0	0.0	0.0	0.7
Gross Profit	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**3.8**
Gross margin	*0%*	*0%*	*0%*	*0%*	*0%*	*85%*
G&A	1.1	3.1	9.0	10.0	11.0	12.1
R&D	1.6	3.4	13.8	17.0	18.7	21.0
Other op ex	0.0	0.0	0.0	0.0	0.0	0.0
EBIT	**(2.7)**	**(6.5)**	**(22.8)**	**(27.1)**	**(29.8)**	**(29.3)**
EBIT margin	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*
Non operating expenses	0.0	0.0	0.0	0.0	0.0	0.0
Net Interest Income/Other	0.1	0.3	(0.4)	0.1	0.1	0.1
Interest expense	0.1	0.1	0.3	0.3	0.1	0.0
EBT	**(2.8)**	**(6.3)**	**(23.5)**	**(27.3)**	**(29.8)**	**(29.2)**
EBT margin	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*
Provision for taxes	0.0	0.0	0.0	0.0	0.0	0.0
Net Income	**(2.8)**	**(6.3)**	**(23.5)**	**(27.3)**	**(29.8)**	**(29.2)**
Participation of preferred stock	(0.0)	(0.0)	0.0	0.0	0.0	0.0
Net Income to common	**(2.8)**	**(6.3)**	**(23.5)**	**(27.3)**	**(29.8)**	**(29.2)**
net margin	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*
NoSH	3.4	3.4	12.0	12.3	15.0	15.5
EPS - basic	**(0.80)**	**(1.82)**	**(1.96)**	**(2.22)**	**(1.99)**	**(1.88)**
EPS - diluted		**(1.82)**	**(1.96)**	**(2.22)**	**(1.99)**	**(1.88)**

Source: Company documents and ROTH Capital Partners estimates

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Quarterly P&L

	Q1'13A	Q2'13E	H1'13E	Q3'13E	9M'13E	Q4'13E	FY'13E	Q1'14E	Q2'14E	H1'14E	Q3'14E	9M'14E	Q4'14E	FY'14E
Licensing	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
R&D collaborations	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Product and Royalties	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Other revenues	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Revenues	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.0**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.0**
CoGS	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Gross Profit	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.0**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.0**
Gross margin	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*	*0%*	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*	*0%*
G&A	2.17	2.22	4.39	2.28	6.67	2.30	9.0	2.41	2.48	4.89	2.54	7.43	2.61	10.0
R&D	3.16	3.20	6.36	3.45	9.81	4.03	13.8	4.11	4.22	8.33	4.28	12.61	4.42	17.0
Other op ex	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
EBITDA	**(5.3)**	**(5.4)**	**(10.7)**	**(5.7)**	**(16.5)**	**(6.3)**	**(22.8)**	**(6.5)**	**(6.7)**	**(13.2)**	**(6.8)**	**(20.0)**	**(7.0)**	**(27.1)**
EBITDA margin							*nm*							*nm*
Non operating expenses	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Net Interest Income/Other	(0.09)	(0.10)	(0.19)	(0.10)	(0.29)	(0.10)	(0.4)	0.03	0.03	0.06	0.03	0.09	0.02	0.1
Interest expense	0.08	0.08	0.16	0.08	0.24	0.09	0.3	0.08	0.08	0.15	0.08	0.23	0.08	0.3
EBT	**(5.5)**	**(5.6)**	**(11.1)**	**(5.9)**	**(17.0)**	**(6.5)**	**(23.5)**	**(6.6)**	**(6.7)**	**(13.3)**	**(6.9)**	**(20.2)**	**(7.1)**	**(27.3)**
EBT margin							*nm*							*nm*
Provision for taxes	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Participation of preferred stock														
Net Income to common	**(5.5)**	**(5.6)**	**(11.1)**	**(5.9)**	**(17.0)**	**(6.5)**	**(23.5)**	**(6.6)**	**(6.7)**	**(13.3)**	**(6.9)**	**(20.2)**	**(7.1)**	**(27.3)**
net margin							*nm*							*nm*
NoSH	6.1	12.0	9.07	12.00	10.05	12.00	12.00	12.3	12.3	12.30	12.30	12.94	12.30	12.30
EPS - diluted	**(0.90)**	**(0.47)**	**(1.22)**	**(0.49)**	**(1.69)**	**(0.54)**	**(1.96)**	**(0.53)**	**(0.55)**	**(1.08)**	**(0.56)**	**(1.56)**	**(0.58)**	**(2.22)**

Source: Company documents and ROTH Capital Partners estimates

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Disclosures:

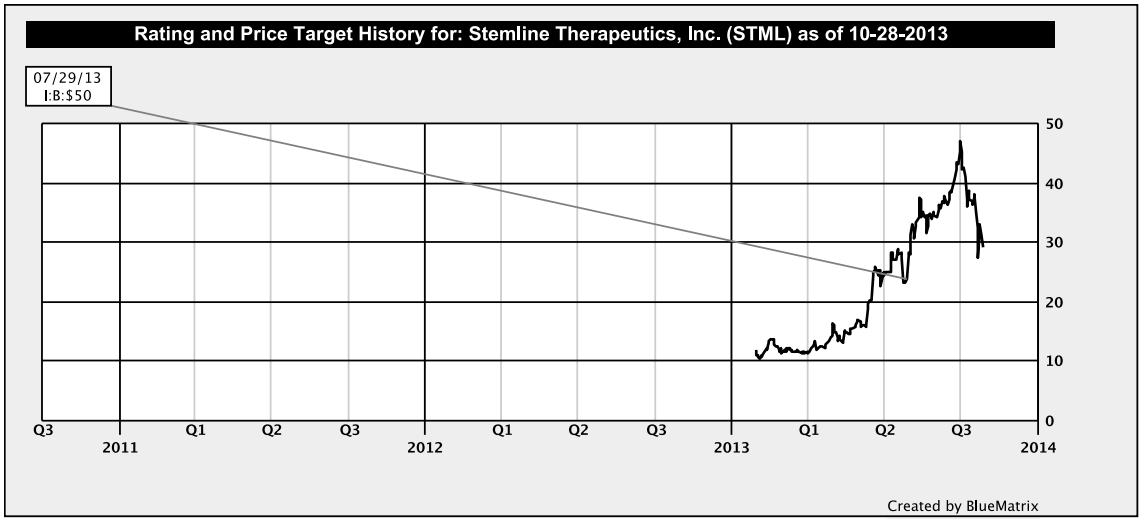
Within the last twelve months, ROTH has received compensation for investment banking services from Stemline Therapeutics, Inc..

ROTH makes a market in shares of Stemline Therapeutics, Inc. and as such, buys and sells from customers on a principal basis.

Within the last twelve months, ROTH has managed or co-managed a public offering for Stemline Therapeutics, Inc..

On September 28, 2010, ROTH changed its rating system in order to replace the Hold rating with Neutral.

On May 26, 2011, ROTH changed its rating system in order to incorporate coverage that is Under Review.



Each box on the Rating and Price Target History chart above represents a date on which an analyst made a change to a rating or price target, except for the first box, which may only represent the first note written during the past three years. **Distribution Ratings/IB Services** shows the number of companies in each rating category from which Roth or an affiliate received compensation for investment banking services in the past 12 month.

Distribution of IB Services Firmwide

			IB Serv./Past 12 Mos. as of 10/29/13	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**156**	**70.27**	**83**	**53.21**
Neutral [N]	**35**	**15.77**	**11**	**31.43**
Sell [S]	**2**	**0.90**	**0**	**0**
Under Review [UR]	**28**	**12.61**	**12**	**42.86**

Our rating system attempts to incorporate industry, company and/or overall market risk and volatility. Consequently, at any given point in time, our investment rating on a stock and its implied price movement may not correspond to the stated 12-month price target.

Ratings System Definitions - ROTH employs a rating system based on the following:

Buy: A rating, which at the time it is instituted and or reiterated, that indicates an expectation of a total return of at least 10% over the next 12 months.

Neutral: A rating, which at the time it is instituted and or reiterated, that indicates an expectation of a total return between negative 10% and 10% over the next 12 months.

Sell: A rating, which at the time it is instituted and or reiterated, that indicates an expectation that the price will depreciate by more than 10% over the next 12 months.

Under Review [UR]: A rating, which at the time it is instituted and or reiterated, indicates the temporary removal of the prior rating, price target and estimates for the security. Prior rating, price target and estimates should no longer be relied upon for UR-rated securities.

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