ROTH Capital Partners

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Healthcare: Biotechnology

Stemline Therapeutics, Inc. | STML - $21.34 - NASDAQ | *Buy*

Company Update

Stock Data	
52-Week Low - High	$10.00 - $47.25
Shares Out. (mil)	12.91
Mkt. Cap.(mil)	$275.4
3-Mo. Avg. Vol.	193,782
12-Mo.Price Target	$55.00
Cash (mil)	$87.7
Tot. Debt (mil)	$0.0

EPS $

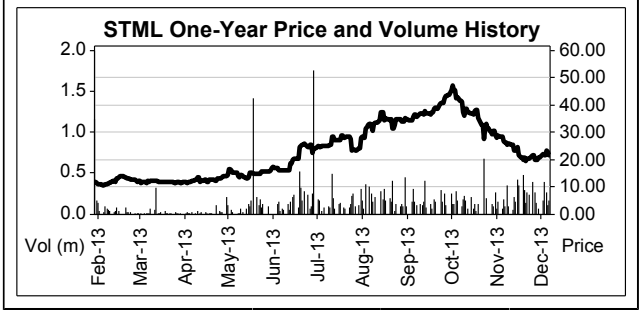
Yr Dec	—2012—	—2013E—	—2014E—
		Curr	Curr
1Q	-	(0.90)A	(0.48)E
2Q	-	(0.55)A	(0.49)E
3Q	-	(0.45)A	(0.51)E
4Q	-	(0.45)E	(0.53)E
YEAR	(1.82)A	(1.73)E	(2.01)E
P/E	NM	NM	NM

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	-	0.0A	0.0E
3Q	-	0.0A	0.0E
4Q	-	0.0E	0.0E
YEAR	0.0A	0.0E	0.0E



STML: BPDCN Update at ASH; Going Pivotal in 2014; Reiterate Buy

We received an update at ASH 2013 from the SL-401 study in BPDCN patients with positive follow up data as well as early data indicating safe retreatment of a patient with a second cycle of the drug, including encouraging efficacy. The company will be moving quickly into two pivotal studies in 2014; Phase IIb in BPDCN and Phase III in 3rd-line AML. Reiterate Buy.

Event

At ASH, we received an update from the SL-401 study in BPDCN patients, with two additional patients being treated since ASCO 2013 and follow-up data from the original 6 patients. Importantly, no dose-limiting or unexpected toxicities have been observed. 8 patients have been treated. Of the 7 evaluable there have been 5 CRs and one PR (86% overall response). One of the patients who achieved a CR saw a duration of several months and then started to relapse. This patient was then re-dosed with a second cycle (first time a patient has received second cycle) with '401 and saw lesion regression again. However this patient had aggressive bone marrow disease and eventually progressed.

Impact

We are impressed with the continued activity of SL-401 in BPDCN patients, who have no other therapeutic option. A key takeaway from today's news is twofold: 1) encouraging clinical activity seen following dosing with a second cycle (despite being suboptimal scheduling after several months of not seeing the drug) and 2) no adverse events were seen with the dosing of the second cycle, which is an important signal for the pivotal program. The company is now in commercial scaleup for manufacturing of SL-401 for the start of the planned pivotal study in 2Q14. This Phase IIb study will enroll ~40-50 patients at 15-20 sites in N. America and the E.U. Overall response rate will be the primary endpoint. Recall the company will also be starting a pivotal study in third line r/r AML in 2014 as well (Phase III randomized study vs. physician's choice - ~240 patients with OS as primary endpoint). We believe the increasing clinical data will increase the attractiveness of any potential business development activity.

Action

We reiterate our Buy rating and are increasing our price target to $55 from $50. 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.

Intraday: $21.90, 10:02 am ET, 12/9/13

ASH 2013 BPDCN Update

Below is the ASH 2013 update for SL-401 in BPDCN patients. The data contains follow up data from the 6 patients presented at ASCO 2013 as well as the two new patients including the first time dosing with a second-cycle of the drug. Following an initial CR, this patient (#6) relapsed, and then 3 months later was allowed to received a compassionate use second cycle of the drug. Unfortunately, the patient's underlying bone marrow disease had progressed significantly and was the reason for the disease progression and not from the skin lesions (discussed below). The table below contains the patient demographics and responses.

BPDCN Clinical and Demographic Update

No.	Age/ Gender	Previous Treatment	Sites of Disease	CD123 Immuno	SL-401 Dose (µg/kg/d)	Response (Duration) (1 cycle)
1	35/F	Two intensive combination chemotherapy regimens	Bone Marrow	+	9	Not evaluable for response
2	40/M	Cytarabine/Daunorubicin/ Etoposide, ABMT, Donor Lymphocyte Infusion	Bone Marrow, Spleen Lymph Nodes	+	12	CR (5 mo)
3	72/M	Cytarabine/Idarubicin, Gemcitabine, ABMTx2	Skin, Bone Marrow	+	12	CR (14+ mo) ongoing
4	65/M	Etoposide/Doxorubicin/Vincristine/ Prednisone/ Cyclophosphamide/ Fludarabine, ABMT	Skin, Bone Marrow	+	12	CR (1 mo)
5	70/M	Decitabine	Skin, Bone Marrow	+	12	PR (1 mo)
6	70/M	None	Skin, Bone Marrow	+	12	CR (3 mo)
7	70M	CHOP (cyclophosphamide, vincristine, doxorubicin, prednisone	Skin, Lymph Nodes	+	12	Mixed Response
8	70M	None	Skin	+	12	CR (4+ mo) ongoing

Abbreviations: ABMT, allogeneic bone marrow transplantation; CR, complete response; PR, partial response.

Source: ASH 2013

The following data points are from two patients, one (#3) who has a CR ongoing at 14+ months after only the single cycle of SL-401 and patient #6 who went on to receive the second cycle (sub-optimally) 3 months later when the CR recurred.

Patient #3

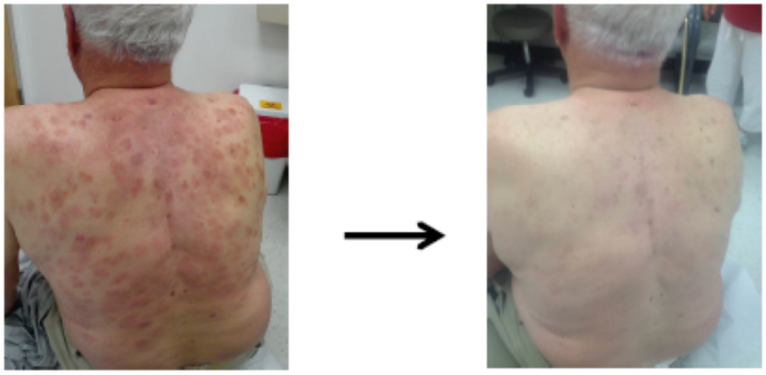
- 72-year old male
- 3 prior lines of intensive chemotherapy, including ABMT
- BPDCN blasts in bone marrow, skin lesions
- CR on day 28 following treatment with single cycle of SL-401
- CR duration (single cycle): 14+ months ongoing.
-

Patient #6 (cycle 1 and compassionate use cycle 2)

- 70-year old male; no prior therapy
- BPDCN blasts in skin and bone marrow
- Skin and bone marrow blasts on day 35 – no BPDCN
- CR duration (single cycle): 3 months
- Recurrence in skin and bone marrow
- Compassionate use approval obtained and patient retreated with fulminant disease
- Complete clearance of skin disease on day 14. Progressive disease in bone marrow on day 45
- No notable AEs associated with retreatment.

The figure below indicates the CR obtained following cycle 1 of SL-401

Patient #6 Initial CR Following One Cycle of SL-401



Pre-SL-401 Post-SL-401 (day 28)

Source: ASH 2013

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 robust clinical activity in both relapsed-refractory and treatment naïve patients with BPDCN.
- A single cycle of SL-401 induced responses in 6 of 7 (87%) BPDCN patients (5 CRs, 1 PR)
- With a single cycle, 4 CRs≥ 3 months duration
- SL-401 single agent, multiple cycle, pivotal program planned in relapsed/refractory BPDCN

Next Steps

The company is now in commercial scaleup for manufacturing of SL-401 for the start of the planned pivotal study in 2Q14. Recall the company will also be starting a pivotal study in third line r/r AML in 2014 as well.

The pivotal Phase IIb study in BPDCN 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.

VALUATION

We reiterate our Buy rating and $55 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	7.8	9.7	10.7	11.8
R&D	1.6	3.4	14.2	17.4	19.2	21.5
Other op ex	0.0	0.0	0.0	0.0	0.0	0.0
EBIT	**(2.7)**	**(6.5)**	**(22.0)**	**(27.2)**	**(29.9)**	**(29.4)**
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	(0.1)	0.1	0.1	0.1
Interest expense	0.1	0.1	0.4	0.0	0.0	0.0
EBT	**(2.8)**	**(6.3)**	**(22.4)**	**(27.1)**	**(29.8)**	**(29.3)**
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)**	**(22.4)**	**(27.1)**	**(29.8)**	**(29.3)**
Participation of preferred stock	(0.0)	(0.0)	0.0	0.0	0.0	0.0
Net Income to common	**(2.8)**	**(6.3)**	**(22.4)**	**(27.1)**	**(29.8)**	**(29.3)**
net margin	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*
NoSH	3.4	3.4	13.0	13.5	15.0	15.5
EPS - basic	**(0.80)**	**(1.82)**	**(1.73)**	**(2.01)**	**(1.99)**	**(1.89)**
EPS - diluted		**(1.82)**	**(1.73)**	**(2.01)**	**(1.99)**	**(1.89)**

Source: Company documents and ROTH Capital Partners estimates

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Quarterly P&L

	Q1'13A	Q2'13A	H1'13A	Q3'13A	9M'13A	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	1.07	3.24	2.25	5.49	2.30	7.8	2.32	2.39	4.71	2.48	7.19	2.55	9.7
R&D	3.16	4.08	7.25	3.32	10.57	3.61	14.2	4.18	4.27	8.45	4.40	12.85	4.60	17.4
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)**	**(5.2)**	**(10.5)**	**(5.6)**	**(16.1)**	**(5.9)**	**(22.0)**	**(6.5)**	**(6.7)**	**(13.2)**	**(6.9)**	**(20.0)**	**(7.1)**	**(27.2)**
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)	0.00	(0.09)	0.00	(0.09)	0.01	(0.1)	0.01	0.01	0.03	0.01	0.04	0.01	0.1
Interest expense	0.08	0.30	0.38	0.00	0.38	(0.00)	0.4	0.00	0.00	0.00	0.00	0.00	0.00	0.0
EBT	**(5.5)**	**(5.5)**	**(11.0)**	**(5.6)**	**(16.5)**	**(5.9)**	**(22.4)**	**(6.5)**	**(6.6)**	**(13.1)**	**(6.9)**	**(20.0)**	**(7.1)**	**(27.1)**
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)**	**(5.5)**	**(11.0)**	**(5.6)**	**(16.5)**	**(5.9)**	**(22.4)**	**(6.5)**	**(6.6)**	**(13.1)**	**(6.9)**	**(20.0)**	**(7.1)**	**(27.1)**
net margin							*nm*							*nm*
NoSH	6.1	9.8	7.99	12.47	9.49	13.00	13.00	13.5	13.5	13.50	13.50	13.50	13.50	13.50
EPS - diluted	**(0.90)**	**(0.55)**	**(1.37)**	**(0.45)**	**(1.74)**	**(0.45)**	**(1.73)**	**(0.48)**	**(0.49)**	**(0.97)**	**(0.51)**	**(1.48)**	**(0.53)**	**(2.01)**

Source: Company documents and ROTH Capital Partners estimates

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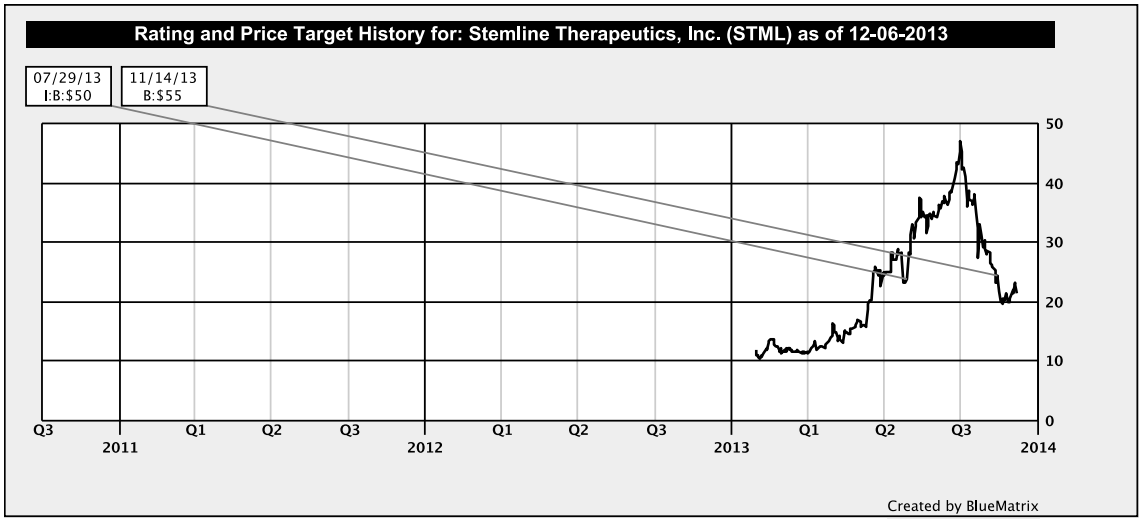
Within the last twelve months, ROTH has received compensation for investment banking services from Stemline Therapeutics, Inc..

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 12/09/13	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**161**	**71.88**	**88**	**54.66**
Neutral [N]	**35**	**15.62**	**11**	**31.43**
Sell [S]	**2**	**0.89**	**0**	**0**
Under Review [UR]	**26**	**11.61**	**10**	**38.46**

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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