ROTH Capital Partners

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Healthcare: Biotechnology

Stemline Therapeutics, Inc. | STML - $30.44 - NASDAQ | *Buy*

Company Update

Stock Data	
52-Week Low - High	$10.00 - $47.25
Shares Out. (mil)	12.91
Mkt. Cap.(mil)	$392.9
3-Mo. Avg. Vol.	209,068
12-Mo.Price Target	$55.00
Cash (mil)	$87.7
Tot. Debt (mil)	$0.0

EPS $

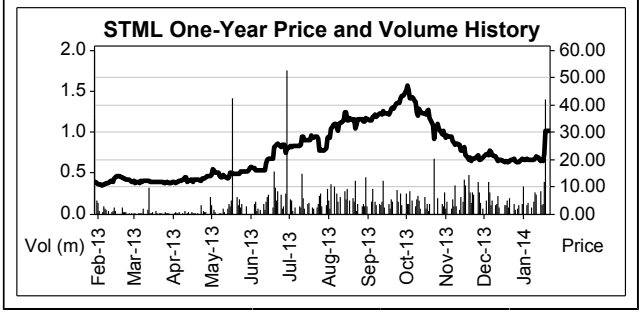
Yr Dec	—2012—	—2013E—	—2014E—
		Curr	Curr
1Q	-	(0.90)A	(0.48)E
2Q	-	(0.55)A	(0.49)E
3Q	-	(0.45)A	(0.51)E
4Q	-	(0.45)E	(0.53)E
YEAR	(1.82)A	(1.73)E	(2.01)E
P/E	NM	NM	NM

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: 2014 Outlook; A Year of Pivotal Studies; Reiterate Buy

STML issued its 2014 outlook. The company is ready to move into two pivotal studies for SL-401 in 2014 and we believe that these two studies in BPDCN and 3rd line AML are poised for success based on data to date. Reiterate Buy.

Event

STML issued its 2014 outlook detailing development plans for SL-401 and SL-701. With manufacturing team set up in 2013 and GMP commercial scale-up complete, the company is now finalizing the SL-401 formulation and is ready to move into pivotal studies in 2014.

Impact

We believe 2014 will be a big year for STML as they advance into pivotal trials for SL-401. Data presented at ASH'13 for SL-401 in BPDCN showed continued encouraging activity. No dose-limiting toxicities were found. Out of 7 evaluable patients who received a single cycle, there were 5 CRs and 1 PR (86% overall response). 4 CRs lasted at least 3 months and 2 CRs are still in remission (one at 15 months now). One CR progressed after several months and was re-dosed, which again led to lesion regression (though the patient eventually died of underlying bone marrow disease progression). We believe this early data bodes well for the Phase IIb pivotal study, which is slated to begin 2Q. The single-arm study will enroll ~40-50 patients in N. America and the E.U. and will have a primary endpoint of overall response rate.

STML has now treated 59 r/r AML patients (35 of whom were 3rd-line or later) and seen a 25% blast reduction in at least 25% of patients after only a single cycle of '401. Cancer stem cells in bone marrow also decreased after one cycle. A randomized Phase III trial of SL-401 vs. physician's choice will enroll ~240 patients in N. America and the E.U. and is slated to begin this year. STML is making plans for a single-arm study of SL-701 in 2nd-line r/r adult high grade glioma, which the company believes could provide a path to accelerated approval. Details should be forthcoming.

Action

We reiterate our Buy rating and $55 price target. We believe that Stemline is poised for significant growth as it begins pivotal studies with SL-401 and also has a potentially leading cancer immunotherapy product in SL-701.

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.

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 Stemline has cash resources to fund operations for two 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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Disclosures:

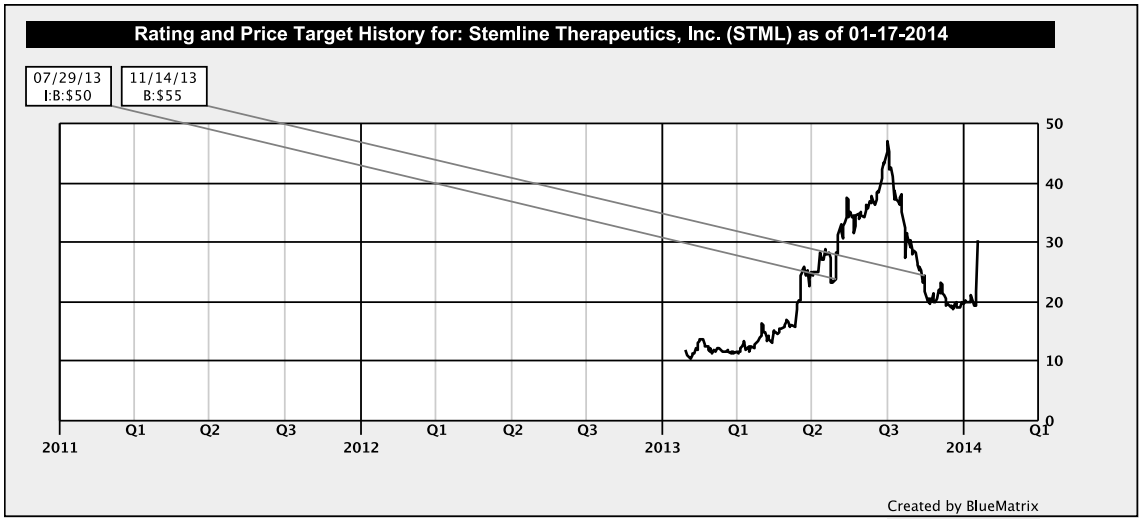
Within the last twelve months, ROTH has received compensation for investment banking services from Stemline Therapeutics, Inc..

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 01/20/14	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**171**	**75.33**	**91**	**53.22**
Neutral [N]	**34**	**14.98**	**13**	**38.24**
Sell [S]	**1**	**0.44**	**0**	**0**
Under Review [UR]	**21**	**9.25**	**8**	**38.10**

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.

Not Covered [NC]: ROTH does not publish research or have an opinion about this security.

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