ROTH Capital Partners

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Healthcare: Biotechnology

Stemline Therapeutics, Inc. | STML - $23.23 - NASDAQ | *Buy*

Company Update

Target Price Changed

Stock Data	
52-Week Low - High	$10.00 - $47.25
Shares Out. (mil)	12.91
Mkt. Cap.(mil)	$299.8
3-Mo. Avg. Vol.	179,517
12-Mo.Price Target	$55.00
Cash (mil)	$87.7
Tot. Debt (mil)	$0.0

EPS $

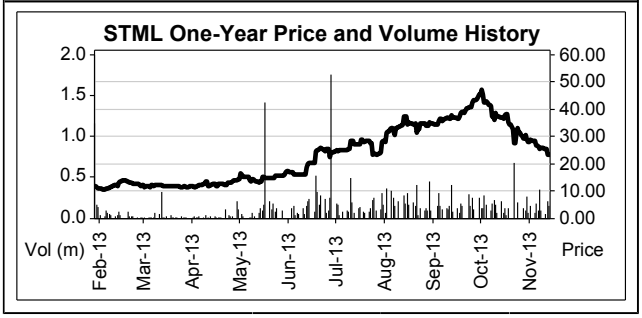
Yr Dec	—2012—	—2013E—	—2014E—
		Curr	Curr
1Q	-	(0.90)A	(0.48)E
2Q	-	(0.55)A	(0.49)E
3Q	-	(0.45)A	(0.51)E
4Q	-	(0.45)E	(0.53)E
YEAR	(1.82)A	(1.73)E	(2.01)E
P/E	NM	NM	NM

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: Nice Increments from BPDCN Program; Target Upped to $55

Stemline announced some nice incremental data out of the SL-401 program in BPDCN patients. Two additional patients have been treated with one complete response. Additionally one patient who previously achieved a CR for several months received a second cycle of the drug with encouraging activity and, importantly, no adverse events after the second cycle. We reiterate our Buy and are raising our price target to $55 from $50.

Event

STML announced incremental data out of its SL-401 program for BPDCN with updates expected at ASH. Two additional patients have been dosed with single cycle of the drug, with one patient achieving a complete response (CR). To date, 8 patients have been treated. Of the 7 evaluable there have been 5 CRs and one PR (86% overall response). Intriguingly today, the company announced that 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. We expect a strong showing at ASH next month with 5 presentations (including one oral) with Stemline making a quick transition to a pivotal stage company next year. Recall the company will also be starting a pivotal study in third line r/r AML in 2014 as well. 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 price: $23.32 at 9:38 am ET, 11/14/13

VALUATION

We reiterate our Buy rating and are increasing our price target to $55 from $50. The primary drivers to our price target change include:

1) change of base year, 2) increasing projected chance of success for BPDCN from 45% to 50% and 3) increasing projected peak sales for BPDCN from $265 million to $300 million.

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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Disclosures:

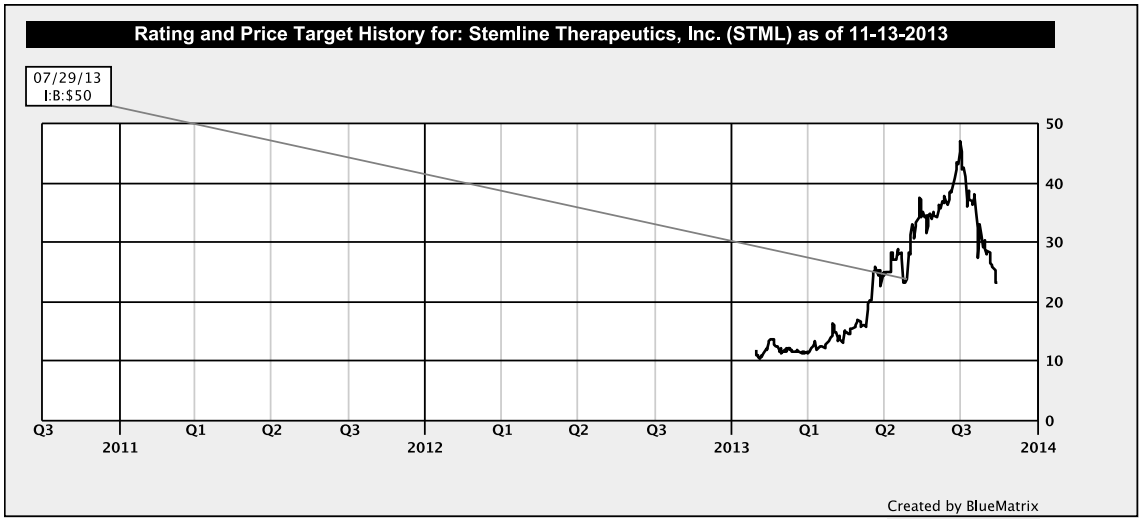
Within the last twelve months, ROTH has received compensation for investment banking services from Stemline Therapeutics, Inc..

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 11/14/13	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**157**	**70.40**	**85**	**54.14**
Neutral [N]	**36**	**16.14**	**11**	**30.56**
Sell [S]	**2**	**0.90**	**0**	**0**
Under Review [UR]	**27**	**12.11**	**11**	**40.74**

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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