

## Healthcare: Biotechnology

# Stemline Therapeutics, Inc. | STML - \$23.29 - NASDAQ | Buy

### Analysis of Sales/Earnings

Estimates Changed

#### Stock Data

52-Week Low - High	\$10.00 - \$47.25
Shares Out. (mil)	12.54
Mkt. Cap.(mil)	\$292.0
3-Mo. Avg. Vol.	179,173
12-Mo.Price Target	\$50.00
Cash (mil)	\$87.7
Tot. Debt (mil)	\$0.0

#### EPS \$

Yr Dec	—2012—	—2013E—		—2014E—	
		Curr	Prev	Curr	Prev
1Q	-	(0.90)A	(0.90)A	(0.48)E	(0.53)E
2Q	-	(0.55)A	(0.47)E	(0.49)E	(0.55)E
3Q	-	(0.45)A	(0.49)E	(0.51)E	(0.56)E
4Q	-	(0.45)E	(0.54)E	(0.53)E	(0.58)E
YEAR	(1.82)A	(1.73)E	(1.96)E	(2.01)E	(2.22)E
P/E	NM	NM	NM	NM	NM

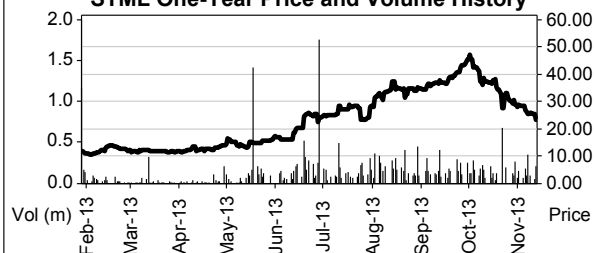
January 2013 IPO

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 One-Year Price and Volume History



## STML 3Q13; Two Pivotal Studies To Start 2014; Compelling Valuation

STML announced 3Q13 results, posting EPS of \$(0.45) versus our estimate of \$(0.49). The company ended the quarter with \$87.7 million in cash. We expect a SL-401 data update at ASH in December, and we look towards 2014, when the company will initiate pivotal studies in both r/r BPDCN and r/r AML. We believe the valuation is compelling after the recent pullback, which was not fundamentally driven, in our belief.

### Event

STML announced 3Q13 results, posting EPS of \$(0.45) versus our estimate of \$(0.49) and consensus estimate of \$(0.46). The company ended the quarter with \$87.7 million in cash. In 2014, SL-401 is expected to enter pivotal studies for both BPDCN and AML patients.

### Impact

The company plans to initiate pivotal studies in for SL-401 in both r/r blastic plasmacytoid dendritic cell neoplasm (BPDCN) and in third line r/r AML in 2014. Both indications currently lack a standard of care. Recall that STML got a vote of confidence from The Leukemia & Lymphoma Society (LLS) last month as LLS pledged \$3 million to support both clinical studies and increasing physician awareness in orphan indication BPDCN. SL-401 has yielded significant activity in advanced hematological cancers in Phase I/II data presented at ASCO 2013. 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. We also expect SL-401 clinical data to be presented at ASH in December. 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.

## 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)

<b>Profit &amp; Loss</b>	<b>2011A</b>	<b>2012A</b>	<b>2013E</b>	<b>2014E</b>	<b>2015E</b>	<b>2016E</b>
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
<b>Revenues</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>4.5</b>
CoGS	0.0	0.0	0.0	0.0	0.0	0.7
<b>Gross Profit</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>3.8</b>
<i>Gross margin</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>85%</i>
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
<b>EBIT</b>	<b>(2.7)</b>	<b>(6.5)</b>	<b>(22.0)</b>	<b>(27.2)</b>	<b>(29.9)</b>	<b>(29.4)</b>
<i>EBIT margin</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>
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
<b>EBT</b>	<b>(2.8)</b>	<b>(6.3)</b>	<b>(22.4)</b>	<b>(27.1)</b>	<b>(29.8)</b>	<b>(29.3)</b>
<i>EBT margin</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>
Provision for taxes	0.0	0.0	0.0	0.0	0.0	0.0
<b>Net Income</b>	<b>(2.8)</b>	<b>(6.3)</b>	<b>(22.4)</b>	<b>(27.1)</b>	<b>(29.8)</b>	<b>(29.3)</b>
Participation of preferred stock	(0.0)	(0.0)	0.0	0.0	0.0	0.0
<b>Net Income to common</b>	<b>(2.8)</b>	<b>(6.3)</b>	<b>(22.4)</b>	<b>(27.1)</b>	<b>(29.8)</b>	<b>(29.3)</b>
<i>net margin</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>
NoSH	3.4	3.4	13.0	13.5	15.0	15.5
<b>EPS - basic</b>	<b>(0.80)</b>	<b>(1.82)</b>	<b>(1.73)</b>	<b>(2.01)</b>	<b>(1.99)</b>	<b>(1.89)</b>
<b>EPS - diluted</b>		<b>(1.82)</b>	<b>(1.73)</b>	<b>(2.01)</b>	<b>(1.99)</b>	<b>(1.89)</b>

Source: Company documents and ROTH Capital Partners estimates

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## Quarterly P&amp;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
<b>Revenues</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.0</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.0</b>
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
<b>Gross Profit</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.0</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.0</b>
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
<b>EBITDA</b>	<b>(5.3)</b>	<b>(5.2)</b>	<b>(10.5)</b>	<b>(5.6)</b>	<b>(16.1)</b>	<b>(5.9)</b>	<b>(22.0)</b>	<b>(6.5)</b>	<b>(6.7)</b>	<b>(13.2)</b>	<b>(6.9)</b>	<b>(20.0)</b>	<b>(7.1)</b>	<b>(27.2)</b>
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
<b>EBT</b>	<b>(5.5)</b>	<b>(5.5)</b>	<b>(11.0)</b>	<b>(5.6)</b>	<b>(16.5)</b>	<b>(5.9)</b>	<b>(22.4)</b>	<b>(6.5)</b>	<b>(6.6)</b>	<b>(13.1)</b>	<b>(6.9)</b>	<b>(20.0)</b>	<b>(7.1)</b>	<b>(27.1)</b>
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														
<b>Net Income to common</b>	<b>(5.5)</b>	<b>(5.5)</b>	<b>(11.0)</b>	<b>(5.6)</b>	<b>(16.5)</b>	<b>(5.9)</b>	<b>(22.4)</b>	<b>(6.5)</b>	<b>(6.6)</b>	<b>(13.1)</b>	<b>(6.9)</b>	<b>(20.0)</b>	<b>(7.1)</b>	<b>(27.1)</b>
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
<b>EPS - diluted</b>	<b>(0.90)</b>	<b>(0.55)</b>	<b>(1.37)</b>	<b>(0.45)</b>	<b>(1.74)</b>	<b>(0.45)</b>	<b>(1.73)</b>	<b>(0.48)</b>	<b>(0.49)</b>	<b>(0.97)</b>	<b>(0.51)</b>	<b>(1.48)</b>	<b>(0.53)</b>	<b>(2.01)</b>

Source: Company documents and ROTH Capital Partners estimates

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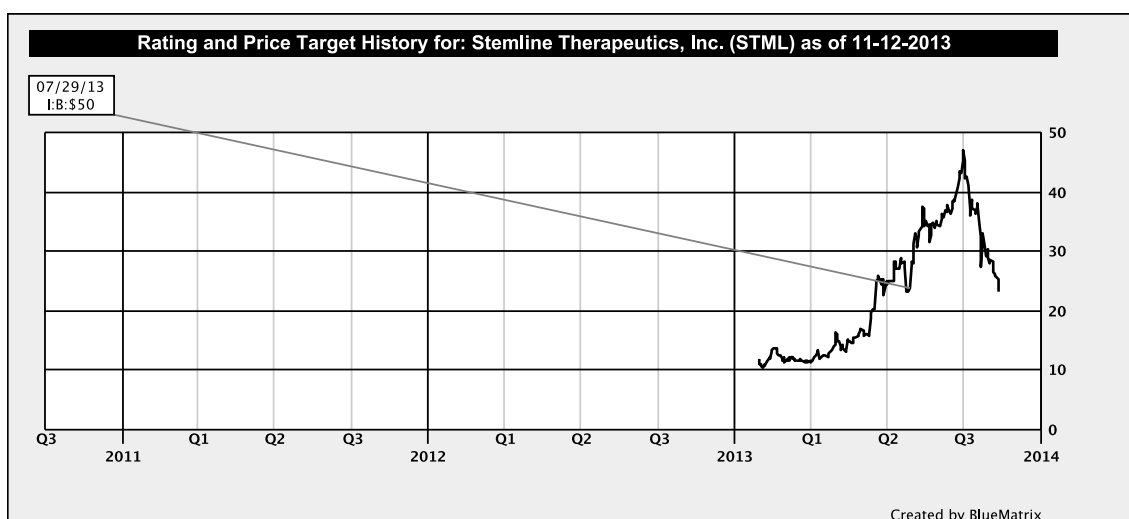
Within the last twelve months, ROTH has received compensation for investment banking services from Stemline Therapeutics, Inc..

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

Rating	Count	Percent	IB Serv./Past 12 Mos. as of 11/13/13	
			Count	Percent
Buy [B]	157	70.09	85	54.14
Neutral [N]	36	16.07	11	30.56
Sell [S]	2	0.89	0	0
Under Review [UR]	28	12.50	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.

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**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.

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