ROTH Capital Partners

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Healthcare: Biotechnology

Stemline Therapeutics, Inc. | STML - $19.95 - NASDAQ | *Buy*

Company Update

Stock Data	
52-Week Low - High	$10.00 - $47.25
Shares Out. (mil)	12.91
Mkt. Cap.(mil)	$257.5
3-Mo. Avg. Vol.	183,505
12-Mo.Price Target	$55.00
Cash (mil)	$87.7
Tot. Debt (mil)	$0.0

EPS $

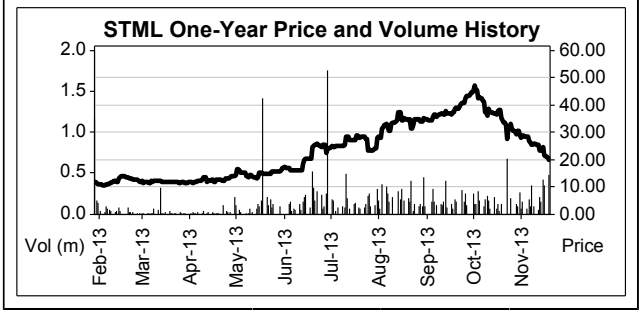
Yr Dec	—2012—	—2013E—	—2014E—
		Curr	Curr
1Q	-	(0.90)A	(0.48)E
2Q	-	(0.55)A	(0.49)E
3Q	-	(0.45)A	(0.51)E
4Q	-	(0.45)E	(0.53)E
YEAR	(1.82)A	(1.73)E	(2.01)E
P/E	NM	NM	NM

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: SL-701 Sneaking Back into the Limelight; Rightly So; Reiterate Buy

With the majority of investor focus currently on SL-401 and its pivotal plans in BPDCN and 3rd-line AML next year, we are enthusiastic on the renewed focus on SL-701 as a compelling cancer immunotherapy candidate for glioblastoma. Potential accelerated approval studies could start next year based on positive data to date and a continuing unmet medical need. Reiterate Buy

Event

STML announced a data presentation for SL-701 at the upcoming World Federation of Neuro-Oncology, in conjunction with the SNO conference, Nov. 21-24, 2013. Specifically, focus and data to date for SL-701 has been on high grade glioma studies and positive clinical results in both adults and children (discussed below). The company will now present new clinical data from a 23-patient study in low-grade glioma patients at SNO. The SL-701 "vaccine" has induced specific and sustained immune responses in patients. Further, data show that patients who saw high levels of immune responses experienced prolonged progression free survival. Based on these data, the company will consider moving into more advanced clinical studies in low-grade glioma, while the current focus for SL-701 is to move into potential accelerated approval studies in high-grade glioma in adults and children.

Impact

With the majority of investor focus currently on SL-401 and its pivotal plans in BPDCN and 3rd-line AML next year, we are enthusiastic on the renewed focus on SL-701. 2014 should be a busy year for the company as they "go pivotal" in three indications with its two lead products. 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. After a strong run-up of the biotech sector as well as STML shares, valuations have come back and we believe the current valuation represents an attractive entry point.

Action

We reiterate our Buy rating and $55 target. 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-701 – Ready to Come Out and Play in a Big Way

What is it? SL-701 is a cancer vaccine designed to target glioblastoma. We discuss the cancer immunotherapy landscape below, but SL-701 fits into the "off-the-shelf" category of vaccines and uses a multiple antigen peptide approach. The goal is to hit antigens on tumor cells expressed on the bulk of the tumor as well as CSCs. The primary peptide antigens in the vaccine are IL-13Ra2 and EphA2. Tetanus toxoid peptide is included for adjuvant "help" as well as a "typical" adjuvant.

SL-701 Clinical Data Impressive To Date

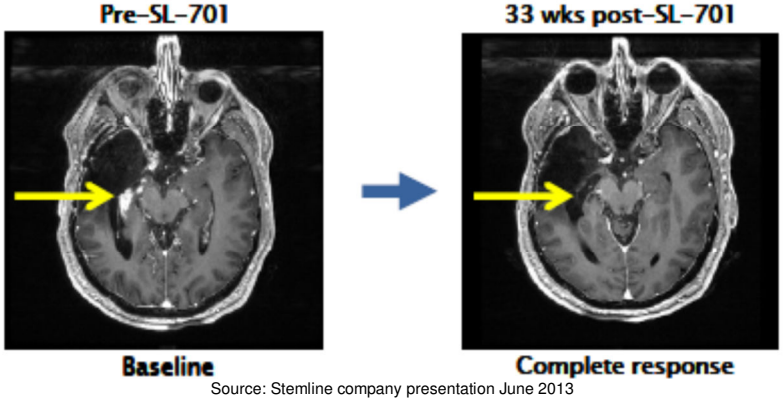
The SL-701 program has been based primarily on two completed Phase I/II studies in both adult and pediatric patients. Data from these studies have been mainly presented at the ASCO 2011 and AACR 2012 conferences. From a cancer immunotherapy standpoint, we believe the data are impressive in that clinical efficacy has not only shown a survival benefit in these late stage patients, but also tumor responses, which could be considered "rare" for a vaccine approach. Immunological data were also published in the *Journal of Clinical Oncology* in 2010 (Okada et al.). In short, we believe the stage has been set for next steps in the clinical path of SL-701 as it looks to join the other cancer immunotherapy approaches to glioblastoma.

Several cancer vaccine approaches have shown to elicit significant "classical" response, i.e. tumor shrinkage by RECIST, and SL-701 is one of these, whereas most look to fit into the category of having the immune system controlling the tumor at later stages.

701 Adult-RHGG Study (completed Phase I/II)
The Phase I/II adult study (RHGG) enrolled 22 recurrent malignant glioma patients (13 glioblastoma, 5 anaplastic astrocytoma, 3 anaplastic oligodendroglioma and 1 oligoastrocytoma). Half the patients in the study were 2nd relapse or greater representing a highly advanced tumor population and 2 of the GBM patients received prior Avastin treatment. In this study, SL-701 was loaded *ex vivo* onto patient specific dendritic cells and then reinjected intra/peri-nodally concurrently with an adjuvant. The goal of the study was to safety, dosage and preliminary efficacy of single agent SL-701 testing in a single arm study. As was to be expected with cancer vaccine approaches the most common adverse events were injection site reactions and most resolved within 24 hours.

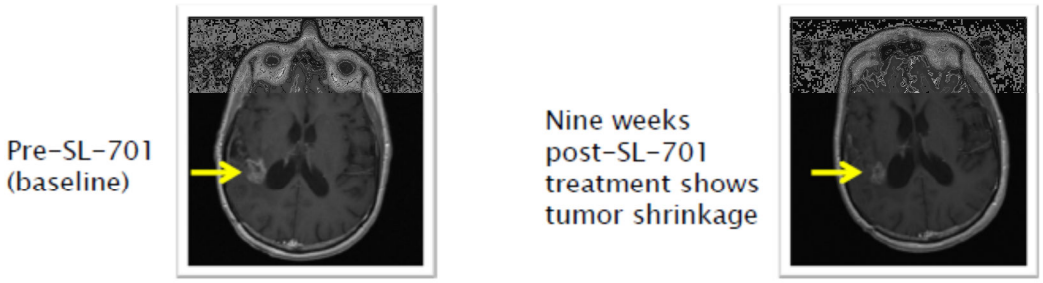
One of the patients who achieved a CR is depicted in the scans below. This patient became refractory to prior surgery, radiation and Temodar therapy. As indicated below, the CR lasted greater than 23 months. Additionally a significant increase in target-specific T-cells was also seen by week 29 (tetramer assay).

SL-701 induced a CR (>23 months in an adult with GBM refractory to 1st line therapy)



Source: Stemline company presentation June 2013

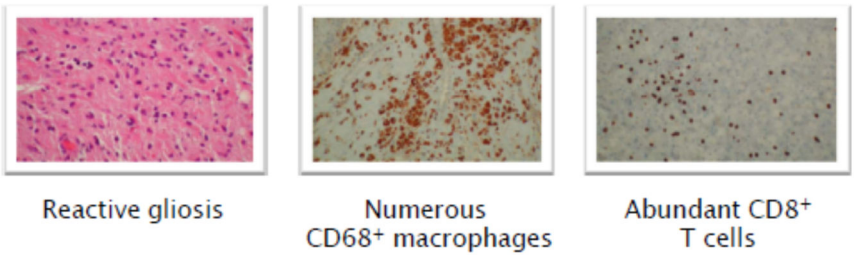
Adult 3rd Line GBM Partial Response



Source: Stemline company presentation June 2013

Indicative of an immune component to the therapy, post SL-701 brain biopsy has shown inflammation, which included CD8+ T cells infiltrating the tumor (shown below).

Adult 3rd Line GBM Immune Response (patient above)



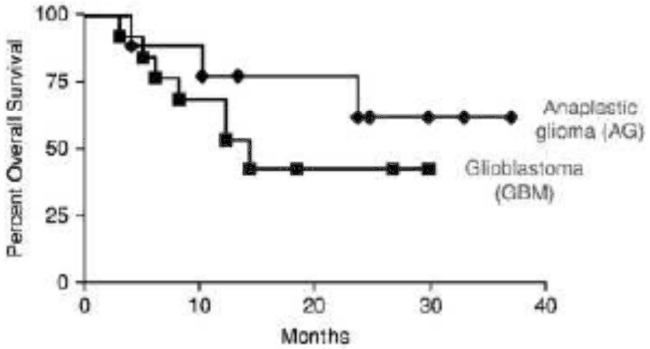
Source: Stemline company presentation June 2013

Survival benefit:
While a single arm study, it appears that single agent SL-701 therapy in this advanced patient population did confer a survival benefit compare to historical controls. The Kaplan-Meier curves are seen below showing extension of survival over the expected survival rates (table below)

Glioblastoma patients	SL-701 Treatment	Historical Controls
Median OS	13 months	5-7 months
6-month OS	80%	38-55%
12-month OS	55%	14-25%

Source: ROTH Capital Partners and Stemline S-1 filing, May 16, 2013

Kaplan-Meier Curve of Recurrent/Refractory Adult HGG Patients



Source: Okada et al. Journal of Clinical Oncology 2011; 29:330-336

Summary in adult patients with recurrent or refractory high grade glioma:

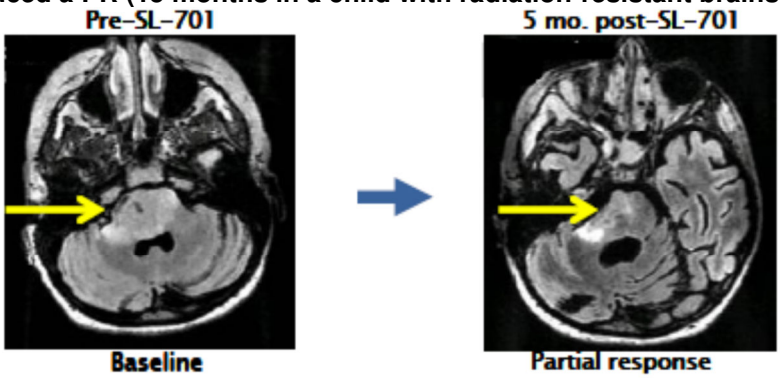
- 59% (13/22) overall response or disease stabilization (46% GBM and 78% AG)
- 2 complete responses (CRs), including a CR of >23 months duration in an adult patient with refractory GBM.

- 3 partial responses (PRs)
- 81% (13/16 evaluable) had at least one positive immunological assay
- Overall survival benefit vs. historical data

701 Ped-G Study (completed Phase I/II)
In this study of pediatric patients with glioma, 27 patients were enrolled (16 with newly diagnosed brainstem glioma, 5 with newly diagnosed non-brainstem glioma, 3 with recurrent non-brainstem glioma and three with multiply recurrent low-grade glioma. The dosing in the study was different from the adult study and SL-701 was delivered subcutaneously once every three weeks for up to 24 weeks with concurrent separate injection of an adjuvant. The goal of the single arm study was to determine the safety, dosage and preliminary efficacy of SL-701 monotherapy.

One of the partial responses seen in the study is shown in the scans below. The pediatric patient's tumor was radiation resistant and we believe the clinical response observed is quite encouraging.

SL-701 induced a PR (15 months in a child with radiation-resistant brainstem glioma)



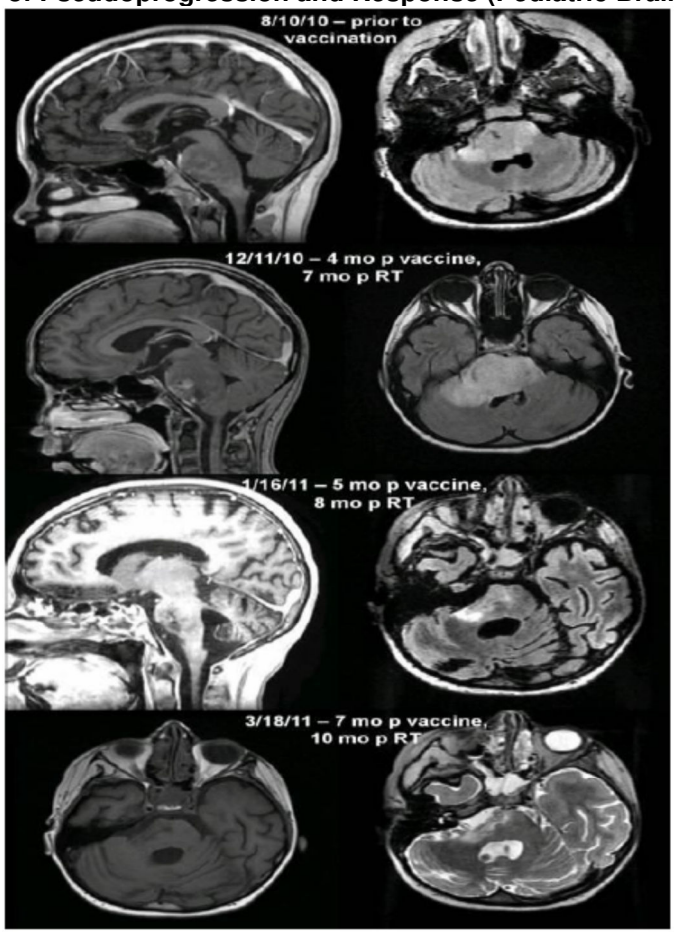
Source: Stemline company presentation June 2013

Summary of pediatric patients with glioma:

- 86% (19/22) of patients showed an overall response or disease stabilization.
- 3 partial responses (PRs) with two of those being ≥14 months in duration
- 1 patient with prolonged (20 months) disease free survival while on SL-701 after surgery
- 4 stable disease (SD) patients with survival ≥13 months
- Positive immunological assays (ELISPOT and tetramer assays) were demonstrated in 6 of 7 evaluable children.

An interesting observation came out of this study where four patients exhibited what is known as pseudoprogression of their tumors. It manifests by edema and contrast enhancement on MRI scans. As the field of cancer immunotherapy has progressed, this pseudoprogression phenomenon is thought to potentially be a surrogate marker for anti-tumor activity (discussed below). The scans below indicated one of the patients where this was seen, showing an apparent increase in the tumor size at the December 2010 scan relative to the baseline scan in August 2010.

MRI Evolution of Pseudoprogression and Response (Pediatric Brainstem Glioma)



Source: Stemline – AACR April 2012 presentation

We look to the FDA, who we believe has actually been relatively progressive regarding cancer immunotherapy. The agency occasionally puts out draft guidance for industry for particular indications, clinical trial strategies and endpoint discussions. In 2009, the FDA published what we consider to be a very important document that discusses the potential reasons for a cancer immunotherapy not showing effects on progression free survival, and put it in writing (something not usually associated with the FDA).

We put forward the following section from the September 2009 Draft Guidance on "Clinical Considerations for Therapeutic Cancer Vaccines".

"Disease progression/recurrence immediately or shortly after the initial administration of cancer vaccines"
"In oncologic practice, patients are usually taken off current treatment when they have disease progression/recurrence. Because cancer vaccines need time to elicit an immune response that could manifest as biological activity (i.e., a tumor specific immune response), a delayed effect can be expected in the subjects who have received the vaccines. Shortly after the initial cancer vaccine administration, subjects may experience disease progression prior to the onset of biological activities or effects from the vaccine (delayed effects).

One potential approach to this situation would be to clearly define a description of disease status for which continued vaccination is intended in the clinical study protocol. The following are potential clinical situations in which you may wish to consider providing provisions in the protocol for continued vaccination.

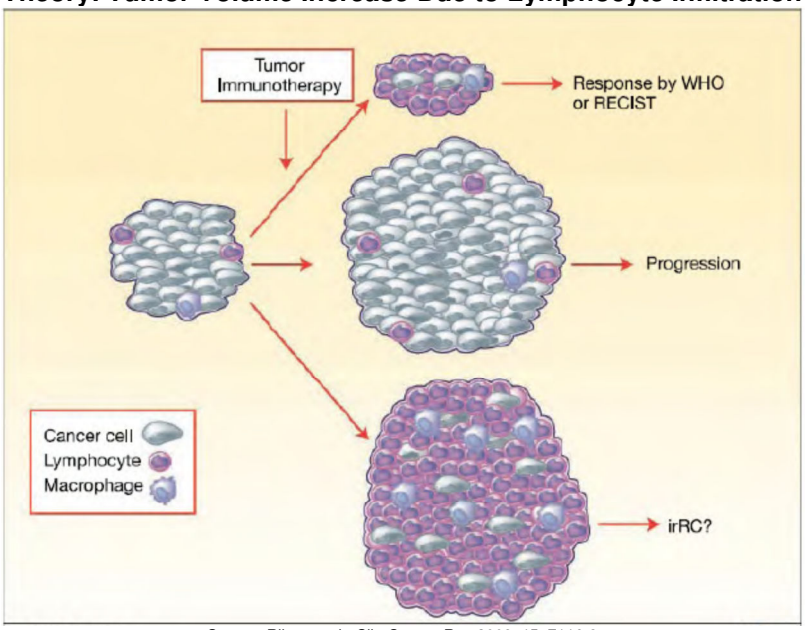
- *Subjects continue to meet all other study protocol eligibility criteria.*
- *No dose limiting toxicity (DLT) has been observed and all toxicities resolved to the baseline level consistent with the entry eligibility criteria.*

- *Subjects may only receive the same dose and schedule that was given before disease progression/recurrence occurs/reoccurs."*

Source: FDA guidance, Sept 2009,
http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Vaccines/UCM182826.pdf)

There are various theories and work being conducted in the field as to why using "conventional criteria" does not necessarily show responses using an immunotherapy approach and why disease progression might be observed (according to conventional metrics). We highlight one potential example in the figure below. Specifically, one potential mechanism of seeing "progression" is that the tumor is becoming infiltrated by immune cells in order to attack the tumor giving the impression of tumor progression. On the proceeding chart, irRC stands for "immune response Response Criteria". One of the theories is that tumors being attacked by an immunotherapy approach might not be entirely eradicated but rather kept "in check".

Theory: Tumor Volume Increase Due to Lymphocyte Infiltration



Source: Ribas et al., Clin Cancer Res 2009; 15: 7116-8

SL-701 Plans and next steps

Two studies are planned to bring the SL-701 program forward. The first is a Phase II pediatric non-brainstem and brainstem glioma study. This study will be performed in collaboration with the St. Jude's Children's Research Hospital and the Pediatric Brain Tumor Consortium. On the adult front, Stemline will be initiating a Phase II 2nd-line GBM study. Depending on the results of this study, the data will be used to design a pivotal Phase III study, however, based on the unmet medical need in the recurrent GBM, alternative more accelerated registration plans may be discussed. Based on the upcoming data at SNO, the company will also now explore the potential of moving SL-701 into advanced clinical studies in low-grade glioma.

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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Regulation Analyst Certification ("Reg AC"): The research analyst primarily responsible for the content of this report certifies the following under Reg AC: I hereby certify that all views expressed in this report accurately reflect my personal views about the subject company or companies and its or their securities. I also certify that no part of my compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in this report.

Disclosures:

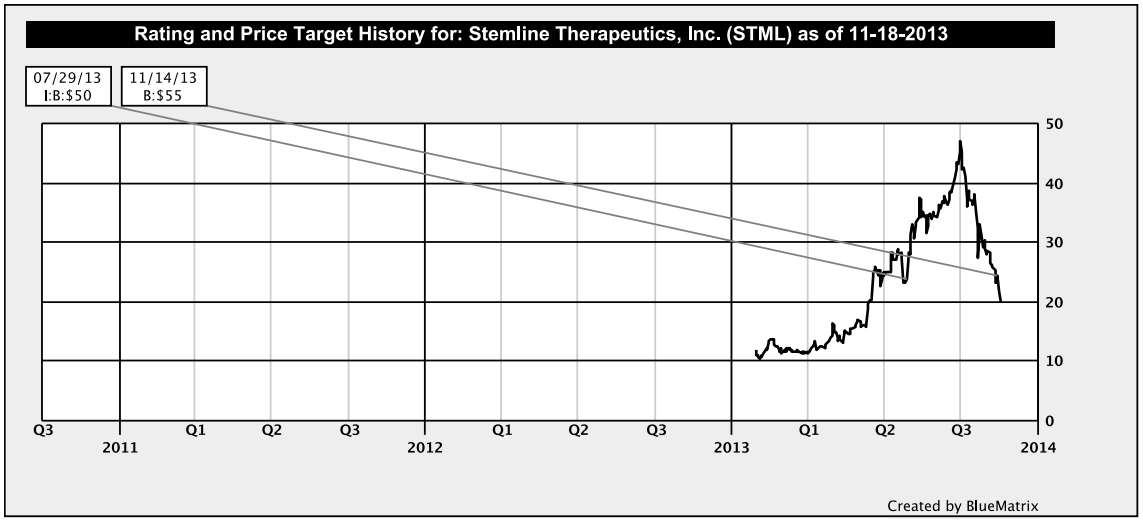
Within the last twelve months, ROTH has received compensation for investment banking services from Stemline Therapeutics, Inc..

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 11/19/13	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**157**	**70.40**	**86**	**54.78**
Neutral [N]	**37**	**16.59**	**11**	**29.73**
Sell [S]	**2**	**0.90**	**0**	**0**
Under Review [UR]	**26**	**11.66**	**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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