



October 30, 2013

Key Metrics

STML - NASDAQ	\$29.74
Pricing Date	Oct 30 2013
Price Target	\$70.00
52-Week Range	\$47.25 - \$10.33
Shares Outstanding (mm)	12.3
Market Capitalization (\$mm)	\$365.8
3-Mo Average Daily Volume	189,545
Institutional Ownership	11%
Debt/Total Capital	NM
ROE	NM
Book Value/Share	\$7.30
Price/Book	4.1x
Dividend Yield	NM
LTM EBITDA Margin	NM

EPS (\$ FY: December

	2012A	Prior 2013E	Curr. 2013E	Prior 2014E	Curr. 2014E
1Q-Mar	(0.39)	--	(0.90)A	--	(0.46)E
2Q-Jun	(0.50)	--	(0.55)A	--	(0.43)E
3Q-Sep	(0.55)	--	(0.42)E	--	(0.41)E
4Q-Dec	(0.60)	--	(0.44)E	--	(0.42)E
FY	(1.82)	--	(2.12)E	--	(1.70)E
P/E	NM		NM		NM



Source: BigCharts.com

Company Description:

Stemline Therapeutics, Inc. (<http://www.stemline.com/>) is a biotechnology firm headquartered in New York, NY.

Stemline Therapeutics, Inc.**Rating: Buy****Scientific Data Adds Value: Raising Price Target****Investment Highlights:**

- Promise In New Indications - Raising Price Target.** Stemline has reported favorable preclinical data for its lead drug candidate, SL-401, in areas such as multiple myeloma (MM) and chronic myelogenous leukemia (CML). In our view, market authorization for SL-401 in MM and additional niche hematological malignancies on top of blastic plasmacytoid dendritic cell neoplasm (BPDCN) and acute myeloid leukemia (AML) could drive peak sales potential from \$800mm to over \$3bn. Further, Stemline's follow-up candidate to SL-401, known as SL-501, is a variant interleukin-3-diphtheria toxin fusion protein that could be used to target CML as a new product. In the wake of these positive developments and in anticipation of further BPDCN data at the American Society for Hematology (ASH) meeting in New Orleans, LA in early December 2013, we reiterate our Buy rating and raise our price target from \$40.00 to \$70.00 on Stemline shares with a 15-month time frame.
- Funding From Leukemia & Lymphoma Society.** Yesterday, Stemline and the Leukemia & Lymphoma Society announced a partnership to accelerate the development of SL-401 for AML and BPDCN. LLS has committed over \$3mm to support this effort, as well as providing a comprehensive educational program to increase physician and patient awareness of BPDCN. In our view, this is a prestigious and valuable collaboration.
- Additional SL-401 Clinical Data Coming Soon.** We expect Stemline to report clinical data from additional patients treated with SL-401 by the end of the year. Much of this data is likely to be presented at the ASH Meeting in December 2013. Furthermore, Stemline is currently completing the final stages of a larger-scale manufacturing run for SL-401, which should provide sufficient cGMP-grade material to conduct additional clinical studies in BPDCN, AML and other niche hematological malignancies such as hairy cell leukemia. In our view, positive data from these indications could substantially increase the value of this candidate.
- No Near-Term Financing Overhang.** Stemline currently trades at an enterprise value of ~\$370mm, whereas other firms with mid- to late-stage oncology assets typically trade in the \$500mm - \$1bn range. We consider the recent weakness in the wake of speculation concerning a near-term financing to be a buying opportunity. Stemline closed 2Q 2013 with over \$90mm in cash on hand, and in our view is well-funded into 2015 with existing capital.

Investment Risks

Financial Outlook. Stemline Therapeutics has been unprofitable since inception and may require additional capital in order to drive the future clinical development of its pipeline and finance the acquisition of other products and pipeline candidates. Thus, the company's stock could experience above-average risk and volatility, in our opinion.

FDA Unpredictability. New therapeutics development is a multi-year process that requires human clinical trials prior to FDA approval. The amount of additional clinical data that may be required to support regulatory filings on Stemline Therapeutics' drug candidates is unclear at this juncture, making it impossible to predict the precise timing of market entry and revenue generation. The FDA could also ask for additional data on Stemline's experimental candidates prior to granting formal licensure. Also, review times at the FDA may take longer than originally expected.

Competitive Landscape. Stemline Therapeutics is likely to face competitors with greater financial resources and larger organizations for marketing, sales, distribution, and service, assuming that the firm's candidates successfully obtain regulatory approval. Many of Stemline's peers may have stronger links to reimbursement agencies. This may allow them to establish more favorable relationships with payers than Stemline.

Partnership Risk. Thus far, Stemline lacks commercial experience as an entity and could eventually find itself having to rely upon partners to establish sales and marketing support for its products if they reach the market. Accordingly, therefore, the company is likely to be dependent upon such sub-licensees to execute on the commercialization of Stemline's proprietary drugs. In addition, certain elements of Stemline's intellectual property and drug candidate ownership rights are licensed from third parties. Should these third parties revoke the rights that they originally provided to Stemline, the company may be unable to further develop its candidate drugs or realize profits from their commercialization.

Intellectual Property. Stemline Therapeutics relies on patents and trade secrets to protect its products from competition. The pharmaceutical industry is litigious, and lawsuits are considered to be a normal part of doing business. A court might not uphold Stemline's intellectual property rights, or it could find that Stemline infringed upon another party's property rights. The company is also dependent in part upon the continued validity of intellectual property in-licensed from third parties.

Industry risks. The securities of emerging biotechnology and specialty pharmaceuticals companies are inherently volatile and increasingly subject to development and regulatory risk. Meeting or missing commercial milestones may result in changes in the perception of the firm and the stock price. We do not anticipate volatility to subside near-term.

For additional risk considerations, please refer to the company's SEC filings.

Valuation

Risk-Adjusted Net Present Value Analysis

We have projected the total firm value for Stemline Therapeutics based upon a sum-of-the-parts valuation. We are forecasting peak revenues for the firm's two clinical-stage drug candidates — SL-401 and SL-701 — of roughly \$3 billion and \$240 million, respectively. This calculation yields a risk-adjusted NPV of roughly \$865 million for these two candidates (see Table 1, below). Our estimates factor in a 40% tax rate and a 20% discount rate on future cash flows. The follow-on molecule to SL-401, designated SL-501, could have applicability in chronic myelogenous leukemia (CML). Since the mechanism of action has been validated, we give this agent a 40% probability of success and ascribe a \$100 million NPV to it despite its preclinical status. We also project that the other preclinical candidates in Stemline's pipeline could provide a \$50 million rNPV contribution. Finally, we ascribe a \$30 million rNPV contribution to the firm's proprietary StemScreen[®] technology platform, which could be leveraged through research agreements or licensing deals to garner additional revenue for the firm.

Thus, the total calculated firm value should, in our view, approximate \$1 billion. In this way, we believe, investors should note that the current market cap of Stemline neither appropriately values the company based on its existing clinical-stage pipeline and its potential for an accelerated pathway to commercialization, nor does it give the company any credit for an early – yet highly diversified – preclinical portfolio or the StemScreen[®] technology platform. Thus, we believe that Stemline Therapeutics may be an undervalued investment proposition with substantial risk-mitigation at this juncture.

Table 1: Composite Net Present Value (rNPV) Analysis

Stemline Therapeutics								
	Product	Launch Year	Patent Expiry	Peak Sales	Royalty Rate	Probability To Launch	NPV	Amount Per Share
Phase 2 / 3								
Hematological Malignancies	SL-401	2015	2027	\$800MM	NA	75%	\$800MM	\$46.40
Brain Cancer	SL-701	2016	2025	\$240MM	NA	60%	\$65MM	\$3.80
Preclinical								
Chronic myelogenous leukemia	SL-501	2019	2032	\$1.5B	NA	40%	\$100MM	\$5.80
Pipeline Candidates	Various	2020	2032	NA	NA	30%	\$50MM	\$3.00
Platform	StemScreen™	NA	NA	NA	NA	NA	\$30MM	\$1.90
Total							\$1.04B	\$61.00
Debt at end-2014							\$MM	
Cash at end-2014							\$140MM	\$9.00
Firm Value							\$1.2B	\$70.00

Source: Company reports; Aegis Capital Corp. estimates

It is appropriate, in our view, to examine the relative valuations of OncoMed Pharmaceuticals, Inc. and Stemline Therapeutics at this juncture. Another CSC-focused company, OncoMed was the subject of a highly-publicized IPO in 2013. Currently, OncoMed trades at a market capitalization of approximately \$410 million, while Stemline now trades at a market capitalization of roughly \$370 million. On an enterprise value basis, OncoMed is currently trading at a premium to the value being attributed by the market to Stemline's pipeline and technology platform.

We note that, of all the cancer stem cell-targeting companies with public listings, Stemline is the only one with a rapid path to regulatory approval. Stemline possesses a lead candidate in SL-401 that could reach the market faster than any of OncoMed's candidates given the accelerated development path possible in BPDCN. Further, we believe that Stemline's CSC-focused early-stage pipeline may be superior in value to OncoMed's portfolio because of the nature of Stemline's screening platform, which in our view is positioned to reliably detect cancer stem cell-targeting drug candidates.

Comparables Analysis

Based on a comparable company analysis, it appears to us that the stock is worth approximately \$70.00 per share (see Table 2, below). This assumes that the shares trade in line with the comp group average enterprise value of roughly \$1.1 billion and that the firm has approximately 17 million shares outstanding as of the end of 2014. We believe that a comparison to a broad-based group of firms across oncology is warranted, since Stemline has a diversified pipeline and competes across multiple cancer types.

Table 2: Comparable Company Analysis
(Millions, Except Per-Share Data)

Development	Therapeutic Area	Company	Ticker	Rating	Closing price 10/29/2013	Shares (MM)	Market cap (\$MM)	Cash (\$MM)	Debt (\$MM)	Enterprise value (\$MM)
Preclinical	Oncology	Agius Pharmaceuticals	AGIO	Not Rated	\$25.68	31	798	99	0	699
Phase 2	RNAi	Alnylam Pharmaceuticals	ALNY	Not Rated	\$61.49	63	3871	210	0	3662
Phase 2	Oncology	Array BioPharma	ARRY	Not Rated	\$55.63	117	659	108	99	650
Phase 1 / 2	Oncology	Clovis Oncology	CLVS	Not Rated	\$55.87	30	1686	372	0	1313
Phase 1 / 2	Oncology	Epizyme	EPZM	Not Rated	\$40.37	28	1147	140	0	1007
Phase 3	Orphan Diseases	Synageva BioPharma	GEVA	Not Rated	\$59.39	27	1632	285	0	1347
Phase 1 / 2	Oncology	Infinity Pharmaceuticals	INFI	Not Rated	\$14.18	48	680	277	0	404
Phase 1 / 2	Oncology	Oncomed Pharmaceuticals	OMED	Not Rated	\$14.63	28	407	56	0	351
Phase 2 / 3	Oncology	Puma Biotechnology, Inc.	PBYI	Not Rated	\$42.42	29	1217	108	0	1109
Phase 2	Oncology	Verastem, Inc.	VSTM	Not Rated	\$10.57	26	270	57	0	213
Average							1237			1076
								Discrepancy		
Current valuation	Oncology	Stemline Therapeutics, Inc.	STML	Buy	\$30.26	12	372	93	0	279
Derived 12-month compa-month comparable value										
Target valuation (18-month)	Oncology	Stemline Therapeutics, Inc.	STML	Buy	\$70.00	17	1216	140	0	1076

Source: First Call and Aegis Capital Corp. estimates

Free Cash Flow: We believe that Stemline Therapeutics is likely to remain unprofitable for the foreseeable future. We define free cash flow as operating cash flow minus capital expenditures and dividend payments. We utilize a discounted cash flow analysis supporting a risk-adjusted Net Present Value (rNPV) framework to derive our \$70.00 price target. This approach is described further in the next section of the report.

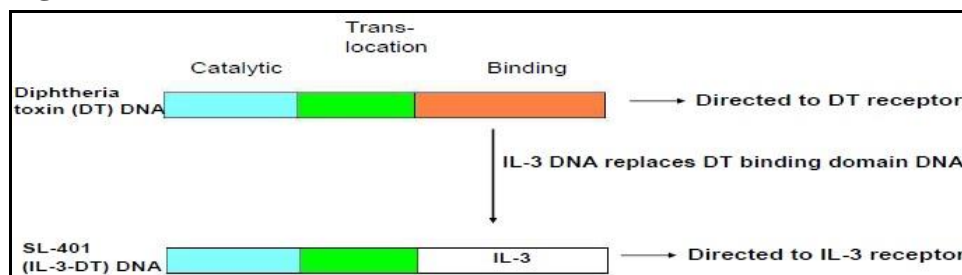
Our detailed analysis is split into three principal components: our discounted cash flow model, including the rNPV assessment of Stemline Therapeutics' clinical-stage development pipeline (presented in the preceding section); our assessment of the markets for Stemline's principal pipeline candidates, and the associated sales model for these drugs; and the near-term financial outlook for the company. Our historical income statement and financial projections are presented toward the back of this report.

Taxes: Stemline Therapeutics, Inc. has guided towards the expectation that the company is likely to continue to report net operating losses for the next several years, as the development of SL-401 and SL-701 through proof-of-concept and registration-quality clinical trials continues. Accordingly, therefore, we do not anticipate substantial tax liability for the foreseeable future. While the firm has not – unlike the majority of biotechnology firms that have been in existence for similar periods of time – accumulated a massive amount of net operating loss carry-forwards, we believe that by the time SL-401 and SL-701 reach the market, the net operating loss carry-forwards that would have been accumulated should offset taxes in the initial launch years of both products. Eventually, however, we would expect that the effective tax rate to be applied in the case of Stemline Therapeutics is likely to approach the federal U.S. statutory corporate tax rate of 35% plus the appropriate state-based tax supplement. Using these assumptions, we apply a roughly 40% effective tax rate to future cash flows.

Recent Scientific Data

Over the course of the past several weeks, Stemline has presented favorable scientific data on the applicability of SL-401 in both multiple myeloma as well as chronic myelogenous leukemia (CML). Epidemiological data indicates that these malignancies are far more prevalent than BPDCN. The potential for SL-401 in multiple myeloma and additional niche indications beyond BPDCN (including hairy cell leukemia and NK / T cell lymphomas) is the primary rationale for our improved outlook and raised price target.

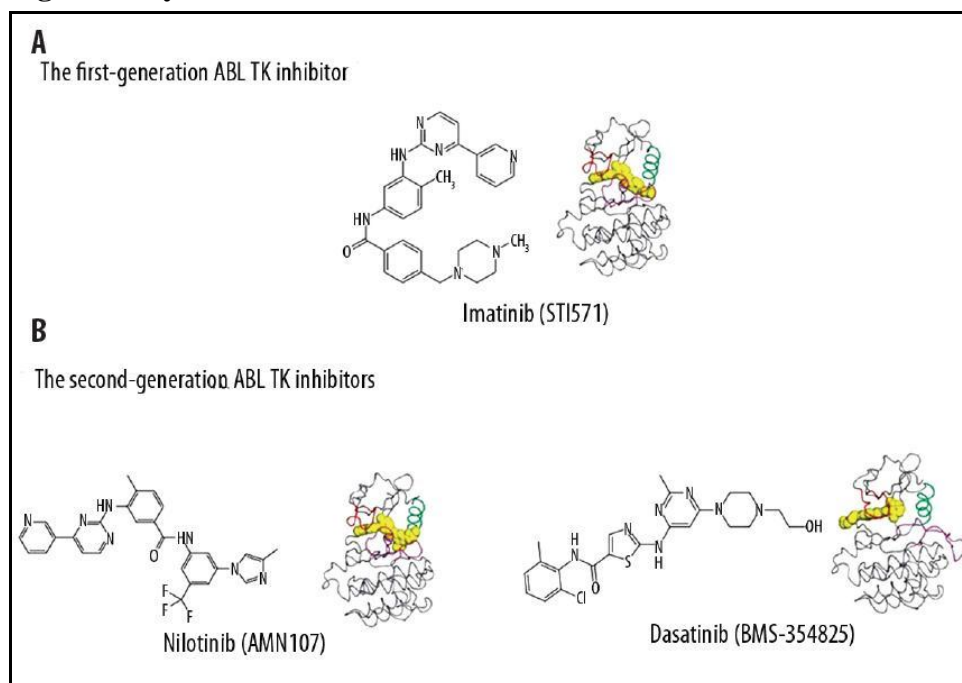
Figure 1: SL-401 Domain Structure



Source: Stemline Therapeutics

We would also point investors to the favorable preclinical data on SL-401 presented by Dr. Marina Konopleva of the world-renowned University of Texas MD Anderson Cancer Center at the 15th International Conference on CML in Estoril, Portugal. While Gleevec (STI571 / imatinib mesylate) and other tyrosine kinase inhibitors (TKIs) have shown considerable efficacy in CML, patients can fail all of them. This is largely because TKIs have limited activity against CD34⁺/CD38⁻ leukemic stem cells (cancer stem cells).

Figure 2: Tyrosine Kinase Inhibitors Utilized In CML



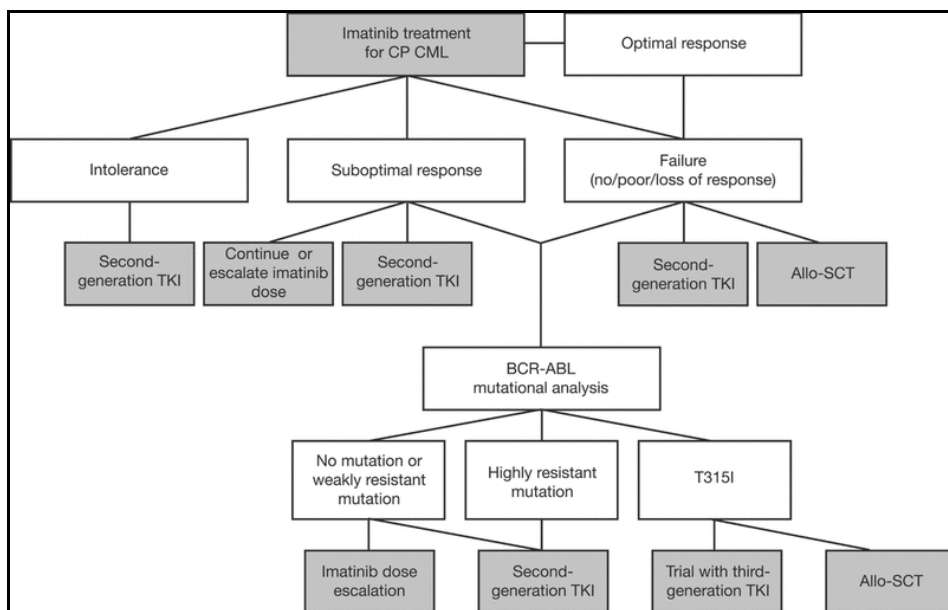
Source: EvaluatePharma

Expression of the IL3 receptor (IL-3R) has been demonstrated on CD34⁺/CD38⁻ leukemic stem cells in many hematological malignancies. However, its role in CML stem cells has not been fully investigated. The MD Anderson researchers found that IL-3R is highly expressed on CD34⁺/CD38⁻ BCR-ABL⁺ stem cells in samples from CML patients in chronic or blast crisis phases. These scientists then examined whether targeting IL-3R with SL-401, which is specifically directed to the IL-3R, could eradicate CML stem cells.

In her presentation, Dr. Konopleva described how SL-401 inhibited cell growth and induced moderate apoptosis in the KBM5 CML-like cell line and its TKI resistant KBM5-ST-I sub-line. Combining Gleevec (1 μ M) with SL-401 (1 μ g/ml) enhanced the apoptotic rate in KBM5, KBM5-STI cells and in primary CML cells (n = 6, p<0.01). In six primary CML samples, including CML cells harboring the T315I mutation that is known to confer resistance to Gleevec, SL-401 reduced the absolute numbers of viable CD34⁺/CD38⁻/CD123⁺ CML progenitor cells (p \leq 0.03) by inducing apoptosis. In order to evaluate the effect on the growth of the most primitive stem cells, CML blasts were pretreated with SL-401 and grown in the Long-Term Culture-Initiating Cell (LTC-IC) assay. The drug significantly reduced the formation of colonies in four primary samples in a dose-dependent manner (average 80% reduction in colony-forming ability at 1 μ g/ml, p \leq 0.009). One cycle of SL-401 (0.2mg/kg daily intra-peritoneally for 5 days) improved the survival of xenograft mice injected with primary CML cells from a TKI-resistant CML blast crisis patient vs. control mice (48 days vs. 37 days, respectively; p = 0.0005).

Thus, in totality these data indicate that SL-401 has novel therapeutic activity for the selective targeting of CML stem cells, and may augment the current therapeutic armamentarium used in CML, which principally targets the tumor bulk. We believe that Stemline may elect to either develop SL-401 for CML or potentially elevate SL-501 as the principal CML-targeting drug. SL-501 is very similar in design to SL-401, and was originated from the same institution – Scott and White Memorial Hospital – in Bell County, TX. Originally referred to as DTIL3K116W, SL-501 is a second-generation IL-3R-targeting agent, typically referred to as a variant diphtheria toxin-IL-3 fusion protein. As shown below, there are multiple points on the CML treatment continuum that could be targeted by either SL-401 or SL-501, making this an attractive opportunity.

Figure 3: CML Treatment Continuum



Source: American Society for Hematology (ASH)

Table 3: Stemline Therapeutics, Inc. (STML) – Historical Income Statements, Financial Projections

FY end December 31

\$ in thousands, except per share data

	2011A	2012A	2013E				2013E	2014E				
			1QA	2QA	3QE	4QE		1QE	2QE	3QE	4QE	2014E
Revenue												
Product revenue	-	-	-	-	-	-	-	-	-	-	-	-
Contract research	-	-	-	-	-	-	-	-	-	-	-	-
Total revenue	-	-	-	-	-	-	-	-	-	-	-	-
Expenses												
Research & development	1,629	3,377	3,162	4,085	4,200	4,400	15,846	4,500	4,600	4,700	4,800	18,600
General and administrative	1,088	3,091	2,167	1,071	1,100	1,200	5,539	1,300	1,400	1,500	1,600	5,800
Total expenses	2,717	6,468	5,329	5,156	5,300	5,600	21,385	5,800	6,000	6,200	6,400	24,400
Gain (loss) from operations	(2,717)	(6,468)	(5,329)	(5,156)	(5,300)	(5,600)	(21,385)	(5,800)	(6,000)	(6,200)	(6,400)	(24,400)
Other income/expense												
Interest income	24	10	-	3	23	18	44	15	6	14	17	52
Interest expense	(99)	(119)	(82)	(298)	-	-	(380)	-	-	-	-	-
Other income	47	302	31	-	-	-	31	-	-	-	-	-
Other expense	(10)	(0)	(125)	-	-	-	(125)	-	-	-	-	-
Total investment income and other	(38)	193	(176)	(295)	23	18	(430)	15	6	14	17	52
Loss before provision for income taxes	(2,755)	(6,275)	(5,506)	(5,451)	(5,277)	(5,582)	(21,815)	(5,785)	(5,994)	(6,186)	(6,383)	(24,348)
Income tax benefit (loss)	-	-	-	-	-	-	-	-	-	-	-	-
Net loss/income	(2,755)	(6,275)	(5,506)	(5,451)	(5,277)	(5,582)	(21,815)	(5,785)	(5,994)	(6,186)	(6,383)	(24,348)
Net loss per share (basic)	(0.80)	(1.82)	(0.90)	(0.55)	(0.42)	(0.44)	(2.12)	(0.46)	(0.43)	(0.41)	(0.42)	(1.70)
Net loss per share (diluted)	(0.80)	(1.82)	(0.90)	(0.55)	(0.42)	(0.44)	(2.12)	(0.46)	(0.43)	(0.41)	(0.42)	(1.70)
Weighted average number of shares outstanding (basic)	3,442	3,442	6,148	9,837	12,564	12,614	10,291	12,664	13,964	15,264	15,314	14,302
Weighted average number of shares outstanding (diluted)	3,442	3,442	6,148	9,837	12,564	12,614	10,291	12,664	13,964	15,264	15,314	14,302

Source: Company Reports and Aegis Capital Corp. estimates

Required Disclosures

Price Target

Our 15-month price target is \$70.00 per share.

Valuation Methodology

We derive our price target using a discounted cash flow-based sum-of-the-parts analysis approach, which derives a \$1.04 billion total enterprise value for the company's clinical-stage assets, SL-401 and SL-701, as well as the early-stage pipeline and the proprietary cancer stem cell-targeting drug discovery platform. Our total firm valuation of \$1.2 billion assumes ~\$140 million in cash as of the end of 2014; this translates into a price target of \$70.00 per share based on approximately 17 million shares (fully-diluted) and no debt as of the end of 2014.

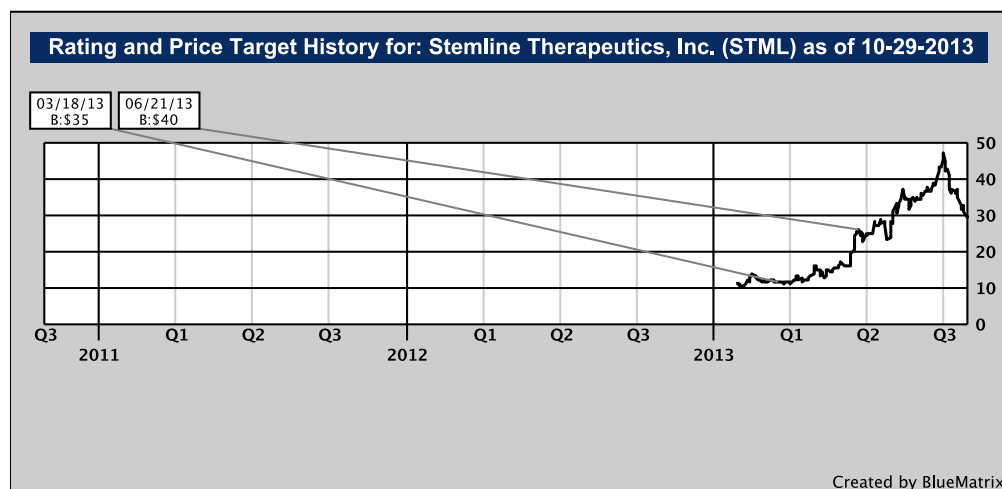
Risk Factors

Various factors may impede or prevent achievement of the price target by the company's shares. Such risk factors may include, but are not limited to, clinical, regulatory, competitive, financial, and reimbursement issues. Products that have yet to be submitted to regulatory agencies for review may not reach the market due to regulatory concerns, which could preclude approval. The company may require financing to sustain and grow its pipeline, which could be dilutive to current shareholders. We expect competition from existing entities against the company's products.

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Rating	Investment Banking Services/Past 12 Mos.	
	Percent	Percent
BUY [BUY]	86.11	29.03
HOLD [HOLD]	13.89	0.00
SELL [SELL]	0.00	0.00

Meaning of Ratings

- A) A Buy rating is assigned when we do not believe the stock price adequately reflects a company's prospects over 12-18 months.
- B) A Hold rating is assigned when we believe the stock price adequately reflects a company's prospects over 12-18 months.
- C) A Sell rating is assigned when we believe the stock price more than adequately reflects a company's prospects over 12-18 months.

Other Disclosures

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