AEGIS CAPITAL CORP

Biotechnology
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Company Update / Price Target Change / Estimates Change

June 21, 2013

Stemline Therapeutics, Inc.

Rating: Buy

Stemline Stays On Fast Track: Raising Price Target

Key Metrics

STML - NASDAQ	$25.43
Pricing Date	Jun 20 2013
Price Target	$40.00
52-Week Range	$25.73 - $10.33
Shares Outstanding (mm)	12.4
Market Capitalization ($mm)	$315.3
3-Mo Average Daily Volume	99,167
Institutional Ownership	NM
Debt/Total Capital	NM
ROE	NM
Book Value/Share	$3.84
Price/Book	6.6x
Dividend Yield	NM
LTM EBITDA Margin	NM

EPS ($) FY: December

	2012A	Prior 2013E	Curr. 2013E	Prior 2014E	Curr. 2014E
1Q-Mar	(0.39)	(0.42)E	(0.90)A	(0.50)E	(0.47)E
2Q-Jun	(0.50)	(0.36)E	(0.53)E	(0.47)E	(0.43)E
3Q-Sep	(0.55)	(0.40)E	(0.44)E	(0.46)E	(0.40)E
4Q-Dec	(0.60)	--	(0.45)E	(0.51)E	(0.41)E
FY	(1.82)	(1.61)E	(2.14)E	(1.94)E	(1.70)E
P/E	NM		NM		NM

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

Investment Highlights:

- **Raising Price Target.** Given the recent progress at Stemline Therapeutics and the fact that the company - following its most recent equity financing - now appears to be exceptionally well-funded, we are maintaining our Buy rating and instituting a 12-month price target of $40.00 per share vs. our original 18-month price target of $35.00 per share. The small-cap oncology sector continues to find favor among biotechnology-focused investors, and we anticipate that Stemline should continue to attract interest based on the accelerated development pathway for its lead drug candidate, SL-401, in blastic plasmacytoid dendritic cell neoplasm (BPDCN) and other hematological malignancies. We note that Stemline has thus far been the best-performing biotech IPO of 2013, and anticipate further outperformance going forward as the firm advances the development of multiple drug candidates simultaneously through the deployment of its strengthened cash resources.
- **Risk-Mitigated Clinical-Stage Pipeline.** The company's lead drug candidate, SL-401, is risk-mitigated from a regulatory as well as a clinical perspective, as it is a fusion protein that utilizes the interleukin-3 (IL-3) protein linked to an exotoxin from the bacterium that causes the infectious disease diphtheria. The drug is internalized into cells expressing high levels of the IL-3 receptor and, once inside, the diphtheria toxin kills the cells. Since many cancer cells in blood cancers express the IL-3 receptor, this drug selectively ablates both tumor bulk and CSCs without injuring healthy tissue. We expect Stemline to complete a scaled-up manufacturing run for SL-401 in the coming weeks and utilize this material to begin testing the drug in additional patients with BPDCN, as well as subjects suffering from other rare blood cancers such as hairy cell leukemia. Stemline's second candidate, SL-701, is a peptide vaccine for brain cancers. Both SL-401 and SL-701 have shown strong survival-enhancing effects in their respective target indications.
- **100% Response Rate Thus Far.** BPDCN, which only afflicts 2,000 people a year, is known as a cancer type associated with high levels of IL-3 receptor expression. Thus far, SL-401 has elicited responses (either partial or complete) in all of the BPDCN patients treated with the drug. If this response rate continues, we believe that the firm could file for approval early next year. In our base case scenario, we project that Stemline could obtain approval for SL-401 on the basis of a single, randomized, open-label study enrolling 40 patients. Under this scenario, the drug could be on the market in late 2015.
- **Valuation Remains Attractive, Despite Recent Runup.** Stemline currently trades at an enterprise value of ~$300mm following the most recent financing, whereas other companies with mid- to late-stage oncology assets typically trade in the $500mm - $1bn range. The firm was founded in 2003 and to date has spent under $20mm.

The Disclosure section may be found on pages 6 - 7 of this report.

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 continue 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 $800 million and $240 million, respectively. This calculation yields a risk-adjusted NPV of roughly $415 million for these two candidates (see Table 1, below). Our estimates factor in a 40% tax rate and a 15% – 20% discount rate on future cash flows. We also project that the preclinical candidates in Stemline's pipeline could provide a $40 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 $625 million. 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%	$350MM	$21.00
Brain Cancer	**SL-701**	2016	2025	$240MM	NA	60%	$65MM	$4.00
Preclinical								
Pipeline Candidates	**Various**	2020	2032	NA	NA	30%	$40MM	$3.00
Platform	**StemScreen™**	NA	NA	NA	NA	NA	$30MM	$2.00
Total							$485MM	$30.00
Debt at end-2Q 2014							$MM	
Cash at end-2Q 2014							$137MM	$10.00
Firm Value							$625MM	$40.00

Source: Company reports; Aegis Capital Corp. estimates

It is appropriate, in our view, to examine the relative valuations of Verastem, Inc. and Stemline Therapeutics at this juncture. Another CSC-focused company, Verastem was the subject of a highly-publicized IPO in 2012. Currently, Verastem trades at a market capitalization of approximately $260 million, while Stemline now trades at a market capitalization of roughly $300 million. On an enterprise value basis, Verastem is currently trading at a slight discount to the value being attributed by the market to Stemline's pipeline and technology platform. When Stemline initially went public, it was trading at roughly a third of the Verastem market cap.

Stemline possesses a lead candidate in SL-401 that could reach the market faster than any of Verastem'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 Verastem's portfolio because some of Stemline's candidates are monoclonal antibodies, which are difficult to genericize, whereas Verastem is developing small molecules that are simpler for generics firms to copy. In our view, the recent rise in Stemline's share price has simply served to bring the company's valuation in line with that of Verastem – while there could be significant additional upside given indications that Stemline's pipeline and technology platforms could be superior to those of Verastem.

Comparables Analysis

Based on a comparable company analysis, it appears to us that the stock is worth approximately $40.00 per share (see Table 2, below). This assumes that the shares trade in line with the comp group average enterprise value of roughly $560 million and that the firm has approximately 17 million shares outstanding as of mid-2014. We believe that a comparison to a broad-based group of firms across the oncology domain 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 6/20/2013	Shares (MM)	Market cap ($MM)	Cash ($MM)	Debt ($MM)	Enterprise value ($MM)
Phase 2	Oncology	Array BioPharma	ARRY	Not Rated	$4.66	117	544	87	96	553
Phase 2	Oncology	Celldex Therapeutics	CLDX	Not Rated	$14.29	81	1156	182	10	983
Phase 1 / 2	Oncology	Clovis Oncology	CLVS	Not Rated	$61.99	30	1865	350	0	1515
Phase 2 / 3	Oncology	ImmunoCellular Therapeutics	IMUC	Not Rated	$2.17	53	114	24	0	90
Phase 1 / 2	Oncology	Infinity Pharmaceuticals	INFI	Not Rated	$18.36	48	878	303	0	576
Phase 1 / 2	Oncology	Merrimack Pharmaceuticals	MACK	Not Rated	$5.83	96	560	87	40	514
Phase 3	Oncology	Northwest Biotherapeutics	NWBO	Not Rated	$3.46	30	104	10	3	98
Phase 3	Oncology	OncoGenex Pharmaceuticals	OGXI	Not Rated	$9.36	15	137	65	0	73
Phase 2 / 3	Oncology	Puma Biotechnology, Inc.	PBYI	Not Rated	$38.89	29	1115	119	0	997
Phase 2	Oncology	Verastem, Inc.	VSTM	Not Rated	$12.38	21	264	67	0	197
		Average					**674**			**560**
								Discrepancy		
Current valuation	**Oncology**	**Stemline Therapeutics, Inc.**	**STML**	**Buy**	**$25.43**	**12**	**316**	**95**	**0**	**221**
					Derived 12-month compa-month comparable value					
										Projected
Target valuation (18-month)	**Oncology**	**Stemline Therapeutics, Inc.**	**STML**	**Buy**	**$40.00**	**17**	**698**	**137**	**0**	**560**

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 $40.00 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.

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

FY end December 31
$ in thousands, except per share data

			2013E					2014E				
	2011A	2012A	1QA	2QE	3QE	4QE	2013E	1QE	2QE	3QE	4QE	2014E
Revenue												
Product revenue	-	-	-	-	-	-	-	-	-	-	-	-
Contract research	-	-	-	-	-	-	-	-	-	-	-	-
Total revenue	-	-	-	-	-	-	-	-	-	-	-	-
Expenses												
Research & development	1,629	3,377	3,162	3,100	3,200	3,300	12,762	3,400	3,500	3,600	3,700	14,200
General and administrative	1,088	3,091	2,167	2,200	2,300	2,400	9,067	2,500	2,500	2,500	2,500	10,000
Total expenses	2,717	6,468	5,329	5,300	5,500	5,700	21,829	5,900	6,000	6,100	6,200	24,200
Gain (loss) from operations	(2,717)	(6,468)	(5,329)	(5,300)	(5,500)	(5,700)	(21,829)	(5,900)	(6,000)	(6,100)	(6,200)	(24,200)
Other income/expense												
Interest income	24	10	-	29	23	18	70	15	6	14	17	52
Interest expense	(99)	(119)	(82)	-	-	-	(82)	-	-	-	-	-
Other income	47	302	31	-	-	-	31	-	-	-	-	-
Other expense	(10)	(0)	(125)	-	-	-	(125)	-	-	-	-	-
Total investment income and other	(38)	193	(176)	29	23	18	(106)	15	6	14	17	52
Loss before provision for income taxes	(2,755)	(6,275)	(5,506)	(5,271)	(5,477)	(5,682)	(21,936)	(5,885)	(5,994)	(6,086)	(6,183)	(24,148)
Income tax benefit (loss)	-	-	-	-	-	-	-	-	-	-	-	-
Net loss/income	(2,755)	(6,275)	(5,506)	(5,271)	(5,477)	(5,682)	(21,936)	(5,885)	(5,994)	(6,086)	(6,183)	(24,148)
Net loss per share (basic)	(0.80)	(1.82)	(0.90)	(0.53)	(0.44)	(0.45)	(2.14)	(0.47)	(0.43)	(0.40)	(0.41)	(1.70)
Net loss per share (diluted)	(0.80)	(1.82)	(0.90)	(0.53)	(0.44)	(0.45)	(2.14)	(0.47)	(0.43)	(0.40)	(0.41)	(1.70)
Weighted average number of shares outstanding (basic)	3,442	3,442	6,148	9,946	12,459	12,509	10,265	12,559	13,859	15,159	15,209	14,196
Weighted average number of shares outstanding (diluted)	3,442	3,442	6,148	9,946	12,459	12,509	10,265	12,559	13,859	15,159	15,209	14,196

Source: Company Reports and Aegis Capital Corp. estimates

Required Disclosures

Price Target

Our 12-month price target is $40.00 per share.

Valuation Methodology

We derive our price target using a discounted cash flow-based sum-of-the-parts analysis approach, which derives a $485 million 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 $625 million assumes ~$140 million in cash as of mid-2014; this translates into a price target of $40.00 per share based on approximately 17 million shares (fully-diluted) and no debt as of mid-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.

For important disclosures go to www.aegiscap.com.

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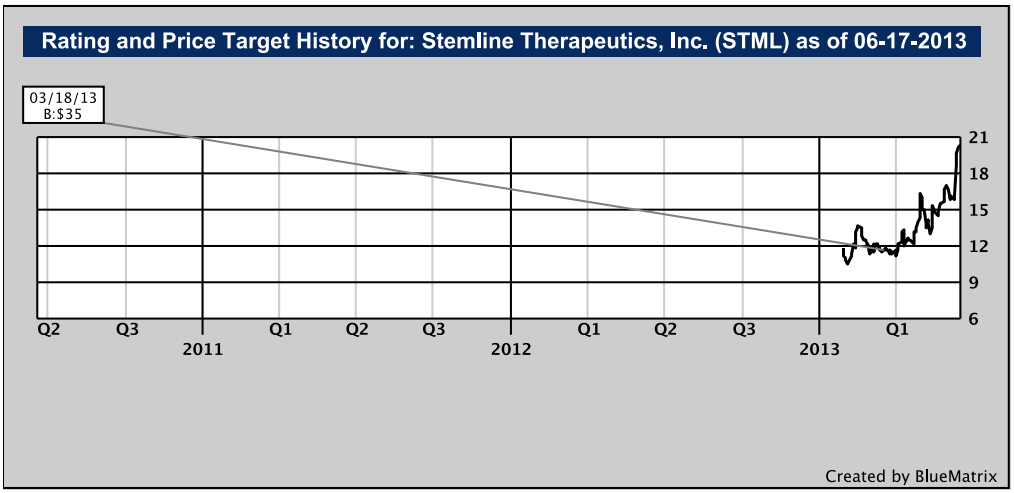
Aegis Capital Corp. intends to seek or expects to receive compensation for investment banking services from the subject company within the next three months.



Rating	Percent	Investment Banking Services/Past 12 Mos. Percent
BUY [BUY]	85.71	23.33
HOLD [HOLD]	14.29	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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