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Industry: Biopharmaceuticals
Initiating Coverage

June 18, 2013
BUY

Stemline Therapeutics, Inc. (STML)

Novel Therapeutics Targeting Cancer Stem Cells; Initiating Coverage with a Buy Rating and a $36.00 Price Target

Investment Rating	**BUY**
Price Target	$36.00
Price (June 17, 2013)	$20.32
52 Week Range	$10.00 - $21.19
Shares Outstanding	12.4 MM
Market Capitalization	$253 MM
Cash (May 23, 2013)	$96 MM
Long term debt (03/31/13)	$0 MM
Volume (ave. daily)	141,196
S&P 500 Index (06/17/13)	1,639.04
NASDAQ Composite (06/17/13)	3,452.13

FY (December 31)	2012A	2013E	2014E
Revenue (MM's):	$0.0	$0.0	$0.0
EPS GAAP:	($1.82)	($2.30)	($2.40)

EPS (Qtr.)	1Q	2Q	3Q	4Q
2013E	($0.90) (A)	($0.46)	($0.53)	($0.55)
2014E	($0.56)	($0.58)	($0.61)	($0.65)

Company Description

Stemline Therapeutics is a biopharmaceutical company focused on the acquisition and development of oncology products that target cancer stem cells. STML's comparative advantage is to identify quality assets to develop. Lead product candidates are SL-401 and SL-701. SL-401 is indicated for AML, BPDCN and possibly other cancers that overexpress IL-3R. SL-701 is indicated for GBM, and is in line with the company's focus to target cancer cells. Stemline's management is a significant shareholder and strongly incentivized to achieve share price growth. Stemline operations are headquartered in New York, NY.

Matthew L. Kaplan
212.891.5247
mkaplan@ladenburg.com

Highlights

We are initiating coverage of Stemline Therapeutics, Inc. (STML) with a BUY rating and $36.00 price target. Stemline is in the process of developing two anti-cancer therapeutic products, SL-401 and SL-701, targeting tumor bulk and cancer stem cells (CSCs), which could potentially enable Stemline to generate greater than $500 million in revenue annually. SL-401 is being developed for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN), acute myeloid leukemia (AML) and other hematologic cancers, while SL-701 is under development for adult glioblastoma multiforme (GBM) and pediatric brainstem and non-brainstem glioma. Our valuation and price target are primarily generated from our forecasted sales of SL-401. We believe Stemline's current valuation offers significant upside potential, particularly if the products are efficacious in the other indications Stemline plans to pursue, beyond BPDCN and AML. STML plans to initiate a pivotal Phase 2b program with SL-401 for the BPDCN indication in 1H14, along with a pivotal Phase 2b trial for AML in 2H14. Additionally, Stemline anticipates initiating two Phase 2b trials for SL-701 in 2014 as well, to consist of one pediatric brainstem and non-brainstem glioma trial and one adult second-line GBM trial. We believe the breadth of the clinical programs Stemline has planned will attract the attention of possible partners, and will continue to de-risk the product portfolio as more data are generated.

We believe STML's current value is primarily driven by SL-401. SL-401 early clinical trial data have shown clear activity in the treatment of both AML and BPDCN. SL-401 with just a single cycle of therapy has shown a solid signal of tumor shrinkage in 5 out of 6 patients (83% ORR) with BPDCN, of which 3 (60%) of the responders were able to obtain a CR, one of which is durable for 9+ months (and is ongoing) and another for 5 months. Notably, there currently is nothing approved or thought to be meaningfully efficacious for the treatment of BPDCN, and the prognosis of BPDCN is dire with a median overall survival of 12 months. Therefore, we believe FDA approval via the BPDCN indication is potentially the most direct regulatory pathway for SL-401. Moreover, the FDA recently granted SL-401 Orphan drug status for the BPDCN indication. The Phase 1/2 data to date has also shown SL-401 to be a highly active compound in relapsed and refractory AML patients. Specifically, SL-401 was able to achieve leukemia blast reductions or disease stabilization in 46% of relapsed and refractory patients with only a single cycle of therapy, including 2 durable CRs. SL-401 also more than tripled overall survival, relative to historical data, of AML patients who were third-line or greater when treated with SL-401 doses circa the MTD. We look forward to additional clinical data with multiple cycles of therapy. If robust data are generated in earlier line patient populations or other indications, demand could also be generated from off label use.

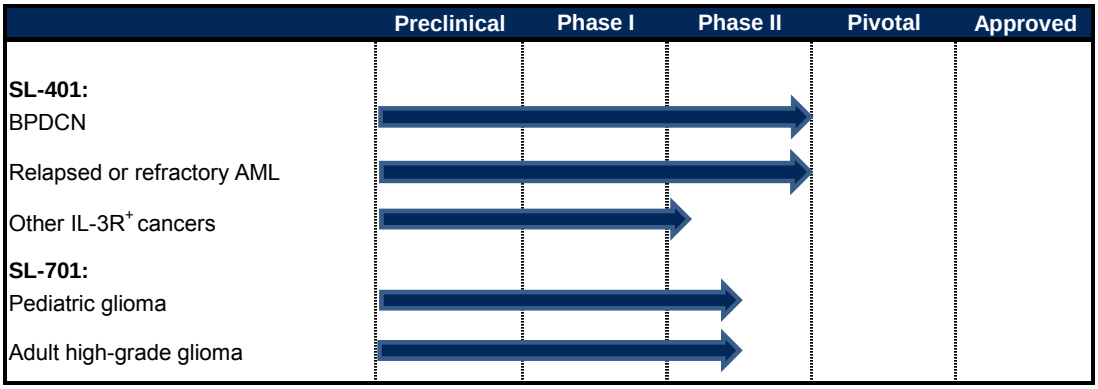
SL-701 represents upside potential. St. Jude's Children Hospital is anticipated to initiate a multi-center Phase 2b pediatric trial for brainstem and non-brainstem glioma with SL-701 in 2H14. This trial will be funded primarily by grants. A single arm adult Phase 2b adult second-line GBM trial is also anticipated to be initiated in mid-2014.

Initiating coverage with a BUY rating and a $36.00 price target. We believe STML is currently undervalued and have employed multiple valuation techniques to assess the opportunity. Specifically, we employed a sum-of-the-parts analysis based on the cash flow generated by SL-401 and based on a probability adjusted peak sales analysis, an EPS multiple analysis, and a DCF analysis. Using an equally weighted average of the various valuation methodologies we determine a price target of $36.00. Our analysis employs only the U.S. revenue generated from SL-401 in relapsed and refractory AML and BPDCN patient populations, as well as the cash position at the projected price target date. We view STML, at current prices, as an attractive investment opportunity with significant upside potential.

COMPANY OVERVIEW

Stemline Therapeutics is a biopharmaceutical company focused on the acquisition and development of oncology products that target tumor bulk and cancer stem cells (CSCs). Stemline's comparative advantage is to identify quality assets to develop, and to develop them in a cost efficient manner. Lead product candidates are SL-401 and SL-701. SL-401 is being developed as a treatment for BPDCN, AML and other cancers which over-express IL-3R (interleukin-3 receptor). SL-701 is being developed as a treatment for adult GBM (glioblastoma multiforme) and pediatric brainstem and non-brainstem glioma, and is in line with the company's focus to target tumor bulk and CSCs. Stemline's management is a significant shareholder and strongly incentivized to achieve share price growth. Stemline operations are headquartered in New York, NY.

STEMLINE THERAPEUTICS PIPELINE



Source: Company documents & Ladenburg Thalmann & Co.

INVESTMENT THESIS

Initiating Coverage with a BUY Rating and $36.00 Price Target

We are initiating coverage with a Buy rating and $36.00 price target, as we believe that Stemline is undervalued based on the potential cash flows which SL-401 may be able to generate, and the strength of management's ability to identify, acquire, and develop quality products. We believe that SL-401 could be approved in 2016 for BPDCN patients. Furthermore, we forecast Stemline to have revenues by late 2016 and to be cash flow positive and profitable in 2017. Additionally, Stemline has a second product, SL-701, which represents an attractive second shot on goal which could provide significant upside potential to our current valuation.

SL-401 is a targeted therapy directed to IL-3R present on tumor bulk and cancer stem cells (CSCs). SL-401 is a biologic recombinant protein comprised of human IL-3 fused to truncated diphtheria toxin (which inhibits protein synthesis). We believe SL-401 has the potential to be a best in class product for the treatment of BPDCN. The human IL-3 of SL-401 is able to target IL-3R, which is overexpressed on CSCs, which are responsible for re-population of the tumor and on leukemia blasts, which are responsible for the tumor bulk of AML, BPDCN, MDS, CML, ALL, Hodgkin's disease, multiple myeloma, and certain NHL's. Furthermore, SL-401 selectively targets cancer cells since IL-3R is only minimally expressed on non-cancer cells. Thus, we believe this explains why SL-401 is more tolerable and potentially has fewer adverse events and side effects (for example no evidence of hematologic toxicity) than the chemotherapies currently used to treat hematologic cancers.

We have estimated the incidence of BPDCN to range from 600 to 800 patients annually in the U.S., which puts BPDCN into the ultra-orphan category (our estimates are conservative and may be an underestimate). Only recently has BPDCN become better defined, and was previously referred to as NK blastic cell lymphoma/leukemia. Due to its limited occurrence, BPDCN is often initially misdiagnosed as another disease including AML, NHL, including cutaneous lymphomas, or melanoma. Unfortunately treatments used for AML, NHL, and other malignancies, while producing some responses, have proven to be largely ineffective in BPDCN on a long-term basis, and the survival time post diagnoses is approximately 12 months. Consequently, the regulatory path forward should be relatively straightforward given the efficacy signal shown to date. Given

BPDCN's ultra-orphan status and limited treatment options, we estimate the cost of an annual course of therapy could range from $190,000 to $250,000, or more. Thus, we estimate that Stemline could generate greater than $100 million annually from the BPDCN indication, marketing SL-401 itself in the U.S. STML is also planning to initiate trials in Europe, and thus the European market could generate an additional $100 million annually. Moreover, in the event of licensing to a European partner, we believe royalty revenue from $20 to $25 million could be generated from E.U. sales of SL-401 for BPDCN. However, if SL-401 is also approved for AML we anticipate the cost to be reduced to approximately $150,000 annually in today's dollars. Importantly, we expect the significant increase in market size to more than offset this per patient price adjustment.

The relapsed and refractory AML market is considerably larger than the BPDCN market, and consists of approximately 9,000 patients annually in the U.S. However, with a market highly concentrated to a select number of treatment centers and specialists and overlapping with a potential BPDCN sales force, we believe Stemline will be able to market SL-401 on its own for this indication as well. We believe SL-401 has shown impressive efficacy and tolerability with a single cycle of therapy, and based on these initial solid clinical results we estimate that SL-401 could capture at least 20% of the relapsed and refractory AML market at peak. Moreover, the tolerability profile and the potential for added efficacy driven by additional cycles of therapy could enable a drug profile that provides considerable upside to our current market penetration estimates. Many advanced patients are unable to tolerate the available chemotherapy regimens, and are not candidates for SCT. Thus, with pricing greater than $150,000 annually we estimate Stemline could generate greater than $450 million annually at peak from the U.S. AML market.

The incidence as a percentage of the population for relapsed and refractory AML is similar in the E.U. to the U.S., driving an incidence of approximately 14,500 patients annually in the U.S. and 19,000 in the E.U. However, in our model, we are using more conservative pricing in the E.U. Specifically, our pricing of $85,000/yr drives a royalty to Stemline of approximately $45 million annually. Again, Phase 2b data with improved efficacy could enable upside to this conservative estimate.

Other indications beyond AML and BPDCN also could provide significant upside if SL-401 displays efficacy. For example the MDS and multiple myeloma (MM) represent two additional indications where SL-401 could potentially play a therapeutic role. MDS and MM both represent significant market opportunities as the incidence of MDS is approximately 16,000 patients in the U.S. and 20,000 patients in the E.U. and the incidence of MM is roughly 22,000 patients in the U.S. and roughly 28,000 patients in the E.U. Consequently, even with lower pricing akin to the E.U. it is possible for SL-401 to become a blockbuster product.

Valuation. Our $36.00 price target is supported by a DCF, EPS multiple, and a sum-of-the-parts analysis. The DCF analysis applies a 35% discount rate, and an 8x multiple of the 2021 EBITDA of $380 million as the terminal value. The sum-of-the-parts (SOP) analysis employs the revenue and generated from SL-401 in the relapsed and refractory AML and BPDCN patient populations, as well as the current cash position. The SOP analysis utilizes a 30% discount rate for SL-401 revenue from the U.S. and a 35% rate from the ex-U.S. royalties. The first line patients for AML and all royalty revenue for SL-701 are left as upside potential. The EPS multiple analysis uses the 2018 fully diluted EPS of $6.86, and utilizes a 20x multiple and a 35% discount rate. The fully diluted share count used in the EPS multiple analysis takes into consideration considerable future potential dilution. Specifically, our forecasts show the fully diluted shares to be about 20 million in 2018, which is more than triple the 1Q13 share count of about 6.1 million shares (Stemline currently has approximately 12.2 million shares outstanding following the recent offering). Using an equally weighted average of the various valuation methodologies we determine a price target of $36.00.

Upside potential. Notably the MDS, multiple myeloma, earlier lines of AML, CML, Hodgkin's, and NHL markets are large with multiple blockbuster products, and yet a remaining unmet clinical need exists as there is no cure. Furthermore, the products in this space are often used as maintenance therapies post treatment, thus extending the product sales. Additionally, the utility of the products in this space extend into multiple indications. Rituximab for example is approved to treat not only NHL and CLL, but also rheumatoid arthritis, Wegener's granulomatosis, and microscopic polyangiitis. Moreover, products are readily used off label. For example Treanda is not approved for first line treatment in either NHL or CLL, yet the National Comprehensive Cancer Network (NCCN) directly recommends its use in first line CLL patients while in combination with rituximab. Therefore, as SL-401 progresses in the clinic, we believe that positive data in these and other indications represent upside revenue potential and may be important catalysts.

Downside risks. The downside risks to the current valuation include the risk of all products failing to generate the anticipated revenue. As with any biotech product in development there is also significant risk of failure in clinical development. Furthermore, if Stemline decides to partner SL-401 for the U.S. market our valuation assumptions may be altered such that a decrease in our price target may result.

Table 1. EPS multiple analysis

2018	Discount rates	Target price based on EPS multiple analysis (fully diluted)					
EPS multiples		15	20	25	30	35	40
	10%	$66.77	$89.03	$111.29	$133.55	$155.81	$178.07
	15%	$54.57	$72.76	$90.95	$109.14	$127.34	$145.53
	20%	$44.98	$59.98	$74.97	$89.97	$104.96	$119.96
	25%	$37.37	$49.83	$62.29	$74.75	$87.21	$99.67
	30%	$31.28	$41.71	$52.13	$62.56	$72.98	$83.41
	35%	$26.35	$35.14	$43.92	$52.71	$61.49	$70.28
	40%	$22.34	$29.79	$37.24	$44.69	$52.13	$59.58

Source: Ladenburg Thalmann & Co. Estimates

Table 2. DCF analysis

2021	Discount rates	Value Per Diluted Share					
EBITDA multiples		6	7	8	9	10	11
	15.0%	$90.53	$100.97	$111.42	$121.86	$132.30	$142.75
	20.0%	$67.29	$74.87	$82.45	$90.03	$97.60	$105.18
	25.0%	$50.82	$56.39	$61.95	$67.52	$73.09	$78.66
	30.0%	$38.96	$43.10	$47.25	$51.39	$55.54	$59.68
	35.0%	$30.32	$33.44	$36.55	$39.67	$42.79	$45.91

Source: Ladenburg Thalmann & Co. Estimates

Table 3. Sum-of-parts analysis

Per share value of assets	
SL-401 in the US	26.26
SL-401 in the EU	2.66
SL-701 in the US	-
SL-701 in the EU	-
Other	
Value of net cash	5.05
TP	$ 33.97

Weighted ave. product discount rate	30.5%

Source: Ladenburg Thalmann & Co. Estimates

Table 4. Sum-of-parts analysis, via a probability adjusted peak revenue multiple

2013 Product Portfolio	Projected Sales ($000)	Projected Peak Net Revs* ($000)	Year of Peak Revs	Revenue Multiple	Valuation (PV) ($000)	Probability (%)	Probability Adjusted Value	Contribution Per Share ($)	Discount rate
Pipeline									
SL-401 Revenue	$580,821	$447,232	2021	5.0x	$951,508	50%	$475,754	$37.42	12%
SL-701 Royalty	$65,520	$65,520	2022	5.0x	$124,461	25%	$31,115	$2.45	12%
						Total	$506,869	$39.86	

Source: Ladenburg Thalmann & Co. Estimates

MILESTONES

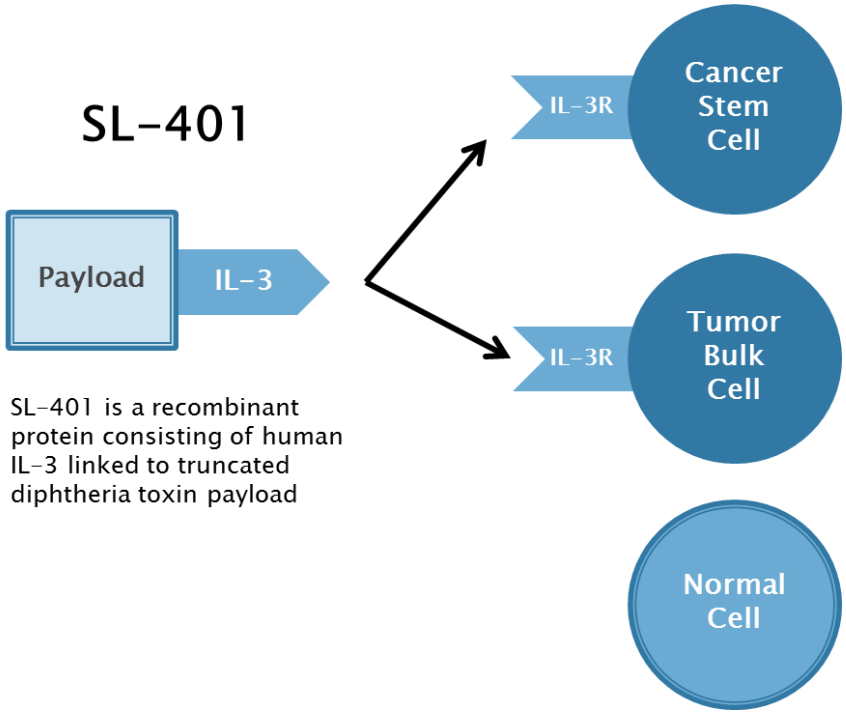
Timing	Compound	Event	Indication
1H14	SL-401	Initiate Pivotal program in BPDCN trial	BPDCN
mid-2014	SL-401	Initiate Phase 2 trial of other IL-3R+ indications	other
mid-2014	SL-701	Initiate Phase 2b adult GBM trial (combo w/ Avastin)	GBM
2H14	SL-701	Initiate Phase 2b pediatric malignant glioma trial	GBM
2H14	SL-401	Initiate Phase 2b of AML trial	AML
1H15	SL-401	Phase 2b data	BPDCN
2H15	SL-401	Interim Phase 2b data	AML
mid-2015	SL-701	Phase 2b data from adult GBM trial (combo w/ Avastin)	GBM
Late-2015	SL-701	Phase 2b data from pediatric malignant glioma trial	GBM

Source: Company documents and Ladenburg Thalmann & Co. Estimates

SL-401: A NOVEL TARGETED THERAPY DIRECTED TO IL-3R+ TUMORS

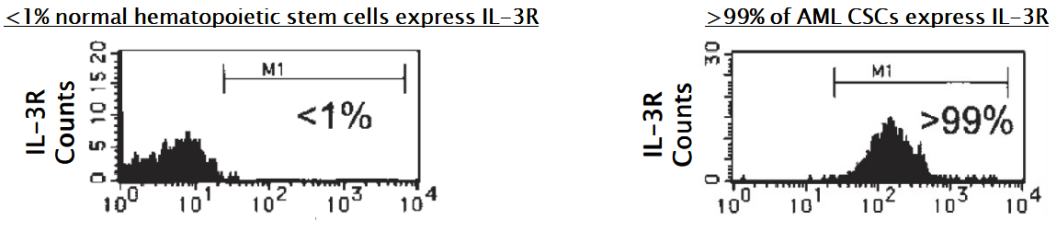
SL-401 is a targeted therapeutic directed to the IL-3 receptor (IL-3R). SL-401 is comprised of recombinant human IL-3 fused to a truncated diphtheria toxin (which inhibits protein synthesis), which we believe has the potential to be a best in class product for the treatment of BPDCN. The human IL-3 of SL-401 is able to target IL-3R, which is overexpressed on CSCs, which are responsible for re-population of the tumor, and on leukemia blasts, which are responsible for the tumor bulk of AML, BPDCN, MDS, multiple myeloma, CML, ALL, Hodgkin's disease, and certain NHL's. Furthermore, SL-401 selectively targets cancer cells since IL-3R is only minimally expressed on non-cancer cells (Figure 1). Thus, we believe this explains why SL-401 is more tolerable and potentially has fewer adverse events and side effects (for example no evidence of hematologic toxicity) than the chemotherapies currently used to treat hematologic cancers.

Figure 1: Diagram of the SL-401 mechanism



Source: Company documents

Figure 2: IL-3R is overexpressed on AML CSCs relative to normal hematopoietic stem cells



Source: Company documents

We believe that the tolerability and efficacy profile of SL-401 in AML should enable the compound to carve out a solid niche in third-line AML patients, and more broadly in the relapsed and refractory AML patient populations. Tolerability is a major concern for many of these patients (as many of these patients have extensive bone marrow impairment from the extent of their disease and prior myleosuppressive therapies; many patients are also elderly and cannot tolerate chemotherapy well), causing limited treatment options. This is also the reason we believe there is a significant opportunity for SL-401 regardless of established therapies used to treat AML. Specifically, there was no evidence of hematologic toxicities, such as infection, fatigue, or bleeding. Furthermore, the side effects that did occur were largely reversible and mild to moderate.

Thus, based on SL-401's efficacy data to date, that we highlight below, which included a 46% rate of disease stabilization and tumor shrinkage in relapsed and refractory AML patients, and a more than tripling of overall survival versus historical data with just a single cycle of therapy at relavant doses, we believe there is a reasonable probability the product will be able to gain regulatory approval. Moreover, we believe SL-401's efficacy signal shown in the BPDCN indication should also enable approval considering that there is no approved or effective therapy to treat BPDCN in the United States, Europe, or the rest of the world.

Future development: Future development may consist of combination trials of SL-401 with traditional chemotherapy for AML, earlier lines (i.e. second and first-line) of AML and the expansion into other indications such as MDS, multiple myeloma, CML, Hodgkin's, and NHLs. Development will also continue through independent investigator sponsored studies.

Currently planned SL-401 Phase 2b trial for AML and BPDCN:

AML registration-directed Phase 2b trial: A total of approximately 240 third-line AML patients are anticipated to be randomized 2:1 to either multiple cycles of SL-401 or physician's choice. Overall survival is the primary endpoint. We are anticipating this trial to be initiated in 2H14 with interim data in 2015-16. Enrollment could take approximately 1.5 years with final data expected by 2H16 (if the trial is not stopped earlier at an interim analysis), and an NDA filing in early- to mid-2017 and potential market launch by late 2017/early 2018. Additionally, with interim analyses an earlier filing and approval is possible based on positive interim data, given the strong overall survival seen to date. We would anticipate such a trial to cost about $25 - $30 million in total and to fulfill both the U.S. and E.U. requirements.

Pivotal BPDCN Phase 2b trial: The pivotal single-arm BPDCN program, which will enroll up to approximately 40 to 50 patients in total with ORR (CR+PR) as the primary endpoint, is on track to start in 1H14. Given the orphan indication and the data from the previous 83 patient Phase 1/2 trial, we anticipate that this trial will satisfy the U.S. and E.U. requirements for marketing approval for the BPDCN indication. Due to the lack of therapeutic alternatives we anticipate a relatively rapid enrollment, which is more dependent on the incidence rate than patient choice. Thus we believe the trial should take approximately 15 to 18 months to complete with pivotal data expected by 2H15. An NDA submission in 1H16 is expected, although an earlier submission date is also plausible if data are approval-worthy prior to full accrual, given that the trial is open-label. Moreover, we believe that an accelerated FDA review is probable due to the stark unmet medical need in this patient population, which could enable approval by mid-2016, with a market launch in 2016 as well.

Phase 2b studies planned in other IL-3R over-expressing rare tumors: Stemline also plans to launch other SL-401 Phase 2 trials to examine the compound in other IL-3R over-expressing tumors including multiple myeloma, myelodysplastic syndrome (MDS) and certain rare disorders including hairy cell leukemia, mastocytosis, and basophilic leukemias. We expect these studies to start throughout 2014. We expect data from these open-label studies by end of 2014 and throughout 2015.

Impressive SL-401 Phase 1/2 data already reported from a trial in relapsed or refractory AML, BPDCN, and high-risk MDS patients:

In a multi-center Phase 1/2 trial, patients with advanced hematologic malignancies were dosed with SL-401 using two different regimens to determine MTD. In regimen A, 45 patients were dosed with up to six intravenous (IV) infusions ranging from 4 to 12.5 µg/kg every other day, and in regimen B 35 patients were dosed with up to five IV infusions ranging from 7.1 to 22.1 µg/kg daily. Of the 83 patients enrolled 59 were relapsed or refractory AML patients, 11 were de-novo AML patients unfit for chemotherapy. Additionally, there were 7 patients with high-risk myelodysplastic syndrome (MDS), and 6 patients with relapsed or refractory BPDCN. Table 5 below gives the full breakdown of patient characteristics, with the majority having greater than 3 prior lines of therapy.

Table 5: Patient characteristics of the SL-401 Phase 1/2 trial

Patient Characteristics	All Patients (n=83)	
Median Age, years (range)	66	(7 - 84)
Gender, n (%)		
Male	49	(59.0%)
Female	34	(41.0%)
Disease, n (%)		
AML	70	(84.3%)
relapsed/refractory disease	59	(71.1%)
de novo unfit for chemotherapy	11	(13.3%)
MDS (high risk)	7	(8.4%)
BPDCN (relapsed/refractory)	6	(7.2%)
Therapy Line for Disease in Study, n (%)		
de novo AML unfit for chemotherapy	11	(13.3%)
2nd Line for AML	24	(28.9%)
3rd Line for AML	16	(19.3%)
>3rd Line for AML	19	(22.9%)
3rd Line for BPDCN	1	(1.2%)
>3rd Line for BPDCN	2	(2.4%)
MDS; various prior lines of therapy	7	(8.4%)
AML Cytogenetic Risk, n (%)		
Intermediate	43	(51.8%)
Poor	25	(30.1%)
Unknown	2	(2.4%)

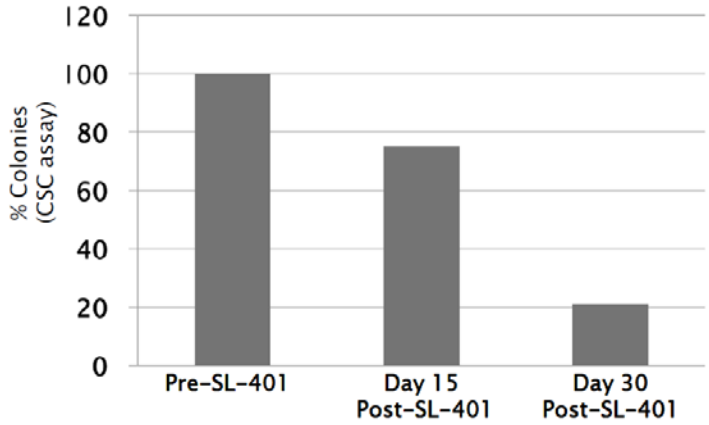
Source: Company documents & Ladenburg Thalmann & Co.

Solid efficacy signal observed: The primary intent of the SL-401 Phase 1/2 trial was to determine the safety and tolerability of SL-401, but the trial also gave a efficacy signal. Given the intent to determine the maximum tolerable dose (MTD), this trial only dosed patients with one cycle of therapy, many of whom were dosed with below the therapeutically optimal doses of SL-401. Notwithstanding this fact, SL-401 was able to achieve responses of stable disease or tumor shrinkage in 46% of patients with relapsed or refractory AML and 83% of patients with relapsed or refractory BPDCN, which included 5 CRs, 2 in AML and 3 in BDPCN. Thus, with more than one cycle of treatment (which could convert patients who did not respond to responders, patients with SD to responders, patients with PRs to CRs, and/or responders to more durable responders) we hope to see an even greater response rate and an increase in the number of CRs and durable CRs achieved. We are impressed with the activiy observed in this Phase 1/2 study. The overall survival (OS) of patients with third-line or greater AML receiving therapeutically relevant doses was improved to a median OS of 5.6 months (95% CI: 2.5, 10.8 months) versus the historical median OS of 1.5 months for patients with third-line AML treated with chemotherapy (Figure 4). This is promising as we anticipate a third-line AML pivotal trial to utilize OS as the primary endpoint.

Perhaps the most striking SL-401 efficacy data were shown in relapsed or refractory BPDCN patients, where 83% (5 out of 6) of patients responded, and 3 out of the 5 responders achieved CRs. One of the BPDCN CRs occurred in a third-line patient who had malignant blasts in the bone marrow and blood at baseline, all of which resolved after a single-cycle of SL-401 and lasted for 5 months. Another BPDCN CR occurred in a 4th line patient who, after a single-cycle of SL-401, has maintained a CR for 9 months and is currently ongoing. SL-401 has also been well toerated, with no DLTs in the six BPDCN patients. Although these very early data are not yet statistically robust, the results are very encouraging given that lack of efficacy and the toxicity that BPDCN patients have experienced with existing therapies in the relapsed or refractory setting.

Beyond the response and survival data, several patients were sampled to determine the clinical effects of SL-401 on CSC activity. In these patients, SL-401 decreased CSC activity, as determined by a CSC colony formation assay (Figure 3), which could be a key contributor to why patients are living longer relative to historical data. We look forward to an updated analysis from the pivotal trial data, where multiple cycles of therapy are anticipated.

Figure 3: Mean CSC activity in SL-401 treated patients



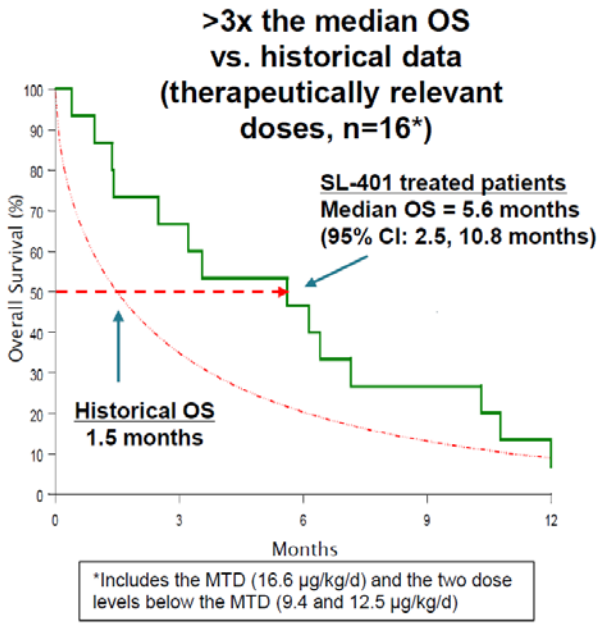
Source: Company documents

Table 6: Efficacy of single agent SL-401 with one cycle of therapy

Efficacy measures	BPDCN (n=6)	AML Relapsed, refractory (n=59)	AML ≥3rd line (n=35)	AML Not chemo candidate (n=11)	MDS Refractory, High risk (n=7)
Tumor shrinkages/SD	83%	46%	43%	55%	43%
Tumor shrinkages	83%	25%	23%	27%	29%

Source: Company documents & Ladenburg Thalmann & Co.

Figure 4: Median overall survival of SL-401 patients receiving higher doses



Source: Company documents

Safety: SL-401 was well tolerated in comparison to SOC, with most adverse events being reversible and mild to moderate. The MTD was determined to be 16.6 µg/kg/day for five days, due to the DLTs of hypoalbuminemia and edema at the 22.1 µg/kg/day dose. Importantly, there was no bone marrow suppression; ≥Grade 3 transient hepatic transaminase elevations did occur, but transaminase elevations largely resolved within 2-3 weeks.

Table 7: Treatment Regimen, DLTs, and Response

Dose, µg/kg/day	Patients Treated (Received All Doses)	Patients with DLT	Responses
Regimen A:			
4.00	7 (5)	0	1 PR
5.32	8 (6)	0	1 PR
7.07	13 (8)	0	2 PR, 1 CR
9.40	7 (3)	0	-
12.50	10 (3)	0	2 PR
Regimen B:			
7.07	5 (3)	0	1 PR
9.40	8 (8)	1[a]	-
12.50	17 (12)	1[b]	2 PR, 4 CR
16.60*	8 (7)	1[c]	-
22.12	2 (0)	2[c]	-

[a]GI bleed; [b]transaminase and creatine kinase elevations; [c]capillary leak syndrome; *Maximum tolerated dose for Regimen B

Source: Company documents (ASCO 2013 Poster #7029)

Table 8: Potential additional Phase II indications SL-401 could enter in 2014

Indications for SL-401 potentially entering Phase II
Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)
Relapsed or refractory Acute Myeloid Leukemia (AML)
High risk Myelodysplastic Syndromes (MDS)
Relapsed or refractory Multiple Myeloma (MM)
Hairy Cell Leukemia
Basophilic Leukemias
Systemic Mastocytosis

Source: Ladenburg Thalmann & Co. Estimates

Market analysis: We believe the initial demand for SL-401 will be driven by BPDCN patients, with a shift in the marketing focus to relapsed or refractory AML patients about 1 year to 1.5 years after SL-401 approval for BPDCN. We estimate the BPDCN market to consist of approximately 2,000 patients annually in the U.S. and Europe; notably this indication is an ultra-orphan indication and not well characterized until recently. Our references show the incidence to be a percentage of other hematologic malignancies. We believe that SL-401 will be the therapy of choice for relapsed or refractory BPDCN patients (and will likely be used off-label in first-line as well), as there is a serious unmet medical need due to limited therapeutic options that are tolerable and effective on a long term basis. Moreover, we anticipate a high penetration rate of 80% at peak, which is in-line with the virtual monopoly that we anticipate SL-401 to have for BPDCN. Therefore, we anticipate approximately 1,600 BPDCN patients to be treated annually at peak in U.S. and Europe. As BPDCN is an ultra-orphan oncologic indication, we anticipate the average annual pricing to range from $190,000 to $250,000 per year initially. However, similarly high priced ultra-orphan indications typically have a patient assistance program, and we would anticipate Stemline to have one also. Thus we have modeled an average annual treatment cost of $200,000 initially. We believe that the likelihood of SL-401 approval in third-line AML patients is high, and that some level of price cut may happen upon the approval of the AML indication which as previously mentioned we anticipate happening in 2017. We have modeled the AML pricing at $150,000 inflation adjusted to $166,000 in 2017, and anticipate this pricing to be comparable for all SL-401 indications post AML approval. With these assumptions we anticipate SL-401 to generate approximately $105 million in total U.S. revenue in 2020 from the BPDCN indication alone (see Table 9). Furthermore, we believe that the revenue generated from the BPDCN indication will create a floor for Stemline's stock price. Stemline acquired worldwide rights to SL-401 from Scott and White Hospital in Texas. The royalty owed to Scott and White is low single digit, which we estimate to be 1%-3% and to pass through COGS.

The AML market in the U.S consists of about 14,500 patients, about 70% of which become treatable as second-line, and about 40% of second-line become treatable as third-line. Thus our target market for third-line consists of about 3,500 patients. A third-line approval, however, would likely carry a significant amount of off-label use in second-line thereby increasing the potential market in the U.S to about 9,000 patients in the U.S. There could also be off-label use in elderly AML patients who are unfit for chemotherapy. Thus we consider our peak penetration rate of 23% to be conservative. With these assumptions we forecast about 2,253 AML patients to be treated with SL-401 in 2021, resulting in total revenues of about $400 million for relapsed or refractory AML alone utilizing inflation adjusted pricing of about $179,000 annually. Notably solid Phase 2b data could enable a higher penetration rate than we have forecasted, however, patient assistance programs may limit the net revenue. That said we believe SL-401 could reasonably generate $400 million annually at peak in the relapsed or refractory AML patient population. Moreover, we anticipate that Stemline will market SL-401 itself in the U.S. We forecast Stemline to pay royalties of approximately 3% to Scott and White hospital, with the assumption that $100 million in U.S. sales will be achieved in total in 2017 when including both AML and BPDCN indications.

Our European assumptions are very conservative with respect to pricing. We assume inflation adjusted pricing of $94,000 for the annual treatment cost in 2017. For the BPDCN market we assume the same incidence as a percent of the population as the U.S., which equates to about 1,100 patients in 2013. We continue to assume a high penetration rate of 80% at peak, due once again to the lack of alternatives. However, we believe that Stemline will most likely out license the ex-U.S. territories, with the exception of Canada. Therefore, with a royalty of 25% we anticipate approximately 900 patients to be treated with SL-401 for BPDCN in 2021, which should generate about $23 million in royalty revenue.

For the European relapsed or refractory AML market the annual incidence is about 19,000 AML patients in 2013, with about 14,500 being relapsed or refractory AML patients. With a penetration rate of 20% at peak, we believe a total of approximately 3,000 patients could be treated in 2022. Thus, SL-401 could generate gross revenue of >$300 million from the AML market in the E.U., with Stemline receiving >$45 million in royalties at a royalty rate of 15%. We have conservatively assumed a lower royalty rate for the AML indication, primarily because the negotiating power may not be as high as it is with BPDCN. Once again, solid Phase 2b data may increase these assumptions, which we will revisit after more clinical data have been generated.

Table 9: Market potential and revenue projections for SL-401 in the U.S.

	U.S. Market for SL-401 for BPDCN	2016E	2017E	2018E	2019E	2020E	2021E	2022E
SL-401	Incidence of BPDCN	723	729	736	742	749	756	763
	% adoption / penetration rate	20.00%	70.0%	80.0%	80.0%	80.0%	80.0%	80.0%
	Patients using SL-401	**145**	**510**	**589**	**594**	**599**	**605**	**610**
	Pricing (inflation adjusted) ('000)	$200	$166	$169	$173	$176	$180	$183
	Total U.S. revenue for SL-401 ('000)	**$28,911**	**$84,743**	**$99,675**	**$102,583**	**$105,577**	**$108,657**	**$111,828**
	U.S. revenues to STML ('000)	**$28,911**	**$84,743**	**$99,675**	**$102,583**	**$105,577**	**$108,657**	**$111,828**
	Royalty owed to Scott and White hospital (COGS)	**$867**	**$2,542**	**$2,990**	**$3,078**	**$3,167**	**$3,260**	**$3,355**

	U.S. Market for SL-401 for AML	2016E	2017E	2018E	2019E	2020E	2021E	2022E
SL-401	Incidence of AML patients	11,709	11,814	11,921	12,028	12,136	12,245	12,356
	Number of Relapsed or Refractory AML patients	**9,367**	**9,452**	**9,537**	**9,622**	**9,709**	**9,796**	**9,885**
	% adoption / penetration rate	0.00%	2.0%	10.0%	15.0%	20.0%	23.0%	25.0%
	Patients using SL-401	-	**189**	**954**	**1,443**	**1,942**	**2,253**	**2,471**
	Pricing (inflation adjusted) ('000)	$162	$166	$169	$172	$176	$179	$183
	Total U.S. revenue for SL-401 ('000)	**$0**	**$31,306**	**$161,096**	**$248,695**	**$341,269**	**$403,912**	**$451,846**
	U.S. revenues to STML ('000)	**$0**	**$31,306**	**$161,096**	**$248,695**	**$341,269**	**$403,912**	**$451,846**
	Royalty owed to Scott and White hospital (COGS)	**$0**	**$939**	**$4,833**	**$7,461**	**$10,238**	**$12,117**	**$13,555**

Source: Ladenburg Thalmann & Co. Estimates

Table 10: Market potential and revenue projections for SL-401 ex-U.S.

	E.U. Market for SL-401 for BPDCN	2016E	2017E	2018E	2019E	2020E	2021E	2022E
SL-401	Incidence of BPDCN	1,129	1,131	1,134	1,136	1,139	1,141	1,144
	% adoption / penetration rate	0.00%	60.0%	70.0%	80.0%	80.0%	80.0%	80.0%
	Patients using SL-401	-	**679**	**794**	**909**	**911**	**913**	**915**
	Pricing (inflation adjusted) ('000)	$92	$94	$96	$98	$100	$102	$104
	Total E.U. revenue for SL-401 ('000)	**$0**	**$63,711**	**$75,977**	**$88,755**	**$90,722**	**$92,733**	**$94,788**
	E.U. Royalty revenues to STML ('000)	**$0**	**$15,928**	**$18,994**	**$22,189**	**$22,681**	**$23,183**	**$23,697**
	Royalty owed to Scott and White hospital (COGS)	**$0**	**$1,911**	**$2,279**	**$2,663**	**$2,722**	**$2,782**	**$2,844**
	Revenue to partner ('000)	$0	$47,783	$56,983	$66,566	$68,042	$69,550	$71,091

	E.U. Market for SL-401	2016E	2017E	2018E	2019E	2020E	2021E	2022E
SL-401	Incidence of AML patients	18,291	18,330	18,369	18,408	18,447	18,486	18,525
	Number of Relapsed or Refractory AML patients	**14,633**	**14,664**	**14,695**	**14,726**	**14,757**	**14,789**	**14,820**
	% adoption / penetration rate	0.00%	0.00%	2.0%	10.0%	15.0%	20.0%	20.0%
	Patients using SL-401	-	-	**294**	**1,473**	**2,214**	**2,958**	**2,964**
	Pricing (inflation adjusted) ('000)	$92.01	$93.85	$95.72	$97.64	$99.59	$101.58	$103.61
	Total E.U. revenue for SL-401 ('000)	**$0**	**$0**	**$28,133**	**$143,783**	**$220,455**	**$300,454**	**$307,113**
	E.U. Royalty revenues to STML ('000)	**$0**	**$0**	**$4,220**	**$21,568**	**$33,068**	**$45,068**	**$46,067**
	Royalty owed to Scott and White hospital (COGS)	**$0**	**$0**	**$844**	**$4,314**	**$6,614**	**$9,014**	**$9,213**
	Revenue to partner ('000)	$0	$0	$23,913	$122,216	$187,387	$255,386	$261,046

Source: Ladenburg Thalmann & Co. Estimates

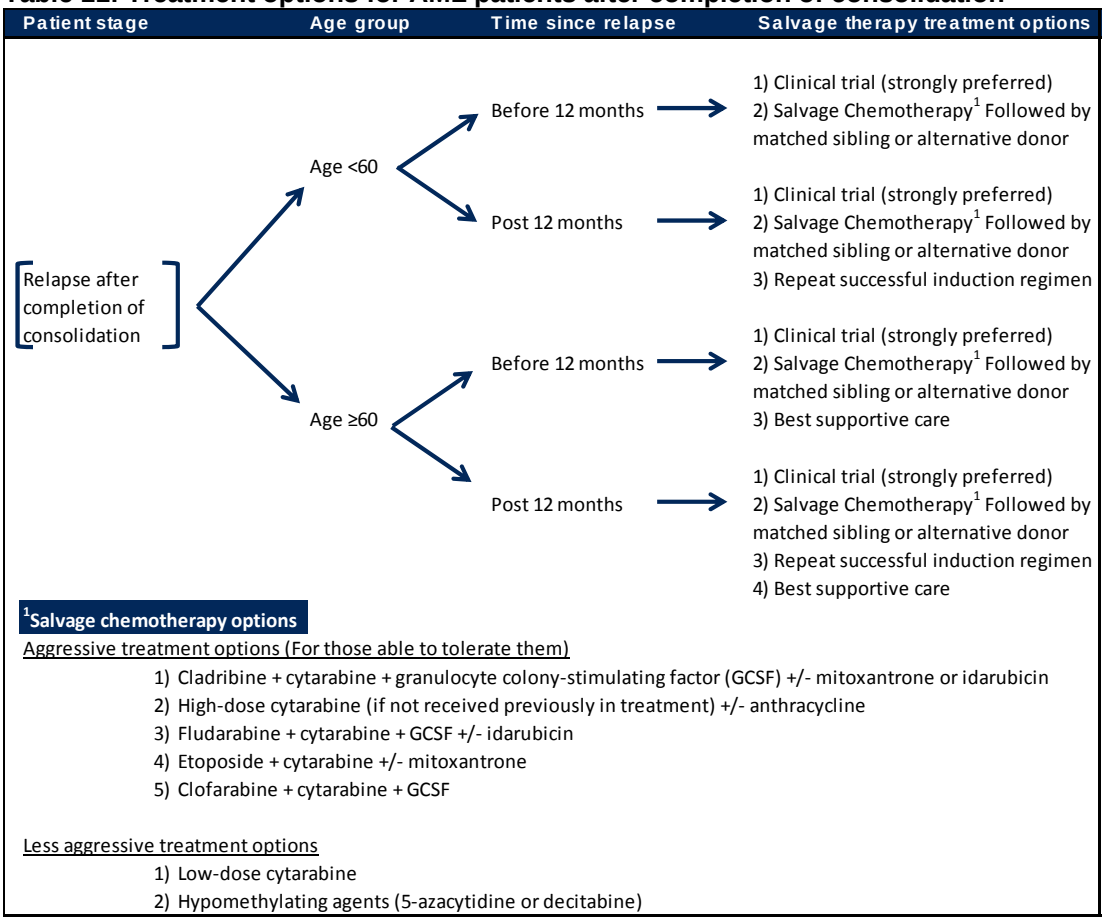
COMPETITIVE LANDSCAPE: FOR AML

Competition: Below we highlight treatment options for relapsed and refractory AML patients (Table 11). Notably the first recommendation by the NCCN is to find a clinical trial and this option is strongly preferred, which speaks to the unmet medical need which still exists for these patients. Alternatively, salvage chemotherapy regimens followed by HSCT, if the patient is eligible for a HSCT, is recommended. However, only approximately 20-30% of patients are able to achieve a CR and receive HSCT. Many patients either choose not to go through HSCT or are unable to find a matched donor. The risk of dying from infection through HSCT is about 25%, which contributes to the patient choice to forgo HSCT along with tolerability. We highlight the response data from most of the salvage regimens below in Table 12.

Although all the response data in Table 12 are from relapsed and refractory AML patients, the patient populations differ significantly, and are particularly different from the planned SL-401 trial. Specifically, the number of salvage regimens completed varies, and the number of prior salvage regimens greatly affects the CR rate and overall survival. It was noted in the GCLAC treatment trial that 64% of the CRs were from patients who were undergoing their first salvage treatment, whereas only 36% of the CRs were from those undergoing their second or greater salvage treatment. The next most relevant factor in determining the ability to achieve a CR was age. Patients who were greater than 50 years old, had a dramatically reduced rate of CR, and this affect is prevalent in all the aggressive treatment options. For example in the etoposide + cytarabine +/- mitoxantrone treatment regimen, the response rate was 76% in patients less than 50 years old, and only 29% in patients >50 years old. Cytogenetics was determined to be a less relevant factor in the determination of achieving a CR. Additionally, patients who have never achieved a CR or who relapsed within 6 months, were found to be less responsive to salvage therapy. The overall salvage chemotherapy refractory rate is between 30% to 35% on average. We anticipate that the refractory salvage chemotherapy patients could demand SL-401 shortly after approval, and increase the likelihood of off label use before the AML indication is approved.

Patients undergoing these aggressive salvage treatments almost unanimously experienced myelosuppression and consequently moderate to severe infections. In fact the treatment related deaths averaged about 9%, most of which were due to infection. We believe the reduced hematological toxicity profile of SL-401 may greatly improve patient's chances of survival. Notably the patient ages and number of prior therapies contributed to the OS data shown Table 12. In the etoposide + cytarabine +/- mitoxantrone treatment regimen, only 28% of patients who were previously resistant to chemotherapy achieved a CR, compared to 85% of patients whose first remission was >6 months, and we can only assume that the OS was less for patients who were previously resistant to chemotherapy.

Table 11: Treatment options for AML patients after completion of consolidation



Source: NCCN clinical practice guidelines & Ladenburg Thalmann & Co.

Table 12: Response rates for AML patients treated with salvage chemotherapy

[1] Salvage chemotherapy regimens	OS	CR (%)	PR (%)	Refractory (%)	Deaths (%)	AEs (most prominent)
Aggressive treatment 1)	9 months	66 (58%)	8 (7%)	49 (35%)	8 (7%)	Hematological toxicity
Aggressive treatment 3) FLAG-IDA	> 17 months	12 (63%)	6 (32%)	1 (5%)	0 (0%)	nausea
FLAG	9 months	21 (55%)			4 (10%)	infection ≥grade 3
Aggressive treatment 4)	8.3 months	21 (66%)		9 (28%)	2 (6%)	infection ≥grade 3
Aggressive treatment 5) GCLAC	9 months	21 (46%)	7 (15%)	18 (39%)	6 (13%)	infection ≥grade 3

CR was defined as < 5% bone marrow blasts with neutrophil count of more than 1.0 g/L, a platelet count of > 100 g/L, and no extramedullary disease

PR was estalished with BM of 5-25%, or a 50% or > decrease in BM blasts, or BM blasts <5% with Auer rods presence

Source: & Ladenburg Thalmann & Co.

SL-401 for the treatment of other over-expressing IL-3R tumor types including high-risk MDS patients and MM

MDS was formerly known as pre-leukemia, or a condition involving inadequate production of blood cells produced by bone marrow or the myeloid cells. MDS patients are on average 65 years old at diagnosis, and typically suffer from severe anemia. Moreover they eventually progress to bone marrow failure. Additionally about 20 to 30% of patients quickly progress to refractory AML in a matter of months or years. The cause of MDS is unknown, but has been associated in some cases with environmental factors such as exposure to benzene, radiation, radiomimetic alkylating agents such as busulfan, nitrosourea, and procarbazine, or DNA topoisomerase inhibitors.

Treatments for MDS are focused on the improvement of OS and the control of symptoms. Treatments utilize chemotherapy agents, such as 5-azacytidine, Decitabine, and Lenalidomide. Decitabine was able to achieve complete response rates as high as 43%. With the efficacy demonstrated by SL-401 in MDS patients in a single cycle of therapy, where 43% of patients achieved at least stable disease (albeit in a small sample size (n=7)), we believe there is more than a reasonable basis to anticipate success in Phase 2 trial based on the activity signal already observed.

The U.S. MDS market is anticipated to consist of about 16,400 patients in 2017, based on an incidence rate of about 5 per 100,000 people. Although some sources indicate that the incidence may be as high 12 per 100,000. For illustrative purposes and perhaps for the future incorporation into our valuation we have modeled the potential revenue opportunity. Thus, using a peak penetration rate of 20% in 2022, and an inflation adjusted annual treatment cost of $94,000 in 2022, SL-401 could generate greater than $300 million at peak. Notably once we have more data on the potential duration of usage of SL-401 in MDS patients, the annual treatment cost could increase toward that of AML. Moreover, Phase 2 data could enable the incorporation of the MDS indication into our model and warrant a higher penetration rate than we have forecasted. Since we anticipate that Stemline will market SL-401 itself in the U.S. this brief analysis simply lumps the MDS indication into that assumption and does not take into consideration the out-licensing of SL-401.

There have been many advances in the treatment of multiple myeloma (MM), with Kyprolis, Velcade, and various combination regimens. However there is still a need for tolerable therapies to treat relapsed and refractory MM patients. Given the single agent clinical signal shown with SL-401 in the treatment of various hematologic cancers coupled with the demonstration of SL-401's anti-MM activity in preclinical models of the disease, we believe there is a strong rationale for SL-401 development in advanced MM.

Table 13. Products in development for the treatment of MDS

Drug/s and therapies used in clinical trials for MDS patients	Stage
5-Azacytidine and Lenalidomide	Phase 2
ACE-536	Phase 2
Cytarabine; 5-Azacytidine; Tosedostat	Phase 2
E7070; Idarubicin; Cytarabine; Dexamethasone	Phase 2
Lenalidomide; Eltrombopag	Phase 2
Omacetaxine & Cytarabine	Phase 2
ON 01910.Na	Phase 3
oral LBH589/panobinostat; oral LBH589/panobinostat + Epoitin Alfa HEXAL®	Phase 2
Panobinostat (LBH589) and 5-Azacytidine	Phase 2
PD-616	Phase 2
PKC412	Phase 2
Plerixafor; AC220; Ganetespib	Phase 2
PRI-724	Phase 2
rigosertib	Phase 2
Sapacitabine	Phase 2
SGI-110	Phase 2
Sotatercept 0.1 mg/kg; Sotatercept 0.3 mg/kg; Sotatercept 0.5 mg/kg	Phase 2
Vorinostat; Azacitidine	Phase 2

Source: Ladenburg Thalmann & Co. Estimates

SL-701: A NOVEL ANALOG PEPTIDE-BASED VACCINE

SL-701 is a novel peptide vaccine, delivered by direct subcutaneous (SQ) injection. SL-701 is comprised of a mixture of short peptides corresponding to targets on brain tumor bulk and CSCs, including a peptide harboring a novel mutant immunogenic sequence of IL-13Rα2, as well as a peptide corresponding to a sequence of Ephrin A2 (EphA2). There have been several SL-701 Phase 1/2 studies conducted in both adult and pediatric patients, and one Phase 1/2 study published in *J Clin Oncol 29: 2011 (suppl; abstr 2506)*. SL-701 has been tested in several types of gliomas including adult high-grade glioma (HGG), which includes glioblastoma multiforme (GBM), and pediatric brainstem and non-brainstem glioma. We elaborate on the Phase 1/2 trials below.

Stemline is progressing SL-701 forward into two Phase 2b trials for patients with advanced brain cancer. One of the trials is a pediatric trial being led by St. Jude's Children Hospital, which is anticipated to be initiated in mid-2014. This trial is expected to enroll roughly 25 non-brainstem and brainstem glioma patients, and could be expanded. The trial will primarily be funded by grants, with some financial support by Stemline, we believe making it a low risk option for the company. The second trial is an open label adult Phase 2b second-line GBM trial, which is anticipated to be initiated in mid-2014. In this study, given the recent negative results observed with Avastin in first-line adult GBM, SL-701 will either be dosed as a single agent versus a comparator arm (in a randomized design) or it will be dosed in combination with Avastin in a single or double arm study. The Company plans to determine the final study design and size later in 2013. Data from this trial could be presented by mid-2015.

To date, SL-701 has been shown to be effective via both direct subcutaneous (SQ) injection and via ex-vivo exposure to dendritic cells (DCs) with DC reinfusion. Accordingly, Stemline plans to utilize SL-701 via direct SQ injection in future trials. The SQ injection has been previously used in pediatric and certain adult studies.

The studies already completed with SL-701 include:

1. A Phase 1/2 study in adult patients with recurrent or refractory high grade gliomas (HGGs), which includes glioblastoma multiforme (GBM).

In this study, patients were dosed intra-perinodally via injection with peptide-loaded dendritic cells (DCs) once every two weeks, and an adjuvant was dosed intramuscularly twice a week. The enrollment consisted of 22 adult patients with recurrent or refractory gliomas, of which 13 patients had GBM, 5 patients had anaplastic astrocytoma, 3 patients had anaplastic oligodendroglioma, and one patient with anaplastic oligoastrocytoma. Most of the patients were heavily pre-treated with prior therapies with 50% of the patients experiencing their second relapse or greater. T-cell responses were assessed with tetramer, IL-12 and Enzyme-linked immune-SPOT assays (ELISPOT). Treatment response was evaluated clinically and by MR imaging according to McDonald criteria.

Efficacy and Safety: In this study, 46% of recurrent GBM patients and 67% of recurrent anaplastic glioma patients experienced tumor shrinkage or stable disease with single agent SL-701. In particular, two recurrent HGG patients achieved CRs, one CR of which lasted for >23 months. There were also 3 recurrent HGG patients who experienced PRs. In recurrent GBM the median OS was 13 months, approximately double that of historical data, with 80% of recurrent GBM patients achieving OS at 6 months, also about double that of historical data. A total of 81% of patients had more than one positive immunogenicity assay. Overall, the regimen was well tolerated, and no DLT was found. There were no grade 3 or greater toxicities. The majority of adverse events were injection site reactions, such as chills, and transient fatigue. We are impressed with the efficacy, safety and immunogenicity profile demonstrated in this study.

2. Phase 1/2 study in adult patients with low-grade glioma

Twenty-four adult patients with WHO Grade 2 low-grade giloma (LGG) were enrolled in one of three cohorts based on disease severity and prior treatment and received direct SQ injection of SL-701. Specifically, 13 patients enrolled into cohort 1 were adult newly diagnosed LGG patients

without prior radiation therapy (RT), one patient was enrolled into cohort 2 was newly diagnosed LGG with prior RT, and 10 patients enrolled into cohort 3 were relapsed and refractory LGG patients. High risk patients are those over 40 years old who had tumor resection, those aged 18-39 with incomplete resection, or those aged 18-39 whose total resection area was ≥4 cm. All patients were dosed with SQ vaccinations of SL-701 every 3 weeks. The primary endpoint was safety and CD8+ T-cell responses against vaccine-targeted GAAs. ELISPOT assays were used to assess the CD8+T-cell responses. Treatment response was evaluated clinically and by MR imaging.

Efficacy and Safety: 10 patients currently have SD (6 from cohort 1, one from cohort 2, and 3 from the third cohort). Eight patients ELISPOT assayed from Cohort 1 & 2 displayed robust and sustained interferon (IFN)-γ (type-1) responses against at least 3 GAA epitopes without IL-5 responses. Preliminary results show the therapy was well tolerated with no DLTs to date, with just one case of Grade 3 fever observed. Moreover SL-701 was able to induce robust type-1 anti-GAA T-cell responses in LGG patents.

3. Phase 1/2 trial in childhood gliomas, including brainstem, non-brainstem, and low-grade gliomas

This pediatric trial enrolled 27 patients dosed SQ with SL-701 once every 3 weeks. The patients had newly diagnosed brainstem glioma (BSG) (n=16), newly diagnosed non-brainstem glioma (n=5), recurrent non-brainstem glioma (n=3), and multiply recurrent low grade glioma (n=3).

Efficacy and Safety: 86% (19/22) of evaluable patients sustained a response or disease stabilization, including 3 durable PRs, one of which lasted 15 months in a radiation-resistant BSG patient. Additionally, one patient had a prolonged disease-free status after surgery. Blood tests confirmed that SL-701 elicited a specific immune response against its targets; these tests including ELISPOT and tetramer assays.

Overall the therapy was well tolerated. We are impressed by the early studies which demonstrate clear signal of SL-701 single-agent activity in this patient population with a clean safety profile. We look forward to additional clinical data from future studies.

Market potential for SL-701: We currently do not include SL-701 in our valuation, but we have modeled the potential of SL-701 in the event that progress with the program and clinical data warrant the addition of SL-701 to our valuation. We anticipate SL-701 would be targeting adult patients with second-line GBM and pediatric patients with brainstem and non-brainstem glioma as an efficacy signal has been observed in these patient populations. We estimate the adult GBM market to consist of approximately 10,000 patients annually in the U.S in 2013. Our market assumption is based on an incidence of 0.003% of the population or 3 patients per 100,000 people. Although, there remains a significant unmet need for these patients, there are number of potential competitive products in development which could compete for market share at the time of approval (which we anticipate could occur in 2017). Therefore, we limit our market penetration assumptions to 22% of the market at peak in 2022. We forecast approximately 2,400 patients to be treated at peak, at a conservative inflation adjusted pricing of approximately $75,000 annually. Therefore, SL-701 may be able to generate revenues of $180 million at peak from the U.S. market alone. Furthermore we assume that Stemline out licenses SL-701, and we model in a royalty of 20% to Stemline. This equates to $36 million in royalties to Stemline at peak, with approximately $7 million going to the licensor (the University of Pittsburgh) based on a tiered low to mid single digit royalty, which we estimate to average approximately 4%. Stemline licensed worldwide rights to the active ingredient of SL-701 from the University of Pittsburgh.

The European GBM prevalence data is similar to the U.S. assumptions, which equates to approximately 15,100 GBM patients in 2013. Additionally we assume a similar penetration rate of 21% at peak, giving a total of approximately 3,200 patients treated in 2022. However we forecast SL-701 to be launched in Europe in 2018, one year behind the U.S. Our European assumptions are very conservative with respect to pricing. We assume inflation adjusted pricing of $60,000 for the annual treatment cost in 2022. Thus SL-701 could generate gross revenue of >$190 million from the GBM market in the E.U., with Stemline receiving >$29 million in royalties at a royalty rate of 15%. We have conservatively assumed a lower royalty rate for the E.U. market, primarily because the negotiating power may not be as high. Moreover our royalty rate assumptions for the licensor are the same as for the U.S. market, which equates to approximately $7.8 million going to the University of Pittsburgh in 2022.

Table 14: Market potential and revenue projections for SL-701 in the U.S.

SL-701 - GBM	U.S. Market for SL-701 for GBM	2016E	2017E	2018E	2019E	2020E	2021E	2022E
	Incidence of glioblastoma multiforme	10,408	10,502	10,596	10,692	10,788	10,885	10,983
	% adoption / penetration rate	0%	5%	10%	15%	20%	21%	22%
	Patients using SL-701 for GBM ('000)	-	525	1,060	1,604	2,158	2,286	2,416
	Pricing (inflation adjusted)	$71	$71	$72	$73	$74	$74	$75
	Total U.S. revenue for SL-701 for GBM ('000)	$0	$37,527	$76,487	$116,921	$158,870	$169,998	$181,493
	U.S. Royalty revenues to STML ('000)	$0	$7,505	$15,297	$23,384	$31,774	$34,000	$36,299
	Royalty owed to University of Pittsburg (COGS)	$0	$1,126	$2,295	$3,508	$6,355	$6,800	$7,260
	Benefit to partner ('000)	$0	$30,022	$61,190	$93,536	$127,096	$135,998	$145,194

Source: Ladenburg Thalmann & Co. Estimates

Table 15: Market potential and revenue projections for SL-701 ex-U.S.

SL-701 - GBM	E.U. Market for SL-701 for GBM	2016E	2017E	2018E	2019E	2020E	2021E	2022E
	Incidence of glioblastoma multiforme	15,243	15,275	15,307	15,340	15,372	15,405	15,437
	% adoption / penetration rate	0%	0%	5%	10%	15%	20%	21%
	Patients using SL-701 for GBM ('000)	-	-	765	1,534	2,306	3,081	3,242
	Pricing (inflation adjusted)	$57	$57	$58	$58	$59	$59	$60
	Total E.U. revenue for SL-701 for GBM ('000)	$0	$0	$44,197	$89,468	$135,831	$183,307	$194,809
	E.U. Royalty revenues to STML ('000)	$0	$0	$6,630	$13,420	$20,375	$27,496	$29,221
	Royalty owed to University of Pittsburg (COGS)	$0	$0	$1,326	$2,684	$5,433	$7,332	$7,792
	Benefit to partner ('000)	$0	$0	$37,568	$76,048	$115,456	$155,811	$165,588

Source: Ladenburg Thalmann & Co. Estimates

INTELLECTUAL PROPERTY AND MARKET EXCLUSIVITY

Stemline has a broad intellectual property (IP) portfolio that covers compounds in clinical development, those in preclinical stages, and IP that covers proprietary technologies of Stemline including cancer stem cell focused IP (broad filings in the cancer stem cell field covering cancer stem cell-targeted therapeutics and companion diagnostics). In total Stemline has approximately 13 issued patents and 30 pending patents.

Patents under the SL-401 worldwide license agreement include U.S. patent 7,763,242, which is a method of use patent for the treatment of MDS, which expires in 2027. There are also pending U.S. and foreign method of use patent applications covering the treatment of MDS and AML with SL-401, if issued would expire in 2027. Importantly, Stemline was granted orphan drug designation for SL-401 indicated for AML which should provide 7 years of exclusivity in the U.S. and 10 years of exclusivity in the E.U. Additionally, Stemline was also recently granted orphan drug designation for SL-401 by the FDA for the BPDCN indication. Notably, recent biosimilar legislation may provide up to 12 years of data exclusivity for orphan biologics in the U.S.

In line with SL-401's mechanism of targeting IL-3R, Stemline has other compounds (including an antibody-conjugate, SL-101) that target IL-3R under patent protection or pending, which if issued would provide patent protection to 2021. These include U.S. patent 7,651,678 and U.S. patent 6,733,743. Moreover, an extensive patent portfolio covering monoclonal antibodies therapeutics directed to additional CSC targets and diagnostics directed to CSCs was acquired from Dr. Bergstein, Stemline's CEO. U.S. patents acquired from Dr. Bergstein that cover monoclonal antibody therapeutics directed to CSCs include U.S. patents: 8,038,998, 7,361,336, 7,427,400, 7,504,103; and 7,608,259. Those that cover diagnostics directed to CSCs include U.S. patent 6,004,528. There are multiple other pending patents.

Stemline also has pending patent applications which protect the novel high throughput screening process designed to find compounds that target CSCs that does not expire until 2025.

Stemline has an exclusive license agreement for the mutant IL-13Ra2 component of SL-701, and a non-exclusive license agreement for the EphA2 component. The mutant IL-13Ra2 component is protected under U.S. composition of matter patent 7,612,162, which expires in 2025. The EphA2 component is protected with method of use U.S. patents 7,297,337 and 8,114,407, which expire in 2025 and 2024 respectively.

FINANCIAL MODELING ASSUMPTIONS

Revenue. Given the orphan designations that Stemline is pursuing, we anticipate that Stemline could commercialize SL-401 itself due to the small focused markets, which is why we project SL-401 to be marketed by Stemline. We project revenue to be generated from SL-401 in 2016. Although Stemline's current products have been in-licensed, Stemline is actively pursuing the discovery of new products internally. Therefore the company's future revenue could be generated not only from products in-licensed, but also from internally developed products commercialized by Stemline or potentially out-licensed by Stemline. The revenues in our current valuation model of Stemline are from its U.S. commercialization of SL-401, and ex-U.S. royalties (although Stemline could commercialize SL-401 in Europe on its own). Revenue from SL-701 is not currently included in our projections. After Stemline has progressed SL-701 in the clinic and presumably somewhat de-risked SL-701 from a clinical development and regulatory aspect and added significant value, a future licensing deal could potentially provide milestones and royalties to Stemline.

R&D. We anticipate total operating expenses for 2013 to be less than $20 million, and for operating expenses to range from $25 to $30 MM in 2014 with R&D of $20 mm to $25mm being the main driver of expenses. We expect a steady increase in Stemline's R&D expenses in 2014 due to the initiation of at least four Phase 2 trials (at least 2 for SL-401 and 2 for SL-701). Additionally the costs for the SL-401 trials are significant, and amount to $30-$40 million in total. We conservatively forecast R&D expense of $24.9 million in 2014. With trials continuing in 2015 we forecast continued growth in R&D. Consequently, we are conservatively estimating $30 million

in R&D expenses in 2015, which includes a potential PDUFA fee for SL-401 indicated for BPDCN. In 2016 and beyond we assume slow R&D growth, with the exception of potential PDUFA filings for the AML and or the BPDCN indications of SL-401 and for SL-701 indicated for second line adult and pediatric brainstem and non-brainstem glioma GBM. Given the possibility for internal development work, we have not reduced the R&D expense in the out years.

G&A. We expect G&A spending to remain relatively flat in 2013 with about $1.25 million anticipated for 2Q 2013 and about $6 million in G&A expenses anticipated for full year 2013. We anticipate modest personnel expansion and assume most fluctuations in the G&A expenses will be correlated with the stock price fluctuations, due to the quarterly changes in non-cash stock compensation expense.

EPS. We anticipate Stemline to record EPS of ($2.30) in 2013, and EPS of ($2.40) in 2014. Our 2013 assumptions include the recent 4.8 million share capital raise in 2Q 2013. Overall we anticipate Stemline to generate positive EPS in 2017 and to remain profitable thereafter. Additionally, we have conservatively projected significant share growth, which equates to about 17.5 million fully diluted shares outstanding in 2017. Our share growth assumptions include the growth of the 12.4 million shares outstanding following the financing in 2Q13.

Balance sheet. Stemline is in a solid cash position with about $95 million in cash and cash equivalents, post the recent follow-on capital raise. Based on the burn rate of $3-$5 million a quarter in 2013, and an anticipated burn of $5-$7.5 million a quarter in 2014, we believe Stemline has at least 30 months of cash, before another capital infusion is necessary even if PDUFA fees are warranted over that timeframe.

MANAGEMENT

Ivan Bergstein, M.D., Founder, President, CEO, and Chairman of the Board. Stemline was founded by Dr. Bergstein in 2003 and since inception he has served as the Chief Executive Officer. Previously Dr. Bergstein was the Medical Director of Access Oncology, Inc., which was a private oncology-focused biotechnology company. Prior to that he was a senior analyst at Cancer Advisors, Inc., where he specialized in the biopharmaceuticals sector and advised investment funds on public oncology focused companies. Dr. Bergstein received a B.A. in Mathematics from the University of Pennsylvania and an M.D. from the Mount Sinai Medical Center, where he completed a general surgery internship. Subsequently, he was named the Jerome A. Urban post-doctoral fellow at Cornell University Medical College. Dr. Bergstein then went on to complete a residency in internal medicine and a clinical Fellowship in hematology-medical oncology at the New York Presbyterian Hospital-Weill Medical College of Cornell University.

Eric Rowinsky, M.D., Chief Medical Officer. Dr. Rowinsky is Stemline's Chief Medical Officer and Head of Research and Development. Dr. Rowinsky has more than 25 years of experience managing clinical trials and developing drugs from preclinical to regulatory approval. He was previously Executive Vice President and Chief Medical Officer for ImClone Systems, Inc., where he led the FDA approval of Erbitux® for head and neck and colorectal cancer, and advanced eight other monoclonal antibodies through clinical development. Dr. Rowinsky was Director of the Institute of Drug Development ("IDD") at the Cancer Therapy and Research Center. In addition, he held the SBC Endowed Chair for Early Drug Development at the IDD and was a Clinical Professor of Medicine at the University of Texas Health Science Center at San Antonio. Dr. Rowinsky was an Associate Professor of Oncology at the Johns Hopkins University School of Medicine. He was a longstanding NCI principal investigator on U01 anticancer drug development grants, and was integrally involved in pivotal clinical and preclinical investigations, which led to the development of paclitaxel, docetaxel, topotecan, irinotecan, erlotinib, gefitinib, and temsirolimus, among others. Dr. Rowinsky is currently an Adjunct Professor of Medicine at New York University School of Medicine and sits on the Board of Directors of a number of public and private biopharmaceutical companies, including Biogen Idec, Inc. Dr. Rowinsky received his M.D. from Vanderbilt University School of Medicine. He completed his residency in internal medicine at the University of California, San Diego and his fellowship in medical oncology at Johns Hopkins Oncology Center.

Kenneth Hoberman, Chief Operating Officer. Kenneth Hoberman serves as Stemline's Chief Operating Officer. Prior to that he served as our Vice President of Operations. Previously, Mr. Hoberman was Vice President of Corporate and Business Development of Keryx Biopharmaceuticals, Inc., where he was instrumental in securing multiple sources of capital including over $200 million in equity investments through public and private offerings. He also initiated and executed a $100 million strategic alliance and originated, negotiated and closed dozens of licensing and operational contracts, and helped grow the company to a $900 million market capitalization at its peak. Previously, he was Managing Director at Hawkins BioVentures, a healthcare advisory firm and has served as a consultant to various healthcare-related companies. Mr. Hoberman received a B.S.B.A. in Finance from Boston University and completed post-baccalaureate studies at Columbia University.

Stephen P. Hall, VP Finance and Chief Accounting Officer. Mr. Hall serves as Stemline's Vice President of Finance and Chief Accounting Officer. Previously, Mr. Hall was founder and managing director of Deimos Consulting, LLC, a management consulting firm specializing in Life Sciences. Mr. Hall has also served as Senior Vice President, Chief Financial Officer, Chief Compliance Officer and Treasurer of Orthocon, Inc. a New York-based medical products company. Prior to this, Mr. Hall served as Senior Vice President, Chief Financial Officer and Treasurer of Helicos BioSciences, a public life science company. Mr. Hall previously served as Senior Vice President and Chief Financial Officer of TriPath Imaging, Inc., a public oncology company, and continued to serve as Senior Advisor upon its acquisition by Becton, Dickinson and Company. Mr. Hall served as Chief Financial Officer and President of the Imaging and Power System Division of Colorado Medtech, Inc., public a medical products and services company. Mr. Hall previously served as Chief Financial Officer for BioTechnica International, Inc., a publicly-held agricultural products company. Mr. Hall worked at the accounting firm of Peat, Marwick, Mitchell & Co. He earned an A.B. degree from Harvard College and an MBA from the Stanford Graduate School of Business.

Michael Szarek, Ph.D., Head of Clinical and Regulatory Affairs. Dr. Szarek has over 15 years of experience in clinical and regulatory affairs in multiple therapeutic areas. He previously led a regulatory affairs team at ImClone Systems, Inc. that was responsible for development strategies for Erbitux® (cetuximab) and multiple other monoclonal antibody therapeutics. Prior to ImClone, he was a director and biotechnology analyst at CIBC World Markets (later Oppenheimer and Co.). Previously, he was the worldwide statistical lead for Lipitor® (atorvastatin) at Pfizer, Inc. Dr. Szarek has published over 30 articles in leading medical and statistical journals and has served on numerous independent academic Steering Committees and Data Monitoring Committees for Phase 3 trials. He earned an MS degree in biostatistics from Harvard School of Public Health, and a PhD in biostatistics from New York University.

PRIMARY RISKS

We think the primary risks to an investment in Stemline shares include, but are not limited to:

Revenue. There is no assurance that Stemline will be able to execute its development strategy, and generate the forecasted revenues. Moreover, there is no assurance that competitive products will not out compete Stemline's products, or that products not yet in existence or in the public space will be developed that may be superior to Stemline's products. Stemline is a development-stage biopharmaceutical company, and does not have any commercial products that generate revenues or any other sources of revenue. Stemline may never be able to successfully develop marketable products. Stemline's pharmaceutical development methods are unproven and may not lead to commercially viable products for any of several reasons. Stemline currently has no marketing and sales organization and no experience in marketing pharmaceutical products. If Stemline is unable to establish sales and marketing capabilities or fails to enter into agreements with third parties to market and sell any products it may develop, Stemline may not be able to effectively market and sell its products and generate product revenue. Stemline also faces product reimbursement risk. Thus, there is risk that our revenue forecasts are not met. Stemline has incurred net operating losses since its inception and we anticipate that they will continue to incur substantial operating losses for the foreseeable future. Stemline may never achieve or

sustain profitability, which would depress the market price of its common stock, and could cause an investor to lose all or a part of their investment.

Commercial Partnerships. There is no assurance Stemline will be able to find a partner for products in it existing portfolio or if they are able to find a partner that the financial terms will be attractive to Stemline. Stemline focuses on in-licensing and developing products as its business strategy, and plans to continue to in-license products. There is no assurance that competitors will not be able to more effectively gain access to additional attractive product opportunities than Stemline. Stemline could face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully, than Stemline.

Regulatory. There can be no assurance that the FDA or other regulatory boards approve Stemline's current or future products. The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if Stemline is ultimately unable to obtain regulatory approval for its product candidates, Stemline's business will be substantially harmed. Furthermore if Stemline initiates a clinical trial with SL-401 or other future product there can be no assurance these studies will be completed in a timely manner, that results will support the intended regulatory or commercial purpose or that results will favorably impact either regulatory reviews or adoption by clinicians. Delays in the commencement of clinical trials and delays in the receipt of data from preclinical or clinical trials conducted by third parties could significantly impact Stemline's product development costs. Results of earlier clinical trials may not be predictive of the results of later-stage clinical trials. Third parties have conducted all clinical trials of SL-401 and SL-701 so far, and Stemline's ability to influence the design and conduct of such trials has been limited. Stemline plans to assume control over the future clinical and regulatory development of such product candidates will entail additional expenses and require Stemline to rely on additional third parties. Any failure by a third party to meet its obligations with respect to the clinical and regulatory development of Stemline's product candidates may delay or impair their ability to obtain regulatory approval for their products.

Financing. The company's current financial resources should fund the company to 2H15. However, the commercial development of the company's products will require substantial direct funding from Stemline. There can be no assurance that revenue will materialize or adequately fund the company. Additionally, should Stemline require additional financial resources, there is no guarantee the company will have access to capital in the future on adequate terms, or at all.

Manufacturing. Stemline relies completely on third parties to manufacture preclinical and clinical pharmaceutical supplies and intends to rely on third parties to produce commercial supplies of any approved product candidate, and Stemline's commercialization of any of its product candidates could be stopped, delayed or made less profitable if those third parties fail to obtain approval of the FDA, fail to provide Stemline with sufficient quantities of pharmaceutical product or fail to do so at acceptable quality levels or prices. Any quality control, manufacturing or stability concerns could negatively impact revenues.

Intellectual Property. Stemline's ability to generate revenue is dependent on market exclusivity of its products, such as SL-401 and SL-701. There is no guarantee that Stemline will be able to successfully defend its patents. Should Stemline's patents fail to provide market exclusivity, and should orphan drug designation also fail to provide market exclusivity, there is no assurance that the company will be able to generate revenue sufficient enough to fund operations. Changes in U.S. patent law could diminish the value of patents in general, thereby impairing Stemline's ability to protect their products.

Table 16: Income Statement

STEMLINE THERAPEUTICS Income Statement (December Fiscal Year; All amounts in '000s except per share items)

	2011A	2012A	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
Sales/Royalties:												
SL-401 Revenue & Royalties	-	-	-	-	-	28,911	131,976	283,985	395,035	502,595	580,821	633,438
SL-701 Royalties	-		-	-	-	-	-	-	-	-	-	-
Total product revenue and royalties	**-**	**-**	**-**	**-**	**-**	**28,911**	**131,976**	**283,985**	**395,035**	**502,595**	**580,821**	**633,438**
COGS		-	-	-	-	6,650	28,602	63,101	87,770	112,110	129,687	141,702
R&D	1,629	3,377	17,659	24,989	30,476	33,524	34,194	34,878	35,576	36,287	37,013	37,753
G&A	1,088	3,091	5,977	5,950	7,465	12,317	19,706	25,618	28,180	30,998	34,098	35,803
Total operating expenses	**2,717**	**6,468**	**23,636**	**30,939**	**37,941**	**52,490**	**82,503**	**123,597**	**151,526**	**179,396**	**200,798**	**215,258**
Operating income (EBIT)	**(2,717)**	**(6,468)**	**(23,636)**	**(30,939)**	**(37,941)**	**(23,579)**	**49,473**	**160,388**	**243,509**	**323,199**	**380,023**	**418,179**
Other expenses											-	-
Other income	47	302	124	130	135	137	140	143	146	149	152	155
Other expense	(10)	(0)	(125)	-	-	-	-	-	-	-	-	-
Interest expense	(99)	(119)	(332)	(339)	(346)	(352)	(360)	(367)	(374)	(382)	(389)	(397)
Interest income	24	10	629	599	740	372	379	387	395	403	411	419
Total other income (expense), net	(38)	193	298	390	529	157	160	163	166	170	173	177
Pretax Income	**(2,755)**	**(6,275)**	**(23,338)**	**(30,550)**	**(37,411)**	**(23,422)**	**49,633**	**160,551**	**243,675**	**323,369**	**380,196**	**418,356**
Benefit or (Provision for) income taxes	-	-	-	-	-	-	(4,963)	(24,083)	(48,735)	(97,011)	(133,069)	(146,425)
Net income	**(2,755)**	**(6,275)**	**(23,338)**	**(30,550)**	**(37,411)**	**(23,422)**	**44,670**	**136,468**	**194,940**	**226,359**	**247,128**	**271,931**
EPS basic	$ (0.80)	$ (1.82)	$ (2.30)	$ (2.40)	$ (2.26)	$ (1.37)	$ 2.56	$ 7.66	$ 10.73	$ 12.22	$ 13.08	$ 14.11
EPS diluted, GAAP	$ (0.80)	$ (1.82)	$ (2.30)	$ (2.40)	$ (2.26)	$ (1.23)	$ 2.29	$ 6.86	$ 9.61	$ 10.94	$ 11.71	$ 12.63
Basic shares outstanding	3,442	3,442	10,138	12,715	16,557	17,116	17,458	17,808	18,164	18,527	18,898	19,275
Diluted shares outstanding	3,442	3,442	10,138	12,715	16,557	19,116	19,498	19,888	20,286	20,692	21,106	21,528

Source: Company documents and Ladenburg Thalmann & Co. estimates

Table 17: Quarterly Income Statement

STEMLINE THERAPEUTICS Income Statement (December Fiscal Year; All amounts in '000s except per share items)

	2011A	2012A	1Q13A	2Q13E	3Q13E	4Q13E	2013E	1Q14E	2Q14E	3Q14E	4Q14E	2014E	2015E
Sales/Royalties:													
SL-401 Revenue & Royalties	-	-	-	-	-	-	-	-	-	-	-	-	-
SL-701 Royalties	-		-	-	-	-	-	-	-	-	-	-	-
Total product revenue and royalties	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
COGS		-	-	-	-	-	-	-	-	-	-	-	-
R&D	1,629	3,377	3,162	3,320	5,453	5,725	17,659	5,840	6,015	6,376	6,758	24,989	30,476
G&A	1,088	3,091	2,167	1,257	1,270	1,282	5,977	1,347	1,427	1,527	1,649	5,950	7,465
Total operating expenses	**2,717**	**6,468**	**5,329**	**4,577**	**6,722**	**7,008**	**23,636**	**7,186**	**7,442**	**7,903**	**8,408**	**30,939**	**37,941**
Operating income (EBIT)	**(2,717)**	**(6,468)**	**(5,329)**	**(4,577)**	**(6,722)**	**(7,008)**	**(23,636)**	**(7,186)**	**(7,442)**	**(7,903)**	**(8,408)**	**(30,939)**	**(37,941)**
Other expenses													
Other income	47	302	31	31	31	32	124	32	32	33	33	130	135
Other expense	(10)	(0)	(125)	-	-	-	(125)	-	-	-	-	-	-
Interest expense	(99)	(119)	(82)	(83)	(83)	(84)	(332)	(84)	(84)	(85)	(85)	(339)	(346)
Interest income	24	10	-	225	210	194	629	178	160	141	120	599	740
Total other income (expense), net	(38)	193	(176)	173	158	142	298	125	108	89	68	390	529
Pretax Income	**(2,755)**	**(6,275)**	**(5,506)**	**(4,404)**	**(6,564)**	**(6,866)**	**(23,338)**	**(7,061)**	**(7,334)**	**(7,815)**	**(8,340)**	**(30,550)**	**(37,411)**
Benefit or (Provision for) income taxes	-	-	-	-	-	-	-	-	-	-	-	-	-
Net income	**(2,755)**	**(6,275)**	**(5,506)**	**(4,404)**	**(6,564)**	**(6,866)**	**(23,338)**	**(7,061)**	**(7,334)**	**(7,815)**	**(8,340)**	**(30,550)**	**(37,411)**
EPS basic	$ (0.80)	$ (1.82)	$ (0.90)	$ (0.46)	$ (0.53)	$ (0.55)	$ (2.30)	$ (0.56)	$ (0.58)	$ (0.61)	$ (0.65)	$ (2.40)	$ (2.26)
EPS diluted, GAAP	$ (0.80)	$ (1.82)	$ (0.90)	$ (0.46)	$ (0.53)	$ (0.55)	$ (2.30)	$ (0.56)	$ (0.58)	$ (0.61)	$ (0.65)	$ (2.40)	$ (2.26)
Basic shares outstanding	3,442	3,442	6,148	9,612	12,359	12,433	10,138	12,545	12,658	12,771	12,886	12,715	16,557
Diluted shares outstanding	3,442	3,442	6,148	9,612	12,359	12,433	10,138	12,545	12,658	12,771	12,886	12,715	16,557

Source: Company documents and Ladenburg Thalmann & Co. estimates

APPENDIX A: IMPORTANT RESEARCH DISCLOSURES

ANALYST CERTIFICATION

I, Matt Kaplan, attest that the views expressed in this research report accurately reflect my personal views about the subject security and issuer. Furthermore, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report, provided, however, that:

The research analyst primarily responsible for the preparation of this research report has or will receive compensation based upon various factors, including the volume of trading at the firm in the subject security, as well as the firm's total revenues, a portion of which is generated by investment banking activities.

COMPANY BACKGROUND

Stemline Therapeutics is a biopharmaceutical company focused on the acquisition and development of oncology products that target cancer stem cells. STML's comparative advantage is to identify quality assets to develop. Lead product candidates are SL-401 and SL-701. SL-401 is indicated for AML, BPDCN and possibly other cancers that overexpress IL-3R. SL-701 is indicated for GBM, and is in line with the company's focus to target cancer stem cells. Stemline's management is a significant shareholder and strongly incentivized to achieve share price growth. Stemline operations are headquartered in New York, NY.

VALUATION METHODOLOGY

Our $36.00 price target is supported by a DCF, EPS multiple, and a sum of parts analysis. The DCF analysis applies a 35% discount rate, and an 8x multiple of the 2021 EBITDA of $380 million as the terminal value. The sum of parts (SOP) analysis employs the revenue and generated from SL-401 in the relapsed and refractory AML and BPDCN patient populations, as well as the current cash position. The SOP analysis utilizes a 30% discount rate for SL-401 revenue from the U.S. and a 35% rate from the ex-U.S. royalties, with a weighted average discount rate of 30%. The EPS multiple analysis uses the 2018 fully diluted EPS of $6.86, and utilizes a 20x multiple and a 35% discount rate. Using an equally weighted average of the various valuation methodologies we determined the price target of $36.00.

RISKS

Revenue. There is no assurance that Stemline will be able to execute its development strategy, and generate the forecasted revenues. Moreover, there is no assurance that competitive products will not out compete Stemline's products, or that products not yet in existence or in the public space will be developed that may be superior to Stemline's products. Stemline is a development-stage biopharmaceutical company, and does not have any commercial products that generate revenues or any other sources of revenue. Stemline may never be able to successfully develop marketable products. Stemline's pharmaceutical development methods are unproven and may not lead to commercially viable products for any of several reasons. Stemline currently has no marketing and sales organization and no experience in marketing pharmaceutical products. If Stemline is unable to establish sales and marketing capabilities or fails to enter into agreements with third parties to market and sell any products it may develop, Stemline may not be able to effectively market and sell its products and generate product revenue. Stemline also faces product reimbursement risk. Thus, there is risk that our revenue forecasts are not met. Stemline has incurred net operating losses since its inception and we anticipate that they will continue to incur substantial operating losses for the foreseeable future. Stemline may never achieve or sustain profitability, which would depress the market price of its common stock, and could cause an investor to lose all or a part of their investment.

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For a full review of Stemline specific risk factors investors should refer to the Company's most recent forms 10K and 10Q on file with the SEC.

STOCK RATING DEFINITIONS

Buy: The stock's return is expected to exceed 12.5% over the next twelve months.
Neutral: The stock's return is expected to be plus or minus 12.5% over the next twelve months.
Sell: The stock's return is expected to be negative 12.5% or more over the next twelve months.

Investment Ratings are determined by the ranges described above at the time of initiation of coverage, a change in risk, or a change in target price. At other times, the expected returns may fall outside of these ranges because of price movement and/or volatility. Such interim deviations from specified ranges will be permitted but will become subject to review.

RATINGS DISPERSION AND BANKING RELATIONSHIPS (AS OF 5/31/13)

Buy:	74%	(39% are banking clients)
Neutral:	26%	(10% are banking clients)
Sell:	0%	(0% are banking clients)

BIOTECHNOLOGY & HEALTHCARE SECTOR STOCKS UNDER AUTHOR ANALYST COVERAGE ("The Universe")

Antares Pharma (ATRS), Aradigm (ARDM), Biodel, Inc. (BIOD), BioDelivery Sciences International (BDSI), Cornerstone Therapeutics (CRTX), Dara Biosciences, Inc. (DARA), Flamel Technologies S.A. (FLML), Furiex Pharmaceuticals, Inc. (FURX), IsoRay (ISR), Keryx Biopharmaceuticals (KERX), MediciNova (MNOV), Nile Therapeutics (NLTX), Prolor Biotech (PBTH), Repros Therapeutics (RPRX), Stemline Therapeutics (STML), TG Biosciences Inc. (TGTX), United Therapeutics (UTHR), and XOMA Ltd (XOMA).

COMPANY SPECIFIC DISCLOSURES

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Dr. Philip Frost serves as the Chairman of Teva and as Chairman of Ladenburg Thalmann Financial Services, the parent company of Ladenburg Thalmann & Co. Inc. Dr. Phillip Frost, Chairman of the Board of PBTH, beneficially owns 1% or more of common equity securities of PBTH. Members of the Board of Directors of the subject company have a noninvestment banking securities-related services client relationship with Ladenburg Thalmann & Co. Inc. A member of the Board of Directors of Stemline Therapeutics (STML) has an affiliation with Teva Pharmaceuticals Industries.

INVESTMENT RATING AND PRICE TARGET HISTORY

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