Stemline Therapeutics (STML)

Initiating Coverage at OUTPERFORM, $49 PT– Targeting Cancer Cells and Cancer Stem Cells

- **Stemline is developing oncology treatments that target both cancer stem cells (CSCs) and tumor bulk with a single therapeutic**. This approach could both reduce the main tumor and prevent a relapse with a better safety profile than currently used therapies.
- **The company's lead product candidate, SL-401, a targeted diphtheria toxin fusion protein, could enter pivotal Phase II trials for the rare cancer blastic plasmacytoid dendritic cell neoplasm (BPDCN) and third-line acute myelogenous leukemia (AML) in 2014, potentially leading to regulatory approval as early as YE:15.**
- **SL-401 has shown a strong clinical response as a single agent, particularly in BPDCN.** In a Phase I/II trial with six advanced BPDCN patients, half of them experienced a complete response, and five of the six experienced tumor shrinkage, after just a single one-week cycle of SL-401. A Phase II trial, which is expected to be sufficient for registration in the U.S. and Europe, is expected to begin in H1:14.
- **The company is also developing SL-701, a therapeutic cancer vaccine set to enter Phase IIb studies for malignant glioma in pediatric patients and recurrent or refractory glioblastoma multiforme (GBM) in adults in mid-2014.** SL-701 has shown strong single agent activity in Phase I/II studies, producing disease stabilization or an overall response in 19 of 22 pediatric glioma patients and 13 of 22 adult patients with high-grade recurrent or refractory glioma.
- **We view STML as undervalued, given the company's rapidly advancing pipeline and strong cash position.** With over $90 million in cash and a potential accelerated approval for SL-401 in BPDCN, STML represents an opportunity for investors looking for a well-funded clinical-stage biotech with relatively near-term commercial opportunities.
- **Initiating coverage of Stemline Therapeutics at OUTPERFORM with a $49 price target.** Our $49 price target is derived by applying a 6x multiple to 2019 SL-401 sales in IL3-R+ cancers, discounted annually by 30%, ($25 of PT). We add that to 6x 2019 estimated sales in AML, discounted annually by 35%, ($15 of PT), and finally, apply a 6x multiple to estimated 2019 sales of SL-701, discounted by 50% annually ($9/share) due to our view that 701 is a higher-risk program.

FYE Dec	2013E	2014E			2015E		
REV	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	0.0A	0.0E		$0.0E	0.0E		N/A
Q2 Jun	0.0A	0.0E		0.0E	0.0E		N/A
Q3 Sep	0.0E	0.0E		0.0E	0.0E		N/A
Q4 Dec	0.0E	0.0E		0.0E	6.8E		N/A
Year*	**0.0E**	**0.0E**		**$0.0E**	**6.8E**		**$0.0E**
Change	--	--			--		
	2013E	2014E			2015E		
EPS	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	($0.74)A	($0.44)E		--	($0.52)E		--
Q2 Jun	($0.55)A	($0.45)E		--	($0.50)E		--
Q3 Sep	($0.41)E	($0.50)E		--	($0.58)E		--
Q4 Dec	($0.43)E	($0.51)E		--	($0.29)E		--
Year*	**($2.14)E**	**($1.89)E**		**--**	**($1.89)E**		**--**
P/E	--	--			--		
Change	--	12%			-0%		

Consensus estimates are from Thomson First Call.
** Numbers may not add up due to rounding.*

September 11, 2013

Price
$36.72

Rating
OUTPERFORM

12-Month Price Target
$49

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Company Information

Shares Outst (M)	12.4
Market Cap (M)	$456.6
52-Wk Range	$10.33 - $39.18
Book Value/sh	$7.15
Cash/sh	$7.45
Enterprise Value (M)	$363.9
LT Debt/Cap %	0.0
Cash Burn (M)	$26.0

Company Description

Stemline Therapeutics, Inc., is developing SL-401, a targeted therapeutic for both cancerous cells and cancer stem cells in hematological malignancies expressing IL3-R. SL-701 is a peptide-based immunotherapy for advanced brain cancers and is in Phase IIb studies.

Source: Thomson Reuters

Investment Thesis

Stemline Therapeutics is a biotechnology company that is developing novel oncology treatments that target cancer stem cells (CSCs) and tumor bulk. Its lead clinical candidate, SL-401, is a targeted, truncated diphtheria toxin, set to begin a pivotal Phase II trial for the treatment of relapsed or refractory blastic plasmacytoid dendritic cell neoplasm (BPDCN), a rare hematologic cancer. In addition, we expect SL-401 to enter a pivotal Phase II trial as a third-line treatment for acute myeloid leukemia (AML). We note that SL-401 targets interleukin-3 receptor (IL-3R), which is expressed on a variety of hematologic cancers, including multiple myeloma, myelodysplastic syndrome (MDS), and other forms of leukemias, and we expect some use in these other indications upon initial approval for BPDCN. The company is also developing SL-701, a peptide-based cancer vaccine, which could enter Phase IIb studies in pediatric patients with malignant glioma and adult patients with recurrent or refractory glioblastoma multiforme (GBM) in 2014. STML's proprietary drug discovery platform, StemScreen, isolates and analyzes CSCs along with identifying compounds that target them. We believe the market is undervaluing these assets, and estimate that STML could generate $776 million in product sales by 2019, our valuation year.

Valuation

Our $49 price target is derived by applying a 6x multiple to 2019 SL-401 sales in IL3-R+ cancers, discounted annually by 30%, ($25 of PT). We add that to 6x 2019 estimated sales in AML, discounted annually by 35%, ($15 of PT), and finally apply a 6x multiple to estimated 2019 sales of SL-701, discounted by 50% annually ($9/share) due to our view that 701 is a higher risk program. We estimate that SL-401 in the BPDCN setting alone could generate $150 million in revenues in 2019, along with $165M in other IL-3R+ oncology settings, and $238 million in revenues in the relapsed AML setting. This is based on our estimates that SL-401 could capture 90% of BPDCN patients, 23% of IL-3R+ patients and 30% of the relapsed AML patient population. Our revenue estimates assume U.S. and European pricing of $15,000 per therapy course ($90,000 estimated per BPDCN patient), on par with other rare cancer therapies. Additionally, we estimate SL-701 could generate $222 million in revenues in 2020 in the pediatric glioma and advanced adult GBM settings, based on average revenue of $45,000 per patient.

Risks

Risks to the achievement of our price target include the clinical failure of SL-401 and/or SL-701, as well as failure to achieve regulatory approval and achieve sales estimates for either drug candidate.

Key points

- SL-401 has shown strong single agent activity in Phase I/II studies, with a single one-week course generating three complete responses in six BPDCN patients.
- In the third-line AML setting, patients treated with a single-cycle of SL-401 experienced a median overall survival of 5.6 months, compared to a typical 1.5 month survival in this setting.
- SL-401 has Orphan Drug status for both BPDCN and AML, and the accelerated approval process could result in a commercial launch in the BPDCN setting by Q4:15. With approval, we expect use in other high-IL3R expressing hematological cancers such as mastocytosis, hairy cell leukemia and others.
- SL-701 has produced durable responses and a possible survival benefit in the pediatric glioma setting, with 86% of patients in a Phase I/II trial showing overall response or disease stabilization.
- In a Phase I/II trial in recurrent or refractory adult patients with high-grade glioma, SL-701 approximately doubled the median overall survival in high-grade glioma patients compared to historical data.
- We estimate SL-401 could reach sales of $315M and $238M in BPDCN/IL-3R+ cancers and relapsed AML setting in 2019, respectively. We also estimate SL-701 to reach peak sales of $75M and $147M in the pediatric glioma and refractory/relapsed adult high-grade glioma settings, respectively. Considering that the company has over $90 million in cash and an enterprise value of about $350 million, we would recommend buying STML shares.

Stemline Therapeutics, Inc. Overview

Stemline Therapeutics, Inc. is based in New York, New York, and is focused on the development of SL-401, set to enter pivotal Phase IIb trials for BPDCN and relapsed/refractory AML. The company is also developing SL-701, which is set to enter Phase IIb trials for malignant glioma in pediatric patients and recurrent or refractory GBM in adult patients.

Upcoming milestones

Q4:13	Additional SL-401 clinical data presented at the American Society of Hematology conference
H1:14	Begin pivotal Phase II trial for SL-401 in BPDCN
Mid:14	Begin Phase II trials for SL-401 in multiple myeloma, MDS, and other IL-3R+ cancers
Mid:14	Initiate Phase IIb trial for SL-701 in second-line adult patients with GBM
H2:14	Initiate Phase IIb trial for SL-401 in third-line AML
H2:14	Initiate Phase IIb trial for SL-701 in pediatric patients with malignant glioma
YE:14	Initial data from Phase IIb trial of SL-401 in BPDCN available
2014	Complete ongoing Phase I/II trial of SL-701 in adult patients with low-grade glioma
2015	Submit NDA for SL-401 in BPDCN
Q4:15	Potential accelerated approval for SL-401 in BPDCN

Figure 1: Products in Clinical Development

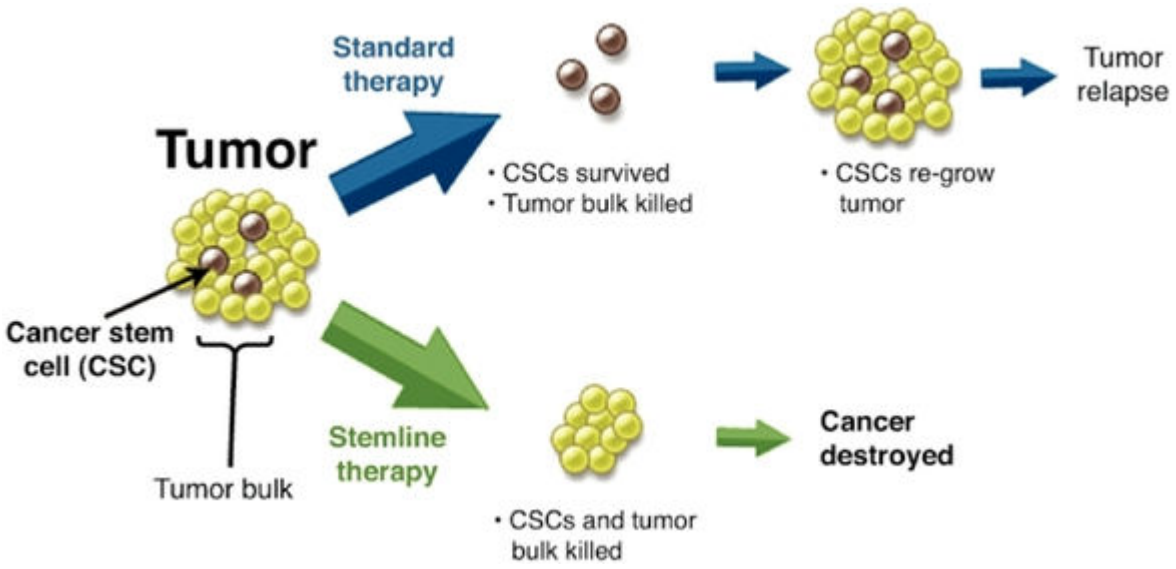
Product	Indication/Field	Stage of Development
SL-401	Relapsed/refractory BPDCN	Phase II/pivotal
	Relapsed/refractory AML	Phase II/pivotal
	Multiple myeloma	Phase I/II
	Relapsed or refractory MDS	Phase I/II
	Hairy cell leukemia, mastocytosis, and basophilic / eosinophilic leukemias that express IL-3R+	Phase I/II
SL-701	Pediatric malignant glioma	Phase IIb
	Adult high-grade glioma	Phase IIb
	Adult low-grade glioma	Phase I/II

Source: Stemline, Wedbush Securities, Inc.

Cancer Stem Cells

Stem cells are distinguished from other cells by pluripotency—the ability to continually divide and differentiate into a variety of cell types. Cancer stem cells (CSCs), which were first discovered in 1994, are cells within a tumor that can self-renew and drive tumorigenesis. CSCs typically make up about 2% of all the cells within a tumor, and it is believed that their slow growth rates and specific protein expression leave them resistant to traditional chemotherapeutic agents. Since their remaining presence after standard chemotherapy is thought to lead to tumor regeneration and metastasis, the targeted destruction of CSCs should reduce disease recurrence and the risk of developing new metastases.

Figure 2: Stemline's Dual Targeting Strategy

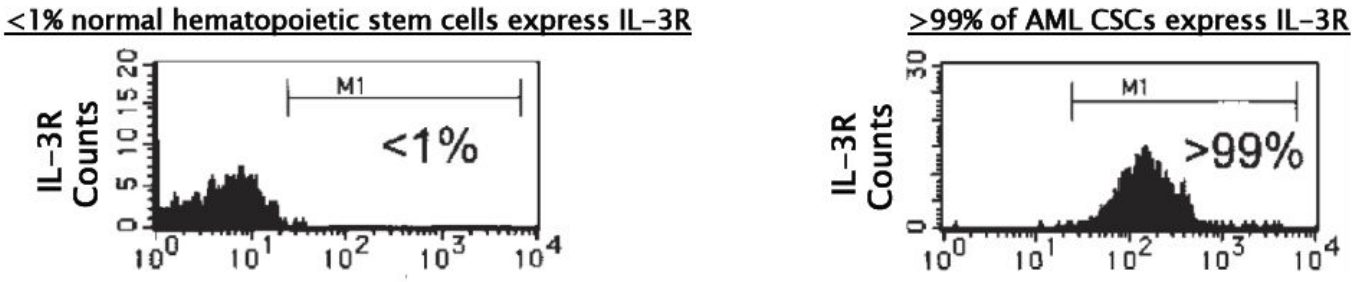


Source: Stemline

SL-401

SL-401 is a targeted therapy directed to interleukin-3 receptor (IL-3R), which is overexpressed on the tumor bulk and CSCs of multiple hematological cancers relative to normal cells. SL-401 is a fusion protein of the first 388 amino acids of diphtheria toxin (the portion of the larger protein that corresponds to the actual toxic portion) to human interleukin-3, expressed in *E. coli*. The IL-3 domain replaces the naturally-occurring cell-binding domain, with the toxic region remaining intact. IL-3R (also CD123 antigen) is generally found on progenitor cells, and is present to a high degree on acute myelogenous leukemia stem cells (Phillips et al. Nature (2000) "The interleukin-3 receptor alpha chain is a unique marker for human acute myelogenous leukemia stem cells." 14: 10; 1777-1784). The specific targeting of SL-401 is expected to result in less off-target toxicity as compared to traditional broad-spectrum chemotherapeutic agents, and higher efficacy. SL-401 binds to, delivers and intracellularly releases a diphtheria toxin payload to IL-3R+ malignant cells, resulting in protein synthesis inhibition and cell death.

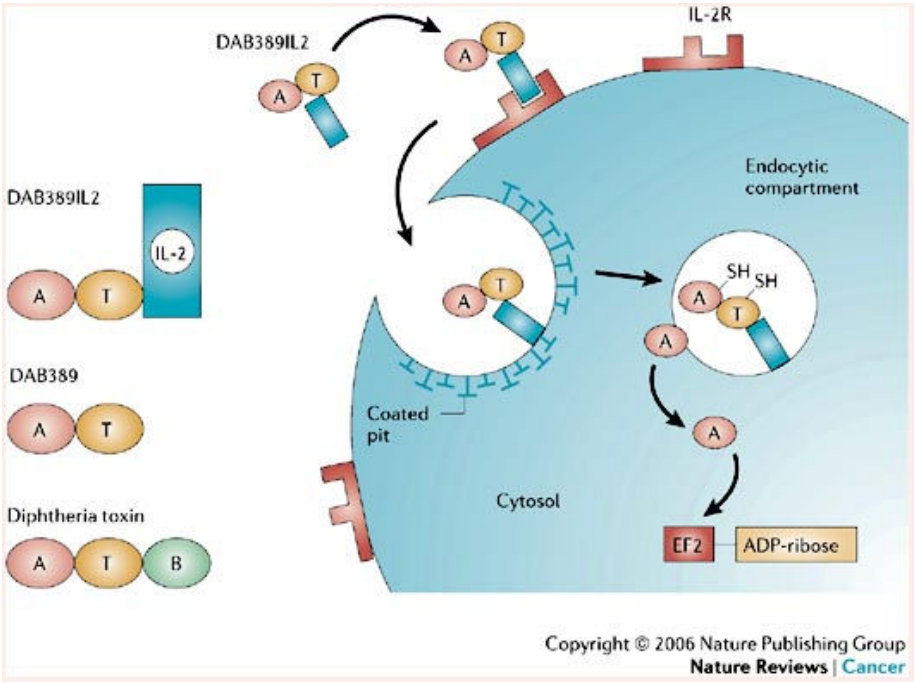
Figure 3: IL-3R Is Widely Expressed on Cancer Stem Cells, But Not Normal Stem Cells



Source: Stemline

This toxin payload does not appear to be subject to the multi-drug resistance highly expressed on CSCs and tumor bulk, and the inhibition of protein synthesis should allow it to destroy not just rapidly dividing cancer cells but also slower-growing ones like CSCs (Hogge et al. Cancer Research 2002 "A diphtheria toxin-interleukin 3 fusion protein is cytotoxic to primitive acute meloid leukemia progenitors, but spares normal progenitors." 62: 1730-1736). SL-401's mechanism of action is analogous to that of denileukin diftitox (Ontak), an approved drug, which is also a fusion protein whereby the binding domain of diphtheria toxin is replaced, in this case, with interleukin-2. Upon infusion into a patient, Ontak binds with the IL-2R receptors located on the cell-surface of certain cancer cells and then enters the cells. As with SL-401, the diphtheria toxin then inhibits protein synthesis, and kills the targeted cell. Ontak was developed by Ligand Pharmaceuticals (LGND, Not Covered), now marketed by Eisai (Not Covered) and was approved in 1999 in the US for the treatment of cutaneous T-cell lymphoma.

Figure 4: Mechanism of Action of Ontak (DAB389IL2)



Source: Nature Publishing Group

We do not expect antibodies from diphtheria-vaccinated individuals to interfere with the activity of SL-401; such antibodies did not interfere with the efficacy of Ontak, even with 8 cycles of treatment, as per Ontak's label. The level of antibodies also did not correlate with response in clinical studies to date for SL-401.

Figure 5: SL-401 Immune Response and Clinical Response

Table 2. Patient PK/Immune Response and Clinical Response

Subject No	Cmax days 1/5 (ng/mL)	Half-lives days1/5 (min)	Antibody pre/day 15-30 (µg/mL)*	Objective Response*	Response Duration (mo)
1	ND	ND	ND	ND	ND
2	0/7	-/50	6/34	CR	5
3	0/-	-/-	8/4590	CR	9+ (ongoing)
4	22/2	40/10	0.5/35	CR	1
5	8/18	30/30	1/ND	PR	1
6	0/-	-/ND	4/ND	PR	0.5+ (ongoing)

*Antibody levels day 15 except #1 was day 39, CR, complete remission; PR, partial remission; ND, not determined.

Source: Stemline, ASCO 2013

Stemline is likely to begin two pivotal studies of SL-401 in patients with BPDCN and third-line AML. SL-401 could also enter Phase II studies for other IL-3R+ hematological cancers, including multiple myeloma and high-risk recurrent/refractory MDS. SL-401 has received Orphan Drug designation for both AML and BPDCN in the U.S.

Stemline has exclusive, worldwide rights to SL-401, as part of a 2006 licensing deal with Scott and White Memorial Hospital. Scott and White is eligible for a single-digit royalty for any sales worldwide of SL-401.

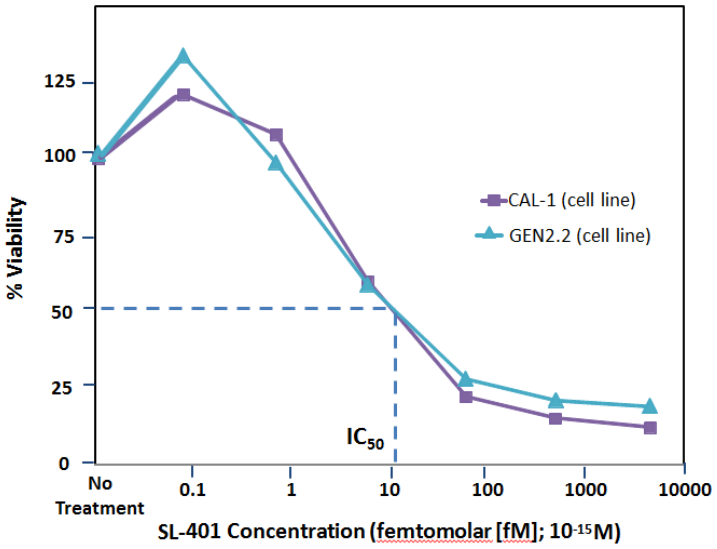
BPDCN—A Rare Hematologic Cancer

BPDCN is a rare hematologic cancer stemming from immature plasmacytoid dendritic cells. The disease was defined by the World Health Organization in 2008, and was previously referred to by various names, including blastic natural killer cell lymphoma and agranular CD4+/CD56+ hematodermic neoplasm. It typically presents itself with skin lesions, as well as other manifestations that may include the bone marrow, blood, lymph nodes and spleen. BPDCN growth in the bone marrow results in decreased blood cell counts, which causes serious infections, bleeding, and eventual death. Conventional chemotherapy has been shown to induce an initial response in BPDCN patients, but relapse is frequent and rapid. The overall incidence of the disease is low, amounting to about 1% of all leukemia and 0.5% of all lymphoma cases, or about 2,000 cases in the U.S. and Europe. It generally occurs in the elderly, with a median age of diagnosis of 66 years, and a male to female affected ratio of 3.5:1. The prognosis for the disease is poor, with a median overall survival from diagnosis of about 12 months. With no approved treatment or standard of care, BPDCN represents a significant unmet medical need.

Phase I/II 401 AHC Study

SI-401 was proposed as a treatment since BPDCN cells express high levels of IL-3R. Preclinical testing established that SL-401 was potent against BPDCN cells in a dose-dependant fashion, with BPDCN cell lines (GEN2.2 and CAL-1) showing sensitivity to SL-401 and IC_{50} values (the concentration that inhibits the growth of 50% of BPDCN cells) in the femtomolar range (10^{-15}).

Figure 6: SL-401 Potency Against BPDCN Cell Lines



Source: Stemline

SL-401 was first evaluated for BPDCN during the Phase I/II 401 AHC Study, which enrolled six patients with BPDCN, among the 85 patients enrolled in total. Patients with BPDCN who had previously failed combination chemotherapy and allogeneic bone marrow transplantation were administered a single cycle of 12.5 ug/kg of SL-401 in a 15 minute infusion daily for five days.

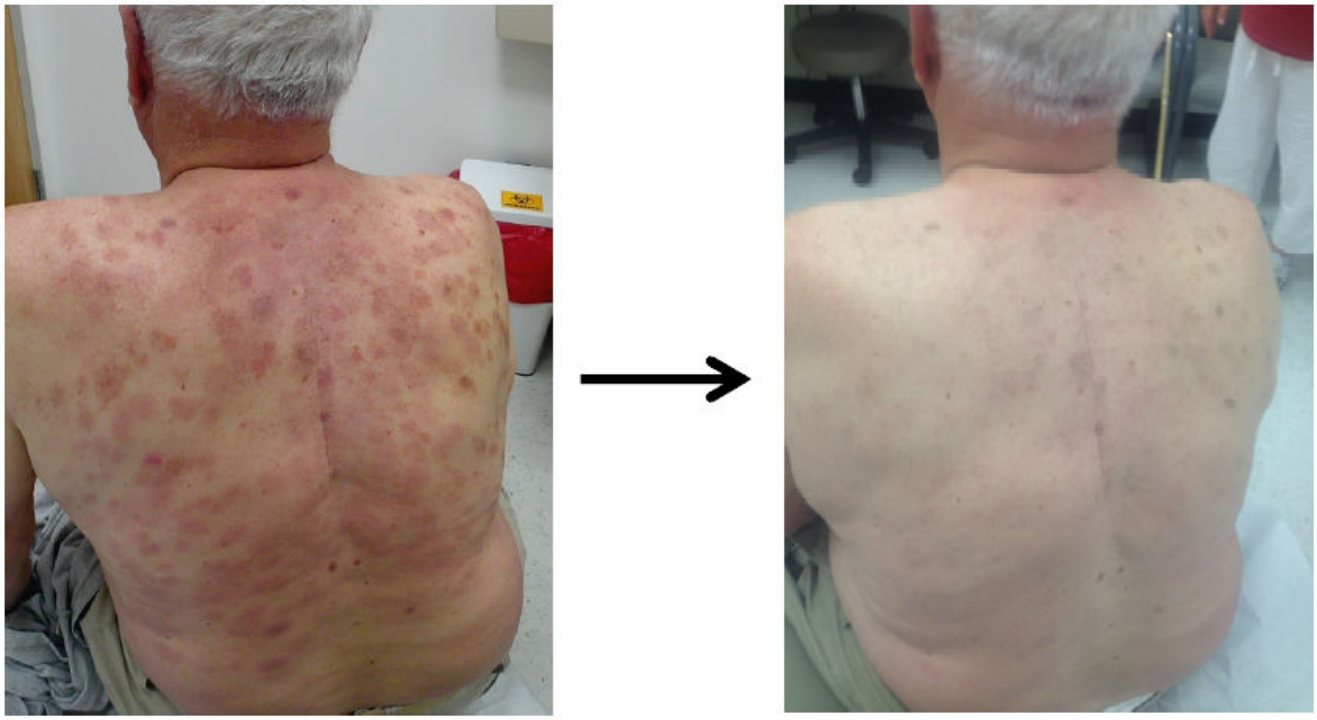
Figure 7: SL-401 BPDCN Patients' Characteristics

Table 1. Relevant Clinical Information				
Subject No.	Age/ Gender	Previous Treatment	Sites of Disease	No. of Doses Received of 5 Daily Doses (1 cycle)
1	35/F	Two intensive combination chemotherapy regimens	Bone Marrow	5/5
2	40/M	Cytarabine/Daunorubicin/Etoposide, BMT, DLI	Bone Marrow, Nodes	5/5
3	72/M	Cytarabine/Idarubicin, Gemcitabine, BMTx2	Skin, Bone Marrow	3/5
4	65/M	Etoposide/Doxorubicin/Vincristine/Prednisone/Cyclophosphamide, Fludarabine, BMT	Skin, Bone Marrow	5/5
5	70/M	Decitabine	Skin,Bone Marrow	5/5
6	70/M	0	skin	5/5

Source: Stemline, ASCO 2013

Of the six patients treated, 5 (83%) showed tumor shrinkage and disease stabilization, including three complete responses (CR). Two of the CRs have lasted longer than three months, including one in a fourth-line patient (11+ months, ongoing) and another in a third-line patient (5 months), as seen in Figure 5. No serious adverse events were observed.

Figure 8: Resolution of Skin Lesions in 70 year old Male Patient with BPDCN



Source: Stemline

SL-401 is set to be evaluated in a single-arm, open-label Phase II trial that could serve as a pivotal trial for accelerated approval in the BPDCN setting. The trial could begin in H1:14 and is expected to enroll a total of 40 to 50 patients with relapsed/refractory BPDCN across 15 to 20 sites in North America and Europe. Up to 6 cycles of 12.5 μg/kg SL-401 will be administered during the trial, which has a primary endpoint of the overall response rate. Interim data from the trial is expected to be available in YE:14. Positive results from an initial number of patients should suffice to support an NDA filing in 2015, with accelerated approval potentially occurring by Q4:15.

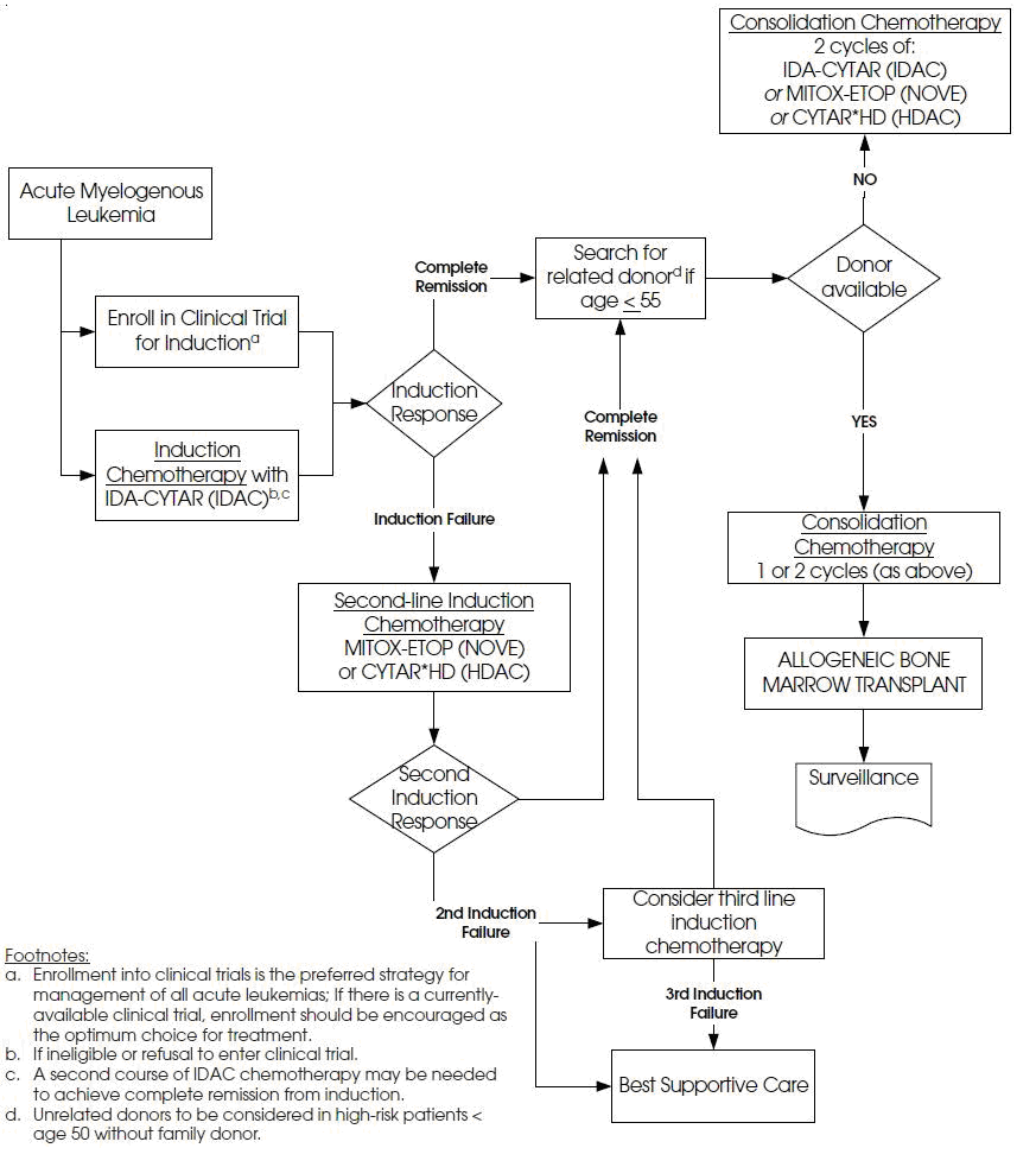
Due to the significant clinical benefit it can provide, and the lack of other treatment options, SL-401 should be able to command a premium if approved in the BPDCN indication. We estimate a price of $15,000 per cycle, with a likely treatment regimen consisting of six cycles. With an estimated annual incidence of 2,000 in the U.S. and Europe, our BPDCN sales estimate is $150 million in 2019, and we estimate another $165M in 2019 revenues from IL-3R+ hematological malignancies (mastocytosis, hairy cell leukemia and others).

Relapsed/refractory AML

AML is characterized by the proliferation of abnormal myeloblasts, leading to improper functioning of the bone marrow. Common symptoms of AML include anemia, infections and blood clots, and, left untreated, results in death within a few months. The disease primarily affects the elderly, with a median age at diagnosis of 67 years. AML is the most common type of acute leukemia in adults, with an annual incidence of about 15,000 in the U.S. and about 18,000 in Europe.

The goal in treating relapsed AML is to produce a complete response in order to allow for a bone marrow transplant in patients where transplant is appropriate (generally patients younger than 60), and to otherwise extend survival for as long as possible. However, with many of these patients being elderly or having poor performance, extending survival solely with chemotherapy is frequently the goal. First- and second-line treatments that are commonly administered include chemotherapy drugs such as cytarabine and anthracyclines at various doses and regimens. Over 50% of patients who receive first-line therapy will relapse, while over 75% of patients receiving second-line therapy will eventually relapse. Since the median overall survival for patients with a second relapse is just 1.5 months, about half of second-relapse patients are directed towards hospice care.

Figure 9: AML Treatment Paradigm



Source: Cancer Care Nova Scotia

Phase I/II 401 AHC Study

Stemline explored SL-401 as a treatment for AML since IL-3R is expressed on over 99% of AML CSCs, compared to less than 1% of normal hematopoietic stem cells (Figure 3). Preclinical *in vitro* and *in vivo* testing of SL-401 also demonstrated activity against both leukemia blasts and CSCs in a variety of human leukemia cells and cell lines. Separately, animal testing in mice implanted with human leukemia xenografts showed that mice administered SL-401 had prolonged survival when compared with untreated mice.

In the 401 AHC Study, 59 of 85 patients enrolled had relapsed/refractory AML. During the trial, patients were administered a single cycle of SL-401 in a 15 minute infusion daily for five days or every other day for 6 days at doses ranging from 7.1 - 22.1 µg/kg or from 4 - 12.5 µg/kg, respectively. Of the 59 patients with relapsed or refractory AML, 27 (46%) experienced either disease stabilization or tumor shrinkage. In the 11 elderly patients with AML who were not candidates for chemotherapy, 6 (55%) had either tumor shrinkage or disease stabilization.

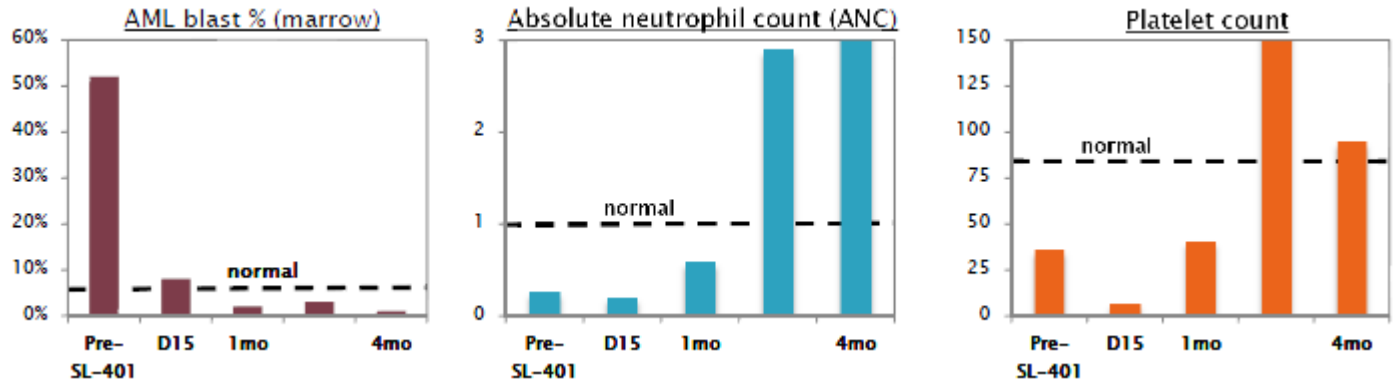
Figure 10: Clinical Responses by Disease of a Single One-Week Course of SL-401 in Phase I/II Trial

	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/ disease stabilization	83%	46%	43%	55%	43%
Tumor shrinkages	83% 3 CRs	25% 2 CRs	23% 1 CR	27%	29%

Source: Stemline

In AML patients who had already suffered at least two relapses, 15 (43%) of 35 evaluable patients had tumor shrinkage or disease stabilization after administration of a single cycle of SL-401, and eight (23%) had tumor shrinkage alone. One complete response, with an ongoing duration exceeding 25 months, has been observed in a heavily pretreated fourth-line patient who had already failed two prior bone marrow transplants.

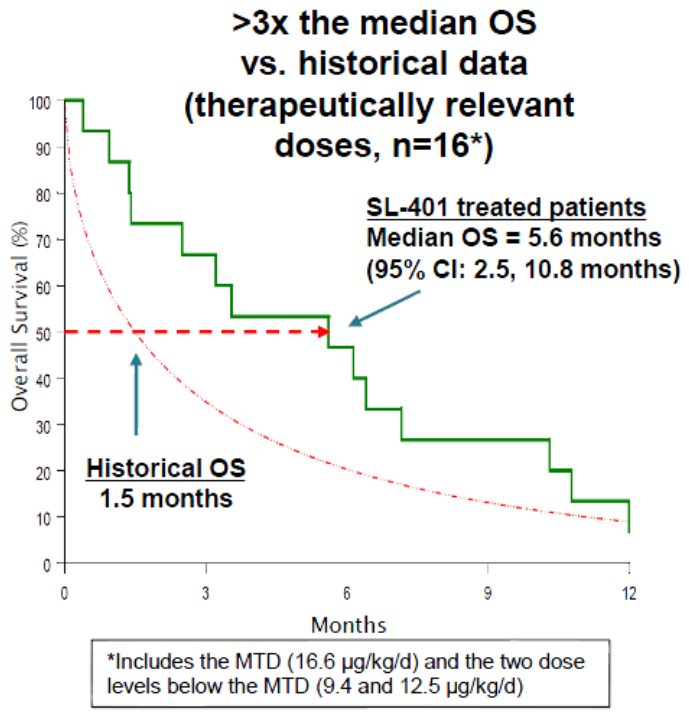
Figure 11: Complete Response in Heavily Pretreated Patient after One Cycle of SL-401



Source: Stemline

For the 16 patients who were administered the 9.4, 12.5 or 16.6 μg/kg per day doses, SL-401 caused a greater than three times increase in overall survival rate compared with historical data (median overall survival of 5.6 months vs. 1.5 months).

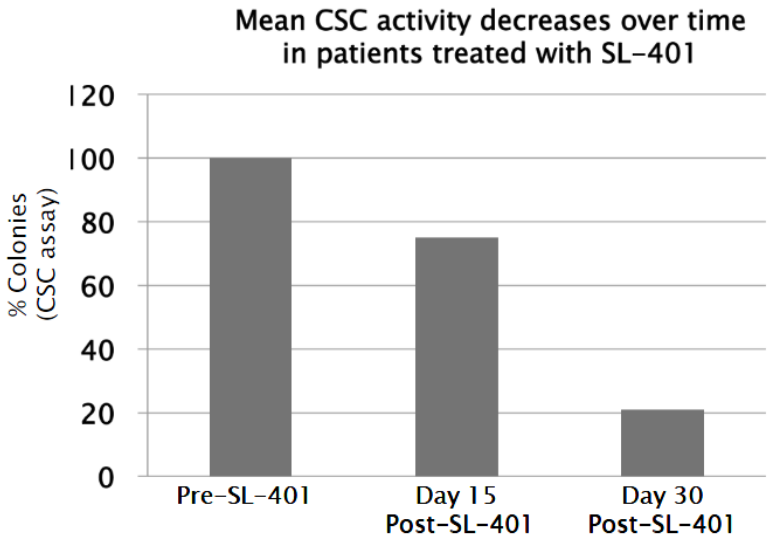
Figure 12: Overall Survival in >=3rd-line AML Patients Administered SL-401



Source: Stemline

Importantly, the link between SL-401 administration and decreased CSC activity was established in a translational study coordinated with the AHC Study. Bone marrow samples were collected from three of the patients enrolled in the AHC study both before and after treatment with SL-401, and then tested for CSC activity in a colony formation assay. A decrease in bone marrow CSC activity was observed at 15 and 30 days after treatment, including an average 79% decrease in CSC activity by 30 days post-treatment. Evidence that decreased CSC activity was correlated to beneficial clinical effects can be seen in the 79% and 84% reduction in CSC activity observed in two patients at 30 days post-treatment who had overall survival times of 7.2 and 13.6 months, respectively.

Figure 13: Decreased Cancer Stem Cell Activity after SL-401 Treatment



Source: Stemline

No serious adverse events occurred, and SL-401 was shown to be non-toxic to the bone marrow (as determined by mean absolute neutrophil, hemoglobin and platelet counts), which differentiates it from other hematologic chemotherapies like nucleoside inhibitors and anthracyclines, and could theoretically allow for combination with other agents by avoiding overlapping toxicities. Although the complete response rate was relatively low compared to that seen for other AML treatments, the rate for the AHC study should be considered in light of the more advanced patient population it was evaluated in and the fact that only one cycle of SL-401 was administered.

Figure 14: Recent Clinical Trial Results for AML Drug Candidates

Study Name	Drug	Patient Population	Median O/S	LFS or early mortality	CR+CRp rate
Phase I/II 401 AHC	SL-401	>=2nd Relapsed, n=35	5.6 mos		3%
Phase II Vosaroxin	Vosaroxin + Cytarabine	1st Relapsed (CR1 median of 7.3 mos), Primary Refractory, n=69 (all doses)	7.1 mos	14.5 median LFS	29%
Litzow	IDAC/IDAC +	1st Relapsed (CR1<12 mos), Primary Refractory	3.4 mos		8%
CEP701	MEC or HiDAC	1st Relapsed (CR1<24 mos), Primary Refractory, n=220	4.6 mos		26% vs. 21%
Onrigin CLI-037 (Phase III)	IDAC (1.5 g/m2) +/- laromustine (600 mg/m2)	1st Relapsed (CR1= 9.7 mos), Primary, n=263	3.5 mos	5.8 mos LFS	35% vs. 19%
Genzyme CLASSIC-1 (Phase III)	IDAC (1 g/m2) +/- clofarabine	1st Relapsed (>6 mos) Primary Refractory (<6 mos), n=320	6.6 vs. 6.4 mos	Median LFS< 4 months	47% vs. 23% (CR+CRi)
Elacytarabine	Elacytarabine	Second Salvage AML, n=61	5.3 mos	30 day mortality = 13%	18%
Ambit	Quizartinib	1st Relapsed (FLT3 ITD+), n=53	6 mos		5%

Source: Wedbush Securities, Inc.

Stemline plans to advance SL-401 into a registration-directed Phase II trial for third-line AML patients in H2:14, in order to support a planned 2016 NDA submission (potentially a supplementary submission, if approved in BPDCN prior to 2016, as we estimate). The trial could enroll about 240 patients, randomized 2:1 to receive up to 6 cycles of SL-401 or physician's choice. The primary endpoints of the study are planned to be overall survival and complete response rate. While this study is planned to be rigorous in defining third-line AML patients as those who have progressed after transplant and a line of chemotherapy or 2 lines of chemotherapy, if approved, we would expect that some off-label use in front-line or primary relapsed/refractory patients would be likely, given AML's generally poor prognosis and SL-401's differentiated side effect profile.

Market:
We estimate $238M in AML revenues by 2019, our valuation year. Our assumptions include an available population of 7500 patients in the US and 9000 in the EU, with a peak market penetration of 45%. We assume an average of 3 cycles of treatment per AML patient at $15,000 per cycle. We do not include in our estimates possible use of SL-401 in earlier settings.

Competition

There are no approved therapies for BPDCN, and we are not aware of any other drugs in development for the indication, nor are we aware of IL-3R-targeted therapies being developed.

Although there are no approved third-line AML treatments, patients can be treated (if they are able to tolerate additional therapy) by additional rounds of chemotherapy. The most commonly prescribed AML treatments are generic cytarabine in combination with an anthracycline like daunorubicin or idarubicin. Front-line treatment with these drugs is commonly referred to as '7+3' therapy, or seven consecutive days of cytarabine IV infusion followed by three consecutive days of anthracycline IV injections. Elderly patients who require a lower-intensity therapy may instead receive drugs like Clolar (clofarabine), Dacogen (decitabine) or Vidaza (azacytidine). However, despite these treatment options, AML remains a very difficult disease to treat, particularly in the elderly, who are the majority of the patients.

There are a number of companies developing drugs for the treatment of relapsed/refractory AML, including Sunesis (SNSS, OUTPERFORM), Astex (ASTX, Not Covered), and Epizyme (EPZM, OUTPERFORM). Sunesis is currently evaluating vosaroxin in combination with cytarabine in its Phase III VALOR trial for relapsed/refractory AML. Vosaroxin is a topoisomerase II inhibitor that has shown a median overall survival of 7.1 months in primary refractory and first relapsed AML patients. Astex is developing SGI-110, a hypomethylating agent that could have improved pharmacokinetic/dynamic properties relative to Dacogen. Epizyme has recently entered EPZ-5676 into Phase I; it is a small molecule inhibitor of the histone methyltransferase DOT1L that could treat a subset of AML patients harboring rearrangements of the MLL gene. Our view is that given SL-401's likely ability to combine with other agents, due to SL-401's favorable safety and tolerability profile, we do not expect newer agents to be in a zero-sum competition with SL-401.

SL-701

SL-701 is a therapeutic cancer vaccine designed to direct the immune system to target CSCs and tumor bulk of brain cancer. The vaccine is comprised of short synthetic peptides that correspond to epitopes of IL-13 receptor alpha 2 protein (IL-13Rα2) and Ephrin receptor A2 (EphA2). IL-13Rα2 and EphA2 are targets that are overexpressed on brain cancer cells, with EphA2 showing overexpression in both brain CSCs and tumor bulk. Stemline is developing SL-701 to treat high-grade glioma in pediatric and adult patients.

Stemline has an exclusive license to SL-701 from the University of Pittsburgh, which is eligible for a single-digit royalty on any sales.

Glioma

Gliomas are brain tumors originating from glial cells. Gliomas are the most common type of primary brain tumor, accounting for 80% of all malignant brain tumors, and they can metastasize through the cerebrospinal fluid to other regions of the central nervous system. Gliomas are graded on a scale of one to four, with higher grades correlating to more aggressive tumors. Grade three gliomas, or anaplastic astrocytomas, and grade four gliomas, or glioblastomas (GBM), are referred to as high-grade gliomas.

Phase I/II Pediatric Glioma Study

Pediatric high-grade glioma has an annual incidence of about 1,800 in the U.S. and 3,400 in Europe. Newly diagnosed patients are typically treated with surgery, chemotherapy and/or radiation, with almost all patients relapsing. Pediatric patients with glioma have a poor prognosis, with a median overall survival from diagnosis of less than a year.

The single-arm Phase I/II "701 Ped-G Study" evaluated SL-701 in 27 pediatric glioma patients, including 16 who had brainstem glioma, five who had cerebral (non-brainstem) high-grade glioma and six who had recurrent low-grade gliomas. SL-701 was administered via subcutaneous injection every three weeks for up to eight cycles, along with a separate adjuvant injection. Of the 22 evaluable children, 19 (86%) sustained durable tumor shrinkage or disease stabilization, including 14 who had stable disease lasting longer than three months. Three of the patients had sustained durable partial responses, with durations of 15 months for a child with newly diagnosed brain-stem glioma, 14 months for a child with non-brainstem glioma, and nine months for a child with recurrent low-grade glioma. In addition, one child had prolonged disease-free status for 20 months following surgery, and four other stable disease patients survived at least 13 months. No serious adverse events were observed. Tumor pseudoprogression, a surrogate marker of anti-tumor activity, was detected in four patients. Immunogenicity was demonstrated in six of seven children through specific T-cell responses to the intended targets, as determined by ELISPOT and tetramer immunological assays.

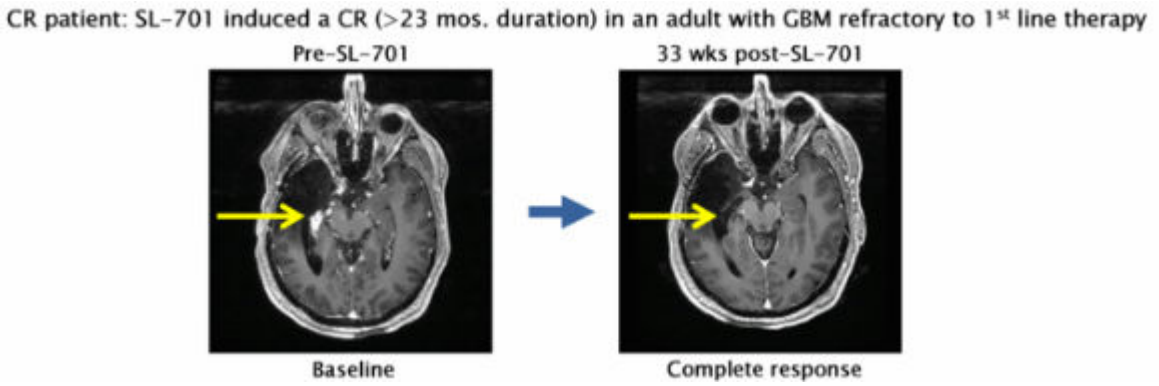
Stemline intends to advance SL-701 into a Phase IIb trial in pediatric glioma patients in the U.S. and Europe in 2014. The U.S. study will be led by the St. Jude's Children's Research Hospital, with the majority of the costs funded by government grants.

Phase I/II Adult, Recurrent or Refractory High-Grade Glioma Study

GBM makes up a majority of high-grade glioma cases, with an annual incidence of 10,000 in the U.S. and 15,000 to 18,000 in Europe. The standard of care for newly diagnosed adult GBM is surgical resection, if possible, followed by a combination of radiation and Temodar (temozolomide). However, 85-90% of patients will relapse, as will most patients who receive the second-line treatment of Avastin (bevacizumab). There are no therapies approved for third-line treatment, with patients having a median overall survival of three to four months.

The single-arm Phase I/II "701 Adult-RHGG Study" evaluated adult patients with recurrent or refractory high-grade glioma, with half of the patients having relapsed at least twice. Of the 22 patients enrolled, 13 had refractory or recurrent GBM and nine had anaplastic glioma. SL-701 was administered *ex vivo* into dendritic cells that had been removed from the patient, with the cells then re-injected back into the patient along with a separate adjuvant injection. Disease stabilization or an anti-tumor response was observed in 6 of the 13 (46%) GBM patients and 7 of the 9 (78%) anaplastic glioma patients. Two durable complete responses were seen, including one exceeding nine months in an anaplastic oligoastrocytoma patient and another exceeding 23 months in a patient who was refractory to prior surgical resection, radiation therapy and temozolomide.

Figure 15: SL-701 Activity in a Patient with Glioblastoma

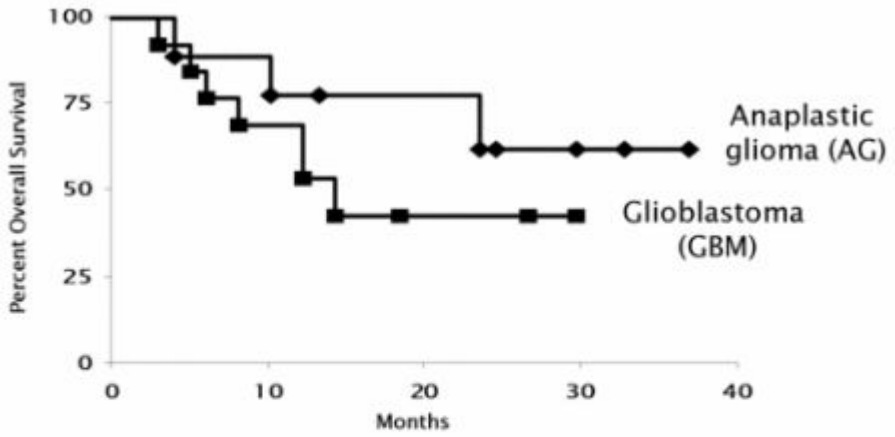


Source: Stemline

The latter patient also demonstrated a significant increase in target-specific T-cells by week 29, as determined by a tetramer assay. Three partial responses were observed during the study, including one lasting seven months in a third-line GBM patient and one exceeding 11 months in another GBM patient. A post-treatment brain biopsy from the third-line GBM patient demonstrated inflammation, including the presence of CD68+ macrophages and CD8+ T cells, suggesting the patient had a tumor pseudoprogression prior to the partial response. Of 16 evaluable patients, 13 (81%) had at least one positive immunological assay.

Median and overall survival improved in high-grade glioma patients treated with SL-701, as compared with historical data. Specifically in comparing recurrent or refractory GBM patients treated with SL-701 versus historical data, median overall survival was 13 months versus five to seven months, six-month overall survival was 80% versus 38% to 55%, and 12-month overall survival was 55% versus 14% to 25%.

Figure 16: Survival Benefit of SL-701 in >=Second-Line Glioblastoma and Anaplastic Glioma



	GBM		AG	
	SL-701	Historical	SL-701	Historical
Median OS	13 months	5-7 months	>22 months	9-11 months
6 month OS	80%	38-55%	85%	66%
12 month OS	55%	14-25%	76%	44-47%

Source: Stemline

SL-701 is currently being evaluated in a Phase I/II trial of 24 adult patients with low-grade glioma. Ten of the patients had recurrent disease, one had newly diagnosed low-grade glioma with prior radiotherapy and 13 had newly diagnosed low-grade glioma without prior radiotherapy. SL-701 is being administered via subcutaneous injection every three weeks for up to eight courses. Interim data showed that of the 17 patients that received eight cycles, ten had stable disease. Sustained and specific immune responses were observed in the majority of evaluable patients, and no serious adverse effects have been observed so far.

Stemline plans to advance SL-701 into a Phase IIb trial in 30 adult patients with relapsed or refractory GBM. The trial is set to begin in mid-2014, and will evaluate SL-701 in combination with Avastin.

Competition

Avastin has been considered the standard of care for patients with second-line GBM. However, the use of Avastin for the indication may decrease due to data released at the 2013 ASCO conference showing that it failed to provide a survival benefit. Although that data was in the first-line setting, doubts about Avastin's efficacy as a single-agent for brain cancer could help establish SL-701 as a replacement or supplemental therapy for Avastin.

Another competitor in the space is Gliadel Wafer (polifeprosan 20 and carmustine) from Eisai, which is approved as a second-line treatment for GBM. Its use has been limited since Gliadel Wafer is an implant that needs to be surgically placed in the brain at the site of the excised tumor, and has limited efficacy. Carmustine is marketed separately by Bristol Myers as BiCNU, and is approved in combination with other approved chemotherapeutic agents for brain cancer.

Temozolomide from Merck and Co. is approved as a first-line treatment for GBM and as a treatment for refractory anaplastic astrocytoma. Although temozolomide is not approved for children due to insufficient efficacy data in that patient population, it is prescribed off-label in pediatric glioma patients for palliative care.

Drug candidates in development for brain cancer include rindopepimut (CDX-110) from Celldex Therapeutics (CLDX, OUTPERFORM). Rindopepimut is currently in a Phase III trial in the first-line GBM setting, and in a Phase II trial in the relapsed GBM setting. We do not expect direct competition between the agents, as rindopepimut targets a subset of patients whose tumors express the target of the drug, epidermal growth factor receptor variant III (EGFRvIII), that is found in about a third of GBM cancers.

Market:

We estimate $222M in global glioma/GBM revenues by 2019, our valuation year. Our assumptions include an available population of 5,700 high-grade glioma patients, with a peak market penetration of 50% and 25,000 GBM patients, with a peak market penetration of 22%. We assume average revenue of $45,000 per patient.

Preclinical compounds & IP

Stemline has several oncology drug candidates in preclinical development, many of them identified with the company's StemScreen proprietary platform technology. StemScreen consists of StemScreen-1, a microarray that analyzes the gene expression of CSCs isolated from tumor tissue or cell lines, and StemScreen-2, a cell-based assay that identifies CSC-directed compounds during high throughput screening.

Figure 17: Select Stemline Preclinical Compounds Proven Efficacious *In Vitro*

Product	Target	Class	Discovery Method
SL-101	CD123	mAb-based	In-licensed
SL-201	T-201	Small molecule	StemScreen
SL-301	Notch	Small molecule	StemScreen
N/A	N/A	Three small molecule hits	StemScreen

Source: Stemline, Wedbush Securities, Inc.

Stemline has 13 issued patents and more than 30 pending patent applications in the U.S. and abroad covering the spectrum of CSC-directed drugs and diagnostics. Patents that cover the use of SL-401 expire in 2027, and patents covering SL-701 expire in 2024-2025. Stemline has not entered into any major partnerships, and holds exclusive rights to all of their clinical and preclinical compounds.

Figure 18: Management

Title	Biography
Chief Executive Officer: Ivan Bergstein, M.D.	Dr. Bergstein founded Stemline and has been CEO since its inception in 2003. Prior to founding Stemline, Dr. Bergstein was Medical Director of Access Oncology, Inc., a private oncology-focused biotechnology company. Previously, he was a senior biopharmaceuticals analyst at Cancer Advisors, Inc. Dr. Bergstein received a B.A. in Mathematics from the University of Pennsylvania and an M.D. from the Mount Sinai Medical Center. 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, where he is currently a voluntary faculty member.
Chief Medical Officer and Head of R&D: Eric Rowinsky, M.D.	Dr. Rowinsky has served as Chief Medical Officer and Head of Research and Development since 2011. He was previously Executive Vice President and Chief Medical Officer for ImClone Systems, Inc. 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 is currently an Adjunct Professor of Medicine at New York University School of Medicine and sits on the Board of Directors of Biogen Idec, Inc., Coronado Biosciences, Inc., and Navidea Biopharmaceuticals, 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.
Chief Operating Officer: Kenneth Hoberman	Kenneth Hoberman has served as Chief Operating Officer since March 2013, and prior to that served as Vice President of Operations since February 2012. From 2004 to 2012, Mr. Hoberman was Vice President of Corporate and Business Development of Keryx Biopharmaceuticals, Inc. 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.
VP of Finance and Chief Accounting Officer: Stephen P. Hall	Mr. Hall serves as Vice President of Finance and Chief Accounting Officer. Prior to joining Stemline full time, Mr. Hall acted as an advisor to Stemline since March 2012 on the company's accounting, finance, human resources, and information technology matters. 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. from October 2009 to October 2010. Prior to this, Mr. Hall served as Senior Vice President, Chief Financial Officer and Treasurer of Helicos BioSciences from May 2008 until August 2009. Mr. Hall previously served as Senior Vice President and Chief Financial Officer of TriPath Imaging, Inc. from September 2001 to December 2006, when it was acquired by Becton, Dickinson and Company (BD), at which time Mr. Hall continued to serve as Senior Advisor to BD from December 2006 to June 2007. Mr. Hall served as Chief Financial Officer and President of the Imaging and Power System Division of Colorado Medtech, Inc. from September 1999 until August 2001. From September 1993 to January 1999, he served as Chief Financial Officer for BioTechnica International, Inc. Mr. Hall spent four years with 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.

Source: Stemline, Wedbush Securities, Inc.

Figure 19: Financial Model

9/9/2013
Ticker: (STML:Nasdaq)
Stemline Therapeutics, Inc

Wedbush PacGrow Life Sciences
David M. Nierengarten, Ph.D.
415-274-6862

Stemline Therapeutics, Inc (STML)
in thousands except per share data

	2012A	Q1	Q2	Q3	Q4	2013E	2014E	2015E	2016E	2017E	2018E	2019E
Revenues:												
US Product Sales	$0	$0	$0	$0	$0	$0	$0	$6,770	$47,789	$126,076	$226,392	$336,572
Other Revenues	0	0	0	0	0	0	0	0	0	0	0	0
Ex-US Product Sales	0	0	0	0	0	0	0	0	12,026	128,973	269,221	439,525
Total Revenues	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**6,770**	**59,815**	**255,049**	**495,613**	**776,098**
Cost and Expenses:												
Cost of Sales	0	0	0	0	0	0	0	1,015	7,168	18,911	33,959	50,486
R&D	3,377	3,162	4,085	4,289	4,504	16,040	21,235	23,835	25,800	27,927	30,229	32,721
SG&A	3,090	2,167	1,071	1,092	1,114	5,445	4,684	9,099	21,408	42,574	60,832	87,566
Total Operating Expenses	**6,467**	**5,329**	**5,156**	**5,382**	**5,618**	**21,485**	**25,920**	**33,949**	**54,377**	**89,413**	**125,020**	**170,773**
Operating Income (Loss)	(6,467)	(5,329)	(5,156)	(5,382)	(5,618)	(21,485)	(25,920)	(27,180)	5,439	165,636	370,593	605,325
Net Interest Income (Expense)/Other Income	193	(177)	(295)	232	217	(22)	2,450	2,340	2,281	3,678	8,153	16,773
Income Before Income Taxes	(6,274)	(5,506)	(5,451)	(5,150)	(5,401)	(21,507)	(23,470)	(24,839)	7,720	169,314	378,746	622,098
Provision for Income Taxes	0	0	0	0	0	0	0	0	695	44,645	147,711	242,618
Net Income (Loss)	(6,274)	(5,506)	(5,451)	(5,150)	(5,401)	(21,507)	(23,470)	(24,839)	7,025	124,669	231,035	379,480
Non-GAAP EPS	**(1.84)**	**(0.74)**	**(0.55)**	**(0.41)**	**(0.43)**	**(1.76)**	**(1.92)**	**(1.88)**	**0.49**	**9.25**	**17.17**	**28.22**
GAAP EPS	**(2.72)**	**(0.74)**	**(0.55)**	**(0.41)**	**(0.43)**	**(2.14)**	**(1.89)**	**(1.89)**	**0.52**	**9.28**	**17.20**	**28.25**
Total Shares Outstanding	3,477	7,459	9,837	12,434	12,434	12,434	12,434	13,434	13,434	13,434	13,434	13,434
Cash Burn	0	0	0	0	0	(25,975)	(24,408)	(27,353)	1,031	155,002	354,658	586,787
Cash Balance	2,025	30,736	92,686	86,973	81,940	81,940	59,982	75,238	75,172	181,795	388,748	741,660

Source: Wedbush Securities, Inc.

Figure 20: Covered Companies Mentioned

COMPANY	TICKER	RATING	PRICE	PRICE TARGET
Celldex	CLDX	OUTPERFORM	$24.50	$35
Epizyme	EPZM	OUTPERFORM	$32.19	$37
Sunesis	SNSS	OUTPERFORM	$4.88	$10

Source: Wedbush Securities, Inc.

Analyst Biography

David Nierengarten, Ph.D.

David is an Analyst covering stocks in the Biotechnology/Biopharmaceuticals/BioDefense sector. His prior sell-side research experience at Robert W. Baird & Co. covered biotechnology companies of all market capitalizations, with a focus on oncology and rare diseases.

David received his B.S. (Biochemistry) from the University of Wisconsin-Madison and Ph.D. (Molecular and Cell Biology) from the University of California-Berkeley.

David's Edge: David's early stage venture capital investing experience gives him a balanced perspective on developmental-stage biotechnology companies and their ultimate risk/reward potential. His experience on the other side of that equation in a clinical-stage, venture backed biotechnology company provides him with insights into corporate operations. The combination of experiences creates a focus on value creation in this event-driven space.

Analyst Certification
I, David M. Nierengarten, Ph.D., Gregory R. Wade, Ph.D., Christopher N. Marai, Ph.D., certify that the views expressed in this report accurately reflect my personal opinion and that I have not and will not, directly or indirectly, receive compensation or other payments in connection with my specific recommendations or views contained in this report.

Disclosure information regarding historical ratings and price targets is available at http://www.wedbush.com/ResearchDisclosure/DisclosureQ213.pdf

Investment Rating System:
Outperform: Expect the total return of the stock to outperform relative to the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.
Neutral: Expect the total return of the stock to perform in-line with the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.
Underperform: Expect the total return of the stock to underperform relative to the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.

The Investment Ratings are based on the expected performance of a stock (based on anticipated total return to price target) relative to the other stocks in the analyst's coverage universe (or the analyst's team coverage).*

Rating Distribution (as of June 30, 2013)	**Investment Banking Relationships (as of June 30, 2013)**
Outperform:54% Neutral: 41% Underperform: 5%	Outperform:15% Neutral: 1% Underperform: 0%

The Distribution of Ratings is required by FINRA rules; however, WS' stock ratings of Outperform, Neutral, and Underperform most closely conform to Buy, Hold, and Sell, respectively. Please note, however, the definitions are not the same as WS' stock ratings are on a relative basis.

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Wedbush Equity Research Disclosures as of September 11, 2013

Company	Disclosure
Stemline Therapeutics	1
Sunesis Pharmaceuticals	1
Epizyme	1,3,5,7
Celldex Therapeutics	1,3,4,5,7

Research Disclosure Legend
1. WS makes a market in the securities of the subject company.
2. WS managed a public offering of securities within the last 12 months.
3. WS co-managed a public offering of securities within the last 12 months.
4. WS has received compensation for investment banking services within the last 12 months.
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6. WS is acting as financial advisor.

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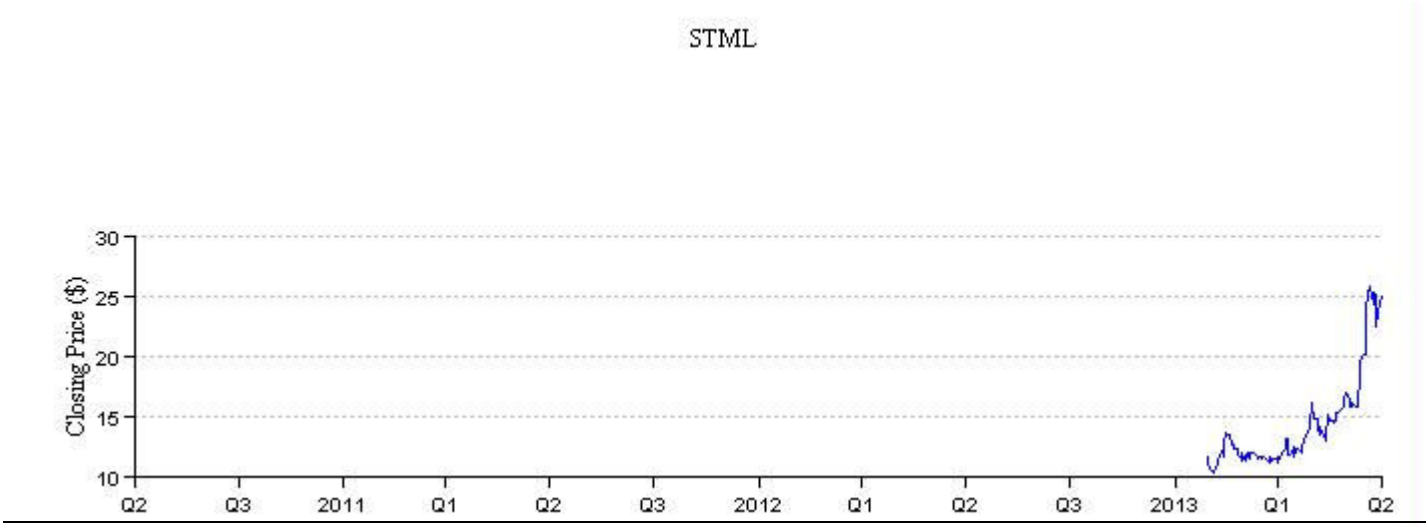

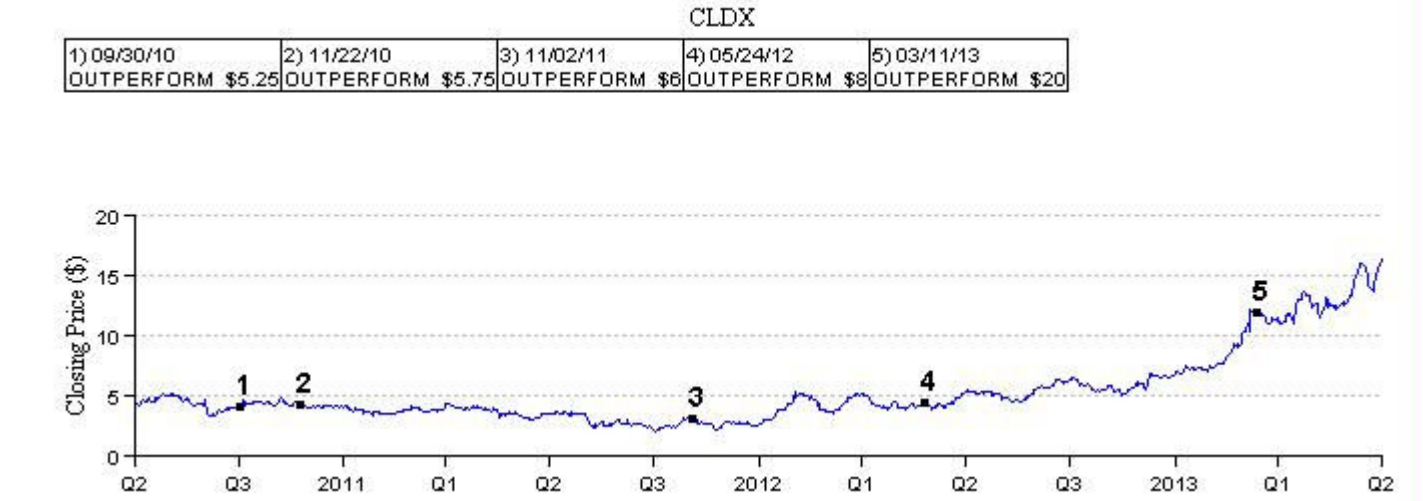

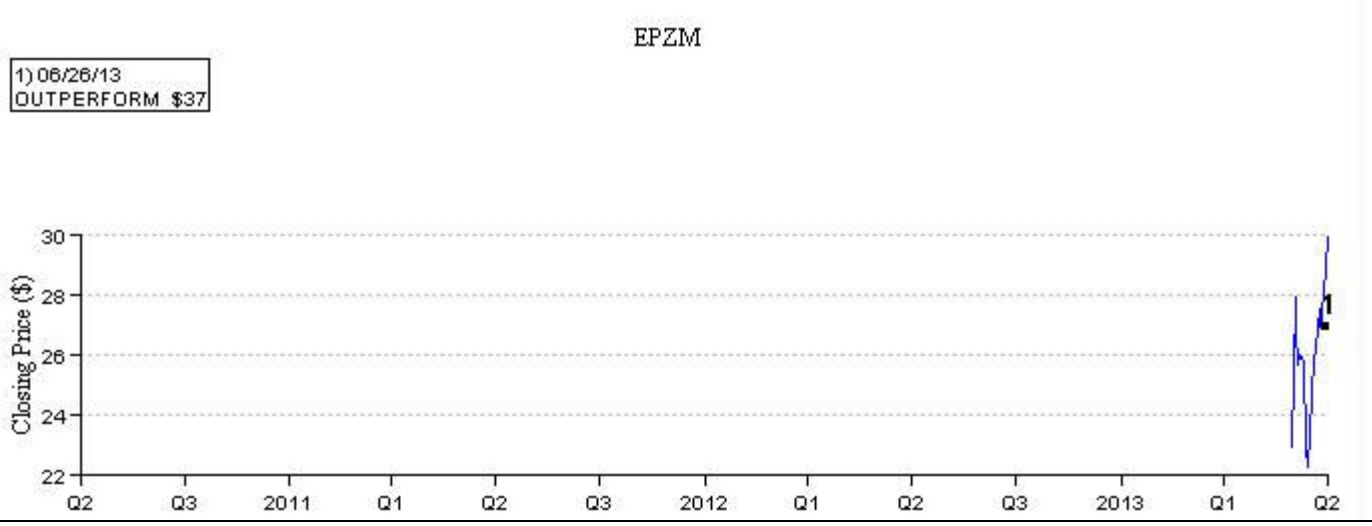

* WS changed its rating system from (Strong Buy/Buy/Hold/Sell) to (Outperform/ Neutral/Underperform) on July 14, 2009.
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