Company Update
July 18, 2012
BIOTECHNOLOGY

Equity Research

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NewLink Genetics Corporation (NLNK-$13.73)

Rating: BUY

Target Price: $18.00

Shares Pull Back After Period of Strength; We Recommend BUY

EPS	1Q	2Q	3Q	4Q
2010A	(1.02)A	(1.21)A	(1.49)A	(1.12)A
2011A	(1.07)A	(1.20)A	(1.09)A	(0.44)A
2012E	(0.23)A	(0.46)E	(0.56)E	(0.54)E
2013E	—	—	—	—

REV	1Q	2Q	3Q	4Q
2010A	0.3A	0.4A	0.4A	1.0A
2011A	0.6A	0.5A	0.4A	0.4A
2012E	0.4A	0.3E	0.3E	0.3E
2013E	—	—	—	—

FY	2010A	2011A	2012E	2013E
EPS	(4.84)A	(2.98)A	(1.77)E	(2.07)E
REV	2.1A	2.0A	1.3E	1.0E

- NewLink shares have experienced weakness over the past few weeks, pulling back about 11% since the beginning of 3Q:12. This pullback comes after the shares advanced 44% in 2Q:12. During the same time period, the NBI (NASDAQ Biotechnology Index) has risen 8% and has fallen roughly 1% thus far in 3Q:12.
- While the shares have pulled back, the company continues on track with its clinical program, and we expect recovery and further share price appreciation. NewLink recently announced that it had surpassed 50% enrollment in the HyperAcute Pancreas Phase III trial, and an interim analysis trigger should be reached by 1Q:13.
- The Phase II dataset for the HyperAcute program has been impressive, and this fuels much of our enthusiasm for the shares. In June 2012, three-year data were disclosed demonstrating median overall survival of roughly 42% (a few patients are yet to read out), and this was met with interest by physicians.
- Although NewLink is a small company, HyperAcute is a platform technology that is being developed for other cancer indications. We anticipate the company will disclose plans to initiate late-stage trials in NSCLC and other indications such as renal cell carcinoma. As HyperAcute products advance, we expect greater pipeline visibility and ultimately valuation appreciation.
- In addition to the HyperAcute platform, NewLink is advancing NLG8189, the first candidate from the IDO program. This candidate has a novel mechanism, which we do not believe has been fully recognized in the company's valuation.
- We like NewLink for the platform technology and pipeline addressing large and lucrative unmet medical needs. Our price target remains $18 and our rating remains BUY; we view trading-related weakness as a buying opportunity.

Current Statistics

Market Cap ($Mil)	**$283.8**	**Float Shares (Mil):**	**NA**
Short Interest (Mil):	**NA**		
52 Wk. Range	**$18.00-$6.25**		
Avg. Daily Trading Volume (3 mo.):	**132,168**		
Shares Out (Mil):	**20.672**		

Company Description

NewLink Genetics is a development-stage company focused on cancer treatments. Founded in 1999, NewLink has two technology platforms, HyperAcute (allogeneic vaccine) and IDO inhibition (oral, small molecule) in various stages of trials. The HyperAcute program is the furthest in development, with the lead candidate, HyperAcute Pancreas, in a Phase III trial for pancreatic cancer. NewLink also has mid-stage trials underway in non small cell lung cancer and melanoma.

The Disclosure Section may be found on pages 8 - 13 of this report.

Solid Pipeline with Many Milestones, Compelling Data

Summary

NewLink is working in the rapidly developing field of cancer immunotherapy. The company has a novel approach based on a solid scientific foundation and is working in areas of tremendous unmet need. We have identified what we believe to be critical success factors for a cancer immunotherapy company and further believe that NewLink meets these criteria. The company has identified appropriate clinical settings with which to test its technology (modest disease burden, consistent booster dosing), has a robust trial design, is addressing critical unmet medical needs, and has a scalable, financially reasonable manufacturing process and technology. Additionally, the stage and depth of NewLink's clinical program is compelling, in our view, and there are multiple opportunities for milestone updates over the next 24 months. We are particularly encouraged by the Phase II HyperAcute Pancreas study as two- and three-year disease free and overall survival showed a strong and sustained response to the vaccine in a statistically significant manner.

- **Indications and Unmet Medical Needs**. Initial clinical programs are focused on pancreatic cancer, lung cancer, and melanoma: three diseases of major unmet medical need. The company has identified patient populations within these groups that are likely to benefit from the HyperAcute immunotherapy program and has designed clinical trials around appropriate patient populations. In addition to the HyperAcute Pancreas (algenpantucel-L) Phase III trial, we expect the company to advance its non small cell lung cancer (NSCLC) program into a later-stage trial. Further, NLG8189 is at the forefront of the immunotherapeutic development, and this program, largely overlooked, could come into greater focus over the next year.

- **Trial design**. NewLink's Phase III trial of HyperAcute Pancreas is a large, randomized Phase III clinical trial consisting of over 700 patients. The company has vetted the trial design with the FDA, and it will be conducted with a Special Protocol Assessment (SPA), mitigating the risk that the Agency takes issue with the trial design or other elements once the trial has been completed. With three-year data from the Phase II trial very close to maturity, overall survival that is 100% greater than historical control is very suggestive of sustained durable response for HyperAcute Pancreas, which in turn, provides us with a greater level of comfort with the current Phase III program.

- **Manufacturing**. NewLink's HyperAcute technology consists of human pancreatic cell lines transduced with a retroviral vector expressing the murine α-GT. As such, there is no need to harvest patient cells, which is time-consuming and expensive, providing the company with a streamlined manufacturing process with attractive margins.

- **NLG8189 is upside, in our view**. This candidate is a novel immunotherapeutic that inhibits the ability of cancer cells to suppress T cell response. To date, management has been quite conservative about this program given its early stage of development. Data from a Phase I and Phase Ib trial, one in combination with docetaxel and the other with a dendritic cell vaccine, were disclosed at ASCO, demonstrating that this pathway and compound appear to be viable candidates for advancement. Early work has thus far been conducted by the NCI.

- **Milestones**. A key component of valuation building for biotechnology companies is derived from milestone events. Though major data releases are behind the company, we believe clinical news flow will stay strong. Our expectation is that the fully mature three-year data for HyperAcute Pancreas will be presented or published in a scientific journal and updates on other HyperAcute programs and their advancement into later-stage trials will be forthcoming, as will an update from the Phase III HyperAcute Pancreas trial. As the HyperAcute Phase III trial has passed the enrollment halfway mark, a scheduled (based on number of events) interim look could occur in 1Q:13.

Valuation

Our 12-month price target is $18 based on our view that the Phase II data generated by HyperAcute Pancreas provide an element of de-risking to the Phase III trial. Hence, we now use a five-year discount rate of 45%. Our price target is based on a 40x multiple on our 2017 EPS forecast of $2.86 discounted by 45%. We have used a multiple on 2017 EPS consistent with valuation for early-stage biotechnology companies, which ranges from 30-50x forward EPS, reflecting opportunity for rapid growth. In arriving at this range, we explored historical data as well as forward consensus multiples for companies with newly launched products.

Risks

NewLink is a development-stage company, and investment is subject to risk. These risks include but are not limited to:

- Development of new drugs carries a high failure rate, either because the drug in question fails to show efficacy or significant safety issues arise during the clinical trial process. Additionally, regulatory authorities such as the Food & Drug Administration (FDA) may delay the approval process or reject NewLink's clinical findings. Because we can never dismiss such a possibility, we use a high discount rate in our valuation model to compensate for such risk. We note that NewLink's HyperAcute Pancreas program is being conducted under a Special Protocol Assessment (SPA), and while it is not a guarantee that the FDA will endorse NewLink's data, it mitigates risk against the FDA disputing the company's clinical trial design.
- Some of NewLink's clinical programs that are being co-sponsored by the NCI are in investigator-initiated clinical trials, which means that the company does not have full control over the conduct of the trials or the release of data, and this may impact trial results and/or milestones as it relates to public disclosure of clinical data.
- NewLink's manufacturing process has been validated in its early clinical trial work. However, we cannot exclude the possibility that this process may not be seamless from clinical trials to commercialization.
- The clinical landscape is crowded with hundreds of oncology clinical trials. It is possible that other technologies show greater benefit to patients than NewLink's product candidates, thus tendering products obsolete or non-competitive.
- NewLink has a large intellectual property estate protecting its technology, know-how, and applications of such. However, it is always possible that a party will bring forward infringement claims that would need to be heard by a court.
- NewLink has a history of net losses. We are forecasting profitability for NewLink in 2016 based on market acceptance of HyperAcute Pancreas, but profitability could be delayed or not reached at all, depending on a variety of clinical and regulatory factors.

Exhibit 1: Annual Income Statement

NewLink Genetics Corporation

All figures in millions, Year Ended 31 December	2017E	2016E	2015E	2014E	2013E	2012E	2011A
Revenue	**$391.54**	**$270.00**	**$28.95**	**$0.65**	**$1.01**	**$1.12**	**$1.87**
Cost of Goods Sold	101.68	77.69	15.47	0.00	0.00	0.00	0.00
Gross Profit	**$289.86**	**$192.31**	**$13.48**	**$0.65**	**$1.01**	**$1.12**	**$1.87**
Gross Profit Margin	*74.03%*	*71.23%*	*46.55%*	*NM*	*NM*	*NM*	*NM*
Operating Expenses							
SG&A	104.37	72.65	41.18	27.51	18.16	14.17	5.68
R&D	87.63	54.31	42.25	37.74	28.66	23.62	14.26
Total Operating Expenses	$192.00	$126.96	$83.43	$65.25	$46.82	$37.79	$19.93
Profit (Loss) from Operations	**$97.86**	**$65.35**	**($69.95)**	**($64.60)**	**($45.81)**	**($36.67)**	**($18.06)**
Operating Profit Margin	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*
Other Income (Expense)	$2.35	$1.15	$0.75	($0.03)	($0.00)	($0.23)	($0.03)
Pretax Income	**$100.21**	**$66.50**	**($69.20)**	**($64.63)**	**($45.81)**	**($36.90)**	**($18.09)**
Pretax Margin	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*
Net loss attributable to noncontrolling interest	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Net Income (Loss)	**$100.21**	**$66.50**	**($69.20)**	**($64.63)**	**($45.81)**	**($36.90)**	**($18.09)**
Net Margin	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*
Basic & Diluted Net Loss Per Share	***$2.86***	***$2.22***	***($2.52)***	***($2.62)***	***($2.07)***	***($1.77)***	***($2.98)***
Shares Outstanding	*35.00*	*30.00*	*27.50*	*24.65*	*22.08*	*20.86*	*6.07*

Percent Change, Year-Over-Year	***2016E***	***2016E***	***2015E***	***2014E***	***2013E***	***2012E***	***2011E***
Revenue	45.01%	832.61%	4354.09%	-35.64%	-9.90%	-40.12%	-9.96%
SG&A	*43.66*	*76.42*	*49.69*	*51.49*	*28.15*	*149.53*	*(6.50)*
R&D	*61.35*	*28.54*	*11.95*	*31.68*	*21.34*	*65.70*	*12.55*
Operating Expenses	*51.23*	*52.18*	*27.86*	*39.36*	*23.89*	*89.58*	*6.37*
Other Income, net	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*

Source: NewLink Genetics, Cantor Fitzgerald estimates

Exhibit 2: Pancreatic Cancer Model

NewLink Genetics Corporation

($ in millions)	2014E	2015E	2016E	2017E	2018E	2019E
Number of diagnoses (US)	45,769	46,341	46,341	46,920	47,507	48,101
% Stage I	8.0%	8.0%	8.0%	8.0%	8.0%	8.0%
% treated	*0.0%*	*1.2%*	*4.8%*	*7.0%*	*7.4%*	*7.5%*
# treated	0.00	556	2,224	3,303	3,497	3,617
% Stage II	27.0%	27.0%	27.0%	27.0%	27.0%	27.0%
% treated	*0.0%*	*1.4%*	*5.9%*	*8.1%*	*12.4%*	*15.9%*
# treated	0.00	626	2,753	3,801	5,900	7,662
Total Treated	**0.00**	**1,182**	**4,977**	**7,104**	**9,397**	**11,280**
Average Injections/year/patient	0	7	15.5	15.7	16.1	16.4
Cost of injection	$0	$3,500	$3,500	$3,500	$3,500	$3,500
Cost per year	$0	$24,500	$54,250	$55,118	$56,275	$57,514
Total sales	**$0.0**	**$29.0**	**$270.0**	**$391.5**	**$528.8**	**$648.7**
Percent Change, year-over-year						
Diagnoses	1.30%	1.30%	1.25%	1.25%	1.25%	1.25%
Stage I - % treated	*NA*	*NA*	300.00	48.50	5.85	3.45
Stage II - % treated	*NA*	*NA*	340.00	38.07	55.25	29.86
Total treated	*NA*	*NA*	321.18	42.73	32.28	20.04
Average Injections/year/patient	*NA*	*NA*	*NA*	1.60	2.10	2.20
Annual cost	*NA*	*NA*	*NA*	0.00	0.00	0.00
Total sales	*NA*	*NA*	832.61	45.01	35.06	22.68

Source: NewLink Genetics, American Cancer Society, CMS, Cantor Fitzgerald estimates

Exhibit 3: R&D Pipeline

Product Name	Description/Indication	Core Technology	Phase of Development				Comments
			PreClinical	Phase I	Phase II	Phase III	
HyperAcute Pancreas	Allogenic vaccine/resectable pancreatic cancer, Stage I & II patients	HyperAcute					722-patient trial, ~300 enrolled, interim look 4Q12/1Q13. Phase II 2 & 3 year data ASCO 2012.
HyperAcute Pancreas	Allogenic vaccine/resectable pancreatic cancer, locally advanced disease	HyperAcute					Will enter Phase II
HyperAcute Lung	Allogenic vaccine/NSCLC	HyperAcute					Data expected 1H12, Phase II/III expected shortly.
HyperAcute Melanoma	Allogeneic vaccine/non-visceral metastatic melanoma	HyperAcute					Data expected, likely next step is Phase II/III in 2H12
HyperAcute Prostate	Allogeneic vaccine/prostate cancer	HyperAcute					Possible partnering candidate
HyperAcute various	Exhibit 16: Pancreatic Cancer Model	HyperAcute					May explore NCI funding
D-1MT	Small molecule inhibitor of IDO/solid tumors	IDO pathway inhibitor					Two posters @ ASCO demonstrate feasibility for advancement.
2nd generation IDO	Small molecule inhibitor of IDO/solid tumors	IDO pathway inhibitor					Higher potency vs. D-1MT

Source: NewLink Genetics, Cantor Fitzgerald

Exhibit 5: Companies Mentioned

Company Name	Ticker	Exchange	Cantor Rating
Agenus	AGEN	NASDAQ	NC
Alexion	ALXN	NASDAQ	NC
Amgen	AMGN	NASDAQ	NC
Ariad	ARIA	NASDAQ	NC
Astex	ASTX	NASDAQ	NC
Biogen Idec	BIIB	NASDAQ	NC
Celgene	CELG	NASDAQ	BUY
Celldex	CLDX	NASDAQ	BUY
Celsion	CLSN	NASDAQ	NC
Curis	CRIS	NASDAQ	NC
Dendreon	DNDN	NASDAQ	HOLD
Endocyte	ECYT	NASDAQ	NC
Exelixis	EXEL	NASDAQ	NC
Galena Biopharma	GALE	NASDAQ	BUY
Gilead	GILD	NASDAQ	NC
Human Genome Sciences	HGSI	NASDAQ	NC
Immunogen	IMGN	NASDAQ	HOLD
Incyte	INCY	NASDAQ	NC
Medivation	MDVN	NASDAQ	NC
Newlink Genetics	NLNK	NASDAQ	BUY
Oncothyreon	ONTY	NASDAQ	BUY
ONYX Pharma	ONXX	NASDAQ	NC
Pharmacyclics	PCYC	NASDAQ	NC
Regeneron	REGN	NASDAQ	NC
Seattle Genetics	SGEN	NASDAQ	NC
Spectrum Pharm	SPPI	NASDAQ	NC
Sunesis Pharmaceuticals	SNSS	NASDAQ	BUY
Vertex	VRTX	NASDAQ	NC
Vical	VICL	NASDAQ	NC

Source: FactSet, Cantor Fitzgerald

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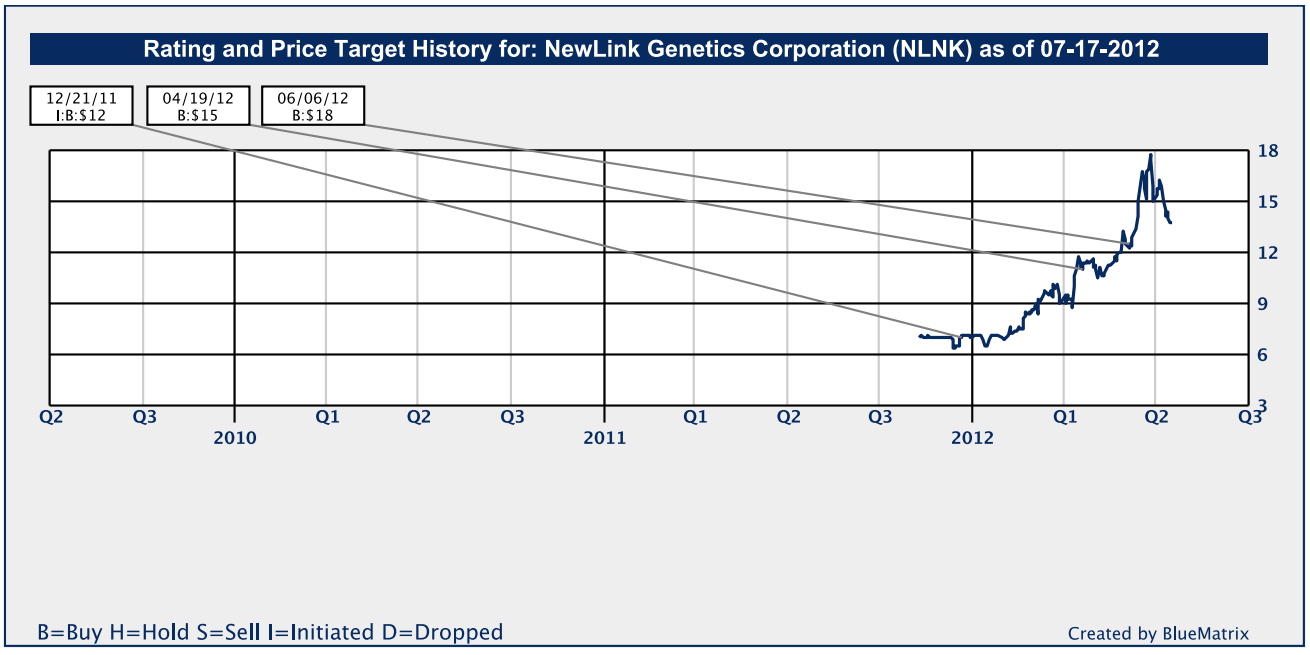

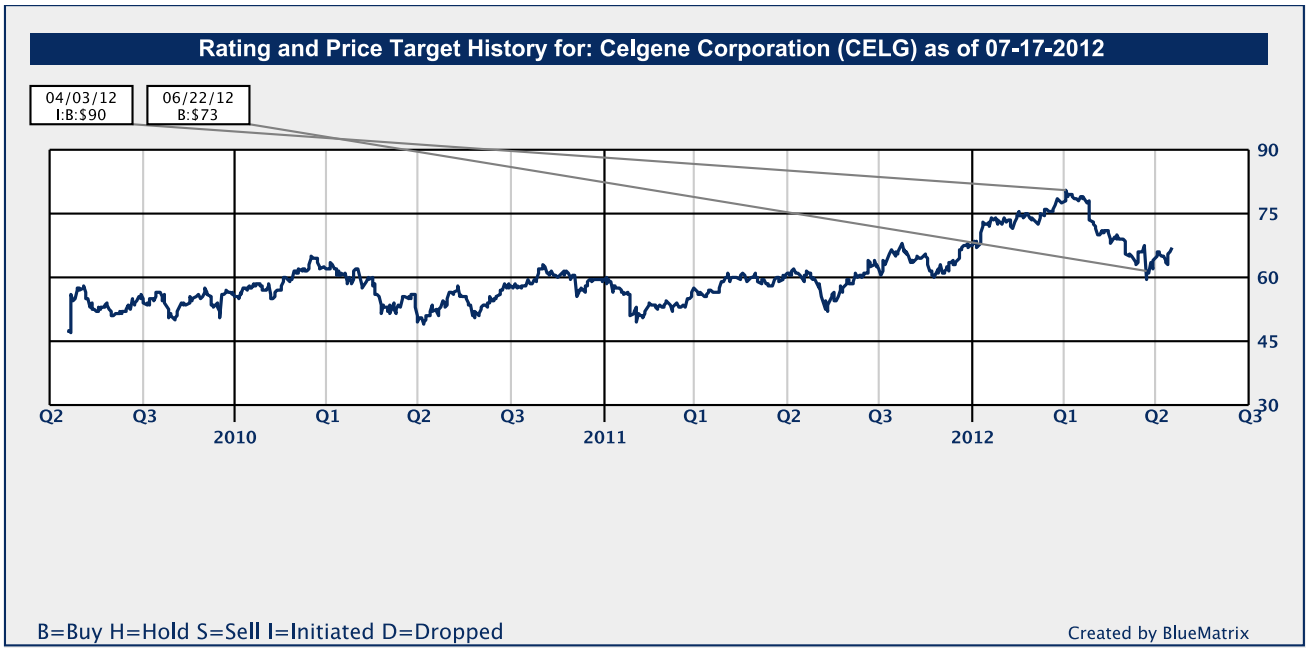
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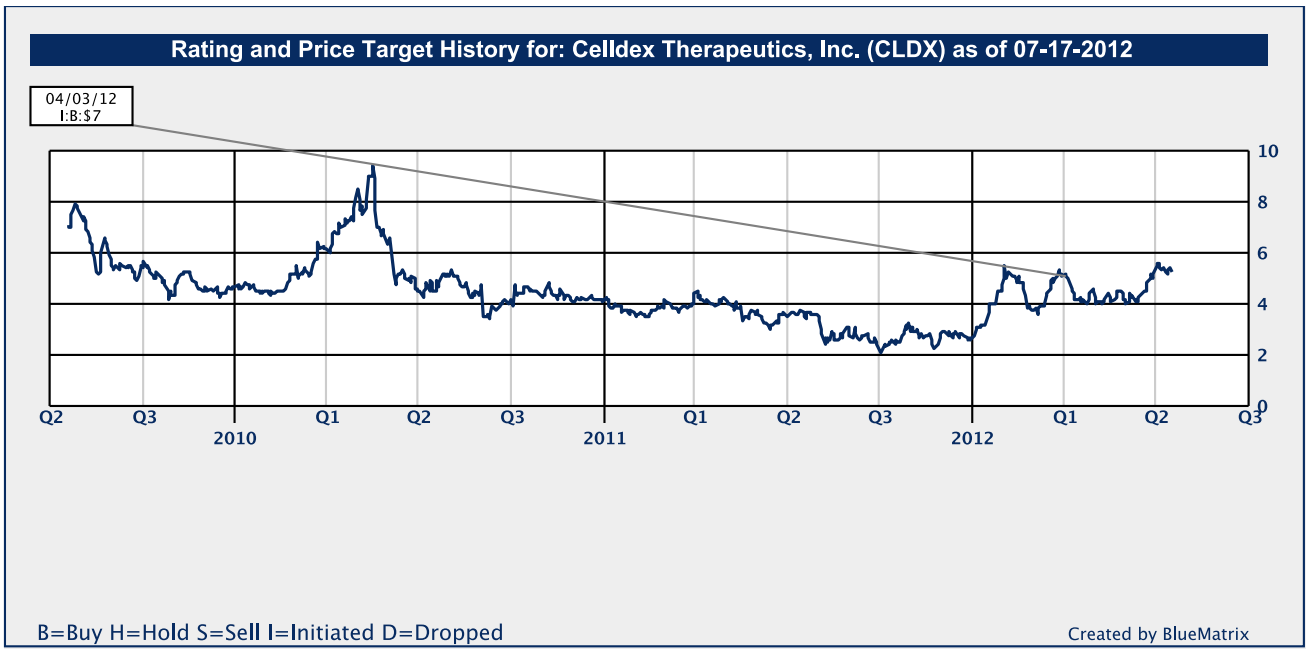
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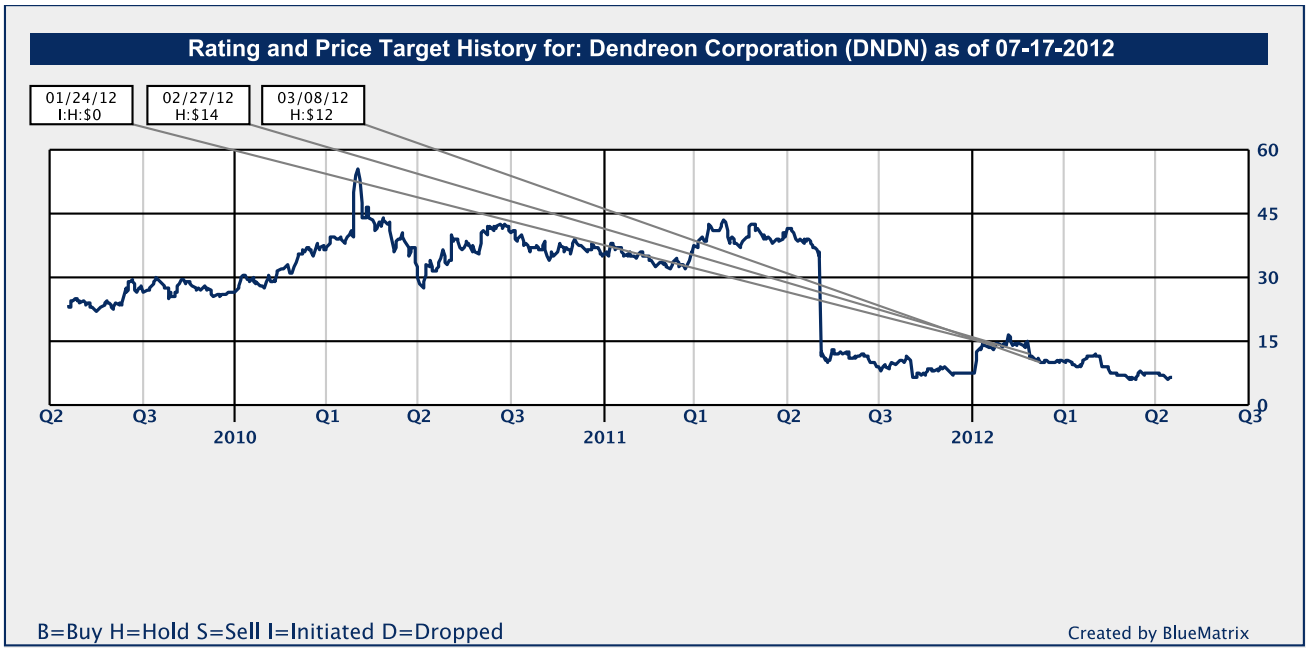
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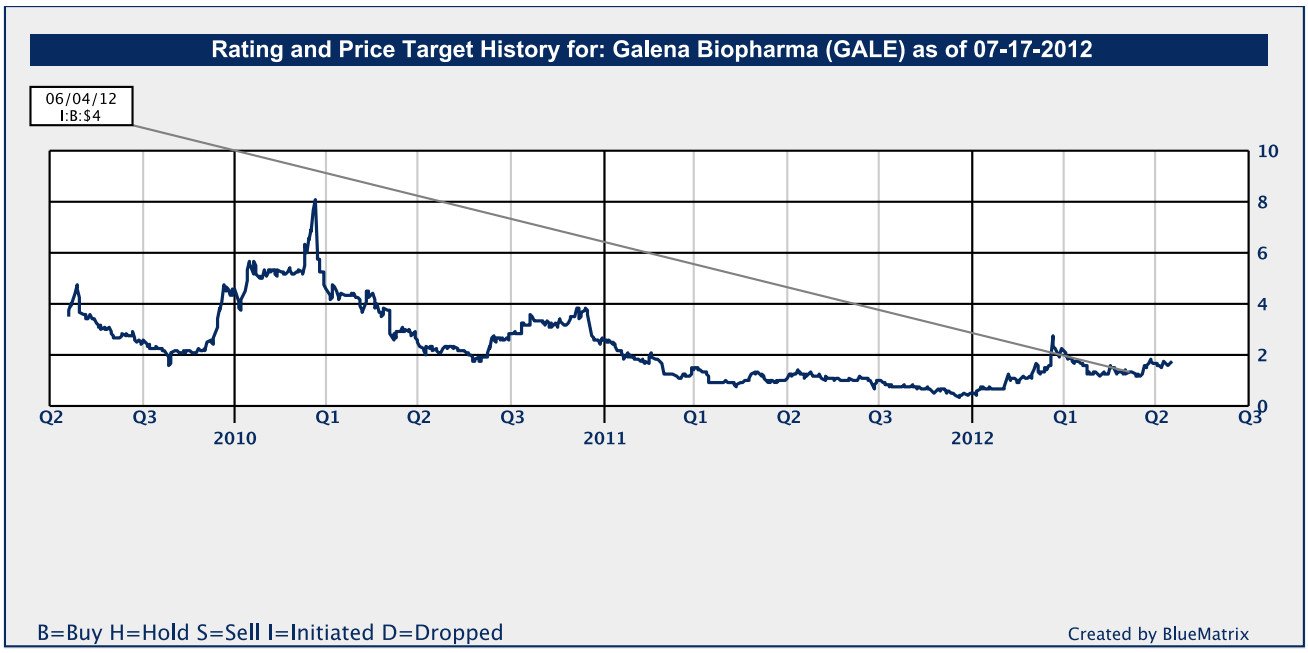
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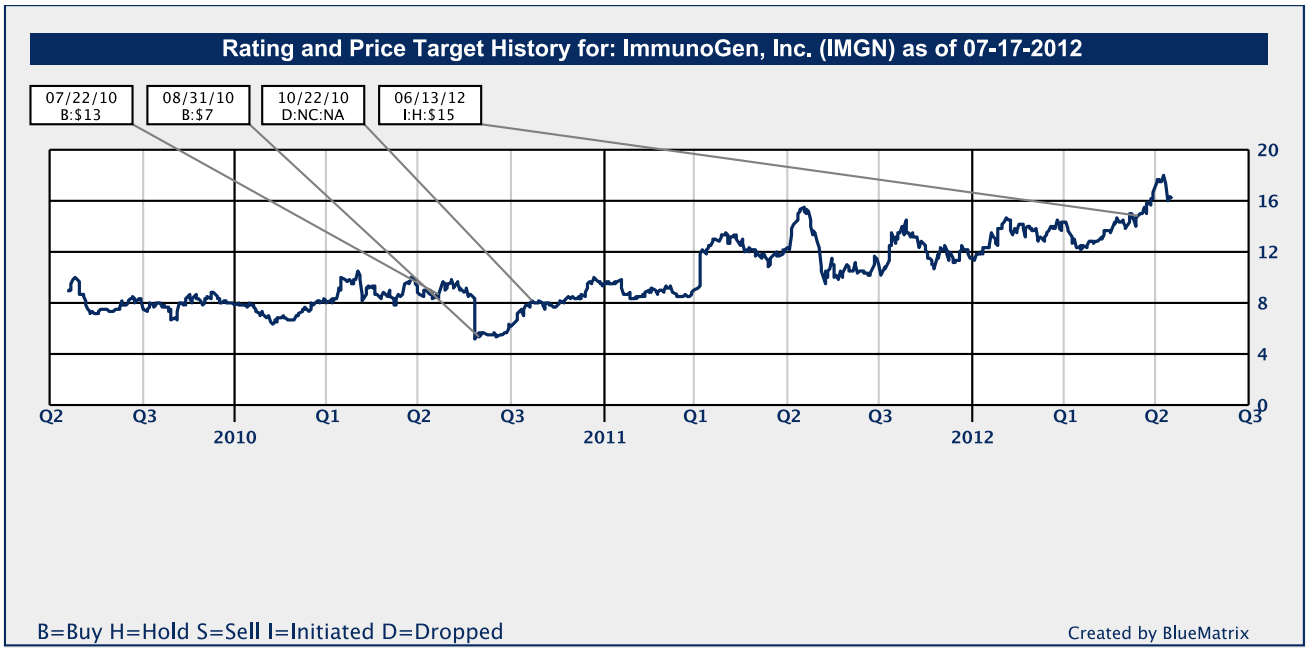
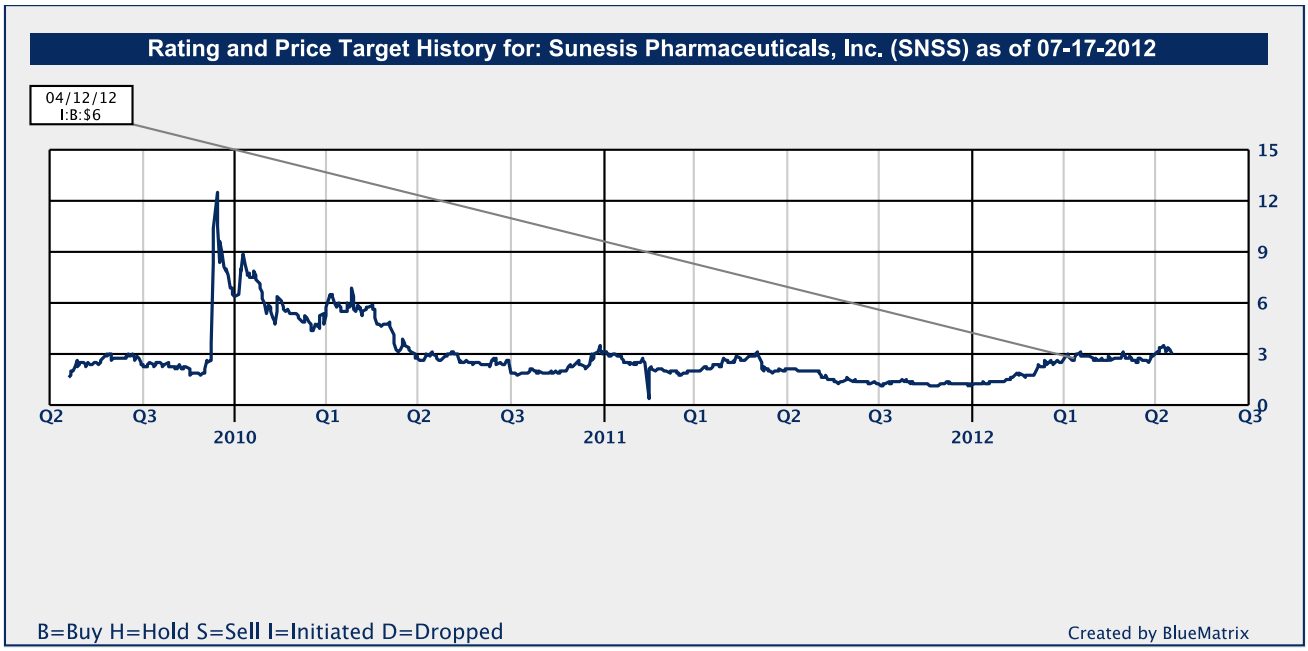
Q1
Q2
Q3
B=Buy H=Hold S=Sell I=Initiated D=Dropped
Created by BlueMatrix


Rating and Price Target History for: ImmunoGen, Inc. (IMGN) as of 07-17-2012
07/22/10
B:$13
08/31/10
B:$7
10/22/10
D:NC:NA
06/13/12
I:H:$15
20
16
12
8
4
0
Q2
Q3
2010
Q1
Q2
Q3
2011
Q1
Q2
Q3
2012
Q1
Q2
Q3
B=Buy H=Hold S=Sell I=Initiated D=Dropped
Created by BlueMatrix


Rating and Price Target History for: Oncothyreon Inc. (ONTY) as of 07-17-2012
01/24/12
I:B:$11
12
10
8
6
4
2
Q2
Q3
2010
Q1
Q2
Q3
2011
Q1
Q2
Q3
2012
Q1
Q2
Q3
B=Buy H=Hold S=Sell I=Initiated D=Dropped
Created by BlueMatrix



Distribution of Ratings/Investment Banking Services (IB) as of 07/18/12

Cantor

			IB Serv./Past 12 Mos.	
Rating	Count	Percent	Count	Percent
BUY [B]	74	55.64	12	16.22
HOLD [H]	47	35.34	4	8.51
SELL [S]	12	9.02	0	0.00