

Equity Research

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NewLink Genetics Corporation (NLNK-\$8.76)

Rating: BUY

Target Price: \$12.00

Data Presentations in 2Q:12 Supportive - Maintain BUY

<u>EPS</u>	<u>1Q</u>	<u>2Q</u>	<u>3Q</u>	<u>4Q</u>
2010A	(1.02)A	(1.21)A	(1.49)A	(1.12)A
2011E	(1.07)A	(1.20)A	(1.09)A	(0.44)A
2012E	(0.59)E	(0.59)E	(0.52)E	(0.44)E
2013E	—	—	—	—
<u>REV</u>	<u>1Q</u>	<u>2Q</u>	<u>3Q</u>	<u>4Q</u>
2010A	0.3A	0.4A	0.4A	1.0A
2011E	0.6A	0.5A	0.4A	0.4E
2012E	0.4E	0.3E	0.3E	0.3E
2013E	—	—	—	—
<u>FY</u>	<u>2010A</u>	<u>2011E</u>	<u>2012E</u>	<u>2013E</u>
EPS	(4.84)A	(2.98)A	(2.98)E	(2.19)E
REV	2.1A	2.0E	1.3E	1.0E

- NewLink announced four data presentations to take place in 2Q:12 at Digestive Diseases Week (DDW), May 19-22, 2012, and the American Society of Clinical Oncology (ASCO), June 1-5, 2012.
- Data from the HyperAcute Pancreas program will be presented in a plenary session May 22nd. We expect additional survival data (possibly 2-year) from the Phase II trial. This trial, completed in 2010, achieved 81% disease-free survival and one-year overall survival of 96% (in the high dose arm) and compared favorably to historical controls.
- ASCO will feature posters from HyperAcute Pancreas, HyperAcute Lung and the DMT-1 (IDO) program, as well as an oral abstract session of Phase I IDO data.
- Our view has been that milestone-related events are likely to drive valuation expansion, and data presentations such as those expected at ASCO and DDW are supportive of our view. Beyond these conferences, we continue to expect incremental news flow such as trial initiations (HyperAcute Lung, IDO) and updates from other earlier stage programs to occur throughout 2H:12.
- The biggest clinical news event of this year is likely to be the announcement of an interim review of HyperAcute Pancreas, which is expected in late 2012/early 2013. As the trigger is event driven, the precise timing is uncertain. Our view is that the trial is likely to continue to its planned second interim review.
- We maintain our price target of \$12 and BUY rating. This is based on a 40x multiple on our forecasted 2016 EPS of \$2.26 discounted at 50%.

Current Statistics

Market Cap (\$Mil)	\$181.0	Float Shares (Mil):	NA
Short Interest (Mil):	NA		
52 Wk. Range	\$10.85-\$6.25		
Avg. Daily Trading Volume (3 mo.):	28,726		
Shares Out (Mil):	20.662		

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.

*Solid Pipeline with Many
Milestones*

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 their 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, and there are multiple opportunities for milestone updates over the next 24 months.

- **Indications & 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 have designed clinical trials around appropriate patient populations.
- **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.
- **Manufacturing.** NewLink's HyperAcute technology is an "off the shelf" vaccine. As such, there is no need to harvest patient cells, which is time consuming and expensive. NewLink's HyperAcute therapeutic vaccine has a streamline manufacturing process with attractive margins.
- **Milestones.** A key component of valuation building for biotechnology companies is derived from milestone events. NewLink has a full milestone calendar over the next 24 months, and we expect news flow from such events will provide incremental opportunities to build value. Data presentations from the HyperAcute Pancreas program will be presented at a plenary session at Digestive Disease Week (DDW) in May, and in a poster at the American Society of Clinical Oncology (ASCO) in June. Additionally, an oral poster session highlighting Phase I IDO data will occur at ASCO as will poster presentations from the combination Phase I IDO program, HyperAcute Lung and HyperAcute Pancreas. We expect that the company will have the opportunity to advance two products into later stage of clinical trials and take an interim look at data from its HyperAcute Pancreas Phase III trial in late 2012/early 2013.

Valuation

Our 12-month price target is \$12, and this is based on a discounted present value earnings calculation of EPS of \$2.26 in 2016, and a multiple on those earnings of 40x, discounted by 50%. We have used a multiple on 2016 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 FDA (Food & Drug Administration) 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 an SPA (special protocol assessment), 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 mean 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 company has \$6 million in outstanding debt under a forgivable loan agreement with the Iowa Department of Economic Development, of which \$4.7 million may be accelerated and require repayment as early March 18, 2012. Though we expect that the Iowa Department of Economic Development will continue to defer repayment of principal until such time that NewLink is in a cash flow positive position, we cannot exclude the possibility that repayment will be required sooner.
- 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

<i>All figures in millions, Year Ended 31 December</i>	2016E	2015E	2014E	2013E	2012E	2011A	2010A	2009A
Revenue	\$270.00	\$28.95	\$0.65	\$1.01	\$1.26	\$1.87	\$2.08	\$0.93
Cost of Goods Sold	77.69	15.47	0.00	0.00	0.00	0.00	0.00	0.00
Gross Profit	\$192.31	\$13.48	\$0.65	\$1.01	\$1.26	\$1.87	\$2.08	\$0.93
<i>Gross Profit Margin</i>	<i>71.23%</i>	<i>46.55%</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>
Operating Expenses								
SG&A	72.65	41.18	27.51	18.16	12.65	5.68	6.07	3.71
R&D	54.31	42.25	37.74	28.66	23.62	14.26	12.67	7.58
Total Operating Expenses	\$126.96	\$83.43	\$65.25	\$46.82	\$36.27	\$19.93	\$18.74	\$11.28
Profit (Loss) from Operations	\$65.35	(\$69.95)	(\$64.60)	(\$45.81)	(\$35.01)	(\$18.06)	(\$16.66)	(\$10.35)
<i>Operating Profit Margin</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>
Other Income (Expense)	\$1.15	\$0.75	(\$0.03)	(\$0.00)	\$0.07	(\$0.03)	\$0.10	\$0.14
Pretax Income	\$66.50	(\$69.20)	(\$64.63)	(\$45.81)	(\$34.94)	(\$18.09)	(\$16.56)	(\$10.21)
<i>Pretax Margin</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>
Net loss attributable to noncontrolling interest	0.00	0.00	0.00	0.00	0.00	0.00	0.35	0.23
Net Income (Loss)	\$66.50	(\$69.20)	(\$64.63)	(\$45.81)	(\$34.94)	(\$18.09)	(\$16.21)	(\$9.97)
<i>Net Margin</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>
Basic & Diluted Net Loss Per Share	\$2.22	(\$2.52)	(\$2.62)	(\$2.07)	(\$2.19)	(\$2.98)	(\$4.84)	(\$3.16)
<i>Shares Outstanding</i>	<i>30.00</i>	<i>27.50</i>	<i>24.65</i>	<i>22.08</i>	<i>15.96</i>	<i>6.07</i>	<i>3.35</i>	<i>3.16</i>

<i>Percent Change, Year-Over-Year</i>	2016E	2015E	2014E	2013E	2012E	2011E	2010A	2009A
<i>Revenue</i>	832.61%	4354.09%	-35.64%	-19.84%	-32.69%	-9.96%	122.59%	47.55%
<i>SG&A</i>	76.42	49.69	51.49	43.56	122.75	(6.50)	63.94	(5.92)
<i>R&D</i>	28.54	11.95	31.68	21.34	65.70	12.55	67.14	30.88
<i>Operating Expenses</i>	52.18	27.86	39.36	29.09	81.95	6.37	66.09	15.98
<i>Other Income, net</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>








Source: NewLink Genetics, Cantor Fitzgerald estimates

Exhibit 2: Pancreatic Cancer Model

NewLink Genetics Corporation						
<i>(\$ in millions)</i>	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%
<i>% treated</i>	<i>0.0%</i>	<i>1.2%</i>	<i>4.8%</i>	<i>7.0%</i>	<i>7.4%</i>	<i>7.5%</i>
# 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%
<i>% treated</i>	<i>0.0%</i>	<i>1.4%</i>	<i>5.9%</i>	<i>9.5%</i>	<i>12.4%</i>	<i>15.9%</i>
# treated	0.00	626	2,753	4,434	5,900	7,662
Total Treated	0.00	1,182	4,977	7,737	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	\$426.5	\$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	61.08	33.07	29.86
Total treated	NA	NA	321.18	55.46	21.45	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	57.94	24.00	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	HyperAcute					722-patient trial, >200 enrolled, interim look 4Q12/1Q13. Phase II data at DDW & ASCO.
HyperAcute Lung	Allogenic vaccine/NSCLC	HyperAcute					Data expected 1H12, Phase II/III expected 1H12. Phase II data @ ASCO.
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					NCI-funded Phase II studies, preliminary data expected. Two posters @ ASCO.
2nd generation IDO	Small molecule inhibitor of IDO/solid tumors	IDO pathway inhibitor					Higher potency vs. D-1MT

Source: NewLink Genetics, Cantor Fitzgerald

Exhibit 4: Selected Immunotherapy Companies

Company	Ticker	Price 4/11/2012	Market Cap	Price/ Cash	Debt (\$ in mln)	Stage of Lead Candidate	Technology
Agenus	AGEN	6.45	\$130.6	7.95	30.90	Phase III	Autologous
Celldex	CLDX	4.60	203.0	2.56	17.00	Phase III	Allogeneic
Dendreon	DNDN	9.45	1,383.5	2.58	536.00	Commercial	Autologous
NewLink	NLNK	9.15	128.1	2.17	7.00	Phase III	Allogeneic
Oncothyreon (a)	ONTY	4.37	196.0	2.70	3.30	Phase III	Allogeneic
Vical	VICL	3.15	232.3	4.51	0.00	Phase III	DNA

EPS Estimates(b)	2010A	2011A	2012E	52WkHi	52WkLo	Rating
Agenus	(1.38)	(1.21)	(1.21)	\$7.18	\$1.92	NC
Celldex	(1.04)	(1.13)	(1.00)	5.66	2.05	BUY
Dendreon	(2.91)	(3.14)	(1.89)	43.96	6.46	HOLD
NewLink	(4.84)	(2.98)	(2.07)	10.85	6.25	BUY
Oncothyreon	(0.58)	(1.12)	(0.63)	11.59	4.02	BUY
Vical	(0.54)	(0.10)	(0.28)	5.30	2.22	NC

(a) pro forma for an equity offering on 3/29/12

(b) EPS estimates for non-covered companies are Thomson One consensus estimate.

Source: Cantor Fitzgerald, Thomson One, the companies

Exhibit 5: Companies Mentioned

Company Name	Ticker	11.99	Cantor Rating
Agenus	AGEN	NASDAQ	NC
Celldex	CLDX	NASDAQ	BUY
Dendreon	DNDN	NASDAQ	HOLD
Galena	GALE	NASDAQ	NC
NewLink Genetics	NLNK	NASDAQ	BUY
Oncothyreon	ONTY	NASDAQ	BUY
Vical	VICL	NASDAQ	NC

Source: Cantor Fitzgerald, Thomson Reuters

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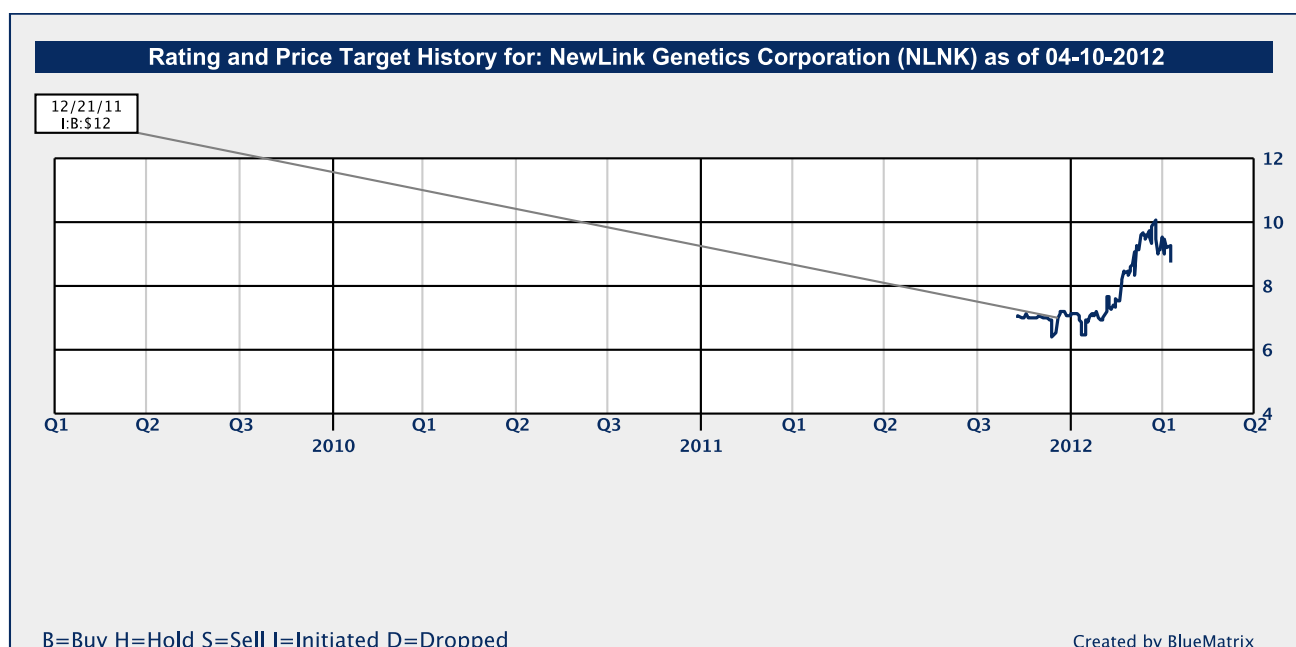
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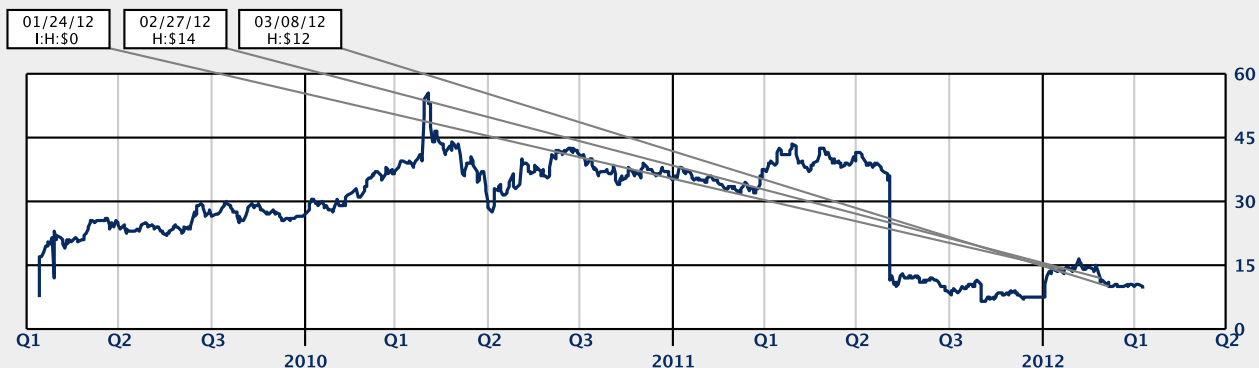
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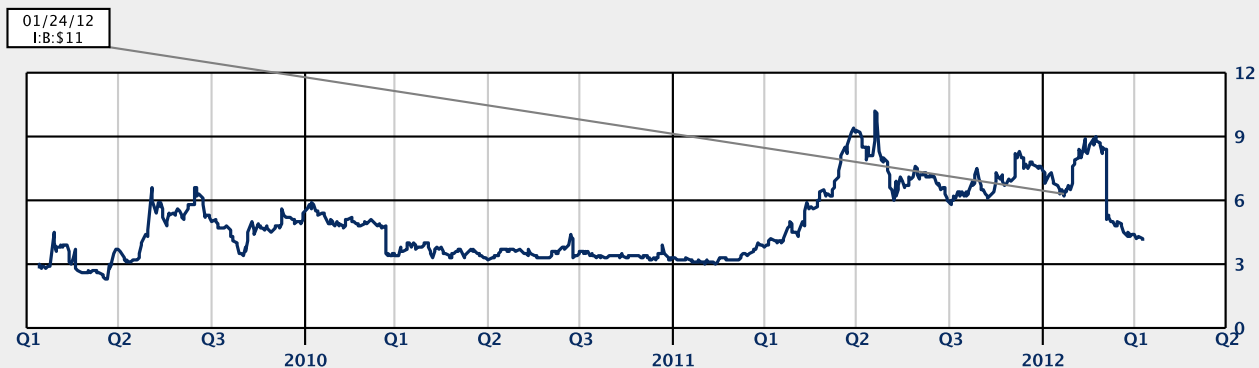
Rating and Price Target History for: Dendreon Corporation (DNDN) as of 04-10-2012



B=Buy H=Hold S=Sell I=Initiated D=Dropped

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Rating and Price Target History for: Oncothyreon Inc. (ONTY) as of 04-10-2012



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Cantor

Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [B]	62	55.86	4	6.45
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