

Equity Research

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NewLink Genetics Corporation (NLNK-\$9.03)

Rating: BUY

Target Price: \$12.00

Quick Read on 4Q:11 EPS - Clinical Programs on Track

<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
<i>Prev</i>	—	—	—	(0.36)E
2012E	(0.59)E	(0.59)E	(0.52)E	(0.44)E
<i>Prev</i>	—	—	—	(0.48)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
<i>Prev</i>	—	(2.73)E	(2.19)E	(2.07)E
REV	2.1A	2.0E	1.3E	1.0E

- NewLink reported 4Q:11 EPS of (\$0.44) vs. (\$1.12) last year and our forecast of (\$0.36). The larger loss is related to a lower share base and likely higher SG&A costs, though the difference is likely due to non-cash items such as D&A and option expense.
- Most importantly, the company's progress toward commercialization remains on track, and the company continues to expect an interim analysis of the HyperAcute Pancreas trial around year-end 2012.
- HyperAcute Pancreas is NewLink's pivotal Phase III program, and much attention will be focused on its progress. We expect that other programs such as HyperAcute NSCLC will gain greater attention this year.
- The company anticipates finishing 2012 with a cash balance of \$20 million, sufficient to fund its existing clinical plan through 2013. This is consistent with prior guidance. We expect, at some point, NewLink will need to access additional cash resources to continue to fund development of clinical candidates, and this has already been factored into our financial projections.
- Milestone-related events are likely to drive valuation expansion, and we continue to expect incremental data from clinical candidates in 2012, both at ASCO in early June and at DDW in mid-May (HyperAcute Pancreas). This, coupled with other potential data releases (IDO inhibitor program), is likely to boost visibility on the shares.
- On the corporate front, we believe NewLink's announcement to convert its loan from the Iowa Economic Development Authority (IEDA) to a 0.5% royalty on future products up to the total amount of the loan is a positive development, as it removes any constraints associated with the loan and loan overhang.
- 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)	\$185.9	Float Shares (Mil):	NA
Short Interest (Mil):	NA		
52 Wk. Range	\$10.85-\$6.25		
Avg. Daily Trading Volume (3 mo.):	23,878		
Shares Out (Mil):	20.591		

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 7 - 8 of this report.

Summary

Investment Thesis: 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 has 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. 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.

4Q:11 and 2011 EPS Review

NewLink reported 4Q:11 EPS of (\$0.44) versus (\$1.12) last year and our forecast of (\$0.36). For 2011, NewLink reported EPS of (\$2.98) vs. (\$4.84) in the year prior. The larger than expected loss was driven by a lower reported share base versus our forecast and higher SG&A of \$2.1 million (our forecast was \$1.7 million), largely due to non-cash charges such as D&A and option expense. Overall, revenues (from grant funding) were in line for the quarter at \$0.3 million, and R&D spending of \$3.98 million was also in line. The company indicated that they are likely to end 2012 with \$20 million in cash, which is in line with our expectations.

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 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 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: Sales & Earnings by Quarter

NewLink Genetics Corporation														
All figures in millions, Year Ended 31 Dec	2012E	4Q12E	9Mos12E	3Q12E	6Mos12E	2Q12E	1Q12E	2011A	4Q11A	9Mos11A	3Q11A	6Mos11A	2Q11A	1Q11A
Revenue	\$1.26	\$0.27	\$0.99	\$0.31	\$0.68	\$0.30	\$0.38	\$1.87	\$0.30	\$1.57	\$0.43	\$1.14	\$0.54	\$0.60
Cost of Goods Sold	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Gross Profit	\$1.26	\$0.27	\$0.99	\$0.31	\$0.68	\$0.30	\$0.38	\$1.87	\$0.30	\$1.57	\$0.43	\$1.14	\$0.54	\$0.60
Gross Profit Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Operating Expenses														
SG&A	12.65	3.24	9.41	3.13	6.28	3.41	2.87	5.68	2.13	3.55	1.10	2.45	1.14	1.32
R&D	23.62	6.96	16.66	6.63	10.03	5.18	4.85	14.26	3.98	10.28	3.30	6.98	3.80	3.18
Total Operating Expenses	\$36.27	10.20	26.07	9.76	\$16.31	\$8.59	7.72	\$19.93	6.11	13.83	4.40	\$9.43	\$4.93	4.50
Profit (Loss) from Operations	(\$35.01)	(\$9.93)	(\$25.08)	(\$9.45)	(\$15.63)	(\$8.29)	(\$7.34)	(\$18.06)	(\$5.80)	(\$12.26)	(\$3.97)	(\$8.29)	(\$4.39)	(\$3.89)
Operating Profit Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Other Income (Expense)	\$0.07	0.02	0.05	0.02	\$0.03	\$0.02	0.01	(\$0.03)	(0.06)	(0.02)	(0.01)	(\$0.01)	\$0.00	(0.01)
Pretax Income	(\$34.94)	(\$9.91)	(\$25.03)	(\$9.43)	(\$15.60)	(\$8.27)	(\$7.33)	(\$18.09)	(\$5.86)	(\$12.28)	(\$3.99)	(\$8.29)	(\$4.39)	(\$3.90)
Pretax Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Income Tax Paid (Benefit)	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Net Income (Loss)	(\$34.94)	(\$9.91)	(\$25.03)	(\$9.43)	(\$15.60)	(\$8.27)	(\$7.33)	(\$18.09)	(\$5.86)	(\$12.28)	(\$3.99)	(\$8.29)	(\$4.39)	(\$3.90)
Net Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Basic & Diluted Net Loss Per Share	(\$2.19)	(\$0.59)	(\$1.59)	(\$0.59)	(\$1.00)	(\$0.52)	(\$0.48)	(\$2.98)	(\$0.44)	(\$3.36)	(\$1.09)	(\$2.28)	(\$1.20)	(\$1.07)
Average Shares Outstanding	15.96	16.75	15.78	16.03	15.54	15.87	15.20	6.07	13.24	3.65	3.66	3.64	3.65	3.64

Source: NewLink Genetics, Cantor Fitzgerald estimates

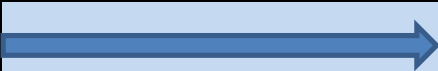
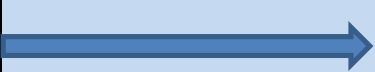





Exhibit 2: Annual Income Statement
NewLink Genetics Corporation

<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 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
HyperAcute Lung	Allogenic vaccine/NSCLC	HyperAcute					Data expected 1H12, Phase II/III expected 1H12
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
2nd generation IDO	Small molecule inhibitor of IDO/solid tumors	IDO pathway inhibitor					Higher potency vs. D-1MT

Source: NewLink Genetics, Cantor Fitzgerald

Disclosures Appendix

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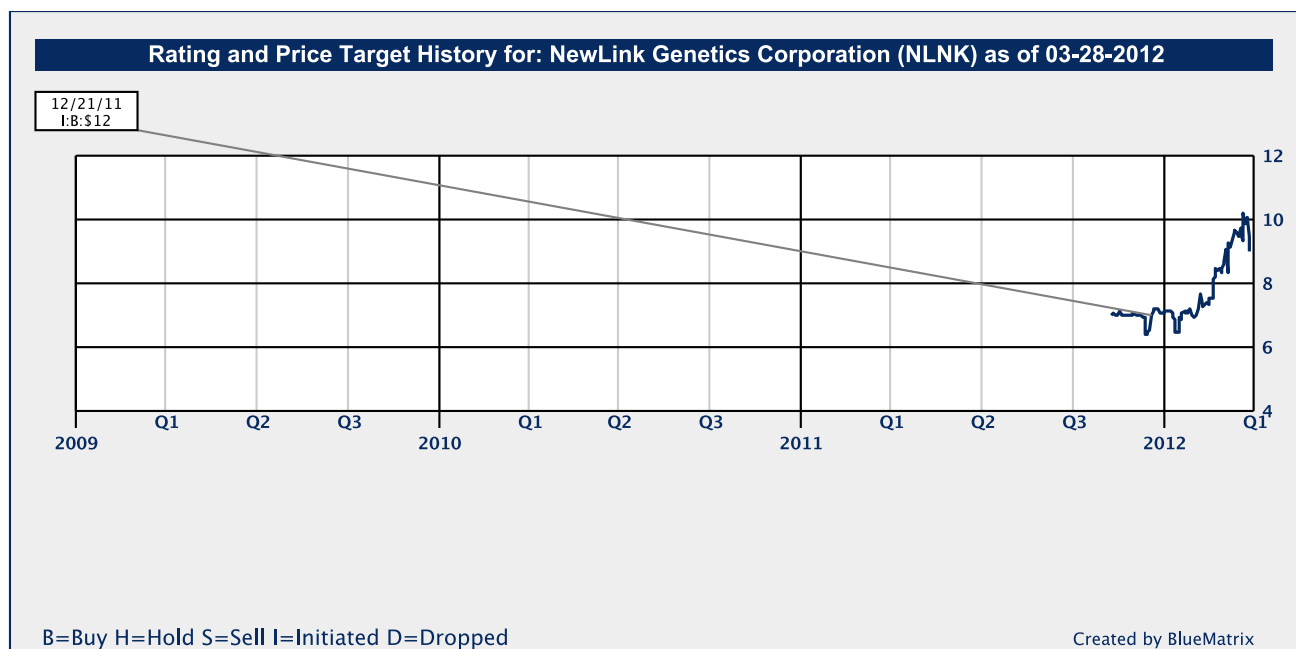
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Rating	Cantor		IB Serv./Past 12 Mos.	
	Count	Percent	Count	Percent
BUY [B]	54	54.00	4	7.41
HOLD [H]	36	36.00	1	2.78
SELL [S]	10	10.00	0	0.00