NewLink Genetics

NLNK : NASDAQ : US$12.76

BUY

Target: US$23.00

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COMPANY STATISTICS:

52-week Range:	6.25 - 13.67
Market Cap (M):	US$274
Avg. Daily Vol. (000s):	263
Shares Out (M):	20.6

EARNINGS SUMMARY:

FYE Dec		2011A	2012E	2013E
EPS:		(2.98)	(1.03)	(0.97)
Revenue:	Q1	0.6	0.5A	-
	Q2	0.5	0.4	-
	Q3	0.4	0.4	-
	Q4	0.3	0.4	-
Total		1.9	1.8	1.6
EPS:	Q1	(1.07)	(0.23)A	-
	Q2	(1.20)	(0.25)	-
	Q3	(1.09)	(0.26)	-
	Q4	(0.44)	(0.29)	-
Total		(2.98)	(1.03)	(0.97)

SHARE PRICE PERFORMANCE:

Source: Interactive Data Corporation

COMPANY DESCRIPTION:

NewLink Genetics is a biotechnology company devoted to the development of cell-based cancer vaccines and other cancer therapeutics.

All amounts in US$ unless otherwise noted.

Life Sciences -- Biotechnology

ASSUMING COVERAGE WITH A BUY; SEE MORE UPSIDE REMAINING

We are assuming coverage of NLNK with a BUY rating and a $23 price target. The key value driver is HyperAcute Pancreas (HAP) – a novel immunotherapy in P3 clinical trial for surgically-resected pancreatic cancer. A positive P2 (we recognize it was a single-arm study) in addition to the novel cancer vaccine platform are encouraging as we look toward P3 data (first interim analysis in late-2012/early-2013E). We model for peak worldwide HAP sales of $850M in 2020, of which $635M is recognized by NLNK. We view the remainder of the pipeline as a free-call option. While NLNK shares are up ~81% YTD, we believe long-term P2 overall survival data at ASCO (June 4) could serve as a near-term catalyst.

- **HAP P2 data is encouraging:** HAP + standard-of-care (SOC; Gemzar + 5-FU/radiation) demonstrated 1-year overall survival (OS) of 86% (96% in the high-dose subset) versus 69% for Gemzar + 5-FU/ radiation in the RTOG 97-04 study (best comparator) with a relatively clean adverse event profile.

- **Physicians are optimistic on HAP:** They believe the theoretical basis behind the vaccines make sense (making human pancreatic cells look foreign so that they get destroyed). In terms of efficacy, they are encouraged when comparing the HAP P2 to SOC in the RTOG 97-04 study (see above). In addition, the MSKCC prognostic model suggested a 63% survival at 12 months (53% under a different model) in a similar patient population versus the 86% demonstrated by HAP. Looking at the P3 trial design, they like that the primary endpoint is OS, that patients now initiate HAP 10 weeks post-surgery (providing more recovery time), and given SOC can now be determined by the patients and oncologists versus the P2.

INVESTMENT THESIS

HyperAcute Pancreas (HAP) is the key value driver for NLNK. HyperAcute Pancreas, a novel cancer immunotherapeutic currently administered in addition to standard of care (SOC; Gemzar + 5-FU/radiation), is in a P3 trial, under an SPA, for the treatment of surgically-resected pancreatic cancer. The P2 trial, while uncontrolled, demonstrated encouraging efficacy, when compared to studies evaluating standard-of-care, specifically 12-month overall survival (OS) of 86% (96% in the high-dose subset) versus 69% for Gemzar + 5-FU/radiation in the RTOG 97-04 study (best comparator given same standard-of-care regimen and similar patient demographics and prognostic factors, apart from lymph node positivity rates of 81% for HAP vs. 68%). Updated P2 OS data will be presented at ASCO. In addition, the drug has demonstrated a relatively clean adverse event (AE) profile in P2. We await the first interim analysis of the P3 trial in late-2012/early-2013. The key question is whether the P2 data can be replicated in the P3? We assume mid-2015 and mid-2016 approvals/launches in the U.S. and E.U., respectively. According to our model, peak WW sales for HAP is $850M+, with $565M in the U.S. and $281M in the E.U. ($70M to NLNK) in 2020E. We view the remaining pipeline, including other HyperAcute (HA) platform therapies (HA Lung in P2 in NSCLC and HA Melanoma in P2 in advanced melanoma, etc.) and the IDO inhibitor program as a free-call option.

A novel cancer vaccine platform with promise. The HA platform drugs consist of allogenic (non-patient specific, unlike DNDN) human cancer cells (same cells as the cancer being treated) that have been genetically altered to produce the alpha-Gal epitope. The patient's immune system recognizes the alpha-Gal epitope and attacks the foreign cells, in turn inducing a multifaceted response against all similar tumor cells – including the patient's own cancer cells. The off-the-shelf cell lines allow for a more consistent, commercially-viable (lower COGS) manufacturing process.

Physicians are optimistic on HAP. They believe the theoretical basis behind the vaccines make sense (making human pancreatic cells look foreign so that they get destroyed). In terms of efficacy, they are encouraged when comparing the HAP P2 to SOC in the RTOG 97-04 study (see above). In addition, the Memorial Sloan-Kettering Cancer Center (MSKCC) prognostic model suggested a 63% survival at 12-months (53% under a different prognostic model) in a similar patient population versus the 86% demonstrated by HAP. In terms of safety, they recognized the safe experience/clean safety profile. Looking at the P3 trial design, they like that the primary endpoint is OS, that patients now initiate HAP 10 weeks post-surgery (providing more recovery time), and given SOC can now be determined by the patients and oncologists versus the P2.

We model for HyperAcute Pancreas U.S. peak sales of $565M/+ in 2020. We estimate ~7K eligible patients annually in the U.S. (20% of the ~44K pancreatic cancer patients are resection-eligible of which 75% are candidates for HAP) and model for peak market share of 65% and pricing of $120K. In terms of the E.U., we model for a partnership ($50M upfront) to emerge in YE14 (post P3 data), with peak sales of $281M ($70M to NLNK based on a tiered 20%-25% royalty) in 2020. We estimate ~5K eligible patients annually (10% of the ~72K pancreatic cancer patients are resection-eligible, surgery is typically performed on healthier patients, of which 75% are candidates for HAP) with peak market share of 50% and pricing at a discount to the U.S. ($100K)

Remaining pipeline represents potential upside. The principles of the HyperAcute platform should apply to any solid tumor. We expect initiation of the P2B/3 HyperAcute Lung and P2 HyperAcute Melanoma trials to both initiate in 2012. We would caveat that these programs are highly leveraged to the success of HAP. NLNK also has a small molecule under development: the Indoleamine-(2,3)-dioxygenase (IDO) inhibitor d-1-methyltryptophan (D-1MT), currently undergoing P1B trials as a combination therapy for various solid tumors.

NLNK cash position of $35.8M is sufficient into 2013E. The company expects to exit FY12 with >$20M in cash.

VALUATION

We arrive at our 12-month price target of $23 by applying a 25x multiple to our FY17 fully diluted GAAP EPS estimate of $4.88, discounted back to mid-2013 at 45%.

INVESTMENT RISKS

The primary investment risks for NLNK include the following:

1) HAP clinical development risks – Given the Phase 2 study was uncontrolled, will the efficacy seen be replicated in a Phase 3 controlled trial? Can the relatively clean safety profile demonstrated in the Phase 2 trial be sustained in the Phase 3 trial? In addition, immunotherapy remains an emerging field, with few immunotherapies approved to date;

2) Regulatory risks including failure to secure U.S. and E.U. approval;

3) Commercial risk, including the possibility that the drug does not achieve the peak commercial revenue estimates in our model (due to market size, penetration rates, and/or pricing);

4) Product competition;

5) Financing risk – We model for an equity offering in 2013.

Figure 1: NLNK pipeline

Product	Indication	Target	Stage
HyperAcute Pacreas	Resected pancreatic cancer	Immune response	Phase 3
HyperAcute Lung	Advanced non-small cell lung cancer	Immune response	Phase 2/3
HyperAcute Melanoma + PEG-Intron	Advanced melanoma	Immune response	Phase 2
HyperAcute RCC	Renal cell carcinoma	Immune response	Phase 1
D-1MT	Solid Tumors	IDO pathway	Phase 1/2

Source: Canaccord Genuity, Company Reports

Figure 2: Upcoming milestones

Timing	Product	Indication	Event
ASCO - June 2012	HyperAcute Pancreas	Pancreatic Cancer	P2 interim analysis
Late-2012/Early-2013	HyperAcute Pancreas	Pancreatic Cancer	First P3 interim analysis
2H13 (6-9 months post)	HyperAcute Pancreas	Pancreatic Cancer	Second P3 interim analysis
2014	HyperAcute Pancreas	Pancreatic Cancer	Final P3 analysis
2013	HyperAcute Lung	NSCLC	First P2B/3 interim analysis
1Q14	D-1MT	Breast Cancer	P1/2 primary completion
4Q14	D-1MT	Prostate Cancer	P2 primary completion

Source: Canaccord Genuity, Company Reports

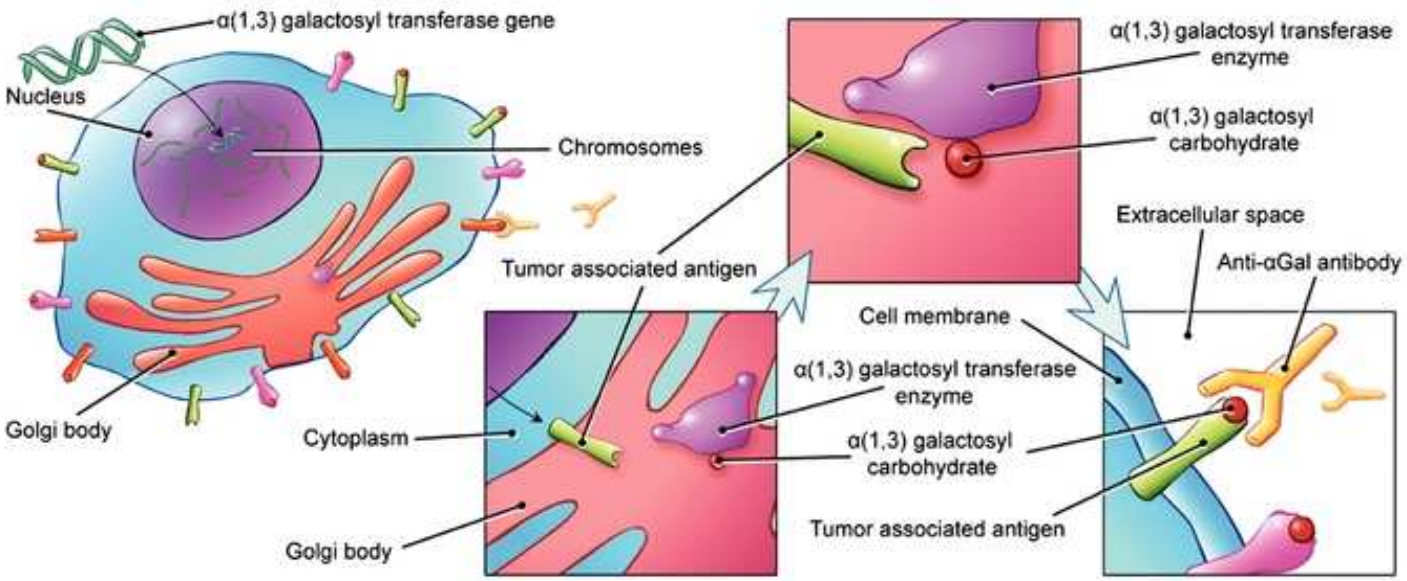
HYPERACUTE: A NOVEL CANCER VACCINE PLATFORM WITH PROMISE

The HyperAcute platform is a novel immunotherapy delivered through a series of intradermal injections, consisting of live, irradiated, allogenic (foreign) human cancer cells that are administered in combination with standard-of-care. These injected cells have been genetically altered to produce the alpha-Gal epitope (a small protein recognized and attacked by the human immune system, ~1% of human antibodies are directed against this epitope). Specificity for a specific cancer type is achieved by injecting genetically modified cells of the same type of cells as the cancer being treated (eg. lung cancer cells for lung cancer treatment). After injection, the alpha-Gal epitope on the delivered cells is recognized by the patient's immune system, which subsequently process the entire injected cell, inducing a multifaceted response against all tumorous cells of the type injected – including the patient's own cancer cells.

Cancer immunotherapies have been approved for treatment of melanoma (BMY's Yervoy) and prostate cancer (DNDN's Provenge). Unlike Provenge which is based on utilizing autologous (patient-specific) cells, the HyperAcute mechanism utilizes allogenic (non-patient specific) cells from previously-established, off-the-shelf cell lines allowing for a simpler, replicable manufacturing process with lower associated COGS. *See Figure 3.*

NLNK's lead product is HyperAcute Pancreas, an adjuvant therapy to standard-of-care in surgically-resected pancreatic cancer. The Phase 2 trial, while uncontrolled, demonstrated strong efficacy (overall survival) with fewer adverse events (AEs) as compared to current standard-of-care, and is currently being evaluated in a Phase 3 trial.

Figure 3: HyperAcute cancer immunotherapy platform



Source: Company reports

HYPERACUTE PANCREAS: WILL THE PHASE 2 RESULTS BE REPLICATED IN PHASE 3?

Promising Phase 2 HyperAcute Pancreas (HAP) trial results

The Phase 2 trial (NLG-0205) was conducted in 69 patients with resected pancreatic cancer in the U.S., who were administered ~12 injections of HAP at two doses (100M [n=44] or 300M [n=26] cells 2x/month over 6 months) in addition to standard-of-care (Gemzar + 5-FU/radiation). These patients presented with higher risk factors (higher levels of high grade tumors, local invasion, lymph node spread, and elevated CA 19-9) relative to previous Gemzar-based Phase 3 trial populations.

The primary endpoint of 12-month disease-free survival (DFS) was 62% with a median DFS of 14.1 months. The secondary endpoint of 12-month OS was 86% with a Kaplan-Meier estimate for median OS at 24.4 months, longer than in the prior Phase 3 trials of Gemzar alone (ESPAC-3) or with 5-FU/radiation (RTOG 97-04) (23.6 months and 20.6 months respectively), and a longer 23-month OS (HAP: 86%, Gem: 80%, Gem+5-FU/rad: 69%, respectively). We would note that the best comparator is RTOG 97-04 given the standard-of-care regimen and baseline patient characteristics, though there was a higher frequency of lymphatic node invasion (68% vs. 81% in HAP Phase 2 trial). *See Figure 4.* The 26-patient high dose subset (300M cells) demonstrated even better results: 12-month DFS of 81%, and 12-month overall survival (OS) of 96% (only 1 of 26 patients died at 12 months).

Despite the fact that HAP was delivered along with the standard-of-care, AE rates were much lower than in Phase 3 trials of the standard-of-care alone: no grade 4 and only 8% grade 3 events in HAP compared to 79% grade 3 or 4 in Gem + 5-FU/rad (RTOG 97-04), albeit in a shorter time frame. We look to the upcoming Phase 3 trial as to whether this AE trend is sustainable, but the survivorship data are encouraging.

Figure 4: Relative data from HAP P2 and other P3 trials of resected pancreatic cancer

Drug	Trial name	Control		Overall survival		Disease-free survival	
			Size	Median	1-yr	Median	1-yr
HAP (high and low dose) + Gem + 5-FU/radiation	NLG-0205 (1)	None (single-arm)	N = 69	24.4 months	86%	14.1 months	62%
HAP (high dose only) + Gem + 5-FU/radiation			N = 26	maturing	96%		81%
Gemzar + 5-FU + radiation	RTOG-9704 (2)	5-FU + rad	N = 221	20.6 mo	69%		
Gemzar	ESPAC-3 (3)	5-FU + rad	N = 537	23.6 mo	80%		

Source: Company Reports; Regine *et al*., JAMA 2008; Neoptolemos *et al*., JAMA 2010.
Data that will be presented (updated) at ASCO is highlighted

From Phase 2 data to Phase 3 trial design

NLNK is currently conducting a U.S.-based Phase 3 trial, NLG-0405 (initiated in May 2010), under a SPA in 700 Stage I and II surgically-resected pancreatic cancer patients randomized 1:1 to HAP + standard-of-care (Gemzar +/- 5-FU/radiation) versus standard-of-care alone. We would note that standard of care allows for Gemzar without 5-

FU/radiation, which is a change from the Phase 2 trial, as more physicians are opting for Gemzar alone in recent practice.

Patients will be treated with the 300 million cell dose, which was associated with better outcomes in the Phase 2 trial versus the low 100 million cell dose. Patients in the treatment arm will receive the same set of 12 bi-weekly injections as in Phase 2, but with six additional monthly injections (1x/month for 6 months) following the initial 6 months.

The primary endpoint is OS and secondary endpoints are DFS, safety, toxicity and immunological responses. Enrollment completion is expected by YE13.

Interim evaluations will take place when 50% (~200-220 deaths) and 75% of the expected deaths have occurred; expected in late-2012/early-2013 and 2H13 (6-9 months post first interim analysis), with the final analysis in 2014.

All eyes on the Phase 3 data

The first interim analysis of the Phase 3 HAP trial is likely in late-2012/early-2013. At this time point, a 45% improvement in survival, if met based on statistical modeling, would allow for the trial to be stopped and a regulatory application filed for approval under the SPA. The second interim look is likely in 2H13, which should be statistically significant on 30% improvement in overall survival, and final analysis is likely in 2014, which should detect a 20% overall survival benefit.

We will specifically be looking for answers to the following three questions: 1) whether the Phase 2-to-Phase 3 comparisons made previously can be sustained?, 2) if the control arm will have an median OS closer to Gem+5-FU/rad at 20.6 months or Gemzar at 23.6 months (comparing these results to Phase 2 HAP data would be the difference between a 3.8 month vs. 0.8 month improvement), and 3) whether the relatively clean safety profile can be sustained.

Physicians are optimistic on HyperAcute Pancreas

We spoke with physician thought leaders who are optimistic on HAP and the HyperAcute platform, as they believe the theoretical basis behind the vaccines makes sense (making human pancreatic cells look foreign so that they get destroyed).

In terms of efficacy, they believe the closest historical control is RTOG 97-04, given the same standard-of-care and similar demographics and prognostic factors (apart from lymph node positivity rates of 81% for HAP vs. 68%). On an indirect head-to-head comparison, HAP demonstrated better efficacy than Gemzar + 5-FU/rad. In addition, the Memorial Sloan-Kettering Cancer Center (MSKCC) prognostic model suggested a 63% survival at 12-months (53% under a different prognostic model) in a similar patient population versus the 86% demonstrated by HAP. In terms of safety, they are encouraged by the safe experience/clean safety profile.

In terms of the Phase 3 trial design, they are encouraged by the endpoint (OS is important). In addition, patients now initiate HAP 10 weeks post-surgery (versus the 6-7weeks in the Phase 2), which provides patients more time to recover. Finally, the standard-of-care (Gemzar +/- 5-FU/rad) can now be chosen by the patients and oncologists versus the Phase 2, where certain physicians (particularly in the E.U. prefer to use chemotherapy alone without radiation).

Gemzar is the standard-of-care for resected pancreatic cancer, and few other options are on the horizon

The current standard-of-care for pancreatic cancer following resection is Gemzar, with or without 5-FU and radiation. Near-term future options include Tarceva (with Gemzar, in Phase 3) and Xeloda (with Gemzar, Cisplatin and Ellence, in Phase 3). Several other therapeutic options are available for metastatic or locally advanced pancreatic cancer, including Gemzar and Xeloda. *See Figure 5.* NLNK intends to initiate a Phase 2 trial in locally-advanced nonresectable patients in 2H12+.

Figure 5: Competition in pancreatic cancer

Drug	Generic name	Drug type	Target	Indication	Other indications	Company	Year approved / status
Gemzar	Gemcitabine	Nucleoside analog	DNA synthesis	Pancreatic cancer	Ovarian cancer, breast cancer, non small-cell lung cancer	Eli Lilly	1996
Xeloda, Gemzar, Cisplatin, Ellence)	Capecitabine, gemcitibine, cisplatin, epirubicin	5-FU prodrug, Pt-based, nuceloside analog, DNA intercalator	DNA synthesis	Resectable pancreatic cancer	Colon cancer, colorectal cancer, breast cancer	Roche, Pfizer	Phase 3
Tarceva (+ Gemzar)	Erlotinib	Tyrosine kinase inhibition	EGFR	Resected pancreatic cancer (on-label for locally advanced, unresectable or metastatic)	Non small-cell lung cancer	Roche, OSI	Phase 3

Source: Canaccord Genuity Research

HyperAcute Pancreas (HAP) market and pricing

We only model for revenue related to HAP. The other HyperAcute platform indications are in early-stages of development (non-small cell lung cancer (NSCLC) and advanced melanoma are in Phase 2 trials) and are highly leveraged to success of HAP.

Our model conservatively assumes FDA approval and launch in mid-15, scaling up to a maximum penetration of 65% in 2020 of the eligible surgically-resected pancreatic cancer market. Literature and physician feedback puts the U.S. pancreatic cancer market at ~44,000 cases annually, with 20% undergoing resection, of which ~75% are eligible for HAP. Given that HAP is a biologic and an allogenic-cell manufacturing process, not autologous (we assume peak COGS of 15% COGS in 2020). The basic composition-of-matter patent protection covering the HyperAcute platform runs to March 2023 in the U.S. (assuming no extensions) and ex-U.S. Our gross price assumption for HAP is $120,000/year (2% annual increases), based on Yervoy. Upside to our estimates would come from higher pricing, greater market penetration, or earlier approval.

In the E.U., we assume for a partnership to be signed post the final Phase 3 data analysis in YE14 and for NLNK to receive a $50M upfront milestone payment (amortized over 9 years) and a tiered-royalty of 20%-25% of revenue. In the E.U., physicians typically resect healthier PC patients, as a result we assume 10% resection-eligible of which 75% are candidates for HAP. We assume gross pricing of $100,000/year (discount to U.S., with no price increases). We model of a mid-16 launch (12-month post U.S., but it is dependent on whether the E.U. accepts the current Phase 3 trial data or requests additional data (eg. Phase 2 study in locally advanced, nonresectable patients).

Figure 6: HyperAcute Pancreas revenue build

Pancreatic Cancer (PC) Market - U.S.	FY 2009A	FY 2010A	FY 2011A	FY 2012E	FY 2013E	FY 2014E	FY 2015E	FY 2016E	FY 2017E	FY 2018E	FY 2019E	FY 2020E
E.U. Population ('000)	308,085	310,858	313,656	316,479	319,327	322,201	325,101	328,027	330,979	333,958	336,963	339,996
Incidence of Pancreatic Cancer	0.0143%	0.0143%	0.0143%	0.0143%	0.0143%	0.0143%	0.0143%	0.0143%	0.0143%	0.0143%	0.0143%	0.0143%
Number of Patients Diagnosed with PC Annually	**44,030**	**44,426**	**44,826**	**45,230**	**45,637**	**46,047**	**46,462**	**46,880**	**47,302**	**47,728**	**48,157**	**48,591**
% of Resection-Eligible PC Patients	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
Number of Resection-Eligible PC Patients	**8,806**	**8,885**	**8,965**	**9,046**	**9,127**	**9,209**	**9,292**	**9,376**	**9,460**	**9,546**	**9,631**	**9,718**
% of Resection-Eligible PC Patients that are Candidates for HA Pancreas	75%	75%	75%	75%	75%	75%	75%	75%	75%	75%	75%	75%
Number of Resection-Eligible PC Patients that are Candidates for HA Pancreas	**6,605**	**6,664**	**6,724**	**6,784**	**6,845**	**6,907**	**6,969**	**7,032**	**7,095**	**7,159**	**7,224**	**7,289**
% of Patients Treated with HA Pancreas	0%	0%	0%	0%	0%	0%	5%	17%	35%	50%	60%	65%
Number of Patients Treated with HA Pancreas	**-**	**-**	**-**	**-**	**-**	**-**	**348**	**1,195**	**2,483**	**3,580**	**4,334**	**4,738**
Annual Gross Cost for HA Pancreas	-	-	-	-	-	-	$120,000	$122,400	$124,848	$127,345	$129,892	$132,490
Annual Net Cost for HA Pancreas	-	-	-	-	-	-	$108,000	$110,160	$112,363	$114,610	$116,903	$119,241
HA Pancreas revenue ($M) - U.S.	**-**	**-**	**-**	**-**	**-**	**-**	**37.6**	**131.7**	**279.0**	**410.3**	**506.7**	**564.9**

Pancreatic Cancer (PC) Market - E.U.	FY 2009A	FY 2010A	FY 2011A	FY 2012E	FY 2013E	FY 2014E	FY 2015E	FY 2016E	FY 2017E	FY 2018E	FY 2019E	FY 2020E
E.U.Population ('000)	500,487	502,489	504,376	507,409	510,585	512,627	514,678	516,736	518,803	520,879	522,962	525,054
Incidence of Pancreatic Cancer	0.0143%	0.0143%	0.0143%	0.0143%	0.0143%	0.0143%	0.0143%	0.0143%	0.0143%	0.0143%	0.0143%	0.0143%
Number of Patients Diagnosed with PC Annually	**71,527**	**71,813**	**72,083**	**72,516**	**72,970**	**73,262**	**73,555**	**73,849**	**74,145**	**74,441**	**74,739**	**75,038**
% of Resection-Eligible PC Patients	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%
Number of Resection-Eligible PC Patients	**7,153**	**7,181**	**7,208**	**7,252**	**7,297**	**7,326**	**7,356**	**7,385**	**7,414**	**7,444**	**7,474**	**7,504**
% of Resection-Eligible PC Patients that are Candidates for HA Pancreas	75%	75%	75%	75%	75%	75%	75%	75%	75%	75%	75%	75%
Number of Resection-Eligible PC Patients that are Candidates for HA Pancreas	**5,365**	**5,386**	**5,406**	**5,439**	**5,473**	**5,495**	**5,517**	**5,539**	**5,561**	**5,583**	**5,605**	**5,628**
% of Patients Treated with HA Pancreas	0%	0%	0%	0%	0%	0%	0%	4%	15%	30%	45%	50%
Number of Patients Treated with HA Pancreas	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**194**	**834**	**1,675**	**2,522**	**2,814**
Annual Gross Cost for HA Pancreas	-	-	-	-	-	-	-	$100,000	$100,000	$100,000	$100,000	$100,000
Annual Net Cost for HA Pancreas	-	-	-	-	-	-	-	$ 90,000	$ 90,000	$ 90,000	$ 90,000	$ 90,000
HA Pancreas revenue ($M) - E.U.	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**19.4**	**83.4**	**167.5**	**252.2**	**281.4**
Royalty to NWLK	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**3.9**	**18.4**	**38.5**	**60.5**	**70.3**

HA Pancreas U.S./E.U. Revenue ('000)						-	**$ 37.6**	**$ 151.1**	**$ 362.4**	**$ 577.7**	**$ 758.9**	**$ 846.3**

Source: Canaccord Genuity estimates

Figure 7: NewLink income statement

NewLink Genetics Corp
(NASDAQ: NLNK)

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Consolidated Income Statement
($thousands, except per share data)

	FY 2009A	FY 2010A	Mar 1Q11A	Jun 2Q11A	Sep 3Q11A	Dec 4Q11A	FY 2011A	Mar 1Q12A	Jun 2Q12E	Sep 3Q12E	Dec 4Q12E	FY 2012E	FY 2013E	FY 2014E	FY 2015E	FY 2016E	FY 2017E	FY 2018E	FY 2019E	FY 2020E
Revenue																				
HyperAcute Pancreas (HAP) - U.S. Revenue	-	-	-	-	-	-	-	-	-	-	-	-	-	-	37,634	131,689	279,037	410,256	506,672	564,912
HyperAcute Pancreas (HAP) - E.U. Royalty	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	3,877	18,351	38,523	60,539	70,348
Grant revenue	934	2,079	604	537	430	301	1,872	471	450	430	410	1,761	1,639	-	-	-	-	-	-	-
Collaboration revenue	-	-	-	-	-	-	-	-	-	-	-	-	-	1,389	5,556	5,556	5,556	5,556	5,556	5,556
Total Revenue	**$ 934**	**$ 2,079**	**$ 604**	**$ 537**	**$ 430**	**$ 301**	**$ 1,872**	**$ 471**	**$ 450**	**$ 430**	**$ 410**	**$ 1,761**	**$ 1,639**	**$ 1,389**	**$ 43,190**	**$141,122**	**$302,943**	**$454,335**	**$572,767**	**$640,816**
COGS	-	-	-	-	-	-	-	-	-	-	-	-	-	-	6,774	26,338	55,807	73,846	81,068	84,737
Gross Profit	934	2,079	604	537	430	301	1,872	471	450	430	410	1,761	1,639	1,389	36,415	114,784	247,136	380,489	491,699	556,079
Operating Expense																				
R&D (GAAP)	7,578	12,666	3,180	3,795	3,301	3,979	14,255	3,830	4,050	4,200	4,450	16,530	19,050	21,555	24,176	26,689	29,122	31,677	34,050	36,500
SG&A (GAAP)	3,705	6,074	1,316	1,136	1,101	2,126	5,679	1,458	1,550	1,650	1,975	6,633	8,050	15,300	28,800	33,800	38,912	43,998	48,923	53,908
Total Operating Expense	11,283	18,740	4,496	4,931	4,402	6,105	19,934	5,288	5,600	5,850	6,425	23,163	27,100	36,855	52,976	60,489	68,034	75,675	82,973	90,408
Operating Income (loss)	**(10,349)**	**(16,661)**	**(3,892)**	**(4,394)**	**(3,972)**	**(5,804)**	**(18,062)**	**(4,817)**	**(5,150)**	**(5,420)**	**(6,015)**	**(21,402)**	**(25,461)**	**(35,466)**	**(16,561)**	**54,295**	**179,102**	**304,814**	**408,726**	**465,671**
Other income (expense)																				
Miscellaneous Income	19	71	1	-	-	4	5	(21)	-	-	-	(21)	-	-	-	-	-	-	-	-
Forgiveness of Debt	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Interest Income	132	75	4	4	2	1	11	4	3	3	2	12	16	11	10	17	65	184	369	612
Interest Expense	(9)	(47)	(11)	(4)	(16)	(11)	(42)	(8)	(8)	(8)	(8)	(32)	(28)	(24)	(20)	(16)	(12)	(2)	-	-
Total Other Income (Expense), Net	142	99	(6)	-	(14)	(6)	(26)	(25)	(5)	(5)	(6)	(41)	(12)	(13)	(10)	1	53	182	369	612
Net income (loss) before Income Tax	**(10,207)**	**(16,562)**	**(3,898)**	**(4,394)**	**(3,986)**	**(5,810)**	**(18,088)**	**(4,842)**	**(5,155)**	**(5,425)**	**(6,021)**	**(21,443)**	**(25,473)**	**(35,479)**	**(16,571)**	**54,297**	**179,155**	**304,995**	**409,095**	**466,283**
Less Net Loss Attributable to Noncontrolling Interest	233	349	1	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Net income (loss) attributable to NLNK before Income Tax	**(9,974)**	**(16,213)**	**(3,897)**	**(4,394)**	**(3,986)**	**(5,810)**	**(18,087)**	**(4,842)**	**(5,155)**	**(5,425)**	**(6,021)**	**(21,443)**	**(25,473)**	**(35,479)**	**(16,571)**	**54,297**	**179,155**	**304,995**	**409,095**	**466,283**
Income Tax (benefit)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	2,715	26,873	76,249	143,183	163,199
Net income (GAAP)	**(9,974)**	**(16,213)**	**(3,897)**	**(4,394)**	**(3,986)**	**(5,810)**	**(18,087)**	**(4,842)**	**(5,155)**	**(5,425)**	**(6,021)**	**(21,443)**	**(25,473)**	**(35,479)**	**(16,571)**	**51,582**	**152,282**	**228,746**	**265,912**	**303,084**
EPS - Basic	**$ (3.16)**	**$ (4.84)**	**$ (1.07)**	**$ (1.20)**	**$ (1.09)**	**$ (0.44)**	**$ (2.98)**	**$ (0.23)**	**$ (0.25)**	**$ (0.26)**	**$ (0.29)**	**$ (1.03)**	**$ (0.97)**	**$ (1.34)**	**$ (0.62)**	**$ 1.85**	**$ 5.34**	**$ 7.67**	**$ 8.64**	**$ 9.59**
EPS - Diluted	**$ (3.16)**	**$ (4.84)**	**$ (1.07)**	**$ (1.20)**	**$ (1.09)**	**$ (0.44)**	**$ (2.98)**	**$ (0.23)**	**$ (0.25)**	**$ (0.26)**	**$ (0.29)**	**$ (1.03)**	**$ (0.97)**	**$ (1.34)**	**$ (0.62)**	**$ 1.67**	**$ 4.88**	**$ 7.26**	**$ 8.35**	**$ 9.43**
Weighted-Average Common Shares Outstanding																				
Basic - GAAP	3,160	3,352	3,636	3,647	3,647	13,238	6,065	20,613	20,716	20,820	20,924	20,768	26,133	26,394	26,658	27,917	28,527	29,805	30,765	31,602
Diluted - GAAP	3,160	3,352	3,636	3,647	3,647	13,238	6,065	20,613	20,716	20,820	20,924	20,768	26,133	26,394	26,658	30,895	31,204	31,516	31,831	32,149
Margin Analysis:																				
Cost of product sales	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	18%	20%	20%	18%	16%	15%
Product gross margin	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	82%	80%	80%	82%	84%	85%
R&D (GAAP)	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	64%	20%	10%	8%	7%	6%
SG&A (GAAP)	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	77%	26%	14%	11%	10%	10%
Operating margin	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	41%	64%	74%	81%	82%
Income tax provision	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	nm	nm	nm	nm	5%	15%	25%	35%	35%
Net margin	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	39%	55%	56%	52%	54%
Y/Y change:																				
HA Pancreas revenue	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	250%	112%	47%	24%	11%
Total revenue	nm	122.6%	nm	nm	nm	nm	-10.0%	-22%	-16%	0%	36%	-5.9%	-6.9%	nm	nm	226.8%	114.7%	50.0%	26.1%	11.9%
COGS	nm	122.6%	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	289%	112%	32%	10%	5%
R&D	nm	67%	nm	nm	nm	nm	13%	20%	7%	27%	12%	16%	15%	13%	12%	10%	9%	9%	7%	7%
SG&A	nm	64%	nm	nm	nm	nm	-7%	11%	36%	50%	-7%	17%	21%	90%	88%	17%	15%	13%	11%	10%
Operating income	nm	61%	nm	nm	nm	nm	8%	24%	17%	36%	4%	18%	19%	39%	-53%	-428%	230%	70%	34%	14%
Net income	nm	63%	nm	nm	nm	nm	12%	24%	17%	36%	4%	19%	19%	39%	-53%	-411%	195%	50%	16%	14%
EPS	nm	53%	nm	nm	nm	nm	-38%	-78%	-79%	-76%	-34%	-65%	-6%	38%	-54%	-397%	189%	44%	13%	11%
Shares outstanding	nm	6%	nm	nm	nm	nm	81%	467%	468%	471%	58%	242%	26%	1%	1%	16%	1%	1%	1%	1%

Source: Canaccord Genuity estimates

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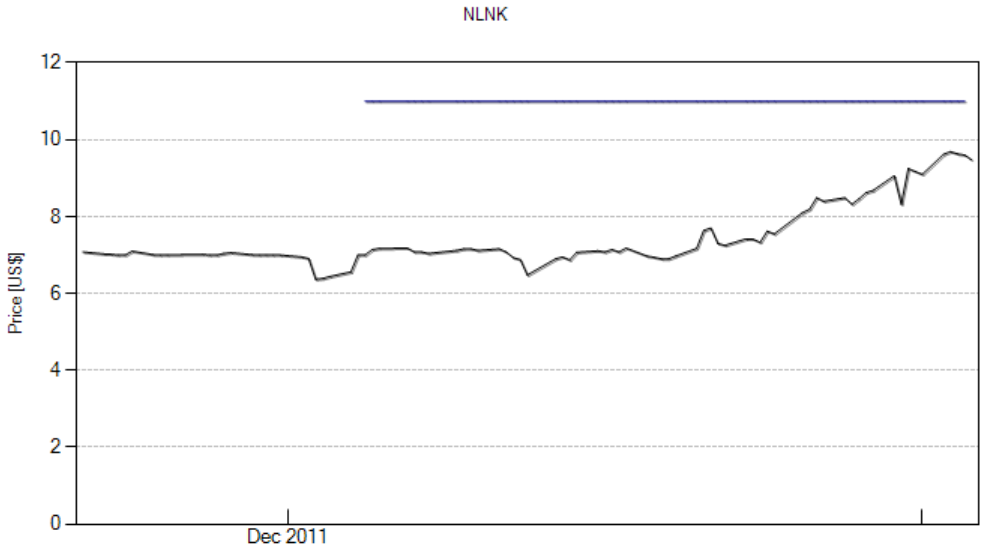
Price Chart:*



	Date	Analyst	Rating	Target Price	Date	Analyst	Rating	Target Price
1)	12/21/2011	Farmer	Buy	11.00	2) 03/16/2012		Suspended	

*Price charts assume event 1 indicates initiation of coverage or the beginning of the measurement period.

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Global Stock Ratings
(as of 2 April 2012)

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Sell	22	2.6%	9.1%
	848	100%	

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Company	Disclosure
NewLink Genetics	1A, 2, 3, 5, 7

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