

### **NewLink Genetics**

NLNK: NASDAQ: US\$13.59

**BUY** 

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**Target: US\$23.00** 

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#### **COMPANY STATISTICS:**

52-week Range:	6.25 - 18.00
Market Cap (M):	US\$289
Avg. Daily Vol. (000s):	84
Shares Out (M):	20.901

#### **EARNINGS SUMMARY:**

	COMMI			
FYE Dec		2011A	2012E	2013E
EPS:		(2.98)	(1.15)	(1.04)
Revenue:	Q1	0.6	0.5A	-
	Q2	0.5	0.6A	-
	Q3	0.4	0.3A	-
	Q4	0.3	0.3	-
Total		1.9	1.7	1.3
EPS:	Q1	(1.07)	(0.23)A	-
	Q2	(1.20)	(0.31)A	-
	Q3	(1.09)	(0.28)A	-
	Q4	(0.44)	(0.33)	-
Total		(2.98)	(1.15)	(1.04)

#### 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

# IN-LINE Q3; HAP P3 INTERIM LOOK IN Q1+

This morning, NLNK reported Q3 GAAP EPS of \$(0.28), above consensus of \$(0.32) and in line with CGe of \$(0.28). Enrollment in the Phase 3 IMPRESS trial for HyperAcute (HA) Pancreas, a novel immunotherapy for surgically-resected pancreatic cancer, is expected to complete by YE13 with the first interim analysis (next potential catalyst) in early-2013 (Q1/Q2). The pipeline continues to progress with HA platform-based drugs in later-line pancreatic and other cancer types (P3 borderline-resectable or locally advanced unresectable pancreatic cancer, P2b/3 in lung cancer and investigator-initiated P2 stage IIIC/IV melanoma), the IDO pathway inhibitor (NLG8189/D-1MT/indoximod) in P1b/2 for solid tumors and DNDN's Provenge + D-1MT in a P2 investigator-initiated trial in asymptomatic or minimally symptomatic metastatic hormone refractory prostate cancer.

- Q3 EPS in line: NLNK ended Q3 with \$28.3M in cash, equivalents, and certificates of deposit (Q3 burn of \$2.8M). R&D expense, which was slightly higher than expected (\$4.8M vs. CGe of \$4.3M), was attributed to an increase in the clinical trial patient number and related expenses and offset by lower-than-expected SG&A expense (\$1.4M vs. CGe of \$2.0M). Management upwardly revised its FY12 cash balance guidance to \$20M \$23M vs. \$20M previously.
- What will each interim look detect? At the first interim analysis of the IMPRESS trial (when 50% or ~200-220 deaths have occurred), 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; however, we note that there will be no futility analysis. This trial is powered to show a 18-20% improvement vs. 37% in Phase 2 and assumes ~21 months OS in control arm vs. 17-18 months historically.



Figure 1: Q3/12 variance table

	Sep	Sep	Variance	Variance	Y/Y	Q/Q
	Q12A	3Q12E	A-E	%	%	%
Revenue						
HyperAcute Pancreas (HAP) - U.S. Revenue	-		-	n/a	n/a	n/a
HyperAcute Pancreas (HAP) - E.U. Royalty	-		-	n/a	n/a	n/a
Grant revenue	327	430	(103)	-31%	#DIV/0!	-45%
Collaboration revenue	-	-	- '	n/a	n/a	n/a
Total Revenue	327	430	(103)	-31%	#DIV/0!	-45%
COGS	_	_		n/a	n/a	n/a
Gross Profit	\$ 327	\$ 430	(103)	-31%	#DIV/0!	-45%
Operating Expense						
R&D (GAAP)	4,779	4,250	529	11%	#DIV/0!	1%
SG&A (GAAP)	1,396	1,990	(594)	-43%	#DIV/0!	-35%
Total Operating Expense	6,175	6,240	(65)	-1%	#DIV/0!	-10%
Operating Income (loss)	(5,848)	(5,810)	(38)	1%	#DIV/0!	-7%
Other income (expense)						
Miscellaneous Income	-	-	-	n/a	n/a	#DIV/0
Forgiveness of Debt	-	-	-	n/a	n/a	n/a
Interest Income	3	3	(0)	0%	#DIV/0!	-30%
Interest Expense	(12)	(12)	-	0%	#DIV/0!	0%
Total Other Income (Expense), Net	(3)	(9)	6	-206%	n/a	-63%
Net income (loss) before Income Tax	(5,851)	(5,819)	(32)	1%	#DIV/0!	-7%
Less Net Loss Attributable to Noncontrolling Interest	-	-	-	n/a	n/a	n/a
Net Income (loss) attributable to NLNK before Income Tax	(5,851)	(5,819)	(32)	1%	#DIV/0!	-7%
Income Tax (benefit)	-	-	-	n/a	n/a	n/a
Net income (GAAP)	\$ (5,851)	\$ (5,819)	(32)	1%	#DIV/0!	-7%
EPS - Basic	\$ (0.28)	\$ (0.28)	(0.00)	0%	#DIV/0!	-8%
EPS - Diluted	\$ (0.28)	(0.28)	(0.00)	0%	#DIV/0!	-8%
Weighted-Average Common Shares Outstanding						
Basic - GAAP	20,888	20,788	99	0%	#DIV/0!	1%
Diluted - GAAP	20,888	20,788	99	0%	#DIV/0!	1%

Source: Canaccord Genuity research, Company reports

Figure 2: Upcoming expected milestones

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

Source: Canaccord Genuity research, Company reports

31 October 2012





Figure 3: Changes to model

(\$thousands, except per share data) Prior Prior <u>Ne w</u> Prior Prior Revenue HyperAcute Pancreas (HAP) - U.S. Revenue 37,634 37,634 131.689 131.689 279.037 279.037 410.256 410.256 506.672 506.672 564.912 564.912 HyperAcute Pancreas (HAP) - E.U. Royalty 3.877 3.877 18.351 18.351 38.523 38.523 60.539 60.539 70.348 70.348 1,715 1,901 1,308 1,499 1,308 981 Collaboration revenue 1,389 1,389 5,556 5,556 5,556 5,556 5,556 5,556 5,556 5,556 5,556 5,556 5,556 5,556 Total Revenue 1,715 1.901 1.308 1,499 2.697 1.389 44,171 \$ 43,190 141.122 141,122 \$ 302,943 302.943 454.334 \$ 454.335 572.767 \$ 572,767 640.815 640.816 COGS 6,774 6,774 26,338 55,807 55,807 73,846 73,846 81,068 84,737 84,737 2.697 380,489 Gross Profit 1.715 1.901 1 308 1,499 1.389 37.396 36.415 114,784 114,784 247 136 247.136 380,488 491 699 491,699 556 079 556.079 Operating Expense R&D (GAAP) 23,003 24,176 26,689 29.122 31.677 34.050 36.500 18.699 17.270 21.617 19.050 21.555 24.176 26,689 29.122 31.677 34.050 36.500 SG&A (GAAP) 6,980 7,574 8,400 8,050 15,300 15,300 28,800 28,800 33,800 33,800 38,912 38,912 43,998 43,998 48,923 48,923 53,908 53,908 Total Operating Expense 24,844 27,100 27,100 38,303 36,855 52,976 52,976 60,489 68,034 68,034 75,675 75,675 82,973 82,973 90,408 90,408 25,679 60,489 Operating Income (loss) (23,964) (22,943) (25,792) (25,601) (35,606) (35,466) (15,580) (16,561) 54,295 54,295 179,102 179,102 304,813 304,814 408,726 408,726 465,671 465,671 Other income (expense) (21) (21) Forgiveness of Debt 56 13 13 12 11 10 17 150 150 550 550 Interest Income 33 56 313 314 (44) (44 (40) (36) (36) (32) (32) (28) (28) (24) (24) Interest Expense (40) (5) (46) (52) (24) (24) (25)(22) (22) (10) (11) 32 145 145 313 314 550 550 Total Other Income (Expense), Net Net income (loss) before Income Tax (24,010) (22,995) (25,799) (25,625) (35,630) (35,491) (15,601) (16,583) 54,285 54,284 179,134 179,133 304,958 304,958 409,039 409,040 466,221 466,221 Less Net Loss Attributable to Noncontrolling Interest Net Income (loss) attributable to NLNK before Income Tax (24,010) (22,995) (25,799) (25,625 (35,630) (35,491 (15,601) (16,583 54,285 54,284 179,134 179,133 304,958 304,958 409,039 409,040 466,221 466,221 Income Tax (benefit) 2,714 26,870 26,870 76,240 76,240 143,164 143,164 163,177 163,177 Net income (GAAP) (24,010) (22,995 (25,625) (16,583) 51,571 152,264 152,263 303,043 (25,799) (35,630) (35,491) (15,601) 51,570 228,719 228,719 265,876 265,876 303,043 EPS - Basic (1.15 (1.11 (0.98 (1.33) (1.35 (0.62) 1.82 1.85 5.27 5.34 7.58 7.68 8.65 9.48 9.60 EPS - Diluted (1.04) (0.98)(1.33)(1.35) (0.58)(0.62) 1.65 1.67 4.83 4.88 7.18 7.26 8.26 8.36 9.44 (1.15)(1.11 Weighted-Average Common Shares Outstanding Basic - GAAP 20,794 20,745 25,025 26,101 26,730 26,362 26,997 26,626 28,260 27,885 28,873 28,494 30,154 29,772 31,118 30,731 31,958 31,568 26,362 31,237 31,550 31,171 31,482 32,184 32,506 32,115 Diluted - GAAP 26.101 30.862 31.865 31.797

Source: Canaccord Genuity research, Company reports



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#### Figure 4: NLNK income statement

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

109A -	2010A	2011A	1Q12A	2Q12A				1Q13E	2Q13E	3Q13E	4Q13E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
-			1	ZQIZA	3Q12A	4Q12E	2012E	1Q13E	2Q13E	3Q13E	4Q13E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
			_		_							,		37,634	131.689	279,037	410.256	506.672	564.912
	-	-	1		1		-	-		-		-	-		. ,		.,		
-	- 0.070	4.070	1				4 745					4 000	4 000				38,523	60,539	70,348
934	2,079	1,872	4/1		327	327	1,715	321		327	321	1,308	· · · · · · · · · · · · · · · ·						
-	-	-	-		-	-	-	-		-	-	-	,				-1	-7	5,556
934	\$ 2,079	\$ 1,872	\$ 471	\$ 590	\$ 327	\$ 327	\$ 1,715	\$ 327	\$ 327	\$ 327	\$ 327	\$ 1,308	\$ 2,697	\$ 44,171	\$ 141,122	\$ 302,943	\$ 454,334	\$ 572,767	\$ 640,815
-	-	-	-	-	-	_	-	-	-	-	-	-	-	6,774	26,338	55,807	73,846	81,068	84,737
934	2,079	1,872	471	590	327	327	1,715	327	327	327	327	1,308	2,697	37,396	114,784	247,136	380,488	491,699	556,079
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3,705	-,-	-,	,	, .	,	,	6,980		,	,		.,		.,	,		-,		53,908
11,283	18,740	19,934	5,288	6,891	6,175	7,325	25,679	6,575	6,675	6,800	7,050	27,100	38,303	52,976	60,489	68,034	75,675	82,973	90,408
10,349)	(16,661)	(18,062)	(4,817)	(6,301)	(5,848)	(6,998)	(23,964)	(6,248)	(6,348)	(6,473)	(6,723)	(25,792)	(35,606)	(15,580)	54,295	179,102	304,813	408,726	465,671
142	99	(26)	(25)	(8)	(3)	(10)	(46)	(8)	(4)	6	(0)	(7)	(24)	(22)	(10)	32	145	313	550
10,207)	(16.562)	(18.088)	(4.842)	(6.309)	(5.851)	(7.008)	(24.010)	(6,256)	(6.352)	(6.467)	(6.723)	(25,799)	(35.630)	(15,601)	54,285	179,134	304,958	409.039	466,221
233	349	1	-					- 1		- 1			`						
(9,974)	(16,213)	(18,087)	(4,842)	(6,309)	(5,851)	(7,008)	(24,010)	(6,256)	(6,352)	(6,467)	(6,723)	(25,799)	(35,630)	(15,601)	54,285	179,134	304,958	409,039	466,221
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	2,714	26,870	76,240	143,164	163,177
(9,974)	(16,213)	(18,087)	(4,842)	(6,309)	(5,851)	(7,008)	(24,010)	(6,256)	(6,352)	(6,467)	(6,723)	(25,799)	(35,630)	(15,601)	51,571	152,264	228,719	265,876	303,043
(3.16)	\$ (4.84)	\$ (2.98)	\$ (0.23)	\$ (0.31)	\$ (0.28)	\$ (0.33)	\$ (1.15)	\$ (0.30)	\$ (0.24)	\$ (0.25)	\$ (0.25)	\$ (1.04)	\$ (1.33)	\$ (0.58)	\$ 1.82	\$ 5.27	\$ 7.58	\$ 8.54	\$ 9.48
(3.16)	\$ (4.84)	\$ (2.98)	\$ (0.23)	\$ (0.31)	\$ (0.28)	\$ (0.33)	\$ (1.15)	\$ (0.30)	\$ (0.24)	\$ (0.25)	\$ (0.25)	\$ (1.04)	\$ (1.33)	\$ (0.58)	\$ 1.65	\$ 4.83	\$ 7.18	\$ 8.26	\$ 9.32
3,160	3,352	6,065	20,613	20,685	20,888	20,992	20,794	21,097	26,203	26,334	26,465	25,025	26,730	26,997	28,260	28,873	30,154	31,118	31,958
3,160	3,352	6,065	20,613	20,685	20,888	20,992	20,794	21,097	26,203	26,334	26,465	25,025	26,730	26,997	31,237	31,550	31,865	32,184	32,506
11 (1)	7,578 3,705 1,283 0,349) 142 0,207) 233 9,974) - 9,974) (3.16) (3.16)	934 \$ 2,079  934 2,079  934 2,079  12,666 3,705 6,074 1,283 18,740 0,349) (16,661)  142 99 142,233 349 9,974) (16,213) (3,16) \$ (4,84) (3,16) \$ (4,84) 3,160 3,352	934 \$ 2,079 \$ 1,872	934 \$ 2,079 \$ 1,872 \$ 471	934	934	934	934	934	934	934	934	934	934	934	934	934	934	934 2,079 1,872 471 590 327 327 1,715 327 327 327 327 1,308 1,308 981 5.56 5.566 5.5

Source: Canaccord Genuity research, Company reports



#### **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 \$4.83, 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.



#### **APPENDIX: IMPORTANT DISCLOSURES**

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Site Visit:

An analyst has visited the issuer's material operations in Ames, Iowa. No payment or reimbursement was received from the issuer for the related travel costs.

#### Price Chart:\*



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

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Coverage Universe						
			IB Clients			
Rating	#	%	%			
Buy	575	60.7%	31.5%			
Speculative Buy	63	6.7%	50.8%			
Hold	267	28.2%	13.9%			
Sell	34	3.6%	5.9%			
	947*	100.0%				

<sup>\*</sup>Total includes stocks that are Under Review

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

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