

## **NewLink Genetics**

NLNK: NASDAQ: US\$7.00

**BUY** 

**Target: US\$11.00** 

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#### **COMPANY STATISTICS:**

52-week Range:	6.25 - 7.26
Market Cap (M):	US\$144.1
Avg. Daily Vol. (000s):	178.0
Shares Out:	20.6

**CANACCORD** Genuity

#### **FARNINGS SUMMARY:**

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FYE Dec		2010A	2011E	2012E		
Revenue (M):		2.1	2.0	2.0		
EPS:		(2.24)	(2.46)	(0.98)		
Revenue (M):	Q1	-	-	-		
	Q2	-	-	-		
	Q3	0.4	0.4A	-		
	Q4	-	0.4	-		
Total		2.1	2.0	2.0		
EPS:	Q1	_	_	_		
	Q2	_	_	_		
	Q3	(1.49)	(1.09)A	_		
	Q4	-	(0.31)	_		
Total	•	(2.24)	(2.46)	(0.98)		

#### **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

# NOVEL CANCER VACCINE PLATFORM SHOWS PROMISE; INITIATING COVERAGE WITH A BUY RATING

**Recommendation.** We initiate coverage of NLNK with a BUY rating and \$11 target, seeing an attractive risk/reward associated with potential success of the company's Phase III trial evaluating HyperAcute Pancreas as add-on to adjuvant pancreatic cancer standard-of-care.

### Investment highlights

- In our view, 70-patient Phase II data evaluating HyperAcute Pancreas (HAP) combined with standard-of-care for post-surgery adjuvant treatment of resectable pancreatic cancer compares favorably with historical controls. For example, this trial is tracking with a projected median survival of 24.4 months vs. ~ 20 months seen in studies employing standard-of-care alone. Importantly, NLNK's Phase II enrolled patients with a much poorer prognosis. We see high potential for success of the ongoing Phase III registration trial as the dosing protocol could yield an additional efficacy margin over Phase II results. Further insight should come from mature Phase II two-year survival data expected in mid-2012 and a possible interim Phase III analysis in late 2012.
- We anticipate brisk commercial HAP uptake if approval is granted, considering 1) its highly attractive tolerability profile, 2) the high unmet medical need it would serve, and 3) off-the-shelf allogeneic vaccine technology (on which HAP is derived) that is free of complicated delivery logistics. We model for \$650M peak US sales in 2018.
- We look for additional clinical data before modeling for potential of the HyperAcute platform in other indications such as non-small cell lung cancer and melanoma. IDO pathway inhibitor D-1MT provides another intriguing opportunity for long-term upside.

**Valuation and risks.** Our \$11 price target is based on a risk-adjusted DCF assuming exit by acquisition, 20% likelihood of HyperAcute Pancreas Phase III success. Risks include clinical trial failures and changes in competitive landscapes.

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## Figure 1: NLNK investment synopsis

#### Key investment driver(s):

 Potential success of the Phase III trial of HyperAcute Pancreas for post-surgery adjuvant treatment of resected pancreatic cancer

#### **Investment themes.** We rate shares a BUY based on:

- Promising Phase II overall survival data that compares favorably with historical controls.
- Excellent tolerability observed to date for HyperAcute Pancreas.
- Upside potential for the HyperAcute technology platform in other cancer indications.

#### CG differentiation from the Street:

Criticism lobbed collectively against immunotherapeutic approaches to cancer treatment may
miss key differentiating attributes of the HyperAcute platform.

**Critical financial metrics.** Estimated 2011-end cash of \$38M, which we view as sufficient into H2/13.

## Risks to BUY thesis:

- Failure of the HyperAcute Pancreas Phase III trial.
- Inability to obtain FDA regulatory approval for HyperAcute Pancreas.
- Changes in competitive landscapes.

Source: Canaccord Genuity

## **INVESTMENT SUMMARY**

We launch coverage of NewLink Genetics with a BUY rating and \$11 price target. Lead asset HyperAcute Pancreas (HAP), an allogeneic cell-based immunotherapeutic, moves through Phase III development as add-on to adjuvant standard-of-care treatment of surgically resected pancreatic cancer. Informed by data supporting the unique HAP mechanism of action and by maturing Phase II data, we see a reasonably high likelihood of Phase III success and subsequently broad use in this niche treatment setting. We believe outcome of an interim analysis could come in H2/12, with final data expected 2014.

Of the 70 Stage I and II surgically resected pancreatic cancer patients treated with two different HAP doses plus standard-of-care chemotherapy/radiation in the Phase II proof-of-concept trial, 86% were alive after one-year. More impressively, in the subgroup treated with the higher of two doses, only one patient had died within one year of surgery. When compared to the most relevant randomized Phase III trial evaluating adjuvant pancreatic cancer therapy outcomes (RTOG-9704), 31% of patients had died within one-year. Management estimates a median survival of 24.4 months in the intent-to-treat, which also compares favorably to the 18.8-month median survival in RTOG-9704. Importantly,



standard diagnostic criteria indicated that 25% of patients in NLNK's Phase II trial had a worse prognosis than those in RTOG-9704, lending further support to HAP clinical activity.

NLNK's HyperAcute technology platform is applicable to practically all solid tumor treatment settings. All of NLNK's other vaccines in development, including HAP, are derived from the same genetic manipulation protocol applied to different tumor-specific cell line collections. End products are easily scalable and delivered to practitioners without complicated logistics. Other vaccines awaiting further development include HyperAcute Melanoma and Lung for treatment of metastatic melanoma and non-small cell lung cancer, respectively. NLNK is also developing a novel small molecule IDO enzyme inhibitor designed to enhance tumor vulnerability to immune system attack.

Following an initial public offering last month, we see shares trading at an attractive valuation relative to our \$11 price target based on a DCF assuming exit by acquisition and sales potential from HAP only. This target assumes only a 20% chance of HAP success, which we think is greater given prevailing data, and peak sales of \$650M in 2018. We expect that revived investor interest in cancer immunotherapy following successful clinical outcomes with high-profile, FDA-approved products Provenge (Dendreon) and Yervoy (Bristol Myers Squibb) will lift NLNK shares as clinical progress continues.

Figure 2: NewLink Genetics	pipeline		
Product	Partner	Indication	Status
HyperAcute Pancreas	None	Adjuvant pancreatic cancer	Phase III
HyperAcute Lung	None	Non-small cell lung cancer	Phase II
HyperAcute Melanoma	None	Advanced melanoma	Phase II
D-1MT (IDO inhibitor)	None	Solid tumors	Phase Ib

Source: Company data

Event	Expected timing
HyperAcute Pancreas Phase II 2-yr survival data	mid 2012
HyperAcute Pancreas Phase III 1st interim analysis	late 2012
HyperAcute Lung Phase IIb trial start	H1/12
HyperAcute Melanoma Phase IIb trial start	2012

Source: Company data and Canaccord Genuity



## **FINANCIALS**

#### Revenues

We model for US market launch of HyperAcute Pancreas in 2015, estimating sales in 2015, 2016, and 2017 of \$56M, \$341M, and \$524M, respectively.

#### **Operating expenses**

We model for \$56M in R&D spend over the next three years, which could increase depending on progress of pipeline candidates.

### **Earnings**

We model for full-year profitability in 2015, estimating EPS in 2015, 2016, and 2017 of \$0.46, \$5.54, and \$8.43, respectively.

#### **Balance sheet**

NLNK raised net proceeds of \$37.5M in its initial public offering, which contribute to an estimated 2011-end balance of about \$38M in cash. NLNK had \$7.2M in notes payable and lease obligations as of September 30, 2011. Based on our burn projections, we estimate sufficient cash into H2/13.

## **VALUATION**

We arrive at our \$11 price target via a DCF model based on what we believe a potential acquirer might pay for NewLink Genetics' outstanding shares. Cash flows are risk-adjusted based on assumptions including:

- 20% chance of HyperAcute Pancreas marketing approval.
- HyperAcute Pancreas launch in 2015 for treatment of resected pancreatic cancer.
- Sales of HyperAcute Pancreas only. Sales of HyperAcute Lung, HyperAcute Melanoma, and D-1MT are not reflected in our model at this time.
- A potential acquirer would dissolve all company R&D efforts after integration.
- An impossibly high barrier to entry for any biosimilar vaccine.



Figure 4	4: N	NLNK	DCF	valuation
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	2012E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
HyperAcute Pancreas sales	0.0	0.0	0.0	55.6	341.3	523.8	655.0	670.2	685.7	701.5	717.8
TOTAL product sales	-	-	-	55.6	341.3	523.8	655.0	670.2	685.7	701.5	717.8
Gross margin				86%	86%	86%	86%	86%	86%	86%	86%
SG&A (% of sales)				45%	38%	35%	35%	35%	35%	35%	35%
total SG&A				(25.0)	(129.7)	(183.3)	(229.3)	(234.6)	(240.0)	(245.5)	(251.2)
Commercial profit		-	-	22.8	163.8	267.1	334.1	341.8	349.7	357.8	366.1
R&D	(16.1)	(18.5)	(21.3)	(24.5)	(28.2)						
Operating profit	(16.1)	(18.5)	(21.3)	(1.7)	135.7	267.1	334.1	341.8	349.7	357.8	366.1
Tax rate	0%	0%	0%	38%	38%	38%	38%	38%	38%	38%	38%
Post-tax net income	(16.1)	(18.5)	(21.3)	(1.0)	84.1	165.6	207.1	211.9	216.8	221.8	227.0
success rate adjustment	100%	100%	100%	100%	20%	20%	20%	20%	20%	20%	20%
NPV adjusted cash flows	(16.1)	(16.5)	(17.0)	(0.7)	10.7	18.8	21.0	19.2	17.5	16.0	14.6

Sum NPV (\$M) 67.4
PV of Terminal Value 149.1
Shares outstanding 20.6
NPV/share \$10.52

Source: Canaccord Genuity estimates





Figure 5: NLNK annual income statement (\$M except EPS)

	2010A	2011E	2012E	2013E	2014E	2015E	2016E	2017E
Revenues								
HyperAcute Pancreas	0.0	0.0	0.0	0.0	0.0	55.6	341.3	523.8
Total Product Revenue	0.0	0.0	0.0	0.0	0.0	55.6	341.3	523.8
Grant revenue	2.1	2.0	2.0	2.0	2.0	2.0	2.0	2.0
Other revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total Revenue	2.1	2.0	2.0	2.0	2.0	57.6	343.3	525.8
Operating Expenses								
Cost of goods sold	0.0	0.0	0.0	0.0	0.0	7.8	47.8	73.3
as % of product sales						14%	14%	14%
Research & development	(13.2)	(14.0)	(16.1)	(18.5)	(21.3)	(24.5)	(28.2)	(32.4)
General & administrative	(5.0)	(5.4)	(6.2)	(7.1)	(10.0)	(21.1)	(119.5)	(183.3)
as % product sales						38%	35%	35%
Total Operating Expenses	(18.3)	(19.4)	(22.3)	(25.6)	(31.2)	(37.8)	(99.8)	(142.4)
Operating Income	(16.2)	(17.4)	(20.3)	(23.6)	(29.2)	19.8	243.5	383.4
Interest income	0.1	0.0	0.1	0.0	0.0	0.0	0.0	0.0
Interest expense	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	0.0
Other	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pre-tax income (loss)	(16.1)	(17.4)	(20.3)	(23.6)	(29.3)	19.7	243.4	383.4
Income tax	0.0	0.0	0.0	0.0	0.0	6.9	85.2	134.2
Tax rate	0.0	0.0	0.0	0.0	0.0	0.4	0.4	0.4
Consolidated net income	(16.1)	(17.4)	(20.3)	(23.6)	(29.3)	12.8	158.2	249.2
Net income, non-controlling interest	0.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net income to NewLink	(15.7)	(17.4)	(20.3)	(23.6)	(29.3)	12.8	158.2	249.2
EPS (basic)	(\$2.24)	(\$2.46)	(\$0.98)	(\$1.10)	(\$1.30)	\$0.54	\$6.44	\$9.74
EPS (diluted)	(\$2.24)	(\$2.46)	(\$0.98)	(\$1.10)	(\$1.30)	\$0.46	\$5.54	\$8.43
Basic Shares (M)	7.0	7.1	20.6	21.6	22.6	23.6	24.6	25.6
Diluted Shares (M)	7.0	7.1	20.6	21.6	22.6	27.6	28.6	29.6

Source: Company data and Canaccord Genuity estimates

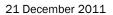




Figure 6: NLNK quarterly income statement (\$M except EPS)

	Mar-10	Jun-10	Sep-10	Dec-10	2010A	Mar-11	Jun-11	Sep-11	Dec-11	2011E
	1Q10A	2Q10A	3Q10A	4Q10A	Annual	1Q11A	2Q11A	3Q11A	4Q11E	Annua
Revenues										
Grant revenue	NA	NA	0.4	NA	2.1	NA	NA	0.4	0.4	2.0
Total Revenue	NA	NA	0.4	NA	2.1	NA	NA	0.4	0.4	2.0
Operating Expenses										
Research & development	NA	NA	(3.9)	NA	(13.2)	NA	NA	(3.3)	(3.7)	(14.0)
General & administrative	NA	NA	(1.5)	NA	(5.0)	NA	NA	(1.1)	(1.8)	(5.4)
Other	NA	NA	-	NA	-	NA	NA	-	-	-
Total Operating Expenses	NA	NA	(5.5)	NA	(18.3)	NA	NA	(4.4)	(5.5)	(19.4)
Operating Income (loss)	NA	NA	(5.1)	NA	(16.2)	NA	NA	(4.0)	(5.1)	(17.4)
Interest income	NA	NA	(0.0)	NA	0.1	NA	NA	0.0	0.0	0.0
Interest expense	NA	NA	(0.0)	NA	(0.0)	NA	NA	(0.0)	(0.0)	(0.0)
Other income (expense)	NA	NA	0.1	NA	0.1	NA	NA	-	(0.0)	-
Consolidated net income	NA	NA	(5.1)	NA	(16.1)	NA	NA	(4.0)	(5.1)	(17.4)
Loss attributable to non-controlling interest	NA	NA	0.0	NA	0.3	NA	NA	-	(0.0)	-
Pre-tax income (loss)	NA	NA	(5.0)	NA	(15.7)	NA	NA	(4.0)	(5.1)	(17.4)
Net income to NewLink	NA	NA	(5.0)	NA	(15.7)	NA	NA	(4.0)	(5.1)	(17.4
EPS	NA	NA	(\$1.49)	NA	(\$2.24)	NA	NA	(\$1.09)	(\$0.29)	(\$2.46
Basic and diluted shares outstanding	NA	NA	3.4	NA	7.0	NA	NA	3.7	17.4	7.1

NA: not available

Source: Company data and Canaccord Genuity estimates



## **Investment risks**

Risks to our BUY thesis on NLNK include:

- 1. Failure of clinical trials
- 2. Regulatory challenges
- 3. Changes in competitive treatment landscapes



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	Coverage Universe		
			IB Clients
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Speculative Buy	88	11.1%	68.2%
Hold	203	25.6%	19.7%
Sell	14	1.8%	14.3%
	794	100%	

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