

4 June 2012

**NewLink Genetics** 

NLNK: NASDAQ: US\$12.20

**Buy | US\$23.00 Target** 

Salveen Richter, CFA

212.389.8052

srichter@canaccordgenuity.com

### NLNK PRESENTS POSITIVE P2 LONG-TERM HAP DATA

NLNK presented a slew of data at ASCO, including 2- and 3-year OS data from its P2 HyperAcute Pancreas (algenpantucel-L or HAP), P1B/2 HyperAcute Lung (tergenpumatucel-L) and P1/1B NLG8189 (D-1MT or 1-methyl-D-tryptophan) trials, as well as investigator-sponsored data from a P2 HyperAcute Melanoma trial. The HAP P2 2- and 3-year OS data is encouraging as we look to the P3 HAP study, with first interim analysis of P3 HAP data, expected in late-2012/early-2013.

- HAP 2- and 3-yr OS data stands out: The key new data from a poster on the P2 HAP trial (N=69, single-arm HAP + Gemzar + 5-FU/rad) presented today were 2- and 3-yr OS: 51% (32% expected) and 42% (19% expected), respectively (the 3-yr OS number is based on a Kaplan-Meier estimate). This 42% 3-yr OS figure compares to 3-yr OS numbers of 30% and 31% from the P3 trials ESPAC-1 (Gemzar) and RTOG (Gemzar + 5-FU/rad), respectively. While that they have not calculated 2- and 3-year OS for the high-dose (300 million cells) subset, we would expect these numbers to be higher, as seen at 1-yr. We note that while it is difficult to extrapolate from a single-arm P2 trial to P3, we are encouraged by this data.
- Additional pipeline data: NLNK also presented data from its other pipeline products. HyperAcute Melanoma (P2 advanced melanoma, N=25, single-arm, investigator initiated) showed a complete response in two patients. HyperAcute Lung (P1B/2 NSCLC, N=17 P1 and N=37 P2, single-arm) efficacy (OS) demonstrated a significant (p=0.044) correlation with interferon-gamma levels (in those patients who had interferon-gamma levels measured). NLG8189 (P1/1B, N=48) in solid tumors demonstrated some putative chemosensitization (response was observed in patients with extensive pre-treatment). The pipeline outside of HAP represents potential upside.



#### **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.



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

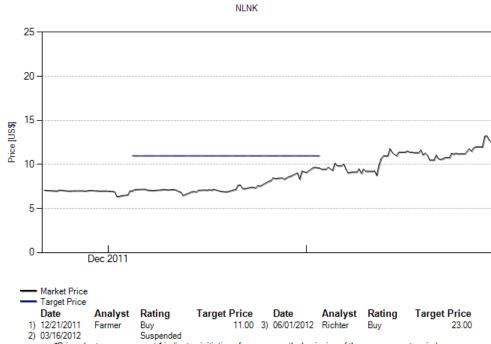
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Site Visit:

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
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	848	100%	

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

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