CANACCORD Genuity

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BUY

NLNK : NASDAQ : US$7.00

TARGET PRICE: US$11.00

Inside

Life Sciences -- Biotechnology

NewLink Genetics

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 and 20% likelihood of HyperAcute Pancreas Phase III success. Risks include clinical trial failures and changes in competitive landscapes.

Company statistics

52-week Range:	6.25 - 7.26
Market Cap (M):	US$144.1
Avg. Daily Vol. (000s):	174.6
Shares Out:	20.6

Price chart

Earnings summary

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	-	(0.29)	-
Total		(2.24)	(2.46)	(0.98)

Company description

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

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

Figure 3: NewLink Genetics expected upcoming events

Event	Expected timing
HyperAcute Pancreas Phase II two-year 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

PLATFORM TECHNOLOGY

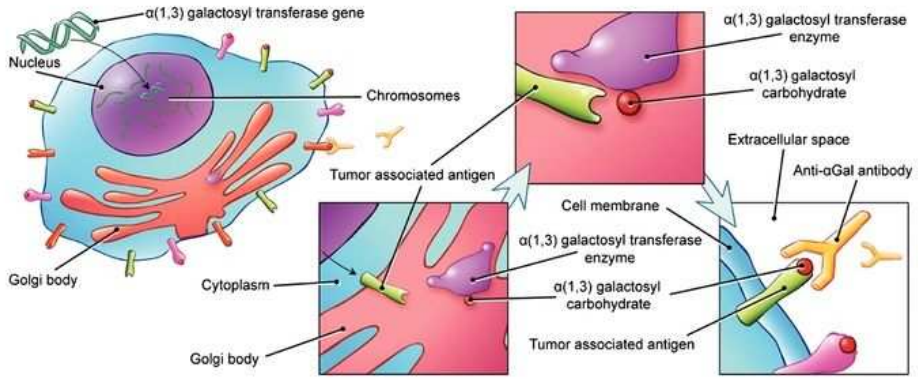
NLNK's HyperAcute technology platform employs an immunotherapeutic strategy designed to mount a broad immune attack against tumor cells while sparing patients of toxicities associated with conventional cancer therapeutics. Immunotherapeutic approaches to cancer treatment have gained significant traction in recent years, highlighted by regulatory approvals for sipuleucel-T (Provenge; Dendreon) in metastatic castration resistant prostate cancer and ipilumumab (Yervoy; Bristol-Myers Squibb) for metastatic melanoma.

Treatment with HyperAcute product candidates involves a series of shallow, intradermal injections with off-the-shelf whole-cell preparations of genetically-manipulated allogeneic cancer cell cultures corresponding to the cancer types being treated. For instance, HyperAcute Pancreas is derived from a collection of human pancreatic tumor cell lines, while HyperAcute Lung is derived from human lung tumor cell lines. As an important distinction from Provenge and other cancer vaccine approaches in development, HyperAcute administration does not require ex vivo (outside of the body) manipulation of autologous blood or cancer cells that involves manufacturing and administrative complexities.

The immunostimulatory properties of HyperAcute therapies are conferred by genetic engineering of the product cells to express an enzyme that deposits alpha (1,3) galactosyl (alpha-gal) sugars upon the cells' surface. The human immune system recognizes alpha-gal sugars as foreign, since these sugars are not naturally produced by humans. NewLink

posits that acute immune recognition of the alpha-gal sugars initiates a multi-faceted immune response to multiple tumor antigens expressed in the cell lines. This leads to destruction of a patient's own tumor cells allegedly expressing a shared variety of tumor-specific targets.

Figure 4: HyperAcute cancer immunotherapy platform



Source: NewLink Genetics S-1

HyperAcute differentiation

Several potentially beneficial attributes differentiate NewLink's technology from other immunotherapeutic platforms:

1. **Allogeneic or "off-the shelf" therapy.** HyperAcute cells are produced from cultured tumor cell lines rather than from harvested cells of individual patients. This enables a centralized manufacturing and shipping process free of complicated back-and-forth delivery logistics required of autologous products, like Provenge.
2. **Recruitment of pre-existing endogenous antibody supply:** The human immune response against alpha-gal is powerful and rapid, as anti-alpha-gal antibodies are already abundant in most humans.
3. **Multi-faceted immune response.** HyperAcute is designed to trigger both antibody- and cell-mediated immune responses, and the use of multiple tumor cell lines within each HyperAcute product promotes broad anti-tumor activity.
4. **Applicability to a variety of tumor types.** The HyperAcute platform can in principle be applied to multiple cancer types through identical manipulation of different tumor-specific cell lines.

HYPERACUTE PANCREAS

About 44,000 patients are diagnosed with pancreatic cancer in the US each year. Prognosis is poor, with a five-year overall survival rate of about 5%. Upon diagnosis, treatment strategies are dictated by whether the disease can be surgically removed, as successful tumor resection can significantly improve prognosis. Nevertheless, of the approximately 20% of pancreatic cancer patients diagnosed with resectable disease, the five-year survival rate is only about 20%.

Surgery alone is most always insufficient, in part because pancreatic cancer typically spreads early in the course of disease, and because residual tumor cells frequently remain despite best efforts. In attempts to eradicate residual disease and enhance disease-free survival, systemic adjuvant therapy is almost always indicated.

National Comprehensive Cancer Network (NCCN) guidelines list the following options for post-resection adjuvant treatment of pancreatic cancer:

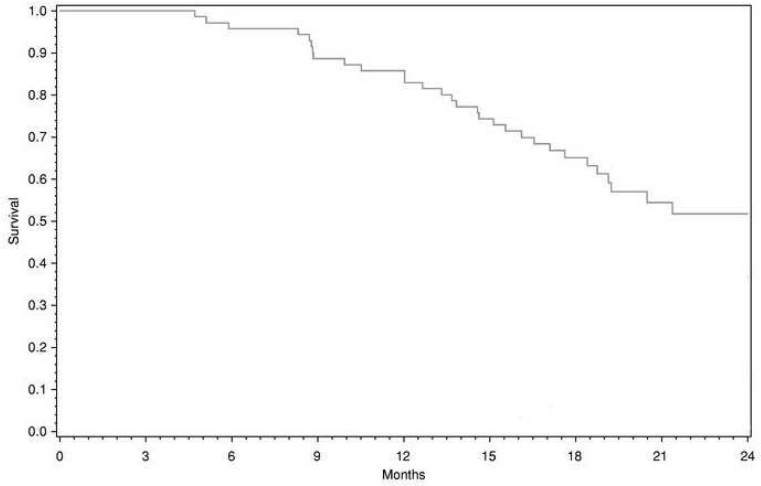
1. clinical trial (preferred), or
2. gemcitabine chemotherapy followed by 5FU-based chemoradiation, or
3. chemotherapy alone: gemcitabine (preferred) or 5FU/leucovorin or capecitabine.

HyperAcute Pancreas (HAP, algenpantucel-L) applies NewLink's platform technology to the treatment of pancreatic cancer, aiming initially for use in the post-surgery adjuvant treatment setting. Per the ongoing Phase III protocol, HAP doses consist of 300 million cells – 150 million cells each of two different allogeneic pancreatic cancer cell lines engineered to express alpha-gal. A course of therapy consists of 18 doses, administered once every two weeks for six months, then once per month for six months, and given in combination with a standard-of-care adjuvant regimen.

Comparing the most recent clinical data for HAP from NewLink's Phase II NLG-0205 trial to data from major clinical trials employing current standards of care informs our view of high potential for HAP benefit over existing treatments. NLG-0205 is an ongoing single-arm, open-label, multicenter Phase II trial designed to provide early evaluation of HyperAcute Pancreas and which enrolled 73 patients with Stage I/II post-resection pancreatic cancer. Patients received 12 HAP doses, approximately twice monthly for six months in addition to standard-of-care gemcitabine chemotherapy plus 5FU-based chemoradiotherapy. Of 70 evaluable patients, 44 received a low HAP dose of 100 million cells, and 26 received a high dose of 300 million cells.

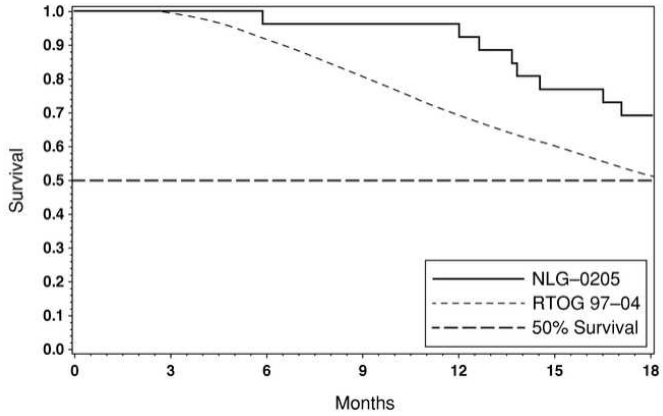
Phase II results from NLG-0205 project an intent-to-treat median overall survival (OS) of 24.4 months (Figure 5). While median OS data for the 300 million cell high dose cohort continues to mature (Figure 6), a statistically significant difference between the high and low dose cohorts has already been observed (p=0.02). The one-year survival difference approaches statistical significance (96% vs. 80%, p=0.053 as of October 2011).

Figure 5: HAP Phase II overall survival data, intent-to-treat population



Includes 100M and 300M cell dose cohorts; n=70
Source: NLNK S-1

Figure 6: Maturing HAP Phase II overall survival data, 300M cell dose cohort



Solid line: 300M cell dose cohort of HyperAcute Pancreas Phase II trial; n=26
Upper dotted line: analysis from RTOG-9704 trial evaluating standard-of-care in adjuvant pancreatic cancer
Source: NewLink Genetics S-1

Figure 7: HAP Phase II data summary

	Intent to treat n=70	Low dose cohort 100M cells/dose n=44	High dose cohort 300M cells/dose n=26
Disease-free survival			
median	14.3 months	12.9 months	15.3 months projected
stats		*p = 0.02*	
1 year DFS rate	not reported	52%	81%
Overall survival			
median	24.4 months projected	Maturing	Maturing
1 year OS rate	86%	80%	96%
stats		*p = 0.053 as of October 2011*	
2 year OS rate	Maturing	Maturing	Maturing

Source: Company filings, company projections

Comparisons to historical clinical trial experience: RTOG-9704 and ESPAC-3

As indications of expected outcomes from existing standard therapies, we point to results from two widely-cited Phase III clinical trials in adjuvant pancreatic cancer, RTOG-9704 and ESPAC-3.

In RTOG-9704, 221 patients in the US and Canada were administered gemcitabine plus 5FU-based chemoradiotherapy, the same combination used as background in NewLink's Phase II and Phase III trials. In these patients, median overall survival was 18.8 months.

In ESPAC-3, 531 adjuvant pancreatic cancer patients in Europe, Australasia, Japan, and Canada were administered gemcitabine alone, consistent with a European treatment paradigm that excludes chemoradiation from standard adjuvant regimens. Results showed a median overall survival of 23.6 months in these patients.

Selected data from the RTOG-9704 and ESPAC-3 trials and from NLG-0205 is summarized in Figure 8. Importantly, we draw attention to cross-trial comparisons showing NLG-0205 with the highest proportion of patients displaying key prognostic risk factors including local invasion (T3/T4), lymph node involvement (N1+), high grade tumors (G3/G4 classification), and elevated CA19-9 biomarker levels. Even within the context of a higher-risk patient population in NLG-0205, median overall survival for patients receiving HyperAcute Pancreas was numerically better than that seen for standard-of-care recipients in RTOG-9704 and numerically comparable to results in ESPAC-3.

Providing additional metrics in support of HyperAcute Pancreas benefit are one-year and two-year survival rate data from the three trials. We are particularly struck by comparison of the 96% one-year survival rate in the high dose cohort of NLG-0205 with the 69% rate seen in RTOG-9704. An update on survival rate data from the HAP Phase II trial is expected mid-2012.

Figure 8: Cross-trial comparison — HAP Phase II vs. standard-of-care trials

Indicates higher risk patients in NLG trial

Trial	Treatment	Patients/ Centers	Patients with prognostic risk factors				Overall survival		
			High grade tumors	Local invasion	Lymph node spread	Elevated CA 19-9	median	@ 1 year	@ 2 years
NLG-0205 (1)	HAP + gem + 5FU/radiation	70 intent-to-treat/US	35%	90%	81%	17%	24.4 months	86%	~52%, maturing
	high dose cohort	26	40%	91%	85%	19%	maturing	96%	maturing
RTOG-9704 (2)	gem + 5FU/radiation	221 / US	30%	81%	68%	14%	18.8 months	69%	~40%
ESPAC-3 (3)	gem	537 / Europe	24%	43%	73%	Not reported	23.6 months	80%	49%

Sources: (1) NewLink Genetics S-1, (2) Regine et al., JAMA, 2008, (3) Neoptolemos et al., JAMA 2010
gem = gemcitabine; 5FU/radiation = 5FU-based chemoradiation; ~ = approximation from Kaplan-Meier survival curves

HyperAcute Pancreas treatment does not appear to contribute to overall adjuvant treatment regimen toxicities. No dose-limiting adverse events or grade 4 adverse events were seen in NLG-0205, and rates of grade 3 events were very low: lymphopenia (4%), pain (3%), pancreatitis (<2%), fatigue (<2%). The most common toxicity was injection-site skin redness and inflammation, which is almost certainly related to vaccine administration. The HAP side effect profile thus compares very favorably with those reported for standards of care in the RTOG-9704 and ESPAC-3 trials.

Figure 9: Safety profile comparison: HAP vs. standard regimens

Trial:	NLG-0205	RTOG-9704	ESPAC-3
Regimen:	HAP + gem + 5FU/radiation	gem + 5FU/radiation	gem
Most common grade 3/4 adverse events:	Grade 3 only	Grade 3 and 4 @ ≥ 10%	Grade 3 and 4
	Lymphopenia (4%)	Diarrhea (15%)	Neutropenia (22%)
	Pain (3%)	Mucous membrane or stomatitis (10%)	Leukopenia (10%)
	Pancreatitis (<2%)	Nausea and vomiting (10%)	Fatigue (6%)
	Fatigue (<2%)		Nausea (2.5%)

gem = gemcitabine; 5FU/radiation = 5FU-based chemoradiation
Sources: Company presentation, Regine et al., JAMA, 2008, Neoptolemos et al., JAMA, 2010

While one must always use caution when making cross-trial comparisons, we believe this data supports the potential for HyperAcute Pancreas to demonstrate meaningful benefit in both efficacy and safety over standard-of-care in Phase III.

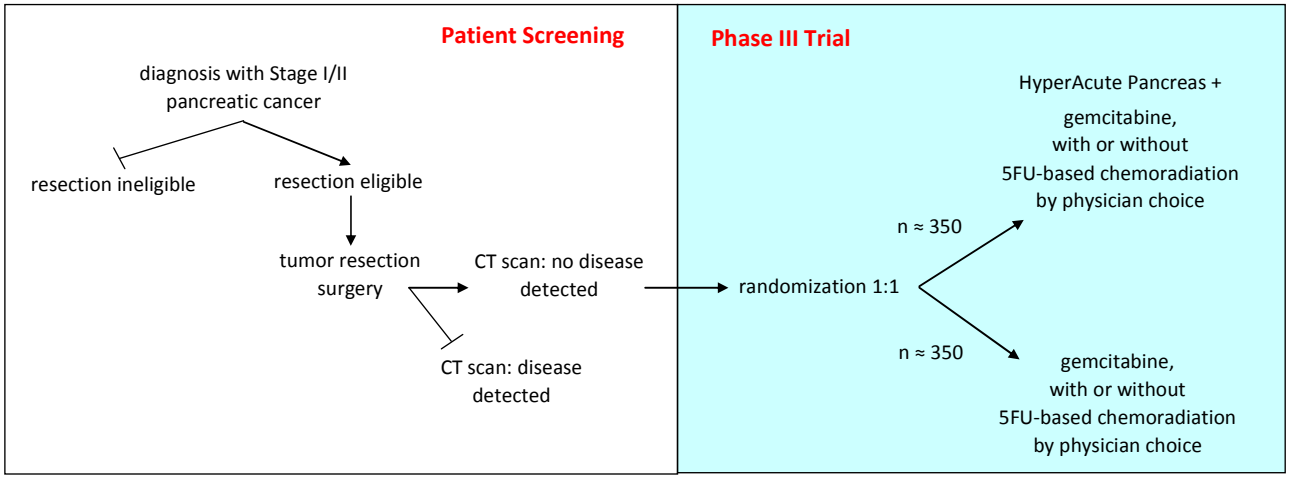
Comparison is also warranted with the GVAX Pancreas Cancer Vaccine, licensed from Johns Hopkins University by BioSante, which uses allogeneic pancreatic cancer cells engineered to secrete the immune-stimulating cytokine GM-CSF. In data published earlier this year (Lutz et al., Annals of Surgery 2011), a 60-patient Phase II trial demonstrated results for GVAX Pancreas Cancer Vaccine in combination with standard adjuvant care in surgically resected patients with prognostic profiles comparable to the NewLink Phase II trial. Median overall survival was 24.8 months, one-year survival rate was 85%, and rate of grade 3/4 adverse events was near zero. BioSante has not indicated intent for further company-sponsored development of GVAX Pancreas, but an investigator-sponsored Phase II trial of GVAX Pancreas plus standard adjuvant therapy with/without cyclophosphamide is ongoing.

Also of note in the Lutz et al. publication is mention of historical data from the Johns Hopkins Hospital, a leading pancreatic cancer care center, showing a 20.3-month median overall survival for patients receiving standard adjuvant therapy. This data approximates the 18.8-month median OS reported in RTOG-9704, and thus helps to inform expectations for the control arm in the HyperAcute Pancreas Phase III trial.

Phase III trial

In May 2010, NewLink Genetics began a US Phase III trial comparing HyperAcute Pancreas plus standard-of-care (gemcitabine plus 5-FU based chemoradiation) versus standard-of-care alone, with a planned enrollment of 722 patients, randomized 1:1. OS is the primary endpoint of this trial. Patients will receive a total of 18 doses at 300 million cells each over 12 months, approximately once every two weeks for six months, then one dose every month for six months. Two interim looks are anticipated, at one-half and three-quarters of targeted events, respectively, with the first interim look expected late 2012. The trial is powered to detect a 45% OS benefit at the first interim analysis, a 30% benefit at the second interim analysis, and a 20% benefit at the final analysis. NewLink is conducting the Phase III trial under a Special Protocol Assessment (SPA) from FDA.

Figure 10: HAP Phase III patient screening and trial design



Source: Canaccord Genuity

In handicapping the likelihood of Phase III success for HyperAcute Pancreas, a key consideration is the expected median overall survival for the control arm. While the 23.6-month median OS observed in ESPAC-3 – the largest adjuvant pancreatic cancer trial to date – may appear to present a high efficacy bar for HAP to overcome, we believe several factors limit the applicability of ESPAC-3 results as read-through into the NewLink Phase III trial:

1. **Lower risk patients in ESPAC-3**. As indicated in Figure 8, significantly fewer patients in ESPAC-3 presented with key prognostic risk factors compared to the patient profile seen in NewLink's Phase II, which is expected to remain similar in Phase III. NewLink's trial protocols include the roughly 30% of patients that present with suspicious lesions, whereas per management commentary, other trials screen out these patients more selectively.

2. **Differing surgical standards between US and EU.** ESPAC-3 was conducted primarily in Europe, where only about 4% of pancreatic cancer patients undergo surgery, versus 20% in the US. This reflects European standards that exclude more high risk patients from receiving surgery upfront.

3. **No radiation given in EU.** 5FU-based chemoradiation that is often employed in adjuvant care in the US is not used in Europe, as reflected by ESPAC-3's use of chemotherapy alone for adjuvant treatment. The actual benefits of radiation are debated, but nevertheless, the differing regimens complicate comparability of data between US and EU trials.

We anticipate the HAP Phase III control arm should yield a median overall survival in range of the 18.8 months reported in the RTOG-9704 trial, for which the patient population and surgical/adjuvant treatment standards are much more comparable to the HyperAcute Pancreas clinical trials. Conservatively, and in line with management-echoed opinion, we use a 20-month base assumption for median overall survival in the Phase III control arm. With this assumption, hypothetical trial stoppage criteria for interim and final analysis checkpoints are shown in Figure 11.

Figure 11: Hypothetical Phase III efficacy hurdles

Control arm median survival assumption	Analysis checkpoint	Expected timing	Required benefit for stoppage	Required treatment arm median overall survival
20 months	1st interim	Q4/12	45%	29 months
	2nd interim	2013	30%	26 months
	Final results	2014	20%	24 months

Source: Canaccord Genuity

Informed by prevailing data, we see a 20% likelihood of HyperAcute Pancreas Phase III success and ultimate FDA approval based on:

1. Phase II data demonstrating encouraging overall survival results in an all-comer patient population including higher risk patients
    a. 24.4-month median survival in the Phase II intent-to-treat, across 100M and 300M cell dose cohorts
    b. exclusive use of the 300M cell dose in Phase III, for which a maturing trend towards superiority over the 100M cell dose is being observed in Phase II
2. Efficacy that compares favorably with commensurable historical controls
3. Demonstration of excellent tolerability for HyperAcute Pancreas
4. Treatment of patients with minimal tumor burden following surgery; absence of bulky disease should promote a thorough immune clearance of existing malignancy
5. High unmet need in resected pancreatic cancer, exemplified by NCCN guideline of clinical trials as preferred treatment method
6. Regulatory validation of immunotherapy approaches from FDA approvals of Dendreon's Provenge and BMS's Yervoy

Risks to Phase III success

While we believe that prevailing evidence supports a positive outcome for the HyperAcute Pancreas Phase III trial, we call attention to several risks that could potentially complicate trial success:

1. **Lack of randomized Phase II data.** NLG-0205, on which we base Phase III expectations, was not a randomized controlled trial. Analysis of historical trial results as comparators is an imperfect predictor of future randomized trial outcomes. If the Phase III control group performs significantly better than expected, the primary endpoint of overall survival benefit for HyperAcute Pancreas may not be met.
2. **Enrollment may lag expectations.** As of October 25, 2011, 200 Stage I and II resected pancreatic cancer patients were enrolled in the Phase III trial. If enrollment stalls, data read-out may be significantly delayed.
3. **Unexpected adverse events.** Key to the HyperAcute value proposition is a tolerability profile with few added side effects beyond those seen with standard-of-care alone. If

unexpected serious adverse events arise, risk/benefit and likelihood of regulatory approval could be threatened.

Market opportunity

The American Cancer Society estimates about 44,000 new cases of pancreatic cancer in the US in 2011. Cases are staged according to the American Joint Committee on Cancer's (AJCC) tumor-node-metastasis or TNM classification system. Approximately 20% of pancreatic cancer patients are staged and evaluated as eligible for surgical resection.

Figure 12: TNM staging of pancreatic cancer

Stage	T	N	M	% diagnosed at Stage*
0	Tis	N0	M0	0.6%
IA	T1	N0	M0	8.3%
IB	T2	N0	M0	
IIA	T3	N0	M0	22.8%
	T1	N1	M0	
IIB	T2	N1	M0	
	T3	N1	M0	
III	T4	Any N	M0	10.6%
IV	Any T	Any N	M1	43.2%
unknown				14.4%

Source: AJCC staging guidelines, * ACS National Cancer Database, 2008 data

With high unmet need in adjuvant resected pancreatic cancer, we would expect rapid uptake if marketing approval for HyperAcute Pancreas is granted. We use the $120,000/course price for immunotherapeutic Yervoy as a base case assumption for HyperAcute Pancreas pricing.

In light of variable adjuvant pancreatic cancer standards-of-care between the US and Europe and absence of a corporate partner for support, we do not include ex-US sales in our model at this time.

Figure 13: HyperAcute Pancreas sales projections

	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
US												
pancreatic cancer incidence	44,000	44,572	45,151	45,738	46,333	46,935	47,545	48,164	48,790	49,424	50,066	50,717
% resection eligible	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
post-surgery pts	8,800	8,914	9,030	9,148	9,267	9,387	9,509	9,633	9,758	9,885	10,013	10,143
penetration					5%	30%	45%	55%	55%	55%	55%	55%
pts treated					463	2,816	4,279	5,298	5,367	5,437	5,507	5,579
price					$120,000	$121,200	$122,412	$123,636	$124,872	$126,121	$127,382	$128,656
US sales ($M)					55.6	341.3	523.8	655.0	670.2	685.7	701.5	717.8
ex-US												
sales not modeled					0	0	0	0	0	0	0	0
Total HyperAcute Pancreas					55.6	341.3	523.8	655.0	670.2	685.7	701.5	717.8

Source: Canaccord Genuity estimates

Competition

To our knowledge, the only other novel agent in a US Phase III adjuvant pancreatic cancer trial is Tarceva (erlotinib), which is being evaluated in the RTOG-0848 trial in combination with gemcitabine, both with and without chemoradiation, versus gemcitabine alone. Tarceva is currently approved as front-line treatment in combination with gemcitabine for locally advanced, unresectable, or metastatic pancreatic cancer. Approval in this setting was based on data showing a marginal yet statistically significant benefit in overall survival for Tarceva plus gemcitabine versus gemcitabine alone (6.4 vs. 6.0 months, HR=0.81, p=0.028). Barring surprisingly positive adjuvant Phase III data for Tarceva, we foresee minimal potential for near-term shift in the clinical and competitive landscape.

HYPERACUTE LUNG AND MELANOMA

HyperAcute Lung

NewLink's HyperAcute Lung (HAL) product is currently undergoing evaluation in a fully enrolled Phase I/II single-center trial in 54 patients with refractory, recurrent, or metastatic non-small cell lung cancer (NSCLC). HAL is administered as a group of three human lung cancer cell lines. Twenty-eight patients in the Phase II portion received doses of 300 million cells every two weeks for up to eight doses.

Interim results from the Phase II portion of this trial demonstrated a median overall survival of 11.3 months. This compares favorably with two standards-of-care in second-line NSCLC, Taxotere (docetaxel) and Alimta (pemetrexed), which in Phase III trials showed median overall survival of 7.5 months and 8.3 months, respectively. With the usual cross-trial caveats, we consider the HAL Phase II data intriguing, but await more mature data before explicitly modeling sales. NewLink is evaluating adaptive designs for a Phase IIb/III trial, planned to start in H1/12.

HyperAcute Melanoma

Treatment with HyperAcute Melanoma involves intradermal injections of three allogeneic melanoma tumor cell lines engineered to express alpha-gal. An investigator-sponsored, 25-patient, single-center Phase II trial is investigating HyperAcute Melanoma in combination with PEG-Intron for the treatment of patients with advanced melanoma.

Data will inform future trial designs employing HyperAcute Melanoma either as monotherapy or in combination with other agents. As development remains early-stage, we do not model for HyperAcute Melanoma sales at this time.

Other indications

Additional Phase I development of the HyperAcute platform in prostate and/or breast cancer is being considered pending lead optimization and resource prioritization.

IDO PATHWAY INHIBITOR

The enzyme indoleamine 2,3-dioxygenase (IDO) regulates T-cell immune responses by inhibiting tryptophan catabolism. Both cancer cells and antigen-presenting cells express this enzyme, which may enable tumor immune evasion. Preclinical data suggests that inhibition of this enzyme can enhance tumor responses to conventional therapies.

NLNK owns rights to D-1MT, a small molecule IDO inhibitor currently being studied in two Phase Ib/II trials with the National Cancer Institute: 1) in combination with an autologous dendritic cell vaccine for p53-mutant solid tumor malignancies, and 2) in combination with Taxotere for treatment of solid tumors.

We await data presentation from these studies before including potential D-1MT sales in our model.

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

NewLink 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 14: NLNK DCF valuation

	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

INVESTMENT RISKS

Risks to our BUY thesis on NLNK include:

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

Figure 15: 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 16: NLNK quarterly income statement ($M except EPS)

	Mar-10 1Q10A	Jun-10 2Q10A	Sep-10 3Q10A	Dec-10 4Q10A	2010A Annual	Mar-11 1Q11A	Jun-11 2Q11A	Sep-11 3Q11A	Dec-11 4Q11E	2011E Annual
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

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