

Equity Research

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NewLink Genetics Corporation (NLNK-\$7.00)

Rating: BUY

Target Price: \$12.00

Late Stage Assets, Many Milestones: Initiate with BUY Rating, \$12 Price Target

EPS	1Q	2Q	3Q	4Q
2010A	(1.02)A	(1.21)A	(1.49)A	(1.12)A
2011E	(1.07)A	(1.20)A	(1.09)A	(0.36)E
2012E	—	—	—	—
2013E	—	—	—	—
REV	1Q	2Q	3Q	4Q
2010A	0.3A	0.4A	0.4A	1.0A
2011E	0.6A	0.5A	0.4A	0.4E
2012E	—	—	—	—
2013E	—	—	—	—
FY	2010A	2011E	2012E	2013E
EPS	(4.84)A	(2.73)E	(2.39)E	(2.07)E
REV	2.1A	2.0E	—	—

- **A pipeline for major unmet medical needs.** NewLink is a cancer immunotherapy company developing drugs for cancer, focusing on major unmet medical needs and collectively addressing multi-billion markets.
- **Significant milestone calendar to boost visibility.** With multiple products in trials, a steady stream of news could be forthcoming through 2013, including advancement of candidates, especially the HyperAcute program.
- **Manufacturing is a differentiator.** The HyperAcute vaccine program is allogeneic with the potential for a modest manufacturing process and cost structure, potentially mitigating production and commercial risk.
- **Leaving room for upside.** NewLink's candidates are unpartnered, and upside, should a partner step in - for either HyperAcute or IDO - could be material.
- **Valuation.** An air of skepticism hangs over immunotherapy, and, thus, strong science and late stage assets are discounted. Our 12-month price target is \$12 based on a discounted (50%) future EPS calculation. Through achievement of milestones, the potential of the clinical programs should advance valuation.

Current Statistics

Market Cap (\$Mil)	\$144.1
Avg. Daily Trading Volume (3 mo.):	NA
Shares Out (Mil):	20.591
Float Shares (Mil):	NA
Short Interest (Mil):	NA

Company Description

NewLink Genetics is a development stage company focused on cancer treatments. Founded in 1999 and based in Ames, Iowa, NewLink has two technology platforms, HyperAcute (allogeneic vaccine) and IDO inhibition (oral, small molecule), in various stages of trials. The HyperAcute program is the furthest in development, with the lead candidate, HyperAcute Pancreas, in a Phase III trial for pancreatic cancer. NewLink also has mid-stage trials underway in non small cell lung cancer and melanoma.

Initiating with \$12 price target

Summary

Investment Thesis: NewLink is working in the rapidly developing field of cancer immunotherapy. The company has a novel approach based on a solid scientific foundation and is working in areas of tremendous unmet need. We have identified what we believe to be critical success factors for a cancer immunotherapy company, and further believe that NewLink meets these criteria. The company has identified appropriate clinical settings with which to test their technology (modest disease burden, consistent booster dosing), has a robust trial design, is addressing critical unmet medical needs and has a scalable, financially reasonable manufacturing process and technology. Additionally, the stage and depth of NewLink's clinical program is compelling, and there are multiple opportunities for milestone updates over the next 24 months.

- **Indications & Unmet Medical Needs.** NewLink's initial clinical programs are focused on pancreatic cancer, lung cancer, and melanoma, three diseases of major unmet medical need. The company has identified patient populations within these groups that are likely to benefit from the HyperAcute immunotherapy program, and have designed clinical trials around appropriate patient populations. We believe that the field of immunotherapy in cancer has evolved, learning from prior clinical failures that trials in the sickest of patients, with the highest of disease burdens, may be the least likely to derive benefit from treatment. Hence, NewLink has honed in on the earlier stage populations but that still have tremendous unmet medical need. For instance, in pancreatic cancer, New Link's program is addressing the roughly 25% of patients that are diagnosed at early stage but still face dire odds of survival.
- **Trial design.** NewLink's Phase III trial of HyperAcute Pancreas is a large, randomized Phase III clinical trial consisting of over 700 patients. The company has vetted the trial design with the FDA, and it will be conducted with a Special Protocol Assessment (SPA), mitigating the risk that the Agency takes issue with the trial design or other elements once the trial has been completed.
- **Manufacturing.** NewLink's HyperAcute technology relies on allogeneic matter. That is, the treatment consists of cells that do not need to be harvested from the patient. In scientific parlance, they are of the same species but antigenically distinct. This helps to create a straightforward and streamline manufacturing process, with attractive margins.
- **Milestone Opportunities.** A key component of valuation building for biotechnology companies is derived from milestone events. NewLink has a full milestone calendar over the next 24 months, and we expect news flow from such events will provide incremental opportunities to build value. In 2012 alone, we expect that the company will have the opportunity to advance two products into later stage of clinical trials and take an interim look at data from its Phase III trial.

Valuation

We examined both traditional discounted present value calculations for projected EPS and multiple of EV for companies engaged in similar research at similar stage of development to arrive at a price target for NewLink. Looking at both these methods, NewLink appears undervalued, and we believe the shares could be worth \$12 based on the opportunity for milestones and other corporate and clinical events to enhance the company's valuation. Our valuation metrics are:

1. Discounted present value earnings calculation of EPS of \$2.26 in 2016, a multiple on those earnings of 40x, discounted by 50%, NewLink shares appear significantly undervalued vs. this calculated value of \$11.91 (75+% upside from today's close price). We have used a multiple on 2016 EPS consistent with valuation for early stage biotechnology companies, which range from 30-50x forward EPS, reflecting the opportunity for rapid growth. In arriving at this range, we explored historical data as well as forward consensus multiples for companies with newly launched products, such as Seattle Genetics, Incyte, Regeneron, Vertex, and Optimer.

2. We also reviewed multiples of sales in first year of product launch, noting that companies such as those mentioned above are currently trading at multiples ranging between 5-9X forward revenue. Using a multiple of 7X 2016 revenues, also discounted at 50%, we arrive at discounted forward revenue for NewLink of \$250 million, or roughly \$12 per share
3. We also examined EV of development stage companies working in cancer immunotherapy – and specifically vaccines, with product candidates and clinical trials at a similar to NewLink. Based on the current close price on December 20, 2011, NewLink’s EV is below peers (107 vs. 235 for peers) and is trading at a discount to multiple of cash (19%) relative to peers – two other benchmarks used in evaluating biotechnology companies. This suggests that there is room for improvement in NewLink’s valuation, with the potential for milestone events to drive valuation as products advance in the clinic.

Focus on oncology

Company History

NewLink’s origin comes from the research interests of Charles Link, M.D., NewLink’s founder and Chief Executive Officer. Dr. Link’s research interests in oncology have roots with the National Institutes of Health (NIH) and followed Dr. Link to the John C. Stoddard Cancer Center at the Iowa Methodist Medical Center. Dr. Link founded NewLink in 1999 through an advantageous relationship with the Iowa Methodist Medical Center that allowed Dr. Link to transfer technology from the university to form the basis of NewLink’s technology platform.

NewLink currently has 78 employees, all based in Iowa. Though Iowa is not often thought of as a hotbed for biotechnology the way that Boston, San Diego or San Francisco are, NewLink’s base there has provided a number of advantages to the company. These include:

- Low cost center
- State and local incentives to attract high tech expansion
- Motivated and talented workforce

This is compelling given the cost to develop new drugs, considered to be in excess of \$800 million, and the cost pressure environment (even for biologicals) that exists today.

Carrying the torch forward in immunotherapy for cancer

Industry Overview

NewLink is working in the field of cancer immunotherapy, with both a vaccine approach to immunotherapy and small molecule inhibitors. The idea of fighting cancer with the body’s own immune system is not novel, but its realization has been less than straightforward. Immunotherapy, as it relates to cancer, can involve antibodies, which is now a multi-billion dollar industry; immune system modulators, fast becoming a billion dollar market; and cancer vaccines, which hold promise but have struggled clinically and commercially.

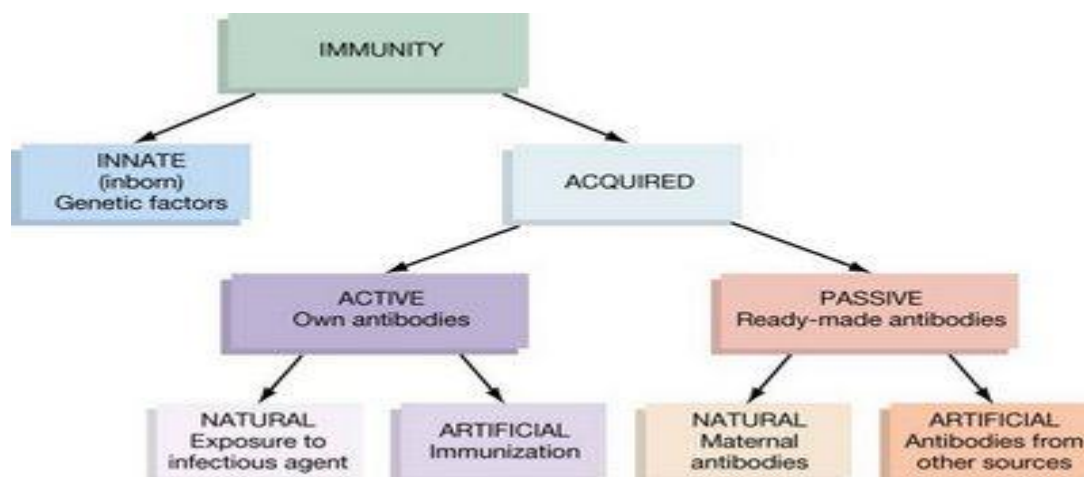
The first vaccine – or therapeutic that teaches the body to attack cancer – was approved in 2010 and has provided the investment community with a roller coaster ride throughout. Dendreon developed and launched the first ever cancer vaccine to treat prostate cancer, Provenge (sipuleucel-T). The regulatory approval was rocked by controversy as was the launch, with concern about commercial potential of this product. This, in turn, has created, in our view, uncertainty among investors as to the potential of other cancer vaccines. However, in our opinion, there are multiple approaches to immunotherapy and cancer, and Provenge’s commercial issues are a function of the product and its own characteristics and are not an indictment for the entire industry. The field remains wide open. We note that today there are over 100 trials (from preclinical to Phase III) examining immunotherapy in cancer (roughly 30% are later stage), and targeted approaches for cancers such as pancreatic, renal cell, glioma, prostate, melanoma and many others. Understanding the potential of immunotherapy overall involves understanding some basics of the human immune system and cancer.

Cancer and the Immune System

While cancer cell growth may appear haphazard and sloppy, cancer cells have very sophisticated mechanisms for evading the human immune system. The body does recognize less mature cancer, or tumor, cells as a danger signal, but as cancer cells mature, so do their mechanisms for avoiding destruction by the immune system. Initially, cancer cells are able to “trick” the immune system by removing certain cell surface receptors that would otherwise signal danger to the immune system. And although tumor cells express antigens that should signal the immune system into action, they more often than not do not express enough of them to raise alarm.

Cancer cells have a variety of other tools to trick the immune system. For instance, some tumors may lose expression of antigens that elicit immune response. Additionally, tumor cells do not express costimulators known as class II MHC molecules that are responsible for inducing an immune system attack through the activation of cytotoxic lymphocytes (CTLs), an immune system component. These are just some of the ways that cancer can evade the immune system. Thus, while the immune system is a powerful tool against invaders, it struggles to fend off attack from “self” cancer cells.

Exhibit 1: Types of Immune Responses

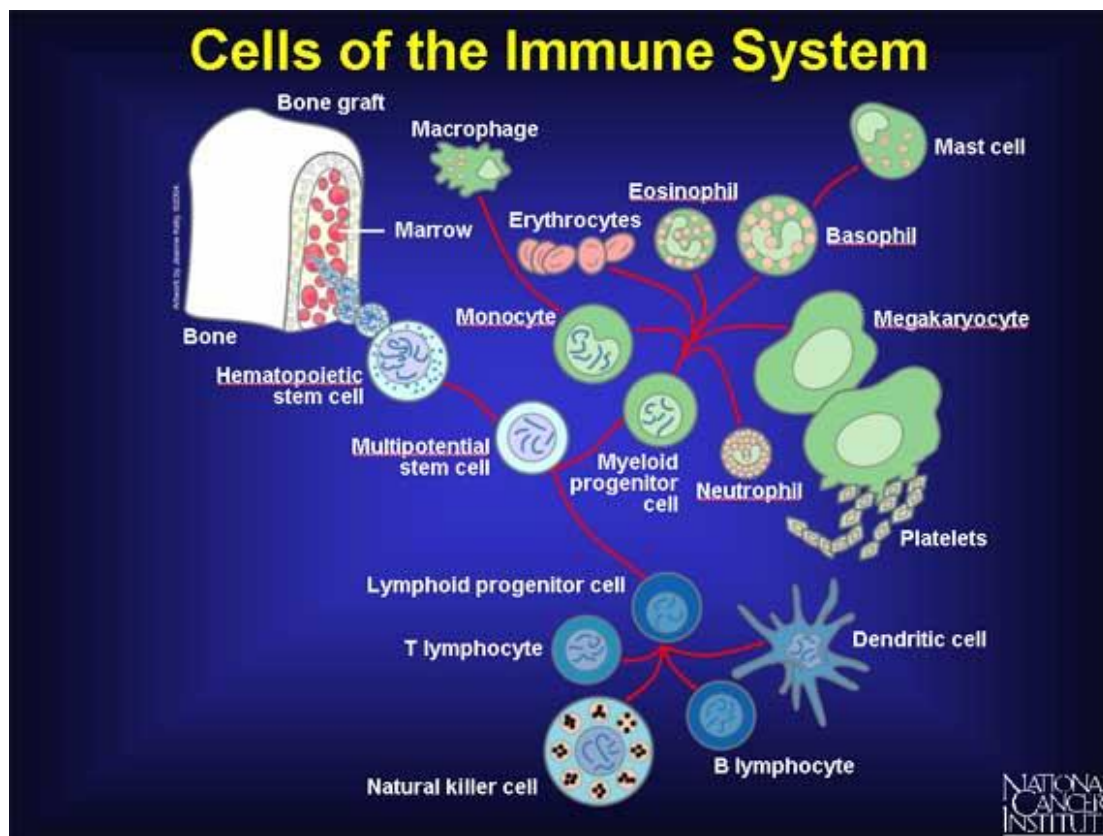


Source: *Immunology for Dummies*

Components of Immune Response

The immune system is comprised of multiple cells taking on different roles to create a dynamic process that protects the human body from harm. At the heart of this process is the dendritic cell, whose job it is to grab hold of an antigen (a substance that stimulates the production of an antibody) and present it to CTLs to teach the immune system to attack such danger signals. Dendritic cells are also known as antigen presenting cells, or APCs, which describes their function. Once the dendritic cell has “taken up” the antigen, it breaks it up into small peptides that are then expressed on the cell’s surface through MHC, or major histocompatibility complex. There are two types, MHC I and MHC II, with MHC II playing a role in immunotherapeutic approaches to cancer. MHC molecules are proteins recognized by T cells that allow the body to distinguish between self and non-self. A self-MHC molecule provides a structure, or scaffolding, that can be recognized by T cells. MHC presents this scaffold with a foreign antigen to the T cell, which triggers an immune response. In humans, MHC antigens are called human leukocyte antigens, or HLA.

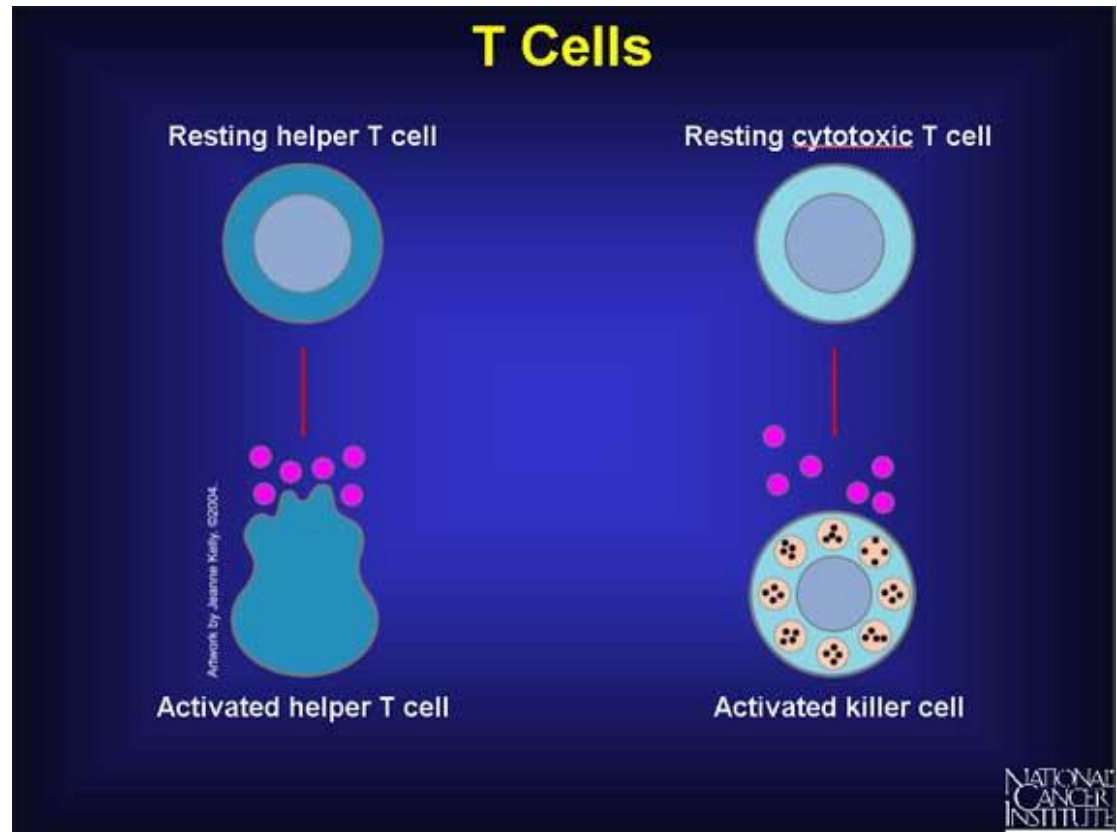
Exhibit 2: The Immune System



Source: National Cancer Institute

Dendritic cells are found throughout the body. They are found in the gastrointestinal and respiratory tracts, the epithelial of the skin, and in spaces between organs. Once dendritic cells have taken up an antigen, processed it, and expressed it on its surface, the cells migrate to the lymph system where they encounter naïve T cells (that is, T cells that have not yet been given instructions on which antigens to attack). Once the dendritic cell “presents the antigen” to the T cell, the T cell is primed and ready to attack, and thus begins a complex interplay between various components of the cellular immune response. Within this interplay is a series of events that activate costimulatory pathways to induce helper T cells, also known as CD4+ or regulatory T cells, into action.

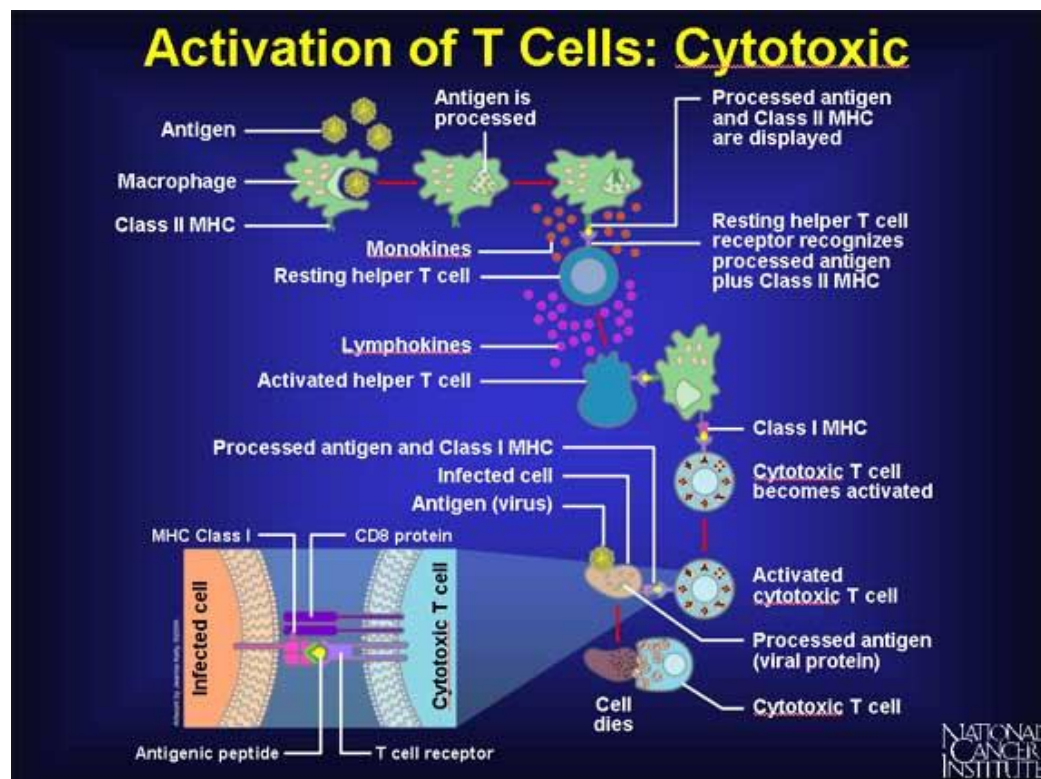
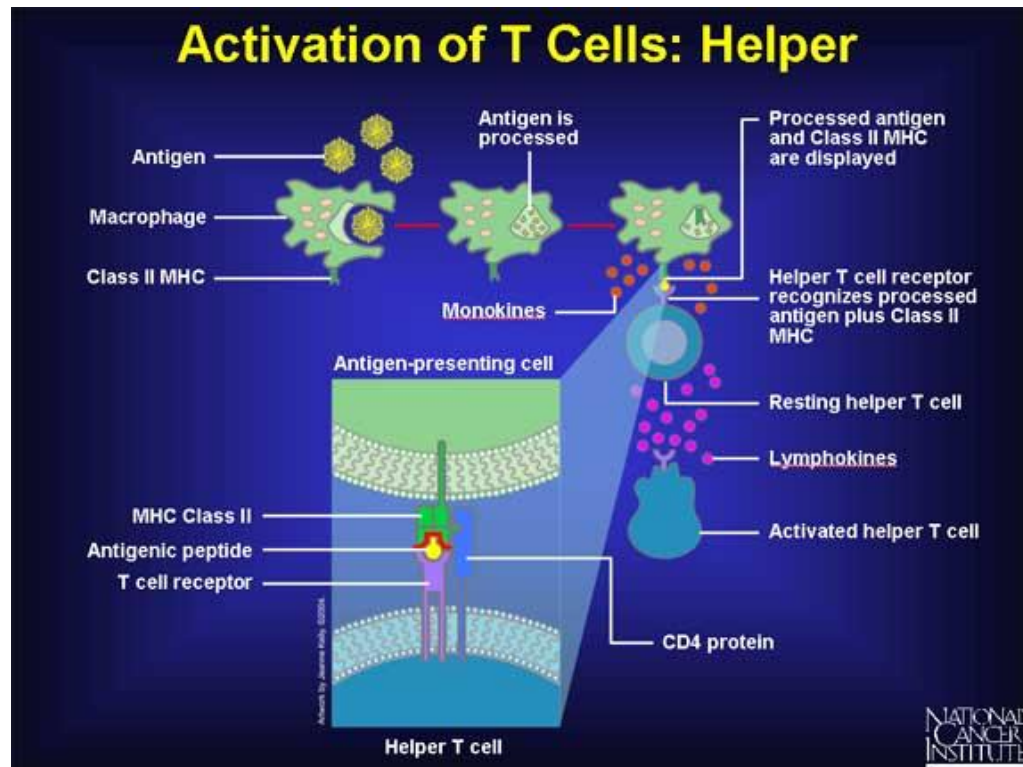
Exhibit 3: T Cells and Their Components



Source: National Cancer Institute

So, with an army of primed T cells, why doesn't the immune system win and the cancer lose? This is primarily due to an arsenal of tools and tricks that cancer cells employ to evade detection. Thus, the idea of teaching the immune system to recognize tumors – essentially to outsmart cancer cells – is the foundation of immunotherapeutic treatment of cancer. Within immunotherapy for cancer, there are basically two approaches – vaccines and immune system modulators.

Exhibit 4: T Cells in Action

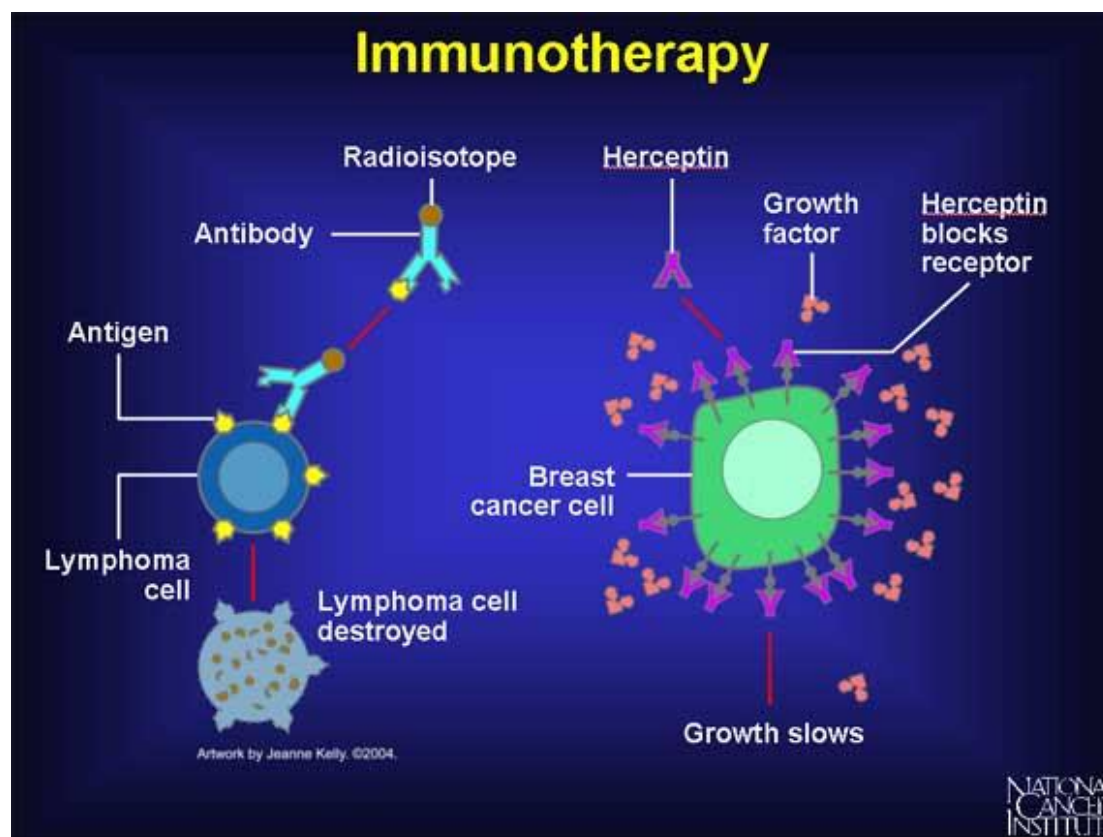


Source: National Cancer Institute

Why Immunotherapy Makes Sense

In its natural state, the human immune system struggles to overcome the destructive effect of cancer. Enter immunotherapy as a novel tool, teaching the immune system to recognize cancer cells so T cells can do what they do best – destroy cells that represent danger to the body. Immunotherapeutic treatment has evolved to represent several approaches. The most widespread therapy today is passive antibody transfer through the use of monoclonal antibodies (mABs). Over 20 mABs are FDA-approved to treat a variety of diseases, including cancer. In this scenario, the mAB essentially fortifies the immune system by honing in on antigens of cancer cells. One of the most widely used mABs for cancer is Herceptin (trastuzumab), and a pictorial of how it works is presented below.

Exhibit 5: Herceptin as Immunotherapy

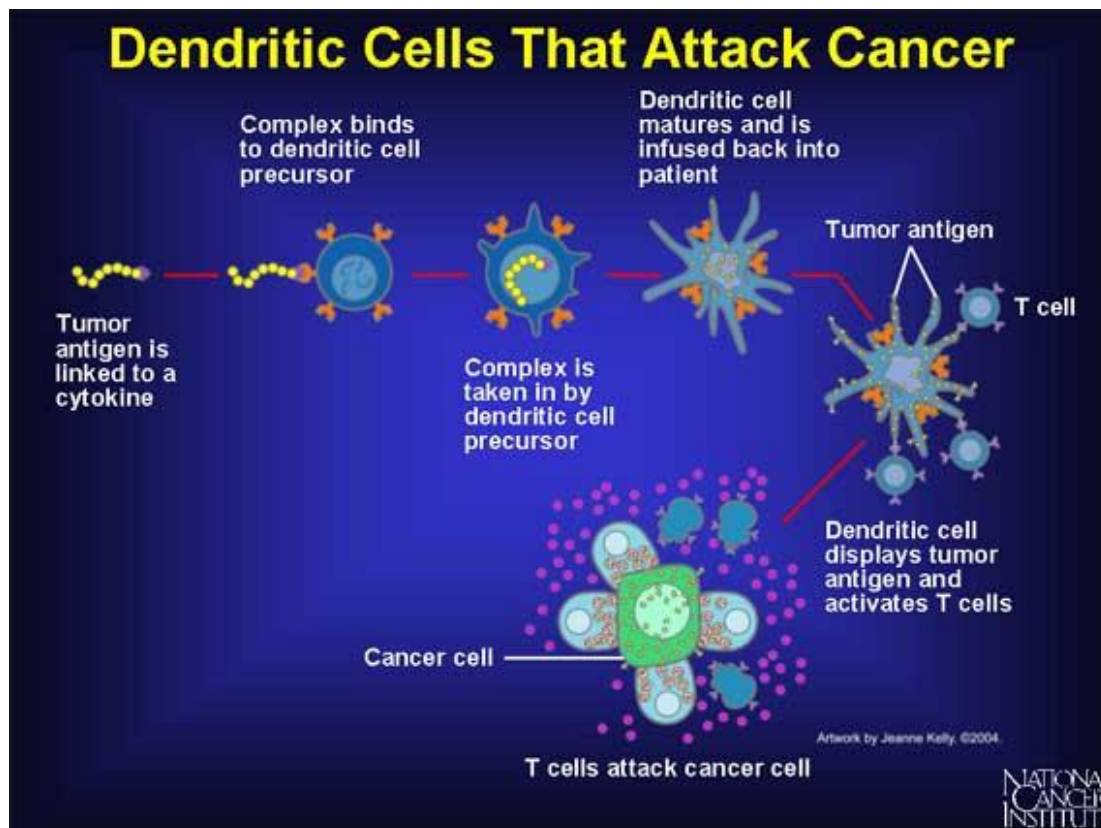


Source: National Cancer Institute

Thus vaccines represent a novel approach because once the immune system is taught to recognize an antigen, it has the ability to forever remember that antigen and jump into action when needed. The entire system stands at the ready with B cells able to bind to antigens and T cells able to destroy “foreign” cells. But stimulating the immune system into a sustained, active response that produces a clinically meaningful outcome has been elusive. Provenge is the only such agent commercially available (for hormone refractory advanced prostate cancer) and this approach, using mature dendritic cells and a known prostate cancer antigen, has been shown to have an impact on overall survival in men with advanced disease. Of note, immunotherapeutic approaches may be associated with better outcomes when used earlier in disease, potentially because of the time required to build an appropriate immune response. Additionally, the clinical landscape is evolving to the idea that these products are likely to have better efficacy if combined with conventional chemotherapy. The combination approach

allows the chemotherapy to do its job in eradicating cancer cells while allowing the body time to build immunity against the cancer cells, thus enhancing overall survival by exhibiting a late treatment effect. Below is a pictorial of how dendritic cells are used in cancer vaccines.

Exhibit 6: Dendritic Cells



Source: National Cancer Institute

Company Overview

NewLink's most advanced program is the HyperAcute allogeneic cancer vaccine program, which targets a phenomenon termed "immune escape." Immune escape refers to the ability of cancer cells to evade the body's immune system by a variety of sophisticated mechanisms. HyperAcute is a novel approach to sustained and targeted immune system stimulation.

Enter HyperAcute

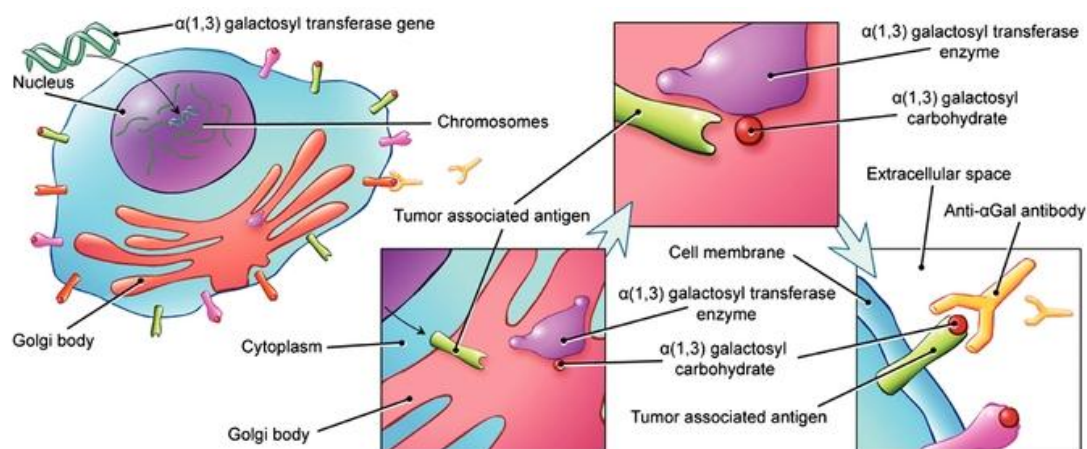
HyperAcute technology is based on the premise that the human body has "innate" immunity and will naturally act to neutralize and/or remove "non-self" matter. In this case, NewLink is harnessing the power of innate immunity that the body employs to protect against infections transmitted from animal species. This activity is related to a specific enzyme, α -GT, which stands for α -galactosyltransferase, which is essentially able to goad the human immune system into action. The presence of α -GT enzyme results in the expression of a non-human form of carbohydrate called α -Gal on the surface of affected cells. Introducing α -gal expressing cells to the human immune system activates an immune response from antibodies against α -Gal. Antibodies directed against α -Gal epitope (a region on the surface of an

antigen capable of activating an immune response) are potentially the most abundant antibody in humans, representing 1% of circulating human antibodies.

HyperAcute therapy incorporates the α -GT gene into the chromosome within the cancer cell. The gene then yields a protein called α -GT enzyme, which is located within the Golgi body of the cell – the region of the cell where macromolecules such as proteins are processed and packaged. Proteins that are processed through the Golgi body are tagged with the α -GAL carbohydrate and placed on the surface of the cell. The α -GAL carbohydrate located on the surface of the tumor associated antigen is now targeted by anti- α -Gal antibodies, and causes a “hyper acute” immune response to be initiated.

NewLink’s hyperacute therapies incorporate irradiated live allogeneic human cancer cells modified to express the gene that makes α -GAL epitopes. This exposure to α -GAL stimulates the immune system to attack and destroy cells on which α -Gal is present by activating complement, a component of the immune system that is capable of cell destruction. After destruction, the remaining cellular fragments bound by anti- α -GAL antibodies could very well be processed by the immune system, thus leading to greater and sustained immune response. If indeed this is true, then patient outcomes are likely to be improved through enhancing overall and progression-free survival.

Exhibit 7: HyperAcute Rejection of α -Gal-Expressing Vaccine



Source: NewLink Genetics

The above model for HyperAcute was outlined in a publication by NewLink scientists. According to the model, the following sequence occurs:

1. Transduction of α -GAL-negative tumor cells (humans or α -GT knockout mice) to express the α -GT enzyme, which generates a multivalent α -Gal+ vaccine;
2. opsonization (process that makes cells more susceptible to the action of phagocytes) of α -GAL+ whole cell vaccines in α -GAL– subjects with high titers of anti- α -GAL antibodies;
3. antibody opsonization of α -GAL epitopes induces complement activation through the classic pathway and cell lysis, and Fc receptor-mediated phagocytosis;
4. complement-mediated cell lysis generates a “danger signal,” releasing heat shock proteins that induce activation and differentiation of APCs to mature dendritic cells; macrophages, granulocytes, and eosinophils are recruited to the site of inflammation;

5. two mechanisms of antigen uptake result in the presentation of the processed antigen on MHC class II and class I molecules and activation of CD4+ T helper cells and CD8+ cytotoxic T cells, respectively; CD1-restricted T cells may be also activated;
6. T cells recognizing tumor antigens expressed in tumor cells lacking the α -GT enzyme proliferate; and
7. these CD8+ T cells migrate within the α -GAL-negative tumor mass and eradicate pre-established tumors.

NewLink believes that the immune cells are educated to attack cancer cells by virtue of the antigens that the immunotherapy and the tumor cells share and by a generalized activation of the immune system. It is the goal of HyperAcute therapy to break tolerance and enable longer duration of anti-tumor effect. In order for this to happen, NewLink believes that the immune response to HyperAcute therapy is triggered by formation of immunocomplexes between the α -GAL containing cells and pre-existing naturally occurring antibodies to α -GAL antibodies present in patients.

Is this Approach Viable?

Clinically, until the Phase III data is in, this approach is still experimental. However, this approach does appear quite robust. According to NewLink research, the formation of immunocomplexes by complement fixing anti- α -GAL antibodies activates complement-mediated cell lysis (destruction of cell through disruption of cellular membrane), which generates “danger signals” to the immune system and that in turn appears to activate and recruit several types of APCs, such as dendritic cells, macrophages and natural killer (NK) cells. These cells, which take up the “lysed” fragments of the HyperAcute immunotherapy cells have responses against multiple tumor targets and activate by the cellular (T cell) and humoral (B cell) components of the immune system. The result of this process is the activation of CD8+ and CD4+ helper T-cells and antigen-specific B-cells, all of which play a potential role in tumor destruction. This is outlined in the sequence list above.

Manufacturing...A Compelling Story

A critical success factor for NewLink and HyperAcute is the relatively straightforward, “off-the-shelf” approach to the manufacture of HyperAcute products. Because HyperAcute is allogeneic, it is not dependent on harvesting cells from patients, and that simplifies the manufacturing process. The manufacture of HyperAcute products can vary depending on the therapeutic application (i.e., pancreas, NSCLC, etc.), but given its storage characteristics (shipped on dry ice, stability up to four days, storable for long periods with liquid nitrogen), the overall process appears quite streamline, commercially appealing and cost effective. NewLink has capacity to create product for its pancreatic and NSCLC Phase III trials, with the option to build out its existing facility to add more capacity upon commercialization. This build out, we believe, will cost less than \$10 million.

Clinical candidates

NewLink has several active HyperAcute clinical programs. The company’s lead candidate is HyperAcute Pancreas, which is well over a year (May 2010) into a Phase III clinical trial program.

HyperAcute Pancreas

HyperAcute Pancreas is NewLink's most advanced product. It is in Phase III clinical trials (initiated in May 2010) in a 722-patient trial of surgically resectable pancreatic cancer. The trial is a randomized open-label study evaluating overall survival (OS), being conducted under an SPA (special protocol assessment). An interim look is planned for the end of 2012. The trial is powered to detect an 18% improvement in OS between treatment groups. Interim looks are planned and should the data meet pre-specified stopping points, NewLink would be able to use this data to file for FDA approval. The planned interim looks and stopping points are:

- 1st interim look - 50% of events (deaths) will have occurred, roughly expected at the end of 2012. Stopping point would be at approximately 40% improvement in OS.
- 2nd interim look could occur around mid-2013. Stopping point is approximately 30% difference at the second look.
- 3rd interim look could be at the end of 2012, and the trial would be concluded at an approximately 820% difference in OS.

The trial, being conducted at 57 sites across the U.S., has 200 patients enrolled as of October 25, 2011. Patients are randomized (1:1) to treatment with HyperAcute Pancreas after surgical resection and standard treatment with Gemzar (gemcitabine) and 5-FU chemoradiation. Patients randomized to HyperAcute Pancreas will receive 12 biweekly injections of 300 million cells of HyperAcute Pancreas with their standard Gemzar + chemoradiation regimen, followed by a maximum of six monthly booster injections, for a total of 18 injections through the course of treatment. Should the trial stop early for efficacy, patients in the non-HyperAcute arm will be allowed to crossover to the active treatment arm.

The Phase III trial was designed based on the results of NLG-0205, a 70-patient 2-arm study of HyperAcute + standard of care (chemoradiation following successful surgical resection). Two doses – 100 million (44 patients) and 300 million (26 patients) – cells were administered biweekly for 26 weeks with the objective of demonstrating clinical benefit and determination of optimal dosing. The study met its primary endpoint of disease-free survival of 14.2 months and a statistically significant difference in disease-free survival at one year between the low and high dose groups ($p=0.02$). An analysis of overall survival – a secondary endpoint – showed one-year survival of 86%. The one-year disease-free survival, the primary endpoint, was 81% for the high dose arm and 52% for the low-dose arm. The one-year survival rates of 96% and 80% were achieved for the low and high doses, respectively, and compare with historical controls of that range in the <50% for disease-free survival and <70% for overall survival.

Phase II results @ 1 Year

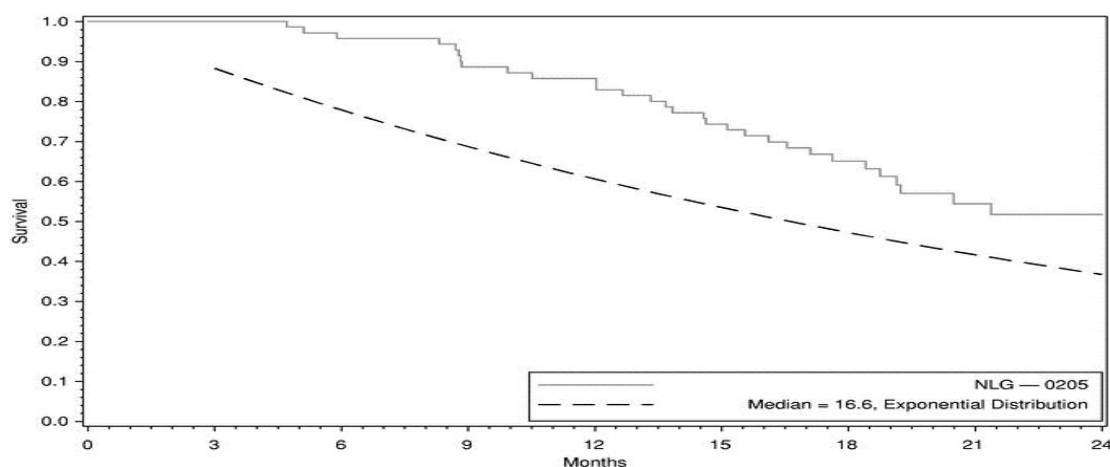
- NLG-0205 Low Dose – 52% disease-free survival, 80% overall survival
- NLG-0205 High Dose – 81% disease-free survival, 96% overall survival
- Historical control (RTOG 97-04) - <50% disease-free survival, 69% overall survival

Tolerability of HyperAcute Pancreas was high with low incidence of side effects. There were no Grade Four adverse events attributable to HyperAcute Pancreas, and less than 8% of patients reported a Grade Three adverse event that could be considered attributable to HyperAcute Pancreas. The most common events were:

- Lymphopenia 4%
- Pain 3%
- Pancreatitis 2%
- Fatigue <2%

Because pancreatic cancer has such a dismal rate of survival, even patients with the lowest risk factors still face devastating survival odds. We typically like to see well controlled, randomized and blinded clinical trials that are free from selection bias. However, this is not always the case in Phase II trials, and we note that of the 22 Phase II trials of immunotherapeutics for the treatment of cancer found on the www.clinicaltrials.gov website, all but three were open label. We discerned no difference between sponsorship of study and trial design, with open label studies conducted by industry (both large and small) and academia. We do find NLG-0205's Kaplan-Meier analysis (survival analysis) compelling, warranting mention here.

Exhibit 8: Kaplan-Meier Analysis



Source: NewLink Genetics

In an analysis of NLG-0205's data and the historical results of the RTOG 97-04 (Radiation Therapy Oncology Group study 97-04) data, the Kaplan-Meier-calculated overall survival of successfully resected pancreatic cancer patients receiving HyperAcute Pancreas plus Gemzar plus 5-FU based chemoradiotherapy (standard of care), the estimate of median overall survival was determined to be 24.4 months. Data at 12 months after surgery in NLG-0205 show overall survival to be 86%. Additionally, stratification for low and high dose groups suggests improved disease-free survival for the high dose group vs. the low dose group and standard of care as described by RTOG 97-04.

Our revenue model for HyperAcute Pancreas assumes that the trial runs to completion at the end of 2013 with a BLA submission to the FDA in 2014. Based on the unmet medical need for pancreatic cancer and the SPA with the agency, we expect accelerated review. Further, because of the relative ease of NewLink's manufacturing technology, we do not believe that there will be a lag between approval and inventory for launch, and thus HyperAcute Pancreas could be launched in 2H:14. Our model assumes a price point for HyperAcute Pancreas at \$3,500 per dose, or \$63,000 for a full course of 18 injections as per Phase III protocol. However, we assume that not all patients will achieve a full course, and so average number of injections per patient is initially below 18. This figure could be adjusted depending on the Phase III trial results and potential for change for optimizing treatment (i.e., additional booster dosing).

We are also assuming that there will be a little fewer than 46,000 individuals in the U.S. with pancreatic cancer in 2014, based on the American Cancer Society's surveillance research. Of the entire patient populations, 8% are likely to be diagnosed at Stage I, and 27% will be diagnosed at Stage 2. This is the Phase III trial population, and given the disease burden of Stage 3 & 4 patients, we are not anticipating off-label use for those patients in our model. We also make the assumption that not all Phase 2 patients will be appropriate given that the mean age at diagnosis is 69 years, though some cancer centers are suggesting that it has fallen to 63 years based on epidemiological data collected. Further, based on a review of drug trials in pancreatic cancer, we do not expect significant change in the treatment of Stage 1 and 2 patients in the time period before HyperAcute Pancreas' launch. While there are a number of late stage trials ongoing in the U.S. for pancreatic cancer, trials for novel agents are concentrated in patients with unresectable disease (Stages 3 & 4), and represent a distinction in treatment for pancreatic cancer. The newest advance in this disease is a new combination of older chemotherapeutic agents (oxaliplatin, irinotecan and 5-fluorouracil), but it is quite toxic and is likely only to be used in a limited patient population.

NewLink is currently conducting U.S.-only registration studies; hence, any partnering for ex-U.S. territories is a possibility.

HyperAcute Lung

NewLink's second furthest product in development is HyperAcute Lung, which utilizes the same proprietary technology as HyperAcute Pancreas, but incorporates known antigens specific to non small cell lung cancer (NSCLC). The trial, being conducted by the National Cancer Institute (NCI) is fully enrolled with 54 patients with refractory, recurrent or metastatic NSCLC primarily (Stage IIIB and Stage IV).

The trial is a two part trial, with 17 and 37 patients enrolled in Phase I and Phase II, respectively. The Phase I consisted of a dose escalation (3, 10, 30 or 100 million cells every four weeks for four doses) group, and a second group that received an initial dose of 500 million cells, followed by injections of 300 million cells every two weeks for up to seven doses. For the Phase II, 28 patients (the evaluable population of the 37 enrolled) received injections of 300 million cells every two weeks for up to eight doses. The trial's arms were compared against historical results of (1) best supportive care, (2) Taxotere (docetaxel), or (3) Alimta (pemetrexed). Data (presented below) suggests that HyperAcute Lung improved survival and was very well tolerated. One serious adverse event (SAE) – grade three lymphopenia – was reported as “possibly or probably” attributable to HyperAcute Lung.

Exhibit 9: NLG-0101 NSCLC Study Data

Survival		Serious Adverse Events (Grade 3 & 4)			
Overall	12-Month	Nausea	Fatigue	Anemia	Neutropenia
11.3	46%	0%	0%	0%	0%

Source: NewLink Genetics

Once the final data set has been fully analyzed, NewLink should be able to identify a path forward with this treatment. Our expectation is that the company will provide an update on this product in mid-2012, and that a Phase III trial will commence sometime in 2012. The trial design has not yet been revealed, but we are inclined to think it will appear similar – in terms of patient population – to those treated in Phase II, treated at doses similar to the pancreatic cancer patients (300 million cells) for a period of time that includes monthly boosters.

As with pancreatic cancer, and most cancers for that matter, stage of diagnosis is heavily correlated with survival. In lung cancer, the overall five-year survival rate is just under 16%, with the highest survival rate – 52% – occurring for patients diagnosed with local disease. This declines to 16% for regional disease and just 2% for those with cancer found at distant sites. Of small cell and non small cell lung cancers, the latter has the greater incidence by far (15% vs. 85%), with greater than 200,000 diagnoses annually. The minority of diagnoses occur at early stage – where the cancer is considered localized – about 15% of the population, or a little over 25,000 patients. The majority of lung cancers are diagnosed when there already has been regional spread (22%) or metastasized (56%).

We have not included any contribution from a HyperAcute NSCLC product in our model, as we do not yet have details of the Phase III clinical program. There are five times the number of NSCLC patients as there are pancreatic cancers, but also more treatment options: NCCN Guidelines recommend 9 adjuvant combination regimens consisting of 15 distinct drugs for the treatment of non-metastatic disease. We do not expect to see contraindications with HyperAcute Lung, and thus the combination opportunity in this disease state is sizable. Importantly, treatment with HyperAcute can be an add-on to standard of care, meaning that a registration study need not prove superiority over the existing standard, but rather incremental improvement.

HyperAcute Melanoma

A third clinical program, HyperAcute Melanoma, is being studied in an investigator-sponsored Phase II trial at Ochsner Cancer Institute in New Orleans, LA. The trial was examining HyperAcute Melanoma, a proprietary mixture of three allogeneic melanoma tumor cell lines modified to express the gene that makes α -galactosyltransferase, given over an eight-week course in combination with PEG-Intron for patients with advanced melanoma. The trial consisted of weekly injections of 50 million cells of HyperAcute Melanoma for weeks 5-12 while co-administered with PEG-Intron. Of 25 patients enrolled in the trial, results for 8 patients with Stage IV melanoma and non-visceral metastases (tumors not found in abdominal organs), show three responders: two complete and one with stable disease. The treatment was well tolerated, and vitiligo was observed in four patients (16%). Vitiligo is thought to be an autoimmune condition aimed at melanocytes, the cells responsible for skin pigmentation. We note that vitiligo was considered a common occurrence in the Yervoy (ipilimumab) clinical trial program but is not particularly common in cancer treatments overall. Yervoy, sold by Bristol-Myers Squibb is an immune system modulator recently approved for the treatment of melanoma, and it is the first agent shown to have an impact on overall survival for this disease.

Melanoma, when found in the latest stages, is a difficult cancer to treat, with five-year survival rates hovering above the 0% mark. Roughly 10% of melanoma diagnoses occur when the disease has spread to the lymph nodes but not yet found in organs of the body, and this is likely the primary population for HyperAcute Melanoma.

HyperAcute Melanoma is an interesting opportunity. Like pancreatic cancer, melanoma is particularly deadly and limited treatment options exist. The approval of Yervoy (ipilimumab) earlier this year was a landmark in that it was the first drug to show an improvement in survival in patients with malignant melanoma (those with unresectable or metastatic melanoma). While a tremendous advance, there is much room for improvement: patients treated with a regimen that included Yervoy plus gp100 (an investigational peptide vaccine) had a median overall survival of 10 months, versus 6 months for the control arm of gp100 alone; an estimated overall survival at one year of 46%, versus 25% in the control arm; and 24% and 14%, respectively, at two years. Yervoy, which is mechanistically different than HyperAcute, was associated with rare but severe and fatal immune-mediated adverse events. This is thought to be due to non-specific activation of T-cells, which is distinct to its mechanism of action (CTLA-4 inhibition).

Our expectations are for HyperAcute Melanoma to enter a IIb trial employing a higher dose (300 million cells) than has been used, and for it to commence in 2012, following patients for 12 months. We expect news on this program in mid-2012.

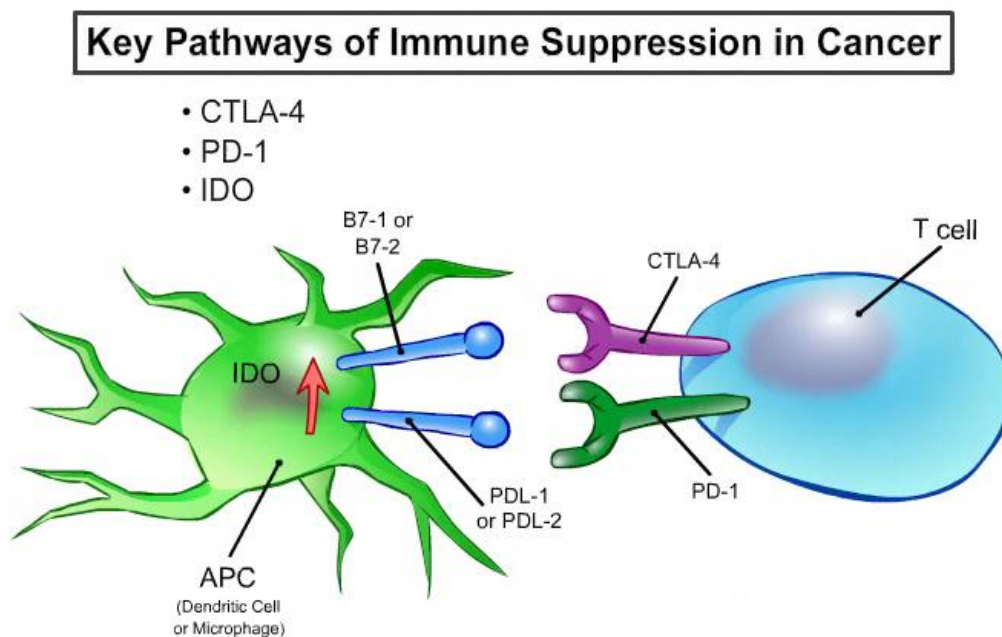
Other HyperAcute Programs

NewLink has a variety of other HyperAcute treatments in earlier stages of development, including HyperAcute Prostate and HyperAcute Breast. However, given the current focus of resources on HyperAcute Pancreas, Lung, and Melanoma we do not expect that there will be substantive news flow over the next 12 months.

IDO Pathway Inhibition

NewLink's second technology platform is based on IDO inhibition. IDO is an enzyme that regulates immune response by suppressing T cell function by breaking down tryptophan, an essential amino acid. This is a "trick" that cancer cells employ to evade the immune system. The IDO pathway is one of three known pathways that are employed by tumor cells to hide from the immune system. IDO, together with CTLA-4 (pathway exploited by Yervoy) and PD-1, promote immune tolerance of cancers. IDO is overexpressed in many cancers, including prostate, colorectal, pancreatic, cervical, endometrial, lung, and bladder, among others.

Exhibit 10: Immune Suppression Pathways



Source: NewLink Genetics

Studies have shown that IDO is found both within tumor cells and within APCs in draining lymph nodes. This is thought to promote peripheral tolerance to tumor-associated antigens (TAAs). When this pathway is exploited by cancer, the result may enhance survival, growth, invasion and metastasis of cells expressing TAAs, and be a primary contributor to tumor tolerance. Recently published work suggests that IDO expression is significantly upregulated in tumors of more advanced stages and with more extensive lymph node metastasis, and correlated to the density of regulatory T cells (Tregs). Tregs act to suppress immune responses to self antigens and have been found in high concentrations in tumors, actively shutting down an immune response to tumors. In a breast cancer model, overexpression of IDO appeared to inhibit local immune response and promote metastasis (Clinical & Development Immunology, 10/2011). Further support for this paradigm is a study published in Nature Medicine earlier this year that states that the immune system contributes to the antitumor effects of Gleevec (imatinib), sold by Novartis through activation of CD8+ T cells and induction of apoptosis of Tregs by reducing tumor expression of the IDO enzyme.

This program is at an earlier stage in development and hence the path forward is less clear. NewLink is examining IDO in combination with other cancer treatments – immunotherapy and conventional chemotherapy. In our opinion, D-1MT (1-methyl-D-tryptophan), NewLink's first candidate from this program, is an interesting approach because it has the potential to be (1) first in class, (2) small molecule/orally bioavailable and (3) an attractive partnering compound. We believe that a key aspect of the development of this program will be managing for off-target effects, as shutting down a pathway that controls immune suppression should allow for activation of T cells, and as with Yervoy, may cause other immune-mediated side effects.

We expect that NewLink will spend roughly \$5 million on this program over the next two years, both on its lead compound and second generation drugs. The path forward is not yet clear, and thus we

would not be surprised to see second-generation compounds ultimately leapfrog D-1MT in clinical trials.

IDO Pipeline

D-1MT is a small molecule, orally bioavailable drug candidate designed to inhibit cell growth via the IDO pathway. NewLink has two ongoing Phase I studies co-sponsored by the National Cancer Institute examining D-1MT in several tumor types, and it plans to initiate a Phase Ib/II study to further characterize the potential of D-1MT in the treatment of cancer. According to NewLink, some serious adverse events have occurred with D-1MT, most notably hypophysitis, an inflammation of the pituitary gland. Additionally, there was one Grade Four report of cerebrovascular stroke and two reports of Grade Three lymphopenia in a combination trial of D-1MT and Ad-p53, an experimental adenoviral immunotherapy. There have been no serious adverse events in the combination trial with Taxotere. We expect that preliminary data from could be forthcoming within the next quarter.

Milestones

One of NewLink's compelling features is the milestone calendar over the next 24 months. We expect some type of clinical announcement from all of the company's clinical trial programs. Given the use of the SPA (special protocol assessment) with the FDA, we expect that upon clinical trial success, FDA review will be expedited. We have not modeled any partnerships into our assumptions, though we note that such news could occur.

Exhibit 11: Milestone Calendar

Candidate	Event	Timeframe
D-1MT	Phase I Preliminary data/p53 study	1Q12
D-1MT	Phase I Preliminary data/taxotere study	1Q12
HyperAcute Lung	Initiate Phase IIB/III	1H12
HyperAcute Melanoma	Phase II update	2H12
HyperAcute Pancreas	1st Interim Analysis	4Q12
HyperAcute Melanoma	Initiate Phase IIB	2H12
2nd Generation IDO	Initiate Phase I	2H12
HyperAcute Pancreas	2nd Interim Analysis	2H13
HyperAcute Pancreas	Complete Enrollment	2013
HyperAcute Lung	1st Interim Analysis	2013

Source: NewLink Genetics, Cantor Fitzgerald estimates

To Partner or Not to Partner?

The age old question in biotechnology, to partner or not? At present, NewLink has not licensed commercial rights to any of its programs. Though cancer vaccines have been a tough sell of late for partnerships, NewLink's technology and straightforward manufacturing could make the program interesting to partners, though we believe that the company is only interested in non-U.S. partnerships. The IDO program may be a different story, however, as the small molecule, orally bioavailable characteristics of D-1MT and next generation compounds could be attractive to larger, commercial companies.

Management

- Charles J. Link, Jr., M.D. founded NewLink in 1999 and has served as Chairman of the Board and Chief Scientific Officer since 1999. Dr. Link also served as President from 2001 to 2009 and has served as Chief Executive Officer since 2003. Dr. Link has been a part-time practicing oncologist at the Medical Oncology and Hematology Associates of Iowa since 1995, one of the largest oncology group practice in Iowa, moving to Iowa to found and direct the John Stoddard Cancer Research Institute, from National Cancer Institute (NCI) and National Institutes of Health (NIH) where he served as a Medical Oncology Clinical Fellow. Through a very advantageous relationship with the Stoddard Cancer Research Institute, Dr. Link was able to transfer technology from the Institute to form the basis of NewLink's HyperAcute platform. The Institute receives a modest royalty and licensing fee in exchange.
- Nicholas N. Vahanian, M.D. has been NewLink's Chief Medical Officer since 2001, Chief Operations Officer since 2003 and President since 2009. Dr. Vahanian served as a research scientist at the NCI from 1992 to 1994 and at the National Center for Human Genome Research, NIH from 1994 to 1995. Dr. Vahanian completed a Molecular Oncology Fellowship at the John Stoddard Cancer Research Institute in 2000, and moved to NewLink shortly thereafter. Dr. Vahanian holds a B.S. in Biology from Virginia Commonwealth University. Dr. Vahanian attended St. Bartholomew's and Royal London Hospital Medical College, and also holds an M.B.A. from the University of Notre Dame.
- Gordon H. Link, Jr. (no relationship to Dr. Link) has served as NewLink's Chief Financial Officer since 2008. Previously, Mr. Link worked for Tapestry Pharmaceuticals as Chief Executive Officer from April to July 2008, Senior Vice President and Chief Financial Officer from 2002 through 2008, President of the Genomics Division from 2000 to 2002 and Vice President and Chief Financial Officer from 1993 to 2002. Prior to joining Tapestry, Mr. Link served as Corporate Controller of Synergen, Inc., Treasurer of the Syntex-Synergen Neuroscience Joint Venture, Treasurer of Synergen Development Corporation and Audit Manager with Deloitte & Touche USA LLP. Mr. Link received a B.S. from Rensselaer Polytechnic Institute and a B.A. in accounting from Metropolitan State College.

Financial Performance and Outlook

NewLink is a development stage company and has only recognized losses through its history. The company has not recorded profit since its inception, with an accumulated deficit in excess of \$71 million. Expenditures on HyperAcute and IDO technology platforms have totaled \$37.9 million and \$9.6 million, respectively. We expect losses to continue through the launch of the company's first product, which we anticipate will be HyperAcute Pancreas in late 2015. Over the next two years, we expect that the company will utilize the net proceeds of its initial public offering (\$37.5 million) to fund research, clinical trials, additional manufacturing, and internal infrastructure and administration. Based on a potential launch of HyperAcute Pancreas in late 2015, we believe the company could be profitable in 2016. This is based on the economics of the HyperAcute program and the advantageous cost structure of the company. We have made the following assumptions:

- HyperAcute Pancreas is launched in late 2015 and is priced in line with current biological cancer treatments, around \$63,000 per year.
- HyperAcute Pancreas has conventional biological gross margin.
- NewLink conducts a secondary equity offering to continue to fund R&D.

- The Iowa Department of Economic Development (IDED) continues to defer the company's \$6.0 million forgivable loan annually (dating from March 2005). This loan was in exchange for the pledge to create 315 positions and retain 35 positions with an agreed upon prespecified total project spend.
- BioProtection Systems Corporation (BPS), a separate company with origins within NewLink continues to carry out work in support of infectious disease vaccine programs under grant agreement with the Department of Defense, and those activities are conducted by NewLink and reimbursed through BPS.

In projecting revenue and earnings for NewLink, we base our market acceptance on trajectories that we have seen for innovative biological products, such as Yervoy, Soliris (eculizumab) sold by Alexion, Gleevec (imatinib) and others. Because of the relatively straightforward manufacturing process for HyperAcute and the limited medical options for a pancreatic cancer therapeutic, it is our belief that a successful Phase III clinical trial will facilitate broad market acceptance. Embedded in our assumptions is likelihood that HyperAcute will be a well-tolerated therapeutic, as prior clinical data suggests this to be the case. The most common adverse event appears to be injection site reaction, which is common among immunotherapy products.

Our model assumes that HyperAcute Pancreas will be commercially available at the end of 2015, and quickly ramp up. This is based on our assessment of the willingness to adopt new products in this market and the likelihood of having adequate supply at and through launch. We further assume that NewLink will seek to market this product on its own, as the target market is relatively modest and can be easily reached in a cost effective manner. We have not included any revenues from a potential partnership, which the company has expressed interest in forming for non-U.S. territories.

We anticipate that NewLink could be profitable within 12 months of launch of HyperAcute Pancreas. This is based on our view that HyperAcute Pancreas will be enthusiastically embraced by the medical community, that the product will be priced competitively with existing biological agents, and that NewLink's cost infrastructure is modest and allows for early and significant net income growth.

Valuation

We examined several factors in arriving at a valuation for NewLink. Though valuations of immunotherapy companies have contracted in sympathy with the commercial concerns of Provenge, there are distinct differences between cancer immunotherapy companies that should allow for divergent valuations. The late stage of HyperAcute Pancreas combined with its promise of being a game changer in this disease, plus NewLink's modest cost structure, suggest the potential for rapid growth. In valuing NewLink, we looked at discounted forward earnings calculation and EV, examining a variety of stocks with similar characteristics as NewLink.

1. We employed a discounted present value earnings calculation of EPS of \$2.26 in 2016, a multiple on those earnings of 40x, discounted by 50%, suggesting an \$11.91 price target (70+% upside from close price as of December 20, 2011). We have used a multiple on 2016 EPS consistent with valuation for early stage biotechnology companies, which range from 30-50x forward EPS, reflecting the opportunity for rapid growth. In arriving at this range, we explored historical data as well as forward consensus multiples for companies with newly launched products, such as Seattle Genetics, Incyte, Regeneron, Vertex, and Optimer. We also used an aggressive discount rate that is meant to capture the inherent uncertainty in drug development.
2. We also reviewed EV for several companies working in immunotherapy. Based on the current close price on December 20, 2011, NewLink's EV is below peers (107 vs. 235) and is trading at a discount to this group's multiple of a cash (19%).

Exhibit 12: Selected Immunotherapy Cancer/Vaccine Companies

Company (rank by market cap)	Price (a)	Market Cap	EV	Price/Cash
Micromet (MITI)	6.90	631.4	444.1	3.4
Oncothyreon (ONTY)	7.71	345.4	290.8	5.8
Vical (VCAL)	4.55	335.3	282.7	6.2
Celldex (CLDX)	2.80	105.0	49.4	1.4
NewLink Genetics (NLNK)	7.00	143.5	106.7	3.3
Average	NM	3121	234.8	4.1
Premium/Discount to Average	NM	-54.0%	-54.54%	-18.8%

(a) Prices as of close 12/19/11

Source: Thomson Reuters, Cantor Fitzgerald, the companies

Risks

NewLink is a development stage company and investment is subject to risk. These risks include but are not limited to:

- Development of new drugs carries a high failure rate, either because the drug in question fails to show efficacy, or significant safety issues arise during the clinical trial process. Additionally, regulatory authorities such as the FDA (Food & Drug Administration) may delay the approval process or reject NewLink's clinical findings. Because we can never dismiss such a possibility, we use a high discount rate in our valuation model to compensate for such risk. We note that NewLink's HyperAcute Pancreas program is being conducted under an SPA (special protocol assessment), and while it is not a guarantee that the FDA will endorse NewLink's data, it mitigates risk against the FDA disputing the company's clinical trial design.
- Some of NewLink's clinical programs are being co-sponsored by the NCI and in investigator-initiated clinical trials, which means that the company does not have full control over the conduct of the trials or the release of data, and this may impact trial results and/or milestones as it relates to public disclosure of clinical data.
- NewLink's manufacturing process has been validated in its early clinical trial work. However, we cannot exclude the possibility that this process may not be seamless from clinical trials to commercialization.
- The company has \$6 million in outstanding debt under a forgivable loan agreement with the Iowa Department of Economic Development, of which \$4.7 million may be accelerated and require repayment as early as March 18, 2012. Though we expect that the Iowa Department of Economic Development will continue to defer repayment of principal until such time that NewLink is in a cash flow positive position, we cannot exclude the possibility that repayment may be required sooner.
- The clinical landscape is crowded with hundreds of oncology clinical trials. It is possible that other technologies show greater benefit to patients than NewLink's product candidate, thus rendering potential products obsolete or non-competitive. However, a review of clinical trials in pancreatic cancer, which NewLink's latest stage product is addressing, reveals that NewLink's focus in early stage disease is not as competitive as the overall category.
- NewLink has a large intellectual property estate protecting its technology, know-how and applications of such. However, it is always possible that a party will bring forward infringement claims that would need to be heard by a court.

- NewLink has a history of net losses, including net losses of \$12.3 million and \$12.2 million for the nine months ended September 30, 2011 and 2010, respectively. We are forecasting profitability for NewLink in 2016 based on market acceptance of HyperAcute Pancreas, but profitability could be delayed or not reached at all, depending on a variety of clinical and regulatory factors.
- NewLink has a patent estate covering its development programs and continues file additional patents to support its intellectual property. The company's patents or those that is has licensed could be challenged by a competitor or the company could fail in securing new patents, though this is a risk industry-wide.

Exhibit 13: Annual Income Statement
NewLink Genetics Corporation

<i>All figures in millions, Year Ended 31 December</i>	2016E	2015E	2014E	2013E	2012E	2011E	2010A	2009A
Revenue	\$270.00	\$28.95	\$0.65	\$1.01	\$1.26	\$1.95	\$2.08	\$0.93
Cost of Goods Sold	76.34	15.33	0.00	0.00	0.00	0.00	0.00	0.00
Gross Profit	\$193.66	\$13.62	\$0.65	\$1.01	\$1.26	\$1.95	\$2.08	\$0.93
<i>Gross Profit Margin</i>	<i>71.73%</i>	<i>47.05%</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>
Operating Expenses								
SG&A	72.65	41.18	27.51	18.16	12.65	5.23	6.07	3.71
R&D	54.31	42.25	37.74	28.66	23.62	14.23	12.67	7.58
Total Operating Expenses	\$126.96	\$83.43	\$65.25	\$46.82	\$36.27	\$19.46	\$18.74	\$11.28
Profit (Loss) from Operations	\$66.70	(\$69.81)	(\$64.60)	(\$45.81)	(\$35.01)	(\$17.51)	(\$16.66)	(\$10.35)
<i>Operating Profit Margin</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>
Other Income (Expense)	\$1.15	\$0.75	(\$0.03)	(\$0.00)	\$0.01	(\$0.03)	\$0.10	\$0.14
Pretax Income	\$67.85	(\$69.06)	(\$64.63)	(\$45.81)	(\$35.00)	(\$17.54)	(\$16.56)	(\$10.21)
<i>Pretax Margin</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>
Net loss attributable to noncontrolling interest	0.00	0.00	0.00	0.00	0.00	0.00	0.35	0.23
Net Income (Loss)	\$67.85	(\$69.06)	(\$64.63)	(\$45.81)	(\$35.00)	(\$17.54)	(\$16.21)	(\$9.97)
<i>Net Margin</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>
Basic & Diluted Net Loss Per Share	\$2.26	(\$2.51)	(\$2.62)	(\$2.07)	(\$2.39)	(\$2.73)	(\$4.84)	(\$3.16)
<i>Shares Outstanding</i>	<i>30.00</i>	<i>27.50</i>	<i>24.65</i>	<i>22.08</i>	<i>14.66</i>	<i>6.44</i>	<i>3.35</i>	<i>3.16</i>

<i>Percent Change, Year-Over-Year</i>	2016E	2015E	2014E	2013E	2012E	2011E	2010A	2009A
<i>Revenue</i>	832.61%	4354.09%	-35.64%	-19.84%	-35.42%	-6.16%	122.59%	47.55%
<i>SG&A</i>	76.42	49.69	51.49	43.56	141.74	(13.85)	63.94	(5.92)
<i>R&D</i>	28.54	11.95	31.68	21.34	66.03	12.32	67.14	30.88
<i>Operating Expenses</i>	52.18	27.86	39.36	29.09	86.39	3.84	66.09	15.98
<i>Other Income, net</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>

Source: NewLink Genetics, Cantor Fitzgerald estimates

Exhibit 14: Sales & Earnings by Quarter

NewLink Genetics Corporation														
All figures in millions, Year Ended 30 June	2011E	4Q11E	9Mos11A	3Q11A	6Mos11A	2Q11A	1Q11A	2010A	4Q2010A	9Mos10A	3Q10A	6Mos10A	2Q10A	1Q10A
Revenue	\$1.95	\$0.38	\$1.57	\$0.43	\$1.14	\$0.54	\$0.60	\$2.08	\$0.97	\$1.11	\$0.38	\$0.73	\$0.41	\$0.32
Cost of Goods Sold	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Gross Profit	\$1.95	\$0.38	\$1.57	\$0.43	\$1.14	\$0.54	\$0.60	\$2.08	\$0.97	\$1.11	\$0.38	\$0.73	\$0.41	\$0.32
Gross Profit Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Operating Expenses	Exhibit 16: Pancreatic Cancer Model													
SG&A	5.23	1.68	3.55	1.10	2.45	1.14	1.32	6.07	2.25	3.82	1.54	2.28	1.54	0.74
R&D	14.23	3.95	10.28	3.30	6.98	3.80	3.18	12.67	3.02	9.64	3.95	5.70	2.83	2.87
Total Operating Expenses	\$19.46	5.63	\$13.83	4.40	\$9.43	\$4.93	4.50	\$18.74	\$5.27	\$13.47	5.49	\$7.98	\$4.37	\$3.61
Profit (Loss) from Operations	(\$17.51)	(\$5.25)	(\$12.26)	(\$3.97)	(\$8.29)	(\$4.39)	(\$3.89)	(\$16.66)	(\$4.30)	(\$12.36)	(\$5.11)	(\$7.25)	(\$3.96)	(\$3.29)
Operating Profit Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Other Income (Expense)	(\$0.03)	(0.01)	(\$0.02)	(0.01)	(\$0.01)	\$0.00	(0.01)	\$0.10	\$0.04	\$0.01	0.05	\$0.01	(\$0.00)	\$0.02
Pretax Income	(\$17.54)	(\$5.26)	(\$12.28)	(\$3.99)	(\$8.29)	(\$4.39)	(\$3.90)	(\$16.56)	(\$4.26)	(\$12.35)	(\$5.07)	(\$7.24)	(\$3.97)	(\$3.27)
Pretax Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Net loss attributable to noncontrolling interest	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.35	0.16	0.19	0.04	0.15	0.11	0.04
Income Tax Paid (Benefit)	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Net Income (Loss)	(\$17.54)	(\$5.26)	(\$12.28)	(\$3.99)	(\$8.29)	(\$4.39)	(\$3.90)	(\$16.21)	(\$4.10)	(\$12.16)	(\$5.03)	(\$7.09)	(\$3.85)	(\$3.23)
Net Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Basic & Diluted Net Loss Per Share	(\$2.73)	(\$0.36)	(\$3.36)	(\$1.09)	(\$2.28)	(\$1.20)	(\$1.07)	(\$4.84)	(\$1.12)	(\$3.81)	(\$1.49)	(\$2.23)	(\$1.21)	(\$2.70)
Average Shares Outstanding	6.44	14.80	3.65	3.66	3.64	3.65	3.64	3.35	3.64	3.20	3.37	3.20	3.20	1.20

Source: NewLink Genetics, Cantor Fitzgerald estimates

Exhibit 15: Pancreatic Cancer Model

NewLink Genetics Corporation						
<i>(\$ in millions)</i>	2014E	2015E	2016E	2017E	2018E	2019E
Number of diagnoses (US)	45,769	46,341	46,341	46,920	47,507	48,101
% Stage I	8.0%	8.0%	8.0%	8.0%	8.0%	8.0%
<i>% treated</i>	<i>0.0%</i>	<i>1.2%</i>	<i>4.8%</i>	<i>7.0%</i>	<i>7.4%</i>	<i>7.5%</i>
# treated	0.00	556	2,224	3,303	3,497	3,617
% Stage II	27.0%	27.0%	27.0%	27.0%	27.0%	27.0%
<i>% treated</i>	<i>0.0%</i>	<i>1.4%</i>	<i>5.9%</i>	<i>9.5%</i>	<i>12.4%</i>	<i>15.9%</i>
# treated	0.00	626	2,753	4,434	5,900	7,662
Total Treated	0.00	1,182	4,977	7,737	9,397	11,280
Average Injections/year/patient	0	7	15.5	15.7	16.1	16.4
Cost of injection	\$0	\$3,500	\$3,500	\$3,500	\$3,500	\$3,500
Cost per year	\$0	\$24,500	\$54,250	\$55,118	\$56,275	\$57,514
Total sales	\$0.0	\$29.0	\$270.0	\$426.5	\$528.8	\$648.7
Percent Change, year-over-year						
Diagnoses	1.30%	1.30%	1.25%	1.25%	1.25%	1.25%
Stage I - % treated	NA	NA	300.00	48.50	5.85	3.45
Stage II - % treated	NA	NA	340.00	61.08	33.07	29.86
Total treated	NA	NA	321.18	55.46	21.45	20.04
Average Injections/year/patient	NA	NA	NA	1.60	2.10	2.20
Annual cost	NA	NA	NA	0.00	0.00	0.00
Total sales	NA	NA	832.61	57.94	24.00	22.68



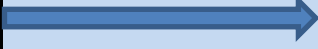




Source: NewLink Genetics, American Cancer Society, CMS, Cantor Fitzgerald estimates

Exhibit 16: Current Balance Sheet
NewLink Genetics Corporation

<i>All figures in millions, Year Ended 31 December</i>	3Q11A	2010A	% Chg:Q/Y	2009A	% Chg:Y/Y
Assets					
Cash & cash equivalents	\$6.29	\$10.57	-40.5%	\$15.22	-30.5%
Marketable securities	0.00	2.27	(100.0)	1.99	13.9
Prepaid expenses	2.00	0.96	108.2	0.11	771.8
State R&D credit receivable	Exhibit 16: F	0.23	#VALUE!	0.17	35.3
Interest receivable	0.00	0.01	(100.0)	0.07	(88.2)
Other receivable	0.46	0.60	(24.2)	1.34	(55.0)
Total current assets	\$8.74	\$14.64	-40.3%	\$18.90	-22.5%
Leasehold improvements & equipment, net	5.09	5.44	(0.06)	2.92	0.86
Leasehold improvements	3.80	3.80	0.0	2.29	65.9
Computer equipment	0.70	0.69	1.9	0.43	60.7
Lab equipment	3.33	3.17	5.1	1.77	79.3
Less accumulated D&A	(2.74)	(2.22)	NM	(1.57)	NM
Notes receivable from related parties	0.00	0.00	NM	0.85	NM
Total assets	\$13.83	\$20.08	-31.1%	\$22.67	-11.4%
Liability & Shareholder Equity					
Accounts payable	\$0.26	\$0.55	-53.6%	\$1.08	-48.9%
Accrued expenses	1.69	1.55	8.9	1.18	32.1
Deferred rent	0.92	0.95	(3.0)	0.95	0.4
Notes payable to Iowa Dept. of Economic Dev.	6.00	0.00	NM	0.00	NM
Obligations under capital lease	0.13	0.12	12.1	0.04	231.4
Current portion of long term debt	0.09	0.09	2.2	0.00	NM
Deposits on restricted shares	0.00	0.00	NM	0.00	NM
Total current liabilities	\$9.09	\$3.27	178.5	\$3.24	0.7
Notes payable to Iowa Dept. of Economic Dev.	0.00	6.00	(100.0)	6.00	0.00
Notes payable to Iowa State University Res. Park	0.57	0.64	(11.1)	0.00	NM
Notes payable to City of Ames	0.30	0.30	0.0	0.00	NM
Obligations under capital lease	0.12	0.15	(19.3)	0.08	85.9
Total liabilities	\$10.08	\$10.35	-2.6%	\$9.32	11.1%
Stockholders' equity					
Redeemable preferred stock	\$75.27	\$61.75	21.9%	\$54.13	14.1%
Series A preferred stock	1.03	1.03	0.0	1.03	0.0
Common stock	0.04	0.04	2.8	0.03	12.5
Additional paid-in capital	3.22	7.37	(56.4)	3.01	144.7
Notes receivable for common stock	0.00	(0.01)	(100.0)	(0.04)	(65.8)
Deficit accumulated during development stage	(75.67)	(63.39)	19.4	(47.18)	34.4
Equity attributable to noncontrolling interests	0.00	2.94	(100.0)	2.35	25.1
Total stockholders' equity	\$3.89	\$9.73	-60.0%	\$13.35	-27.1%
Total liabilities & stockholders' equity	\$13.97	\$20.08	-30.4%	\$22.67	-11.4%

Source: NewLink Genetics

Exhibit 17: R&D Pipeline

Product Name	Description/Indication	Core Technology	Phase of Development				Comments
			PreClinical	Phase I	Phase II	Phase III	
HyperAcute Pancreas	Allogenic vaccine/resectable pancreatic cancer	HyperAcute					722-patient trial, >200 enrolled, interim look 4Q12
HyperAcute Lung	Allogenic vaccine/NSCLC	HyperAcute					Data expected 1H12, Phase II/III expected 1H12
HyperAcute Melanoma	Allogeneic vaccine/non-visceral metastatic melanoma	HyperAcute					Data expected, likely next step is Phase II/III in 2H12
HyperAcute Prostate	Allogeneic vaccine/prostate cancer	HyperAcute					Possible partnering candidate
HyperAcute various	Exhibit 16: Pancreatic Cancer Model	HyperAcute					May explore NCI funding
D-1MT	Small molecule inhibitor of IDO/solid tumors	IDO pathway inhibitor					NCI-funded Phase II studies, preliminary data expected
2nd generation IDO	Small molecule inhibitor of IDO/solid tumors	IDO pathway inhibitor					Higher potency vs. D-1MT

Source: NewLink Genetics, Cantor Fitzgerald

Exhibit 18: Companies Mentioned

Company Name	Ticker	Exchange	Cantor Rating
Alexion	ALXN	NASDAQ	NC
Bristol-Myers Squibb	BMY	NYSE	NC
Celldex	CLDX	NASDAQ	NC
Dendreon	DNDN	NASDAQ	NC
Incyte	INCY	NASDAQ	NC
Micromet	MITI	NASDAQ	NC
NewLink Genetics	NLNK	NASDAQ	BUY
Novartis	NVS	NYSE	NC
Oncothyreon	ONTY	NASDAQ	NC
Optimer	OPTR	NASDAQ	NC
Regeneron	REGN	NASDAQ	NC
Seattle Genetics	SGEN	NASDAQ	NC
Vertex	VRTX	NASDAQ	NC
Vical	VICL	NASDAQ	NC

Source: Cantor Fitzgerald, Thomson Reuters

Disclosures Appendix

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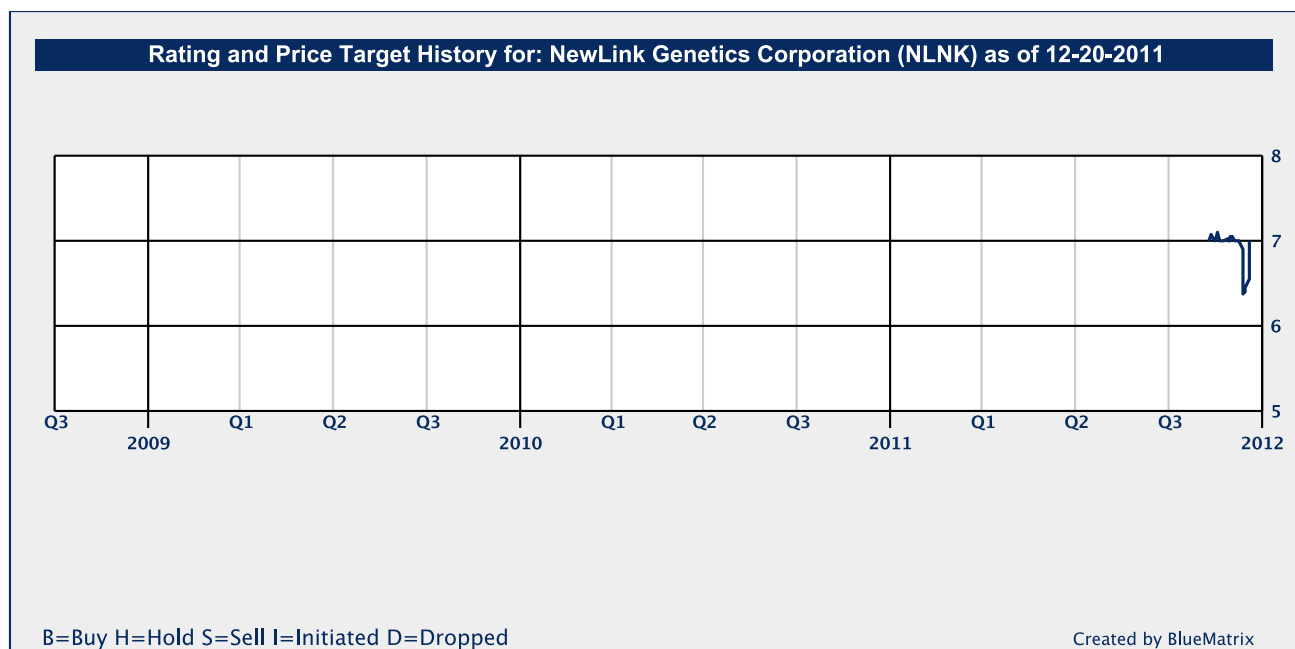
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