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May 3, 2011

United States Securities and Exchange Commission Division of Corporate Finance Mail Stop 4720 100 F Street, N.E. Washington, D.C. 20549 Attn: Jeffrey Riedler Staci Shannon Lisa Vanjoske Jennifer Riegel Daniel Greenspan

# Re: NewLink Genetics Corporation Registration Statement on Form S-1 (File No. 333-171300)

Dear Mr. Riedler, Ms. Shannon, Ms. Vanjoske, Ms. Riegel and Mr. Greenspan:

In connection with the Registration Statement on Form S-1 (the "*Registration Statement*") of our client NewLink Genetics Corporation ("*NewLink*" or the "*Company*") originally filed with the Securities and Exchange Commission (the "*Commission*") on December 21, 2010, and amended by Amendment No. 1 the Registration Statement ("*Amendment No. 1*") originally filed with the Commission on February 28, 2011 and Amendment No. 2 the Registration Statement ("*Amendment No. 2*") originally filed with the Commission on March 18, 2011, please find attached the Company's responses to comments received from the staff of the Commission (the "*Staff*") by letter dated March 30, 2011 with respect to Amendment No. 2 (the "*Comment Letter*"). The numbering of the paragraphs below corresponds to the numbering in the Comment Letter, the text of which we have incorporated into this response letter for convenience. Except where otherwise indicated, page references in the text of the responses below correspond to the page numbers of Amendment No. 2. The Company's proposed revisions to disclosure as contained in this response are focused on the Company's reporting as of December 31, 2010. Should the Company's December 31, 2010 financial statements become stale, proposed revisions will be updated to incorporate the Company's reporting requirements as of the appropriate interim period.

# **Staff Comments and Company Responses**

<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> <u>Critical Accounting Policies and Significant Judgments and Estimates</u> <u>Stock-Based Compensation</u> <u>Stock Option Valuation, page 57</u>

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1. Please tell us whether the Black-Scholes model assumptions disclosed on page 57 are related to GAAP grants in the respective periods presented. For example, the upper end of the exercise price ranges in the table appears to be related to subsequent period grants (i.e., for 2009, \$1.41 is related to a 2010 GAAP grant and for 2010, \$3.41 is related to a 2011 GAAP grant). Please revise your disclosure as appropriate, and tell us whether this has any impact on your compensation expense recorded in the periods presented in accordance with GAAP.

**Response:** The Company acknowledges the Staff's comment and respectfully submits the information related to the Black-Scholes model assumptions as disclosed on page 57 of Amendment No. 2 were related to grants with grant dates that occurred in the respective calendar years even though the measurement date under GAAP occurred later. The Company intends to revise these disclosures as set forth below in the Company's next amendment to the Registration Statement, which will conform the information included in the disclosure to the GAAP measurement dates of the applicable grants and be equivalent to the disclosures in the financial statements with respect to such grants. The change in these disclosures had no impact on the Company's compensation expense recorded in the periods presented in accordance with GAAP.

In the next amendment to the Registration Statement, the Company intends to revise the disclosure as follows:

# **Proposed Revision:**

		Year Ended			
	2008		2009	2010	
Exercise price	\$1.00	\$	1.00	\$1.41 - \$1.91	
Expected volatility	52.0% - 52.1%		44.7%	57.4% - 62.5%	
Expected term (in years)	5.5 – 7.5		7.5	5.0 - 7.5	
Risk-free interest rate	1.5%-3.3%		1.6%	2.3% - 3.5%	
Expected dividend yield	0.0%		0.0%	0.0%	

<u>Common Stock Fair Value</u> <u>Fair Value Estimates, page 61</u> 2. Refer to your response to prior comment two. It remains unclear why the GAAP measurement date has not yet occurred for the options granted in November and December 2010. It appears the fair value of your common stock as of December 31, 2010 has already been determined per your disclosure on page 62. Please tell us how you are able to disclose the fair value of your common stock as of December 31, 2010 without the completion and approval for the December 31, 2010 common stock valuation report, and address why the GAAP measurement date has not yet occurred given the common stock fair value appears to be have already been determined.

**Response:** The Company acknowledges the Staff's comment and respectfully submits that the GAAP Measurement Date of the options in question had not occurred at the time of filing Amendment No. 2. The GAAP Measurement Date requires a mutual understanding of the terms of the award, including the exercise price. The Company's past practice has been to treat

the date of the formal approval and acceptance of the applicable valuation report as determinative of final exercise price for stock options because the exercise price of the Company's option awards is not finally determined until the Company's Board of Directors (the "Board") receives and approves the relevant valuation report prepared by the Mentor Group, Inc. ("Mentor"). Prior to that approval, the exact exercise price of the options had not yet been finally determined and, therefore, could not have been the subject of a mutual understanding.

The exercise price was determined at the April 14, 2011 meeting of the Board when the valuation performed by Mentor as of December 31, 2010 was approved. The disclosure of the fair value of the common stock of the Company as of December 31, 2010, at page 62 of Amendment No. 2, was based on the content of the Mentor report dated February 28, 2011.

In the next amendment to the Registration Statement, the Company intends to revise the disclosure as follows:

# **Proposed Revision:**

### **Options Granted on Shares of Common Stock**

GAAP Measurement Date(2)	Number of shares	Exercise price per share	Common Stock values	Intrinsic value per share
September 2, 2009	364,000	1.00	0.95	0
September 2, 2009	490,000	1.00	0.95	0
September 2, 2009	2,267,000	1.00	0.95	0
March 3, 2010	1,706,500	1.41	2.02	0.61
June 2, 2010	1,005,250	1.46	2.08	0.62
October 8, 2010	13,000	1.91	2.25	0.34
January 19, 2011	26,500	3.41	4.02	0.61
April 14, 2011	25,000	4.77	4.77	0
April 14, 2011	160,000	4.77	4.77	0
	Measurement Date(2)           September 2, 2009           September 2, 2009           September 2, 2009           March 3, 2010           June 2, 2010           October 8, 2010           January 19, 2011           April 14, 2011	Measurement Date(2)         of shares           September 2, 2009         364,000           September 2, 2009         490,000           September 2, 2009         2,267,000           March 3, 2010         1,706,500           June 2, 2010         1,005,250           October 8, 2010         13,000           January 19, 2011         26,500           April 14, 2011         25,000	Measurement Date(2)of sharesprice per shareSeptember 2, 2009364,0001.00September 2, 2009490,0001.00September 2, 20092,267,0001.00March 3, 20101,706,5001.41June 2, 20101,005,2501.46October 8, 201013,0001.91January 19, 201126,5003.41April 14, 201125,0004.77	Measurement Date(2)of sharesprice per shareStock valuesSeptember 2, 2009364,0001.000.95September 2, 2009490,0001.000.95September 2, 20092,267,0001.000.95March 3, 20101,706,5001.412.02June 2, 20101,005,2501.462.08October 8, 201013,0001.912.25January 19, 201126,5003.414.02April 14, 201125,0004.774.77

3. Refer to your response to prior comment two. The assumptions utilized in your Black-Scholes model in order to determine compensation expense should be timely, including the fair value of your common stock. Please revise your financial statements and disclosure to use the fair value of your common stock on the GAAP measurement date.

**Response:** The Company acknowledges the Staff's comment and respectfully submits the compensation expense as recorded in the periods presented in accordance with GAAP is materially correct.

The share-based compensation expense recognized by the Company's subsidiary, BioProtection Systems Corporation, was \$19,400 and \$19,700 for the years ended December

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31, 2009 and 2010, respectively, and is therefore immaterial to the Company as a whole. Therefore, the remainder of this analysis is focused exclusively on NewLink.

The Company has reviewed the assumptions utilized in its Black-Scholes model to assess the related financial impact of potential differences in the fair value of common stock for all option grants issued by NewLink subsequent to the adoption of SFAS No. 123R. This review included consideration of differences in fair value which resulted from NewLink's policy for measuring the grant date fair value of awards based on the common stock fair market value according to the most current valuation report that was available and approved by the Board after the approval of the award. The Company believes that any adjustment based on these differences would be immaterial, both quantitatively and qualitatively.

Quantitatively, the adjustment would be immaterial. The increase in compensation expense for awards under the Company's revised assumptions was approximately \$56,000 and \$82,000 for 2009 and 2010, respectively. This change would generate a 0.6% and 0.5% increase in net loss for 2009 and 2010, respectively, and a 0.5% and 0.3% increase in operating expenses for 2009 and 2010, respectively.

Qualitatively this adjustment does not affect the financial statement elements most important to current financial statement users and would therefore also be immaterial. At the Company's current stage of development, the major users of the Company's financial statements include investors (including option holding employees) and the Iowa Department of Economic Development. Potential users would include vendors and any investors relying on disclosure in the form S-1 when making a purchase decision in an eventual IPO. As NewLink is a development stage drug development company and has no meaningful current revenue or net income stream, each of these constituencies will generally focus on scientific (including clinical) development of the Company's core technologies and the market potential of these technologies and secondarily focus on the company's cash position, how it is capitalized, the experience of the

management team and how are they compensated, including their incentives to share in the long-term growth objectives of the Company. This focus leads the constituencies to be more concerned about possible future dilution from (number of shares) as opposed to the pricing or value of options and to be more focused on cash flows and cash balances as opposed to non-cash expenses and net loss.

### <u>Loan Agreements</u>

March 2005 Iowa Department of Economic Development Loan, page 66

4. We have reviewed your response to prior comment 4. Please expand your disclosure to disclose that the Iowa Department of Economic Development has communicated to you that they have agreed to extend the project completion date from March 18, 2011 to March 18, 2012, but this agreement has not been documented in writing.

**Response:** The Company acknowledges the Staff's comment and both the City of Ames and the Iowa Department of Economic Development have signed the extension. The extension will be filed with the next amendment to the Registration Statement.

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Index to Financial Statements Notes to Consolidated Financial Statements 2. Significant Accounting policies (j) Pro Forma Stockholders' Equity, page F-12

5. Refer to your response to prior comment eight and your disclosure that pro forma equity, pro forma net loss per share and weighted-average pro forma shares outstanding include the effect of this transaction as if it occurred on December 31, 2010. Please note that pro forma adjustments to the income statement should be reflected as of the beginning of the period presented, and therefore, your pro forma net loss per share and weighted average pro forma shares outstanding should include the pro forma related to the series E preferred shares as of January 1, 2010.

**Response:** The Company acknowledges the Staff's comment and in the next amendment to the Registration Statement intends to revise the disclosures on page F-12, note 2(j) of Amendment No. 2 to include the pro forma related to the Series E Preferred shares as of January 1, 2010 in the Company's pro forma net loss per share and weighted average pro forma shares outstanding, as follows:

# **Proposed Revision:**

# (j) Pro Forma Stockholders' Equity (Unaudited)

In October 2010, the Company's Board of Directors authorized the filing of a registration statement with the Securities and Exchange Commission (SEC) to sell shares of its common stock to the public in an IPO. The Company filed an initial S-1 registration statement with the SEC on December 21, 2010. All of the Company's convertible preferred stock outstanding at December 31, 2010 will convert into 16,375,568 shares of common stock upon completion of the IPO. The Company's Series AA, AAA, B, BB, C and D convertible preferred stock have a current conversion ratio of one share of common stock for every share of convertible preferred stock. The Company's Series A convertible preferred stock has a current conversion ratio of 1.389 shares of common stock for every share of convertible preferred stock. The Company's Series E preferred stock will convert into the number of shares of common stock obtained by dividing \$31.25 by the Series E conversion price. The Series E conversion price is currently \$6.25 and the number of common shares issuable upon conversion in an IPO has been calculated based on this price. If the Company closes this initial public offering on or before September 1, 2011 resulting in gross proceeds of at least \$20 million to the Company (prior to underwriting discounts and commissions), the Series E conversion price will automatically be adjusted to a price equal to the product of (A) the price at which shares of common stock are sold to the public in this initial public offering and (B) 0.85 (as adjusted appropriately to reflect any adjustments to the Series E conversion price occurring prior to any such adjustment occurring in connection with this initial public offering). Because the number of common shares that will be issued upon conversion of the Series E preferred stock depends upon the initial public offering price per share in this offering, the actual number of common shares issuable upon such conversion will likely differ from the respective number of shares set forth above. Pro forma equ

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forma net loss per share and weighted-average pro forma shares outstanding include the effect of this transaction as if it occurred on January 1, 2010.

6. Refer to your response to prior comment eight. Please revise your pro forma equity at December 31, 2010 on page F-4, to reflect the pro forma adjustment for the automatic conversion of your series preferred into common stock immediately upon the closing of the IPO.

**Response:** The Company acknowledges the Staff's comment and in the next amendment to the Registration Statement intends to revise its disclosure on pages F-4 and F-5 of Amendment No. 2 to reflect the pro forma adjustment for the automatic conversion of the series preferred into common stock immediately upon the closing of the IPO, as follows:

# **Proposed Revision:**

	Pro forma
	Equity at
	December
	31, 2010
Redeemable preferred stock, \$0.01 par value:	

Authorized shares — 14,327,777 at December 31, 2009 and 15,327,777 at December 31, 2010 and December 31, 2010 pro forma; issued and outstanding shares — 13,200,436 at December 31, 2009, 13,417,435 at December 31, 2010 and 0 at December 31, 2010 pro forma; liquidation preference of \$54,136 at December 31, 2009, \$61,782 at December 31, 2010 and \$0 December 31, 2010 pro forma

#### Equity:

Blank check preferred stock, \$0.01 par value: Authorized shares — 1,388,889 at December 31, 2009 and 2010 and December 31,

2010 pro forma; issued and outstanding shares — 0 at December 31, 2009 and 2010 and December 31, 2010 pro forma	
Series A preferred stock, \$0.01 par value: Authorized shares — 450,000 at December 31, 2009 and 2010 and December 31, 2010 pro	
forma; issued and outstanding shares — 420,000 at December 31, 2009 and 2010 and 0 at December 31, 2010 pro forma;	
liquidation preference — \$1,050,000 at December 31, 2009 and 2010 and \$0 at December 31, 2010 pro forma	
Common stock, \$0.01 par value: Authorized shares — 32,000,000 at December 31, 2009 and 38,833,334 at December 31, 2010 and	
December 31, 2010 pro forma; issued and outstanding shares — 6,671,401 at December 31, 2009 and 7,618,973 at December 31,	
2010 and 23,994,541 at December 31, 2010 pro forma	240
Additional paid-in capital	72,267
Note receivable for common stock	(13)
Deficit accumulated during the development stage	(62,707)
Total NewLink Genetics shareholders' equity	9,787
Equity attributable to noncontrolling interests	
Total equity	9,787

The Company proposes the following revision to its pro forma net loss per share and pro forma weighted average shares outstanding disclosure on page F-5 of Amendment No. 2:

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Pro forma net loss per share, basic and diluted (unaudited) (note 2)	(0.67)
Weighted-average pro forma shares outstanding, basic and diluted (unaudited) (note 2)	23,415,463

# (k) Research and Development, page F-13

7. Your response to comment nine indicates legal costs were reclassified to research and development expense. ASC 730-10-55-2i states legal work in connection with patent applications or litigation, and the sale of licensing of patents are excluded from research and development. Please reclassify these costs or tell us why you believe the costs are appropriately classified as research and development. Tell us how salaries of the CEO and Chief Medical Officer were allocated to research and development for 2008 and 2009 and whether the supporting documentation was prepared contemporaneously.

**Response:** The Company acknowledges the Staff's comment and respectfully submits it will revise in the next amendment to the Registration Statement the disclosures related to reclassified research and development to exclude legal costs related to patent applications and litigation, and the sale of licensing of patents from research and development expense. Such legal costs are now included in general and administrative expense. The decrease in research and development expense and offsetting increase in general and administrative expense under the revised assumptions would be approximately \$2,422,000 over the timeframe from inception to date, of which \$438,000 would be attributable to 2008 and \$423,000 would be attributable to 2009. The Company has concluded these adjustments are not material.

Footnote 2(k) at page F-13 of the current filing reflects the following disclosure:

The following table represents a summary of the effects of the immaterial error correction on the consolidated statements of operations for the years ended December 31, 2009 and 2008 (in thousands):

		2008			2009			
	R	Research						
	Dev	and elopment		General and Iministrative	Research and Development		General and Administrative	
As previously reported	\$	5,451	\$	4,598	\$ 5,559	\$	5,192	
Adjustment		1,066		(1,066)	2,077		(2,077)	
As adjusted	\$	6,517	\$	3,531	\$ 7,636	\$	3,115	

Footnote 2(k) would be revised to reflect the following disclosure:

The following table represents a summary of the effects of the immaterial error correction on the consolidated statements of operations for the years ended December 31, 2009 and 2008 (in thousands):

	2008			2009			
	search and lopment		eneral and ministrative		Research and Development		General and dministrative
As previously reported	\$ 5,451	\$	4,598	\$	5,559	\$	5,192
Adjustment	628		(628)		1,654		(1,654)
As adjusted	\$ 6,079	\$	3,969	\$	7,213	\$	3,538

The salaries of the Chief Executive Officer and Chief Medical Officer were allocated to research and development for 2008 and 2009 based on a review of their respective management by objective goals that were established contemporaneously. The relative accomplishment of these goals was also reviewed contemporaneously by the Board of Directors for such periods, accompanied by discussion with the Chief Executive Officer and Chief Medical Officer individually and further discussion with the Compensation Committee. The supporting documentation related to the goals for the Chief Executive Officer and the Chief Medical Officer were both prepared and evaluated contemporaneously.

# Note 12. Common Stock Equity Incentive Plan, page F-22

8. With regard to your response to comment 11, it does not appear that Alexion Pharmaceuticals, Cubist Pharmaceuticals, Endo Pharmaceuticals and Sanofi-Aventis are similar entities to NewLink and BioProtection at comparable developmental stages, therapeutic area and size of company. Tell us why

these companies were selected rather than other companies with a market capitalization more similar to NewLink. Explain why each company selected was considered comparable to NewLink and BioProtection including why companies with developed products being sold and companies reporting net income were considered comparable during the measurement period. Tell us what companies the underwriters used in determining the offering price of New Link and whether those companies were used in determining volatility and if not, why not. Provide us the volatility of each similar company used in determining the volatility assumptions for NewLink and BioProtection for each period.

**Response:** The Company acknowledges the Staff's comment and respectfully submits that it has considered the appropriateness of Alexion Pharmaceuticals, Cubist Pharmaceuticals, Endo Pharmaceuticals and Sanofi-Aventis as comparable companies (the comparison group) for the purpose of determining the Company's expected volatility in the Black-Scholes calculation for options issued and notes the following:

# A. Selection of Comparison Group

The calculated value of stock-based awards requires that the Company make assumptions regarding the stock price, or value of its common stock, and volatility of its common stock. The Company believes its assumptions have been reasonable and based on a consistent sample and methodology.

The accounting guidance supports using data from companies that are comparable to the Company throughout the expected life of the stock options in question for this purpose. The registrant necessarily must exercise judgment in determining the expected volatility, including not only the selection of comparable companies, but also in selecting how frequently to accumulate the data. The Company believes it has sought to consistently apply appropriate accounting principles in

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connection with its selection of comparable companies and determinations of volatility in connection with the Company's determination of the value of stockbased awards. In particular, the Company notes the following:

- As a private company with no active market for its securities, the Company believes the accounting guidance supports the use of data from public comparables in calculating the value of the Company's stock-based awards. As discussed under ASC 718-10-55-51, nonpublic entities may have sufficient information available on which to base a reasonable and supportable estimate of the expected volatility of their share prices. For example, a nonpublic entity that has an internal market for its shares, has private transactions in its shares, or issues new equity or convertible debt instruments may be able to consider the historical volatility, or implied volatility, of its share price in estimating expected volatility based on those transactions alone. ASC 718-10-55-51 continues on to state that, as an alternative to using private market data, a nonpublic entity that can identify similar public entities for which share or option price information is available may be able to consider the historical, expected volatility of those entities' share prices in estimating expected volatility. Similarly this information may be used to estimate the fair value of its shares or to benchmark various aspects of its performance.
- The Company also submits that it is appropriate to select comparable public companies with reference to the Company's projected development during the anticipated life of the stock options in question. Per ASC 718-10-55-38, "a marketplace participant would not use historical volatility without considering the extent to which the future is likely to differ from the past." Similarly, the Company's present market capitalization and development stage, if different from anticipated changes, should not be the sole basis for selecting comparable companies for the purpose of estimating volatility. In the Company's five-year projections, it believes that it will be revenue producing and reporting net income. Therefore, the Company does not believe that the volatility determined from exclusively using a pool of pre-revenue comparable companies would provide an accurate indication of the expected volatility for the options in accordance with ASC 718-10-55-38.
- Consistent with the foregoing, the Company has historically sought to select public comparable companies to estimate the value of stock based awards in a manner that adequately recognizes the Company's current size and stage of development and the Company's projected development during the life of the options. During the period from 2008 through 2010, the expected term for the Company's stock options ranged between 5.0 and 7.5 years. In accordance with foregoing principles, through 2009, the Company estimated its volatility by selecting the two most scientifically and developmentally similar public companies that reported volatility, specifically Dendreon Corporation ("*Dendreon*") and Cell Genesys, Inc. ("*Cell Genesys*"), as well as two commercial drug companies with large franchises in cancer therapy or vaccines, specifically Celgene Corporation ("*Celgene*") and Sanofi-Aventis. Similar to NewLink, both Cell Genesys and Dendreon were in clinical trials using active cellular immunotherapies to attempt to treat

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cancer, but neither had successfully completed clinical trials and taken their therapies into the market. Celgene and Sanofi-Aventis were included to represent NewLink's expected volatility after it achieves commercial status in the final two to seven years of the expected life of the options.

- In 2010, two of the historical comparables (Dendreon and Cell Genesys) underwent changes and the Company felt it was appropriate to remove them from the Company's analysis of estimated volatility. Cell Genesys was removed because its lead clinical trials failed and it was forced to sell its immunotherapy assets, which moved Cell Genesys into a much earlier stage of development than NewLink. Dendreon was removed because it successfully completed its clinical trials and filed for approval its lead active cellular immunotherapy, moving it out of the pre-commercial stage of development in which NewLink is currently situated.
- The Company believes that since the underlying security for the Company's stock options is the Company's common stock, similarity between the comparison groups in the context of its valuation reports and for purposes of computing an estimate of volatility is appropriate. The comparison group for valuation of the Company's common stock has been selected to have development stages, therapeutic area and size similar to the projected development cycle of NewLink at a future point in time when NewLink's revenue streams and cash flows are developed. These developed revenues and cash flows could then be discounted to assist in the development of the Company's valuations. In order to determine the value of common stock, valuation specialists use comparable companies to estimate the market multiples in the market approach, the WACC (i.e., betas, capital structure, etc.) in the income approach, and various other assumptions within the analysis (i.e., working capital levels). The Company believes that the Company's common stock valuation analysis methods correspond to the accounting guidance suggesting the private companies give

consideration to industry, stage of life cycle, size and financial leverage as contemplated under ASC 718-10-55-25 within the constraints of the available data in combination with the need to look at both past and future development for volatility purposes in accordance with ASC 718-10-55-38. Therefore, the Company submits that companies selected by NewLink as comparable for valuation purposes serve as an appropriate pool from which to select comparable companies for computation of estimated volatility.

- With the need to update its comparable companies for computing estimated volatility in 2010 due to the removal of Cell Genesys and Dendreon, the Company determined to utilize a comparison group that both (i) adequately recognized the Company's current size and stage of development and the Company's projected development during the life of the options and (ii) was drawn from with the group selected for the Company's valuations of its underlying common stock. The comparison group selected for the volatility analysis in 2010 is consistent with those two goals.
- The comparison group selected for the volatility analysis in 2010 was first selected during the preparation of the Company's valuations performed by Mentor. In 2010, XOMA Ltd. (*"XOMA"*), Aceto Corporation (*"Aceto"*), Lannett Company, Inc. (*"Lannet"*),

Keryx Biopharmaceuticals, Inc. ("Keryx"), Alexion Pharmaceuticals ("Alexion"), and Cubist Pharmaceuticals ("Cubist"), were selected as guideline companies for volatility estimation purposes and were also companies included in the set of comparable companies used by NewLink for common stock valuation purposes. XOMA, a biopharmaceutical company, engages in the discovery, development and manufacture of therapeutic antibodies to treat inflammatory, autoimmune, infectious and oncological diseases. XOMA's focus on immunology and oncology parallels NewLink's focus. XOMA has a market capitalization of \$90 million. Aceto, together with its subsidiaries, engages in sourcing, quality assurance, regulatory support, marketing and distributing chemically derived pharmaceuticals, biopharmaceuticals, specialty chemicals and crop protection products. Aceto is publically traded and has a market capitalization of about \$200 million. Lannett develops, manufactures, packages, markets and distributes generic pharmaceutical products sold under generic chemical names in the United States. Although Lannett is focused more on the manufacturing, marketing and distribution of smaller, mainly generic, pharmaceutical products, instead of innovative new chemical entities, Lannett's market capitalization of about \$160 million and its presence in the pharmaceutical industry make it an appropriate comparable. Keryx, a biopharmaceutical company, focuses on the acquisition, development and commercialization of pharmaceutical products for the treatment of life-threatening diseases, including cancer and renal disease. Keryx has a number of candidates in clinical trials and no approvals. Keryx's current stage of development and focus on biopharmaceuticals for the treatment of cancer closely parallels NewLink's stage of development and focus. Keryx's market capitalization is about \$300 million and it has about 25 employees. Alexion, a biopharmaceutical company, engages in the discovery, development and commercialization of biologic therapeutic products in the United States, Europe, Latin America, Japan and Asia Pacific. Alexion focuses on products for severe and life-threatening disease states, including hematologic, kidney, and neurologic diseases; transplant rejection; cancer; and autoimmune disorders. Alexion's focus on oncology and immunology compare well with NewLink's focus, but Alexion has one approved drug that it markets as well as a number of ongoing clinical trials representing the stage of development NewLink hopes to achieve in the four to seven year timeframe. Although Alexion has a current market capitalization of about \$8 billion, significant increases in market capitalization generally coincide with a biopharmaceutical company's first drug approval and Alexion has been the target of recent takeover speculation. Alexion's market capitalization was about half its current level 10 months ago. Cubist operates as a biopharmaceutical company focused on the research, development and commercialization of pharmaceutical products that address unmet medical needs in the acute care environment. Cubist markets two antibiotics and has a number of candidates in earlier stages of development. Cubist's focus on infectious diseases is similar to NewLink's infectious disease division. Cubist's market capitalization is about \$2 billion. Endo Pharmaceuticals Holdings Inc. ("Endo"), through its subsidiary, Endo Pharmaceuticals Inc., engages in the research, development, manufacture, marketing and sale of branded and generic prescription pharmaceuticals in the United States. Endo markets a number of smaller specialty pharmaceuticals including drugs for cancer related pain and

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has drugs in development for the treatment of cancer. With a market capitalization of about \$4.8 billion, Endo is small by commercial pharmaceuticals standards and may represent NewLink's stage of development in about seven years, near the end of new option expected lives.

With respect to the Staff's question regarding why the Company included Alexion, Cubist and Endo as comparable companies, the Company submits that they were selected along with the other companies for the 2010 volatility analysis based on both qualitative and quantitative factors that indicate similarity to the Company's industry, stage of life cycle, size and financial leverage as contemplated under ASC 718-10-55-25 in light of the Company's projected development during the expected duration of the stock options in question. When taken in the context of the overall pool, the Company feels they are appropriate. Four out of the seven companies above that were added in 2010 represent companies at or near NewLink's expected current valuation and stage of development. The remaining three companies represent commercial scale pharmaceutical companies with limited experience marketing their drugs similar to the status NewLink might expect to achieve in the years two through seven of any newly issued options after gaining marketing approval for one of NewLink's product candidates. In particular, the Company notes the following with respect to Alexion, Cubist and Endo:

# Qualitative factors

The Company reviewed the 2008, 2009 and 2010 clinical pipelines for Alexion, Cubist and Endo.

- Alexion has one commercial drug and multiple other candidates in preclinical, Phase I and Phase II development. Likewise, NewLink had
  multiple candidates in preclinical, Phase I and Phase II development. In addition, Alexion expanded its focus on cancer therapies in 2009,
  similar to NewLink.
- Cubist has two commercial drugs and a focus on acute care, primarily infections. Cubist also has multiple other candidates in clinical trials, similar to NewLink.
- Endo has multiple branded commercial drugs in the market and expanded its clinical trial candidates since 2008, similar to NewLink. Furthermore, due to the acquisition of Indevus in 2009, Endo expanded their focus in cancer and oncology, similar to NewLink.

NewLink restricted its selection of the guideline companies to those companies that had started similar to NewLink and grew as a going concern. By doing this, NewLink felt that looking at the historical volatility of the companies would be a reasonable benchmark for the forward looking volatility of NewLink since management believes that the Company is expected to grow in a similar fashion that the guideline companies have historically grown.

### Quantitative factors

Because the Company believes volatility of life science companies is directly related to growth rates in earnings and profit margins, as referenced above, the Company selected guideline companies that had comparable historical growth rates to the growth rates NewLink believes will be similar to itself.

Company	Revenue Growth	EBITDA Growth
Alexion	331%	300%
Cubist	135%	153%
Endo	117%	122%
NewLink	145%	312%

NewLink's growth rates are projected growth rates. Consequently, NewLink emphasized trying to match guideline companies that had historical growth rates that were similar to NewLink's projected growth in an effort to capture the forward looking volatility that NewLink could reasonably expect to experience. The Company felt it was most reasonable to use actual volatility factors from guideline companies that had experienced comparable growth to what NewLink is projected to achieve.

### B. Investment Bank Comparable Companies

The Company believes the five investment banks currently anticipated to serve as underwriters in the offering each used a different set of comparable companies to begin to develop their valuation models; however, the Company has not had detailed valuation discussions with its banking syndicate; therefore the Company is not currently aware of the comparable companies that they will choose to finally model the Company's expected market price. The Company believes further analysis of comparables will only represent one factor in their valuations and that the investment bankers and analysts will probably favor a discounted revenue multiple or PE ratio. The Company believes the underwriters will likely use the annual discount rate as a subjective measure to attempt to compare the risk and the opportunity of NewLink's product candidate pipeline when comparing NewLink to the selected comparable company group. The Company will continue to reevaluate the comparable companies used to estimate its volatility until it has enough trading history to determine its computed volatility. A part of the ongoing analysis of comparable companies will include evaluating changes that might be suggested by considering the comparable comparable companies suggested by the Company's investment bankers.

### C. Volatility of Comparable Companies

The volatility of the common stock of the guideline companies used in the calculation of the volatility for Company and BioProtection Systems for Black-Scholes purposes for the periods in question is as follows:

Company	Year	Comparable	Volatility
Company	Itar	Comparable	volatinty
NewLink	2008	Dendreon Celgene Cell Genesys Sanofi-Aventis	90.58% 40.85% 55.11% 21.49%
NewLink	2009	Dendreon Celgene Cell Genesys Sanofi-Aventis	74.56% 33.55% 48.94% 21.64%
NewLink	2010	Aceto Corporation Alexion Pharmaceuticals Cubist Pharmaceuticals Endo Pharmaceuticals Keryx Biopharmaceuticals Lannett Company, Inc. XOMA Ltd.	46.03% 44.89% 51.28% 36.50% 119.05% 68.71% 62.31%
BioProtection Systems	2008	DOR BioPharma VaxGen Celldex Therapeutics Sanofi-Aventis	106.56% 103.73% 69.70% 20.96%
BioProtection Systems	2009	Soligenix, Inc. (DOR BioPharma) VaxGen Celldex Therapeutics Sanofi-Aventis	92.29% 80.84% 55.37% 21.64%

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BioProtection Systems	2010	Soligenix, Inc. (DOR BioPharma)	94.34%
		Diadexus (VaxGen)	75.71%
		Celldex Therapeutics	57.06%

Considering the facts noted above, the Company believes its use of the comparison group and resulting expected volatility assumptions are reasonable.

The Company respectfully requests the Staff's assistance in completing the review of the Registration Statement and Amendment No. 2 as soon as possible. Please advise us if we can provide any further information or assistance to facilitate your review. Please direct any further comments or questions regarding this response letter to me at (720) 566-4010 or Brent D. Fassett at (720) 566-4025.

Sincerely,

Cooley LLP

/s/ James C. T. Linfield James C. T. Linfield

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