



DIVISION OF  
CORPORATION FINANCE

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

January 18, 2011

Charles J. Link, Jr.  
Chief Executive Officer  
NewLink Genetics Corporation  
2503 South Loop Drive  
Ames, IA 50010

**Re: NewLink Genetics Corporation  
Registration Statement on Form S-1  
Filed December 21, 2010  
File No. 333-171300**

Dear Dr. Link:

We have reviewed your registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by amending your registration statement and providing the requested information. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing any amendment to your registration statement and the information you provide in response to these comments, we may have additional comments.

**FORM S-1**

**General**

1. Please note that when you file a pre-effective amendment containing pricing-related information, we may have additional comments. As you are likely aware, you must file this amendment prior to circulating the prospectus.
2. Please note that when you file a pre-effective amendment that includes your price range, it must be bone fide. We interpret this to mean that your range may not exceed \$2 if you price below \$20 and 10% if you price above \$20.
3. Please provide us proofs of all graphic, visual or photographic information you will provide in the printed prospectus prior to its use, for example in a preliminary prospectus. Please note that we may have comments regarding this material.

4. Please note that where we provide examples to illustrate what we mean by our comments, they are examples and not exhaustive lists. If our comments are applicable to portions of the filing that we have not cited as examples, make the appropriate changes in accordance with our comments.

Prospectus Summary, page 1

5. Please revise your summary on pages 1 and 2 to remove the discussion of the results of your clinical trials. In order to provide a proper context for the results of these trials, the data should be balanced with a full discussion of the results of these trials. A full discussion of the results of each of the trials is not appropriate in your Prospectus Summary. Accordingly, please remove the discussion of the results of your clinical trials from your summary.
6. Please revise your disclosure to attribute the below statements and other similar statements to the source from which you obtained the information. In addition, where you cite your own estimates, please explain how you arrived at those estimates and disclose any third-party sources you relied upon.
  - Pages 1 and 84: “As a result, a 96% mortality rate is associated with [pancreatic cancer], with one-year and five-year survival rates of 24% and 5%, respectively.”
  - Pages 1 and 84: “Approximately 20% of patients in the United States are eligible for resection at initial diagnosis.”
  - Pages 1 and 84: “Resection followed by chemotherapy or chemoradiotherapy, known as adjuvant therapy, extends median survival to approximately 18 months.”
  - Page 92: “About 85% to 90% of lung cancers are classified as NSCLC... About 80% of NSCLC cases are detected when they have progressed to stages III or IV. The current expected overall survival for a nonresectable stage IIIB or IV NSCLC patient who has failed first line treatment is approximately seven months.”
  - Page 94: “...while overall five-year survival rates for cases of prostate cancer approach 100%, the outlook for advanced, metastasized cases is poor with five-year survival rates of 31.7%.
  - Page 98: “Median survival for the most common metastatic breast cancer is approximately three years.”

Our Risks, page 3

7. Please expand your disclosure in this section to disclose that to date you have not had a product candidate that has been approved for sale by the FDA.
8. Please quantify the amount of your outstanding debt and the amount of debt that may be accelerated as early as March 18, 2011.

9. Please disclose the amount of your net losses for the nine-months ended September 30, 2010 and the fiscal year ended December 31, 2009 and the amount of your accumulated deficit in the penultimate bullet-point.

Risk Factors

“Failure to attract and retain key personnel could impede our ability...” page 17

10. To the extent that you have experienced problems attracting or retaining key personnel, or are aware of the imminent departure of key personnel, please expand your disclosure to describe these problems.

“We will require substantial additional capital in the future...” page 25

11. You disclose that the projections you provide in the risk factor are based on expenditures related to continued preclinical and clinical development of your product candidates during this period falling within budgeted levels. Please disclose your budgeted level of expenditures for your continued preclinical and clinical development.

“Even though we have received governmental support in the past, we may not continue to receive support at the same level or at all.” page 28

12. Please revise your risk factor to identify the government entities that you are referring to in this risk factor. Based on your disclosure on page 55, it appears that this risk factor is referring to your grants and contracts with the Departments of Defense and the National Institute of Health. Please also file copies of these agreements and expand your Business section to disclose the material terms of these agreements, including, but not limited to any payment provisions, a range of royalty rates, aggregate milestones, usage restrictions, obligations/rights to defend, duration and termination provisions. Alternatively, please provide us with an analysis that supports your conclusion that these agreements are not required to be filed.

“We rely on single source vendors for some key components...” page 32

13. Please identify each of your single source suppliers used in the manufacturing process for your HyperAcute immunotherapy product candidates. Please also file copies of these agreements and expand your Business section to disclose the material terms of these agreements, including, but not limited to any payment provisions, a range of royalty rates, aggregate milestones, usage restrictions, obligations/rights to defend, duration and termination provisions. Alternatively, please provide us with an analysis that supports your conclusion that these agreements are not required to be filed.

“We may be subject to litigation with respect to the ownership and use of intellectual property...” page 34

14. To the extent you are aware of any pending claims or have experienced any of the events described in this risk factor, please revise the risk factor to describe your experience or pending claims.

“We are exposed to potential product liability or similar claims, and insurance against these claims...” page 35

15. Please expand your disclosure to disclose the level of your product liability insurance coverage. Please also disclose the cost to you of such coverage, if material. Similarly, please revise your risk factor on page 20 regarding your insurance coverage.

Cautionary Note Regarding Forward-Looking Statements, page 43

16. Please delete the statements “we have not independently verified market and industry data from third-party sources” and “neither such research nor these definitions have been verified by any independent source.” These statements appear to imply that you are not taking liability for the statistical and other industry and market data included in your registration statement. It is not appropriate to state or imply that you do not have liability for the statements in your registration statement. Alternatively, please expand your disclosure to include a statement specifically accepting liability for this information.

Use of Proceeds, page 45

17. You disclose that you intend to use approximately \$            million of the net proceeds from this offering to fund your Phase 3 clinical trial and related development activities for HyperAcute Pancreas. Please expand your disclosure to disclose the stage of development for HyperAcute Pancreas that you expect this portion of the offering proceeds will enable you to complete. Similarly, please revise your disclosure for your other HyperAcute immunotherapy product candidates and IDO pathway inhibitor product candidates to state the stage of development you expect those proceeds will enable you to complete.

Management’s Discussion and Analysis of Financial Condition and Results of Operations

Financial Overview

Research and Development Expenses, page 55

18. Please tell us whether you track research and development expense by product candidate. If so, please disclose research and development expense by product candidate for each period presented and to date. If not, please revise your tabular disclosure of research and development expense on page 56 to also include expense incurred to date for each technology type presented.

Critical Accounting Policies and Significant Judgments and Estimates

Stock-Based Compensation

Common Stock Fair Value

Common Stock Valuations, page 60

19. You disclose on page 61 that your valuation specialist performed two distinct valuations for two different purposes, and you disclose on page 60, “We engaged a third-party valuation specialist to value our common stock...” Please revise your disclosure to clearly state whether your Board, management, or your valuation specialist determined the fair value of your common stock for the purpose of calculating compensation expense for options grants. If fair value was determined by your valuation specialist, please name them and identify them as an expert in your disclosure, and include a signed and dated consent from the valuation expert.

Fair Value Estimates, page 63

20. Please revise your grant dates to reflect the grant dates that comply with GAAP, and ensure your disclosure herein is consistent with your disclosure in the Notes to Consolidated Financial Statements, or explain why you believe no revision is necessary.
21. Please disclose the following information relating to your issuances of options to purchase common stock:
- A discussion of each significant factor contributing to the difference between the fair value of your common stock as of each grant date through September 30, 2010, the fair value as of the date of each grant subsequent to September 30, 2010 through the date of your filing, and the estimated IPO price; and
  - The anticipated effects on results of operations for equity issuances made subsequent to the date of your financial statements (i.e., September 30, 2010) through the date of your filing.

Loan Agreements

March 2005 Iowa Department of Economic Development Loan, page 66

22. You disclose that you do not anticipate fulfilling the requirements for loan forgiveness under this agreement by March 18, 2011, but based on your progress on the project you anticipate asking for and believe you can obtain a further one-year extension of the project completion date from the IDED. Please provide us with your basis for your belief that you can obtain a further one-year extension of the project completion date.
23. Please expand your disclosure to disclose the consequences, including the approximate amount that you will need to pay, if you do not fulfill the requirements of the loan and you cannot obtain a further extension.

Contractual Obligations and Commitments, page 69

24. Please revise your Contractual Obligations Due table to include cash payment obligations related to each of your Licensing Agreements as disclosed in Note 16 to your Consolidated Financial Statements. Where uncertainties prevent making a reasonable estimate of the obligations, explain the uncertainties in your disclosure below the table. Quantify aggregate license and milestone obligations, their timing, events triggering their payment and expected effects on financial position, operations and capital resources. Also, revise Note 16 to your Consolidated Financial Statements to include this disclosure.

Collaborative Agreements with Medical Institutions, page 71

25. Please file a copy of your December 22, 2007 Cooperative Research & Development Agreement with Public Health Services and revise your Business section to disclose the material terms of this agreement, including, but not limited to any payment provisions, duration and termination provisions. Alternatively, please provide us with an analysis that supports your conclusion that this agreement is not required to be filed.

Acquisition of BioProtection Systems Corporation, page 73

26. Please file copies of the relevant agreement(s) related to your acquisition of the minority ownership of BPS.
27. Please disclose when this closing occurred or when you expect this closing to occur.

Related Party Transactions, page 74

28. Please file copies of the loan and forgiveness agreements disclosed in this section pursuant to Item 601(b)(10)(ii)(B) of Regulation S-K.

Quantitative and Qualitative Disclosures about Market Risk, page 76

29. You disclose that you may be subject to fluctuations in foreign currency rates in connection with your global contract research organization and investigational site agreements. Please disclose the foreign currencies to which you have exposure. Also, tell us which quantitative disclosure alternative you have utilized under Item 305(a) of Regulation S-K with respect to your foreign currency exchange rate risk, and revise your disclosure to comply with this Item.

Business, page 77

30. Please expand your disclosure in this section to provide the material terms of your research agreements with Medical College of Georgia Research Institute, Inc. which you

file as exhibits 10.42 through 10.45, including, but not limited to any payment provisions, duration and termination provisions.

31. Please expand your disclosure in this section to provide the material terms of your cooperative research and development agreements with the National Cancer Institute which you file as exhibits 10.27 through 10.36, including, but not limited to any payment provisions, duration and termination provisions.

Our HyperAcute Cancer Immunotherapy Product Candidates, page 77

32. We note that you disclose the “most common non-serious adverse events” for each product candidate. Please revise your disclosure throughout the prospectus to disclose all adverse events, including pages 77-78, 86, 93 and 94.

BioProtection Systems Corporation, page 100

33. Please expand your disclosure in this section to disclose the material terms of the license agreement by and between the Regents of the University of California and BPS and the license agreement by and between Her Majesty the Queen in Right of Canada and BPS, including, but not limited to the payments to date, a range of royalty rates, aggregate milestones, usage restrictions, obligations/rights to defend, duration and termination provisions. Alternatively, please provide us with an analysis that supports your conclusion that these agreements are not required to be filed.

Manufacturing, page 100

34. Please expand your disclosure in this section to disclose the name of your existing contract manufacturer for D-1MT and the components used in the HyperAcute product candidates.

Intellectual Property, page 102

35. Please revise your disclosure regarding each material owned or licensed patent family to disclose the number of patents in such family and the range of expiration dates.

License Agreements, page 104

36. For each of the agreements disclosed in this section, please disclose the date of the last to expire patent licensed under the respective agreement.
37. Please expand your disclosure here and on page 69 regarding your agreement with Central Iowa Health System to disclose when your royalty obligations expire under the agreement, the shares of common stock issued to CIHS and a range of royalty payments

(e.g. low single-digit or a range not to exceed ten percent) as we believe these are material terms of this agreement.

38. Please expand your disclosure here and on pages 69-71 for each agreement with your remaining licensors to disclose the payments made to date, the aggregate milestone payments and a range of royalty payments (e.g. low single-digit or a range not to exceed ten percent) as we believe these are material terms of these agreements.

#### Executive and Director Compensation

39. Please expand your disclosure in this section to disclose the material terms of your employment agreements with your executive officers.

#### Compensation Discussion and Analysis

##### Role of Our Board and Compensation Committee in Setting Executive Compensation, page 125

40. It appears that you use the data described on the top of page 125 as a reference point on which, wholly or in part, to base, justify or provide a framework for your compensation decisions. Please revise your disclosure to disclose all the names of the companies included in these benchmarks. If you benchmarked against a survey in its entirety, you may provide the name of the survey. See Question 118.05 of the Regulation S-K Compliance and Disclosure Interpretations.

##### Elements of our Executive Compensation Program, page 126

41. You disclose that in establishing the 2009 base salaries of your executive officers, your Compensation Committee and Board of Directors took into account a number of factors, including the executive's seniority, position, functional role and level of responsibility and individual performance during 2008. Please disclose for each executive officer whether such executive's salary remained the same as 2008, increased or decreased. If there was a change in salary, please disclose the amount or percentage of the change.
42. Please revise your disclosure to clarify whether corporate and/or individual performance goals were established and communicated to your named executive officers in the beginning of your fiscal year. If such goals were established, please expand your disclosure to disclose the corporate and/or individual goals that were established and communicated to your executives, an analysis of the company's performance against those goals and how that achievement led to the bonus awarded. If such goals were not established and communicated to your executives, please revise your disclosure to clarify that no such goals were established and the corporate and individual accomplishments are solely evaluated at the time the bonus is awarded.



Certain Relationships and Related Party Transactions, page 151

43. You disclose that your Series A preferred stock will convert into one share of common stock. Based on your disclosure on pages 158 and F-26, it appears that each share of Series A preferred stock will convert into 1.389 shares of your common stock. Please revise to remove the inconsistency.

Description of Capital Stock, page 158

44. Please disclose your conversion ratio or how such ratio will be calculated for your Series E preferred stock. On page 152, you disclose that each share of Series E preferred stock will convert into five shares of common stock.

Index to Financial Statements

Consolidated Balance Sheets, page F-3

45. Please revise your pro forma as adjusted columns within your Consolidated Financial Statements to remove the offering proceeds as presentation of the offering proceeds is not appropriate within the historical financial statements. Please also note that your pro forma earnings per share that you present alongside your historical basic and diluted earnings per share within your Consolidated Statements of Operations should exclude offering proceeds.

Consolidated Statements of Equity (Deficit), page F-7

46. Please revise your Consolidated Statement of Equity (Deficit) at September 30, 2010 on page F-9 to disclose that statement for the interim period ending September 30, 2010 was unaudited.

Notes to Consolidated Financial Statements, page F-12

47. Please revise your Notes to Consolidated Financial Statements to include a Note related to your grant revenue. Specifically, disclose the terms and your obligations under the grants that you have received for the periods presented, including grants received from the Department of Defense and National Institute of Health, the amount recognized under each grant, and the amounts available under each grant received thus far.

2. Significant Accounting Policies

(k) Unaudited Pro Forma and Pro Forma as Adjusted Stockholders' Equity, page F-14

48. Please revise your disclosure to indicate the date as of which you assumed the pro forma adjustments within your Consolidated Pro forma and Pro forma as adjusted Balance Sheets as of September 30, 2010 and Pro forma as adjusted Basic and Diluted Net loss

per share for the Nine Months Ended September 30, 2010. Refer to Rule 11-02(b)(6) of Regulation S-X for guidance.

49. You disclose on page F-15 that 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 within your pro forma adjustments. Please tell us and disclose whether you are using the midpoint of the price range in order to estimate the number of common shares issuable upon conversion of your Series E preferred stock.

Stock Option Valuation, page F-16

50. In May 2009 you granted 2,234,000 options which began vesting on June 29, 2007 (page 128). In December 2009 you granted 1,700,000 options which began vesting in December 2009 but have a GAAP grant measurement date in 2010. Tell us how you accounted for these grants in the financial statements and the basis for your accounting. We refer to ASC 718-10-55-111 and 55-112.

3. Acquisition of OncoRx Corporation, page F-19

51. Please revise your Note disclosure to address the following:
- The nature of the technology you acquired including that it is the fundamental technology for your IDO pathway inhibitor product candidates as you disclose on page 72; and
  - The terms of the July 29, 2010 amendment to your purchase agreement, including the consideration issued and the valuation of the consideration.

Note 12 - Common Stock Equity Incentive Plan, page F-29

52. Tell us how you determined the expected volatility you used in determining stock based compensation expense and why the volatility used for the BPS plan is so much higher than for the NewLink plan. Also, tell us how you determined the risk-free interest rate of .1%.

16. Licensing Agreements, page F-37

53. Please revise your disclosure to include the amount of payments made in the periods presented for each of your license agreements and the accounting treatment for each. Additionally, you disclose that you have exclusive rights to the use and sublicensing of the technologies in question for the duration of the intellectual property patent protection in question. Please expand your disclosure to specify the duration and termination provisions of each agreement.

18. Related-Party Transactions, page F-39

54. You disclose in Note 4 that you modified outstanding options with officers to increase the exercise price by an amount equal to the amount of notes and interest forgiveness plus the bonus paid, and in Note 18, you disclose that the options for officers were modified to increase intrinsic value equal to the amount of the loan forgiveness. As increasing the exercise price typically reduces intrinsic and fair value, these statements appear to be inconsistent. Please reconcile these statements and revise your disclosure as appropriate.

19. Subsequent Events (Unaudited as to events after July 21, 2010), page F-39

55. You disclose on page F-40 that you entered into an agreement on December 1, 2010, to acquire all of the minority interest in BPS, and the acquisition is treated as an equity transaction. Please revise your Note disclosure to address the following:
- The value assigned to the net assets received in the transaction;
  - The basis for the value and method of determining the value you assigned to the preferred stock issued in the transaction;
  - Whether you recorded a loss on the transaction and if so, where it is reflected in your Pro Forma Stockholders' Equity for the Nine Months Ended September 30, 2010, and where it will be in your Consolidated Financial Statements for the Fiscal Year Ended December 31, 2010; and
  - The terms of your series E preferred stock issued in the transaction, including whether it is redeemable, and if so, the redemption value, and your accounting treatment of such redeemable shares.
56. You disclose all options to purchase shares of BPS stock will become options to purchase your common stock. Please tell us and revise your disclosure to address how you determined the number of options into which the outstanding BPS options will convert, and how you will account for the exchange of options.

We urge all persons who are responsible for the accuracy and adequacy of the disclosure in the filing to be certain that the filing includes the information the Securities Act of 1933 and all applicable Securities Act rules require. Since the company and its management are in possession of all facts relating to a company's disclosure, they are responsible for the accuracy and adequacy of the disclosures they have made.

Notwithstanding our comments, in the event you request acceleration of the effective date of the pending registration statement please provide a written statement from the company acknowledging that:

- should the Commission or the staff, acting pursuant to delegated authority, declare the filing effective, it does not foreclose the Commission from taking any action with respect to the filing;

- the action of the Commission or the staff, acting pursuant to delegated authority, in declaring the filing effective, does not relieve the company from its full responsibility for the adequacy and accuracy of the disclosure in the filing; and
- the company may not assert staff comments and the declaration of effectiveness as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

Please refer to Rules 460 and 461 regarding requests for acceleration. We will consider a written request for acceleration of the effective date of the registration statement as confirmation of the fact that those requesting acceleration are aware of their respective responsibilities under the Securities Act of 1933 and the Securities Exchange Act of 1934 as they relate to the proposed public offering of the securities specified in the above registration statement. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

You may contact Staci Shannon at (202) 551-3374 or Lisa Vanjoske at (202) 551-3614 if you have questions regarding comments on the financial statements and related matters. Please contact Jennifer Riegel at (202) 551-3575, Daniel Greenspan at (202) 551-3623 or me at (202) 551-3715 with any other questions.

Sincerely,

Jeffrey Riedler  
Assistant Director

cc: James C.T. Linfield  
Brent D. Fassett  
Cooley LLP  
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Broomfield, CO 80021