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May 29, 2013

### **VIA EDGAR**

United States Securities and Exchange Commission Division of Corporation Finance Mail Stop 4561 100 F. Street, N.E. Washington, D.C. 20549 Attention: Jeffrey P. Riedler

Re: bluebird bio, Inc.

**Registration Statement on Form S-1** 

Filed May 14, 2013 File No. 333-188605

Dear Mr. Riedler:

This letter is submitted on behalf of bluebird bio, Inc. (the "Company") in response to the comments of the staff of the Division of Corporation Finance (the "Staff") of the Securities and Exchange Commission (the "Commission") with respect to the Company's Registration Statement on Form S-1 filed on May 14, 2013 (the "Registration Statement"), as set forth in your letter dated May 24, 2013 addressed to Nick Leschly, President and Chief Executive Officer of the Company (the "Comment Letter").

For reference purposes, the text of the Comment Letter has been reproduced herein with responses below each numbered comment. For your convenience, we have italicized the reproduced Staff comments from the Comment Letter. The responses provided herein are based upon information provided to Goodwin Procter LLP by the Company.

# Cover Page

1. Please remove the photographic images included on the front and back cover pages. As your products are in clinical stages or preclinical, it is not appropriate to include photographs or images that may give the impression of patients being treated or cured with your products. Further, please delete or revise your statement that you are "transforming the lives of patients" given that you have treated a very limited number of

patients in your limited clinical studies and that neither your current viral vectors nor your current product candidates have ever been evaluated in human clinical studies. Lastly, in the section "Make hope a reality" please balance your disclosure by disclosing that neither your current viral vectors nor your current product candidates have ever been evaluated in human clinical studies.

RESPONSE: The Company advises the Staff that it will remove from the Company's next amendment to the Registration Statement ("Amendment No. 2") (1) the photographic images included on the front and back cover pages of the Registration Statement, (2) the statement that the Company is "transforming the lives of patients" on the cover page of the Registration Statement and (3) the section "Make hope a reality" on the cover page of the Registration Statement.

### Notes to Consolidated Financial Statements

Note 11. Significant Agreements

Celgene Corporation, page F-35

Please revise your disclosure to specifically include your consideration of the platform technology sublicense agreement, opt-in option and the manufacturing and supply agreement as separate deliverables and to clarify your accounting therefor. Separately reference for us the authoritative literature you rely upon to support your accounting.

RESPONSE: In response to the Staff's comment, the Company proposes to revise the disclosure in Amendment No. 2 as set forth on <u>Exhibit A</u> attached hereto.

The Company notes that the term "deliverable" is not defined in accounting literature. As a result, analyzing arrangements requires the use of judgment to determine if a deliverable exists. Generally, the Company considered the following factors in determining whether an item included in an arrangement constitutes a deliverable at the inception of the arrangement:

- It is explicitly referred to as an obligation of the Company in a contractual arrangement.
- It requires a distinct action by the Company.
- The Company's failure to complete an action would result in a significant contractual penalty.
- The inclusion or exclusion of the item in the arrangement reasonably would be expected to cause the arrangement consideration to vary by
  more than an insignificant amount.

The Company also considers options in its arrangement to purchase additional products and services to assess whether they represent deliverables at the inception of the arrangement. In assessing these potential deliverables, the Company considers whether it is truly at risk as to whether the option will be exercised, whether the optional products and services are essential to the functionality of any other element of the arrangement and whether such products and services are available from other vendors. The Company also considers whether the option is priced at a significant and incremental discount.

As it relates to the Platform Technology Sublicense Agreement, the Company respectfully advises the Staff that through the sublicense it received, the Company has obtained a sublicense to certain intellectual property from Celgene Corporation (Celgene). The Platform Technology Sublicense Agreement is between the Company and Celgene; however, the underlying sublicense relates to intellectual property that is licensed by Celgene from Baylor College of Medicine (Baylor). Under the terms of the Platform Technology Sublicense Agreement, the Company does not have any performance obligations imposed on it by Celgene or Baylor. Additionally, none of the factors outlined above relating to the identification of deliverables are present. As a result, no items included within the Platform Technology Sublicense Agreement constitute deliverables.

Secondly, the Company advises the Staff that under the terms of the collaboration agreement, Celgene has the ability to obtain a license to a product candidate for product candidates which Celgene did not initially exercise its option prior to the expiration of the applicable option period. Product candidates for which Celgene does not elect to exercise its option to obtain a license are referred to as Declined Product Candidates. Under the terms of the collaboration arrangement with Celgene, Celgene has the option to license Declined Product Candidates resulting from the collaboration for a period extending through a specified period following the completion of a pivotal study for such Declined Product Candidate. In substance, the opt-in right operates in the same manner as Celgene's option to license any other product candidates resulting from the collaboration, but relates exclusively to Declined Product Candidates. Consistent with the Company's conclusion related to the options to license any other product candidate resulting from the collaboration, the Company has concluded that the opt-in right is not a deliverable because the opt-in right is a substantive option and is not priced at a significant and incremental discount.

Lastly, as it relates to the manufacturing and supply agreement, the Company notes that it is not obligated to manufacture or have manufactured supplies of vectors and

associated payloads for incorporation into an optioned product candidate unless and until Celgene exercises its option to license a product candidate resulting from the collaboration whereupon the parties will execute a separate manufacturing and supply agreement. As it is contingent upon Celgene licensing a product candidate, the Company's potential obligation under a manufacturing and supply agreement is not considered a deliverable at the inception of the arrangement.

- 3. Please revise your disclosure in the second paragraph on page F-36 to disclose a description of each milestone and its related contingent consideration as required by AS 605-28-50-2b. To the extent that you consider the aggregation of milestones in your disclosure to be meaningful to investors, in lieu of the requirement to disclose each such milestone, please revise your disclosure to:
  - Disclose the nature of payment triggering events underlying each milestone included in the aggregated categories you disclose.
  - Separately disclose the nature and related contingent consideration for any individual milestone that is significant. To the extent you do not believe any of the individual milestones in the agreement is significant please demonstrate to us why not.

RESPONSE: In response to the Staff's comment, the Company proposes to revise the disclosure in Amendment No. 2 as set forth on Exhibit A attached hereto.

The Company respectfully acknowledges the Staff's comment to disclose a description of each individual milestone and its related contingent consideration as required by ASC 605-28-50-2b; however, in applying the guidance in ASC 605-28-50-2b, the Company considered which individual milestones, if any, would be material from a disclosure perspective. As a result, the Company has concluded that the aggregation of milestones by category in its disclosure to be more meaningful to investors than disclosing individual milestones. One of the factors the Company considered is that it is not eligible to receive milestone payments unless and until Celgene exercises its option to license a product candidate resulting from the collaboration. Upon Celgene's exercise of its option to license a product candidate, the parties would execute a license agreement or co-development, co-promote and profit share agreement, the terms of which are included as exhibits to the overall collaboration agreement, wherein the milestones are included as potential payments to be received by the Company based on the achievement of specified clinical, regulatory and commercial events.

Moreover, the Company believes that disclosure of the individual milestones and the related contingent consideration may be misleading to investors because achievement of such milestones is subject to the successful discovery, development and commercialization of product candidates, which is subject to numerous risks and uncertainties, including uncertainties relating to:

- The successful identification, discovery and development of product candidates,
- · The progress and results of clinical trials,
- The timing and outcome of regulatory reviews,
- The Company's ability to maintain the strategic alliance and the success of the strategic alliance,
- · The emergence of competing technologies and products and other adverse market developments, and
- Maintaining, enforcing and defending intellectual property-related claims.

These risks and uncertainties make it difficult to predict if any of the milestones will be achieved by the Company and when such milestones might be achieved. In addition, given the contingent nature of milestone payments, many milestones address contingencies that have a very low probability of being achieved. Providing a description of each potential milestone and the related contingent consideration could potentially mislead investors as the inclusion of such detailed information may imply that the Company has a substantial likelihood of achieving some or many of such milestones and receiving the related payments, while the actual prospects for achievement of such milestones is inherently uncertain and many of the milestones may never ultimately be achieved.

Additionally, the Company believes that the individual milestones and payment amounts are not material to investors unless there is a high likelihood of achieving a particular milestone. As described above, the Company's prospects for achieving any of the milestones included in the Celgene arrangement are both uncertain and difficult to determine. The Company also believes that the expected time frame in which a milestone may be achieved is a relevant factor in determining whether disclosure of individual milestones and payment amounts are material to investors. The Company is in the early stages of discovery and development in the collaboration with Celgene. Currently, the product candidate(s), if any, for further development under the collaboration have not yet been selected. Accordingly, a substantial amount of time is anticipated to pass between the up-front payment and any potential milestone payments. For example, the first clinical milestone that could be received occurs upon the initiation of a pivotal study for a product candidate. Therefore, the Company believes the disclosure of individual milestones that are both highly uncertain and many years from being achieved, if at all, is not material to investors.

For the reasons discussed above, the Company does not consider any of the individual milestones in its arrangement with Celgene to be significant. Instead, the Company believes that separate disclosure of the more immediate contingent payment related to the product candidate option fees to be more meaningful and useful to investors. Such disclosure places appropriate emphasis on the contingent consideration that will have potential impact to the Company's financial results in the nearer term. As a result, the Company proposes to revise the disclosure in Amendment No. 2 as set forth in Exhibit A attached hereto to include additional disclosure of the product candidate option fees. The Company has also included additional disclosure of the events that trigger achievement of the milestones. By aggregating the remaining potential future milestones into categories of: (i) clinical milestones, (ii) regulatory milestones and (iii) commercial milestones, and providing further information with respect to the related milestone triggering events, the Company believes it is providing investors with all material relevant information as well as with an understanding of the possible scope of the collaboration. Such categorization of milestone payments allows investors to differentiate amounts that are at risk at each development phase prior to regulatory approval from amounts that are at risk as to the successful commercialization of the related product candidate.

If you should have any questions concerning the enclosed matters, please contact the undersigned at (617) 570-1933.

Sincerely,

/s/ Michael H. Bison

Michael H. Bison, Esq.

**Enclosures** 

cc: Nick Leschly, bluebird bio, Inc. Jeffrey T. Walsh, bluebird bio, Inc.

#### Exhibit A

### **Proposed Revised Footnote Disclosure**

### Celgene Corporation

Summary of the Collaboration Agreement

On March 19, 2013, the Company entered into a Master Collaboration Agreement (the "Collaboration Agreement") with Celgene to discover, develop and commercialize disease-altering gene therapies in oncology. The collaboration is focused on applying gene therapy technology to genetically modify a patient's own T cells, known as chimeric antigen receptor, or CAR, T cells, to target and destroy cancer cells. Additionally, on March 19, 2013, the Company entered into a Platform Technology Sublicense Agreement (the "Sublicense Agreement") with Celgene pursuant to which the Company sublicensed a sublicense to certain intellectual property from Celgene, originating under Celgene's license from Baylor College of Medicine, for use in the collaboration.

Under the terms of the Collaboration Agreement, the Company received a \$75,000 up-front, non-refundable cash payment. The Company will be responsible for conducting discovery, research and development activities through completion of Phase I clinical studies, if any, during the initial term of the agreement, or three years. The collaboration will be governed by a joint steering committee ("JSC") formed by an equal number of representatives from the Company and Celgene. The JSC will, among other activities, review the collaboration program, review and evaluate product candidates and approve regulatory plans. In addition to the JSC, the Collaboration Agreement provides that the Company and Celgene will each appoint representatives to establish a patent committee, which will be responsible for managing the intellectual property developed and used during the collaboration.

Prior to expiration of the initial term of the Collaboration Agreement, Celgene has two options to extend the term, through March 19, 2019, with the payment of significant extension fees. Separately, Celgene has an option to license an unlimited number of product candidates resulting from the collaboration during a period commencing upon execution of the Collaboration Agreement and continuing through a specified period following the completion of Phase I clinical study for each individual product candidate. In the event such option is exercised, the Company would grant Celgene an exclusive worldwide license to develop and commercialize such product candidate. Upon exercise of the option to license a product candidate, Celgene is required to pay an option fee, which is subject to reduction if the Company elects to co-develop and co-promote such product candidate in the United States. For any product candidates licensed by Celgene, the Company may be responsible, at Celgene's election, to continue performing certain development activities contemplated as part of the collaboration plan. If Celgene does not exercise its option with respect to a product candidate prior to the expiration of the applicable option period <u>("declined product candidate")</u>, then the Company has the right to develop the product candidate outside the scope of the collaboration, subject to a Celgene opt-in right to obtain a license to that <u>declined</u> product candidate for <u>significant</u> additional cash consideration. The opt-in right exists through <u>a specified period following the</u> completion of a pivotal study for the specific <u>declined</u> product candidate <u>and functions in the same manner as the option to license any other product candidates resulting from the collaboration</u>.

In addition, Celgene would be required to make certain milestone payments upon the achievement of specified clinical, regulatory and commercial events. For each product candidate that is licensed by Celgene, the Company would be eligible to receive per product up to \$30,000 in aggregate potential option fees and, up to \$10,000 in clinical milestone payments, up to \$117,000 in regulatory milestone payments and up to \$78,000 in commercial milestone payments. Clinical milestone payments are triggered upon initiation of a defined phase of clinical research for a product candidate. Regulatory milestone payments are triggered upon approval to market a product candidate by the FDA or other global

regulatory authorities. Commercial milestone payments are triggered upon the first commercial sale of an approved pharmaceutical product and when an approved pharmaceutical product reaches certain defined levels of net sales by the licensee or receives approval to be marketed by certain global regulatory authorities in a specified number of countries outside the United States. In addition, to the extent any of the product candidates licensed by Celgene are commercialized, the Company would be entitled to receive tiered royalty payments ranging from the mid-single digits to mid-teens based on a percentage of net sales. Royalty payments are subject to certain reductions, including for any royalty payments required to be made by Celgene to acquire patent rights, with an aggregate minimum floor. The Company is not eligible to receive either milestone payments or royalty payments unless and until Celgene exercises its option to license a product candidate resulting from the collaboration whereupon the parties will execute a license agreement, the terms of which are included as part of the collaboration arrangement.

Additionally, the Company may elect to co-develop and co-promote product candidates licensed by Celgene. If the Company elects to co-develop and copromote a product candidate, then the parties would share equally in all costs incurred relating to the development, commercialization and manufacture of the product candidate within the United States and share equally in the profits generated by such product candidate in the United States. Additionally, if the Company elects to co-develop and co-promote a product candidate, then the option fees, milestones and royalties would changedecrease compared to those described above. Under this scenario, the Company would receive per product up to \$20,00010,000 in aggregate potential option fees and, up to \$10,000 in clinical milestone payments and outside the United States, up to \$54,000 in regulatory milestone payments and up to \$36,000 in commercial milestone payments. Clinical milestone payments are triggered upon initiation of a defined phase of clinical research for a product candidate. Regulatory milestone payments are triggered upon approval to market a product candidate by global regulatory authorities. Commercial milestone payments are triggered when an approved pharmaceutical product reaches certain defined levels of net sales by the licensee or receives approval to be marketed by certain global regulatory authorities in a specified number of countries outside the United States. In addition, to the extent any of the product candidates licensed by Celgene and co-developed and copromoted by the Company are commercialized, the Company would be entitled to receive tiered royalty payments ranging from the mid-single digits to mid-teens based on a percentage of net sales from sales generated outside of the United States. Royalty payments are subject to certain reductions, including for any royalty payments required to be made by Celgene to acquire patent rights, with an aggregate minimum floor. The Company is not eligible to receive profit share payments, milestone payments or royalty payments unless and until Celgene exercises its option to license a product candidate resulting from the collaboration whereupon the parties will execute a co-development, co-promote and profit share agreement, the terms of which are included as part of the collaboration arrangement.

In the event Celgene elects to license a product candidate discovered and developed as part of the Collaboration Agreement, Celgene would be solely responsible for all costs and expenses of manufacturing and supplying any product candidates. Subject to customary back-up supply rights granted to Celgene, the Company has the sole right to manufacture or have manufactured supplies of vectors and associated payloads manufactured for incorporation into the associated product candidate. Celgene would reimburse the Company for the costs incurred to manufacture and supply such vectors and associated payloads, plus a modest mark-up. The Company is not obligated to manufacture or have manufactured supplies of vectors and associated payloads for incorporation into an optioned product candidate unless and until Celgene exercises its option to license a product candidate resulting from the collaboration whereupon the parties will execute a separate manufacturing and supply agreement.

The Collaboration Agreement may be terminated by either the Company or Celgene, upon written notice, in the event of the other party's uncured material breach. Celgene may terminate the Collaboration Agreement for any reason upon written notice to the Company. If the Collaboration Agreement is

terminated, rights to product candidates in development at the time of such termination will be allocated to the parties through a mechanism included in the Collaboration Agreement. In addition, if Celgene terminated the Collaboration Agreement as a result of a breach by the Company, then any then-existing codevelopment and co-promotion agreement will be automatically terminated and replaced with a license agreement for such product candidate and any amounts payable by Celgene under any then-existing product license agreements will be reduced.

#### Call Option

Effective upon completion of the Company's initial public offering, during the initial three-year term of the collaboration and, if extended, during the first two-year extension term of the collaboration, in the event that the Company engages in a change in control transaction, including for such purposes a merger or consolidation of the Company or the sale of all or substantially all of the Company's assets, or if another person or entity or group of persons or entities acquires at least 50% of the Company's voting capital stock, then Celgene has the right, but not the obligation, to terminate the Collaboration Agreement and obtain perpetual, non-terminable, worldwide, exclusive, fully paid-up licenses to all, but not less than all, of the product candidates previously identified under the Collaboration Agreement (the "Call Option"). Under the Call Option, the product candidates to which Celgene would have the right to acquire licenses include any product candidate previously licensed out of the collaboration during the term of the collaboration, any product candidate for which the Company has exercised the right to co-develop and co-promote within the United States, any product candidate for which Celgene previously declined its option to obtain a license and any product candidate for which at least in vivo efficacy studies have been initiated or authorized by the JSC. The purchase price for such licenses would be based on the fair value of these rights received and obligations assumed determined pursuant to a binding arbitration process.

In addition, during the initial three-year term of the collaboration, but not during any extension term, in the event that Celgene exercises the Call Option, in addition to the right to acquire the fully paid-up licenses described above, Celgene would obtain a perpetual, non-terminable, worldwide, exclusive license to the Company's intellectual property to develop one or more CAR T cell products targeting one or more oncology associated target antigens for the remainder of the initial collaboration term. Following the initial collaboration term, the license to the Company's intellectual property is limited to target antigens identified by Celgene promptly following the initial collaboration term for which Celgene reasonably intends to develop CAR T cell products. There is no limit to the number of oncology-related target antigens Celgene may select under this license. Upon commercialization of any such product candidate so licensed by Celgene, Celgene would be obligated to pay the Company a specified milestone payment upon regulatory approval and a percentage of net sales as a royalty.

The Company has concluded that the value of the Call Option is immaterial based primarily on the probability that the Call Option would become exercisable.

## Accounting Analysis

The Company's arrangement with Celgene contains the following deliverables: (i) discovery, research and development services, (ii) participation on the JSC and (iii) participation on the patent committee. The Company has determined that the options to extend the term of the agreement and the options to license product candidates, including those related to Celgene's opt-in right for a declined product candidate, are substantive options. Celgene is not contractually obligated to exercise the options. Additionally, as a result of the uncertain outcome of the discovery, research and development activities, the Company is at risk with regard to whether Celgene will exercise the options. Moreover, the Company has determined that the options are not priced at a significant and incremental discount. Accordingly, the options are not considered deliverables at the inception of the arrangement and the associated option fees are not included in allocable arrangement consideration. The Company has determined that the potential

obligation to manufacture or have manufactured supplies of vectors and associated payloads for incorporation into an optioned product candidate is contingent upon Celgene exercising its option to license a product candidate resulting from the collaboration. Therefore, consistent with the treatment of the options to license product candidates, the Company's potential obligation under a manufacturing and supply agreement is not considered a deliverable at the inception of the arrangement and the associated fees are not included in allocable arrangement consideration.

The Company has concluded that each of the three deliverables identified at the inception of the arrangement (discovery, research and development services; participation on the JSC and participation on the patent committee) has standalone value from the other undelivered elements. Additionally, the Collaboration Agreement does not include return rights related to the initial collaboration term. Accordingly, each deliverable qualifies as a separate unit of accounting.

The Company has identified the allocable arrangement consideration as the \$75,000 up-front payment. The Company determined that each of the identified deliverables have the same period of performance (the three year initial term) and have the same pattern of revenue recognition, ratably over the period of performance. As a result, the \$75,000 arrangement consideration will be recognized over the three year initial term.

The Company has evaluated all of the milestones that may be received in connection with Celgene's option to license a product candidate resulting from the collaboration. In evaluating if a milestone is substantive, the Company assesses whether: (i) the consideration is commensurate with either the Company's performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the Company's performance to achieve the milestone, (ii) the consideration relates solely to past performance and (iii) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. All clinical and regulatory milestones are considered substantive on the basis of the contingent nature of the milestone, specifically reviewing factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the milestone as well as the level of effort and investment required. Accordingly, such amounts will be recognized as revenue in full in the period in which the associated milestone is achieved, assuming all other revenue recognition criteria are met. All commercial milestones will be accounted for in the same manner as royalties and recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

During the three months ended March 31, 2013, the Company recognized \$1,042 of revenue associated with its collaboration with Celgene related to the recognition of discovery, research and development services. As of March 31, 2013, there is \$73,958 of deferred revenue related to the Company's collaboration with Celgene which is classified as current or long-term in the accompanying balance sheet based on the contractual term of the arrangement.