

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

September 17, 2010

Dr. Hyunil Choi Catch By Gene, Inc. 4-209 Medical Industry Park, Taejang-2dong, Wonju, Gangwon-do Korea

> Re: Catch By Gene, Inc. Form 10-12G Filed August 20, 2010 File No. 000-54087

Dear Dr. Choi:

We have reviewed your filing 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 within ten business days by amending your filing, by providing the requested information, or by advising us when you will provide the requested response. 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 filing and the information you provide in response to these comments, we may have additional comments.

#### General

- 1. Please note that the Form 10-12G goes effective by lapse of time within 60 days of the date filed pursuant to Exchange Act Section 12(g)(1). Please note that the effectiveness of your Form 10-12G will commence your periodic reporting obligations under the Exchange Act even if all of our comments have not yet been resolved.
- 2. 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.

# Industry and Market Data, page 1

3. Please revise your disclosure to clarify that you are liable for all statements in the registration statement, even those obtained from third parties.

## <u>Item 1. Business, page 1</u> General

- 4. Your description of your product candidates in Item 1 implies that your products have been developed and are ready for commercialization. In the Risk Factors section, however, you state that your product candidates are currently in research and development and will require additional research and development, extensive clinical testing and regulatory approval prior to any commercial sales. Please revise your disclosure throughout the filing to eliminate these inconsistencies. To the extent your products are still in the development stage, please revise your disclosure throughout Item 1 to:
  - refer to your products as "product candidates;"
  - refer to products the company is "developing" rather than products the company has "developed;"
  - clarify that your products will require additional development, clinical testing and regulatory approval prior to commercialization;
  - describe the nature of the clinical trials that must be accomplished prior to commercialization;
  - describe whether you have started clinical trials and, if so, the status of those clinical trials; and
  - indicate the source(s) of your current revenues.
- 5. You have stated throughout your filing that you are focused on developing and commercializing therapeutic and diagnostic products. However, it does not appear that any of your products are focused on treating diseases. Please explain the therapeutic nature of your products or delete statements that they are therapeutic.

# Introduction, page 1

- 6. Please disclose that the FDA has not approved your product candidates for commercialization in the United States.
- 7. We note your statement that the "markets for diagnostic and therapeutic products for HPV are substantial and growing, and the limitations of many current diagnostic and therapeutic products are widely recognized." Please disclose the source or sources of that statement and quantify the size of the "substantial and growing" market.

#### Company History, page 1

8. You state in the first paragraph of this subsection that there are a total of 44,000,000 common shares issued and outstanding and that the company has no other securities outstanding. You state in the second paragraph that there are 44,000,232 shares outstanding. Please revise to eliminate this apparent inconsistency.

#### Our Products, page 1

- 9. Your disclosure is unclear as to the level of development of each of your product candidates. Please expand your disclosure to describe how far you are in the development process of each of your product candidates and what is still required for commercialization of your products in each of the jurisdictions where you will seek to sell your products.
- 10. Please revise your disclosure to state the sources for all market data and statistics that appear in your filing. For example:
  - "nearly 5% of the world's population is currently infected with Hepatitis B virus"
  - "almost 400 million are chronic carriers of HBV"
  - "Supplements sales rose 8.2%, and natural personal care sales increased 12.1%."

Please note that the above list is not intended to be exhaustive.

- 11. Your language in this section is overly technical. Please replace technical language and jargon with language that can be understood by persons who do not work in your industry. Also, please provide an explanation of the following terms where you first use them:
  - "noncytopathic, enveloped virus"
  - "transcriptional transactivator"
  - "necroinflammatory disease"
  - "hepatocellular carcinoma"
  - "hybridization assay"
  - "quantization"
  - "chemiluminescent emission analyzer"
  - "random primer labeling"
  - "degoxigenin-dUTP"
  - "dot blot hybridization"
  - "interferon-α, lamivudine(3-TC)"
  - "stratified epithelium"
  - "microplate colorimetry method"

- "biotin labeled"
- "ELISA reader"

#### CBG HBV-DNA Quantitative Assay Intended Use and Significance, page 2

12. In the third paragraph you use for the first time the acronym "PCR." Please indicate what PCR stands for.

## Principle of the procedure, page 3

- 13. The language in this section is overly technical. Using language that can be understood by persons who do not work in your industry, please explain how your product candidate works and how it is different from other types of tests currently available.
- 14. Please disclose, for both the CBG HBV-DNA assay and the CBG HPV-DNA assay, the type of testing you have conducted to test efficacy of your product candidate.

#### Principle of the Product, page 4

15. Please explain what you mean by the "fragment was made from extracted genomic DNA by Amplifying."

#### Intended Use of the System, page 4

16. Please explain the reference to "16/18/31/33/35/39/45/51/52/53/56/58/59/66/68." Are these the types of HPV that your product can detect?

#### Features and Advantage points of product, page 4

17. Please describe the testing conducted to support the statement that your product candidate produces "[h]igh accuracy & good reproducibility."

#### CBG HPV-DNA Genotyping assay System, page 5

18. The disclosure in this section appears to repeat most of the disclosure that appears starting on page 3. Please consider combining the disclosure in order to avoid repetition.

#### CBG Smoke Detector Kit, page 6

19. Please describe what is shown in the picture on page 7. Also, please confirm that this is the only graphic, visual or photographic information you will include in your filing. Alternatively, provide us with copies of all other graphic, visual or photographic information you plan to include in your filing.

# Regulatory Matters, page 9 Foreign Regulation, page 11

20. Please revise to indicate whether you have received regulatory approval or plan to seek approval to market your product in any foreign country.

#### Intellectual Property, page 12

21. Please disclose the expiration date of the patent that was granted in Korea.

# Competition, page 12

22. Please expand your disclosure to provide a more fulsome disclosure about competition. For example, please describe the two classes of competitors referenced and identify the markets you seek to reach. See Item 101(c)(x) of Regulation S-K.

# Item 1A. Risk Factors, page 13

- 23. Please include a new risk factor relating to the fact that your financial statements have been prepared assuming that the Company will continue as a going concern.
- 24. The headings for a number of your risk factors extend far beyond the margins of the page when viewing your EDGAR submission online or printing it. Please revise the format of your EDGAR filing to avoid having headings extend past the margins.

#### We are dependent on key personnel and scientific consultants..., page 16

25. Please disclose that you have not entered into employment agreements with Dr. Choi, Mr. Park and Mr. Shin.

# We plan to rely upon third-party partners for the manufacture..., page 17

26. To the extent you have entered into agreements with third parties relating to the manufacture of your products, please describe the material terms of those agreements in your Business section and file copies of the agreements as exhibits to the filing, or provide us with a detailed analysis supporting your conclusion that you are not substantially dependent on those third parties. If you have not yet entered into such agreements, please state so in the risk factor.

<u>Item 2. Financial Information, page 22</u>
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations, page 22</u>

27. Please expand your disclosure by referring to the Division of Corporation Finance "Current Issues and Rulemaking Projects Quarterly Update" under section VIII – Industry Specific Issues – Accounting and Disclosure by Companies Engaged in Research and Development Activities. You can find it at the following website address: <a href="http://www.sec.gov/divisions/corpfin/cfcrq032001.htm#secviii">http://www.sec.gov/divisions/corpfin/cfcrq032001.htm#secviii</a>.

Please disclose the following information for each of your major research and development projects:

- a) The nature, objective, and current status of the project and the extent that its success relies on parties other than you;
- b) The costs incurred during each period presented and to date on the project;
- c) The nature, timing and estimated costs of the efforts necessary to complete the project;
- d) The anticipated completion dates;
- e) The risks and uncertainties associated with completing development on schedule, and the consequences to operations, financial position and liquidity if the project is not completed timely; and finally
- f) The period in which material net cash inflows from significant projects are expected to commence.

Regarding b., if you do not maintain any research and development costs by project, disclose that fact and explain why management does not maintain and evaluate research and development costs by project. Provide other quantitative or qualitative disclosure that indicates the amount of the company's resources being used on the project.

Regarding c., d. and f., disclose the amount or range of estimated costs and timing to complete the phase in process and each future phase. To the extent that information is not estimable, disclose those facts and circumstances indicating the uncertainties that preclude you from making a reasonable estimate.

#### Overview, page 22

- 28. Please revise your disclosure to state the sources for the statements that:
  - "markets for diagnostic and therapeutic products for these cancers are substantial and growing," and
  - "the limitations of many current diagnostic and therapeutic products are widely recognized."

- 29. Please expand your disclosure to describe the significance of acquiring a "High Technology Venture Company Certificate" in Korea.
- 30. We note that you have entered into "Memorandum of Understandings with multiple companies." To the extent any of those Memorandum of Understandings contain binding provisions that are material to you, please describe the material terms of the Memorandum of Understanding and file a copy as an exhibit to your filing.

#### Critical Accounting Policies and Estimates, page 23

- 31. Please identify and discuss your accounting policies requiring material critical accounting estimates, the methods used to make the estimates, how accurate they have been in the past and expected to be prospectively. These would generally include, at a minimum, revenue recognition (including allowances for sales returns and discounts), accounts receivable and allowance for doubtful accounts, income taxes, and research and development.
- 32. Please expand your disclosure related to estimates of items that reduce gross revenue such as product returns, chargebacks, customer rebates and other discounts and allowances. Please include the following:
  - a) The nature and amount of each accrual at the balance sheet date and the effect that could result from using other reasonably likely assumptions than what you used to arrive at each accrual such as a range of reasonably likely amounts or other type of sensitivity analysis.
  - b) The factors that you consider in estimating each accrual such as historical return of products, levels of inventory in the distribution channel, estimated remaining shelf life, price changes from competitors and introductions of generics and/or new products.
  - c) To the extent that information you consider in b) is quantifiable, discuss both quantitative and qualitative information and discuss to what extent information is from external sources (e.g., end-customer prescription demand, third-party market research data comparing wholesaler inventory levels to end-customer demand). For example, in discussing your estimate of product that may be returned, consider disclosing, preferably by product and in tabular format, the total amount of product (in sales dollars) that could potentially be returned as of the balance sheet date and disaggregated by expiration period.
  - d) If applicable, discuss any shipments made as a result of incentives and/or in excess of your customer's ordinary course of business inventory level. Discuss your revenue recognition policy for such shipments.
  - e) A roll forward of the liability for each estimate for each period presented showing the following:

- Beginning balance,
- Current provision related to sales made in current period,
- Current provision related to sales made in prior periods,
- Actual returns or credits in current period related to sales made in current period,
- Actual returns or credits in current period related to sales made in prior periods, and
- Ending balance.
- f) In your discussion of results of operations for the period to period revenue comparisons, discuss the amount of and reason for fluctuations for each type of reduction of gross revenue (i.e. product returns, chargebacks, customer rebates and other discounts and allowances) including the effect that changes in your estimates of these items had on your revenues and operations.

## Results of Operations, page 23

33. In your discussion of revenue and various other items in your period to period comparisons you reference several factors that contributed to the changes or provide insufficient discussion of the changes. Please revise your disclosure to quantify the changes that resulted from each of the significant factors which contributed to the changes. Please refer to FRC Section 501.04.

# Three Months Ended March 31, 2010 Compared to Three Months Ended March 31, 2009, page 23

- 34. Please update this section to discuss the periods ended June 30, 2010 compared to June 30, 2009.
- 35. You disclose that for the three months ended March 31, 2010 you realized income derived from sales of your products. Throughout the rest of the filing you have disclosure about the need to conduct clinical trials and obtain approval in order to market your products. Please clarify throughout the filing how you realize income from sales of your products if you still have not conducted the clinical trials or obtained the approvals needed to market your products.

#### Revenue, page 24

36. Please expand your disclosure to explain what you mean by the statement that for the year ended 2009 the realized revenues of \$365,952 were "due in large part to our merger with Catch by Gene Co, Ltd."

#### Liquidity and Capital Resources, page 25

37. Please revise your disclosure to provide an analysis and explanation of the sources and uses of cash and material changes in particular items underlying the major

captions reported in your financial statements, see SEC Release No. 33-8350, IV, B.

- 38. Your statement that your available cash, cash equivalents, in combination with additional capital you plan to raise and loans from related parties will be sufficient to meet your anticipated capital requirements seems inconsistent with risk factor disclosure on page 13 that states that you expect you "will require substantial additional funds before we can expect to realize revenues from commercial sales." Please revise your disclosure to eliminate this apparent inconsistency.
- 39. We note that you rely, or plan to rely, on loans from related parties to fund your operations. To the extent you have entered into any loans agreements with related parties, please file those agreements as exhibits to this filing and, to the extent applicable, describe the terms of the related party transactions under Item 7 of this Form 10.

#### Item 5. Directors and Executive Officers, page 27

40. Please provide for each of your directors a description of the experience, qualifications, attributes or skills that led to the conclusion that the person should serve as a directors for the company. See Item 401(e) of Regulation S-K.

# Item 6. Executive Compensation, page 28

- 41. Please provide the disclosure required by Item 407(e)(4) of Regulation S-K.
- 42. The headings "Option Awards" and "All Other Compensation" in the summary compensation table reference footnotes 1 and 2, respectively, which have not been provided. Please revise your disclosure to include those footnotes.

#### 2009 Director Compensation, page 29

43. We note that directors receive stock awards as compensation. Please revise your disclosure to include the tabular disclosure required by Item 402(r) of Regulation S-K.

# <u>Item 15. Financial Statements and Exhibits</u> <u>Audited Consolidated Financial Statements, page 33</u> Report of Independent Registered Public Accounting Firm, page F-1

- 44. Please present an audit report for the year ended December 31, 2008.
- 45. Your auditors are located in New Jersey; however it appears that the majority of your assets, liabilities, revenues and expenses relate to operations located in Korea. Please have your auditors tell us how the audit of the operations in Korea was conducted. The response should include a discussion of the following:
  - a) Whether another auditor was involved in the audit of the operations in Korea. If so, please tell us the name of the firm and indicate whether they are registered with the Public Company Accounting Oversight Board (PCAOB). Additionally, please tell us how your U.S. auditor assessed the qualifications of the other auditor and the other auditor's knowledge of US GAAP and PCAOB Standards;
  - b) Whether your U.S. auditor performed all the required audit procedures within the United States or whether a portion of the audit was conducted by your U.S. auditor in Korea. Explain how the audit and observation of inventories was performed.

#### General

46. Please add subtotals, lines and align amounts with captions and/or delete unnecessary columns and lines and captions without amounts on pages F-1 through F-5. Refer to the presentation of the unaudited consolidated financial statements for the three and six months ended June 30, 2010 and 2009. Additionally, since you are presenting two set of Financial Statements (one set of audited financials and one set of interim unaudited financials) please do not duplicate the "F" page numbers.

#### Consolidated Statements of Operations, page F-3

- 47. Disaggregate key components of operating costs either here or in a note to financial statements for these and your interim financial statements.
- 48. Please provide, in your notes to financial statements, an explanation for non-operating income in the amounts of \$82,526 and \$47,662 respectively for years 2009 and 2008 and interim periods presented.
- 49. Your earnings per share disclosure is incomplete for 2009 and appears in error for 2008. Please revise or explain.

# Consolidated Statement Of Stockholders' Equity, page F-5

50. Please revise this statement to recast the historical common shares outstanding to reflect the exchange ratio of the September 21, 2009 transaction. For example the common shares at January 1, 2008 of 60,000 should be recast as 34,285,714. In addition, please add a detailed description of the transaction, including how it was accounted for, and the shares issued in Note 1. Completion of Acquisition, on page F-6.

#### Notes to Consolidated Financial Statements

Note 2. Summary of Significant Accounting Policies and Nature of Operations, Nature of Business and Basis of Presentation

Liquidity, page F-6

51. Please provide a discussion and calculations, with page references, to support your statement that "Additionally the profitable operations has started generating internal cash flow from within." On page F-5 of the Cash Flows Statements, you reflect a (\$113,988) cash deficit from Operating Activities. Further your unaudited financial statements for the six months ended June 30, 2010 (page F-4), continues to reflect a (\$13,832) cash deficit from Operating Activities.

# Research and Development, page F-8

52. Please present your research and development expense as a separate line item on your Consolidated Statements of Operations.

#### Recent Accounting Pronouncements, page F-8

- 53. Please expand your disclosures to list the recently issued accounting standards that management evaluated per guidance provided by SAB Topic 11M. The object of the disclosure should be to (1) notify the reader of the disclosure documents that a standard has been issued which the registrant will be required to adopt in the future and (2) assist the reader in assessing the significance of the impact that the standard will have on the financial statements of the registrant when adopted. At a minimum your disclosures should provide:
  - a) A brief description of the new standard, the date that adoption is required and the date that the registrant plans to adopt, if earlier.
  - b) A discussion of the methods of adoption allowed by the standard and the method expected to be utilized by the registrant, if determined.
  - c) A discussion of the impact that adoption of the standard is expected to have on the financial statements of the registrant, unless not known or reasonably estimable. In that case, a statement to that effect may be made.

## Note 4. Inventories, page F-8

54. Please explain what products constitute raw material and finished goods inventories.

#### Note 9. Subsequent Events

<u>Pro Forma Condensed Combined Balance Sheets and Statements of Operations, page F-10</u>

55. Reference is made here to supplemental Pro Forma and historical financial data included in accompanying tables. This data has not been included with your filings. Please include them with the next filing.

<u>Unaudited Consolidated Financial Statements For the Three and Six Months Ended June</u> 30, 2010 and 2009

Statements of Operations, page F-3

- 56. When you update your results of operations, please provide a discussion of why you are showing a negative gross profit from sales and include what management intends to do to reverse this and when.
- 57. Please add Earnings per Share tables.

#### Notes To Condensed Consolidated Financial Statements

Note 3. Accounts Receivables – Trade

Allowance for Doubtful Accounts, page F-7

- 58. Please expand your disclosure to provide an explanation for the following:
  - a) Why the Accounts Receivable balances are not being reduced.
  - b) Provide an aging of Accounts Receivable.
  - c) Disclose your payment terms and explain why you have recorded no allowance for those receivables that have not been collected by the due date.

State the steps you take in collecting accounts receivable. Disclose your policy with respect to determining when a receivable is recorded as a bad debt and when a write off is recorded. Clarify the threshold (amount and age) for account balance write-offs.

#### Note 5. Borrowing from Financial Institutions, page F-7

- 59. At June 30, 2010, the maturity date (May 7, 2010) of the \$247,002 bank loan had passed. We have the following comments:
  - If the loan has been renewed, disclose the new maturity date and what changes, if any, have been made to the interest rate and collateral. If the

- loan is in default, provide disclosure of the financial implications and what management's plans are to cure the default.
- Disclose how interest expense in the Statements of Operations could amount to only \$983 and \$11,422 for the three and six months ended June 30, 2010 respectively when the annual interest on the \$247,002 bank loan is over 15% and there appears to be an additional outstanding loan as well.

#### Exhibit 3.1

60. Please file the most recent version of your certificate of incorporation. We note that the most recent amendment filed under Exhibit 3.1 still refers to Clinicares, Inc. and is dated November 29, 2007.

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 Exchange Act of 1934 and all applicable Exchange 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.

In responding to our comments, please provide a written statement from the company acknowledging that:

- the company is responsible for the adequacy and accuracy of the disclosure in the filing;
- staff comments or changes to disclosure in response to staff comments do not foreclose the Commission from taking any action with respect to the filing; and
- the company may not assert staff comments as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

You may contact James Peklenk at (202) 551-3661 or Joel Parker at (202) 551-3651 if you have questions regarding comments on the financial statements and related matters. Please contact Sebastian Gomez Abero at (202) 551-3578 or Suzanne Hayes at (202) 551-3675 with any other questions.

Sincerely,

Jeffrey Riedler Assistant Director

Cc: Jillian Ivey Sidoti 34721 Myrtle Court Winchester, CA 92596