



March 28, 2016

<u>Via Edgar</u>
Amanda Ravitz
Assistant Director
Office of Electronics and Machinery
United States Securities and Exchange Commission
Washington, D.C. 20549

Re: Pulse Biosciences, Inc.
Amendment No. 1 to Registration Statement on Form S-1
Filed March 7, 2016
File No. 333-208694

Dear Ms. Ravitz:

Our client, Pulse Biosciences, Inc., (the "Company"), has forwarded to me your letter to the Company of March 21, 2016, in which you set forth several comments. I am responding to the comments on behalf of the Company. Each of the comments is reproduced below with the Company's response thereafter.

If you have further questions about this response, please forward them to me as well as to the Company. My email address is <a href="mailto:ahudders@golenbock.com">ahudders@golenbock.com</a>, and my telephone number is 212-907-7349.

### Prospectus Summary, page 1

1. Please provide us with copies of the documents mentioned in the footnotes on pages 1-3 and in the footnotes that now appear on pages 26-30 as we requested in the second sentence of prior comment 4.

### Response:

Supplementally, we have provided the requested document copies that are noted in the footnotes on pages 1-3 and 26-30, and highlighted the relevant supporting information in the documents for the statements in the prospectus. These are being sent directly to you by Fed Ex.

2. We note your response to prior comment 5. Revise the disclosure in the first full paragraph on page 2 to disclose which footnotes throughout your document are related to

studies and papers authored by Dr. Nuccitelli. Also, ensure that you have disclosed the relationship between you and the authors mentioned in the footnotes throughout your document. For example, we note the reference to "Nuccitelli P." in footnote (3) on page 2, footnote (19) on page 28 and footnote (30) on page 30.

### **Response:**

We have added to the disclosure on page 2 to indicate the footnotes where articles by Dr. Nuccitelli and his wife, Patricia Nuccitelli, are identified. The company, in the text, has noted statements that are based on the work of Dr. Nuccitelli.

3. We note your response to prior comment 7. Please revise the disclosure about "pre-clinical data" mentioned in the second paragraph on page 1 to remove any implication that the data is the result of your studies. Also, revise the disclosure about "Animal studies" mentioned in the second paragraph on page 26, "Animal trials have suggested" mentioned in the penultimate paragraph on page 27 and "Existing animal data suggest" mentioned in the last paragraph on page 27 to remove any implication that the data is the result of your studies.

### Response:

The Company has added information to identify that the discussion in our document includes citations to work performed by others. The Company believes that citing data generated independent of the Company, and presented in peer reviewed scientific papers, is valuable to investors, because unaffiliated, peer reviewed data provides corroboration of the Company's hypothesis' surrounding its core technology.

An advantage of peer-reviewed papers is that one or more other people in the field of study have examined the research performed and independently concluded that the paper is suitable for publication. The peer-review process is intended to ensure conclusions drawn are well supported by evidence and that enough information is contained for experiments to be repeated and the results verified. In addition, the process verifies that the author has discussed and explained contradictory theories and considered whether the results obtained can be applied generally or only narrowly due to carefully chosen specific experiments. The criteria by which a paper can be judged as suitable can vary, but usually includes; technical accuracy, significance of the data, relevance, timeliness, etc. This process intends to provide the reader with confidence in the level of quality of the research performed. Again, we believe the peer-reviewed data are complimentary to the work performed by the Company and valuable to potential investors.

4. Refer to your discussion of 510(k) clearance on page 4. Please revise further so an investor may understand why their might exist a "predicate device" for these purposes, in light of your disclosure elsewhere that you believe your device is the first or only device to perform the functions described in your prospectus.

#### Response:

The term "predicate device" as defined in FDA guidance is a substantial equivalence test with two principal pillars; the device must have 1) the same intended use as the predicate device and 2) the same technological characteristics or different technological characteristics that do not raise different questions of safety and effectiveness than the predicate device. We believe our technology is the first ablation technology to utilize nano-pulse electro-signaling; however, our planned product meets the criteria for substantial equivalence as defined by the Agency.

We point to our discussion in the Registration Statement for a discussion of this topic:

#### "510(k) pathway

... "Substantial equivalence" means that the proposed device or product has the same intended use as the predicate device and the same or similar technological characteristics and the information submitted in the 510(k) demonstrates that the proposed device is as safe and effective as the predicate device, and the proposed device does not raise different questions of safety and effectiveness than the predicate device."

5. We note your response to our prior comment 9. Please revise further to discuss the limited nature of certain of the referenced studies and trials. For example, we note the limited subject pool of several of the studies.

### Response:

The Company does not believe that the referenced studies and trials were limited beyond their pre-clinical nature. The use of animals for testing new medical devices for tumor ablation is strictly regulated by the NIH Office of Laboratory Animal Welfare. All animal experiments must be reviewed and approved by our Institutional Animal Care and Use Committee. For every experiment the Company must provide statistical justification of the number of animals used with the overriding principle of using the minimal number of animals to obtain a statistically significant result with a power of at least 0.8. For most experiments using a strong ablation method such as ours, this power can be obtained using a small pool of subjects, such as an N of 10 experimental animals and 10 controls. We believe that the studies and trials performed were statistically powered to achieve scientifically meaningful data and the pool of subjects in the studies was appropriate in accordance with prevailing scientific standards.

### Because we and one of our licensors have used federal funding, page 11

6. We note your response to prior comment 13. Please remove the disclosure in the sixth sentence in this risk factor that mitigates the risk.

### Response:

The sentence about mitigation has been removed from the risk factor.

### License and Other Agreements, page 37

7. We note your response to prior comment 17. Please tell us with specificity where the provision concerning the milestone mentioned in the fifth paragraph of this section appears in your license agreement with ODURF and EVMS.

# Response:

The milestone appears in Exhibit C to the License agreement with ODURF and EVMS. The company will add that exhibit to the form of license agreement and seek confidential treatment with respect to the milestones consistent with the public disclosure and regulation. The company points out that all but the last milestone, which is discussed in the prospectus, have been satisfied.

### Executive Employment Agreements, page 68

8. Please tell us why you did not include in this filing the disclosure regarding Dr. Richard Nuccitelli that appeared on page 71 of your prior filing.

### Response:

The discussion about Dr. Nuccitelli's employment agreement was excluded because Dr. Nuccitelli is not a "named executive officer" of the company in accordance with SEC regulations. The content of the deleted paragraph has been added to the section on related party transactions.

### Related Party Transactions, page 70

9. Please tell us with specificity where you included the disclosure in response to prior comment 26 regarding proceeds of this offering to be used to pay the amounts owed to the related parties.

### Response:

The related party disclosures have been updated to reflect the amount anticipated to be paid to related parties.

No amount of the proceeds will be used to pay The Frank Reidy Research Center under the Research and Funding Agreement. During the year ended December 31, 2015, the company paid \$1,036,364 related to the various task orders, and in the months of January and February paid the final \$163,636 due. The full amount of the contract amount, \$1,200,000 has been fully paid, and currently, there are no additional tasks to be undertaken by the Reidy Center for the company.

# Principal Stockholders, page 72

10. Refer to footnote (2). Tell us how you determined it was appropriate to exclude the shares underlying options from the table.

#### Response:

The company has disclosed in the second paragraph of the section "Principal Stockholders" the following sentences: "The SEC has defined "beneficial ownership" to mean more than ownership in the usual sense. For example, a person has beneficial ownership of a share not only if he owns it, but also if he has the power (solely or shared) to vote, sell or otherwise dispose of the share. Beneficial ownership also includes the number of shares that a person has the right to acquire within 60 days of the date of this prospectus, pursuant to the exercise of options or warrants or the conversion of notes, debentures or other indebtedness."

The company respectfully believes that this disclosure is adequate to indicate the shares that are included in the table, and the footnote disclosure of the additional shares that may vest in the future and become beneficially owned as defined by the SEC regulation is supplemental, helpful, investor information. The table is updated as the company files amendments, and the corresponding date for the data is updated as well.

Therefore, there is no change to the footnotes to the table of Principal Stockholders.

### Underwriting Discounts and Expenses, page 88

11. Tell us whether you considered whether the rights offering should be valued and included in underwriting compensation.

#### Response:

The provision of the rights offering is an obligation of the company to make an offering to its then stockholders at the future time it plans on making an offering of securities that are themselves common stock or a derivative of common stock. There are certain exceptions to this obligation, which are stated in the prospectus. The rights offering requirement is with respect to any offering, private or public, by the company, which is not excepted. It relates to any form of security that the company may develop as the offered instrument, as long as it is or has a component of common stock. This security must first be offered to the stockholders as a rights offering. The obligation does not require the company to engage MDB Capital Group LLC or Feltl and Company, Inc. to act in any capacity with respect to the rights offering, such as a standby underwriter, placement agent, solicitation agent or information agent. Actually, the company can conduct the entire rights offering on its own, without the facilities of an underwriter or other FINRA member. We have also been informed that this term of the underwriting agreement is not an element of compensation to the underwriters of this proposed offering. Therefore, there is no requirement of the rights offering provision to be valued or included in underwriting compensation.

#### Report of Independent Registered Accounting Firm, page F-2

12. We note that the report of your independent auditor is not signed. Please amend your filing to include a signed audit report. Refer to Rule 2-02(a) (2) of Regulation S-X and

Item 302 of Regulation S-T which provides guidance on including signatures in electronic filings.

#### **Response**:

The newly filed report of the independent auditor has been duly indicated in the filing as signed. The report had been signed, and the omission of the conformed signature was an error.

## **Exhibits**

13. We note your response to prior comment 29. Please file as an exhibit the research and funding agreement mentioned on page 39.

### Response:

As noted above, the Reidy Center agreement for research has been fully performed and has been fully paid. Therefore, no amount of the proceeds of the offering will be used to make the payments due thereunder. The company has not commissioned any further research engagements from the Reidy Center at this time, and cannot currently predict if it will have further engagements requiring the research capabilities of the Reidy Center.

The company considers the Reidy Center agreement to be one entered into in the ordinary course of business. It is typical that the company in the medical fields will engage research institutes of one kind or another to conduct defined research and experimentation. There are many of these sorts of entities that exist to conduct third-party research, which include educational institutions, medical centers and private research institutions. In the areas relevant to the company there are many different research organizations that can be employed, which will depend on the research to be undertaken. For example, there are those that can deal with nanopulse and other electrical pulse research, human and veterinary oncology, dermatological ablation, etc. The company anticipates engaging different research institutions from time to time as it implements its product development and then pursues its clinical research.

Based on the forgoing, the fact that the agreement is fully performed and the fact that this is a common form of agreement that the company will enter into from time to time, and the fact that the amount of funding was a portion of the overall assets of the company when the agreement was made and performed and there could have been other research facilities available to perform the research, the company takes the position that it is an agreement entered into in the ordinary course.

Sincerely,

/s/ Andrew D. Hudders

Andrew D. Hudders Golenbock Eiseman Assor Bell & Peskoe LLP