

PULSE BIOSCIENCES, INC.
3957 Point Eden Way
Hayward, California 94545

June 9, 2022

VIA EDGAR

United States Securities and Exchange Commission
100 F. Street, NE
Washington, DC 20549

Attention: Frank Wyman
Mary Mast

**Re: Pulse Biosciences, Inc.
Form 10-K for the Fiscal Year Ended December 31, 2021
Filed March 31, 2022
File No. 001-37744**

Dear Ladies and Gentlemen:

This letter sets forth responses on behalf of Pulse Biosciences, Inc., a Delaware corporation (the “Company”), to the comments received from the staff (the “Staff”) of the Securities and Exchange Commission (the “Commission”) set forth in your letter dated May 25, 2022 (“Comment Letter”) regarding the Company’s Form 10-K for the Fiscal Year Ended December 31, 2021 (the “Form 10-K”).

For the convenience of the Staff, the comment from the Comment Letter corresponds to the numbered paragraphs in this letter and is restated prior to the response to such comment.

Form 10-K for the Fiscal Year Ended December 31, 2021

Notes to Consolidated Financial Statements

9. Revenue

Performance Obligations, page 86

1. **You state that the Cycle Units (CUs) are credits that authorize the customer to perform a procedure and that each procedure requires a specific number of CUs. Once the CUs are reduced to zero, the customer is required to purchase additional CUs to perform additional procedures. Please address the following with regard to your revenue recognition policy for your Cycle Units:**
 - **Tell us, and clarify in future filings, if the CUs are bundled together into a single performance obligation when you record the initial sale of the CellFX System pursuant to ASC 606-10-25-22.**
 - **If such is the case, please tell us why recognition at a point in time for the sale is appropriate given the CUs are utilized over time and the System cannot be used without the CUs. Refer to ASC 606-10-25-27.**

RESPONSE:

The Company has identified the promised goods and services in its contracts with customers¹ and assessed whether they are distinct and represent performance obligations. The initial sale of the CellFX System typically includes a CellFX console together with embedded software, as well as handpieces, disposable tips and CUs. As discussed in more detail below, we concluded each of these items represent promised goods. Also, each is capable of being distinct and is distinct in the context of the contract, and thus can be characterized as a separate performance obligation.

Our conclusion that CUs (which can be seen as a specialized consumable) included in the initial CellFX System sale are both capable of being distinct and distinct in the context of the contract is consistent with the approach in Example 11 Case E included in Accounting Standards Codification (ASC) Topic 606 (ASC 606-10-55-150G through 55-150K) and follows the same rationale as applies to all other units (the console, handpieces, and disposable tips) included in the initial CellFX System sale.

¹ Our customers are physicians; in the context of this letter, we use words “customers” and “physicians” interchangeably.

We respectfully note that we already disclose in footnotes to our financial statements that CUs are a separate performance obligation.

Refer to footnote 9 in the Form 10-K, which we will supplementally enhance in future filings as follows, subject to change based on changes in circumstances (the additional language has been underscored, the removed language stricken through): “CUs represent a distinct performance obligation which is satisfied when upon delivery of the CUs are made available for customers to download from the Company’s to CellFX CloudConnect, as customers can use purchased CUs at any time at their discretion, and the Company does not provide any ongoing service or other forms of involvement after the sale occurs.”

The availability of the cloud is not considered a part of the performance obligation because the CellFX System can be used without being connected to the Internet, or to the Company’s cloud in particular.

The Company has determined that CUs are each capable of being distinct based on the guidance in ASC 606-10-25-20. The Company sells CUs on a standalone basis, following the initial system sale. The Company also sells all other goods (handpieces, tips and consoles) on a standalone basis. Standalone console sales are, for example, to replace a console damaged outside the warranty protection, or to add another console, e.g., in a different physical location. A physician can transfer any of the existing CUs from an existing console to a new one.

Customers bear all rights and risks associated with the console ownership and can also sell their consoles to third parties. Thus, CUs (as well as all other goods sold by the Company) are capable of being distinct as customers can benefit from them together with other readily available resources (i.e., either previously purchased or separately sold console, CUs, tips and handpieces as applicable). Additionally, the physician has the right to transfer the CUs to another physician.

We assessed that each promised good (the console, handpieces, tips and CUs) is distinct in the context of the contract based on the guidance in ASC 606-10-25-21. We concluded that none of the factors (a) through (c) discussed in this paragraph apply to our goods.

The Company supplies these goods separately and provides no service to integrate them into a combined output. Also, none of these goods significantly modify or customize any of the other goods sold by the Company. Finally, these goods are not highly interdependent nor highly interrelated. If an entity cannot fulfil its promise to transfer each of the goods independently, this may indicate that the goods are highly interdependent or highly interrelated. However, as discussed above, the Company sells each of its goods separately. The Company’s ability to fulfill its promise and sell any of its goods (including CUs) does not depend on its ability (or inability) to sell or transfer any of the remaining goods.

Based on the above considerations, we concluded that each of the goods sold by the Company is both capable of being distinct and also distinct in the context of the contracts with customers. Therefore, CUs are not bundled together into a single performance obligation with any other goods when the initial sale of the CellFX System is recorded.

The Company reviewed ASC 606-10-25-27 and concluded that none of the criteria (a), (b) or (c) are met, and therefore recognition of revenue from CUs is at a point in time. The customer does not consume the benefit of the CU simultaneously with their receipt. This is because the benefit is consumed when/as customers perform patient treatments. Until then, CUs represent customer-controlled assets that are stored inside the CellFX System. Additionally, by its very nature, there is no period of time over which the asset is created.

In your analysis, please distinguish your accounting treatment between sales of the CellFX Systems in and outside the Controlled Launch Program.

RESPONSE:

As further discussed below in response to question 3, as part of the Controlled Launch Program the Company provides and sets up a CellFX System at a participating physician site and provides the physician with the necessary related products and specialized consumables to enable him/her to complete the requirements of the Controlled Launch. The Controlled Launch is a program focused on procurement of services from physicians, does not contemplate an immediate sale and does not require the physician to purchase the CellFX System or other components. Therefore, the CellFX System and any unused component products remain the property of the Company throughout the Controlled Launch. Typically a participating physician completes his/her involvement in the Controlled Launch in 6 months to a year.

The Controlled Launch Program does allow participating physicians to elect to purchase the CellFX System at the end of the program by applying the accumulated credits to the purchase price. Once the purchase by the physician occurs, the Company accounts for the sale in the same manner as for any sales outside the Controlled Launch Program. We address other aspects of the accounting for the Controlled Launch Program in our response to question 3 below.

- **Tell us your basis for concluding the CUs represent a "good" vs. a "service" (e.g., not accompanied by subsequent Pulse Bio consultation regarding CUs necessary for a novel dermatological procedure). Tell us the nature/form of the CUs, how they are delivered to the customer and how unused CUs are stored.**

RESPONSE:

The downloaded CUs reside on the customer's console and the Company has no involvement when the physician performs treatments. The Company also does not provide consultations to physicians beyond basic information on how to operate the CellFX System. The system is substantially "plug and play" and can be operated out of the box as-is.

- **For sales of additional CUs outside the initial sale of the CellFX System, tell us, and clarify in future filings, why immediate revenue recognition at a point in time is appropriate upon delivery to the CellFX CloudConnect given the performance obligation does not appear to have been met until the customer redeems the CU upon performing a procedure.**

RESPONSE:

CUs are delivered electronically within minutes of placing a reorder through the System console. The Company is not involved in any manner when the treatments are conducted and neither monitors nor can influence their timing. Connection to the Internet is not required for the console to perform a treatment. Therefore, we concluded our obligation to transfer CUs is satisfied at the time CUs are delivered electronically and not when they are used. The Company has reviewed its historical disclosures and will supplement footnote 9 to our consolidated financial statements in future filings with disclosure substantially similar to the following, subject to change based on changes in circumstances (the additional language has been underscored, ~~the removed language stricken through~~):

Performance Obligations

CUs represent a distinct performance obligation which is satisfied when upon delivery of the CUs are made available for customers to download from the Company's to CellFX CloudConnect, as customers can use purchased CUs at any time at their discretion, and the Company does not provide any ongoing service or other forms of involvement after the sale occurs.

Performance Obligations, page 86

2. **Disclose how you determine the transaction price. Refer to ASC 606-10-50-20.**

RESPONSE:

In response to the Staff question, the Company has reviewed its historical disclosures and will supplement in future filings with disclosure substantially similar to the following, subject to change based on changes in circumstances (the additional language has been underscored, ~~the removed language stricken through~~):

9. Revenue

...

Transaction Price

The transaction price is the consideration to which the Company expects to be entitled to in exchange for providing the promised goods to customers. Customer orders placed for cash contemplate a fixed amount of consideration. Customer orders placed by physicians participating in the Controlled Launch when they elect to purchase the CellFX System are paid for via conversion of accumulated earned credits for prior services provided by the physicians under the terms of their participation in the Controlled Launch. For these transactions, the transaction price includes noncash consideration. The services rendered by the physicians are accounted for separately from the subsequent sales of the CellFX Systems because they are distinct from the system sales. They are distinct because they provide the Company with treatment data that can also be procured, and historically has been procured by the Company, without the corresponding system sales. This data is used by the Company to enhance marketing and promotion of its products.

[The existing paragraph on allocation considerations will be relocated as noted below.]

The Company evaluates the possible impact of variable consideration in determining the transaction price, in particular the possibility of future returns or credits. Sales agreements allow for a right of return only if the product does not conform to the agreed upon quality standards or if the product was shipped due to Company error. The Company anticipates such returns will be minimal and has made no adjustments to the transaction price for any estimated returns. The transaction price is determined at the time of the initial revenue recognition and updated each quarter for any changes in circumstances (e.g. changes in estimated return or credit rates).

The Company has made an accounting policy election to exclude from the measurement of the transaction price all taxes which are imposed on and concurrent with a specific revenue-producing transaction and collected by the entity from a customer.

When there are multiple performance obligations present, the total transaction price shall be allocated to each of the performance obligations based upon the relative standalone selling price (“SSP”) of those performance obligations. The Company establishes SSPs based on multiple factors including, prices charged by the Company for similar offerings, product-specific business objectives, and the estimated cost to provide the performance obligation. However, upon the sale of a new CellFX System, all performance obligations are delivered concurrently and therefore there is no impact to revenue recognition timing, and the Company has determined allocations are not necessary. Should the customer purchase additional CUs, handpieces, or tips at a later time, those purchases will be made under separate purchase agreements, with all promised goods generally transferred at the same time, containing only one performance obligation each, therefore no price allocation is necessary in that scenario either.

Controlled Launch Agreements, page 87

3. **You state on page 85 that as patient procedures and surveys are completed under the Controlled Launch, you accrue the value of credits earned by the participants in accrued expenses with a corresponding charge to sales and marketing expense. You state on page 55 that the majority of your revenue for the year-ended December 31, 2021 was recognized on a non-cash basis when Controlled Launch Program participants applied their earned credits towards the purchase of a CellFX System. You disaggregate your revenue on page 87 of the 10-K by product and disclose on page 85 the amount of the accrued liability related to the Controlled Launch that was relieved and recognized as revenue on a non-cash basis. Please address the following:**
- **Provide us an analysis of the basis for your accounting treatment for the earned credits.**
 - **Help us understand your basis for recognizing revenue on the sale of the CellFX System that in substance has been provided "free-of-charge".**
 - **Tell us your accounting treatment and the basis thereof for relieving the accrued expenses for CellFX Systems included in the Controlled Launch Program. Separately discuss when the accrued expenses are relieved for a sale and for which a sale is not ultimately consummated.**
 - **Tell us the basis for initially recording the earned credits as sales and marketing expenses.**

RESPONSE:

We respectfully submit that in our opinion we do not sell the CellFX System to physicians participating in the Controlled Launch Program “free-of-charge”, i.e., for no consideration.

As noted above, the Controlled Launch Agreement does not require the physician to purchase the CellFX System. Therefore, there is no contract with the customer under ASC Topic 606. The Company considers the CellFX Systems distributed under the Controlled Launch Agreements to remain the Company's assets.

Under the Controlled Launch, the physician completes evaluation surveys for each treatment and provides various other information, along with the related consents. The surveys and other treatment information enable the Company to observe the effectiveness of treatments using its CellFX Systems, help it structure a sales and marketing plan and future marketing and promotional efforts, improve commercialization techniques, promotional materials, etc. It is also helpful to defining best practices for the introduction of the CellFX System into the clinical practice.

This information is collected prior to and immediately after the treatments, and in follow up visits. Absent such arrangements, the physicians are not required to share this information with the Company. Thus, the Controlled Launch Program is for the benefit of the Company's own marketing and promotional activities and is therefore considered distinct from any sales the Company may subsequently make to the participating physicians.

Upon completion of the procedures and submission of each treatment information to the Company, the physician earns a credit which can be used towards the future purchase of the CellFX System in their possession. During the year ended December 31, 2021, a substantial majority of the credits issued could also be redeemed for cash, with the physicians controlling the choice whether to use the credits for purchase of the system or for payment in cash.

If the physician accumulates the maximum number of credits that can be earned, this will equate to the entire cash price (i.e., the current SSP) for which the CellFX System can be purchased. However, the physician may also elect to cancel its participation in the Controlled Launch Program and either purchase the CellFX System for its cash price net of the available accumulated credits, or return the system and, where applicable, redeem the credits for cash. The cash value of the credits is a percentage (less than 100%) of its value towards the purchase of the system.

We supplementally clarify that the Controlled Launch is not a part of any clinical trial or clinical study conducted by the Company. While the information received could be used to an extent for purposes of future product improvements, the Company has previously substantially completed its research and development related to the approved treatments. Therefore, the Company concluded any cost incurred as part of the Controlled Launch should be characterized as sales and marketing expense in its consolidated statements of operations.

The amount of the cost the Company incurs for each treatment performed and each survey submitted by the physician is uncertain. This is because most of the physicians have a choice to either eventually apply the accumulated credits to the purchase of the CellFX System in their possession, redeem them for a smaller amount in cash, or forfeit them and return the system to the Company.

When the physician elects to participate in the Controlled Launch Agreement, the Company believes there is at least reasonable contemplation that the purchase of the CellFX System will occur. Absent such contemplation, there is no practical reason for the physician to invest time and effort to participate in the program. We also expect physicians to elect the more beneficial settlement alternative for the accumulated credits, i.e., apply them to the purchase of the system. Therefore, the Company has determined that it is appropriate to accrue for the full value of the credit as a marketing expense, as the value of the data related to the procedures performed by the physician. As the Company does not have a contract with a customer at the time the liability for the credits is recorded, the amount is initially classified as an accrued expense.

If the physician eventually applies the credits to purchase the CellFX System, he/she will become a customer. Consequently, the Company applied the guidance on consideration payable to a customer to determine if the costs incurred should be reported separately from the revenue from the sale of the system, as specified in ASC 606-10-32-25 and 32-26. This guidance specifies that consideration payable to a customer may be in the form of credits (coupons, vouchers) that may be applied against the amounts owed to the entity, and should be accounted for as a reduction in the transaction price unless it is in exchange for a distinct good or service acquired from the customer, and then only to the extent of the fair value of such distinct good or service.

As discussed above, the Company determined that the data (surveys and the treatment information) received from the physicians is distinct from the potential subsequent sale of the CellFX System.

The Company has previously purchased such data in standalone transactions from other entities who were not and would not become its customers. The Company derives its estimates of the fair value of such data from these third-party transactions. The Company has determined the consideration it pays to the physicians in the Controlled Launch (in the form of credits on a per patient basis) is substantially less than the per-patient price of the data as paid in standalone transactions with third parties, and therefore the value of the credits satisfies the fair value requirements of ASC 606-10-32-26.

In addition to the guidance on consideration payable to customers, the Company also considered the guidance on determination of transaction price where consideration is noncash, included in ASC 606-10-32-21 and 32-22. This guidance requires noncash consideration to be measured based on its fair value, or in the absence thereof, based on the SSP of the sold goods or services.

In applying the above guidance, the Company concluded that upon the physician election to purchase the CellFX System in their possession, revenue should be measured at the amount of the redeemed credits, which satisfies both the requirements of ASC 606-10-32-22 as the SSP of the sold CellFX System and ASC 606-10-32-26 as it does not exceed the fair value of the data purchased from the customer. The maximum credit available to be earned by the physician through the Controlled Launch Program equals the SSP of the CellFX System, and the physicians who participate in the Controlled Launch Program would not be expected to pay more than SSP for the purchase the CellFX System.

If the physician elects to purchase the CellFX System, the accumulated accrued liability is recognized as revenue when the System ownership is transferred, as a result of there now being a contract with a customer.

If the physician elects not to purchase the system, cash is paid to settle the amount owed. Any remaining accrued liability is reversed as a reduction in sales and marketing expense. Such reversals have been rare in practice.

We supplementally note that the overall volume of revenues from the physicians purchased at completion of their participation in the Controlled Launch is not expected to be a significant source of revenue for the Company in the future.

- o **In this regard, we note on page 5 that you are expanding your clinical studies to broaden the approved uses of the CellFX System. Reference key terms in the contractual arrangements with the physicians and practices that support your accounting as sales and marketing expense.**

RESPONSE:

The Company respectfully notes that the clinical studies discussed on page 5 are not related to the Controlled Launch. In February 2021, subsequent to the Company receiving 510(k) clearance from the U.S. FDA for its proprietary CellFX System for dermatologic procedures requiring ablation and resurfacing of the skin, the Company commenced the Controlled Launch of the CellFX System in the United States and European Union, and later in Canada. This Controlled Launch Program is primarily promotional and marketing in nature, as discussed above, and focuses on the physicians' use of the CellFX Systems for already approved treatments.

The clinical studies mentioned on page 5 relate to our ongoing efforts to broaden the approved uses of the CellFX Systems. For example, we discuss on page 10 of our Form 10-K in more detail our ongoing clinical studies in dermatofibroma and Basal Cell Carcinoma ("BCC") in the US, dermatofibroma, moles, actinic keratosis and BCC in Europe, and plantar warts in Canada. These studies are currently a focus of our research and development efforts and the related costs are included in research and development expenses.

- **Confirm that the customer has title to the CellFX System upon consummation of the sale transaction. If the CellFX System may revert back to the company, tell us your consideration of recording the portion of the sale relating to the System as a lease pursuant to ASC 842.**

RESPONSE:

As noted above, the initial placement of the CellFX System under the Controlled Launch is for the Company to obtain the benefit of the data from the participating physician, while the system remains the Company's asset. Title and control of the CellFX System transfer to the physician only after execution of a purchase agreement.

Customers have rights of return only in the following limited circumstances: (1) the system when received by customer did not conform to the Company's quality standards or was damaged prior to shipment by the Company, or (2) the system was sent to the customer due to the Company's error. These circumstances are not applicable in sales arising from the Controlled Launch. In addition, any returns in our sales of CellFX Systems for cash are expected to be minimal. We have discussed the effect of the rights of return on the transaction price in Note 9 to our consolidated financial statements included in our Form 10-K, and in our response to Question 2 above. Therefore, we do not believe the guidance in ASC 842 is applicable to our sale transactions.

- **Notwithstanding the above, tell us why you believe recognizing the revenue recorded on a non-cash basis in the same line item on the Statement of Operations as revenue earned on a cash basis is appropriate.**

RESPONSE:

The Company respectfully notes that we are not aware of a requirement to separately disclose revenue earned in exchange for noncash consideration on the face of the statement of operations. Additionally, the Company respectfully notes by analogy the staff interpretations in SAB Topic 14.F, where the Commission has suggested that cash and non-cash share-based compensation should be presented in the same line in the statements of operations. We do believe in the importance of transparent disclosure to the users of our consolidated financial statements of the relevant facts and circumstances applicable to the consideration received from customers. The Company respectfully refers the Commission to footnotes 8 and 9 in our consolidated financial statements and also page 55 in the Company's Form 10-K, where we discuss that approximately \$1.1 million of revenue was driven by the redemption of non-cash credits earned as part of Controlled Launch. The Company advises the Commission that non-cash revenue as a percentage of total revenue is expected to decrease in the future as the system becomes more established in the market.

- **Tell us why the presentation of relieving the accrued expenses as Revenue is appropriate when the cost of revenue was previously recorded as sales and marketing expense.**
- **In addition, we note that revenue is being recorded without a related cost of Sales.**

RESPONSE:

The Company respectfully refers the Commission to our conclusions presented above related to the nature of the activities that are part of the Controlled Launch Program, which are reported in sales and marketing expenses and are distinct from our sales of CellFX Systems to the participating physicians. These sales and marketing costs are different and unrelated to the cost of the systems we sell. We also discussed above how the accrued liability is settled and revenue is recognized when the customer elects to purchase the CellFX System by applying the accumulated credits to the purchase price.

As related to the cost of sales of CellFX Systems sold to physicians following their participation in the Controlled Launch Program, we confirm that it is reported in cost of sales when such sales occur and revenue is recognized. We supplementally note that in February 2021, the Company received 510(k) clearance from the U.S. FDA for its proprietary CellFX System for dermatologic procedures requiring ablation and resurfacing of the skin. The Company had commenced manufacturing of CellFX System inventories prior to the clearance, to minimize the time to the market. However, as the FDA clearance was uncertain, in the periods through December 31, 2020, all costs of manufacturing were recorded as research and development expenses as incurred. Commencing January 1, 2021, these costs have been capitalized as cost of inventories, and recognized in cost of revenues when the inventories are sold. As a result, the cost of sales reported in our statement of operations for the year ended December 31, 2021, as a percentage of revenue, is lower than what we expect it to be on a recurring basis.

- **Cite any applicable guidance you used in determining the accounting treatment.**

RESPONSE:

The Company respectfully refers the Commission to the guidance cited throughout this letter.

Should you have any further questions or comments, please do not hesitate to contact me at Sandra.Gardiner@pulsebiosciences.com or (510) 906-4630, or alternatively, Ken Stratton, General Counsel, at Ken.Stratton@pulsebiosciences.com or (510) 905-1106.

Sincerely,

/s/ Sandra A. Gardiner
Sandra Gardiner
Chief Financial Officer

cc: Ken Stratton, General Counsel
Adam Finerman, BakerHostetler