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

DIVISION OF
CORPORATION FINANCE

March 14, 2022

Jonathan Kaufman
Chief Executive Officer
Lipella Pharmaceuticals Inc.
7800 Susquehanna St., Suite 505
Pittsburgh, PA 15208

Re: Lipella Pharmaceuticals Inc.
Draft Registration Statement on Form S-1
Submitted February 14, 2022
CIK No. 0001347242

Dear Mr. Kaufman:

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

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. 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 the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form S-1 submitted February 14, 2022

Prospectus Summary, page 1

1. Please tell us the basis for your disclosure that you are "developing LP-10 and [y]our Platform to be, to [y]our knowledge, the first drug candidate and drug delivery technology used to treat cancer survivors who acquire HC."

Our Product Pipeline, page 2

2. We note your disclosure in your pipeline table that you anticipate reporting top-line data in 4Q22 for your phase 2a clinical trial of LP-10. However, we note your disclosure elsewhere, including at the top of page 3, where you state you "expect to report top-line

data from LP-10's phase 2a clinical trial in the third quarter of 2022." Please correct for this inconsistency or otherwise advise.

3. We note the inclusion of LP-310 in your pipeline table. Given the limited disclosure related to this program, please explain why it is sufficiently material to your business to warrant inclusion in your pipeline table. If it is material, please expand your disclosure in the Business section to provide a more fulsome discussion of this program, including a description of studies or development activities conducted. Alternatively, remove any programs that are not currently material from your pipeline table.

Risk Factors Summary, page 5

4. Please expand your disclosure to add a risk factor and summary risk factor discussing your independent registered public accounting firm's doubt about your ability to continue as a going concern.

5. Please expand you risk factor bullet regarding your Chief Executive Officer and Chief Medical Officer's substantial influence on all matters submitted to your stockholders to quantify the percentage of voting power that will be held by such individuals after this offering.

Use of Proceeds, page 43

6. Please revise your disclosure to indicate how far the proceeds from the offering will allow you to progress with continued development of each program referenced. For example, please clarify whether or not you expect to complete the Phase 2a trial for LP-10 with the $7 million you currently have allocated "for the advancement of the LP-10 clinical trials" in your use of proceeds section.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Critical Accounting Policies and Significant Judgments and Estimates
Stock-Based Compensation, page 54

7. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the IPO and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances. Please discuss with the staff how to submit your response.

Business, page 58

8. We note statements throughout your Business section regarding the performance of your product candidates. For example only, we note the following statements:
   - "[w]e believe that LP-10 is an effective therapy against HC"; and
   - "interim results indicate the potential safety and efficacy of LP-10 for HC patients."

Please revise these statements and similar statements throughout the prospectus so that the basis for each performance claim is clear. Safety and efficacy determinations are the exclusive authority of the FDA or comparable foreign regulators. You may provide a summary of the data that you used to draw these conclusions, but not the conclusions or predictions that the product candidates are safe or effective.

Our Background, page 58

9. We note your disclosure here that, "[p]reclinical studies evaluating the delivery of LP-10 via [y]our Platform have been completed and have demonstrated successful reduction of both chemotherapy-induced and radiation-induced bladder inflammation and damage." Please revise your disclosure here to clearly state, if true, that these studies were animal trials. In this regard, we note your disclosure on pages 63 and 64.

Our Strategy, page 60

10. We note your disclosure here and in the Manufacturing Facility section that your strategy is to "rapidly advance" your product candidates and "[y]our manufacturing compliance needs may increase rapidly because early-stage 505(b)(2) regulatory pathway products can quickly obtain NDA approval." Please revise this disclosure to remove any implication that you will be successful in commercializing your product candidates in a rapid or accelerated manner as such statements are speculative.

LP-10 and the Treatment of Hemorrhagic Cystitis, page 61

11. We refer to your statements that you intend to pursue a section 505(b)(2) approval pathway, and that this path may expedite the development of your programs. Please expand your explanation of this process so that investors understand the steps necessary to achieve FDA approval using this process. Additionally, identify and describe the studies and results you intend to rely on, including the identification of the parties that performed the studies. Please also disclose whether the FDA has given any indication that you may use such pathway for LP-10 or your other material product candidates.

Prevalence, page 62

12. We note your disclosure here that you "have measured annual cyclophosphamide and ifosphamide use in a large commercial database and inferred the upper range of consequential HC to potentially reach 60,000 new cases per year." Please disclose any material assumptions and limitations associated with your estimate of the 60,000 new consequential HC cases per year or otherwise advise.

Our Addressable Market, page 64

13. We note your disclosure here that you could receive "approximately $1.2 billion in gross revenues annually." Please revise to include balancing disclosure that your product candidate, LP-10, is not currently approved for any indication and is being studied in

ongoing clinical trials and that there can be no assurance that your product candidate will receive FDA approval.

Our Metastable Liposome Intravesical Drug Delivery Platform, page 66

14. Please revise your disclosure to explain what you mean by "extensive clinical history with the liposomal delivery vehicle." In addition, please provide your basis for your belief that "[y]our Platform provides an optimal approach for treating urinary bladder conditions," given your current, clinical and discovery stages of development of your product candidates.

Intellectual Property, page 67

15. Please revise your intellectual property disclosure to clearly describe the expiration year of each patent, and the jurisdiction, including any foreign jurisdiction, of each material pending or issued patent. In addition, we note you are "actively prosecuting additional patent applications in the United States and in Europe, Canada, Mexico and Australia." Please update your disclosure here to clarify whether or not you have material pending patent applications in these jurisdictions. To the extent material, please disclose the type of patent protection you are seeking, the applicable jurisdictions and the potential patent expiration dates for each material pending patent application.

Expedited Development and Review Programs, page 70

16. We note your disclosure that, "LP-10, and the specific indication for which it is being studied, meets the qualifications for Fast Track designation" and "LP-10, and the specific indication for which it is being studied, meets the qualifications for Breakthrough Therapy designation." Please revise your disclosure to clarify that even though you believe LP-10 meets the qualification for Fast Track designation and Breakthrough Therapy designation, the FDA will ultimately make such determination.

Executive Employment Arrangements, page 78

17. Please file as exhibits the employment agreements entered into with your named executive officers. See Item 601(b)(10) of Regulations S-K.

Certain Relationships and Related Party and Other Transactions, page 84

18. We note your disclosure on page 67 that you entered into a non-binding memorandum of understanding, dated November 6, 2021, with Cook MyoSite. In addition, we note your disclosure on page 72 where it appears that Dr. Chancellor is affiliated with Cook MyoSite. Please revise your disclosure to provide more details of your arrangements with Cook Myosite and disclose this arrangement as a related party transaction under Item 404(a) of Regulation S-K or otherwise advise. In addition, please file any related party transaction agreements as exhibits, as required by Item 601(b)(10)(i)(A) of Regulation S-K.

Principal Stockholders, page 85

19. For each stockholder in the principal stockholders table that is neither a natural person nor a public reporting company, please revise to identify the natural person with voting and investment control.

Provisions of Our Certificate of Incorporation and Bylaws
Choice of Forum., page 90

20. Consistent with your risk factor disclosure on page 36, please add disclosure describing whether this provision applies to actions arising under the Securities Act or Exchange Act. In that regard, we note that Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder, and Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

General

21. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

You may contact Eric Atallah at 202-551-3663 or Jeanne Baker at 202-551-3691 if you have questions regarding comments on the financial statements and related matters. Please contact Jason Drory at 202-551-8342 or Anne Parker at 202-551-3611 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Michael DeDonato, Esq.