



DIVISION OF
CORPORATION FINANCE

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

February 28, 2020

Eli Hazum
Acting Chief Executive Officer
PainReform Ltd.
60C Medinat Hayehudim
Herzliya, 4676670, Israel

Re: PainReform Ltd.
Draft Registration Statement on Form F-1
Submitted February 3, 2020
CIK No. 0001801834

Dear Mr. Hazum:

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 F-1 submitted on February 3, 2020

Prospectus Summary

Overview, page 1

1. We note your disclosure that your proprietary extended release drug-delivery system prolongs the in vivo activity of active pharmaceutical ingredients, thus increasing the therapeutic window for patient treatment. Given that you have not yet achieved commercialization of your sole product candidate, it is premature and inappropriate to state your conclusion that your drug-delivery system achieves the intended benefit. Please revise your disclosure to remove this conclusion. Similarly, we note your disclosure that in a Phase 2 clinical study in hernia repair, PRF-110 provided substantial pain reduction for up to 72 hours. Please briefly explain how “substantial” pain reduction was determined

and place this selected disclosure in its full and proper context with reference to the limited number of subjects in the referenced study. Please also expand your disclosure to identify the “other studies” referenced.

Our Strengths, page 2

2. We note your reference to the safety and efficacy of PRF-110 as a competitive strength. As safety and efficacy determinations are solely within the authority of the U.S. Food and Drug Administration (FDA) and comparable regulatory bodies, please revise to eliminate the implication that your candidate is likely to be found to be safe or effective for the therapeutic indication you are pursuing. Please revise throughout your prospectus. As a non-exhaustive list of examples only, we note the following statements:
 - PRF-110’s physical characteristics and composition are key to its safety, efficacy and ease of use.
 - You have amassed an extensive safety toxicology portfolio for PRF-110, demonstrating its tolerability and safety in both healthy controls and in surgical patients.
 - Based on extensive safety studies and the positive Phase 2 results, the FDA granted an investigational new drug application (IND) for PRF-110 and approved the initiation of Phase 3 trials for the treatment of post-operative pain.
3. Please provide the basis for your claim that you are "a market leader in research and innovation" within your industry. Alternatively, please remove this disclosure.
4. Please expand your disclosure to discuss the Phase 2 trials conducted regarding PRF-110. Please disclose the number of trials conducted; the number of patients, the established endpoints; whether the trials were powered to determine statistical significance; and whether any serious adverse events occurred. Please provide similar disclosure with respect to PRF-110's Phase 1 trials.
5. We note your disclosure on page 3 that your Phase 2 clinical trial was conducted in 15 patients who underwent hernia repair. Please revise your disclosure to state the surgical indication that will be the subject of the Phase 3 clinical trials and if true, that you plan to initially commercialize PRF-110 for hernia repair surgeries. We note also your disclosure that you intend to conduct post-approval trials in a number of additional surgical indications. Please expand your disclosure to discuss the timing, funding and related regulatory requirements with respect to such post-approval trials as these relate to your business. Please also explain the basis for your disclosure that your drug-delivery system may be used for administering antibiotics and chemotherapeutics.

Use of Proceeds, page 36

6. Please revise to disclose whether the net proceeds of the offering will be sufficient to fund the clinical trials and regulatory approval from the FDA for PRF-110. If a material amount of other funds is necessary, please revise to state the amount necessary and sources of such other funds.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Results of Operations, page 46

7. Please revise the disclosure to disaggregate research and development expenses by nature or type of expense for each period presented.

Business

The Opportunity , page 51

8. Please expand your disclosure to briefly explain why 40 to 45 million surgical procedures out of 70 million would be eligible for treatment with your product candidate.
9. Your prospectus should provide a balanced and factual presentation of your business. Given your limited clinical data to date, it does not appear appropriate to present your business as having the potential to impact the opioid epidemic. Please revise your disclosure accordingly.

Intellectual Property, page 55

10. Please expand your disclosure provide the type of patent protection (composition of matter, use or process), expiry dates and relevant jurisdiction for each foreign patent and patent application.

General

11. 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.

Eli Hazum
PainReform Ltd.
February 28, 2020
Page 4

You may contact Ameen Hamady at 202-551-3891 or Al Pavot at 202-551-3738 if you have questions regarding comments on the financial statements and related matters. Please contact William Mastrianna at 202-551-3778 or Christine Westbrook at 202-551-5019 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Steven Glusband, Esq.