
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

Form 6-K

Report of Foreign Private Issuer

**Pursuant to Rule 13a-16 or 15d-16
of the Securities Exchange Act of 1934**

For the month of December 2024

Commission File Number: 001-39481

PainReform Ltd.

(Translation of registrant's name into English)

65 Yigal Alon St., Tel Aviv 6744316
Israel

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

This first three paragraphs of the press release attached as Exhibit 99.1 to this Report on Form 6-K is incorporated by reference into the Company's Registration Statements on Form S-8 (Registration No. 333-257968 and 333-265902) and the Company's Registration Statements on Form F-3 (Registration No. 333-282264, 333-254982, 333-276485 and 333-277594), to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.

On December 27, 2024 PainReform Ltd. issued a press release entitled "PainReform Provides Further Update on Phase 3 Clinical Trial of PRF-110". A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated December 27, 2024.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: December 27, 2024

PAINREFORM LTD.

By: /s/ Ehud Geller
Ehud Geller
Executive Chairman of the Board and
Interim Chief Executive Officer



PainReform Provides Further Update on Phase 3 Clinical Trial of PRF-110

Tel Aviv, Israel – December 26, 2024 – PainReform Ltd. (Nasdaq: PRFX) ("**PainReform**" or the "**Company**"), a clinical-stage specialty pharmaceutical company focused on the reformulation of established therapeutics, today announced an update regarding its Phase 3 clinical trial evaluating PRF-110 in post-surgical pain management of patients undergoing bunionectomy.

PainReform previously disclosed initial topline data from its Phase 3 clinical trial in which it reported that it demonstrated statistically significant superiority over placebo in reducing pain during the first 48 hours following surgery. Yet, at that time, data pertaining to the last 24-hour period of the 72-hour study follow-up was unclear, and efforts were made to resolve the incoherence and complete the analysis.

Following further investigation, PainReform has determined that the data from the final 24- hour period could not be clarified to satisfy the study's primary endpoint 72 hours requirement and therefore it did not meet the primary endpoint of the study. Despite this setback, the Company has initiated research and development (R&D) activities to better understand and refine the pharmacokinetics and pharmacodynamics of PRF-110 based on the data received from the study. These efforts are intended to potentially resolve this issue to support future clinical trials.

"We are focused on resolving the issue of the last 24 of the 72hour requirement through the use of high level, in-vitro models prior to any additional clinical work," said Dr. Ehud Geller, Chairman and interim CEO of PainReform. "This update reflects our determination to leverage these learnings and continue our mission to provide effective pain relief solutions for surgical patients. Our ongoing R&D efforts aim to deepen our understanding of PRF-110's profile and enhance its potential in future evaluations. In parallel, we are reviewing our strategic options. There can be no assurance that our review will result in any transaction or that it will enhance shareholder value..

About PainReform

PainReform is a clinical-stage specialty pharmaceutical company focused on the reformulation of established therapeutics. PRF-110, the Company's lead product is based on the local anesthetic ropivacaine, targeting the postoperative pain relief market. PRF-110 is an oil-based, viscous, clear solution that is deposited directly into the surgical wound bed prior to closure to provide localized and extended postoperative analgesia. The Company's proprietary extended- release drug-delivery system is designed to provide an extended period of post-surgical pain relief without the need for repeated dose administration while reducing the potential need for the use of opiates. For more information, please visit www.painreform.com.

Notice Regarding Forward-Looking Statements

This press release contains forward-looking statements about our expectations, beliefs and intentions including with respect to objectives, plans and strategies and expected timing of results. Forward-looking statements can be identified by the use of forward-looking words such

as "believe", "expect", "intend", "plan", "may", "should", "could", "might", "seek", "target", "will", "project", "forecast", "continue" or "anticipate" or their negatives or variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical matters. These forward-looking statements are based on assumptions and assessments made in light of management's experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements in this press release are made as of the date of this press release, and we undertake no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties, many of which are outside of our control. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements, including, but not limited to, the following: our ability to identify, evaluate and complete any strategic alternative that yields value for our shareholders, our ability to continue as a going concern, our history of significant losses, our need to raise additional capital and our ability to obtain additional capital on acceptable terms, or at all; our dependence on the success of our initial product candidate, PRF-110; the outcomes of preclinical studies, clinical trials and other research regarding PRF-110 and future product candidates; our limited experience managing clinical trials; our ability to retain key personnel and recruit additional employees; our reliance on third parties for the conduct of clinical trials, product manufacturing and development; the impact of competition and new technologies; our ability to comply with regulatory requirements relating to the development and marketing of our product candidates; our ability to establish and maintain strategic partnerships and other corporate collaborations; the implementation of our business model and strategic plans for our business and product candidates; the scope of protection we are able to establish and maintain for intellectual property rights and our ability to operate our business without infringing the intellectual property rights of others; the overall global economic environment; our ability to develop an active trading market for our ordinary shares and whether the market price of our ordinary shares is volatile; our ability to maintain our listing on the Nasdaq Capital Market; and statements as to the impact of the political and security situation in Israel on our business, including due to the current war in Israel. More detailed information about the risks and uncertainties affecting us is contained under the heading "Risk Factors" included in the Company's most recent Annual Report on Form 20-F and in other filings that we have made and may make with the Securities and Exchange Commission in the future.

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