

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

**FORM 8-K**

**CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): September 7, 2021**

**PLIANT THERAPEUTICS, INC.**

(Exact name of Registrant as Specified in Its Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-39303**  
(Commission  
File Number)

**47-4272481**  
(IRS Employer  
Identification No.)

**260 Littlefield Avenue,  
South San Francisco, CA**  
(Address of Principal Executive Offices)

**94080**  
(Zip Code)

**Registrant's Telephone Number, Including Area Code: (650) 481-6770**

**Not Applicable**

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	PLRX	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 8.01 Other Events.**

On September 7, 2021, Pliant Therapeutics, Inc. (the “Company”) announced positive interim results from a Phase 2a positron emission tomography (“PET”) imaging-based clinical trial of PLN-74809, an oral small molecule dual selective inhibitor of  $\alpha_v\beta_6/\alpha_v\beta_1$ , in patients with idiopathic pulmonary fibrosis (“IPF”). Across four dose levels, all patients achieved greater than 50% target engagement after a single dose of PLN-74809. Target engagement of 50% was previously established in a Phase 1b trial as the threshold for predicted clinical anti-fibrotic effect. In addition, there was a dose- and plasma concentration-dependent response with the two highest doses approaching target saturation. A copy of the Company’s press release, titled “Pliant Therapeutics Reports Positive Interim Results from Phase 2a PET Imaging Clinical Trial in Patients with Idiopathic Pulmonary Fibrosis,” is attached as Exhibit 99.1 to this Current Report and is incorporated by reference herein.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release, dated September 7, 2021, titled “Pliant Therapeutics Reports Positive Interim Results from Phase 2a PET Imaging Clinical Trial in Patients with Idiopathic Pulmonary Fibrosis.”</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

**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.

PLIANT THERAPEUTICS, INC.

Date: September 7, 2021

By: /s/ Keith Cummings  
Keith Cummings, M.D., MBA  
Chief Financial Officer



**Pliant Therapeutics Reports Positive Interim Results from  
Phase 2a PET Imaging Clinical Trial in Patients with Idiopathic Pulmonary Fibrosis**

- Single dose administration of PLN-74809 achieved  $\alpha_v\beta_6$  target engagement up to 98% in the lungs of IPF patients
- All doses achieved target engagement above the threshold for predicted anti-fibrotic activity, with an observed dose-response relationship
- PLN-74809 reached highly fibrotic regions of the lung and was bound to  $\alpha_v\beta_6$  in IPF patients
- Data provide insight into potential anti-fibrotic activity of PLN-74809 at the doses being evaluated in the ongoing Phase 2a INTEGRIS-IPF trial
- Company to host conference call and webcast today at 8:00 a.m. ET

SOUTH SAN FRANCISCO, CA- September 7, 2021 — Pliant Therapeutics, Inc. (Nasdaq: PLRX), a clinical stage biotechnology company focused on discovering and developing novel therapeutics for the treatment of fibrosis, today announced positive interim results from a Phase 2a positron emission tomography (PET) imaging-based clinical trial of PLN-74809, an oral small molecule dual selective inhibitor of  $\alpha_v\beta_6/\alpha_v\beta_1$ , in patients with idiopathic pulmonary fibrosis (IPF). Across four dose levels, all patients achieved greater than 50% target engagement after a single dose of PLN-74809. Target engagement of 50% was previously established in a Phase 1b trial as the threshold for predicted clinical anti-fibrotic effect. In addition, there was a dose- and plasma concentration-dependent response with the two highest doses approaching target saturation.

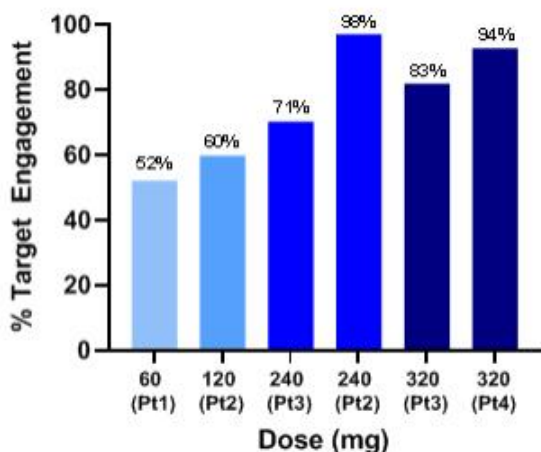
“We believe the high target engagement levels seen after the administration of just a single dose illustrate the potential of PLN-74809 to show a potent anti-fibrotic effect in our longer-term clinical trials,” said Éric Lefebvre, M.D., Chief Medical Officer of Pliant Therapeutics. “Furthermore, these data represent a significant step forward in our understanding of the potential anti-fibrotic activity of PLN-74809 and support the selected doses in our ongoing 12-week Phase 2a INTEGRIS-IPF trial.”

The ongoing Phase 2a open-label PET imaging clinical trial is designed to evaluate  $\alpha_v\beta_6$  target engagement levels achieved by PLN-74809 when administered across single-doses of 60 mg, 120 mg, 240 mg or 320 mg in IPF patients. The trial is also evaluating safety, tolerability and pharmacokinetics. Patients undergo a PET scan prior to dosing and at four hours post-dose to evaluate target  $\alpha_v\beta_6$  specific engagement. Images are analyzed for regions of high fibrotic activity, which are then evaluated for target engagement. Following completion of a standard washout period, patients may consent to receive a second dose of PLN-74809 at a different dose level followed by a second post-dose PET scan.

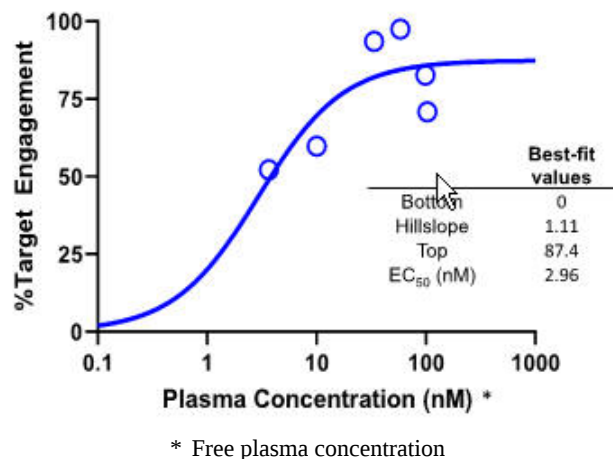
As fibrosis is a chronic disease, proof-of-efficacy in human trials is expensive and takes years to complete. Pliant utilizes pharmacodynamic biomarkers and advanced imaging techniques, including PET, to evaluate target engagement by our product candidates over relatively short time periods and de-risk Pliant’s programs by designing clinical trials that allow the Company to show proof-of-mechanism in advance of clinical efficacy data.

## Interim Phase 2a PET Clinical Trial Results

Four IPF patients were administered six single doses of PLN-74809 across 60 mg, 120 mg, 240 mg or 320 mg, generating a total of six post-dose scans.



*Target Engagement by Dose*



*Target Engagement by Plasma Concentration*

### PLN-74809 Demonstrated Lung Penetration, with Greater than 50% Target Engagement Achieved in the Lungs of All IPF Patients Across All Dose Cohorts

- Up to 98% target engagement of PLN-74809 achieved
- Greater than 50% target engagement of PLN-74809 achieved across all doses

### Dose and Plasma Concentration Response Established

- PLN-74809 achieved a dose response across all single-doses from 60 mg to 320 mg
- Suggests target engagement levels along the entire exposure curve of PLN-74809
- Supports potential anti-fibrotic activity of PLN-74809 at the doses being evaluated in the ongoing Phase 2a INTEGRIS-IPF trial

### PLN-74809 Well-Tolerated Across All Doses

- No serious adverse events reported

### Conference Call and Webcast

Pliant will host a conference call and webcast today at 8:00 a.m. ET to discuss this update. The webcast will be available in the [Events & Presentations](#) section of Pliant's website. This update can also be accessed by dialing (833) 519-1340 (United States and Canada) or (914) 800-3902 (international) and providing the passcode 6186023. An archived reply of the webcast will be available on Pliant's website for 90 days following the event.

## About Pliant Therapeutics, Inc.

Pliant is a clinical stage biopharmaceutical company focused on discovering and developing novel therapies for the treatment of fibrotic and related diseases. Pliant's lead product candidate, PLN-74809, is an oral small-molecule dual selective inhibitor of  $\alpha\text{v}\beta\text{6}$  and  $\alpha\text{v}\beta\text{1}$  integrins that is in development for the treatment of idiopathic pulmonary fibrosis, or IPF, and primary sclerosing cholangitis, or PSC. PLN-74809 has received Orphan Drug Designation from the U.S. Food and Drug Administration for both IPF and PSC. Pliant is currently recruiting for Phase 2a trials of PLN-74809 in the lead indications of IPF and PSC. Pliant has also developed PLN-1474, a small-molecule selective inhibitor of  $\alpha\text{v}\beta\text{1}$  for the treatment of nonalcoholic steatohepatitis, or NASH with liver fibrosis, which Pliant has transferred to Novartis pursuant to its development partnership. In addition to clinical stage programs, Pliant currently has two preclinical programs targeting oncology and muscular dystrophies. For additional information about Pliant, visit [www.pliantrx.com](http://www.pliantrx.com) and follow us on [Twitter](#), [LinkedIn](#), [Facebook](#), and [YouTube](#).

## Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "anticipate," "estimate," "intend," and similar expressions (as well as other words or expressions referencing future events, conditions, or circumstances) are intended to identify forward-looking statements. These statements include those regarding the pharmacodynamics and therapeutic potential of PLN-74809, our plans for the future development of PLN-74809, the potential of our Phase 2a PET trial to predict future clinical outcomes and the potential for the preliminary results of this trial to predict future results. Because such statements deal with future events and are based on our current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of Pliant Therapeutics could differ materially from those described in or implied by the statements in this press release. These forward-looking statements are subject to risks and uncertainties, including those related to the development and commercialization of our product candidates, including any delays in our ongoing or planned preclinical or clinical trials, the ongoing nature of our Phase 2a PET trial and the possibility that the preliminary data will not be predictive of full data from this trial, the possibility that results from this trial will not be predictive of future clinical outcomes, the impact of the ongoing COVID-19 pandemic on our business, operations, clinical supply and plans, the risks inherent in the drug development process, the risks regarding the accuracy of our estimates of expenses and timing of development, our capital requirements and the need for additional financing, and our ability to obtain and maintain intellectual property protection for our product candidates. These and additional risks are discussed in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K filed with the SEC on March 16, 2021, as updated by our Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, each available on the SEC's website at [www.sec.gov](http://www.sec.gov). Unless otherwise noted, Pliant is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events, or otherwise.

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**Investor and Media Contact:**

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