
**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): May 10, 2021.

PLIANT THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware 001-39303 47-4272481
(State or Other (State or Other
Jurisdiction (Commission Employer
of (Commission Identification
Incorporation) File Number) No.)

260
Littlefield
Avenue,
South San
Francisco,
CA 94080
(Address of (Address of
Principal Principal
Executive Executive
Offices) Offices) (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 2.02 Results of Operations and Financial Condition.

On May 10, 2021, Pliant Therapeutics, Inc. (the "Company") issued a press release announcing the Company's financial results for the first quarter ended March 31, 2021. A copy of this press release is furnished as Exhibit 99.1 to this report and incorporated herein by reference.

The information in this Current Report on Form 8-K including the exhibits furnished herewith shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (as amended, the "Exchange Act") or otherwise subject to the liabilities of that Section, and shall not be or be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release issued by the Company dated May 10, 2021.

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: May 10, 2021

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



Pliant Therapeutics Provides Corporate Update and Reports First Quarter 2021 Financial Results

- *PLN-74809 Phase 2a PET Imaging Trial Continues to Enroll with Preliminary Data Expected First Half of 2021*
- *PLN-74809 Phase 2a 12-week trials in IPF and PSC Currently on Track to Complete Enrollment by the End of 2021 and First Half of 2022, Respectively*

SOUTH SAN FRANCISCO - May 10, 2021 - Pliant Therapeutics, Inc. (Nasdaq: PLRX) (“the Company”), a clinical stage biotechnology company focused on discovering and developing novel therapeutics for the treatment of fibrosis, today provided a corporate update and reported first quarter 2021 financial results.

“During the first quarter, we continued the strong momentum of advancing our broad and novel clinical and development-stage portfolio,” said Bernard Coulie, M.D., Ph.D., President and Chief Executive Officer of Pliant Therapeutics. “With this progress and a financial runway taking us into 2023, we are well positioned to advance toward our objective of bringing potentially transformative treatments to patients in need.”

First Quarter and Recent Highlights

- **PLN-74809 Phase 2a positron emission tomography (PET) imaging trial preliminary data expected in the first half 2021.** This open-label, dose ranging trial is evaluating target receptor occupancy levels of PLN-74809 in the lungs of IPF patients across multiple single-dose cohorts utilizing a PET tracer of the integrin $\alpha_v\beta_6$. The goal of the trial is to confirm the ability of PLN-74809, a dual selective inhibitor of $\alpha_v\beta_6/\alpha_v\beta_1$, to penetrate highly fibrotic areas of the lung where $\alpha_v\beta_6$ expression is highest and bind to its target receptor. Additionally, the trial will establish a pharmacokinetic/ pharmacodynamic (PK/PD) relationship between PLN-74809 plasma exposure and $\alpha_v\beta_6$ receptor occupancy, allowing us to build a PK/PD model that will inform dose selection in later stage trials.
- **PLN-74809 Phase 2a INTEGRIS trial in idiopathic pulmonary fibrosis (IPF) continued to build momentum, currently on track to complete enrollment by the end of 2021.** The primary endpoints of this 12-week randomized, dose-ranging, double-blind, placebo-controlled trial are the evaluation of PLN-74809’s safety, tolerability, and pharmacokinetics in IPF patients. The Company will also evaluate exploratory efficacy endpoints including Quantitative Lung Fibrosis, or QLF, imaging as well as pulmonary function tests.
- **PLN-74809 Phase 2a INTEGRIS trial in primary sclerosing cholangitis (PSC) continued to advance, currently on track to complete enrollment in the first half 2022.** The primary endpoints of this 12-week randomized, dose-ranging, double-blind, placebo-controlled trial are the evaluation of PLN-74809’s safety, tolerability, and pharmacokinetics in PSC patients. The Company will also evaluate exploratory efficacy endpoints including fibrosis biomarkers such as Pro-C3 and ELF, changes in ALP, and liver imaging.
- **Successful completion of PLN-1474 Phase 1 trial and transfer of PLN-1474 to Novartis.** The Phase 1 trial of PLN-1474 was a safety, tolerability, and pharmacokinetics dose-escalating first-in-human trial that enrolled 84 healthy volunteers. PLN-1474 was rapidly absorbed and well tolerated with no dose- or treatment-limiting toxicities or severe/ serious adverse events observed. In preclinical studies, PLN-1474 was observed to

selectively block the $\alpha_v\beta_1$ integrin-mediated activation of TGF- β , reducing liver fibrosis in animal models. Following the successful completion of this study, PLN-1474 has been transferred to Novartis.

COVID-19 Preparedness

The Company continues to develop and maintain policies and procedures to enable us to operate safely and productively during the COVID-19 pandemic. The Company has experienced delays in clinical trial operations which have impacted and may further impact the expected timing of data readouts. The Company continues to work closely with clinical sites to continue site initiation and operation activities in compliance with study protocols while observing government and institutional guidelines.

First Quarter 2021 Financial Results

- Research and development expenses were \$18.5 million, as compared to \$13.9 million for the prior-year quarter. The increase was due primarily to employee related expenses and higher costs related to the advancement of several programs and ongoing Phase 1/2 clinical trials.
- General and administrative expenses were \$6.6 million, as compared to \$4.0 million for the prior-year quarter. The increase was due to higher personnel-related and professional services expenses.
- Net loss of \$22.9 million as compared to a net income of \$11.0 million for the prior-year quarter due to a decrease in related party revenue driven by the achievement of a first-patient-first-dose milestone in the first quarter of 2020 for the PLN-1474 Phase 1 trial.
- As of March 31, 2021, the Company had cash, cash equivalents and short-term investments of \$264.1 million. The Company believes it has sufficient funds to meet its operating and capital requirements into 2023.

About Pliant Therapeutics, Inc.

Pliant Therapeutics is a clinical stage biopharmaceutical company focused on discovering and developing novel therapies for the treatment of fibrosis. Pliant's lead product candidate, PLN-74809, is an oral small-molecule dual selective inhibitor of $\alpha_v\beta_6$ and $\alpha_v\beta_1$ integrins that is in development in the lead indications 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 Phase 2a trials of PLN-74809 in the lead indications of IPF, PSC. Pliant has also developed PLN-1474, a small-molecule selective inhibitor of $\alpha_v\beta_1$ for the treatment of nonalcoholic steatohepatitis, or NASH with liver fibrosis, which Pliant has transferred to Novartis pursuant to our development partnership. In addition to clinical stage programs, Pliant currently has two preclinical programs targeting oncology and muscular dystrophies. For additional information about Pliant Therapeutics, visit 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 our product candidates, including their development and therapeutic potential, the advancement of our clinical and preclinical pipeline, including the timing, enrollment and results of our clinical trials, the impact of the ongoing COVID-19 pandemic on our business, operations, clinical trials, clinical supply and plans and our financial position and cash runway. 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 impact of the ongoing COVID-19 pandemic on our business, operations, clinical supply and plans, the risks inherent in the drug development process, the risk that we may not realize the intended benefits of our collaboration, 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 March 31, 2021, which we are filing with the SEC today, each available on the SEC's website at 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.

Investor and Media Contact:

Christopher Keenan
Vice President, Investor Relations and Corporate Communications
Pliant Therapeutics, Inc.
ir@pliantrx.com

Pliant Therapeutics, Inc.
Condensed Statements of Operations
(Unaudited)

(In thousands, except number of shares and per share amounts)

	Three Months Ended	
	March 31,	
	2021	2020
Revenue — related party	\$ 2,174	\$ 28,938
Operating expenses:		
Research and development	(18,527)	(13,919)
General and administrative	(6,566)	(4,011)
Total operating expenses	(25,093)	(17,930)
(Loss) income from operations	(22,919)	11,008
Interest and other income (expense), net	63	21
Net (loss) income	\$ (22,856)	\$ 11,029
Less: Undistributed earnings to preferred stockholders	—	(11,029)
Net loss attributable to common stockholders	\$ (22,856)	\$ —
Net loss per share, attributable to common stockholders:		
Basic	\$ (0.64)	\$ —
Diluted	\$ (0.64)	\$ —
Shares used in computing net loss per share attributable to common stockholders:		
Basic	35,645,205	1,897,669
Diluted	35,645,205	1,897,669
Comprehensive income (loss):		
Net income (loss)	\$ (22,856)	\$ 11,029
Net unrealized gain (loss) on short-term investments	\$ 14	\$ 60
Total other comprehensive income	14	60
Comprehensive income (loss)	\$ (22,842)	\$ 11,089

Pliant Therapeutics, Inc.
Condensed Balance Sheets
(Unaudited)
(In thousands)

	March 31, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	\$ 50,819	\$ 50,882
Short-term investments	213,281	226,012
Accounts receivable	2,174	9,279
Tax credit receivable	83	83
Prepaid expenses and other current assets	4,180	4,498
Total current assets	270,537	290,754
Property and equipment, net	4,266	4,321
Other non-current assets	451	451
Total assets	\$ 275,254	\$ 295,526
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 2,886	\$ 2,023
Accrued liabilities	7,364	9,576
Total current liabilities	10,250	11,599
Other long-term liabilities	835	866
Total liabilities	11,085	12,465
Stockholders' equity		
Common stock	3	3
Additional paid-in capital	404,868	400,918
Accumulated deficit	(140,684)	(117,828)
Accumulated other comprehensive loss	(18)	(32)
Total stockholders' equity	264,169	283,061
Total liabilities and stockholders' equity	\$ 275,254	\$ 295,526