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): August 9, 2021.

PLIANT THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

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

260 Littlefield Avenue, South San Francisco, CA	**94080**
(Address of Principal Executive 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 August 9, 2021, Pliant Therapeutics, Inc. (the "Company") issued a press release announcing the Company's financial results for the second quarter ended June 30, 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 August 9, 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: August 9, 2021

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

Exhibit 99.1

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

- SAD cohorts up to 640 mg and MAD cohorts up to 320 mg completed in extended Phase 1a trial of PLN-74809 in healthy volunteers with no safety concerns identified

- 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

- Analysis of PLN-74809 Phase 2a PET images underway, including a 320 mg cohort, with preliminary data anticipated upon analysis completion

SOUTH SAN FRANCISCO, CA - August 9, 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 second quarter 2021 financial results.

"Driven by our progress throughout the second quarter, enrollment continues to be on track for our Phase 2a trials of PLN-74809 in IPF and PSC with strong advancement in our development stage oncology and DMD programs," said Bernard Coulie, M.D., Ph.D., President and Chief Executive Officer of Pliant Therapeutics. "PLN-74809 continues to demonstrate a favorable safety profile as additional dose cohorts from the single and multiple ascending dose Phase 1a trial show PLN-74809 to be generally well tolerated at all dose levels tested, with a predictable pharmacokinetic profile similar to previous dose cohorts."

Second Quarter and Recent Highlights

- **Single ascending dose (SAD) cohorts up to 640mg and multiple ascending dose (MAD) cohorts up to 320mg completed in extended Phase 1a dose escalation trial of PLN-74809 in healthy volunteers.** PLN-74809 has completed dosing of additional SAD cohorts of up to 640 mg and MAD cohorts of up to 320 mg once daily dose in an extended dose escalation trial. The pharmacokinetic profile remains generally dose proportional with PLN-74809 continuing to be generally well tolerated, with no severe adverse events or serious adverse events reported.

- **Enrollment on track for PLN-74809 Phase 2a trial in idiopathic pulmonary fibrosis (IPF).** INTEGRIS-IPF is a 12-week randomized, dose-ranging, double-blind, placebo-controlled trial evaluating the safety, tolerability, and pharmacokinetics of PLN-74809 in IPF patients. This trial is evaluating exploratory endpoints including quantitative lung fibrosis score, or QLF, imaging as well as pulmonary function tests. Enrollment is currently on track to be completed by the end of 2021.

- **Enrollment on track for PLN-74809 Phase 2a trial in primary sclerosing cholangitis (PSC).** INTEGRIS-PSC is a 12-week randomized, dose-ranging, double-blind, placebo-controlled trial evaluating the safety, tolerability, and pharmacokinetics of PLN-74809 in PSC patients. The trial is evaluating exploratory endpoints including fibrosis biomarkers such as Pro-C3 and ELF, changes in ALP, and liver imaging. Enrollment is currently on track to be completed in the first half of 2022.

- **Image analysis from PLN-74809 Phase 2a positron emission tomography (PET) trial underway, including addition of a 320 mg cohort, with preliminary data anticipated upon completion of the analysis.** This open-label, dose ranging trial is evaluating target receptor occupancy levels of PLN-74809 in the lungs of IPF patients across ascending single-dose cohorts, utilizing a PET tracer of the integrin αvβ6. The Company recently amended the protocol to increase the maximum dose to 320 mg. In the second quarter, the first patients were dosed in this cohort.

- **Preclinical stage integrin-based programs continue to progress.** The Company's early-stage programs targeting oncology and muscular dystrophies continue to advance toward the clinic. The oncology program is focused on increasing tumor checkpoint sensitivity through small molecule inhibition of $\alpha_v\beta_8$. The muscular dystrophy program is focused on improving muscle function through activation of an integrin compensatory mechanism with a monoclonal antibody.

- **Resources redeployed in support of ongoing PLN-74809 Phase 2a trials in IPF and PSC.** Despite the rise of recently identified COVID-19 variants, the broad availability of vaccines, as well as the increased and successful measures taken over the past nine months to contain the virus have resulted in a dramatic decrease in the number of severe and critical COVID-19 patients with acute respiratory distress syndrome (ARDS). Given the declining number of addressable patients, the Company has discontinued enrollment in the PLN-74809 Phase 2a COVID-19-related ARDS trial allowing for resources to be directed toward our lead indications.

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.

Second Quarter 2021 Financial Results

- Research and development expenses were $19.2 million, as compared to $17.5 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 $5.5 million, as compared to $3.0 million for the prior-year quarter. The increase was due to higher personnel-related and professional services expenses.
- Net loss of $22.8 million as compared to $17.0 million for the prior-year quarter due an overall increase in expense associated with our research and development programs as well as personnel-related costs.
- As of June 30, 2021, the Company had cash, cash equivalents and short-term investments of $244.0 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 the anticipated progress of our clinical trials and timing of enrollment and data disclosures, the potential future impact of the COVID-19 pandemic and expectations regarding how far into the future our cash on hand will fund our operating and capital requirements. 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 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 filed with the SEC on May 10, 2021 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 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.
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Pliant Therapeutics, Inc.
Condensed Statements of Operations
(Unaudited)
(In thousands, except number of shares and per share amounts)

	Three Months Ended June 30,	
	2021	**2020**
Revenue — related party	$ 1,789	$ 3,600
Operating expenses:		
Research and development	(19,218)	(17,536)
General and administrative	(5,475)	(3,040)
Total operating expenses	(24,693)	(20,576)
Loss from operations	(22,904)	(16,976)
Interest and other income (expense), net	73	(25)
Net income loss	$ (22,831)	$ (17,001)
Less: Undistributed earnings to preferred shareholders	—	—
Net loss attributable to common stockholders	$ (22,831)	$ (17,001)
Net loss per share, attributable to common stockholders:		
Basic	$ (0.64)	$ (1.39)
Diluted	$ (0.64)	$ (1.39)
Shares used in computing net loss per share attributable to common stockholders:		
Basic	35,746,922	12,253,943
Diluted	35,746,922	12,253,943
Comprehensive income loss:		
Net loss	$ (22,831)	$ (17,001)
Net unrealized loss on short-term investments	$ (12)	$ (89)
Total other comprehensive loss	(12)	(89)
Comprehensive loss	$ (22,843)	$ (17,090)

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

	June 30, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 35,193	$ 50,882
Short-term investments	208,788	226,012
Accounts receivable	1,830	9,279
Tax credit receivable	83	83
Prepaid expenses and other current assets	4,825	4,498
Total current assets	250,719	290,754
Property and equipment, net	4,367	4,321
Other non-current assets	630	451
Total assets	$ 255,716	$ 295,526
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 2,764	$ 2,023
Accrued liabilities	8,168	9,576
Total current liabilities	10,932	11,599
Other long-term liabilities	804	866
Total liabilities	11,736	12,465
Stockholders' equity		
Common stock	3	3
Additional paid-in capital	407,522	400,918
Accumulated deficit	(163,515)	(117,828)
Accumulated other comprehensive loss	(30)	(32)
Total stockholders' equity	243,980	283,061
Total liabilities and stockholders' equity	$ 255,716	$ 295,526