

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): March 16, 2021.

PLIANT THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware  
(State or Other Jurisdiction  
of Incorporation)

001-39303

47-4272481  
(IRS Employer  
Identification No.)

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

(Commission File Number)

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 Global Select Market

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 March 16, 2021, Pliant Therapeutics, Inc. (the "Company") issued a press release announcing the Company's financial results for the fourth quarter and year ended December 31, 2020. 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.

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press Release issued by the Company dated March 16, 2021.</a>

## 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: March 16, 2021

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



## Pliant Therapeutics Provides Corporate Update and Reports Fourth Quarter and Full Year 2020 Financial Results

*- PLN-74809 Phase 2a PET Imaging Trial Resumed, with Preliminary Data Expected First Half of 2021*

*- PLN-74809 Phase 2a 12-week trials in IPF and PSC Gained Momentum in the Fourth Quarter, Currently on Track to Complete Enrollment by the End of 2021 and First Half of 2022, Respectively*

**SOUTH SAN FRANCISCO - March 16, 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 fourth quarter and full year 2020 financial results.

“We entered 2021 in a strong position resulting from our team’s execution throughout the fourth quarter despite the challenges of the evolving backdrop of the COVID-19 pandemic,” said Bernard Coulie, M.D., Ph.D., President and Chief Executive Officer of Pliant Therapeutics. “Our focus remains on continuing to actively drive our lead Phase 2a programs in IPF and PSC towards near term data readouts, to advance our earlier-stage oncology and muscular dystrophy portfolio towards the clinic while also leveraging our robust discovery engine to create a broad and differentiated product portfolio focused on delivering novel treatments to areas of unmet medical need.”

### Fourth Quarter and Recent Highlights

- **PLN-74809 Phase 2a positron emission tomography (PET) imaging trial resumed, with preliminary data expected in the first half 2021.** With the reopening of the trial site in November, we were able to resume the Phase 2a PET trial. This open-label dose ranging trial will evaluate target engagement of PLN-74809 in IPF patients utilizing a PET tracer of the integrin  $\alpha\beta6$ . We will assess receptor occupancy levels achieved by PLN-74809, a dual selective inhibitor of  $\alpha\beta6/\alpha\beta1$ , across multiple single-dose cohorts.
  - **PLN-74809 Phase 2a INTEGRIS trials in idiopathic pulmonary fibrosis (IPF) and primary sclerosing cholangitis (PSC) gained momentum in the fourth quarter and are currently on track to complete enrollment by the end of 2021 and the first half of 2022, respectively.** These 12-week randomized, dose-ranging, double-blind, placebo-controlled trials will evaluate safety, tolerability, and pharmacokinetics, as well as exploratory efficacy endpoints in patients with IPF and PSC.
  - **IND open for development of a PET tracer of the protein integrin  $\alpha\beta1$ .** Following a December 2020 Investigational New Drug (IND) filing and the recently issued a “Safe to Proceed Letter”, Pliant expects to rapidly advance into clinical trials a study of a wholly owned  $\alpha\beta1$  PET tracer to evaluate expression levels of  $\alpha\beta1$  in various fibrotic tissues. This marks the Company’s fifth IND.
-

- **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- $\beta$ , reducing liver fibrosis in animal models. Following the successful completion of this study, PLN-1474 has been transferred to Novartis.

### **Leadership Team**

- The Company appointed Gregory P. Cosgrove, M.D., FCCP as Vice President of Clinical Development to lead the execution of the IPF clinical development program. Dr. Cosgrove brings to Pliant over 20 years of pulmonary and critical care expertise in academic clinical research. Dr. Cosgrove most recently served as Associate Professor at the National Jewish Health in Denver, Colorado, the leading respiratory hospital in the United States and as the Chief Medical Officer of the Pulmonary Fibrosis Foundation, a leading pulmonary fibrosis focused nonprofit organization.
- The Company appointed Dr. David Pyott to the Company's Board of Directors. Dr. Pyott brings over 30 years of leadership and management experience with expertise in organizational scaling to the Company. Most recently, Dr. Pyott served as Chairman and Chief Executive Officer of Allergan Inc., a role he held for over 17 years.

### **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 is working closely with clinical sites to continue site initiation and operation activities in compliance with study protocols while observing government and institutional guidelines. The Company intends to provide more specific guidance regarding clinical trial progress and the timing of data readouts as the long-term impacts of the pandemic become better understood.

### **Fourth Quarter 2020 Financial Results**

- Research and development expenses were \$17.9 million, as compared to \$11.7 million for the prior-year quarter. The increase was due primarily to higher costs related to the advancement of several programs and ongoing Phase 1/2 clinical trials.
  - General and administrative expenses were \$5.6 million, as compared to \$3.1 million for the same period in 2019. The increase was due to higher personnel-related and professional services expenses.
  - Net loss of \$19.0 million as compared to a net income of \$42.2 million for the prior-year quarter due to a decrease in related party revenue.
  - As of December 31, 2020, the Company had cash, cash equivalents and short-term investments of \$276.9 million. Pliant 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  $\alpha\text{v}\beta\text{6}$  and  $\alpha\text{v}\beta\text{1}$  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's second product candidate, PLN-1474, is 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 partnered with Novartis. 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](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 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, our collaboration with Novartis for PLN-1474 and the intended benefits of such collaborations, 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 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 prospectus dated June 3, 2020 as filed with the Securities and Exchange Commission pursuant to Rule 424(b) under the Securities Act 1933, as amended, the Quarterly Report for the second quarter of 2020 filed with the SEC on Form 10-Q on August 11, 2020, and the Quarterly Report for the third quarter of 2020 filed with the SEC on Form 10-Q on November 10, which are available on the SEC's website at [www.sec.gov](http://www.sec.gov). Additional information will be made available in Pliant Therapeutics Annual Report on Form 10-K for the year ended December 31, 2020 forward looking statements, or to update the reasons if actual results differ materially from those anticipated in the forward-looking statements.

## **Investor and Media Contact:**

Christopher Keenan  
Vice President, Investor Relations and Corporate Communications  
Pliant Therapeutics, Inc.  
[ir@pliantrx.com](mailto:ir@pliantrx.com)

---

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

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

	<u>Three Months Ended December 31,</u>		<u>Year Ended December 31,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Revenue — related party	\$ 4,465	\$ 57,052	\$ 41,817	\$ 57,052
Operating expenses:				
Research and development	(17,854)	(11,727)	(66,193)	(47,353)
General and administrative	(5,627)	(3,103)	(17,269)	(10,930)
Total operating expenses	(23,481)	(14,830)	(83,462)	(58,283)
(Loss) income from operations	(19,016)	42,222	(41,645)	(1,231)
Interest income	86	115	478	816
Other expense, net	(97)	(168)	(366)	(216)
Net (loss) income	<u>\$ (19,027)</u>	<u>\$ 42,169</u>	<u>\$ (41,533)</u>	<u>\$ (631)</u>
Accretion to redemption value and dividends on redeemable convertible preferred stock	—	(2,147)	—	(6,225)
Less: Undistributed earnings to preferred shareholders	—	(13,789)	—	—
Net (loss) income attributable to common stockholders	<u>\$ (19,027)</u>	<u>\$ 26,233</u>	<u>\$ (41,533)</u>	<u>\$ (6,856)</u>
Net (loss) income per share, attributable to common stockholders:				
Basic	<u>\$ (0.54)</u>	<u>\$ 15.82</u>	<u>\$ (1.95)</u>	<u>\$ (4.22)</u>
Diluted	<u>\$ (0.54)</u>	<u>\$ 1.50</u>	<u>\$ (1.95)</u>	<u>\$ (4.22)</u>
Shares used in computing net (loss) income per share attributable to common stockholders:				
Basic	<u>35,495,414</u>	<u>1,658,559</u>	<u>21,344,236</u>	<u>1,623,358</u>
Diluted	<u>35,495,414</u>	<u>17,527,829</u>	<u>21,344,236</u>	<u>1,623,358</u>

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

	December 31, 2020	December 31, 2019
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 50,882	\$ 85,807
Short-term investments	226,012	16,966
Accounts receivable	9,279	7,052
Tax credit receivable	83	333
Prepaid expenses and other current assets	4,498	1,742
Total current assets	290,754	111,900
Property and equipment, net	4,321	4,079
Other non-current assets	451	3,085
<b>Total assets</b>	<b>\$ 295,526</b>	<b>\$ 119,064</b>
<b>Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)</b>		
Current liabilities		
Accounts payable	\$ 2,023	\$ 1,250
Accrued liabilities	9,576	6,922
Total current liabilities	11,599	8,172
Other long-term liabilities	866	912
Total liabilities	12,465	9,084
Series A redeemable convertible preferred stock	—	62,468
Series B redeemable convertible preferred stock	—	75,860
Series C redeemable convertible preferred stock	—	47,947
Stockholders' equity (deficit)		
Preferred stock	—	—
Common stock	3	1
Additional paid-in capital	400,918	—
Accumulated deficit	(117,828)	(76,295)
Accumulated other comprehensive loss	(32)	(1)
Total stockholders' equity (deficit)	283,061	(76,295)
<b>Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)</b>	<b>\$ 295,526</b>	<b>\$ 119,064</b>