
**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): November 10, 2020.

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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 November 10, 2020, Pliant Therapeutics, Inc. (the "Company") issued a press release announcing the Company's financial results for the quarter ended September 30, 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.

Exhibit No.	Description
99.1	Press Release issued by the Company dated November 10, 2020.

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: November 10, 2020

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



Pliant Therapeutics Provides Corporate Update and Reports Third Quarter 2020 Financial Results

- *Enrollment of PLN-74809 Phase 2a 12-week trials in IPF and PSC progressing*
- *Phase 2a PET imaging trial of PLN-74809 in IPF enrolling*
- *Completed dosing of an extended Phase 1 dose escalation trial of PLN-74809 in healthy volunteers*

SOUTH SAN FRANCISCO — November 10, 2020 — 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 third quarter 2020 financial results.

"Reflecting back on the first three quarters of 2020, I'm proud of the progress we've made despite the challenges related to the COVID-19 pandemic," said Bernard Coulie, M.D., Ph.D., Chief Executive Officer and President of Pliant Therapeutics. "We closed a successful IPO, took important steps in advancing our clinical programs across four indications, and further strengthened our leadership team. Looking ahead, with a strong cash position to advance our robust pipeline, we remain deeply committed to bringing novel treatments to people with fibrotic diseases."

Recent Highlights

- **Enrollment of Phase 2a 12-week trials of PLN-74809 in idiopathic pulmonary fibrosis (IPF) and primary sclerosing cholangitis (PSC) progressing.** After resuming enrollment earlier in the year, Pliant has remained in close coordination with its global trial sites in order to facilitate enrollment in both Phase 2a trials. The Company also continues to open additional trial sites as COVID-19 related restrictions are eased. The hybrid approach to clinical trial participation utilizing home-health solutions to maximize patient safety is expected to aid in trial recruitment.
 - **Phase 2a PET imaging trial of PLN-74809 in IPF is enrolling.** The Phase 2a PET trial will evaluate safety, tolerability, and target engagement of PLN-74809 in IPF patients. We expect to report preliminary data by the first half of 2021.
 - **Completed dosing of an extended Phase 1 dose escalation trial of PLN-74809 in healthy volunteers.** PLN-74809 has completed dosing multiple ascending dose cohorts of 120mg and 160mg once daily in an extended dose escalation trial. The pharmacokinetic profile remains in line with previous cohorts, and PLN-74809 remains generally well tolerated with no drug related severe adverse events or serious adverse events reported in either cohort.
 - **Phase 2a trial of PLN-74809 treatment of COVID-19 related acute respiratory distress syndrome (ARDS) has been initiated.** The Company initiated a Phase 2a trial evaluating safety, tolerability and pharmacokinetics (PK) of PLN-74809, as well as exploratory clinical outcome measures in patients hospitalized with severe and critical COVID-19.
-

- **Phase 1 trial of PLN-1474 in healthy volunteers is nearing completion.** The Phase 1 trial is designed to evaluate safety and tolerability, as well as PK of PLN-1474 in approximately 100 healthy volunteers across a dose range compared to placebo. After resuming enrollment following delays related to COVID-19, the trial remains on track to deliver topline data by the first quarter of 2021. PLN-1474 is partnered with Novartis.

COVID-19 Preparedness

Pliant continues to develop policies and procedures to enable the Company 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. Pliant 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 impacts of the pandemic become better understood.

Third Quarter 2020 Financial Results

- Related party revenue was \$4.8 million, as compared to none for the prior-year quarter.
- Research and development expenses were \$16.9 million, as compared to \$10.8 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 \$4.6 million, as compared to \$2.6 million for the same period in 2019. The increase was due to higher personnel-related and professional services expenses.
- Net loss of \$16.5 million as compared to a net loss of \$13.3 million for the prior-year quarter.
- As of September 30, 2020, Pliant had cash, cash equivalents and short-term investments of \$294.0 million, compared to \$312.5 million as of June 30, 2020. 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 $\alpha v\beta 6$ and $\alpha v\beta 1$ integrins that it is developing 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 for the treatment of IPF and PSC. Pliant's second product candidate, PLN-1474, is a small-molecule selective inhibitor of $\alpha v\beta 1$ for the treatment of liver fibrosis associated with nonalcoholic steatohepatitis, or NASH, which Pliant has partnered with Novartis. PLN-1474 is currently undergoing a Phase 1 trial. In addition to clinical stage programs, Pliant currently has two preclinical programs targeting oncology and muscular dystrophies.

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, and the Quarterly Report for the second quarter of 2020 filed with the SEC on Form 10-Q on August 11, 2020 which are available on the SEC's website at www.sec.gov. Additional information will be made available in Pliant Therapeutics quarterly report on Form 10-Q for the quarter ended September 30, 2020 forward looking statements, or to update the reasons if actual results differ materially from those anticipated in the forward-looking statements.

Investor Contact:

ir@pliantrx.com

Media Contact:

Cambria Fuqua

Canale Communications

cambria.fuqua@canalecomm.com

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue — related party	\$ 4,814	\$ —	\$ 37,352	\$ —
Operating expenses:				
Research and development	(16,884)	(10,779)	(48,339)	(35,626)
General and administrative	(4,591)	(2,583)	(11,642)	(7,827)
Total operating expenses	<u>(21,475)</u>	<u>(13,362)</u>	<u>(59,981)</u>	<u>(43,453)</u>
Loss from operations	(16,661)	(13,362)	(22,629)	(43,453)
Interest income	72	148	392	701
Other income (expense), net	55	(41)	(269)	(48)
Net loss	<u>\$ (16,534)</u>	<u>\$ (13,255)</u>	<u>\$ (22,506)</u>	<u>\$ (42,800)</u>
Accretion to redemption value and cumulative dividends on redeemable convertible preferred stock	—	(1,375)	—	(4,078)
Net loss attributable to common stockholders	<u>\$ (16,534)</u>	<u>\$ (14,630)</u>	<u>\$ (22,506)</u>	<u>\$ (46,878)</u>
Net loss per share, attributable to common stockholders:				
Basic	<u>\$ (0.47)</u>	<u>\$ (8.53)</u>	<u>\$ (1.36)</u>	<u>\$ (30.03)</u>
Diluted	<u>\$ (0.47)</u>	<u>\$ (8.53)</u>	<u>\$ (1.36)</u>	<u>\$ (30.03)</u>
Shares used in computing net loss per share attributable to common stockholders:				
Basic	<u>35,445,504</u>	<u>1,714,285</u>	<u>16,592,746</u>	<u>1,561,242</u>
Diluted	<u>35,445,504</u>	<u>1,714,285</u>	<u>16,592,746</u>	<u>1,561,242</u>
Comprehensive loss:				
Net loss	\$ (16,534)	\$ (13,255)	\$ (22,506)	\$ (42,800)
Net unrealized gain (loss) on short-term investments	\$ 12	\$ (10)	\$ (17)	\$ 1
Total other comprehensive income (loss)	12	(10)	(17)	1
Comprehensive loss	<u>\$ (16,522)</u>	<u>\$ (13,265)</u>	<u>\$ (22,523)</u>	<u>\$ (42,799)</u>

Pliant Therapeutics, Inc.
Condensed Balance Sheets
(Unaudited)

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

	September 30, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	\$ 55,224	\$ 85,807
Short-term investments	238,776	16,966
Accounts receivable	7,131	7,052
Tax credit receivable	83	333
Prepaid expenses and other current assets	6,515	1,742
Total current assets	307,729	111,900
Property and equipment, net	4,144	4,079
Other non-current assets	451	3,085
Total assets	\$ 312,324	\$ 119,064
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	\$ 3,140	\$ 1,250
Accrued liabilities (Note 5)	7,886	6,922
Total current liabilities	11,026	8,172
Other long-term liabilities (Note 5)	952	912
Total liabilities	11,978	9,084
Commitments and Contingencies (Note 13)		
Preferred stock, \$0.0001 par value; 10,000,000 shares and 0 shares authorized at September 30, 2020 and December 31, 2019, respectively; 0 shares issued and outstanding at September 30, 2020 and December 31, 2019;	—	—
Series A redeemable convertible preferred stock, \$0.0001 par value; 0 and 56,000,000 shares authorized at September 30, 2020 and December 31, 2019, respectively; 0 and 56,000,000 shares issued and outstanding, at September 30, 2020 and December 31, 2019, respectively; aggregate liquidation preference of \$0 and \$62,468 at September 30, 2020 and December 31, 2019, respectively;	—	62,468
Series B redeemable convertible preferred stock, \$0.0001 par value; 0 shares and 49,501,221 shares authorized at September 30, 2020 and December 31, 2019, respectively; 0 shares and 49,501,221 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively; aggregate liquidation preference of \$0 and \$75,860 at September 30, 2020 and December 31, 2019, respectively;	—	75,860
Series C redeemable convertible preferred stock, \$0.0001 par value; 0 shares and 44,000,000 shares authorized at September 30, 2020 and December 31, 2019, respectively; 0 shares and 26,360,745 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively; aggregate liquidation preference of \$0 and \$47,947 at September 30, 2020 and December 31, 2019, respectively;	—	47,947
Stockholders' equity (deficit)		
Common stock, \$0.0001 par value; 300,000,000 and 181,000,000 shares authorized at September 30, 2020 and December 31, 2019; and 35,465,715 and 1,846,024 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively;	3	1
Additional paid-in capital	399,162	—
Accumulated deficit	(98,801)	(76,295)
Accumulated other comprehensive loss	(18)	(1)
Total stockholders' equity (deficit)	300,346	(76,295)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	\$ 312,324	\$ 119,064