

**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 11, 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:

| 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 August 11, 2020, Pliant Therapeutics, Inc. (the "Company") issued a press release announcing the Company's financial results for the quarter ended June 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 August 11, 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: August 11, 2020

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



Pliant Therapeutics Provides Corporate Update and Announces Second-Quarter 2020 Financial Results

-Raised over \$175 million in initial public offering and concurrent private placement to advance lead product candidate PLN-74809 for the treatment of idiopathic pulmonary fibrosis and primary sclerosing cholangitis

-Continued progress of Phase 2a 12-week trials of IPF and PSC with sites enrolling

-IND open for PLN-74809 in COVID-19-related acute respiratory distress syndrome

-Completed dosing of initial cohorts in Phase 1 trial of PLN-1474 in healthy volunteers

South San Francisco, CA, August 11, 2020 – Pliant Therapeutics, Inc. (Nasdaq: PLRX), 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 2020 financial results.

“2020 has been a productive year as we’ve made progress on multiple fronts, including the initiation of a 12-week Phase 2a clinical trial evaluating PLN-74809 in patients with idiopathic pulmonary fibrosis, as well as dosing initial cohorts in our first-in-human trial of our Novartis partnered program, PLN-1474, for the potential treatment of liver fibrosis,” said Bernard Coulie, M.D., Ph.D., chief executive officer and president of Pliant Therapeutics. “Bolstered by a strong cash position from our Series C financing in February and our IPO in June, we continue to advance our robust pipeline. We’re now focused on executing our Phase 2a program for PLN-74809 and look forward to sharing further updates on all of our programs.”

Recent Highlights

- **Completed an initial public offering (IPO) and concurrent private placement with Novartis.** The IPO priced at \$16.00 per share, generating gross proceeds of \$165.6 million including shares sold to the underwriters pursuant to the full exercise of their overallotment option before deducting underwriting discounts, commissions and other offering expenses payable by Pliant. The company also received \$10.0 million in additional proceeds from a concurrent private placement with Novartis Institutes for BioMedical Research, Inc. at the public offering price of \$16.00 per share. The Company's common stock commenced trading on the Nasdaq Global Select Market under the ticker symbol "PLRX" on June 3rd, 2020.
 - **Phase 2a 12-week trials of PLN-74809 in idiopathic pulmonary fibrosis (IPF) and primary sclerosing cholangitis (PSC) have resumed enrollment.** Through close coordination with over 100 global trial sites, Pliant has continued to conduct site initiation activities throughout the COVID-19 pandemic. The Company is offering a hybrid approach to clinical trial participation with home-health solutions designed to minimize the requirements for visits to healthcare facilities, as well as a campaign to raise awareness of the IPF and PSC programs across patient communities and patient advocacy groups. Phase 2a clinical trial sites are currently enrolling patients in both the IPF and PSC trials.
 - **Opened Investigational New Drug (IND) Application for PLN-74809 for treatment of acute respiratory distress syndrome (ARDS) associated with COVID-19.** Pliant submitted the COVID-19 ARDS IND in June and the FDA has since issued a "safe to proceed" letter. The Company plans to initiate a Phase 2 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 in the second half of 2020. This represents the fourth IND that Pliant has successfully opened since operations began in 2016.
 - **Completed dosing of initial cohorts of a Phase 1 trial of PLN-1474.** The Phase 1 trial is designed to evaluate safety, tolerability and PK of PLN-1474 in approximately 100 healthy volunteers across a dose range compared to placebo. The Phase 1 trial site has experienced delays due to COVID-19; however, it is now open and expected to continue dosing the remaining cohorts with topline data expected in the first quarter of 2021, subject to further impact of the COVID-19 pandemic. PLN-1474 is partnered with Novartis.
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COVID-19 Preparedness

Pliant has worked proactively to establish policies and procedures to enable the Company to operate safely and productively during the pandemic. The Company has experienced delays in clinical trial operations which will impact the expected timing of data readouts, but is working closely with clinical sites to continue site initiation activities in compliance with study protocols while observing government and institutional guidelines. The clinical site conducting Pliant's Phase 2a PET trial of PLN-74809 in IPF remains closed to clinical research, but expects to resume trial activities in the third quarter. Pliant has made significant progress in opening trial sites for its Phase 2a 12-week IPF and PSC trials by offering a hybrid approach to clinical trial participation with home-health solutions designed to minimize the requirements for visits to healthcare facilities, as well as a campaign to raise awareness of the IPF and PSC programs across patient communities and patient advocacy groups. The Company intends to provide more specific guidance regarding clinical trial progress and the timing of data readouts as the impacts of the pandemic are better understood.

Second-Quarter 2020 Financial Results

- Related party revenue was \$3.6 million as compared to nil for the prior-year period.
- Research and development expenses were \$17.5 million, as compared to \$13.1 million for the prior-year period. The increase was primarily related to higher external research and development expenses associated with the advancement of several programs and ongoing Phase 2 clinical trials.
- General and administrative expenses were \$3.0 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 \$17.0 million as compared to a net loss of \$15.5 million for the prior-year period.
- As of June 30, 2020, Pliant had cash, cash equivalents and short-term investments of \$312.5 million, compared to \$102.8 million as of December 31, 2019. 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 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 $\alpha\text{v}\beta\text{1}$ 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, which is 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 June 30, 2020 forward looking statements, or to update the reasons if actual results differ materially from those anticipated in the forward-looking statements.

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

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|--------------------------------|--------------------|------------------------------|--------------------|
| | 2020 | 2019 | 2020 | 2019 |
| Revenue — related party | \$ 3,600 | \$ — | \$ 32,538 | \$ — |
| Operating expenses: | | | | |
| Research and development | (17,536) | (13,098) | (31,455) | (24,847) |
| General and administrative | (3,040) | (2,643) | (7,051) | (5,244) |
| Total operating expenses | <u>(20,576)</u> | <u>(15,741)</u> | <u>(38,506)</u> | <u>(30,091)</u> |
| Loss from operations | (16,976) | (15,741) | (5,968) | (30,091) |
| Interest income | 111 | 240 | 320 | 553 |
| Other expense, net | (136) | (21) | (324) | (7) |
| Net loss | <u>\$ (17,001)</u> | <u>\$ (15,522)</u> | <u>\$ (5,972)</u> | <u>\$ (29,545)</u> |
| Accretion to redemption value and cumulative dividends on redeemable convertible preferred stock | — | (1,359) | — | (2,703) |
| Net loss attributable to common stockholders | <u>\$ (17,001)</u> | <u>\$ (16,881)</u> | <u>\$ (5,972)</u> | <u>\$ (32,248)</u> |
| Net loss per share, attributable to common stockholders: | | | | |
| Basic | <u>\$ (1.39)</u> | <u>\$ (10.82)</u> | <u>\$ (0.85)</u> | <u>\$ (21.70)</u> |
| Diluted | <u>\$ (1.39)</u> | <u>\$ (10.82)</u> | <u>\$ (0.85)</u> | <u>\$ (21.70)</u> |
| Shares used in computing net loss per share attributable to common stockholders: | | | | |
| Basic | <u>12,253,943</u> | <u>1,559,942</u> | <u>7,062,780</u> | <u>1,486,109</u> |
| Diluted | <u>12,253,943</u> | <u>1,559,942</u> | <u>7,062,780</u> | <u>1,486,109</u> |
| Comprehensive loss: | | | | |
| Net loss | \$ (17,001) | \$ (15,522) | \$ (5,972) | \$ (29,545) |
| Net unrealized (loss) gain on short-term investments | \$ (89) | \$ 8 | \$ (29) | \$ 11 |
| Total other comprehensive (loss) income | (89) | 8 | (29) | 11 |
| Comprehensive loss | <u>\$ (17,090)</u> | <u>\$ (15,514)</u> | <u>\$ (6,001)</u> | <u>\$ (29,534)</u> |

Pliant Therapeutics, Inc.
Condensed Balance Sheets
(Unaudited)

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

| | June 30, 2020 | December 31, 2019 |
|---|-------------------|----------------------|
| Assets | | |
| Current assets | | |
| Cash and cash equivalents | \$ 178,461 | \$ 85,807 |
| Short-term investments | 134,007 | 16,966 |
| Accounts receivable | 3,599 | 7,052 |
| Tax credit receivable | 83 | 333 |
| Prepaid expenses and other current assets | 8,173 | 1,742 |
| Total current assets | 324,323 | 111,900 |
| Property and equipment, net | 4,029 | 4,079 |
| Other non-current assets | 451 | 3,085 |
| Total assets | \$ 328,803 | \$ 119,064 |
| Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) | | |
| Current liabilities | | |
| Accounts payable | \$ 2,483 | \$ 1,250 |
| Accrued liabilities (Note 5) | 9,553 | 6,922 |
| Total current liabilities | 12,036 | 8,172 |
| Other long-term liabilities (Note 5) | 951 | 912 |
| Total liabilities | 12,987 | 9,084 |
| Commitments and Contingencies (Note 13) | | |
| Preferred stock, \$0.0001 par value; 10,000,000 shares and 0 shares authorized at June 30, 2020 and December 31, 2019, respectively; 0 shares issued and outstanding at June 30, 2020 and December 31, 2019; | — | — |
| Series A redeemable convertible preferred stock, \$0.0001 par value; 0 and 56,000,000 shares authorized at June 30, 2020 and December 31, 2019, respectively; 0 and 56,000,000 shares issued and outstanding, at June 30, 2020 and December 31, 2019, respectively; aggregate liquidation preference of \$0 and \$62,468 at June 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 June 30, 2020 and December 31, 2019, respectively; 0 shares and 49,501,221 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively; aggregate liquidation preference of \$0 and \$75,860 at June 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 June 30, 2020 and December 31, 2019, respectively; 0 shares and 26,360,745 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively; aggregate liquidation preference of \$0 and \$47,947 at June 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 June 30, 2020 and December 31, 2019; and 35,427,199 and 1,846,024 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively; | 3 | 1 |
| Additional paid-in capital | 398,110 | — |
| Accumulated deficit | (82,267) | (76,295) |
| Accumulated other comprehensive loss | (30) | (1) |
| Total stockholders' equity (deficit) | 315,816 | (76,295) |
| Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit) | \$ 328,803 | \$ 119,064 |