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 6, 2024

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 May 6, 2024, Pliant Therapeutics, Inc. (the "Company") issued a press release announcing the Company's financial results for the first quarter ended March 31, 2024. A copy of this press release is furnished as Exhibit 99.1 to this report.

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 6, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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 6, 2024

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

Exhibit 99.1

Pliant Therapeutics Provides Corporate Update and
Reports First Quarter 2024 Financial Results
BEACON-IPF pivotal, adaptive Phase 2b/3 trial design implementation significantly accelerates bexotegrast development in IPF

Data from completed 12 week Phase 2a imaging trial measuring bexotegrast's effect on total lung collagen and FVC in IPF patients expected in the coming weeks

Regulatory clearance received for muscular dystrophy program PLN-101325, allowing conduct of a first-in-human Phase 1 clinical study

SOUTH SAN FRANCISCO, CA., May 6, 2024 - Pliant Therapeutics, Inc. (Nasdaq: PLRX), a late-stage clinical biotechnology company and leader in the discovery and development of novel therapeutics for the treatment of fibrotic diseases, today provided a corporate update and reported first quarter 2024 financial results.

"In the first quarter, we made significant progress across our portfolio, highlighted by the positive safety and exploratory efficacy data from our Phase 2a INTEGRIS-PSC trial, as well as completion of a Phase 2a PET imaging trial evaluating bexotegrast's effects on total lung collagen and lung function in IPF patients," said Bernard Coulie, M.D., Ph.D., President and Chief Executive Officer of Pliant Therapeutics. "Our strong execution has also allowed us to accelerate the ongoing BEACON-IPF Phase 2b trial through the implementation of an adaptive Phase 2b/3 design which will reduce the time to Phase 3 data by up to two years."

First Quarter and Recent Highlights

Bexotegrast Highlights

- **Acceleration of bexotegrast development plan with implementation of BEACON-IPF as a pivotal, adaptive Phase 2b/3 trial in patients with idiopathic pulmonary fibrosis (IPF).** The adaptive design implementation, based on acceptance by the European Union (EU) and other global health authorities, is expected to significantly shorten bexotegrast's late-stage development compared to standalone Phase 2b and Phase 3 trials. As part of the adaptive Phase 2b/3 implementation, the Phase 2b portion of BEACON-IPF was upsized from 267 patients to 360 patients. Enrollment is progressing and we expect to complete enrollment of the upsized Phase 2b study expected in the first quarter of 2025.
- **Completion of a 12 week Phase 2a PET imaging trial, measuring the effects of bexotegrast on total lung collagen and forced vital capacity (FVC) in IPF patients**. This randomized, double-blind, placebo-controlled trial (NCT05621252) was conducted at Massachusetts General Hospital. The trial's primary endpoint is the change in total lung collagen in 10 participants with IPF following once-daily treatment with bexotegrast at 160 mg for 12 weeks. Collagen will be evaluated with PET imaging, utilizing a collagen-binding probe. The secondary endpoint is safety and tolerability. Exploratory endpoints include change in FVC, cough severity and fibrosis biomarkers. Conduct of this trial has been completed, with topline data expected in the coming weeks.
- **Completion of INTEGRIS-PSC Phase 2a trial in patients with primary sclerosing cholangitis (PSC) with data readout expected mid-year.** As previously announced, at a once-daily dose of 320 mg, bexotegrast was well tolerated over 12 weeks of treatment with no drug-related severe or serious adverse events. At the 320 mg dose, bexotegrast reduced both Enhanced Liver Fibrosis (ELF) scores and PRO-C3 levels and showed improvements in hepatocyte function and bile flow by contrast MRI imaging relative to placebo at Week 12. The final 24-week data readout from the 320 mg dose group is expected in mid-2024.

Pipeline Programs

- **Muscular dystrophy program cleared for conduct of Phase 1 study.** PLN-101325 is a monoclonal antibody designed to act as an allosteric agonist of integrin α7β1. The Company recently received regulatory clearance from Australia's Research Ethics Committee (HREC) for the conduct of a first-in-human Phase 1 clinical study of

PLN-101325 which is being developed as a potential treatment for muscular dystrophies, including Duchenne muscular dystrophy (DMD).

- **Phase 1 trial of PLN-101095 in solid tumors is progressing with dosing of the third of five cohorts.** PLN-101095 is an oral, small molecule, dual selective inhibitor of αvβ8 and αvβ1 integrins designed to block TGF-β activation in the tumor microenvironment. The Company is currently enrolling the third of five cohorts in the Phase 1 open label, dose-escalation trial of PLN-101095 as monotherapy and in combination with pembrolizumab in patients with solid tumors that are resistant to immune checkpoint inhibitors. Preliminary data could be available as early as late 2024.

Corporate Highlights

- **Loan facility with Oxford Finance LLC (Oxford), upsized by $50 million to a total of $150 million of available non-dilutive capital.** To date, the Company has drawn a total of $30 million from the facility. The remaining funds available under this facility, along with the Company's March 31, 2024 cash and cash equivalents and short-term investments of $483.9 million are expected to fund Pliant's anticipated operating expenses and capital expenditure requirements through 2026.

First Quarter 2024 Financial Results

- Research and development expenses were $37.1 million, as compared to $29.3 million for the prior-year quarter. The increase was due primarily to higher employee-related expenses and increased clinical and manufacturing-related costs associated with our lead program, bexotegrast, partially offset by a decrease in preclinical manufacturing costs for our pipeline product candidates.
- General and administrative expenses were $15.2 million, as compared to $14.2 million for the prior-year quarter. The increase was due to higher employee-related expenses.
- Net loss of $47.0 million as compared to $37.5 million for the prior-year quarter. The increase was due to higher operating expenses coupled with a decrease in collaboration revenues under the Novartis agreement during the quarter.
- As of March 31, 2024, the Company had cash, cash equivalents and short-term investments of $483.9 million.

About Pliant Therapeutics, Inc.

Pliant Therapeutics is a late-stage biopharmaceutical company and leader in the discovery and development of novel therapeutics for the treatment of fibrotic diseases. Pliant's lead product candidate, bexotegrast (PLN-74809), is an oral, small molecule, dual selective inhibitor of αvß6 and αvß1 integrins that is in development in the lead indications for the treatment of idiopathic pulmonary fibrosis, or IPF, and primary sclerosing cholangitis, or PSC. Bexotegrast has received Fast Track Designation and Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) in IPF and PSC and Orphan Drug Designation from the European Medicines Agency in IPF and PSC. Pliant has initiated BEACON-IPF, an adaptive Phase 2b/3 trial of bexotegrast in IPF. Pliant is conducting a Phase 1 study for its third clinical program, PLN-101095, a small molecule, dual-selective inhibitor of αvß8 and αvß1 integrins, that is being developed for the treatment of solid tumors. In addition, Pliant has received regulatory clearance for the conduct of a Phase 1 study of PLN-101325, a monoclonal antibody agonist of integrin α7β1 targeting muscular dystrophies. For additional information, please visit: www.PliantRx.com. Follow us on social media X, 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 safety, tolerability, pharmacodynamics and therapeutic potential of bexotegrast; our expectation that the expansion of BEACON-IPF Phase 2b Trial into a pivotal, adaptive Phase 2b/3 Trial will significantly accelerate bexotegrast's late-stage development compared to a traditional Phase 3 trial and potentially shorten the time to Phase 3 data; our plans for the future development of bexotegrast, PLN-101325 and PLN-101095; bexotegrast's potential to become a treatment for IPF or PSC; the anticipated timing of data and progress from our clinical studies and public announcements related thereto; discussions with regulatory authorities; our access to future capital under the Oxford debt facility and the sufficiency of our cash runway to fund operations through the 2026. 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 current macroeconomic and marketplace conditions, including the effects of COVID-19, on our business, operations, clinical supply and plans, our reliance on third parties for

critical aspects of our development operations, 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, including the availability of additional term loans under our loan facility, 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 Quarterly Report on Form 10-Q for the period ended March 31, 2024 which we are filing with the SEC today, 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 March 31,	
	2024	**2023**
Revenue	$ —	$ 1,332
Operating expenses:		
Research and development	(37,146)	(29,273)
General and administrative	(15,246)	(14,154)
Total operating expenses	(52,392)	(43,427)
Loss from operations	(52,392)	(42,095)
Interest and other income (expense), net	5,882	4,858
Interest expense	(445)	(311)
Net loss	$ (46,955)	$ (37,548)
Net loss per share - basic and diluted	$ (0.78)	$ (0.67)
Shares used in computing net loss per share - basic and diluted	60,180,921	56,057,603

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

	March 31, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 114,297	$ 63,234
Short-term investments	368,092	431,011
Prepaid expenses and other current assets	7,509	11,257
Total current assets	489,898	505,502
Property and equipment, net	5,605	3,567
Operating lease right-of-use assets	24,228	1,211
Restricted cash	1,482	1,482
Other non-current assets	392	392
Total assets	$ 521,605	$ 512,154
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 7,327	$ 4,531
Accrued research and development	16,423	12,456
Accrued liabilities	5,868	10,219
Operating lease liabilities, current	773	1,318
Total current liabilities	30,391	28,524
Operating lease liabilities, non-current	23,880	—
Long-term debt	30,002	10,054
Total liabilities	84,273	38,578
Stockholders' equity		
Preferred stock	—	—
Common stock	6	6
Additional paid-in capital	984,518	972,973
Accumulated deficit	(546,703)	(499,748)
Accumulated other comprehensive (loss) gain	(489)	345
Total stockholders' equity	437,332	473,576
Total liabilities and stockholders' equity	$ 521,605	$ 512,154