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 7, 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.)**
331 Oyster Point Blvd., 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 November 7, 2024, Pliant Therapeutics, Inc. (the "Company") issued a press release announcing the Company's financial results for the third quarter ended September 30, 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 November 7, 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: November 7, 2024

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

Exhibit 99.1

Pliant Therapeutics Provides Corporate Update and Reports Third Quarter 2024 Financial Results

BEACON-IPF Phase 2b trial on track for full enrollment in the first quarter of 2025
with data anticipated in mid-2026

SOUTH SAN FRANCISCO, CA., November 7, 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 third quarter 2024 financial results.

“A highlight to this quarter’s progress was the continued strong execution of our BEACON-IPF Phase 2b/3 trial which is enrolling well and on track to complete enrollment in the first quarter of 2025,” said Bernard Coulie, M.D., Ph.D., President and Chief Executive Officer of Pliant. “We are pleased with the interest from the global physician and patient communities in participating in BEACON-IPF and look forward to sharing data in mid-2026. Additionally, we made progress across the portfolio with the goal of bringing potential therapies to patients.”

Third Quarter and Recent Highlights

Bexotegrast Highlights

- **Enrollment remains on track in BEACON-IPF, a pivotal adaptive Phase 2b/3 trial of bexotegrast in patients with idiopathic pulmonary fibrosis (IPF)**. The BEACON-IPF Phase 2b/3 trial is a 52-week, multinational, randomized, dose-ranging, double-blind, placebo-controlled trial evaluating bexotegrast at once-daily doses of 160 mg or 320 mg. The Phase 2b portion of BEACON-IPF will enroll 360 patients with IPF. Enrollment in this portion of this trial is expected to be complete in the first quarter of 2025 with data anticipated in mid-2026.
- **Results from Phase 2a PET imaging target engagement trial published in the American Journal of Respiratory and Critical Care Medicine (AJRCCM).** Also known as the “Blue Journal,” AJRCCM is a leading peer-reviewed journal published by the American Thoracic Society. The publication reviews the previously reported positive results from an open-label trial in which bexotegrast showed dose-dependent αvβ6 integrin receptor occupancy in lungs of patients with IPF.

Pipeline Programs

- **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 has completed enrollment in the third of five cohorts in the Phase 1 open-label, dose-escalation trial. In this trial, PLN-101095 is being tested as monotherapy and in combination with pembrolizumab in patients with solid tumors that are resistant to immune checkpoint inhibitors. Preliminary data is expected in early 2025.
- **PLN-101325 applications beyond muscular dystrophies.** PLN-101325 is a monoclonal antibody that acts as an allosteric agonist of integrin α7β1, currently in development for treatment of muscular dystrophies. The Company is currently generating additional evidence in support of potential expansion of the scope of PLN-101325 prior to initiating a Phase 1 trial.

Corporate Highlights

- **Appointment of Gary Palmer, M.D. as Senior Vice President of Medical Affairs.** Dr. Palmer brings over 25 years of global leadership experience in medical affairs from biopharmaceutical companies of various sizes and stages, and across multiple therapeutic areas including pulmonary medicine, immunology and neurology. Most recently, Dr. Palmer served as Senior Vice President of Global Medical Affairs, Immunology and Neuroscience at Bristol Myers Squibb.

Third Quarter 2024 Financial Results

- Research and development expenses were $47.8 million, as compared to $32.3 million for the prior-year quarter. The increase was primarily driven by BEACON-IPF, a Phase 2b/3 trial of bexotegrast in patients with IPF.
- General and administrative expenses were $14.3 million, as compared to $15.3 million for the prior-year quarter. The decrease was primarily due to professional service expenses.
- Net loss of $57.8 million as compared to $41.5 million for the prior-year quarter. The increase was primarily due to higher operating expenses driven by BEACON-IPF.
- As of September 30, 2024, the Company had cash, cash equivalents and short-term investments of $406.0 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 and Facebook.

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 ability to complete enrollment in BEACON-IPF in the first quarter of 2025; our plans for the future development of bexotegrast, PLN-101325 and PLN-101095, including the potential expansion of PLN-101325 into additional indications in organ systems outside of muscle; 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; and discussions with regulatory authorities. 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 September 30, 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 September 30,	
	2024	**2023**
Revenue	$ —	$ —
Operating expenses:		
Research and development	(47,754)	(32,339)
General and administrative	(14,260)	(15,346)
Total operating expenses	(62,014)	(47,685)
Loss from operations	(62,014)	(47,685)
Interest and other income (expense), net	5,128	6,515
Interest expense	(877)	(317)
Net loss	$ (57,763)	$ (41,487)
Net loss per share - basic and diluted	$ (0.95)	$ (0.70)
Shares used in computing net loss per share - basic and diluted	60,730,935	59,688,451

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

	September 30, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 79,616	$ 63,234
Short-term investments	324,897	431,011
Prepaid expenses and other current assets	5,518	11,257
Total current assets	410,031	505,502
Property and equipment, net	5,671	3,567
Operating lease right-of-use assets	28,054	1,211
Restricted cash	1,482	1,482
Other non-current assets	427	392
Total assets	$ 445,665	$ 512,154
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 6,890	$ 4,531
Accrued research and development	23,025	12,456
Accrued liabilities	9,715	10,219
Operating lease liabilities, current	322	1,318
Total current liabilities	39,952	28,524
Operating lease liabilities, non-current	29,752	—
Long-term debt	30,139	10,054
Total liabilities	99,843	38,578
Stockholders' equity		
Preferred stock	—	—
Common stock	6	6
Additional paid-in capital	1,005,288	972,973
Accumulated deficit	(660,320)	(499,748)
Accumulated other comprehensive gain	848	345
Total stockholders' equity	345,822	473,576
Total liabilities and stockholders' equity	$ 445,665	$ 512,154