Pliant Therapeutics Provides Corporate Update and Reports Third Quarter 2022 Financial Results

November 8, 2022

SOUTH SAN FRANCISCO, Calif., Nov. 08, 2022 (GLOBE NEWSWIRE) -- 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 third quarter 2022 financial results.

“Our strong third quarter progress was highlighted by positive data from our lead candidate PLN-74809 in IPF, the further strengthening of our financial position through a successful public offering and the positive DSMB safety review of the ongoing INTEGRIS-IPF trial that added to the growing favorable safety profile of this novel drug candidate,” said Bernard Coulie, M.D., Ph.D., President and Chief Executive Officer of Pliant Therapeutics. “This progress sets the stage for several near-term clinical data readouts, including the 12-week and 24-week data from the INTEGRIS-IPF program in early 2023 and the first half of 2023, respectively.”

Third Quarter and Recent Highlights

PLN-74809 (bexotegrast) Highlights

- **The International Nonproprietary Names (INN) Expert Group adopted “bexotegrast” as the unique non-proprietary or generic name for PLN-74809.** Going forward, Pliant will use bexotegrast in place of PLN-74809.
- **Positive safety and efficacy data from Phase 2a INTEGRIS-IPF trial of PLN-74809 (bexotegrast) in patients with idiopathic pulmonary fibrosis (IPF).** PLN-74809 (bexotegrast), at once-daily doses of 40 mg, 80 mg, 160 mg, demonstrated a dose-dependent treatment effect on forced vital capacity (FVC) and quantitative lung fibrosis (QLF) and serum biomarkers of PRO-C3 versus placebo over 12 weeks of treatment. A treatment effect was observed at all three doses tested on top of standard of care therapy and as monotherapy. In addition, PLN-74809 (bexotegrast) was well tolerated over 12 weeks of treatment with no drug related serious adverse events (SAEs) and no treatment discontinuations due to adverse events.
- **Positive independent Data Safety Monitoring Board (DSMB) review of the ongoing INTEGRIS-IPF Phase 2a trial.** This regularly scheduled DSMB review was held in August after the completion of enrollment of the 320 mg cohort. The DSMB examined the safety data from all patients enrolled, approximately half of whom had completed at least 12 weeks of treatment, and recommended the INTEGRIS-IPF trial continue without modification.
- **INTEGRIS-IPF Phase 2a trial of PLN-74809 (bexotegrast) at 320 mg on track for 12-week data readout in early first quarter 2023.** This randomized, double-blind, placebo-controlled trial is also evaluating PLN-74809 (bexotegrast) at a once daily dose of 320 mg administered for at least six months and up to 48 weeks in approximately 28 patients with IPF. The trial will evaluate primary and secondary endpoints of safety, tolerability, and pharmacokinetics. Exploratory efficacy endpoints will include effect on FVC and QLF imaging as well as biomarkers. Trial enrollment was completed in the second quarter of 2022 with interim 12-week data expected early in the first quarter of 2023 and 24-week data expected in the first half of 2023.
- **Positive independent DSMB review of the ongoing INTEGRIS-PSC Phase 2a trial of PLN-74809 (bexotegrast) in patients with primary sclerosing cholangitis (PSC).** This regularly scheduled DSMB review was held in October to examine the safety data from all patients enrolled. The DSMB recommended the INTEGRIS-PSC trial continue without modification. Topline data from this trial is expected in the third quarter of 2023.

Early-Stage Development Programs

- **Oncology program is completing Investigational New Drug (IND) enabling activities.** Based on encouraging preclinical data generated to date, the Company is prioritizing the oncology program as the next program to enter clinical development. IND application submission is expected by the end of 2022.
- **Muscular dystrophy program progressing through IND enabling activities.** IND application submission is expected in 2023.

Corporate Highlights

- **Closing of underwritten public offering of $230 million in common stock.** The Company closed a public offering

yielding $215.4 million in net proceeds to the Company, which included the underwriter's exercise in full of their option to purchase additional shares. Pliant intends to use the net proceeds from the offering, together with its existing cash, cash equivalents and investments, to develop its ongoing and future preclinical and clinical programs including PLN-74809 (bexotegrast), further develop its integrin targeting platform, to fund working capital, operating expenses and capital expenditures, and for other general corporate purposes.

- **Appointment of Dr. Katharine Knobil to the Company's Board of Directors.** Dr. Knobil brings over 20 years of clinical development and medical affairs expertise from strategic leadership roles from across the globe to the Company. Dr. Knobil currently serves as the Chief Medical Officer at Agilent Technologies, Inc.

Third Quarter 2022 Financial Results

- Research and development expenses were $24.6 million, as compared to $21.1 million for the prior-year quarter. The increase was due primarily to employee related expenses and higher manufacturing related costs which was partially offset by a decrease in clinical trial expenses given several Phase 1 studies completed prior to the third quarter of 2022.

- General and administrative expenses were $8.8 million, as compared to $7.7 million for the prior-year quarter. The increase was due to higher personnel-related and professional services expenses.

- Net loss of $30.6 million as compared to $27.0 million for the prior-year quarter due to an increase in operating expenses coupled with a slight decrease in collaboration revenues under the Novartis collaboration during the quarter.

- As of September 30, 2022, the Company had cash, cash equivalents and short-term investments of $360.2 million and considering full utilization of the Oxford loan facility, the Company expects to be able to fund operations to mid-2025.

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 (bexotegrast), 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. PLN-74809 (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 PSC. Pliant is currently conducting Phase 2a trials of PLN-74809 (bexotegrast) in the lead indications of IPF and PSC. Pliant has also developed PLN-1474, a small molecule selective inhibitor of αvß1 for the treatment of nonalcoholic steatohepatitis, or NASH with liver fibrosis, which Pliant has transferred to Novartis pursuant to our development partnership. 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 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 planned INDs in our oncology and muscular dystrophy programs; anticipated progress of our clinical trials and timing of regulatory, enrollment and data disclosures; the efficacy and safety profile of our product candidates; our intended use the net proceeds from our common stock offering; the sufficiency of our cash runway to fund operations to mid-2025 and the availability of additional term loans under our loan facility;. 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, 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, 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 Annual Report on Form 10-K filed for the year ended December 31, 2021 with the SEC on March 1, 2022, as updated by our Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, which we are filing with the SEC today, each 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.
ir@pliantrx.com

Condensed Statements of Operations
(Unaudited)
(In thousands, except number of shares and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue	$ 1,482	$ 1,610	$ 7,720	$ 5,573
Operating expenses:				
Research and development	(24,606)	(21,052)	(71,822)	(58,797)
General and administrative	(8,823)	(7,671)	(25,698)	(19,712)
Total operating expenses	(33,429)	(28,723)	(97,520)	(78,509)
Loss from operations	(31,947)	(27,113)	(89,800)	(72,936)
Interest and other income (expense), net	1,332	68	1,539	204
Net loss	$ (30,615)	$ (27,045)	$ (88,261)	$ (72,732)
Net loss attributable to common stockholders	$ (30,615)	$ (27,045)	$ (88,261)	$ (72,732)
Net loss per share attributable to common stockholders:				
Basic and diluted	$ (0.65)	$ (0.75)	$ (2.22)	$ (2.03)
Shares used in computing net loss per share attributable to common stockholders:				
Basic and diluted	46,799,058	35,906,303	39,735,342	35,787,022

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

	June 30, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 44,617	$ 51,665
Short-term investments	315,624	148,931
Accounts receivable	1,482	1,998
Tax credit receivable	83	83
Prepaid expenses and other current assets	4,159	6,764
Total current assets	365,965	209,441
Property and equipment, net	4,799	4,606
Operating lease right-of-use assets	6,020	6,330
Other non-current assets	397	838
Total assets	$ 377,181	$ 221,215
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 3,206	$ 2,971
Accrued liabilities	20,306	11,991
Lease liabilities, current	2,649	1,869
Total current liabilities	26,161	16,831
Lease liabilities, non-current	4,126	5,325
Term loan	9,871	—
Total liabilities	40,187	22,156
Stockholders' equity		
Common stock	5	3
Additional paid-in capital	642,795	414,348
Accumulated deficit	(303,352)	(215,091)
Accumulated other comprehensive loss	(2,454)	(201)
Total stockholders' equity	336,994	199,059
Total liabilities and stockholders' equity	$ 377,181	$ 221,215