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

May 9, 2022

$100 million Oxford loan facility extends cash runway to mid-2024

FDA Fast Track designation granted to PLN-74809 in IPF

INTEGRIS-IPF Phase 2a data readout in mid-2022

EMA Orphan Drug designation granted to PLN-74809 in PSC

SOUTH SAN FRANCISCO, Calif., May 09, 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 first quarter 2022 financial results.

“Our achievements so far in 2022 have built on the momentum we generated last year. We’ve advanced our portfolio, built upon the favorable safety profile of our lead asset and strengthened our financial position,” said Bernard Coulie, M.D., Ph.D., President and Chief Executive Officer of Pliant Therapeutics. “Solid execution across all areas of our business has allowed us to advance with confidence toward multiple near-term clinical milestones. The first of these will be the expected mid-year data readout of our INTEGRIS-IPF Phase 2a trial.”

First Quarter and Recent Highlights

PLN-74809 Highlights

- **INTEGRIS-IPF Phase 2a trial data readout anticipated in mid-2022.** All patients enrolled in the trial have completed treatment. This is a 12-week, randomized, double-blind, placebo-controlled trial evaluating PLN-74809 in patients with idiopathic pulmonary fibrosis (IPF) at once daily doses of 40, 80 and 160 mg. Data will include the primary and secondary endpoints of safety, tolerability, and pharmacokinetics. Exploratory efficacy endpoints will include quantitative lung fibrosis (QLF) imaging as well as pulmonary function tests and biomarkers.

- **Positive independent Data Safety Monitoring Board (DSMB) review provides additional support for tolerability profile for PLN-74809.** The DSMB recommended the INTEGRIS-IPF trial continue without modification. This review occurred after completion of enrollment and included all patients enrolled in all dose cohorts of the trial. To date, no safety concerns have been identified by the DSMB. The INTEGRIS-IPF trial completed enrollment in December 2021.

- **Phase 2a trial evaluating PLN-74809 at 320 mg for 6 months currently enrolling patients with IPF.** This randomized, double-blind, placebo-controlled trial will evaluate PLN-74809 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 QLF imaging as well as pulmonary function tests and biomarkers over 6 months of treatment.

- **FDA Fast Track designation received for PLN-74809 for the treatment of idiopathic pulmonary fibrosis (IPF).** FDA’s Fast Track designation is intended to facilitate and expedite the development and review of new drugs to treat serious or life-threatening conditions. The benefits of Fast Track designation include opportunities for frequent meetings with the FDA to discuss trial design, development plans and data needed to support drug approval, as well as the ability to submit a New Drug Application (NDA) on a rolling basis, and eligibility for priority review, if relevant criteria are met.

- **Expanded PLN-74809 Phase 1b proof-of-mechanism trial demonstrated durable inhibition of TGF-β signaling in the lungs of healthy participants.** Results from an expanded Phase 1b proof-of-mechanism trial of PLN-74809 demonstrated on-target biological activity in the lungs of 36 healthy participants with inhibition of TGF-β activation by up to 92% and 76% at 6- and 24-hours, respectively, following seven days of once-daily dosing. TGF-β activation strongly contributes to fibrotic disorders including IPF.

- **EMA Orphan Drug designation received for PLN-74809 for the treatment of primary sclerosing cholangitis (PSC).** Benefits of the European Medicines Association (EMA) Orphan Drug designation include trial design assistance, a centralized EU approval process, and 10 years of market exclusivity. To qualify, an investigational medicine must target a seriously debilitating or life-threatening condition affecting fewer than five in 10,000 people in the EU and must show sufficient non-clinical or clinical data to suggest it may produce clinically relevant outcomes. PLN-74809 received Orphan Drug designation from the United States Food and Drug Administration (FDA) in 2018. Topline data from the ongoing

Phase 2a INTEGRIS-PSC 12-week, randomized, double-blind, placebo-controlled trial is expected in the first half of 2023.

Early-Stage Development Programs

- **Oncology and muscular dystrophy programs progressing through Investigational New Drug (IND) enabling studies.** IND application submissions for both programs expected by the end of 2022.

Corporate Highlights

- **Cash runway extended to mid-2024 with $100 million loan facility from Oxford Finance.** Under the terms of the loan agreement, Pliant drew $10 million of an initial $25 million tranche at closing, with the remaining $15 million available through the end of the year. The Company has access to an additional $75 million over three tranches, $50 million of which is based on pre-determined milestones, and $25 million at Oxford's discretion. The loan carries an interest-only period of 48 months (extendable to 60 months) and total term of 60 months (extendable to 72 months). Interest is based on a floating rate which is subject to both a floor and a cap. There are no warrants or financial covenants in the agreement.

First Quarter 2022 Financial Results

- Research and development expenses were $20.9 million, as compared to $18.5 million for the prior-year quarter. The increase was due primarily to employee related expenses and higher costs related to the advancement of several programs and ongoing Phase 1/2 clinical trials.

- General and administrative expenses were $8.6 million, as compared to $6.6 million for the prior-year quarter. The increase was due to higher personnel-related and professional services expenses.

- Net loss of $28.1 million as compared to $22.9 million for the prior-year quarter due to an increase in operating expenses and a decrease in collaboration revenue.

- As of March 31, 2022, the Company had cash, cash equivalents and short-term investments of $178.3 million. With the initial drawdown of $10.0 million from the Oxford Finance loan facility, the Company had pro-forma cash, cash equivalents and short-term investments of $188.3 million as of March 31, 2022. With the facility in place, Pliant expects to be able to fund operations to mid-2024.

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 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 has received Fast Track Designation and Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) in IPF and Orphan Drug Designation from the FDA and European Medicines Agency in PSC. Pliant is currently conducting Phase 2a trials of PLN-74809 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 the de-risking of our ongoing and potential future clinical programs; 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 expectations regarding our interactions with regulators, including the FDA; the sufficiency of our cash runway and the availability of additional term loans under our loan facility; the anticipated benefits of Fast Track and Orphan Drug designations for PLN-74809; and anticipated progress of our pre-clinical programs, including timing expectations for regulatory filings. 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 March 31, 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

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

	Three Months Ended March 31,	
	2022	**2021**
Revenue	$ 1,249	$ 2,174
Operating expenses:		
Research and development	(20,881)	(18,527)
General and administrative	(8,579)	(6,566)
Total operating expenses	(29,460)	(25,093)
Loss from operations	(28,211)	(22,919)
Interest and other income (expense), net	111	63
Net loss	$ (28,100)	$ (22,856)
Net loss per share:		
Basic	$ (0.78)	$ (0.64)
Diluted	$ (0.78)	$ (0.64)
Shares used in computing net loss per share:		
Basic	36,116,440	35,645,205
Diluted	36,116,440	35,645,205

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

	March 31, 2022	**December 31, 2021**
Assets		
Current assets		
Cash and cash equivalents	$ 32,545	$ 51,665
Short-term investments	145,735	148,931
Accounts receivable	1,249	1,998
Tax credit receivable	83	83
Prepaid expenses and other current assets	5,751	6,764
Total current assets	185,363	209,441
Property and equipment, net	4,738	4,606
Operating lease right-of-use assets	6,086	6,330
Other non-current assets	835	838
Total assets	$ 197,022	$ 221,215
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 4,684	$ 2,971
Accrued liabilities	11,626	11,991
Lease liabilities, current	1,999	1,869
Total current liabilities	18,309	16,831
Lease liabilities, non-current	4,920	5,325
Total liabilities	23,229	22,156
Stockholders' equity		
Common stock	3	3
Additional paid-in capital	417,931	414,348
Accumulated deficit	(243,191)	(215,091)
Accumulated other comprehensive loss	(950)	(201)
Total stockholders' equity	173,793	199,059
Total liabilities and stockholders' equity	$ 197,022	$ 221,215