Pliant Therapeutics Provides Corporate Update and Reports Third Quarter 2021 Financial Results

November 9, 2021

SOUTH SAN FRANCISCO, Calif., Nov. 09, 2021 (GLOBE NEWSWIRE) -- Pliant Therapeutics, Inc. (Nasdaq: PLRX) ("the Company"), 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 2021 financial results.

"The third quarter was productive for the company, highlighted by the interim data readout from our PET trial which exceeded our expectations, showing a dose response and achieving near target saturation of PLN-74809 at the higher doses," said Bernard Coulie, M.D., Ph.D., President and Chief Executive Officer of Pliant Therapeutics. "In addition to the positive data readout, our Phase 2a INTEGRIS-IPF and INTEGRIS-PSC programs are making great progress in enrollment, and, with the additional Phase 1b BAL doses, we continue to methodically de-risk the current and future clinical development of PLN-74809."

Third Quarter and Recent Highlights

Positive interim results from Phase 2a PET imaging clinical trial show αvβ6 target engagement up to 98% in the lungs of patients with idiopathic pulmonary fibrosis (IPF). The ongoing Phase 2a open-label PET imaging clinical trial is evaluating αvβ6 target engagement levels achieved by PLN-74809 across single-doses of 60, 120, 240 or 320 mg in up to 12 IPF patients. Interim results showed a dose response and a greater than 50% target engagement across all doses and established a model of the dose and plasma concentration response. Furthermore, these data support potential anti-fibrotic activity of PLN-74809 at the doses being evaluated in the ongoing Phase 2a INTEGRIS-IPF trial.

PLN-74809 Phase 2a trial in idiopathic pulmonary fibrosis (IPF) enrollment on track with topline data anticipated by mid-2022. INTEGRIS-IPF is a 12-week randomized, dose-ranging, double-blind, placebo-controlled trial evaluating the safety, tolerability and pharmacokinetics of PLN-74809 at doses of 40, 80 or 160 mg in IPF patients. Exploratory endpoints include quantitative lung fibrosis (QLF) imaging, pulmonary function tests as well as biomarkers. Enrollment is currently on track to be completed by the end of 2021 with topline data anticipated by mid-2022.

Data anticipated in the first quarter of 2022 from additional doses in the PLN-74809 Phase 1b proof-of-mechanism study evaluating inhibition of TGF-β signaling in the lungs of healthy volunteers. In a previously reported Phase 1b proof-of-mechanism study, 40 mg once-daily dosing of PLN-74809 inhibited activation of TGF-β, a key driver of fibrosis. Based on additional safety and pharmacokinetic data from the Phase 1a study, Pliant initiated an extension of the Phase 1b study. This study extension evaluates inhibition of TGF-β signaling at doses above 40 mg of PLN-74809. These data, coupled with the recently reported positive interim Phase 2a PET target engagement data, will provide important information about the relationship between PLN-74809 plasma exposure, target engagement, TGF-β signaling inhibition and potential antifibrotic activity across the dose range currently being tested in the INTEGRIS-IPF trial. Data from this Phase 1b study is anticipated in the first quarter of 2022.

PLN-74809 Phase 2a trial in primary sclerosing cholangitis (PSC) enrollment on track. INTEGRIS-PSC is a 12-week randomized, dose-ranging, double-blind, placebo-controlled trial evaluating the safety, tolerability, and pharmacokinetics PLN-74809 at doses of 40, 80 or 160 mg in PSC patients. Exploratory endpoints include fibrosis biomarkers such as Pro-C3 and ELF, changes in ALP and liver imaging. Enrollment is currently anticipated to be completed by mid-2022.

Muscular Dystrophy and Oncology programs advancing towards IND. Early-stage integrin targeting programs focused on developing novel therapies in oncology and muscular dystrophies continue to advance towards IND. The muscular dystrophy program utilizes an antibody to improve muscle function through activation of an integrin compensatory mechanism. The oncology program focuses on increasing tumor sensitivity to checkpoint inhibitors through small molecule inhibition of $\alpha_V\beta_8$.

COVID-19 Preparedness
The Company continues to develop and maintain policies and procedures to enable us to operate safely and productively during the COVID-19 pandemic. The Company has experienced delays in clinical trial operations which have impacted and may further impact the expected timing of data readouts. The Company continues to work closely with clinical sites to continue site initiation and operation activities in compliance with study protocols while observing government and institutional guidelines.

Third Quarter 2021 Financial Results

- Research and development expenses were $21.1 million, as compared to $16.9 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 $7.7 million, as compared to $4.6 million for the prior-year quarter. The increase was due to higher personnel-related and professional services expenses.
- Net loss of $27.0 million as compared to $16.5 million for the prior-year quarter due an overall increase in expense associated with our research and development programs as well as personnel-related costs.
- As of September 30, 2021, the Company had cash, cash equivalents and short-term investments of $221.0 million. The Company 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 $\alpha_v\beta_6$ and $\alpha_v\beta_1$ 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 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 in the lead indications of IPF and PSC. Pliant has also developed PLN-1474, a small molecule selective inhibitor of $\alpha_v\beta_1$ 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 anticipated progress of our clinical trials and timing of enrollment and data disclosures, the potential of our early-stage programs to de-risk future development, the potential future impact of the COVID-19 pandemic and expectations regarding how far into the future our cash on hand will fund our operating and capital requirements. 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 Annual Report on Form 10-K filed with the SEC on March 16, 2021, as updated by our Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, 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 September 30,	
	2021	**2020**
Revenue — related party	$ 1,610	$ 4,814
Operating expenses:		
Research and development	(21,052)	(16,884)
General and administrative	(7,671)	(4,591)
Total operating expenses	(28,723)	(21,475)
Loss from operations	(27,113)	(16,661)
Interest and other income (expense), net	68	127
Net income loss	$ (27,045)	$ (16,534)
Less: Undistributed earnings to preferred shareholders	—	—
Net loss attributable to common stockholders	$ (27,045)	$ (16,534)
Net loss per share, attributable to common stockholders:		
Basic	$ (0.75)	$ (0.47)
Diluted	$ (0.75)	$ (0.47)
Shares used in computing net loss per share attributable to common stockholders:		
Basic	35,906,303	35,445,504
Diluted	35,906,303	35,445,504
Comprehensive income loss:		
Net loss	$ (27,045)	$ (16,534)
Net unrealized gain (loss) on short-term investments	$ (10)	$ 12
Total other comprehensive income (loss)	(10)	12
Comprehensive loss	$ (27,055)	$ (16,522)

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

	September 30, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 45,231	$ 50,882
Short-term investments	175,813	226,012
Accounts receivable	1,610	9,279
Tax credit receivable	83	83
Prepaid expenses and other current assets	5,847	4,498
Total current assets	228,584	290,754
Property and equipment, net	4,706	4,321
Other non-current assets	831	451
Total assets	$ 234,121	$ 295,526
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 2,605	$ 2,023
Accrued liabilities	10,320	9,576
Total current liabilities	12,925	11,599
Other long-term liabilities	756	866
Total liabilities	13,681	12,465
Stockholders' equity		
Common stock	3	3
Additional paid-in capital	411,037	400,918
Accumulated deficit	(190,560)	(117,828)
Accumulated other comprehensive loss	(40)	(32)
Total stockholders' equity	220,440	283,061
Total liabilities and stockholders' equity	$ 234,121	$ 295,526