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

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- Positive data from bexotegrast INTEGRIS-IPF 320 mg dose group demonstrated a continued favorable safety profile and statistically significant increases in FVC

- INTEGRIS-IPF 320 mg dose 24-week data expected in the second quarter of 2023

- $287.5 million equity financing extends runway into the second half of 2026

SOUTH SAN FRANCISCO, Calif., March 09, 2023 (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 fourth quarter 2022 financial results.

"2022 was a transformative year for Pliant. We delivered positive interim data from our Phase 2a INTEGRIS-IPF trial, strengthened our financial position with our first follow-on financing and continued to advance our clinical- and early-stage portfolio. We are positioned to deliver multiple clinical catalysts in 2023," said Bernard Coulie, M.D., Ph.D., President and Chief Executive Officer of Pliant Therapeutics. "2023 has already been productive with the release of additional positive data from the INTEGRIS-IPF 320 mg cohort, where bexotegrast displayed a continued favorable safety profile and outperformed all lower dose cohorts on exploratory efficacy endpoints. We look forward to sharing additional clinical data readouts and portfolio milestones throughout the remainder of this year."

Fourth Quarter and Recent Highlights

Bexotegrast (PLN-74809) Highlights

- **INTEGRIS-IPF Phase 2a clinical data from bexotegrast 320 mg dose group at 12 weeks showed bexotegrast was well tolerated and demonstrated statistically significant forced vital capacity (FVC) increases at all time points in patients with idiopathic pulmonary fibrosis (IPF).** Bexotegrast at 320 mg was well tolerated with no drug-related severe or serious adverse events and showed dose-proportional increases in plasma concentrations, consistent with prior studies. Exploratory efficacy endpoints demonstrated strong treatment effects on FVC, Quantitative Lung Fibrosis (QLF) imaging and biomarkers over 12 weeks. In addition, no bexotegrast-treated patients experienced disease progression as defined by FVC percent predicted (FVCpp) decline of greater than or equal to 10%, a risk factor associated with increased mortality in IPF patients.

- **INTEGRIS-IPF Phase 2a trial on track for final 24-week data readout from the bexotegrast 320 mg dose group in the second quarter of 2023.** This randomized, double-blind, placebo-controlled trial is evaluating 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 effects on FVC and QLF, as well as serum biomarkers.

- **INTEGRIS-PSC enrollment complete with topline Phase 2a data expected in the third quarter of 2023.** This 12-week randomized, dose-ranging, double-blind, placebo-controlled trial is evaluating the safety, tolerability and pharmacokinetics of bexotegrast in primary sclerosing cholangitis (PSC) patients. The trial is also evaluating exploratory efficacy endpoints including fibrosis biomarkers such as PRO-C3 and enhanced liver fibrosis (ELF), changes in alkaline phosphatase (ALP), and liver imaging.

- **EMA Orphan Drug designation received for bexotegrast for the treatment of IPF.** European Medicines Agency's (EMA's) Orphan Drug designation is designed to encourage the development of new treatments for rare conditions. The benefits of Orphan Drug designation include trial design assistance, a centralized EU approval process, and 10 years of market exclusivity. Bexotegrast received Orphan Drug designation for the treatment of IPF from the United States Food and Drug Administration (FDA) in 2018.

Early-Stage Development Programs

- **IND open for PLN-101095 for the treatment of solid tumors resistant to immune checkpoint inhibitors.** In January 2023, the FDA cleared the company's Investigational New Drug (IND) application for PLN-101095, an oral, small molecule, dual selective inhibitor of αvβ8 and αvβ1 integrins. Initiation of a Phase 1 trial of PLN-101095 in patients with solid tumors that are resistant to immune checkpoint inhibitors is expected in the second quarter of 2023.

- **Muscular dystrophy program progressing through IND enabling activities.** IND submission for this program is expected in 2023.

Corporate Highlights

- **Closing of underwritten public offering of $287.5 million in common stock.** The Company closed a public offering in January 2023, yielding $269.9 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 bexotegrast and PLN-101095, further develop its integrin targeting platform, to fund working capital, operating expenses and capital expenditures, and for other general corporate purposes.

- **Appointment of Lily Cheung as Chief Human Resources Officer.** Ms. Cheung brings over 25 years of Human Resources experience across the technology and biopharmaceutical industries, including more than 15 years of commercial-stage experience.

- **Appointments of Darren Cline and Thomas McCourt to the Company's Board of Directors.** Mr. Cline and Mr. McCourt each bring over 30 years of strategic and operational experience in building commercial organizations. Mr. Cline currently serves as Chief Executive Officer and President of Epygenix Therapeutics. Mr. McCourt currently serves as Chief Executive Officer of Ironwood Pharmaceuticals.

- **Work has completed under the Novartis collaboration.** During the three-year term of the collaboration, Pliant achieved successful validation of a novel integrin receptor as a potential next generation target for the treatment of fibrotic diseases and is in the process of developing candidates against the target. As part of a broad strategic realignment, Novartis has discontinued clinical development in NASH. As a result, Novartis has terminated development of PLN-1474, an inhibitor of αvβ1 targeting NASH-associated advanced liver fibrosis, which they licensed in 2019, and returned global rights to Pliant. PLN-1474 is a phase 2-ready asset, having shown a favorable safety and pharmacokinetic profile in Phase 1 trials.

2023 Anticipated Milestones

- 24-week data from the 320 mg dose group of the INTEGRIS-IPF Phase 2a trial in patients with IPF is expected in the second quarter of 2023.

- Initiation of a Phase 2b trial of bexotegrast in patients with IPF is expected in mid-2023.

- Initiation of a Phase 1 trial of PLN-101095 in patients with solid tumors resistant to immune checkpoint inhibitors is expected in the second quarter of 2023.

- Topline data from the 40, 80 and 160 mg dose groups of the INTEGRIS-PSC Phase 2a trial in patients with PSC is expected in the third quarter of 2023.

Fourth Quarter 2022 Financial Results

- Research and development expenses were $25.1 million, as compared to $18.8 million for the prior-year quarter. The increase was due primarily to employee-related expenses, including stock-based compensation, and higher clinical and manufacturing-related costs.

- General and administrative expenses were $14.3 million, as compared to $7.8 million for the prior-year quarter. The increase was due to higher personnel-related and professional services expenses.

- Net loss of $35.1 million as compared to $24.5 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 December 31, 2022, the Company had cash, cash equivalents and short-term investments of $331.2 million, and including the net proceeds from the January 2023 public offering, the Company expects to be able to fund operations into the second half of 2026.

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, 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. Bexotegrast has received Fast Track Designation and Orphan Drug Designation from the U.S. Food and Drug Administration in IPF and PSC and Orphan Drug Designation from the European Medicines Agency in IPF and PSC. Pliant is currently conducting Phase 2a trials of 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. In December 2022, Pliant submitted an IND for its third clinical program, PLN-101095, a small molecule dual-selective inhibitor of αvβ8 and αvβ1 integrins, that is being developed for the treatment of solid tumors. In addition to clinical stage programs, Pliant currently has a preclinical program targeting 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 safety, tolerability, pharmacodynamics and therapeutic potential of bexotegrast; our plans for the future development of bexotegrast and PLN-101095; bexotegrast's potential to become a treatment for IPF; the anticipated timing of data from the 320 mg group of the INTEGRIS-IPF Phase 2a trial in patients treated for at least 24 weeks; the timing and design of Pliant's Phase 2b clinical trial of bexotegrast; the timing of Pliant's Phase 1 trial of PLN-101095; the timing and availability of topline data from the 40, 80 and 160 mg dose groups of the INTEGRIS-PSC Phase 2a trial in patients with PSC; discussions with regulatory authorities; planned INDs in our oncology and muscular dystrophy programs; anticipated progress of our clinical trials and timing of enrollment and data disclosures; the efficacy and safety profile and potential of our product candidates; our intended use of the net proceeds from our common stock offering; the sufficiency of our cash runway to fund operations into the second half of 2026 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 for the year ended December 31, 2022 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.

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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 December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
Revenue	$ 1,965	$ 1,999	$ 9,685	$ 7,572
Operating expenses:				
Research and development	(25,114)	(18,752)	(96,936)	(77,549)
General and administrative	(14,251)	(7,846)	(39,949)	(27,558)
Total operating expenses	(39,365)	(26,598)	(136,885)	(105,107)
Loss from operations	(37,400)	(24,599)	(127,200)	(97,535)
Interest and other income (expense), net	2,657	68	4,670	272
Interest expense	(317)	—	(791)	—
Net loss	$ (35,060)	$ (24,531)	$ (123,321)	$ (97,263)
Net loss attributable to common stockholders	$ (35,060)	$ (24,531)	$ (123,321)	$ (97,263)
Net loss per share attributable to common stockholders:				
Basic and diluted	$ (0.72)	$ (0.68)	$ (2.94)	$ (2.71)
Shares used in computing net loss per share attributable to common stockholders:				
Basic and diluted	48,783,242	35,925,697	42,015,908	35,846,421

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

	December 31,	December 31,

	2022	2021
Assets		
Current assets		
Cash and cash equivalents	$ 33,685	$ 51,665
Short-term investments	297,502	148,931
Accounts receivable	1,983	1,998
Tax credit receivable	83	83
Prepaid expenses and other current assets	7,058	6,764
Total current assets	340,311	209,441
Property and equipment, net	4,486	4,606
Operating lease right-of-use assets	5,422	6,330
Other non-current assets	394	838
Total assets	$ 350,613	$ 221,215
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,580	$ 2,971
Accrued research and development	11,218	5,868
Accrued and other liabilities	8,658	6,123
Lease liabilities, current	2,457	1,869
Total current liabilities	23,913	16,831
Lease liabilities, non-current	3,429	5,325
Long-term debt	9,929	—
Total liabilities	37,271	22,156
Stockholders' equity		
Common stock	5	3
Additional paid-in capital	653,707	414,348
Accumulated deficit	(338,412)	(215,091)
Accumulated other comprehensive loss	(1,958)	(201)
Total stockholders' equity	313,342	199,059
Total liabilities and stockholders' equity	$ 350,613	$ 221,215