Pliant Therapeutics Provides Corporate Update and Reports First Quarter 2023 Financial Results

May 9, 2023

Positive long-term data from INTEGRIS-IPF 320 mg dose group at 24-weeks demonstrated bexotegrast was well tolerated with durable improvement shown across multiple measures

INTEGRIS-PSC 12-week data expected in the third quarter of 2023

BEACON-IPF Phase 2b trial initiation expected in mid-2023

$577 million in cash, cash equivalents and short-term investments at end of first quarter 2023, expected to fund operations into second half of 2026

SOUTH SAN FRANCISCO, Calif., May 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 first quarter 2023 financial results.

“So far in 2023 we have made significant progress in advancing the portfolio including positive 12- and 24-week data readouts from our INTEGRIS-IPF trial and a successful follow-on offering that extended our expected operating runway into the second half of 2026,” said Bernard Coulie, M.D., Ph.D., President and Chief Executive Officer of Pliant Therapeutics. “With clinical data and development milestones expected throughout the remainder of 2023, including Phase 2a data from INTEGRIS-PSC and initiation of our BEACON-IPF Phase 2b and our oncology Phase 1 trials, we look forward to building upon an already productive year.”

First Quarter and Recent Highlights

Bexotegrast (PLN-74809) Highlights

- **INTEGRIS-IPF Phase 2a 24-week 320 mg clinical data showed bexotegrast was well tolerated and demonstrated durable improvements in exploratory endpoints.** This 24-week Phase 2a data from the 320 dose group showed bexotegrast was well tolerated up to 40 weeks, displayed a favorable pharmacokinetic profile and in exploratory efficacy endpoints showed improvements in forced vital capacity (FVC), Quantitative Lung Fibrosis (QLF) imaging, patient reported cough severity and biomarkers in patients with idiopathic pulmonary fibrosis (IPF) to Week 24. In January, 12-week data from the 320 mg dose group showed bexotegrast demonstrated statistically significant FVC increases at all time points, was well tolerated with no drug-related severe or serious adverse events and showed dose-proportional increases in plasma concentrations, consistent with prior dose groups.
- **Initiation of BEACON-IPF, a Phase 2b trial of bexotegrast in patients with IPF, expected in mid-2023.** BEACON-IPF is a 52-week, multinational, randomized, placebo-controlled trial evaluating bexotegrast at doses of 160 mg or 320 mg in approximately 270 patients with IPF.
- **INTEGRIS-PSC Phase 2a 12-week clinical data expected in the third quarter of 2023.** INTEGRIS-PSC is a 12-week randomized, dose-ranging, double-blind, placebo-controlled trial evaluating safety, tolerability and pharmacokinetics of bexotegrast at doses of 40, 80 or 160 mg in approximately 84 patients with primary sclerosing cholangitis (PSC). Exploratory efficacy endpoints include fibrosis biomarkers such as PRO-C3 and enhanced liver fibrosis (ELF) score, changes in alkaline phosphatase (ALP), and liver imaging. INTEGRIS-PSC is fully enrolled.
- **First patient dosed in the INTEGRIS-PSC Phase 2a 320 mg dose cohort, evaluating bexotegrast for at least 24 weeks.** This cohort is evaluating the safety, tolerability and pharmacokinetics of bexotegrast at a dose of 320 mg versus placebo over at least 24 weeks of treatment in approximately 28 patients with PSC. The trial is also evaluating exploratory efficacy endpoints including fibrosis biomarkers such as PRO-C3 and ELF score, changes in ALP and liver imaging.

Early-Stage Development Programs

- **Initiation of a Phase 1 first-in-human trial of PLN-101095 in oncology expected in the second quarter of 2023.** 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. Initiation of a Phase 1 trial 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.** PLN-101325 is a monoclonal antibody designed to act as an allosteric agonist of the integrin α7β1. An IND submission for Duchenne muscular dystrophy (DMD)

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.

First Quarter 2023 Financial Results

- Research and development expenses were $29.3 million, as compared to $20.9 million for the prior-year quarter. The increase was due primarily to employee related expenses and increased clinical and manufacturing related costs associated with our lead program, bexotegrast, partially offset by a decrease in preclinical manufacturing costs for our pipeline product candidates.
- General and administrative expenses were $14.2 million, as compared to $8.6 million for the prior-year quarter. The increase was due to higher personnel-related and professional services expenses.
- Net loss of $37.5 million as compared to $28.1 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 March 31, 2023, the Company had cash, cash equivalents and short-term investments of $577.3 million, which the Company expects to be sufficient 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 a Phase 2a trial of bexotegrast in the PSC and is planning a Phase 2b trial in IPF. 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 and progress from our clinical studies; discussions with regulatory authorities; the sufficiency of our cash runway to fund operations into the second half of 2026. 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, 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 three months ended March 31, 2023 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 March 31,	
	2023	2022
Revenue	$ 1,332	$ 1,249
Operating expenses:		
Research and development	(29,273)	(20,881)
General and administrative	(14,154)	(8,579)
Total operating expenses	(43,427)	(29,460)
Loss from operations	(42,095)	(28,211)
Interest and other income (expense), net	4,858	111
Interest expense	(311)	$ —
Net loss	$ (37,548)	$ (28,100)
Net loss attributable to common stockholders	$ (37,548)	$ (28,100)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.67)	$ (0.78)
Shares used in computing net loss per share attributable to common stockholders:		
Basic and diluted	56,057,603	36,116,440

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

	March 31, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 102,527	$ 33,685
Short-term investments	474,787	297,502
Accounts receivable	3,297	1,983
Tax credit receivable	83	83
Prepaid expenses and other current assets	7,533	7,058
Total current assets	588,227	340,311
Property and equipment, net	4,197	4,486
Operating lease right-of-use assets	4,813	5,422
Other non-current assets	644	394
Total assets	$ 597,881	$ 350,613
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,419	$ 1,580
Accrued research and development	14,621	11,218
Accrued liabilities	4,733	8,658
Lease liabilities, current	2,380	2,457
Total current liabilities	23,153	23,913
Lease liabilities, non-current	2,850	3,429
Long-term Debt	9,958	—
Total liabilities	35,961	37,271
Stockholders' equity		
Common stock	6	5
Additional paid-in capital	939,205	653,707
Accumulated deficit	(375,960)	(338,412)
Accumulated other comprehensive loss	(1,331)	(1,958)
Total stockholders' equity	561,920	313,342
Total liabilities and stockholders' equity	$ 597,881	$ 350,613