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

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Initiation of Phase 2b BEACON-IPF trial of bexotegrast in patients with IPF

INTEGRIS-PSC Phase 2a 12-week data of bexotegrast in patients with PSC expected in the third quarter of 2023

Initiation of Phase 1 trial of PLN-101095 in patients with solid tumors resistant to checkpoint inhibitors

SOUTH SAN FRANCISCO, Calif., Aug. 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 second quarter 2023 financial results.

“We are extremely pleased with the continued progress in the second quarter across the portfolio, including positive long-term data from our INTEGRIS-IPF Phase 2a trial of bexotegrast in IPF, as well as the entry of our third drug candidate, PLN-101095, into Phase 1 testing for treatment of solid tumors. Our team’s strong execution over the quarter positions us well for multiple expected milestones throughout the remainder of the year, including the recent initiation of BEACON-IPF, our Phase 2b trial in IPF, and an upcoming interim Phase 2a data readout from INTEGRIS-PSC which is expected in the third quarter,” said Bernard Coulie, M.D., Ph.D., President and Chief Executive Officer of Pliant Therapeutics.

Second Quarter and Recent Highlights

Bexotegrast Highlights

- **BEACON-IPF, a Phase 2b trial of bexotegrast in patients with IPF, has been initiated.** BEACON-IPF is a 52-week, multinational, randomized, dose-ranging, double-blind, placebo-controlled trial evaluating bexotegrast at once-daily doses of 160 mg or 320 mg. BEACON-IPF is expected to enroll approximately 270 patients with IPF.
- **INTEGRIS-IPF Phase 2a 24-week 320 mg clinical data showed bexotegrast was well tolerated and demonstrated durable improvements in exploratory efficacy endpoints.** Phase 2a 24-week data from the 320 mg dose cohort showed bexotegrast was well tolerated up to 40 weeks, displayed a favorable pharmacokinetic profile and showed durable improvements in forced vital capacity (FVC), Quantitative Lung Fibrosis (QLF) imaging, patient reported cough severity and fibrosis biomarkers in patients with idiopathic pulmonary fibrosis (IPF).
- **INTEGRIS-PSC Phase 2a 12-week interim data expected in the third quarter of 2023.** INTEGRIS-PSC is a randomized, dose-ranging, double-blind, placebo-controlled trial evaluating the safety, tolerability and pharmacokinetics of bexotegrast in 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. Interim 12-week data from approximately 84 patients in the 40, 80 and 160 mg cohorts is expected in the third quarter of 2023.
- **INTEGRIS-PSC 320 mg dose cohort enrollment complete with interim 12-week data expected in the first quarter of 2024.** This trial is evaluating the safety, tolerability and pharmacokinetics of bexotegrast at 320 mg versus placebo at 12 and 24 weeks of treatment in approximately 28 patients with PSC. The trial is also evaluating exploratory efficacy endpoints including fibrosis biomarkers such as serum PRO-C3 and ELF score, changes in ALP and liver imaging. The final 24-week data is expected in mid-2024.

Pipeline Programs

- **Phase 1 trial of PLN-101095 in solid tumors recruiting.** A Phase 1 open label trial of PLN-101095, an oral, small-molecule, dual selective inhibitor of αvβ8 and αvβ1 integrins designed to block TGF-β activation in the tumor microenvironment, was initiated in the second quarter. This trial is recruiting patients with solid tumors that are resistant to immune checkpoint inhibitors.
- **Muscular dystrophy program progressing through IND enabling activities.** PLN-101325 is a monoclonal antibody designed to act as an allosteric agonist of the α7β1 integrin. An IND submission for PLN-101325 for Duchenne muscular dystrophy (DMD) is expected in the first quarter of 2024.

Corporate Highlights

- **Scott Turner, Ph.D. promoted to Chief Scientific Officer.** The Company is announcing the promotion of Dr. Scott Turner

to the role of Chief Scientific Officer. Dr. Turner joined Pliant in 2016 and most recently served as the Company's Senior Vice President of Research. In his new role, Dr. Turner will oversee all early stage drug discovery initiatives and manage the Company's development portfolio.

Second Quarter 2023 Financial Results

- Research and development expenses were $33.0 million, as compared to $26.3 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 $14.6 million, as compared to $8.3 million for the prior-year quarter. The increase was due to higher personnel-related expenses.
- Net loss of $41.2 million as compared to $29.5 million for the prior-year quarter due to an increase in operating expenses coupled with a decrease in collaboration revenues under the Novartis collaboration during the quarter.
- As of June 30, 2023, the Company had cash, cash equivalents and short-term investments of $555.2 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 (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. 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 IPF and PSC. Pliant has initiated BEACON-IPF, a Phase 2b trial of bexotegrast in IPF. Pliant has also developed PLN-1474, a small molecule, selective inhibitor of αvß1 integrin for the treatment of nonalcoholic steatohepatitis, or NASH with liver fibrosis. Pliant has initiated a Phase 1 study for its third clinical program, PLN-101095, a small molecule, dual-selective inhibitor of αvß8 and αvß1 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, please visit: www.PliantRx.com. Follow us on social media: 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, PLN-101325 and PLN-101095; bexotegrast's potential to become a treatment for IPF or PSC; 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 current macroeconomic and marketplace conditions, including lingering effects of the 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 June 30, 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 June 30,	
	2023	**2022**

Revenue	$ 248	$ 4,989
Operating expenses:		
Research and development	(33,002)	(26,335)
General and administrative	(14,574)	(8,296)
Total operating expenses	(47,576)	(34,631)
Loss from operations	(47,328)	(29,642)
Interest and other income (expense), net	6,455	269
Interest expense	(319)	(173)
Net loss	$ (41,192)	$ (29,546)
Net loss attributable to common stockholders	$ (41,192)	$ (29,546)
Net loss per share, attributable to common stockholders - basic and diluted	$ (0.70)	$ (0.82)
Shares used in computing net loss per share attributable to common stockholders - basic and diluted	59,172,869	36,173,135

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

	June 30, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 54,951	$ 33,685
Short-term investments	500,208	297,502
Accounts receivable	1,580	1,983
Tax credit receivable	77	83
Prepaid expenses and other current assets	8,885	7,058
Total current assets	565,701	340,311
Property and equipment, net	4,332	4,486
Operating lease right-of-use assets	4,186	5,422
Other non-current assets	672	394
Total assets	$ 574,891	$ 350,613
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 2,310	$ 1,580
Accrued research and development	18,216	11,218
Accrued liabilities	6,762	8,658
Lease liabilities, current	2,232	2,457
Total current liabilities	29,520	23,913
Lease liabilities, non-current	2,318	3,429
Long-term debt	9,988	9,929
Total liabilities	41,826	37,271
Stockholders' equity		
Common stock	6	5
Additional paid-in capital	952,452	653,707
Accumulated deficit	(417,152)	(338,412)
Accumulated other comprehensive loss	(2,241)	(1,958)
Total stockholders' equity	533,065	313,342
Total liabilities and stockholders' equity	$ 574,891	$ 350,613