Pliant Therapeutics Provides Corporate Update and Reports Second Quarter 2024 Financial Results

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Positive data from a 12-week Phase 2a PET imaging trial demonstrated reduced total lung collagen, improved FVC and reduced cough severity in IPF patients treated with bexotegrast

Positive long-term data from INTEGRIS-PSC 320 mg dose group demonstrated bexotegrast was well tolerated with continued antifibrotic and anti-cholestatic activity observed at 24 weeks across multiple measures

BEACON-IPF Phase 2b trial on track for full enrollment in the first quarter of 2025 with data anticipated in mid-2026

SOUTH SAN FRANCISCO, Calif., Aug. 07, 2024 (GLOBE NEWSWIRE) -- Pliant Therapeutics, Inc. (Nasdaq: PLRX), a late-stage clinical biotechnology company and leader in the discovery and development of novel therapeutics for the treatment of fibrotic diseases, today provided a corporate update and reported second quarter 2024 financial results.

Second Quarter and Recent Highlights

"The recent bexotegrast data releases in IPF and PSC have exceeded our expectations continuing to demonstrate bexotegrast's favorable long-term safety profile and strong antifibrotic effect across multiple indications," said Bernard Coulie, M.D., Ph.D., President and Chief Executive Officer of Pliant. "The consistently positive data generated to date, including from the recent Phase 2a PET imaging trial and from INTEGRIS-PSC, illustrate bexotegrast's potential to provide clinical benefit to the many IPF patients in need."

Bexotegrast Highlights

- **Results from a 12-week Phase 2a PET imaging trial of bexotegrast in IPF showed reduced total lung collagen and improved forced vital capacity (FVC), suggesting potential for reversal of fibrosis.** Results from this randomized, double-blind, placebo-controlled trial (NCT05621252) showed that bexotegrast at a once-daily dose of 160 mg was well tolerated over 12 weeks of treatment and demonstrated reduced total lung collagen as measured by positron emission tomography (PET) imaging, improvements in FVC and reduced cough severity across all time points compared to placebo. These results provide further support of bexotegrast's antifibrotic mechanism of action and suggest the potential for reversal of fibrosis.
- **Enrollment remains on track in BEACON-IPF, a pivotal adaptive Phase 2b/3 trial of bexotegrast in patients with idiopathic pulmonary fibrosis (IPF)**. The BEACON-IPF Phase 2b trial 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 in 360 patients with IPF. Enrollment is expected to be complete in the first quarter of 2025 with data anticipated in mid-2026.
- **INTEGRIS-IPF Phase 2a trial results published in the American Journal of Respiratory and Critical Care Medicine (AJRCCM).** Also known as the "*Blue Journal*", AJRCCM is a leading peer-reviewed journal published by the American Thoracic Society. The publication *Bexotegrast in Patients with Idiopathic Pulmonary Fibrosis: The INTEGRIS-IPF Study* reviews the previously reported positive results from the multinational, randomized, double-blind, placebo-controlled INTEGRIS-IPF Phase 2a trial that enrolled 119 patients with IPF.
- **Positive long-term data from the INTEGRIS-PSC 320 mg cohort showed bexotegrast was well tolerated up to 40 weeks of treatment and demonstrated continued improvements across multiple fibrotic and cholestatic endpoints**. The 24-week Phase 2a data readout from the 320 mg dose group showed bexotegrast was well tolerated up to 40 weeks of treatment and showed improvement in liver stiffness, statistically significant reduction in alkaline phosphatase (ALP) and evidence of continued improvement in hepatocyte function and bile flow. Pliant recently met with U.S. Food and Drug Administration (FDA), with the Agency expressing support for a 52-week, dose-ranging Phase 2b trial employing non-invasive endpoints. Pliant continues to evaluate the best path forward for this program.

Pipeline Programs

- **Phase 1 trial of PLN-101095 in solid tumors is progressing with dosing of the third of five cohorts.** 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. The Company is currently enrolling the third of five cohorts in the Phase 1 open label, dose-escalation trial of PLN-101095 as monotherapy and in combination with pembrolizumab in patients with solid tumors that are resistant to immune checkpoint inhibitors. Preliminary data is expected in late 2024 or early 2025.

- **PLN-101325 applications beyond muscular dystrophies.** PLN-101325 is a monoclonal antibody that acts as an allosteric agonist of integrin α7β1, currently in development for treatment of muscular dystrophies. Based on preclinical data, PLN-101325 may have the potential to treat additional indications in organ systems outside of muscle. The Company is currently generating additional evidence in support of potential expansion of the scope of PLN-101325 prior to initiating a Phase 1 trial.

Corporate Highlights

- **Appointment of Steve Krognes to the Company's Board of Directors.** Mr. Krognes brings over 30 years of financial and corporate strategy experience in leading and guiding life science companies across all stages of development. Most recently, Mr. Krognes served as Chief Financial Officer of Denali Therapeutics.

Second Quarter 2024 Financial Results

- Research and development expenses were $45.6 million, as compared to $33.0 million for the prior-year quarter. The increase was driven by BEACON-IPF, a Phase 2b study of bexotegrast in patients with IPF.
- General and administrative expenses were $15.0 million, as compared to $14.6 million for the prior-year quarter. The increase was primarily due to professional service expenses.
- Net loss of $55.9 million as compared to $41.2 million for the prior-year quarter. The increase was primarily due to higher operating expenses driven by BEACON-IPF.
- As of June 30, 2024, the Company had cash, cash equivalents and short-term investments of $438.1 million.

About Pliant Therapeutics, Inc.

Pliant Therapeutics is a late-stage biopharmaceutical company and leader in the discovery and development of novel therapeutics for the treatment of fibrotic diseases. 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, an adaptive Phase 2b/3 trial of bexotegrast in IPF. Pliant is conducting 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, Pliant has received regulatory clearance for the conduct of a Phase 1 study of PLN-101325, a monoclonal antibody agonist of integrin α7β1 targeting muscular dystrophies.

For additional information, please visit: www.PliantRx.com. Follow us on social media X, LinkedIn and Facebook.

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 ability to complete enrollment in BEACON-IPF in the first quarter of 2025; our ability to pursue a 52-week, dose-ranging Phase 2b trial of bexotegrast employing non-invasive endpoints; our plans for the future development of bexotegrast, PLN-101325 and PLN-101095, including the potential expansion of PLN-101325 into additional indications in organ systems outside of muscle; bexotegrast's potential to become a treatment for IPF or PSC; the anticipated timing of data and progress from our clinical studies and public announcements related thereto; and discussions with regulatory authorities. 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 the effects of COVID-19, 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 period ended June 30, 2024 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,	
	2024	**2023**
Revenue	$ —	$ 248
Operating expenses:		
Research and development	(45,617)	(33,002)
General and administrative	(15,022)	(14,574)
Total operating expenses	(60,639)	(47,576)
Loss from operations	(60,639)	(47,328)
Interest and other income (expense), net	5,653	6,455
Interest expense	(868)	(319)
Net loss	$ (55,854)	$ (41,192)
Net loss per share - basic and diluted	$ (0.92)	$ (0.70)
Shares used in computing net loss per share - basic and diluted	60,382,796	59,172,869

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

	June 30, 2024	**December 31, 2023**
Assets		
Current assets		
Cash and cash equivalents	$ 80,386	$ 63,234
Short-term investments	356,221	431,011
Prepaid expenses and other current assets	10,946	11,257
Total current assets	447,553	505,502
Property and equipment, net	5,395	3,567
Operating lease right-of-use assets	28,863	1,211
Restricted cash	1,482	1,482
Other non-current assets	437	392
Total assets	$ 483,730	$ 512,154
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 3,247	$ 4,531
Accrued research and development	19,383	12,456
Accrued liabilities	8,196	10,219
Operating lease liabilities, current	98	1,318
Total current liabilities	30,924	28,524
Operating lease liabilities, non-current	30,058	—
Long-term debt	30,070	10,054
Total liabilities	91,052	38,578
Stockholders' equity		
Preferred stock	—	—
Common stock	6	6
Additional paid-in capital	995,846	972,973
Accumulated deficit	(602,557)	(499,748)
Accumulated other comprehensive (loss) gain	(617)	345
Total stockholders' equity	392,678	473,576
Total liabilities and stockholders' equity	$ 483,730	$ 512,154