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

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Discontinuation of BEACON-IPF following DSMB and outside expert panel recommendation

SOUTH SAN FRANCISCO, Calif., March 03, 2025 (GLOBE NEWSWIRE) -- Pliant Therapeutics, Inc. (Nasdaq: PLRX), a clinical-stage 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 fourth quarter 2024 financial results.

Fourth Quarter and Recent Highlights

Bexotegrast Highlights

- **BEACON-IPF discontinued following recommendation from expanded data safety monitoring board (DSMB).** Following a prespecified data review and recommendation by the trial's independent DSMB, as well as a secondary review and recommendation by an outside expert panel, Pliant has discontinued the BEACON-IPF Phase 2b trial. While an imbalance in unadjudicated IPF-related adverse events between the treatment and placebo groups led to the discontinuation of the trial, early evidence of efficacy on the forced vital capacity (FVC) endpoint was also observed. The Company plans to analyze the complete data from the BEACON-IPF trial and evaluate next steps for bexotegrast's development. 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 in patients with idiopathic pulmonary fibrosis (IPF).

Oncology Program

- **Phase 1 trial of PLN-101095 in solid tumors continues to enroll, with interim data expected in the first quarter 2025.** This is 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. The trial is currently dosing the fourth of five planned dose cohorts in a 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. Interim data from the first three cohorts is expected in the first quarter of 2025.

Neuromuscular Program

- **PLN-101325 for treatment of 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. PLN-101325 is Phase 1 ready with clinical trial approval (CTA) open in Australia.

Corporate Highlights

- **Appointment of Delphine Imbert, Ph.D. as Chief Technical Officer.** Dr. Imbert brings 25 years of product development, process optimization and manufacturing experience across multiple drug modalities. Most recently, Dr. Imbert served as Senior Vice President of CMC and Technical Operations at Chinook Therapeutics.

Fourth Quarter 2024 Financial Results

- Research and development expenses were $38.8 million, as compared to $33.2 million for the prior-year quarter. The increase was primarily due to costs associated with the BEACON-IPF Phase 2b/3 clinical trial.
- General and administrative expenses were $14.5 million, as compared to $13.9 million for the prior-year quarter. The increase was primarily due to employee-related expenses driven by increased headcount over prior year.
- Net loss was $49.7 million as compared to $41.1 million for the prior-year quarter. The increase was due to higher operating expenses primarily attributable to costs associated with the BEACON-IPF Phase 2b/3 clinical trial and reduced interest income on short-term investments.

- As of December 31, 2024, the Company had cash, cash equivalents, restricted cash and short-term investments of $357.2 million which the Company expects to be sufficient to fund operations for the next 12 months and beyond.

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 indication for the treatment of idiopathic pulmonary fibrosis, or IPF. Bexotegrast has received Fast Track Designation and Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) and Orphan Drug Designation from the European Medicines Agency in IPF. Pliant has initiated BEACON-IPF, an adaptive Phase 2b/3 trial of bexotegrast in IPF. Pliant is conducting a Phase 1 study of, 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 Company's, the DSMB's and the outside expert panel's further review and analysis of data, the ability of the outside expert panel and the DSMB to reach a consensus recommendation regarding BEACON-IPF and the timing thereof; the Company's current and future plans for bexotegrast, including with respect to the BEACON-IPF clinical trial; our plans for the future development of PLN-101325 and PLN-101095; bexotegrast's potential to become a treatment for IPF; the anticipated timing of data and progress from our clinical studies and public announcements related thereto; discussions with regulatory authorities; and our access to future capital pursuant to the Oxford Loan Agreement and the sufficiency of such capital, together with 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 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 Annual Report on Form 10-K for the period ended December 31, 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 December 31,		Twelve Months Ended December 31,	
	2024	2023	2024	2023
Revenue	$ —	$ —	$ —	$ 1,580
Operating expenses:				
Research and development	(38,793)	(33,183)	(169,310)	(127,797)
General and administrative	(14,527)	(13,854)	(59,055)	(57,928)
Total operating expenses	(53,320)	(47,037)	(228,365)	(185,725)
Loss from operations	(53,320)	(47,037)	(228,365)	(184,145)
Interest and other income (expense), net	4,422	6,249	21,085	24,076
Interest expense	(834)	(321)	(3,024)	(1,267)
Net loss	$ (49,732)	$ (41,109)	$ (210,304)	$ (161,336)
Net loss per share - basic and diluted	$ (0.82)	$ (0.69)	$ (3.47)	$ (2.75)
Weighted average shares used in computing net loss per share - basic and diluted	60,854,322	59,904,481	60,538,639	58,719,083

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

	December 31, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 71,188	$ 63,234
Short-term investments	284,536	431,011
Prepaid expenses and other current assets	6,540	11,257
Total current assets	362,264	505,502
Property and equipment, net	5,525	3,567
Operating lease right-of-use assets	27,243	1,211
Restricted cash equivalent	1,482	1,482
Other non-current assets	435	392
Total assets	$ 396,949	$ 512,154
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 5,960	$ 4,531
Accrued research and development	14,363	12,456
Accrued liabilities	12,353	10,219
Lease liabilities, current	542	1,318
Total current liabilities	33,218	28,524
Lease liabilities, non-current	29,439	—
Long-term debt	30,211	10,054
Total liabilities	92,868	38,578
Stockholders' equity		
Preferred stock	—	—
Common stock	6	6
Additional paid-in capital	1,013,806	972,973
Accumulated deficit	(710,052)	(499,748)
Accumulated other comprehensive gain	321	345
Total stockholders' equity	304,081	473,576
Total liabilities and stockholders' equity	$ 396,949	$ 512,154