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

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Positive interim 12-week safety and efficacy data reported from Phase 2a INTEGRIS-PSC trial in patients with PSC

Enrollment continues in BEACON-IPF, a Phase 2b trial in patients with IPF

SOUTH SAN FRANCISCO, Calif., Feb. 27, 2024 (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 2023 financial results.

“The progress made by our teams during the fourth quarter of 2023 position us well for executing upon our 2024 milestones including the recent positive data from the INTEGRIS-PSC trial that support the late-stage development of bexotegrast in this important indication," said Bernard Coulie, M.D., Ph.D., President and Chief Executive Officer of Pliant Therapeutics. “In 2024, our focus will be on the advancement the BEACON-IPF late-stage program, gathering clarity on next steps for a late-stage PSC program and providing updates to our early-stage portfolio including from our oncology and muscular dystrophy programs."

Fourth Quarter and Recent Highlights

Bexotegrast Highlights

- **Positive safety and efficacy data from 320 mg dose cohort of INTEGRIS-PSC Phase 2a trial in patients with primary sclerosing cholangitis (PSC).** At a once-daily dose of 320 mg, bexotegrast was well tolerated over 12 weeks of treatment with no drug-related severe or serious adverse events. At the 320 mg dose, bexotegrast reduced both Enhanced Liver Fibrosis (ELF) scores and PRO-C3 levels and showed improvements in hepatocyte function and bile flow by contrast MRI imaging relative to placebo at Week 12. Twenty-four-week data from the 320 mg dose group is expected in mid-2024.
- **Enrollment continues in BEACON-IPF, a Phase 2b trial of bexotegrast in patients with idiopathic pulmonary fibrosis** (**IPF).** 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.

Pipeline Programs

- **Phase 1 trial of PLN-101095 in solid tumors is enrolling.** 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 third 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. Preliminary data is expected in late 2024.
- **Muscular dystrophy program on track for regulatory filing in the first quarter of 2024.** PLN-101325 is a monoclonal antibody designed to act as an allosteric agonist of integrin α7β1. Filing for first-in-human clinical studies in Duchenne muscular dystrophy (DMD) is expected in the first quarter of 2024.

Fourth Quarter 2023 Financial Results

- Research and development expenses were $33.2 million, as compared to $25.1 million for the prior-year quarter. The increase was due primarily to higher employee-related expenses and increased clinical and manufacturing-related costs associated with our lead program, bexotegrast.
- General and administrative expenses were $13.9 million, as compared to $14.3 million for the prior-year quarter. The decrease was primarily due to a decrease in stock-based compensation as we achieved a clinical development milestone in the fourth quarter of 2022 that triggered the vesting of certain performance based awards.
- Net loss was $41.1 million as compared to $35.1 million for the prior-year quarter. The increase was due to higher operating expenses coupled with a decrease in collaboration revenues under the Novartis collaboration during the quarter.
- As of December 31, 2023, the Company had cash, cash equivalents and short-term investments of $495.7 million which the Company expects, together with funds available under the Oxford Loan Agreement, to be sufficient to fund operations into the second half of 2026.

About Pliant Therapeutics, Inc.

Pliant Therapeutics is a clinical-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, 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 X, 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 and 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 the effects of health epidemics and pandemics, such as 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 Annual Report on Form 10-K for the period ended December 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 December 31,		Twelve Months Ended December 31,	
	2023	2022	2023	2022
Revenue	$ —	$ 1,965	$ 1,580	$ 9,685
Operating expenses:				
Research and development	(33,183)	(25,114)	(127,797)	(96,936)
General and administrative	(13,854)	(14,251)	(57,928)	(39,949)
Total operating expenses	(47,037)	(39,365)	(185,725)	(136,885)
Loss from operations	(47,037)	(37,400)	(184,145)	(127,200)
Interest and other income (expense), net	6,249	2,657	24,076	4,670
Interest expense	(321)	(317)	(1,267)	(791)
Net loss	$ (41,109)	$ (35,060)	$ (161,336)	$ (123,321)
Net loss attributable to common stockholders	$ (0.69)	$ (0.72)	$ (2.75)	$ (2.94)
Net loss per share, attributable to common stockholders - basic and diluted	59,904,481	48,783,242	58,719,083	42,015,908

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

	December 31, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 63,234	$ 33,685
Short-term investments	431,011	297,502
Accounts receivable	—	1,983
Tax credit receivable	—	83
Prepaid expenses and other current assets	11,257	7,058
Total current assets	505,502	340,311
Property and equipment, net	3,567	4,486
Operating lease right-of-use assets	1,211	5,422
Restricted cash	1,482	—
Other non-current assets	392	394
Total assets	$ 512,154	$ 350,613
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 4,531	$ 1,580
Accrued research and development	12,456	11,218
Accrued liabilities	10,219	8,658
Lease liabilities, current	1,318	2,457
Total current liabilities	28,524	23,913
Lease liabilities, non-current	—	3,429
Long-term debt	10,054	9,929
Total liabilities	38,578	37,271
Stockholders' equity		
Preferred Stock	—	—
Common stock	6	5
Additional paid-in capital	972,973	653,707
Accumulated deficit	(499,748)	(338,412)
Accumulated other comprehensive gain (loss)	345	(1,958)
Total stockholders' equity	473,576	313,342
Total liabilities and stockholders' equity	$ 512,154	$ 350,613