# Pliant Therapeutics Provides Corporate Update and Reports Fourth Quarter and Full Year 2021 Financial Results

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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 fourth quarter and full year 2021 financial results.

“In 2021 strong execution drove significant advancement of our pipeline. The achievement of strategic milestones and positive data further de-risked our ongoing and potential future clinical programs,” said Bernard Coulie, M.D., Ph.D., President and Chief Executive Officer of Pliant Therapeutics. “We are building on this momentum in 2022 with significant data readouts anticipated in our lead programs of idiopathic pulmonary fibrosis and primary sclerosing cholangitis, as well as planned investigational new drug applications in our oncology and muscular dystrophy programs.”

**Fourth Quarter and Recent Highlights**

- **Results from expanded PLN-74809 Phase 1b proof-of-mechanism trial demonstrated clear evidence of on-target biological activity in the lungs of healthy participants.** Earlier today, the Company announced that positive data from an expanded PLN-74809 Phase 1b proof-of-mechanism trial demonstrated clear evidence of on-target biological activity in the lungs of 36 healthy participants. Results demonstrated that PLN-74809 inhibited TGF-β activation by up to 92% and 76% at 6- and 24-hours, respectively, following seven days of once-daily dosing. At all dose levels, PLN-74809 demonstrated durable pSmad suppression relative to placebo at 6 hours and 24 hours. PLN-74809 was well tolerated with mostly mild adverse events, and no severe adverse events.

- **Enrollment was completed in the PLN-74809 Phase 2a INTEGRIS-IPF trial in idiopathic pulmonary fibrosis.** INTEGRIS-IPF is a 12-week randomized, dose-ranging, double-blind, placebo-controlled trial evaluating the safety, tolerability and pharmacokinetics of PLN-74809 at doses of 40, 80 or 160 mg in approximately 84 IPF patients. Exploratory endpoints include quantitative lung fibrosis (QLF) imaging, pulmonary function tests as well as select biomarkers. Topline data is anticipated mid-2022.

- **The U.S. Food and Drug Administration (FDA) authorized the evaluation of long-term treatment with PLN-74809 in patients with IPF.** The FDA has authorized evaluation of long-term dosing of PLN-74809 up to 320 mg daily in patients with IPF. This authorization will facilitate longer-term pivotal trials in IPF. PLN-74809 has been administered to over 450 study participants, including healthy volunteers and patients, with no drug-related serious adverse events or severe adverse advents reported to date.

- **Independent Data Safety Monitoring Board (DSMB) recommended INTEGRIS-IPF Phase 2a Trial continue without modifications.** Following the full enrollment of the INTEGRIS-IPF Phase 2a trial, on February 17, 2022, the DSMB recommended the INTEGRIS-IPF trial continue without modification. This review included all patients enrolled in all dose cohorts of the trial. To date, no safety concerns have been identified by the DSMB.

- **Commenced enrollment of a Phase 2a trial of PLN-74809 at a dose of 320 mg in patients with IPF.** The Company began enrollment in a randomized, double-blind, placebo-controlled trial evaluating PLN-74809 at doses of 320 mg administered daily over at least six months, and up to 48 weeks, in approximately 28 patients with IPF. The primary endpoint is the evaluation of PLN-74809 safety and tolerability and the secondary endpoint is the assessment of pharmacokinetics. Exploratory endpoints will measure QLF imaging and pulmonary function tests as well as select biomarkers over 6 months of treatment.

- **PLN-74809 Phase 2a trial in primary sclerosing cholangitis (PSC) enrollment on track to be completed mid-2022.** INTEGRIS-PSC is a 12-week randomized, dose-ranging, double-blind, placebo-controlled trial evaluating the safety, tolerability, and pharmacokinetics of PLN-74809 at doses of 40, 80 or 160 mg in approximately 84 PSC patients. Exploratory endpoints include fibrosis biomarkers such as Pro-C3 and ELF, changes in ALP and liver imaging. Topline data is expected in late 2022 or early 2023.

- **Oncology and muscular dystrophy programs progressing through Investigational New Drug (IND) enabling studies.** Both programs on track with IND application submissions planned by the end of 2022.

**COVID-19 Preparedness**

The Company continues to develop and maintain policies and procedures to enable us to operate safely and productively during the COVID-19 pandemic. The Company has experienced delays in clinical trial operations which have impacted and may further impact the expected timing of data readouts. The Company is working closely with clinical sites to continue site initiation and operation activities in compliance with study protocols while observing government and institutional guidelines. The Company intends to provide more specific guidance regarding clinical trial progress and the timing of data readouts as the long-term impacts of the pandemic become better understood.

**Fourth Quarter 2021 Financial Results**

- Research and development expenses were $18.8 million, as compared to $17.9 million for the prior-year quarter. The increase was due primarily to employee related expenses and higher costs related to the advancement of several programs and ongoing Phase 1/2 clinical trials.
- General and administrative expenses were $7.8 million, as compared to $5.6 million for the prior-year quarter. The increase was due to higher personnel-related and professional services expenses.
- Net loss of $24.5 million, as compared to $19.0 million for the prior-year quarter. The increase is due an overall increase in operating expense coupled with a decrease in revenues generated from our license and collaboration agreement.
- As of December 31, 2021, the Company had cash, cash equivalents and short-term investments of $200.6 million. The Company believes it has sufficient funds to meet its operating and capital requirements into the second half of 2023.

**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, PLN-74809, is an oral small molecule dual selective inhibitor of $\alpha_v\beta_6$ and $\alpha_v\beta_1$ integrins that is in development in the lead indications for the treatment of idiopathic pulmonary fibrosis, or IPF, and primary sclerosing cholangitis, or PSC. PLN-74809 has received Orphan Drug Designation from the U.S. Food and Drug Administration for both IPF and PSC. Pliant is currently conducting Phase 2a trials of PLN-74809 in the lead indications of IPF and PSC. Pliant has also developed PLN-1474, a small molecule selective inhibitor of $\alpha_v\beta_1$ for the treatment of nonalcoholic steatohepatitis, or NASH with liver fibrosis, which Pliant has transferred to Novartis pursuant to our development partnership. In addition to clinical stage programs, Pliant currently has two preclinical programs targeting oncology and 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 de-risking of our ongoing and potential future clinical programs; planned INDs in our oncology and muscular dystrophy programs; anticipated progress of our clinical trials and timing of regulatory, enrollment and data disclosures; the efficacy and safety profile of our product candidates; our expectations regarding our interactions with regulators, including the FDA; and anticipated progress of our pre-clinical programs, including timing expectations for regulatory filings. 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, 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 filed for the year ended December 31, 2020 with the SEC on March 16, 2021, as updated by our Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, filed with the SEC on November 9, 2021 filed for the year ended December 31, 2020 with the SEC on March 16, 2021, as updated by our Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, filed with the SEC on November 9, 2021, and our subsequent filings with the SEC, which are 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, | Year Ended December 31, |
|---|---|---|

| | 2021 | 2020 | 2021 | 2020 |
|---|---|---|---|---|
| Revenue | $ 1,999 | $ 4,465 | $ 7,572 | $ 41,817 |
| Operating expenses: | | | | |
| Research and development | (18,752) | (17,854) | (77,549) | (66,193) |
| General and administrative | (7,846) | (5,627) | (27,558) | (17,269) |
| Total operating expenses | (26,598) | (23,481) | (105,107) | (83,462) |
| Loss from operations | (24,599) | (19,016) | (97,535) | (41,645) |
| Interest and other income (expense), net | 68 | (11) | 272 | 112 |
| Net income loss | $ (24,531) | $ (19,027) | $ (97,263) | $ (41,533) |
| Less: Undistributed earnings to preferred shareholders | — | — | — | — |
| Net loss attributable to common stockholders | $ (24,531) | $ (19,027) | $ (97,263) | $ (41,533) |
| Net loss per share, attributable to common stockholders: | | | | |
| Basic | $ (0.68) | $ (0.54) | $ (2.71) | $ (1.95) |
| Diluted | $ (0.68) | $ (0.54) | $ (2.71) | $ (1.95) |
| Shares used in computing net loss per share attributable to common stockholders: | | | | |
| Basic | 36,022,148 | 35,495,414 | 35,846,421 | 21,344,236 |
| Diluted | 36,022,148 | 35,495,414 | 35,846,421 | 21,344,236 |

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

| | December 31, 2021 | December 31, 2020 |
|---|---|---|
| **Assets** | | |
| Current assets | | |
| Cash and cash equivalents | $ 51,665 | $ 50,882 |
| Short-term investments | 148,931 | 226,012 |
| Accounts receivable | 1,998 | 9,279 |
| Tax credit receivable | 83 | 83 |
| Prepaid expenses and other current assets (Note 5) | 6,764 | 4,498 |
| Total current assets | 209,441 | 290,754 |
| Property and equipment, net | 4,606 | 4,321 |
| Operating lease right-of-use assets | 6,330 | — |
| Other non-current assets | 838 | 451 |
| **Total assets** | $ 221,215 | $ 295,526 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities | | |
| Accounts payable | $ 2,971 | $ 2,023 |
| Accrued liabilities (Note 6) | 11,991 | 9,576 |
| Lease liabilities, current | 1,869 | — |
| Total current liabilities | 16,831 | 11,599 |
| Lease liabilities, non-current | 5,325 | — |
| Other long-term liabilities (Note 6) | — | 866 |
| Total liabilities | 22,156 | 12,465 |
| Stockholders' equity (deficit) | | |
| Common stock | 3 | 3 |
| Additional paid-in capital | 414,348 | 400,918 |
| Accumulated deficit | (215,091) | (117,828) |
| Accumulated other comprehensive loss | (201) | (32) |
| Total stockholders' equity | 199,059 | 283,061 |
| **Total liabilities and stockholders' equity** | $ 221,215 | $ 295,526 |


Source: Pliant Therapeutics, Inc.