



Pliant Therapeutics Provides Corporate Update and Reports Second Quarter 2022 Financial Results

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SOUTH SAN FRANCISCO, Calif., Aug. 08, 2022 (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 2022 financial results.

"A highlight to our team's progress in 2022 is the positive safety and efficacy data from the INTEGRIS-IPF Phase 2a trial. The trial met its primary endpoint demonstrating that PLN-74809 was well tolerated over a 12-week treatment period, and delivered compelling efficacy results demonstrating a clear dose dependent treatment effect in patients with IPF," said Bernard Coulie, M.D., Ph.D., President and Chief Executive Officer of Pliant Therapeutics. "These data reflect the significant preclinical and clinical derisking conducted that allows for PLN-74809's late-stage development and moves this program closer to potentially assisting patients in need."

Second Quarter and Recent Highlights

PLN-74809 Highlights

- **INTEGRIS-IPF Phase 2a trial results showed PLN-74809 was well tolerated with dose-dependent treatment effects on forced vital capacity (FVC) and quantitative lung fibrosis (QLF) in patients with idiopathic pulmonary fibrosis (IPF).** Exploratory endpoints showed a dose-dependent treatment effect on FVC and QLF versus placebo in all PLN-74809 dose groups, both with and without standard of care therapy. In addition, a dose-dependent reduction in the proportion of patients with percent-predicted FVC (FVCpp) decline of $\geq 10\%$, a risk factor associated with increased mortality in IPF patients, was observed across all treatment groups.
- **INTEGRIS-IPF Phase 2a trial of PLN-74809 at 320 mg completed enrollment in patients with IPF.** Enrollment is complete in the randomized, double-blind, placebo-controlled trial evaluating PLN-74809 at a once daily dose of 320 mg administered for at least six months and up to 48 weeks in approximately 28 patients with IPF. The trial will evaluate primary and secondary endpoints of safety, tolerability, and pharmacokinetics. Exploratory efficacy endpoints will include effect on FVC and QLF imaging as well as biomarkers. Interim 12-week data is anticipated in early 2023.
- **INTEGRIS-PSC Phase 2a data anticipated in the first half of 2023.** This 12-week randomized, dose-ranging, double-blind, placebo-controlled trial is evaluating the safety, tolerability, and pharmacokinetics of PLN-74809 in primary sclerosing cholangitis (PSC) patients. The trial is also evaluating exploratory endpoints including fibrosis biomarkers such as PRO-C3 and ELF, changes in ALP, and liver imaging. Topline data from this trial is expected in the first half of 2023.
- **FDA Fast Track designation received for PLN-74809 for the treatment of PSC.** FDA's Fast Track designation is intended to facilitate and expedite the development and review of new drugs to treat serious or life-threatening conditions. The benefits of Fast Track designation include opportunities for frequent meetings with the FDA to discuss trial design, development plans, and data needed to support drug approval, as well as the ability to submit a New Drug Application (NDA) on a rolling basis, and eligibility for priority review, if relevant criteria are met.

Early-Stage Development Programs

- **Advancement of integrin target in fibrosis under strategic collaboration.** A fibrosis-directed integrin target moved into development as part of Pliant's 2019 research and development collaboration with Novartis. Pliant earned a \$4.0 million milestone payment and research funding in support of the development work.
- **Oncology and muscular dystrophy programs progressing through Investigational New Drug (IND) enabling studies.** IND application submissions for both programs expected by the end of 2022.

Corporate Highlights

- **Underwritten public offering raised approximately \$215.7 million in net proceeds.** In July 2022, the Company closed a public offering of \$230.0 million of common stock including the underwriter's exercise in full of their overallotment option to support development of ongoing and future preclinical and clinical programs including PLN-74809.
- **Loan facility agreement with Oxford Finance LLC provides up to \$100 million of non-dilutive financing.** The

agreement provides support for the continued clinical development of PLN-74809 in the lead indications of IPF and PSC. The Company drew \$10.0 million at closing of an initial \$25.0 million tranche. Following the achievement of a development milestone, the Company now has access to the second \$25.0 million tranche.

Second Quarter 2022 Financial Results

- Research and development expenses were \$26.3 million, as compared to \$19.2 million for the prior-year quarter. The increase was due primarily to employee related expenses and higher costs related to the advancement of preclinical programs and ongoing Phase 1/2 clinical trials.
- General and administrative expenses were \$8.3 million, as compared to \$5.5 million for the prior-year quarter. The increase was due to higher personnel-related and professional services expenses.
- Net loss of \$29.5 million as compared to \$22.8 million for the prior-year quarter due to an increase in operating expenses partially offset by an increase in collaboration revenue resulting from a \$4.0 million target validation fee earned under the Novartis collaboration during the quarter.
- As of June 30, 2022, the Company had cash, cash equivalents and short-term investments of \$163.6 million. With the aggregate net proceeds from the public offering of approximately \$215.7 million, the Company had pro-forma cash, cash equivalents and short-term investments of \$379.8 million as of June 30, 2022. With current cash and full utilization of our loan facility, the Company expects to be able to fund operations to mid-2025.

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 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 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](http://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 derisking 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; the sufficiency of our cash runway and the availability of additional term loans under our loan facility; the anticipated benefits of Fast Track and Orphan Drug designations for PLN-74809; 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, 2021 with the SEC on March 1, 2022, as updated by our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, which we are filing with the SEC today, each 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,	
	2022	2021
Revenue	\$ 4,989	\$ 1,789
Operating expenses:		
Research and development	(26,335)	(19,218)
General and administrative	(8,296)	(5,475)
Total operating expenses	<u>(34,631)</u>	<u>(24,693)</u>
Loss from operations	(29,642)	(22,904)
Interest and other income (expense), net	96	73
Net loss	<u>\$ (29,546)</u>	<u>\$ (22,831)</u>
Net loss attributable to common stockholders	<u>\$ (29,546)</u>	<u>\$ (22,831)</u>
Net loss per share attributable to common stockholders:		
Basic and diluted	<u>\$ (0.82)</u>	<u>\$ (0.64)</u>
Shares used in computing net loss per share attributable to common stockholders:		
Basic and diluted	<u>36,173,135</u>	<u>35,746,922</u>

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

	June 30, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	\$ 25,070	\$ 51,665
Short-term investments	138,527	148,931
Accounts receivable	4,989	1,998
Tax credit receivable	83	83
Prepaid expenses and other current assets	4,857	6,764
Total current assets	<u>173,526</u>	<u>209,441</u>
Property and equipment, net	4,534	4,606
Operating lease right-of-use assets	5,646	6,330
Other non-current assets	913	838
Total assets	<u>\$ 184,619</u>	<u>\$ 221,215</u>
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 3,116	\$ 2,971
Accrued liabilities	17,395	11,991
Lease liabilities, current	2,042	1,869
Total current liabilities	<u>22,553</u>	<u>16,831</u>
Lease liabilities, non-current	4,407	5,325
Term loan	<u>9,871</u>	<u>—</u>
Total liabilities	<u>36,831</u>	<u>22,156</u>
Stockholders' equity		
Common stock	3	3
Additional paid-in capital	421,781	414,348
Accumulated deficit	(272,737)	(215,091)
Accumulated other comprehensive loss	(1,259)	(201)
Total stockholders' equity	<u>147,788</u>	<u>199,059</u>
Total liabilities and stockholders' equity	<u>\$ 184,619</u>	<u>\$ 221,215</u>