



Palisade Bio Reports Third Quarter 2022 Financial Results and Provides Business Update

November 14, 2022

Carlsbad, CA, Nov. 14, 2022 (GLOBE NEWSWIRE) -- [Palisade Bio, Inc.](#), (Nasdaq: PALI) a clinical stage biopharmaceutical company advancing therapies for acute and chronic gastrointestinal (GI) complications (the "Company" or "Palisade"), reported its financial results for the quarter ended September 30, 2022. The Company also provided an update on the status of its clinical development programs for LB1148.

Clinical Program Update for LB1148

Advancement of U.S. Phase 2 Adhesions Study is Company's Priority

The Company is conducting an ongoing randomized, double-blind, placebo-controlled, parallel-group, multicenter Phase 2 clinical trial of LB1148 in patients undergoing elective bowel resection surgery in the United States (U.S.). This trial is designed to evaluate whether patients treated with LB1148 experience fewer postoperative intra-abdominal adhesions.

To date, the Company has enrolled 31 of an expected 70 patients in its U.S. Phase 2 adhesions study. The Company expects to announce interim data from this U.S. Phase 2 study within the first half of 2023 and believes it has sufficient capital to fund operations into the second half of 2023, at which time the Company expects it will announce topline data results for the completed U.S. Phase 2 study.

Robert McRae, Senior Vice President, Operations and Strategic Development of Palisade, stated, "Adhesions are reported to occur in more than 90% of abdominal surgeries and pose a serious risk of post-surgical complications including bowel obstruction, infertility, and severe pain. We are excited about the potential of LB1148 to impact the millions of patients at risk to these serious complications, which represents a costly and significant unmet medical need and large global commercial opportunity."

Status of Palisade Bio's Return of Bowel Function U.S. Phase 3 Study

In May 2022, the Company's co-development partner in China received clearance from the Center for Drug Evaluation of the National Medical Products Administration of the People's Republic of China to proceed with their Phase 3 clinical trial to evaluate LB1148 for accelerated return of bowel function in adult patients undergoing gastrointestinal surgery. In June 2022, based on data generated by this co-development partner in its earlier Phase 2 study, the Company initiated a Phase 3 clinical trial in the U.S. evaluating LB1148 to accelerate the return of bowel function in adult patients undergoing gastrointestinal surgery.

In October 2022, Palisade's Board commenced a thorough review of the Company's ongoing clinical programs of LB1148. The Company believes that the current U.S. Phase 3 study protocol requires additional standardization across sites and further clarification in the definition of endpoints to permit an adequate assessment of the efficacy of LB1148 to recover GI function.

Given the foregoing, as well as the financial resources available to the Company at this time, the Company believes it is in its stakeholders' best interests to pause enrollment in the U.S. Phase 3 study in order to determine next steps for the study. The Company will prioritize the advancement of its U.S. Phase 2 adhesions study, which, it believes, will maximize the value of its current product pipeline.

J.D. Finley, interim CEO of Palisade, commented, "Our number one priority is advancing the U.S. Phase 2 study of LB1148 for the prevention of post-surgical abdominal adhesions in GI surgery. We are well funded through an interim data readout for this study in the first half of 2023 and topline results in the second half of 2023. Our new leadership along with our Board strongly believe the execution of this strategy will be the catalyst for unlocking significant value for our shareholders in the near-term."

Notwithstanding this review and the pausing of the trial, the Company remains optimistic as to the efficacy of LB1148 for the return of bowel function based on the Company's co-development partner's Phase 2 data and its plan to continue its Phase 3 study in China.

Summary of Financial Results for Third Quarter 2022

As of September 30, 2022, the Company had cash and cash equivalents of \$14.0 million. Based on management's current expectations, the Company has enough cash to fund operations into the second half of 2023.

Net loss was \$4.0 million for the three months ended September 30, 2022, compared to net income of \$8.1 million for the three months ended September 30, 2021. Net income for the three months ended September 30, 2021 includes a non-cash gain of \$12.8 million associated with the revaluation of the Company's liability-classified warrants.

Research and development expenses were \$1.9 million in the third quarter of 2022, compared to \$0.6 million in the third quarter of 2021, an increase of \$1.3 million, or approximately 209%. The increase is a result of the restart of the Company's LB1148 Phase 2 clinical study of the prevention of post-surgical abdominal adhesions and the initiation of its Phase 3 clinical study of the accelerated return of bowel function following gastrointestinal surgery.

General and administrative expenses decreased from \$2.4 million for the three months ended September 30, 2021 to \$2.1 million for the three months ended September 30, 2022. The decrease of \$0.3 million for the three months ended September 30, 2022 compared to the three months ended September 30, 2021 was primarily attributable to a \$0.6 decrease in professional and recruiting fees and a \$0.1 decrease in consultants and contract labor, partially offset by (i) a \$0.2 increase in net payroll and employee-related costs, (ii) a \$0.1 million increase in insurance costs, and (iii) a \$0.1 million increase in stock-based compensation expense.

The Company recognized restructuring costs of \$0.4 million for the three months ended September 30, 2022, consisting of severance and benefits

payments pursuant to employment agreements and the execution of severance and release agreements with employees terminated under a September 2022 cost-reduction plan.

About Palisade Bio

Palisade Bio is a biopharmaceutical company focused on developing therapeutics that protect the integrity of the intestinal barrier. The Company utilizes over three decades of research and established science that links the role of intestinal barrier biology and human disease to develop novel therapeutics that target and improve the integrity of the intestinal barrier.

The Company's lead program, LB1148, is a broad-spectrum serine protease inhibitor which acts to neutralize digestive enzymes, potentially reducing intestinal damage. In clinical studies, LB1148 has demonstrated positive results in accelerating the time to return of postoperative bowel function, and the Company recently presented analysis that LB1148 reduced the incidence and severity of post-surgical abdominal adhesions. LB1148 is currently being evaluated in a Phase 2 study for the prevention of post-surgical abdominal adhesions.

The Company believes that addressing the disruption of the intestinal barrier can fundamentally change the way diseases are treated and establish new standards of patient care. For more information, please go to www.palisadebio.com.

Forward Looking Statements

This communication contains "forward-looking" statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding the Company's intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: progress of studies, including opening additional clinical trial sites, timing of results or data, progress and completion of patient enrollment, including timing thereof and the Company's co-development partner's expectation to complete enrollment; regulatory progress and strategy, including potential registration and commercialization of LB1148; the extent of the cash runway; the closing of the underwritten public offering; and expected proceeds from financings. Any statements contained in this communication that are not statements of historical fact may be deemed to be forward-looking statements. These forward-looking statements are based upon the Company's current expectations. Forward-looking statements involve risks and uncertainties. The Company's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, the Company's ability to advance its clinical programs, the uncertain and time-consuming regulatory approval process; the Company's ability to achieve additional financing to fund future operations and the Company's ability to comply with the continued listing requirements for Nasdaq. Additional risks and uncertainties can be found in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the Securities and Exchange Commission ("SEC") on March 17, 2022, Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, filed with the SEC on November 14, 2022, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof and the Company expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in the Company's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

Investor Relations Contact

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Source: Palisade Bio

Palisade Bio, Inc.
Condensed Consolidated Balance Sheets
 (in thousands, except share and per share amounts)

	September 30, 2022	December 31, 2021
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 13,985	\$ 10,495
Prepaid expenses and other current assets	1,173	1,011
Total current assets	15,158	11,506
Restricted cash	26	26
Right-of-use asset	324	109
Other noncurrent assets	746	868
Property and equipment, net	12	3
Total assets	\$ 16,266	\$ 12,512
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,725	\$ 1,323
Accrued liabilities	1,242	463
Accrued compensation and benefits	93	511
Current portion of lease liability	101	112
Debt	352	87

Total current liabilities	3,513	2,496
Warrant liability	84	2,651
Lease liability, net of current portion	239	—
Total liabilities	3,836	5,147
Commitments and contingencies		
Stockholders' equity:		
Series A Convertible Preferred Stock, 7,000,000 shares authorized, \$0.01 par value; 200,000 issued and outstanding at September 30, 2022 and December 31, 2021	2	2
Common stock, \$0.01 par value; 300,000,000 shares authorized as of September 30, 2022 and December 31, 2021, 77,080,169 and 14,239,177 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	771	143
Additional paid-in capital	116,839	101,862
Accumulated deficit	(105,182)	(94,642)
Total stockholders' equity	12,430	7,365
Total liabilities and stockholders' equity	\$ 16,266	\$ 12,512

Palisade Bio, Inc.
Condensed Consolidated Statements of Operations (Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	\$ 1,928	\$ 624	\$ 4,204	\$ 1,630
In-process research and development	—	—	—	30,117
General and administrative	2,075	2,392	7,259	6,080
Restructuring costs	410	—	410	—
Total operating expenses	4,413	3,016	11,873	37,827
Loss from operations	(4,413)	(3,016)	(11,873)	(37,827)
Other income (expense):				
Gain on forgiveness of PPP loan	—	—	—	279
Loss on issuance of secured debt	—	—	—	(686)
Gain on change in fair value of warrant liability	385	12,764	2,403	17,939
Gain on change in fair value of share liability	—	18	—	91
Interest expense	(4)	(26)	(10)	(2,393)
Other income	41	20	50	36
Loss on issuance of LBS Series 1 Preferred Stock	—	—	—	(1,881)
Loss on issuance of warrants	—	(1,673)	(1,110)	(3,247)
Total other income (expense)	422	11,103	1,333	10,138
Net (loss) income	\$ (3,991)	\$ 8,087	\$ (10,540)	\$ (27,689)
(Loss) income per common share:				
Basic	\$ (0.08)	\$ 0.42	\$ (0.37)	\$ (3.50)
Diluted	\$ (0.08)	\$ 0.42	\$ (0.37)	\$ (4.13)
Weighted average shares used in computing (loss) income per common share:				
Basic	48,709,846	12,100,292	28,634,209	7,902,104
Diluted	48,709,846	12,106,771	28,634,209	7,952,998
Net (loss) income attributable to common shares - basic	\$ (3,991)	\$ 5,118	\$ (10,540)	\$ (27,689)
Net (loss) income attributable to common shares - diluted	\$ (3,991)	\$ 5,119	\$ (10,540)	\$ (32,808)

Palisade Bio, Inc.
Condensed Consolidated Statements of Cash Flows (Unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2022	2021
Net loss	\$ (10,540)	\$ (27,689)

Adjustments to reconcile net loss to net cash used in operating activities:

Depreciation and amortization	1	2
In-process research and development	—	30,117
Noncash transaction costs shared with Seneca	—	(135)
Noncash lease expense	140	122
Gain on forgiveness of PPP loan	—	(279)
Accretion of debt discount and non-cash interest expense	—	2,334
Loss on issuance of LBS Series 1 Preferred Stock	—	1,881
Loss on issuance of secured debt	—	686
Loss on issuance of warrants	1,110	3,247
Change in fair value of warrant liabilities	(2,403)	(17,939)
Change in fair value of share liability	—	(91)
Stock-based compensation	946	1,208
Other	(213)	(191)

Changes in operating assets and liabilities:

Other receivables	—	84
Prepaid and other assets and other noncurrent assets	744	(1,264)
Accounts payable and accrued liabilities	706	(2,145)
Accrued compensation	(418)	(1,544)
Operating lease liabilities	(127)	(122)
Net cash used in operating activities	(10,054)	(11,718)

Cash flows from investing activities:

Cash acquired in connection with the Merger	—	3,279
Acquisition related costs paid	—	(3,333)
Net cash used in investing activities	—	(54)

Cash flows from financing activities:

Payments on debt	(524)	(949)
Proceeds from issuance of debt	—	1,250
Proceeds from issuance of LBS Series 1 Preferred Stock	—	19,900
Proceeds from issuance of common stock and warrants	14,401	5,209
Redemption of warrants	—	(99)
Payment of equity issuance costs	(333)	—
Payment of debt issuance costs	—	(148)
Net cash provided by financing activities	13,544	25,163

Net (decrease) increase in cash, cash equivalents and restricted cash

Cash, cash equivalents and restricted cash, beginning of period

Cash, cash equivalents and restricted cash, end of period

Reconciliation of cash, cash equivalents and restricted cash to the balance sheets:

Cash and cash equivalents	13,985	14,104
Restricted cash	26	26
Total cash, cash equivalents and restricted cash	\$ 14,011	\$ 14,130



Source: Palisade Bio, Inc.