Palisade Bio Reports First Quarter 2022 Financial Results and Provides Corporate Update

May 13, 2022

Phase 3 study of LB1148 in lead indication for postoperative return of bowel function on track to commence Q2 2022

Ongoing Phase 2 study of LB1148 for the prevention of post-surgical abdominal adhesions

CARLSBAD, Calif., May 13, 2022 (GLOBE NEWSWIRE) -- Palisade Bio (Nasdaq: PALI), a clinical stage biopharmaceutical company advancing therapies for acute and chronic gastrointestinal (GI) complications, today reported its financial results for the quarter ended March 31, 2022.

Additionally, the Company provided a clinical program update for its lead asset in development, LB1148, an oral formulation of a broad-spectrum serine protease inhibitor designed to neutralize the activity of potent digestive proteases released from the gut during surgery.

Recent Highlights

- Extended cash runway with a $2.0 million registered direct offering.
- Received National Medical Products Administration (NMPA) clearance to commence Phase 3 clinical trial in China evaluating LB1148 to accelerate the return of bowel function following abdominal surgery.
- Received "Study May Proceed" letter from the U.S. Food and Drug Administration (FDA) for Phase 3 clinical trial evaluating LB1148 to accelerate the return of bowel function following abdominal surgery.
- Presented data from a pooled-analysis of studies LBS-IST-POI-101 and LBS-POI-201-CN (PROFILE-CN) demonstrating LB1148 reduced the extent and severity of post-surgical intraabdominal adhesions by 93% at the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) 2022 Annual Meeting.
- Appointed Robert McRae as Senior Vice President, Operations and Strategic Development.

"We have made exciting progress on the operational, clinical, and regulatory fronts over the course of the past quarter and are poised to execute on our near-term milestones. With the clearance from the FDA, as well as the NMPA, to proceed with our Phase 3 program in the United States and China, our team is laser focused on driving LB1148 forward as quickly and efficiently as possible. Additionally, we made progress on the financial front by bolstering our cash position with the completed financing," commented Tom Hallam, Ph.D., Chief Executive Officer of Palisade Bio. "This will position us to take an important step closer to the registration and commercialization of LB1148, which we believe has the potential to establish the standard of care, globally. The leadership team and board are focused on building on our momentum with our pipeline and look forward to unlocking value for all stakeholders of Palisade Bio."

Clinical Program Update

LB1148 is a novel oral liquid formulation of the well-characterized digestive enzyme inhibitor, tranexamic acid ("TXA"), with potential to both reduce abdominal adhesions and help restore bowel function following surgery. The therapy is being developed for administration prior to surgeries that are at risk of disrupting the intestinal epithelial barrier. Evidence suggests that the release of digestive proteases contributes to the temporary loss of normal gastrointestinal function and the formation of postoperative adhesions. By inhibiting the activity of these digestive proteases, LB1148 has the potential to prevent damage to GI tissues, accelerate the time to the return of normal GI function, and shorten the duration of costly post-surgery hospital stays.

Postoperative Return of Bowel Function: GI Surgery

In March 2022, the Company received a "Study May Proceed" letter from the FDA to initiate its Phase 3 clinical trial evaluating LB1148 to accelerate the return of bowel function in adult patients undergoing gastrointestinal surgery. The trial is designed as a multi-centered, randomized, double-blinded, parallel-group, placebo-controlled clinical trial set to enroll approximately 600 patients, and will assess the safety and efficacy of LB1148. All patients enrolled in the trial will undergo a scheduled bowel resection surgery that will include either laparotomy or laparoscopic surgical approaches.

Additionally, in May 2022 the Company's co-development partner Newsoara Biopharma Co. Ltd, received clearance from the NMPA in China to proceed with their Phase 3 clinical trial to evaluate LB1148 for accelerated return of bowel function in adult patients undergoing gastrointestinal surgery.

The expected timelines are management's current forecasts and will be updated as enrollment progresses.

Expected Upcoming Milestones

- Q2 2022: U.S. Phase 3 study initiation
- 2H 2022: U.S. Phase 3 study first patient enrolled

Prevention of Post-Surgical Abdominal Adhesions: GI Surgery

Digestive enzymes can escape the intestine during abdominal surgery and cause damage to the intestines and surrounding organs resulting in the formation of scar tissue known as adhesions. Adhesion prevalence has historically reported to be >90% in patients who undergo abdominal surgery and represents a potentially significant contribution to serious complications. Adhesions can be the cause of chronic pain and may prevent normal organ function, including bowel obstructions of the intestine. Adhesions can increase the difficulty of subsequent surgeries causing complications and are the leading cause of secondary infertility in women. In some cases, adhesions require a second corrective surgical procedure. There are currently

no approved medications to prevent or treat adhesions.

The Company previously reported data on three patients who had been assessed for adhesions following GI surgery. In the Company's recent data presentation at the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) 2022 Annual Meeting, a pooled-study analysis of 17 patients demonstrated LB1148 reduced incidence of adhesions by 72% and reduced the extent and severity of adhesions by 93% in patients undergoing bowel resection.

The Company is conducting an ongoing randomized, double-blind, placebo-controlled, parallel-group, multicenter Phase 2 clinical trial of LB1148 in up to 200 patients undergoing elective bowel resection surgery in the United States. This trial is designed to evaluate whether patients treated with LB1148 experience fewer postoperative intra-abdominal adhesions. The trial will also assess LB1148's impact on recovery of GI function, as compared to placebo.

Expected Upcoming Milestones

- Q4 2022: Phase 2 enrollment completion
- 1H 2023: Phase 2 study completion
- 2H 2023: Report Phase 2 topline results

Postoperative Return of Bowel Function: Cardiovascular Surgery

The Company previously announced positive topline data from its Phase 2 trial demonstrating LB1148 achieved its primary endpoint with statistically significant improvement in return of bowel function following cardiovascular (CV) surgery. The Phase 2 clinical trial was a randomized, double-blind, parallel, placebo-controlled trial in 120 subjects undergoing coronary artery bypass grafting (CABG) and/or heart valve replacement surgery requiring cardiopulmonary bypass (CPB) with patients randomized to receive LB1148 or placebo in conjunction with surgery. LB1148 provided a 30% improvement in the time to normal bowel function following cardiovascular surgery ($p<0.001$) compared to placebo. This improvement resulted in a 1.1-day reduction in average length of stay in the ICU and a 1.0-day reduction in average hospital length of stay. LB1148 was also shown to be safe and well-tolerated in the trial. The Company plans to initiate additional CV surgery studies with LB1148 after the completion of the studies to accelerate the return of bowel function in patients undergoing gastrointestinal surgery.

The U.S. FDA has granted Fast Track designation to LB1148 for two clinical indications: reduction of adhesions following abdominal or pelvic surgery and treatment of postoperative GI dysfunction in pediatric patients undergoing cardiac surgery.

Summary of Financial Results for First Quarter 2022

Net loss was $4.2 million and $4.0 million for the three months ended March 31, 2022, and 2021, respectively.

Research and development expenses were $1.0 million and $0.7 million for the three months ended March 31, 2022, and 2021, respectively. The increase of approximately $0.3 million, or 39%, was primarily attributable to the Company's increased clinical trial activities. In the quarter, the Company's clinical trial activities, which had been virtually halted in the first quarter of 2021 due to the COVD-19 pandemic, continued to increase as the Company proceeded with its Phase 2 trial of the prevention of post-surgical abdominal adhesions and advanced towards its Phase 3 postoperative return of bowel function trial for which a protocol has been agreed to with the FDA. The Company expects research and development expenses to continue to increase in 2022 as it executes on its clinical development plan for LB1148.

General and administrative expenses for the three months ended March 31, 2022, increased approximately $1.7 million or 132%, from $1.3 million for three months ended March 31, 2021, to $2.9 million. The increase, as compared to the first quarter of 2021, was primarily related to higher general and administrative expenses associated with operating as a public company, as compared to those of the Company's accounting predecessor, Leading Biosciences, Inc. Although difficult to predict, the Company expects general and administrative expenses will be lower in the remaining quarters of 2022.

As of March 31, 2022, the Company had cash and cash equivalents of $6.6 million. Subsequent to quarter end, the Company closed on a $2.0 million registered direct offering of 3,646,690 shares of its common stock at a purchase price of $0.55 per share. The Company also agreed to issue to the investors in a concurrent private placement, unregistered warrants to purchase up to an aggregate of 3,646,690 shares of its common stock. The warrants have an exercise price of $0.7105 per share of common stock, will be exercisable six months after the date of issuance, and will expire five and a half years following the initial issuance date. The Company intends to use the net proceeds from the financing for working capital and general corporate purposes, including the development of the Company's lead product candidate LB1148.

About Palisade Bio

Palisade Bio is a clinical stage biopharmaceutical company advancing therapies that aim to aid patients suffering with acute and chronic gastrointestinal complications stemming from post-operative digestive enzyme damage. Palisade Bio's innovative lead asset LB1148, advancing toward Phase 3, is a protease inhibitor with the potential to both reduce abdominal adhesions and help restore bowel function following surgery. Positive data from Phase 2 trials of LB1148 demonstrated safety and tolerability as well as a statistically significant improvement in the return of bowel function and a decrease in the length of stay in ICU and hospital compared to placebo. Palisade Bio believes that its investigational therapies have the potential to address the myriad health conditions and complications associated with the chronic disruption to the gastrointestinal epithelial barrier. 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 Palisade's intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: the expected commencement date for a Phase 3 study, expected near-term Phase 2 milestones, the use of proceeds from the financing, expectations regarding regulatory submissions, the potential for LB1148 to transform the current standard of care, if approved, and the ability for the Company to unlock value for our stakeholders. 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 Palisade's current expectations. Forward-looking statements involve risks and uncertainties. Palisade'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, and the Company's ability to achieve additional financing to fund future operations and to comply with the continued listing requirements of the applicable stock exchange. Additional risks and uncertainties can be found in Palisade Bio's Quarterly Report on Form 10-Q for the quarter ended March 31, 2022. Palisade 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 Palisade's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

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

	March 31, 2022 (Unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,644	$ 10,495
Prepaid expenses and other current assets	1,614	1,879
Total current assets	8,258	12,374
Restricted cash	26	26
Right-of-use asset	64	109
Property and equipment, net	2	3
Total assets	$ 8,350	$ 12,512
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,147	$ 1,323
Accrued liabilities	580	463
Accrued compensation and benefits	72	511
Current portion of lease liability	65	112
Current portion of debt	—	87
Total current liabilities	1,864	2,496
Warrant liability	1,694	2,651
Total liabilities	3,558	5,147
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Series A Convertible Preferred Stock, 7,000,000 shares authorized, $0.01 par value; 200,000 issued and outstanding at March 31, 2022 and December 31, 2021	2	2
Common stock, $0.01 par value; 300,000,000 shares authorized as of March 31, 2022 and December 31, 2021, respectively; 18,233,479 and 14,239,177 shares issued and outstanding at March 31, 2022 and December 31, 2021	183	143
Additional paid-in capital	103,454	101,862
Accumulated deficit	(98,847)	(94,642)
Total stockholders' equity	4,792	7,365
Total liabilities and stockholders' equity	$ 8,350	$ 12,512

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

	Three Months Ended March 31,	
	2022	2021
Operating expenses:		
Research and development	$ 959	$ 692
General and administrative	2,929	1,262
Total operating expenses	3,888	1,954
Loss from operations	(3,888)	(1,954)
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	793	42
Interest expense	(1)	(1,711)
Other income	1	—
Loss on issuance of warrants	(1,110)	—
Total other expense	(317)	(2,076)
Net loss	$ (4,205)	$ (4,030)
Basic and diluted loss per common share	$ (0.26)	$ (1.45)
Weighted average shares used in computing basic and diluted loss per common share	16,223,656	2,774,502

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

	Three Months Ended March 31,	
	2022	2021
Net loss	$ (4,205)	$ (4,030)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1	1
Noncash lease expense	45	39
Gain on forgiveness of PPP loan	—	(279)
Accretion of debt discount and non-cash interest expense	—	1,590
Loss on issuance of secured debt	—	686
Loss on issuance of warrants	1,110	—
Change in fair value of warrant liabilities	(793)	(42)
Stock-based compensation	358	569
Changes in operating assets and liabilities:		
Trade and other receivables	—	59
Prepaid and other assets	265	21
Accounts payable and accrued liabilities	(59)	183
Accrued compensation	(439)	(8)
Operating lease liabilities	(47)	(39)
Net cash used in operating activities	(3,764)	(1,250)
Cash flows from financing activities:		
Payments on debt	(87)	(11)
Proceeds from issuance of debt	—	1,250
Payment of debt issuance costs	—	(87)
Net cash (used in) provided by financing activities	(87)	1,152
Net decrease in cash, cash equivalents and restricted cash	(3,851)	(98)
Cash, cash equivalents and restricted cash, beginning of period	10,521	739
Cash, cash equivalents and restricted cash, end of period	$ 6,670	$ 641


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