Panbela Provides Business Update and Reports Q3 2023 Financial Results

MINNEAPOLIS, Nov. 9, 2023, (GLOBE NEWSWIRE) - Panbela Therapeutics, Inc. (Nasdaq: PBLA), a clinical stage company developing disruptive therapeutics for the treatment of patients with urgent unmet medical needs, today provides a business update and reports financial results for the quarter ended September 30, 2023. As previously announced, management is hosting an earnings call today at 4:30 p.m. ET.

Q3 2023 and Recent Highlights

Collaborations

- Divestiture of assets within eflornithine (DFMO) pediatric neuroblastoma program to US WorldMeds® for an upfront payment of $400,000 and contingent payments totaling up to an additional $9.1 million.

Clinical

- The independent Data Safety Monitoring Board (DSMB) of the ASPIRE trial completed its pre-specified review of safety data for treated patients in the trial. The DSMB recommended that the study continue without modification.

- Opened enrollment in the UK and Germany and have all planned countries in the ASPIRE trial for pancreatic cancer now open and actively enrolling.

- Entered into a clinical trial agreement for a Phase 2 trial in castration resistant metastatic prostate cancer (mCRPC) which is actively enrolling.

Financial/Business

- Last week, certain holders of our existing warrants exercised for an aggregate 2,130,000 shares of common stock at a reduced exercise price of $0.78 per share, in exchange for receiving new warrants, the exercisability of which remains subject to stockholder approval. The aggregate gross proceeds from the exercise of the existing warrants totaled approximately $1.9 million, before deducting financial advisory fees.

- Issued a new patent in China for claims of a novel process for the production of ivospemin (SBP-101). Patent developed in collaboration with Syngene International Ltd.

- Issued a new patent in Chile for claims of a novel process for the production of Flynpovi, Patent developed in collaboration with Sanofi.

- Issued a new patent in Australia for claims of a novel process for the production of ivospemin (SBP-101).

"In the third quarter, we achieved important milestones and advanced our robust product pipeline, primarily funded through strategic collaboration. Notably, our Phase III ASPIRE trial for untreated metastatic pancreatic ductal adenocarcinoma received a favorable safety review from the independent DSMB, recommending no changes to the trial protocol. We have opened enrollment in the UK and Germany, and now have all planned countries in the ASPIRE trial open and actively enrolling," said Jennifer K. Simpson, PhD, MSN, CRNP, President & CEO of Panbela. "Additionally, we fortified our intellectual property portfolio, obtaining patents in China, Chile, and Australia. Moreover, we finalized an agreement for up to $9.5M in non-dilutive funding through the divestiture of our neuroblastoma program to our strategic partner, US WorldMeds, who recently received a positive vote from the Oncologic Drugs Advisory Committee (ODAC) meeting on October 4, 2023."

Dr. Simpson added, "Looking ahead, Panbela remains committed to delivering value for both patients and shareholders. We are moving towards a number of upcoming catalysts, including the release of ASPIRE interim data around mid-year 2024."

Third Quarter ended September 30, 2023 Financial Results

General and administrative expenses were $1.1 million in the third quarter of 2023, compared to $1.3 million in the third quarter of 2022. The change is primarily due to decreased legal and financial services costs.

Research and development expenses were $6.7 million in the third quarter of 2023, compared to $2.3 million in the third quarter of 2022. The increase is primarily due to the cost of approximately $3.2 million or approximately 6 months' supply of Abraxane, a standard of care drug, used in the ASPIRE clinical trial and first made available to the clinical sites during the three months ended September 30, 2023. The remaining increase is associated with other ASPIRE clinical trial costs.

Net loss in the third quarter of 2023 was $7.8 million, or $2.69 per diluted share, compared to a net loss of $4.4 million, or $257.36 per diluted share, in the third quarter of 2022. All share and per share amounts have been restated for two reverse stock splits which occurred in the nine months ended September 30, 2023.

Total cash was $0.9 million as of September 30, 2023. Total current assets were $1.9 million and current liabilities were $8.9 million as of the same date. Notes payable, plus accrued interest, on the balance sheet, which was the result of the acquisition of CPP, included 1.2 million in current liabilities and 4.2 in debt, net of current portion.

Conference Call Information
To participate in this event, dial approximately 5 to 10 minutes before the beginning of the call.
Date: November 9, 2023
Time: 4:30 PM Eastern Time
Participant Numbers: Toll Free: 888-506-0062; Code: 100225
International: 973-528-0011; Code: 100225
Webcast: **https://www.webcaster4.com/Webcast/Page/2556/49149**

Conference Call Replay Information
Toll Free: 877-481-4010
International: 919-882-2331
Replay Passcode: 49149
Webcast replay: **https://www.webcaster4.com/Webcast/Page/2556/49149**

About our Pipeline
The pipeline consists of assets currently in clinical trials with an initial focus on familial adenomatous polyposis (FAP), first-line metastatic pancreatic cancer, neoadjuvant pancreatic cancer, colorectal cancer prevention, ovarian cancer and diabetes. The combined development programs have a steady cadence of catalysts with programs ranging from pre-clinical to registration studies.

SBP-101 Ivospemin
Ivospemin is a proprietary polyamine analogue designed to induce polyamine metabolic inhibition (PMI) by exploiting an observed high affinity of the compound for pancreatic ductal adenocarcinoma and other tumors. It has shown signals of tumor growth inhibition in clinical studies of metastatic pancreatic cancer patients, demonstrating a median overall survival (OS) of 14.6 months and an objective response rate (ORR) of 48%, both exceeding what is typical for the standard of care of gemcitabine + nab-paclitaxel suggesting potential complementary activity with the existing FDA-approved standard chemotherapy regimen. In data evaluated from clinical studies to date, ivospemin has not shown exacerbation of bone marrow suppression and peripheral neuropathy, which can be chemotherapy-related adverse events. Serious visual adverse events have been evaluated and patients with a history of retinopathy or at risk of retinal detachment will be excluded from future SBP-101 studies. The safety data and PMI profile observed in the previous Panbela-sponsored clinical trials provide support for continued evaluation of ivospemin in the ASPIRE trial. For more information, please visit **https://clinicaltrials.gov/study/NCT03412799**.

Flynpovi™
Flynpovi is a combination of CPP-1X (eflornithine) and sulindac with a dual mechanism

inhibiting polyamine synthesis and increasing polyamine export and catabolism. In a Phase 3 clinical trial in patients with sporadic large bowel polyps, the combination prevented > 90% subsequent pre-cancerous sporadic adenomas versus placebo. Focusing on FAP patients with lower gastrointestinal tract anatomy in the recent Phase 3 trial comparing Flynpovi to single agent eflornithine and single agent sulindac, FAP patients with lower GI anatomy (patients with an intact colon, retained rectum or surgical pouch), Flynpovi showed statistically significant benefit compared to both single agents ($p \leq 0.02$) in delaying surgical events in the lower GI for up to four years. The safety profile for Flynpovi did not significantly differ from the single agents and supports the continued evaluation of Flynpovi for FAP.

CPP-1X Eflornithine

CPP-1X (eflornithine) is being developed as a single agent tablet or high dose power sachet for several indications including prevention of gastric cancer and recent onset Type 1 diabetes. Preclinical studies as well as Phase 1 or Phase 2 investigator-initiated trials suggest that CPP-1X treatment may be well-tolerated and has potential activity.

About Panbela

Panbela Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing disruptive therapeutics for patients with urgent unmet medical needs. Panbela's lead assets are Ivospemin (SBP-101) and Flynpovi. Further information can be found at **www.panbela.com**. Panbela's common stock is listed on The Nasdaq Stock Market LLC under the symbol "PBLA".

Cautionary Statement Regarding Forward-Looking Statements

This press release contains "forward-looking statements," including within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "anticipate," "design," "may," "plan," and "will." Examples of forward-looking statements include statements we make regarding timing of trials and results of collaborations with third parties and future studies. All statements other than statements of historical fact are statements that should be deemed forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations, and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially and adversely from the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the following: (i) our ability to obtain additional funding to execute our business and clinical development plans; (ii) our lack of diversification and the corresponding risk of an investment in our Company; (iii) our ability to maintain our listing on a national securities exchange; (iv) the progress and success of our clinical development program; (v) our ability to demonstrate the safety and effectiveness of our product

candidates: ivospemin (SBP-101), Flynpovi, and eflornithine (CPP-1X); (vi) our ability to obtain regulatory approvals for our product candidates, SBP-101, Flynpovi and CPP-1X in the United States, the European Union or other international markets; (vii) the market acceptance and level of future sales of our product candidates, SBP-101, Flynpovi and CPP-1X; (viii) the cost and delays in product development that may result from changes in regulatory oversight applicable to our product candidates, SBP-101, Flynpovi and CPP-1X; (ix) the rate of progress in establishing reimbursement arrangements with third-party payors; (x) the effect of competing technological and market developments; (xi) the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims; and (xii) such other factors as discussed in Part I, Item 1A under the caption "Risk Factors" in our most recent Annual Report on Form 10-K, any additional risks presented in our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K. Any forward-looking statement made by us in this press release is based on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement or reasons why actual results would differ from those anticipated in any such forward-looking statement, whether written or oral, whether as a result of new information, future developments or otherwise.

Contact Information:

Investors:
James Carbonara
Hayden IR
(646) 755-7412
james@haydenir.com

Media:
Tammy Groene
Panbela Therapeutics, Inc.
(952) 479-1196

Panbela Therapeutics, Inc.

Consolidated Statements of Operations and Comprehensive Loss (unaudited)

(In thousands, except share and per share amounts)

	Three months ended September 30,			Nine months ended September 30,		
	2023	2022	Percent Change	2023	2022	Percent Change
Operating expenses:						
General and administrative	$ 1,107	$ 1,294	-14.5%	$ 4,102	$ 4,349	-5.7%
Research and development	6,739	2,329	189.4%	14,501	24,563	-41.0%
Operating loss	(7,846)	(3,623)	116.6%	(18,603)	(28,912)	-35.7%
Other income (expense):						
Interest income	49	6	-	114	10	1040.0%
Gain on sale of intellectual property	400	-	-	-	-	-
Interest expense	(71)	(87)	-18.4%	(245)	(107)	129.0%
Other income (expense)	(382)	(754)	-49.3%	(622)	(1,293)	-51.9%
Total other income (expense)	(4)	(835)	-99.5%	(753)	(1,390)	-45.8%
Loss before income tax benefit	(7,850)	(4,458)	76.1%	(19,356)	(30,302)	-36.1%
Income tax benefit	19	56	-66.1%	167	104	60.6%
Net loss	(7,831)	(4,402)	77.9%	(19,189)	(30,198)	-36.5%
Foreign currency translation adjustment	381	727	-47.6%	612	1,240	-50.6%
Comprehensive Loss	$ (7,450)	$ (3,675)	102.7%	$ (18,577)	$ (28,958)	-35.8%
Basic and diluted net loss per share	$ (2.69)	$ (257.36)	-99.0%	$ (14.35)	$ (2,255.96)	-99.4%
Weighted average shares outstanding - basic and diluted	2,914,600	17,107	16937.5%	1,309,137	13,386	9679.9%

Panbela Therapeutics, Inc.
Consolidated Balance Sheets (unaudited)
(In thousands, except share amounts)

	September 30, 2023	December 31, 2022
ASSETS	(Unaudited)	
Current assets:		
Cash and cash equivalents	$ 907	$ 1,285
Prepaid expenses and other current assets	824	443
Income tax receivable	155	49
Total current assets	1,886	1,777
Other non-current assets	8,742	3,201
Total assets	$ 10,628	$ 4,978
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 6,612	$ 2,865
Accrued expenses	1,133	2,993
Accrued interest payable	172	325
Note payable	-	650
Debt, current portion	1,000	1,000
Total current liabilities	8,917	7,833
Debt, net of current portion	4,194	5,194
Total non-current liabilities	4,194	5,194
Total liabilities	13,111	13,027
Stockholders' deficit:		
Preferred stock, $0.001 par value; 10,000,000 authorized; no shares issued or outstanding as of September 30, 2023 and December 31, 2022	-	-
Common stock, $0.001 par value; 100,000,000 authorized; 2,996,753 and 34,761 shares issued, and 2,996,334 and 34,761 outstanding as of September 30, 2023 and December 31, 2022, respectively	3	-
Treasury Stock at cost; 419 and 0 shares as of September 30, 2023 and December 31, 2022, respectively	-	-
Additional paid-in capital	106,026	82,286
Accumulated deficit	(109,883)	(91,094)
Accumulated comprehensive income	1,371	759
Total stockholders' deficit	(2,483)	(8,049)
Total liabilities and stockholders' deficit	$ 10,628	$ 4,978

Panbela Therapeutics, Inc.
Consolidated Statements of Cash Flows (unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (18,789)	$ (30,198)
Adjustments to reconcile net loss to net cash used in operating activities:		
Write off of in process research and development (IPR&D)	-	17,737
Stock-based compensation	699	857
Non-cash interest expense	172	97
Gain on sale of intellectual property	(400)	-
Changes in operating assets and liabilities:		
Income tax receivable	(112)	302
Prepaid expenses and other current assets	(381)	(451)
Other non-current assets	(5,541)	(2,561)
Accounts payable	4,370	5,392
Accrued liabilities	(2,187)	(1,448)
Net cash used in operating activities	(22,169)	(10,273)
Cash flows from investing activities:		
Investment in IPR&D	-	(660)
Proceeds from sale of intellectual property	400	-
Cash acquired in merger	-	4
Net cash used in investing activities	400	(656)
Cash flows from financing activities:		
Proceeds from sale of common stock and warrants, net of $2.1 million of offering costs	23,052	-
Cash paid for fractional shares	(9)	-
Proceeds from exercise of stock purchase warrants	-	5
Principal payments on notes	(1,650)	-
Net cash provided by financing activities	21,393	5
Effect of exchange rate changes on cash	(2)	(2)
Net change in cash	(378)	(10,926)
Cash and cash equivalents at beginning of period	1,285	11,867
Cash and cash equivalents at end of period	$ 907	$ 941
Supplemental disclosure of cash flow information:		
Cash paid during period for interest	$ 398	$ 9
Supplemental disclosure of non-cash transactions:		
Fair value of common stock, stock options and stock warrants issued as consideration for asset acquisition	$ -	$ 9,605