Panbela Provides Business Update and Reports Q4 and FY 2024 Financial Results

MINNEAPOLIS, March 26, 2024 (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 and full year ended December 31, 2023. As previously announced, management is hosting earnings call today at 4:30 p.m. ET.

2023 and early 2024 Highlights:

Collaborations

- Divestiture of Assets within Eflornithine (DFMO) Pediatric Neuroblastoma Program to US WorldMeds – Panbela to receive up to $9.5 Million
- Entered into Sponsored Research Agreement with MD Anderson Cancer Center to Evaluate Polyamine Metabolic Inhibitor Therapy in Combination with CAR-T Cell Therapy and bispecific monoclonal antibodies
- New Research Agreement with Johns Hopkins University School of Medicine

Clinical

- Acceptance of Ivospemin (SBP-101) Abstract for Poster Presentation at American Association for Cancer Research (AACR) meeting April 5-10, 2024
- ASPIRE trial exceeded 50% enrollment; complete enrollment of approximately 600 patients anticipated by Q1 2025
- Publication of Clinical Data: *Phase 1 study of high-dose DFMO, celecoxib, cyclophosphamide and topotecan for patients with relapsed neuroblastoma: a New Approaches to Neuroblastoma Therapy trial. Br J Cancer 130, 788–797 (2024)*
- Opened – Phase I non-small cell lung cancer (NSCLC) Trial
- Opened – Phase II recent onset Type I Diabetes Trial
- Announced Futility Analysis Phase III Colon Cancer Risk Reduction Trial (PACES) – trial continues without modification
- Adoption of Commission Implementing Decision from the EMA for Orphan Designation of Ivospemin (SBP-101)
- Prespecified Safety Analysis by Data Safety Monitoring Board (DSMB) for the ASPIRE Trial – continue without modification (two meetings held: July and November)

- Publication of Phase I Type I early onset Diabetes Data: *Inhibition of Polyamine Biosynthesis Preserves β Cell Function in Type 1 Diabetes.* Cell Rep Med. 2023 Nov 21; 4(11):102161. Doi:10.1016/j.xcrm.2023.101261.Epub 2023 Nov 1

Financial / Business

- In aggregate, closed $39.1 million gross proceeds from equity during 2023 and Q1 2024
- Validation of European Patent for Claims of a Novel Process for the Production of SBP-101 (ivospemin)
- Issuance of New Patent in China, Australia, and Japan for Claims of a Novel Process for the Production of SBP-101 (ivospemin)
- Issuance of New Patent in Chile for Claims of a Novel Process for the Production of Flynpovi

“For Panbela, 2023 and early 2024 has been characterized by remarkable achievements across collaborations, clinical endeavors, and financial milestones. Significantly, our Phase III ASPIRE trial for untreated metastatic pancreatic ductal adenocarcinoma exceeded 50% enrollment and we anticipate full enrollment of approximately 600 patients to be completed by the first quarter of 2025. With the recent approval of Onivyde in first line metastatic pancreatic cancer, the first approval in this space in approximately 11 years, we are encouraged and look forward to our interim analysis and the potential for another option for metastatic pancreatic cancer patients,” said Jennifer K. Simpson, PhD, MSN, CRNP, President & CEO of Panbela. “Looking ahead, Panbela remains unwavering in its commitment to patients and in its pursuit of maximizing value for stockholders. We are progressing towards several catalysts, including the overall survival interim analysis in our Phase III ASPIRE Trial."

Fourth Quarter ended December 31, 2023 Financial Results

General and administrative expenses were $0.9 million in the fourth quarter of 2023, compared to $1.7 million in the fourth quarter of 2022.

Research and development expenses were $6.1 million in the fourth quarter of 2023, compared to $3.5 million in the fourth quarter of 2022.

Net loss in the fourth quarter of 2023 was $6.5 million, or $65.90 per diluted share, compared to a net loss of $4.7 million, or $344.61 per diluted share, in the fourth quarter of 2022.

Total cash was $2.6 million as of December 31, 2023. Total current assets were $3.1 million and current liabilities were $12.3 million as of the same date. Notes payable, plus accrued interest, on the balance sheet, the result of the acquisition of CPP, totaled approximately $5.4 million. The current portion of the notes payable plus accrued interest totaled approximately $1.2 million and was paid to the noteholder in the first quarter of 2024.

Subsequent to the end of the year, the Company completed a registered public offering. Gross proceeds from the raise, which closed on January 31, 2024, were approximately $9 million.

Conference Call Information

March 26, 2024 at 4:30PM EST

Toll Free: 888-506-0062
International: 973-528-0011
Participant Access Code: 195310
Webcast Link: https://www.webcaster4.com/Webcast/Page/2556/49978

Conference Call Replay Information

Toll Free: 877-481-4010
International: 919-882-2331
Replay Passcode: 49978
Webcast Replay: https://www.webcaster4.com/Webcast/Page/2556/49978

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" and is currently trading on the OTCPink market under the same ticker. Panbela is currently pursuing a new listing of its common stock on a national securities exchange.

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 obtain or 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.

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Panbela Therapeutics, Inc.

Consolidated Statements of Operations and Comprehensive Loss (unaudited)

(In thousands, except share and per share amounts)

	Three months ended December 31,			Year ended December 31,		
	2023	2022	Percent Change	2023	2022	Percent Change
Operating expenses:						
General and administrative	$ 931	$ 1,661	-43.9%	$ 5,033	$ 6,044	-16.7%
Research and development	6,116	3,463	76.6%	20,614	28,049	-26.5%
Operating loss	(7,047)	(5,124)	37.5%	(25,647)	(34,093)	-24.8%
Other income (expense):						
Interest income	9	3	200.0%	123	14	778.6%
Gain on sale of intellectual property	-	-	-	400	0	-
Interest expense	(71)	(181)	-60.8%	(317)	(288)	10.1%
Other income (expense)	597	556	7.4%	(8)	(682)	-98.8%
Total other income (expense)	535	378	41.5%	198	(956)	-120.7%
Loss before income tax benefit	(6,512)	(4,746)	37.2%	(25,449)	(35,049)	-27.4%
Income tax benefit	19	13	46.2%	186	116	60.3%
Net loss	(6,493)	(4,733)	37.2%	(25,263)	(34,933)	-27.7%
Foreign currency translation adjustment (loss)	(626)	(615)	1.8%	(14)	626	-102.2%
Comprehensive Loss	$ (7,119)	$ (5,348)	33.1%	$ (25,277)	$ (34,307)	-26.3%
Basic and diluted net loss per share	$ (65.90)	$ (344.61)	-80.9%	$ (316.52)	$ (41,341.21)	-99.2%
Weighted average shares outstanding - basic and diluted	237,234	1,374	17165.9%	108,691	845	12762.8%

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

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,578	$ 1,285
Prepaid expenses and other current assets	299	443
Income tax receivable	183	49
Total current assets	3,060	1,777
Other noncurrent assets	8,742	3,201
Total assets	$ 11,802	$ 4,978
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 9,939	$ 2,865
Accrued expenses	1,141	2,993
Accrued interest payable	238	325
Note payable	-	650
Debt, current portion	1,000	1,000
Total current liabilities	12,318	7,833
Debt, net of current portion	4,194	5,194
Total non current liabilities	4,194	5,194
Total liabilities	16,512	13,027
Stockholders' deficit:		
Preferred stock, $0.001 par value; 10,000,000 authorized; no shares issued or outstanding as of December 31, 2023 and December 31, 2022	-	-
Common stock, $0.001 par value; 100,000,000 authorized; 480,095 and 1,738 shares issued, and 480,025 and 1,738 shares outstanding, as of December 31, 2023 and December 31, 2022, respectively	-	-
Treasury Stock at cost; 70 and 0 shares as of December 31, 2023 and December 31, 2022, respectively	(1)	-
Additional paid-in capital	120,043	82,286
Accumulated deficit	(125,497)	(91,094)
Accumulated comprehensive income	745	759
Total stockholders' deficit	(4,710)	(8,049)
Total liabilities and stockholders' deficit	$ 11,802	$ 4,978

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

	Year Ended December 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (25,263)	$ (34,933)
Adjustments to reconcile net loss to net cash used in operating activities:		
Write off of in process research and development (IPR&D)	-	17,737
Gain on sale of intellectual property	(400)	-
Stock-based compensation	823	1,088
Non-cash interest expense	238	273
Changes in operating assets and liabilities:		
Income tax receivable	(132)	212
Prepaid expenses and other current assets	145	(127)
Deposits held for clinical trial costs	(5,541)	(2,561)
Accounts payable	7,060	2,249
Accrued liabilities	(2,179)	786
Net cash used in operating activities	(25,249)	(15,276)
Cash flows from investing activities:		
Proceeds from sale of intellectual property	400	-
Investment in IPR&D	-	(660)
Cash acquired in merger	-	4
Net cash used in investing activities	400	(656)
Cash flows from financing activities:		
Proceeds from sale of common stock,net of fees and offering costs, $49 and $47 respectively	1,597	46
Proceeds from public offering of common stock and warrants net of underwriters discount and offering costs of $2,075 and $727 respectively	21,456	5,303
Proceeds from induced exercise of warrants, net of costs of $359	3,526	-
Proceeds from voluntary exercise of warrants	1,223	5
Payments made on notes payable	(1,650)	-
Cash paid for fractional shares	(10)	
Net cash provided by financing activities	26,142	5,354
Effect of exchange rate changes on cash	-	(4)
Net change in cash	1,293	(10,582)
Cash and cash equivalents at beginning of year	1,285	11,867
Cash and cash equivalents at end of year	$ 2,578	$ 1,285
Supplemental disclosure of cash flow information:		
Cash paid during period for interest	$ 404	$ 15
Supplemental disclosure of non-cash transactions:		
Fair value of common stock, stock options and stock warrants issued as consideration for asset acquisition	$ -	$ 9,605
Adjustment for the value offered to induce warrant exercise	$ 9,140	$ -