Panbela Provides Business Update and Reports Q2 2024 Financial Results

MINNEAPOLIS, August 13, 2024 (GLOBE NEWSWIRE) -- Panbela Therapeutics, Inc. (OTCQB: 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 June 30, 2024. As previously announced, management is hosting an earnings call today at 4:30 p.m. ET.

Q2 2024 and Recent Highlights:

Clinical

- Phase 3 ASPIRE clinical trial received favorable third independent safety review: DSMB recommended continuation without modification.

- Completed Oral Presentation at Digestive Disease Week (DDW): Evaluation of the Safety and Efficacy of Eflornithine (Difluoromethylornithine, DFMO) in Patients with Gastric Premalignant Conditions in the High Incidence Areas of Latin American.

- Provided revised timing for the interim data analysis for its ongoing ASPIRE trial, evaluating ivospemin (SBP-101) in combination with standard-of-care for metastatic pancreatic ductal adenocarcinoma (mPDAC). The analysis is now expected in Q1 2025 due to a lower-than-anticipated event rate, which suggests the potential for improved survival outcomes for patients in the trial.

Financial / Business

- Gained eligibility for quotation of common stock on the OTCQB.

- Issuance of a New Patent in the US and Canada for Claims of a Fixed Dose Combination of Eflornithine and Sulindac.

Jennifer K. Simpson, PhD, MSN, CRNP, President & CEO of Panbela, commented:

"In the second quarter, we continued to make significant progress in our clinical programs and corporate initiatives. Our Phase III ASPIRE clinical trial received a favorable third independent safety review, with the Data and Safety Monitoring Board (DSMB) recommending continuation without modification. We were also honored to have an oral presentation at Digestive Disease

Week (DDW), where we evaluated the safety and efficacy of eflornithine (difluoromethylornithine, DFMO) in patients with gastric premalignant conditions in high incidence areas of Latin America.

Furthermore, we recently announced revised timing for the interim data analysis of our ongoing ASPIRE trial, evaluating ivospemin (SBP-101) in combination with standard-of-care for metastatic pancreatic ductal adenocarcinoma (mPDAC). Due to a lower-than-anticipated event rate, which suggests the potential for improved survival outcomes for patients in the trial, the analysis is now expected in Q1 2025. This is a testament to the potential of our lead candidate, ivospemin, and its ability to make a meaningful difference in the lives of patients with mPDAC.

As we move forward, Panbela remains committed to advancing our clinical programs, exploring new indications, and creating value for our stockholders. With several key milestones on the horizon, including the highly anticipated overall survival interim analysis in our Phase III ASPIRE Trial, we are excited about the future and the potential impact our therapies can have on patients in need."

Second Quarter ended June 30, 2024 Financial Results

General and administrative expenses were approximately $1.1 million in the quarter, compared to $1.6 million in the same period last year. The decrease is due primarily to reduced legal and compensation expense.

Research and development expenses were approximately $7.0 million, compared to $4.2 million in the same period last year. This increase is primarily due to significant growth in the number of active sites and enrollment in project ASPIRE.

Net loss in the quarter was approximately $7.1 million, or $1.47 per diluted share, compared to a net loss of $5.8 million, or $159.15 per diluted share, in the same period last year. This increased loss is due to the incremental research and development expenses.

Total cash was $59,000 as of June 30, 2024. Total current assets were $0.8 million and current liabilities were $16.8 million as of the same date. In April, Panbela's partner in Pediatric Neuroblastoma, US WorldMeds®, provided a nondilutive payment of approximately $0.8 million in exchange for a reduction in the potential future milestone payments. In July, Panela secured a loan from this same partner for $1.5 million.

Notes payable, plus accrued interest, on the balance sheet, the result of the acquisition of Cancer Prevention Pharmaceuticals, Inc., totaled approximately $4.3 million. The current portion of the notes payable plus accrued interest totaled approximately $1.1 million.

Conference Call Information

Toll Free: 888-506-0062
International: 973-528-0011
Participant Access Code: 405072
Webcast Link: https://www.webcaster4.com/Webcast/Page/2556/50956

Conference Call Replay Information

Toll Free: 877-481-4010
International: 919-882-2331
Replay Passcode: 50956
Webcast Replay: https://www.webcaster4.com/Webcast/Page/2556/50956

The replay will be available within approximately two hours after the completion of the call for approximately one year.

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 III 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 eligible for quotation on the OTCQB under the symbol "PBLA".

Cautionary Statement Regarding Forward-Looking Statements

This press release contains "forward-looking statements, "which can be identified by words such as: "anticipate," "design," "hope," "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 capital, on acceptable terms or at all, required to implement our business plan; (ii) our lack of diversification and the corresponding risk of an investment in our Company and the corresponding risk of potential deterioration of our financial condition and results due to failure to diversify; (iii) our ability to obtain and maintain our listing on a national securities exchange; (iv) results, progress and success of our randomized Phase Ia/Ib and Phase II/III clinical trials; (v) our ability to demonstrate the safety and effectiveness of our product candidates: ivospemin (SBP-101), Flynpovi, and eflornithine (CPP-1X); (vi) potential delays or risks to the

success of our randomized Phase II/III clinical trial resulting from a termination in our relationship with our CRO; (vii) 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; (viii) the market acceptance and level of future sales of our product candidates, SBP-101, Flynpovi and CPP-1X ; (ix) 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 ; (x) the rate of progress in establishing reimbursement arrangements with third-party payors; (xi) the effect of competing technological and market developments; (xii) the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims; and (xiii) 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 June 30,			Six months ended June 30,		
	2024	2023	Percent Change	2024	2023	Percent Change
Operating expenses:						
General and administrative	$ 1,106	$ 1,643	-32.7%	$ 2,310	$ 2,995	-22.9%
Research and development	6,997	4,234	65.3%	12,519	7,750	61.5%
Operating loss	(8,103)	(5,877)	37.9%	(14,829)	(10,745)	38.0%
Other income (expense):						
Interest income	-	49	-100.0%	-	65	-100.0%
Gain on sale of intellectual property	775	-	-	775	-	-
Interest expense	(59)	(70)	-15.7%	(121)	(173)	-30.1%
Other income (expense)	248	(82)	-402.4%	(223)	(247)	-9.7%
Total other income (expense)	964	(103)	-1035.9%	431	(355)	-221.4%
Loss before income tax benefit	(7,139)	(5,980)	19.4%	(14,398)	(11,100)	29.7%
Income tax benefit	-	147	-100.0%	138	149	-7.4%
Net loss	(7,139)	(5,833)	22.4%	(14,260)	(10,951)	30.2%
Foreign currency translation adjustment	(242)	68	-455.9%	217	231	-6.1%
Comprehensive Loss	$ (7,381)	$ (5,765)	28.0%	$ (14,043)	$ (10,720)	31.0%
Basic and diluted net loss per share	$ (1.47)	$ (159.15)	-99.1%	$ (3.58)	$ (441.77)	-99.2%
Weighted average shares outstanding - basic and diluted	4,854,861	36,650	13146.6%	3,984,355	24,790	15972.4%

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

	June 30, 2024	December 31, 2023
ASSETS	(Unaudited)	
Current assets:		
Cash and cash equivalents	$ 59	$ 2,578
Prepaid expenses and other current assets	393	299
Income tax receivable	320	183
Total current assets	772	3,060
Other non-current assets	8,642	8,742
Total assets	$ 9,414	$ 11,802
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 14,293	$ 9,939
Accrued expenses	1,408	1,141
Accrued interest payable	87	238
Debt, current portion	1,000	1,000
Total current liabilities	16,788	12,318
Debt, net of current portion	3,194	4,194
Total non-current liabilities	3,194	4,194
Total liabilities	19,982	16,512
Stockholders' deficit:		
Preferred stock, $0.001 par value; 10,000,000 authorized; no shares issued or outstanding as of June 30, 2024 and December 31, 2023	-	-
Common stock, $0.001 par value; 100,000,000 authorized; 4,854,931 and 480,095 issued as of June 30, 2024 and December 31, 2023 respectively; 4,854,861 and 480,025 shares outstanding as of June 30, 2024 and December 31, 2023, respectively	5	-
Treasury Stock at cost; 70 shares at both of June 30, 2024 and December 31, 2023	(1)	(1)
Additional paid-in capital	128,223	120,043
Accumulated deficit	(139,757)	(125,497)
Accumulated comprehensive income	962	745
Total stockholders' deficit	(10,568)	(4,710)
Total liabilities and stockholders' deficit	$ 9,414	$ 11,802

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

	Six Months Ended June 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (14,260)	$ (10,951)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	103	509
Non-cash interest expense	87	107
Gain on sale of intellectual property	(775)	-
Changes in operating assets and liabilities:		
Income tax receivable	(140)	(149)
Prepaid expenses and other current assets	(96)	(2,967)
Other non-current assets	100	(5,541)
Accounts payable	4,578	5,811
Accrued liabilities	30	(2,311)
Net cash used in operating activities	(10,373)	(15,492)
Cash flows from investing activities:		
Proceeds from sale of intellectual property	775	-
Net cash provided by investing activities	775	-
Cash flows from financing activities:		
Proceeds from public offering of common stock and warrants, net of fees and offering costs of $0.9 million and $2.1 million respectively	8,082	23,071
Cash paid for fractional shares	-	(9)
Principal payments on notes	(1,000)	(1,650)
Net cash provided by financing activities	7,082	21,412
Effect of exchange rate changes on cash	(3)	-
Net change in cash	(2,519)	5,920
Cash and cash equivalents at beginning of period	2,578	1,285
Cash and cash equivalents at end of period	$ 59	$ 7,205
Supplemental disclosure of cash flow information:		
Cash paid during period for interest	$ 272	$ 386
Supplemental disclosure of non-cash transactions:		
Cashless exercise of warrants	$ -	$ (8)