Panbela Provides Business Update and Reports Q1 2024 Financial Results

MINNEAPOLIS, May 15, 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 March 31, 2024. As previously announced, management is hosting earnings call today at 4:30 p.m. ET.

Q1 2024 and recent Highlights:

Clinical

- Announced 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 high potential for improved survival outcomes for patients in the trial.

- Poster presentation of Ivospemin (SBP-101) at AACR highlighting the efficacy of SBP-101 in combination with doxorubicin to treat platinum-resistant ovarian cancer

- ASPIRE trial has 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)*

Financial / Business

- Gained eligibility for quotation of common stock on the OTCQB

- Closed $9.0 million public offering of common stock and warrants

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

"We were thrilled to announce that our ongoing ASPIRE trial, evaluating ivospemin (SBP-101) in combination with standard-of-care for metastatic pancreatic ductal adenocarcinoma, or mPDAC, is now expected to reach its interim data analysis in the first quarter of 2025, due to a lower-than-anticipated event rate, suggesting improved survival outcomes for patients in the trial. This gives us hope for meaningful advancements in mPDAC treatment beyond the incremental benefits seen with recently approved therapies," said Jennifer K. Simpson, PhD, MSN, CRNP, President & CEO of Panbela.

"In addition to the progress in our ASPIRE trial, which has now exceeded 50% enrollment with complete enrollment of approximately 600 patients anticipated by Q1 2025, we were pleased to present a poster highlighting the efficacy of SBP-101 in combination with doxorubicin for treating platinum-resistant ovarian cancer at AACR. We also welcomed the publication of clinical data from our Phase I study of high-dose DFMO, celecoxib, cyclophosphamide, and topotecan for patients with relapsed neuroblastoma in the British Journal of Cancer. On the financial and business front, we announced the transfer of our common stock to the OTCQB market and successfully closed a $9.0 million public offering. As we look ahead, Panbela remains steadfast in its commitment to improving patient outcomes and driving value for our stockholders, with several key catalysts on the horizon, including the highly anticipated overall survival interim analysis in our Phase III ASPIRE Trial."

First Quarter ended March 31, 2024 Financial Results

General and administrative expenses were approximately $1.2 million in the quarter, compared to $1.4 million in the same period last year. The decrease is due primarily to reduced legal and other professional services.

Research and development expenses were approximately $5.5 million, compared to $3.5 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 $2.28 per diluted share, compared to a net loss of $5.1 million, or $392.76 per diluted share, in the same period last year. This increased loss is due to the incremental research and development expenses.

Total cash was $262,000 as of March 31, 2024. Total current assets were $1.8 million and current liabilities were $10.5 million as of the same date. In April the Company’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.

Notes payable, plus accrued interest, on the balance sheet, the result of the acquisition of CPP, totaled approximately $4.2 million. The current portion of the notes payable plus accrued interest totaled approximately $1.3 million and was paid to the noteholder in the first quarter of 2024.

During the first quarter, the Company completed a registered public offering. Net proceeds from the raise, which closed on January 31, 2024, were approximately $8.1 million.

Conference Call Information

May 15, 2024 at 4:30PM EST

Toll Free: 877-545-0523
International: 973-528-0016
Participant Access Code: 234396
Webcast Link: https://www.webcaster4.com/Webcast/Page/2556/50531

Conference Call Replay Information

Toll Free: 877-481-4010
International: 919-882-2331
Replay Passcode: 50531
Webcast Replay: https://www.webcaster4.com/Webcast/Page/2556/50531

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; (iii) our ability to maintain our listing on a national securities exchange; (iv) progress and success of our randomized Phase II/III clinical trial; (v) our ability to demonstrate the safety and effectiveness of our product candidates: ivospemin (SBP-101), Flynpovi, and eflornithine (CPP-1X) (v) 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 March 31,		
	2024	2023	Percent Change
Operating expenses:			
General and administrative	$ 1,204	$ 1,352	-10.9%
Research and development	5,522	3,508	57.4%
Operating loss	(6,726)	(4,860)	38.4%
Other income (expense):			
Interest income	0	16	-
Interest expense	(63)	(102)	-38.2%
Other income (expense)	(469)	(167)	180.8%
Total other income (expense)	(532)	(253)	110.3%
Loss before income tax benefit	(7,258)	(5,113)	42.0%
Income tax benefit	138	-	-
Net loss	(7,120)	(5,113)	39.3%
Foreign currency translation adjustment	459	163	181.6%
Comprehensive Loss	$ (6,661)	$ (4,950)	34.6%
Basic and diluted net loss per share	$ (2.28)	$ (392.76)	-99.4%
Weighted average shares outstanding - basic and diluted	3,125,835	13,018	23911.6%

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

	March 31, 2024	December 31, 2023
ASSETS	(Unaudited)	
Current assets:		
Cash and cash equivalents	$ 262	$ 2,578
Prepaid expenses and other current assets	1,210	299
Income tax receivable	313	183
Total current assets	1,785	3,060
Other non-current assets	8,742	8,742
Total assets	$ 10,527	$ 11,802
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 8,506	$ 9,939
Accrued expenses	979	1,141
Accrued interest payable	34	238
Debt, current portion	1,000	1,000
Total current liabilities	10,519	12,318
Debt, net of current portion	3,194	4,194
Total non-current liabilities	3,194	4,194
Total liabilities	13,713	16,512
Stockholders' deficit:		
Preferred stock, $0.001 par value; 10,000,000 authorized; no shares issued or outstanding as of March 31, 2024 and December 31, 2023	-	-
Common stock, $0.001 par value; 100,000,000 authorized; 4,854,931 and 480,095 issued as of March 31, 2024 and December 31, 2023 respectively; 4,854,861 and 480,025 shares outstanding as of March 31, 2024 and December 31, 2023, respectively	5	-
Treasury Stock at cost; 70 shares at both of March 31, 2024 and December 31, 2023	(1)	(1)
Additional paid-in capital	128,223	120,043
Accumulated deficit	(132,617)	(125,497)
Accumulated comprehensive income	1,204	745
Total stockholders' deficit	(3,186)	(4,710)
Total liabilities and stockholders' deficit	$ 10,527	$ 11,802

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

	Three Months Ended March 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (7,120)	$ (5,113)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	103	180
Non-cash interest expense	34	42
Changes in operating assets and liabilities:		
Income tax receivable	(140)	-
Prepaid expenses and other current assets	(912)	(2,108)
Other non-current assets	-	(5,441)
Accounts payable	(957)	4,644
Accrued liabilities	(400)	(1,955)
Net cash used in operating activities	(9,392)	(9,751)
Cash flows from financing activities:		
Proceeds from public offering of common stock and warrants net of underwriters discount and offering costs of $926 and $1,302 respectively	8,082	15,358
Cash paid for fractional shares	-	(4)
Principal payments on notes	(1,000)	(1,650)
Net cash provided by financing activities	7,082	13,704
Effect of exchange rate changes on cash	(6)	(3)
Net change in cash	(2,316)	3,950
Cash and cash equivalents at beginning of period	2,578	1,285
Cash and cash equivalents at end of period	$ 262	$ 5,235
Supplemental disclosure of cash flow information:		
Cash paid during period for interest	$ 266	$ 386
Supplemental disclosure of non-cash transactions:		
Cashless exercise of warrants	$ -	$ (8)