Sun BioPharma, Inc. Provides Business Update and Reports Q3 2020 Financial Results

MINNEAPOLIS, November 12, 2020 (GLOBE NEWSWIRE) -- Sun BioPharma, Inc. (Nasdaq: SNBP), a clinical stage biopharmaceutical company developing disruptive therapeutics for the treatment of patients with pancreatic cancer, today provides a business update and reports financial results for the quarter ended September 30, 2020. Management is hosting an earnings call today at 4:30 p.m. ET.

The third quarter of 2020 was marked by meaningful corporate, financial and clinical progress.

Highlights

- New CEO appointed on July 15, 2020
- Fast Track designation received for SBP-101
- Uplisted to Nasdaq Capital Market
- Closed $10.5 Million Public Offering

“During the third quarter we strengthened our leadership team, bolstered the balance sheet and broadened our potential investor audience by uplisting to Nasdaq,” said Jennifer K. Simpson, PhD, MSN, CRNP President & Chief Executive Officer of Sun BioPharma. “These Q3 accomplishments lay the foundation to execute on near-term milestones. Those upcoming milestones include completing SBP-101’s enrollment in the current Phase 1b trial in Q4 2020, reporting data from our Phase 1 trial in 1H 2021, initiating a randomized Phase 2 study in 1H 2021 while evaluating additional opportunities for SBP-101. Looking ahead, we’re focused on rapidly advancing SBP-101’s clinical development to create significant shareholder value.”

Based on interim data from our Phase I trial, SBP-101 demonstrated a 54% objective response rate in combination with gemcitabine & abraxane (G&A); more than double historical standard of care for metastatic pancreatic cancer with G&A.

We believe SBP-101 has the potential to expand into other cancers with known elevated levels of polyamine metabolism.

Upcoming Milestones

- Completion of enrollment in the expansion cohort targeting (Q4'20)
- Data from phase 1 trial (1H'21)

- Conference presentations (1H'21 or 2H'21)

- Initiation of randomized phase 2 study (1H'21)

Third Quarter ended September 30, 2020 Financial Results

General and administrative expenses increased to $1.2 million in the third quarter of 2020, up from $0.6 million in the third quarter of 2019. The change in the third quarter is due primarily to increased employee compensation expense.

Research and development expenses increased to $0.8 million in the third quarter of 2020, up from $0.7 million in the third quarter of 2019. The change in the third quarter is due to increased spending on the company's clinical study.

Operating expenses in the third quarter of 2020 were partially offset by a foreign currency exchange gain on the intercompany receivable balance; for the same quarter in 2019 other expense, net was primarily a foreign currency exchange loss.

Net loss in the third quarter of 2020 was $1.7 million, or $0.21 per diluted share, compared to a net loss of $1.4 million, or $0.23 per diluted share, in the third quarter of 2019.

Total cash was $10.9 million as of September 30, 2020. Total current assets were $11.4 million and current liabilities were $1.9 million as of the same date.

Conference Call Information

To participate in this event, dial approximately 5 to 10 minutes before the beginning of the call.

Date: November 12, 2020
Time: 4:30 PM Eastern Time
Toll Free: 877-407-9205
International: 201-689-8054

A replay of the call will be available from November 13, 2020 through November 26, 2020

Toll Free: 877-481-4010
International: 919-882-2331
Replay Passcode: 38324

The call will also be available over the Internet and accessible at:
https://www.webcaster4.com/Webcast/Page/2556/38324

About SBP-101

SBP-101 is a proprietary polyamine analogue designed to induce polyamine metabolic inhibition (PMI) by exploiting an observed high affinity of the compound for the exocrine pancreas and pancreatic ductal adenocarcinoma. The molecule has shown signals of tumor growth inhibition in clinical studies of US and Australian metastatic pancreatic cancer patients, suggesting complementary activity with an existing FDA-approved chemotherapy regimen. In clinical studies to date, SBP-101 has not shown exacerbation of the typical chemotherapy-related adverse events of bone marrow suppression and peripheral neuropathy. The safety data and PMI profile observed in Sun BioPharma's current clinical trial provides support for continued evaluation of the compound in a randomized clinical trial. For more information, please visit **https://clinicaltrials.gov/ct2/show/NCT03412799**.

About Sun BioPharma

Sun BioPharma Inc. is a clinical-stage biopharmaceutical company developing disruptive therapeutics for patients with urgent unmet medical needs. The company's initial product candidate, SBP-101, is for the treatment of patients with metastatic pancreatic ductal adenocarcinoma, the most common type of pancreatic cancer. Sun BioPharma Inc. is dedicated to treating patients with pancreatic cancer and exploring SBP-101's potential for efficacy in combination with other agents and in treating other types of cancer. SBP-101 was invented by Raymond J. Bergeron, PhD, a Distinguished Professor Emeritus at the University of Florida. Sun BioPharma has scientific collaborations with pancreatic disease experts at Cedars Sinai Medical Center in Los Angeles, the University of Rochester in New York, Scripps MD Anderson Cancer Center in San Diego, California, the University of Florida, the Austin Health Cancer Trials Centre in Melbourne, Australia, the Ashford Cancer Centre in Adelaide, Australia, the Blacktown Cancer and Haematology Centre in Sydney, Australia and the John Flynn Private Hospital in Tugun, Queensland, Australia. The company's independent Data Safety Monitoring Board (DSMB) is Chaired by James Abbruzzese, MD, Professor of Medicine, and Chief, Division of Medical Oncology at Duke University School of Medicine. Professor David Goldstein, FRACP, Senior Staff Specialist at the Prince Henry & Prince of Wales Hospital / Cancer Care Centre in Sydney, Australia is Co-Chair of the DSMB. Further information can be found at: **www.sunbiopharma.com**. Sun BioPharma's common stock is listed on The Nasdaq Stock Market LLC under the symbol SNBP.

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: "believes," "dedicated," "expects," "intends," "may," "milestone," or "plans." Examples of forward-looking statements include, among others, statements we make regarding, potential effects of FDA Fast Track designation, future determinations of the characteristics of SBP-101 and its effectiveness, uses of proceeds from recent financings. 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 complete Phase 1 clinical trial; (ii) progress and success of our Phase 1 clinical trial; (iii) the impact of the current COVID-19 pandemic on our ability to complete enrollment in our current clinical trial; (iv) our ability to demonstrate the safety and effectiveness of our SBP-101 product candidate (v) our ability to obtain regulatory approvals for our SBP-101 product candidate in the United States, the European Union or other international markets; (vi) the market acceptance and level of future sales of our SBP-101 product candidate; (vii) the cost and delays in product development that may result from changes in regulatory oversight applicable to our SBP-101 product candidate; (viii) the rate of progress in establishing reimbursement arrangements with third-party payors; (ix) the effect of competing technological and market developments; (x) the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims; and (xi) 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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Sun BioPharma, 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,		
	2020	2019	Percent Change	2020	2019	Percent Change
Operating expenses:						
General and administrative	$ 1,223	$ 622	96.6%	$ 2,348	$ 1,505	56.0%
Research and development	773	720	7.4%	1,805	1,578	14.4%
Operating loss	(1,996)	(1,342)	48.7%	(4,153)	(3,083)	34.7%
Other income (expense):						
Interest expense	(3)	(3)	0.0%	(12)	(2,187)	-99.5%
Other income	239	(219)	-209.1%	55	(287)	-119.2%
Total other income (expense)	236	(222)	-206.3%	43	(2,474)	-101.7%
Loss before income tax benefit	(1,760)	(1,564)	12.5%	(4,110)	(5,557)	-26.0%
Income tax benefit	89	190	-53.2%	222	331	-32.9%
Net loss	(1,671)	(1,374)	21.6%	(3,888)	(5,226)	-25.6%
Foreign currency translation adjustment (loss)	(246)	202	-221.8%	(164)	219	-174.9%
Comprehensive Loss	$ (1,917)	$ (1,172)	63.6%	$ (4,052)	$ (5,007)	-19.1%
Basic and diluted net loss per share	$ (0.21)	$ (0.23)	-8.7%	$ (0.55)	$ (0.97)	-43.3%
Weighted average shares outstanding - basic and diluted	7,888,609	6,009,904	31.3%	7,085,326	5,385,986	31.6%

Sun BioPharma, Inc.
Consolidated Balance Sheets (unaudited)
(In thousands, except share amounts)

	September 30, 2020	December 31, 2019
ASSETS	(Unaudited)	
Current assets:		
Cash	$ 10,870	$ 2,449
Prepaid expenses and other current assets	335	283
Income tax receivable	228	361
Total current assets	11,433	3,093
Other noncurrent assets	52	51
Total assets	$ 11,485	$ 3,144
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 422	$ 597
Accrued expenses	632	304
Term debt	37	116
Payroll protection plan loan	103	-
Unsecured promissory note payable	742	742
Total current liabilities	1,936	1,759
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 authorized; no shares issued or outstanding as of September 30, 2020 and December 31 2019	-	-
Common stock, $0.001 par value; 100,000,000 authorized; 9,649,427 and 6,631,308 shares issued and outstanding as of September 30, 2020 and December 31, 2019 respectively	10	7
Additional paid-in capital	54,544	42,331
Accumulated deficit	(45,146)	(41,258)
Accumulated comprehensive income	141	305
Total stockholders' equity	9,549	1,385
Total liabilities and stockholders' equity	$ 11,485	$ 3,144

Sun BioPharma, Inc.
Consolidated Statements of Cash Flows (unaudited)
(In thousands)

	Nine Months Ended September 30	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (3,888)	$ (5,226)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	969	958
Amortization of debt discount	-	2,061
Amortization of debt issuance costs	-	12
Non-cash interest expense	-	102
Changes in operating assets and liabilities:		
Income tax receivable	133	44
Prepaid expenses and other current assets	64	(12)
Accounts payable	(347)	179
Accrued liabilities	328	15
Net cash used in operating activities	(2,741)	(1,867)
Cash flows from financing activities:		
Proceeds from sale of common stock and warrants net of offering costs of $2	1,746	3,142
Proceeds from public offering of common stock and warrants net of underwriters discount and offering costs of $1,165	9,335	-
Proceeds from the sale of convertible promissory notes, net of debt issuance costs of $7	-	810
Proceeds from exercise of warrants	52	-
Proceeds from payroll protection loan	103	-
Repayment of demand note	-	(25)
Repayments of term debt	(81)	(82)
Net cash provided by financing activities	11,155	3,845
Effect of exchange rate changes on cash	7	(6)
Net change in cash	8,421	1,972
Cash at beginning of period	2,449	1,405
Cash at end of period	$ 10,870	$ 3,377
Supplemental disclosure of cash flow information:		
Cash paid during period for interest	$ 5	$ 11
Supplemental disclosure of non-cash transactions:		
Warrants issued for future services	$ 228	$ -
Warrants issued to underwriter	$ 353	$ -
Cashless exercise of warrants	$ 8	$ -
Amortization of warrants as offering costs	$ 114	$ -
Beneficial conversion feature on convertible notes	$ -	$ 353
Warrants issued with convertible notes	$ -	$ 419
Common stock converted into convertible notes payable	$ -	$ 25
Conversion of convertible notes payable and accrued interest into common stock	$ -	$ 2,281
Issuance of unsecured promissory note in exchange of vendor accounts payable	$ -	$ 742