Sun BioPharma, Inc. Provides a Business Update and Reports Q3 2019 Financial Results

- Enrollment in Third Cohort of the PDA Combination Study completed; Fourth Cohort planned
- New U.S. sites added in anticipation of further clinical development
- Company raised $3.1 million in new capital

MINNEAPOLIS, MN, November 13, 2019 (GLOBE NEWSWIRE) – Sun BioPharma, Inc. (OTCQB: 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, 2019.

First-Line Combination Pancreatic Cancer Dose Escalation Study Expanded
The Company's second clinical trial, a Phase 1a/1b combination of SBP-101 with gemcitabine and nab-paclitaxel in patients previously untreated for metastatic pancreatic ductal adenocarcinoma ("PDA"), completed enrollment of patients in the third dose level cohort in October. Following an upcoming meeting of the Data Safety Monitoring Board ("DSMB"), the Company plans to add a fourth cohort to the study protocol to examine an alternative and more convenient dosing schedule.

In anticipation of continued clinical development new sites are now being added in the U.S. The Company has opened new clinical sites at the University of Rochester in Rochester, New York and Scripps MD Anderson Cancer Center in San Diego, California. Several additional sites are planned to be open in the first half of 2020.

Dr. Darren Sigal, director of GI Oncology and Principal Investigator at Scripps Clinic and Scripps MD Anderson commented, "We are pleased to be joining the Sun BioPharma study of SBP-101 for the treatment of patients with pancreatic cancer. More effective treatments remain urgently needed."

Sale of Common Stock and Warrants to Purchase Common Stock Raised $3.1M
The Company completed a private offering of common stock and warrants in September that raised approximately $3.1 million to support ongoing clinical trials. A total of 902,067 shares of common stock were issued as well as warrants to purchase an equal number of shares of common stock.

Amendment to Worldwide Exclusive License of SBP-101 Eliminates Milestone Payments and Reduces Future Royalty Obligations

In early October, Sun BioPharma and the University of Florida Research Foundation ("UFRF") entered into a second amendment to the License Agreement effective December 22, 2011. The license agreement continues to entitle the Company to a worldwide exclusive license from UFRF for the polyamine analogue compound (SBP-101). The second amendment eliminated the Company's obligation to make any future milestone or minimum royalty payments to UFRF. It also reduced the period during which Sun BioPharma is required to pay royalties on future commercial sales of SBP-101.

Financial Results for the Three and Nine months ending September 30, 2019

Operating Results

General and administrative ("G&A") expenses increased 33.2% to $622,000 in the third quarter of 2019 up from $467,000 in the second quarter of 2018. G&A expenses decreased 15.4% to 1.5 million in the nine months ended September 30, 2019, down from $1.8 million in the nine months ended September 30, 2018. The increase in the quarter is primarily associated with higher stock compensation expense offset in part by reduced headcount versus the same quarter in the prior year. For the nine-months ended September 30, 2019 the decrease is due to a combination of lower salary expense and lower stock compensation expense.

Research and development ("R&D") expenses increased 60.0% to $720,000 in the third quarter of 2019 up from $450,000 in the third quarter of 2018. R&D expense increased 7.0% to $1.6 million in the nine months ended September 30, 2019, up from $1.5 million in the nine months ended September 30, 2018. The increase in the quarter ended September 30, 2019 was due primarily to incremental expenses associated with a manufacturing study, increased cost of the clinical trial and higher stock compensation expense. The increase in the nine-months ended September 30, 2019 was due to manufacturing and preclinical studies, offset in part by reduced stock compensation expense.

Other net expense was $222,000 and $63,000 for the three months ended September 30, 2019 and 2018, respectively. Other expense in the third quarter of both years is primarily a foreign currency translation loss. Other net expense increased 19.3% to $2.5 million in the nine months ended September 30, 2019. This increase is due primarily to the increase in interest expense associated with the amortization the debt discount on notes sold in December 2018 and January 2019. The debt discount was fully amortized in the first half of 2019 and converted to common stock on June 30, 2019.

Net loss in the third quarter of 2019 was $1.4 million, or $0.23 per diluted share, compared to a net loss of $0.9 million, or $0.18 per diluted share, in the third quarter of 2018. The net loss for the nine months ended September 30, 2019 was $5.2 million, or $0.97 per diluted share, compared to a net loss of $5.2 million, or $1.14 per diluted share, for the first nine months of 2018.

Balance Sheet and Cash Flow

Total cash was $3.4 million and $1.4 million as of September 30, 2019 and December 31, 2018, respectively. Total current assets were $3.8 million and $1.8 million as of September 30, 2019, and December 31, 2018, respectively. During the nine months ended September 30, 2019 proceeds of $810,000 from the sale of unsecured convertible promissory notes in January and proceeds of approximately $3.1 million in the third quarter from a private sale of 902,067 shares of common stock and warrants to purchase an additional 902,067 shares was partially offset by cash used in operations of $1.9 million.

Current liabilities decreased to $689,000 as of September 30, 2019, compared to $1.6 million as of December 31, 2018. The decrease in current liabilities is primarily the result of a vendor payable balance moving to a zero-interest, unsecured promissory note payable on December 31, 2020.

Net cash used in operating activities was $1.9 million in the nine-months ended September 30, 2019, compared to $2.2 million in the same period of the prior year. The net cash used in each of these periods primarily reflects the net loss for these periods and was partially offset by the effects of changes in operating assets and liabilities.

About SBP-101

SBP-101 is a first-in-class, proprietary, polyamine analogue designed to induce polyamine metabolic inhibition (PMI), exploiting a high affinity for the compound specific to the exocrine pancreas and pancreatic ductal adenocarcinoma. Sun BioPharma originally licensed SBP-101 from the University of Florida Research Foundation in 2011. The molecule has been shown to be highly effective in preclinical studies of human pancreatic cancer models, demonstrating superior and complementary activity to existing FDA-approved chemotherapy agents. SBP-101 is expected to differ from current pancreatic cancer therapies in that it specifically targets the exocrine pancreas and pancreatic adenocarcinoma, demonstrating efficacy against primary and metastatic disease in animal models of human pancreatic cancer. Therefore, management believes that SBP-101 may effectively treat both primary and metastatic pancreatic cancer, while leaving the insulin-producing islet cells unharmed. The safety and PMI profile demonstrated in Sun BioPharma's first-in-human safety study further support evaluation of the potential for additive or synergistic effects in combination with current standard pancreatic cancer treatment.

About Sun BioPharma

Sun BioPharma Inc. is a clinical-stage biopharmaceutical company developing disruptive therapeutics for urgent unmet medical needs. The Company's development program is currently targeting pancreatic cancer; the Company's initial product candidate is SBP-101 for the treatment of patients with metastatic pancreatic cancer. SBP-101 was invented by Raymond Bergeron, Ph.D., 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 Haemotology 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 currently quoted on the OTCQB tier of the over-the-counter markets administered by the OTC Markets Group, Inc. 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," "may," "expects," or "plans." Examples of forward-looking statements include, among others, statements we make regarding the Company's plans with respect to the timing of our clinical trial. 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 those indicated in 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) the anticipated timing of first patient enrollment, (ii) our need to obtain additional capital, which may not be available on acceptable terms or at all, (iii) risks inherent in the development and/or commercialization of potential products, and (iv) uncertainty in the results or timing of clinical trials or regulatory approvals. Any forward-looking statement made by us in this press release is based only 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,		
	2019	2018	Percent Change	2019	2018	Percent Change
Operating expenses:						
General and administrative	$ 622	$ 467	33.2%	$ 1,505	$ 1,779	-15.4%
Research and development	720	450	60.0%	1,578	1,475	7.0%
Operating loss	(1,342)	(917)	46.3%	(3,083)	(3,254)	-5.3%
Other income (expense):						
Grant income	-	29	-100.0%	-	51	-100.0%
Interest expense	(3)	(3)	0.0%	(2,187)	(1,763)	24.0%
Other expense	(219)	(89)	146.1%	(287)	(362)	-20.7%
Total other income (expense)	(222)	(63)	252.4%	(2,474)	(2,074)	19.3%
Loss before income tax benefit	(1,564)	(980)	59.6%	(5,557)	(5,328)	4.3%
Income tax benefit	190	55	245.5%	331	163	103.1%
Net loss	(1,374)	(925)	48.5%	(5,226)	(5,165)	1.2%
Foreign currency translation adjustment (loss)	202	155	30.3%	219	324	-32.4%
Comprehensive Loss	$ (1,172)	$ (770)	52.2%	$ (5,007)	$ (4,841)	3.4%
Basic and diluted net loss per share	$ (0.23)	$ (0.18)	27.8%	$ (0.97)	$ (1.14)	-14.9%
Weighted average shares outstanding - basic and diluted	6,009,904	5,060,594	18.8%	5,385,986	4,522,606	19.1%

Consolidated Balance Sheets (unaudited)
(In thousands, except share amounts)

	September 30, 2019	December 31, 2018
ASSETS	(Unaudited)	
Current assets:		
Cash	$ 3,377	$ 1,405
Prepaid expenses and other current assets	119	110
Income tax receivable	275	332
Total current assets	3,771	1,847
Other noncurrent assets	49	51
Total assets	$ 3,820	$ 1,898
LIABILITITES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 261	$ 1,064
Accrued expenses	223	212
Convertible notes payable, net of debt discounts	-	64
Term debt, current portion	204	286
Accrued interest	1	4
Total current liabilities	689	1,630
Unsecured promissory note payable	742	-
Total liabilities	1,431	1,630
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 authorized; no shares issued or outstanding as of September 30, 2019 and December 31, 2018	-	-
Common stock, $0.001 par value; 100,000,000 authorized; 6,624,166 and 5,077,483 shares issued and outstanding, as of September 30, 2019 and December 31, 2018, respectively	7	5
Additional paid-in capital	42,164	35,038
Accumulated deficit	(40,284)	(35,058)
Accumulated comprehensive income	502	283
Total stockholders' equity	2,389	268
Total liabilities and stockholders' equity	$ 3,820	$ 1,898

Consolidated Statements of Cash Flows (unaudited)

(In thousands)

	Nine Months Ended September 30,	
	2019	2018
Cash flows from operating activities:		
Net loss	$ (5,226)	$ (5,165)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	958	1,202
Amortization of debt discount	2,061	1,687
Amortization of debt issuance costs	12	9
Non-cash interest expense	102	6
Changes in operating assets and liabilities:		
Income tax receivable	44	(157)
Prepaid expenses and other current assets	(12)	23
Accounts payable	179	186
Accrued liabilities	15	(16)
Net cash used in operating activities	(1,867)	(2,225)
Cash flows from financing activities:		
Proceeds from the sale of convertible promissory notes and warrants, net of debt issuance costs of $7	810	-
Proceeds from sale of common stock and warrants, net of offering costs of $16 and $27 respectively	3,142	2,314
Repayment of demand note	(25)	-
Repayments of term debt	(82)	-
Net cash provided by financing activities	3,845	2,314
Effect of exchange rate changes on cash	(6)	(2)
Net change in cash	1,972	87
Cash at beginning of period	1,405	152
Cash at end of period	$ 3,377	$ 239
Supplemental disclosure of cash flow information:		
Cash paid during period for interest	$ 11	$ 61
Supplemental disclosure of non-cash transactions:		
Beneficial conversion feature on convertible notes	$ 353	$ 121
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 and warrants	$ -	$ 2,908
Conversion of convertible notes payable and accrued interest into common stock	$ 2,281	$ 350
Issuance of unsecured promissory note in exchange for vendor accounts payable	$ 742	$ -
Options granted in exchange for release from contingent payment obligations	$ -	$ 1,094