Sun BioPharma, Inc. Provides a Business Update and Files Report for Q1 2019

- Enrollment in Second Cohort of PDA Combination Study Completed
- New Funding Totaling $0.8 Million Secured

MINNEAPOLIS, MN, May 13, 2019 (GLOBE NEWSWIRE) – Sun BioPharma, Inc. (OTCQB:SNBP), a clinical stage biopharmaceutical company developing disruptive therapeutics for the treatment of pancreatic diseases, today provides a business update and reports financial results for the quarter ended March 31, 2019.

Front-Line Combination PDA Study

The Company's current trial, a Phase 1a/1b combination of SBP-101 to be administered with gemcitabine and nab-paclitaxel in previously untreated patients with metastatic pancreatic ductal adenocarcinoma (PDA), completed cohort 2 enrollment and expects the Data Safety Monitoring Board to meet before the end of May 2019 to review interim results of the cohort. The Company also added a fifth clinical site, the John Flynn Private Hospital in Tugun, Queensland Australia at the end of the first quarter. In the Phase 1a portion of this study treatment of up to 18 PDA patients was planned in three cohorts to determine a recommended dose of SBP-101 to be given in combination with standard treatment. The Phase 1b portion will be an expansion at the recommended dose of SBP-101 and will guide SBP-101's subsequent development for patients with PDA. This multi-center, front-line study has 3 other sites in Australia: The Austin Health Cancer Trials Centre in Melbourne, The Adelaide Cancer Centre in Adelaide, The Blacktown Cancer and Haematology Centre in Sydney and one site in the United States, The University of Florida Health Cancer Center in Gainesville, Florida. The Company intends to open additional clinical sites in the US in anticipation of the expansion phase of the study.

Suzanne Gagnon, MD, Chief Medical Officer for Sun BioPharma, Inc. commented, "Currently one additional cohort is planned prior to entering the expansion phase; we have amended our protocol to include up to 36 patients in Phase 1b. Based on our prior study we plan to follow these patients for overall survival in addition to tumor response, disease control rate and progression free survival."

Completion of Sale of Convertible Notes

During the quarter ended March 31, 2019 the Company completed the sale of convertible notes payable which was initiated in the last quarter of 2018 (the "Notes"). In total the Company raised $2.2 million, $1.33 million in December 2018 and $0.84 million in January 2019 from accredited investors. The funds are intended to be used primarily for the Company's clinical trial.

Michael T. Cullen, MD, Executive Chairman, President and CEO commented, "This private placement, managed by the Company and supported by both new and loyal previous investors, provided capital necessary to continue the first phase of our current front-line combination trial of SBP-101 in patients with previously untreated metastatic pancreatic cancer. We are gratified by our investors' continued support of SBP-101 clinical trials in this next stage of the development process."

Financial Results for the Three Months ending March 31, 2019

Operating Results

General and administrative ("G&A") expenses decreased 54.0% to $303,000 in the first quarter of 2019 down from $658,000 in the first quarter of 2018. The decrease in the first quarter is due primarily to a decrease in stock compensation expense and temporary salary reductions which were in effect for a portion of the quarter.

Our research and development ("R&D") expenses decreased 39.7% to $350,000 in the first quarter of 2019 down from $580,000 in the first quarter of 2018. The decrease for the quarter ended March 31, 2019 was primarily associated with lower stock compensation expense, and temporary salary reductions which were in effect for a portion of the quarter.

Other net expense was $1.0 million and $0.5 million for the three months ended March 31, 2019 and 2018, respectively. Other expense in the current quarter was primarily the amortization of debt discount included as interest expense on the Company's 2018 Notes. Other expense in the quarter ended March 31, 2018 was primarily interest expense on the Company's 2017 convertible notes payable.

Net loss in the first quarter of 2019 was $1.6 million, or $0.31 per diluted share, compared to a net loss of $1.8 million, or $0.45 per diluted share, in the first quarter of 2018.

Balance Sheet and Cash Flow

Total cash was approximately $1.4 million as of both March 31, 2019 and December 31, 2018. Total current assets were $1.9 million and $1.8 million as of March 31, 2019, and December 31, 2018, respectively. During the quarter ended March 31, 2019 cash used in operations was offset by funds raised from the sale of convertible notes payable.

Current liabilities increased to $2.5 million as of March 31, 2019, compared to $1.6 million as of December 31, 2018. The increase in current liabilities is primarily the result of the increase in the balance of convertible notes payable (net of unamortized debt discount).

Net cash used in operating activities was $0.8 million in the three-months ended March 31, 2019, compared to $0.6 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 compound designed to exert therapeutic effects in a mechanism specific to the pancreas. 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 activity to existing FDA-approved chemotherapy agents. Combination therapy potential has also been shown for pancreatic cancer. SBP-101 is expected to differ from current pancreatic cancer therapies in that it specifically targets the exocrine pancreas and has shown 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 and non-pancreatic tissue unharmed. The safety and metabolic profile demonstrated in our first-in-human safety study further supports 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 programs target diseases of the pancreas, including pancreatic cancer and pancreatitis; the Company's initial product candidate is SBP-101 for the treatment of patients with 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 Miami, the University of Florida, the Austin Health Cancer Trials Centre in Melbourne, Australia, the Ashford Cancer Centre in Adelaide, Australia and The Blacktown Cancer and Haemotology Centre in Sydney, Australia and the John Flynn Private Hospital in Tugun, Australia. The Company's independent Data Safety Monitoring Board (DSMB) is Chaired by James Abbruzzese, MD, Professor of Medicine, Charles Johnson, M.D. Professor of Medicine, a member of the Duke Cancer Institute 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" within the meaning of the Private Securities Litigation Reform Act of 1995. For example, statements regarding the Company's next study, the timing and effects of the reverse stock split and potential eligibility and approval for listing on a national securities exchange are forward-looking statements. Any other statements that are not historical fact (including, but not limited to statements that contain words such as "will", "believes," "may," "anticipates," "expects," "estimates" or "plans") should also be considered to be forward-looking statements. Forward-looking statements are not a guarantee of future performance or results and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved. Forward-looking statements are based on information available at the time the statements are made and involve known and unknown risks, uncertainties and other factors that may cause our results, levels of activity, performance or achievements to be materially different from the information expressed or implied by such forward-looking statements, including, without limitation, the anticipated timing of first patient enrollment, our need to obtain additional capital, which may not be available on acceptable terms or at all, risks inherent in the development and/or commercialization of potential products, uncertainty in the results or timing of clinical trials or regulatory approvals, timing of necessary regulatory processes relating to the reverse stock split, and other material changes in our business that could jeopardize our ability to qualify for listing on a national securities exchange. Actual results may differ materially from the results anticipated in these forward-looking statements and as such should be evaluated together with the many uncertainties that affect the Company and its business, particularly those disclosed from time to time in its filings with the Securities and Exchange Commission. Stockholders and other readers are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they are made. The Company disclaims any intent or obligation to update these forward-looking statements.

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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 March 31,		
	2019	2018	Percent Change
Operating expenses:			
General and administrative	$ 303	$ 658	-54.0%
Research and development	350	580	-39.7%
Operating loss	(653)	(1,238)	-47.3%
Other (expense) income:			
Grant income	-	10	-100.0%
Interest expense	(1,033)	(473)	118.4%
Other (expense) income:	34	(80)	-142.5%
Total other expense	(999)	(543)	84.0%
Loss before income tax benefit	(1,652)	(1,781)	-7.2%
Income tax benefit	71	28	153.6%
Net loss	(1,581)	(1,753)	-9.8%
Foreign currency translation adjustment (loss)	(32)	69	-146.4%
Comprehensive Loss	$ (1,613)	$ (1,684)	-4.2%
Basic and diluted net loss per share	$ (0.31)	$ (0.45)	-31.1%
Weighted average shares outstanding - basic and diluted	5,072,397	3,927,296	29.2%

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

	March 31, 2019	December 31, 2018
ASSETS	(Unaudited)	
Current assets:		
Cash	$ 1,379	$ 1,405
Prepaid expenses and other current assets	73	110
Income tax receivable	408	332
Total current assets	1,860	1,847
Other noncurrent assets	51	51
Total assets	$ 1,911	$ 1,898
LIABILITITES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 905	$ 1,064
Accrued expenses	200	212
Convertible notes payable, net of debt discounts	1,083	64
Term debt, current portion	259	286
Accrued interest	52	4
Total current liabilities	2,499	1,630
Stockholders' (deficit) equity:		
Preferred stock, $0.001 par value; 10,000,000 authorized; no shares issued or outstanding as of March 31, 2019 and December 31 2018	-	-
Common stock, $0.001 par value; 100,000,000 authorized; 5,070,341 and 5,077,483 shares issued and outstanding, as of March 31, 2019 and December 31, 2018, respectively	5	5
Additional paid-in capital	35,795	35,038
Accumulated deficit	(36,639)	(35,058)
Accumulated comprehensive income	251	283
Total stockholders' (deficit) equity	(588)	268
Total liabilities and stockholders' (deficit) equity	$ 1,911	$ 1,898

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

	Three Months Ended March 31,	
	2019	2018
Cash flows from operating activities:		
Net loss	$ (1,581)	$ (1,753)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	10	698
Amortization of debt discount	974	427
Amortization of debt issuance costs	6	2
Non-cash interest expense	48	43
Changes in operating assets and liabilities:		
Income tax receivable	(74)	(36)
Prepaid expenses and other current assets	38	(15)
Accounts payable	(193)	111
Accrued liabilities	(11)	(65)
Net cash used in operating activities	(783)	(588)
Cash flows from financing activities:		
Proceeds from the sale of convertible promissory notes, net of debt issuance costs of $7	810	-
Proceeds from sale of common stock and warrants, net of offering costs of $152	-	1,261
Deposits received for possible future stock sales	-	350
Repayment of demand note	(25)	-
Repayments of term debt	(27)	-
Net cash provided by financing activities	758	1,611
Effect of exchange rate changes on cash	(1)	(6)
Net change in cash	(26)	1,017
Cash at beginning of period	1,405	152
Cash at end of period	$ 1,379	$ 1,169
Supplemental disclosure of cash flow information:		
Cash paid during period for interest	$ 5	$ 21
Supplemental disclosure of non-cash transactions:		
Beneficial conversion feature on convertible notes	$ 353	$ -
Warrants issued with convertible notes	$ 419	$ -
Common stock converted into convertible notes payable	$ 25	
Options granted in exchange for release from contingent payment obligations	$ -	$ 1,094