Sun BioPharma, Inc. Provides a Business Update and Files Report for Q2 2019

- Enrollment in Third Cohort of PDA Combination Study is Encouraging
- Preliminary Efficacy Signals Improve with New Data Regarding Second Cohort
- Entire $2.3 million Owed under Convertible Notes Converted to Equity

MINNEAPOLIS, MN, August 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 June 30, 2019.

Front-Line Combination Pancreatic Cancer Dose Escalation Study
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") began dosing patients in the third and final dose level cohort in mid – July, immediately following a review of cohort two data and approval by the Data Safety Monitoring Board ("DSMB'). The Phase 1a portion of this study is planned to have a total of 3 dosing levels and determine a recommended dose of SBP-101 to be given in combination with standard treatment. The protocol for the next phase of this study, originally planned for just ten patients, was recently expanded to 36.

The Company completed enrollment of an expanded second cohort during the quarter ended June 30, 2019. Encouraging signals of efficacy have been noted in the second cohort. Six of 6 evaluable subjects (100%) had significant decreases in Tumor Marker CA19-9 levels during treatment, ranging from 75% to 95%. The CA19-9 level improvements were accompanied by Response Evaluation Criteria in Solid Tumors ("RECIST") assessments of 4 partial responses and 2 subjects with stable disease at that interim analysis. Subsequent to the review of second cohort data by the DSMB an updated RECIST tumor assessment on one subject was changed from stable disease to partial response, resulting in interim efficacy RECIST assessments of 5 partial responses and 1 stable disease, for an overall response rate of 83% at dose level 2.

Michael T. Cullen, MD, Executive Chairman, President and CEO commented, "We are delighted with the observed response rates to this intermediate dose level SBP-101 regimen for patients with previously untreated metastatic pancreatic cancer. The safety profile continues to support the feasibility of this combination."

Conversion of Convertible Promissory Notes

On June 30, 2019 the $2.2 million principal amount and $0.1 million of accrued interest under outstanding unsecured convertible promissory notes were converted into 651,758 shares of common stock based on a conversion rate of $3.50.

Financial Results for the Three and Six Months ending June 30, 2019

Operating Results

General and administrative ("G&A") expenses decreased 11.3% to $580,000 in the second quarter of 2019 down from $654,000 in the second quarter of 2018. G&A expenses decreased 32.7% to 883,000 in the six months ended June 30, 2019, down from $1.3 million in the six months ended June 30, 2018. The decrease in the second quarter is due primarily to a decrease in lower salary expense due to a reduction in headcount. The decrease in the six months ended June 30, 2019 is also due primarily to lower salary and stock compensation expense.

Research and development ("R&D") expenses increased 14.9% to $508,000 in the second quarter of 2019 up from $442,000 in the second quarter of 2018. R&D expense decreased 16.2% to $858,000 in the six months ended June 30, 2019, down from $1.0 million in the six months ended June 30, 2018. The increase for the quarter is due primarily to a preclinical study and higher stock compensation expense. The decrease for the six months ended June 30, 2019 was due primarily to decreased stock compensation expense.

Other net expense was $1.3 million and $1.5 for the three months ended June 30, 2019 and 2018, respectively. Other expense in the second quarter of both years is primarily interest expense on outstanding promissory notes. Lower interest expense and foreign currency translation loss contributed to the lower other net expense for the quarter ended June 30, 2019. Other net expense increased 11.9% to $2.3 million in the six months ended June 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 six months ended June 30, 2019 and converted to common stock as discussed above.

Net loss in the second quarter of 2019 was $2.3 million, or $0.45 per diluted share, compared to a net loss of $2.5 million, or $0.54 per diluted share, in the second quarter of 2018. The net loss for the first half of 2019 was $3.9 million, or $0.76 per diluted share, compared to a net loss of $4.2 million, or $1.00 per diluted share, for the first half of 2018.

Balance Sheet and Cash Flow

Total cash was $0.7 million and $1.4 million as of June 30, 2019 and December 31, 2018, respectively. Total current assets were $1.3 million and $1.8 million as of June 30, 2019, and December 31, 2018, respectively. During the six months ended June 30, 2019 cash used in operations of $1.4 million was partially offset by $810,000 cash proceeds from the sale of unsecured convertible promissory notes.

Current liabilities decreased to $714,000 as of June 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 $1.4 million in the six-months ended June 30, 2019, compared to $1.6 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 polyamine metabolic inhibition (PMI), exploiting a high affinity for the compound specific to the exocrine 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 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 while 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 and non-pancreatic tissue unharmed. The safety and PMI 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, 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 June 30,			Six months ended June 30,		
	2019	2018	Percent Change	2019	2018	Percent Change
Operating expenses:						
General and administrative	$ 580	$ 654	-11.3%	$ 883	$ 1,312	-32.7%
Research and development	508	442	14.9%	858	1,024	-16.2%
Operating loss	(1,088)	(1,096)	-0.7%	(1,741)	(2,336)	-25.5%
Other income (expense):						
Grant income	-	12	-100.0%	-	22	-100.0%
Interest expense	(1,152)	(1,288)	-10.6%	(2,184)	(1,761)	24.0%
Other income	(101)	(192)	-47.4%	(68)	(273)	-75.1%
Total other income (expense)	(1,253)	(1,468)	-14.6%	(2,252)	(2,012)	11.9%
Loss before income tax benefit	(2,341)	(2,564)	-8.7%	(3,993)	(4,348)	-8.2%
Income tax benefit	70	79	-11.4%	141	108	30.6%
Net loss	(2,271)	(2,485)	-8.6%	(3,852)	(4,240)	-9.2%
Foreign currency translation adjustment (loss)	49	101	-51.5%	17	169	-89.9%
Comprehensive Loss	$ (2,222)	$ (2,384)	-6.8%	$ (3,835)	$ (4,071)	-5.8%
Basic and diluted net loss per share	$ (0.45)	$ (0.54)	-16.7%	$ (0.76)	$ (1.00)	-24.0%
Weighted average shares outstanding - basic and diluted	5,070,341	4,570,601	10.9%	5,071,378	4,248,603	19.4%

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

	June 30, 2019	December 31, 2018
ASSETS	(Unaudited)	
Current assets:		
Cash	$ 721	$ 1,405
Prepaid expenses and other current assets	93	110
Income tax receivable	474	332
Total current assets	1,288	1,847
Other noncurrent assets	51	51
Total assets	$ 1,339	$ 1,898
LIABILITITES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	$ 289	$ 1,064
Accrued expenses	192	212
Convertible notes payable, net of debt discounts	-	64
Term debt, current portion	232	286
Accrued interest	1	4
Total current liabilities	714	1,630
Unsecured promissory note payable	742	-
Total liabilities	1,456	1,630
Stockholders' (deficit) equity:		
Preferred stock, $0.001 par value; 10,000,000 authorized; no shares issued or outstanding as of June 30, 2019 and December 31 2018	-	-
Common stock, $0.001 par value; 100,000,000 authorized; 5,722,099 and 5,077,483 shares issued and outstanding, as of June 30, 2019 and December 31, 2018, respectively	6	5
Additional paid-in capital	38,487	35,038
Accumulated deficit	(38,910)	(35,058)
Accumulated comprehensive income	300	283
Total stockholders' (deficit) equity	(117)	268
Total liabilities and stockholders' (deficit) equity	$ 1,339	$ 1,898

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

	Six Months Ended June 30,	
	2019	2018
Cash flows from operating activities:		
Net loss	$ (3,852)	$ (4,240)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	422	1,056
Amortization of debt discount	2,061	1,687
Amortization of debt issuance costs	12	9
Non-cash interest expense	102	43
Changes in operating assets and liabilities:		
Income tax receivable	(144)	(106)
Prepaid expenses and other current assets	17	53
Accounts payable	(12)	(67)
Accrued liabilities	(20)	(20)
Net cash used in operating activities	(1,414)	(1,585)
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 $27	-	2,341
Repayment of demand note	(25)	-
Repayments of term debt	(55)	-
Net cash provided by financing activities	730	2,341
Effect of exchange rate changes on cash	-	(3)
Net change in cash	(684)	753
Cash at beginning of period	1,405	152
Cash at end of period	$ 721	$ 905
Supplemental disclosure of cash flow information:		
Cash paid during period for interest	$ 8	$ 22
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