



Sun BioPharma Provides Business Update and Reports Operating Results for FY2019

- *Enrollment completed in fourth cohort of Phase 1a/1b trial of SBP-101 in pancreatic cancer; expansion cohort initiated*
- *Interim Phase 1 data presented at ASCO GI meeting demonstrated tolerability and tumor response in treatment-naïve patients with metastatic pancreatic cancer*

MINNEAPOLIS, MN, March 24, 2020 (GLOBE NEWSWIRE) – Sun BioPharma, Inc. (OTCQB: SNBP), a clinical stage biopharmaceutical company developing disruptive therapeutics for the treatment of pancreatic cancer, today provides a business update and reports financial results for the year ended December 31, 2019. Sun BioPharma is developing SBP-101, a proprietary polyamine analogue designed to induce polyamine metabolic inhibition (PMI), a metabolic pathway of critical importance to cell function in multiple tumor types, including pancreatic cancer.

“I am delighted with the progress we have made in advancing the development of SBP-101 for patients with metastatic pancreatic cancer. In the past 12 months, we have completed enrollment in the four dose escalation cohorts of our current trial, presented interim data ASCO GI Cancer Symposium, initiated two new clinical sites in the United States, and opened an expansion cohort to patient enrollment at what we believe to be the optimal dose and schedule,” said Michael T. Cullen, MD, MBA, Chairman and CEO of Sun BioPharma. “We look forward to completing the design of a randomized phase 2 study.”

Significant Progress Made in Advancing SBP-101 Clinical Development

In early 2020, enrollment was completed in the fourth cohort of the ongoing Phase 1a/1b study of SBP-101 in patients with metastatic pancreatic ductal adenocarcinoma (PDA). Based upon the study data generated to date, an expansion cohort in patients with PDA was initiated in February of 2020. This expansion phase will enroll up to 36 additional patients at the recommended dose and schedule. A total of six clinical sites are now participating in the SBP-101 clinical program.

Interim Phase 1 Results Presented in Poster Session at ASCO GI Cancers Symposium

Interim Phase 1 clinical data for SBP-101 was presented in a poster session at the American Society for Clinical Oncology (ASCO) 2020 Gastrointestinal Cancers Symposium on January 24, 2020. The adverse event profile of SBP-101 below the maximal tolerated dose was manageable, and SBP-101 was well tolerated in combination with gemcitabine and nab-paclitaxel. The addition of SBP-101 to the combination of gemcitabine plus nab-paclitaxel did not increase the

frequency of moderate or severe hematologic adverse events, peripheral neuropathy, nausea or diarrhea when compared to historical control data for patients who were treated with gemcitabine plus nab-paclitaxel. The most common adverse events attributed to treatment with SBP-101 were fatigue, elevated hepatic enzymes, and injection site pain.

Available study results in 13 evaluable subjects enrolled in the two highest dose cohorts (n=16) demonstrated an overall response rate (ORR) of 62% by RECIST criteria. The disease control rate (DCR) was 85% by RECIST criteria. Eleven subjects in those cohorts (69%, n=16) saw a maximum decrease in CA 19-9 of more than 60%.

Financial Results for the Three Months and Full Year Ended December 31, 2019

General and administrative (G&A) expenses were flat at \$468,000 in the fourth quarter of 2019, compared with \$467,000 in the fourth quarter of 2018. G&A expenses for the full year decreased 6.4% to \$2.0 million in 2019, down from \$2.1 million in 2018. The decrease for the full year of 2019 is primarily due to fewer staff members versus the 2018 staff level.

Research and development (R&D) expenses increased 74.9% to \$787,000 in the fourth quarter of 2019 up from \$450,000 in the fourth quarter of 2018. R&D expenses for the full year of 2019 increased 31.7% to \$2.3 million as compared with \$1.8 million for 2018. The increase in the fourth quarter resulted from the cost to begin production of drug substance for future phase 2 clinical trials. The full-year increase in R&D expenses resulted from an increase in spending on the Company's clinical trial during 2019 and the manufacturing of drug substance initiated during the fourth quarter of 2019.

Other income, net, was \$196,000 in the current quarter compared to other expense, net, of \$64,000 in the fourth quarter of 2018. Other expense, net, was flat at \$2.3 million for both 2019 and 2018. The amounts reflected in the fourth quarter of each year are primarily a foreign currency translation adjustment on the intercompany balance with our Australian subsidiary. For both 2018 and 2019 the full year expense is primarily the amortization of debt discount, which is recorded as interest expense.

Net loss for the quarters ended December 31, 2019 and 2018 was \$1.0 million and \$0.9 million, or \$0.15 and \$0.18 per diluted share, respectively. The net loss for the full year 2019 was \$6.2 million, or \$1.09 per diluted share, compared to a net loss of \$5.9 million, or \$1.27 per diluted share, for 2018.

Balance Sheet and Cash Flow

Total cash resources were \$2.4 million as of December 31, 2019, compared to \$1.4 million as of December 31, 2018. Total current assets were \$3.1 million and \$1.8 million as of December 31, 2019, and December 31, 2018, respectively. These increases resulted primarily from the proceeds raised from the sale of convertible promissory notes in January 2019 of \$0.8 million and the sale of equity securities in the second half of 2019 totaling \$3.2 million, partially offset by the Company's use of cash to fund operations during 2019.

Current liabilities increased to \$1.8 million as of December 31, 2019, compared to \$1.6 million as of December 31, 2018. The increase in current liabilities is reflective of an increase in vendor payables associated with increased clinical and manufacturing activity in 2019.

Net cash used in operating activities was \$2.7 million for the year ended December 31, 2019, compared to \$2.4 million for the year ended December 31, 2018. The net cash used in each of these periods primarily reflected the net loss for these periods and was partially offset by stock-based compensation expense and amortization of debt discount as well as by the effects of changes in operating assets and liabilities.

About Sun BioPharma

Sun BioPharma Inc. is a clinical-stage biopharmaceutical company developing disruptive therapeutics for urgent unmet medical needs. Sun BioPharma's development program is currently targeting pancreatic cancer; its initial product candidate is SBP-101 for the potential 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 Haematology Centre in Sydney, Australia and the John Flynn Private Hospital in Tugun, Queensland, Australia. Sun BioPharma'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 plans to advance SBP-101 in clinical trials and expansion cohorts. 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. As with any pharmaceutical product like SBP-101, there are substantial risks and uncertainties in the process of development and commercialization. There can be no guarantees that this treatment will receive regulatory approval or, if approved, will achieve the intended benefits or become commercially successful. 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.

Contact Information:

Investor & Media Contact:

Susan Horvath – Sun BioPharma, Inc.
952 479 1196

Sun BioPharma, Inc.

Consolidated Statements of Operations and Comprehensive Loss (unaudited)

(In thousands, except share and per share amounts)

	Three months ended December 31,			Year ended December 31,		
	2019	2018	Percent Change	2019	2018	Percent Change
Operating expenses:						
General and administrative	\$ 468	\$ 467	0.2%	\$ 1,973	\$ 2,108	-6.4%
Research and development	787	450	74.9%	2,349	1,783	31.7%
Operating loss	(1,255)	(917)	36.9%	(4,322)	(3,891)	11.1%
Other income (expense):						
Grant income	-	-	-	-	54	-100.0%
Interest expense	(8)	29	-127.6%	(2,194)	(1,814)	20.9%
Other income (expense)	204	(93)	-319.4%	(99)	(508)	-80.5%
Total other income (expense)	196	(64)	-406.3%	(2,293)	(2,268)	1.1%
Loss before income tax benefit	(1,059)	(981)	8.0%	(6,615)	(6,159)	7.4%
Income tax benefit	82	54	51.9%	415	254	63.4%
Net loss	(977)	(927)	5.4%	(6,200)	(5,905)	5.0%
Foreign currency translation adjustment (loss)	(197)	255	-177.3%	22	448	-95.1%
Comprehensive Loss	\$ (1,174)	\$ (672)	74.7%	\$ (6,178)	\$ (5,457)	13.2%
Basic and diluted net loss per share	\$ (0.15)	\$ (0.18)	-16.7%	\$ (1.09)	\$ (1.27)	-14.2%
Weighted average shares outstanding - basic and diluted	6,630,584	5,070,481	30.8%	5,700,314	4,662,080	22.3%

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

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash	\$ 2,449	\$ 1,405
Prepaid expenses and other current assets	283	110
Income tax receivable	361	332
Total current assets	3,093	1,847
Other noncurrent assets	51	51
Total assets	\$ 3,144	\$ 1,898
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 597	\$ 1,064
Accrued expenses	304	216
Convertible notes payable, net of debt discounts	-	64
Term debt, current portion	116	286
Unsecured promissory note payable	742	-
Total current liabilities	1,759	1,630
Total liabilities	1,759	1,630
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 authorized; no shares issued or outstanding as of December 31, 2019 and December 31, 2018	-	-
Common stock, \$0.001 par value; 100,000,000 authorized; 6,631,308 and 5,077,483 shares issued and outstanding, as of December 31, 2019 and December 31, 2018, respectively	7	5
Additional paid-in capital	42,331	35,038
Accumulated deficit	(41,258)	(35,058)
Accumulated comprehensive income	305	283
Total stockholders' equity	1,385	268
Total liabilities and stockholders' equity	\$ 3,144	\$ 1,898

Sun BioPharma, Inc.

Consolidated Statements of Cash Flows (unaudited)

(In thousands)

	Year Ended December 31,	
	2019	2018
Cash flows from operating activities:		
Net loss	\$ (6,200)	\$ (5,905)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,093	1,279
Amortization of debt discount	2,066	1,732
Amortization of debt issuance costs	12	9
Non-cash interest expense	102	4
Changes in operating assets and liabilities:		
Income tax receivable	(31)	50
Prepaid expenses and other current assets	(174)	25
Accounts payable	301	360
Accrued liabilities	92	59
Net cash used in operating activities	(2,739)	(2,387)
Cash flows from financing activities:		
Proceeds from the sale of convertible promissory notes and warrants, net of debt issuance costs of \$7 and \$5 respectively	810	1,329
Proceeds from sale of common stock and warrants, net of offering costs of \$16 and \$27 respectively	3,160	2,328
Repayment of demand note	(25)	-
Repayments of term debt	(161)	(14)
Net cash provided by financing activities	3,784	3,643
Effect of exchange rate changes on cash	(1)	(3)
Net change in cash	1,044	1,253
Cash at beginning of period	1,405	152
Cash at end of period	\$ 2,449	\$ 1,405
Supplemental disclosure of cash flow information:		
Cash paid during period for interest	\$ 14	\$ 67
Supplemental disclosure of non-cash transactions:		
Beneficial conversion feature on convertible notes	\$ 353	\$ 716
Warrants issued with convertible notes	\$ 419	\$ 739
Warrants issued in exchange for modification of term debt	\$ 14	\$ -
Common stock converted into convertible notes payable	\$ (25)	\$ -
Conversion of convertible notes payable and accrued interest into common stock and warrants	\$ -	\$ 3,258
Conversion of convertible notes payable and accrued interest into common stock	\$ 2,281	\$ -
Issuance of unsecured promissory note in exchange for vendor accounts payable	\$ 742	\$ -
Options granted in exchange for release from contingent payment obligations	\$ -	\$ 1,094