



Sun BioPharma Files Form 10-Q for Third Quarter 2017 and Provides Business Update

- *Enrollment Completed in Phase 1a Safety Trial*
- *Study Design Finalized for Front-Line Combination Study with Gemcitabine and Nab-Paclitaxel*

MINNEAPOLIS, MN, November 14, 2017 (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 third quarter ending September 30, 2017.

Patient Enrollment Completed in Phase 1a Trial;

As previously announced, the Company completed the enrollment of patients in its Phase 1a dose escalation safety study using SBP-101 for patients with previously treated locally advanced or metastatic pancreatic ductal adenocarcinoma (“PDA”). In total, 29 patients were enrolled in the study and 24 had received multiple prior chemotherapy regimens. In addition to being evaluated for safety, 24 of the patients were evaluable for preliminary signals of efficacy prior to or at the eight-week conclusion of their first cycle of treatment. Based upon Response Evaluation Criteria in Solid Tumors (“RECIST”), the current standard for evaluating changes in the size of tumors, 8 of the 24 patients (33%) had Stable Disease (“SD”). Of the 28 patients who had follow-up blood tests measuring the tumor marker CA 19-9 associated with PDA, 11 (39%) had reductions in CA 19-9 levels, as measured at least once after the baseline assessment.

To date, the best response outcome and survival have been observed in the group of 13 patients who received total cumulative doses of SBP-101 between 2.5 and 8.0mg/kg. Twelve patients in this group were evaluable for preliminary signs of efficacy at eight weeks. Five (42%) had SD at week eight accompanied by stable or decreased levels of CA19-9. Although enrollment is complete, three patients continued to be followed for survival. As of the most

recent updates from study sites, median survival in this group was 3.8 months. Nine patients (69%) have exceeded 3 months of overall survival (“OS”), four patients (31%) had exceeded 4 months of OS, three patients (23%) had exceeded 8 months of OS and two patients (15%) had exceeded 10 months of OS.

Focus Shifts to Next Study

The Company also previously announced, that after reviewing data from the sixth and final cohort of patients, as well as data from all 29 patients enrolled in the study, the Data Safety Monitoring Board (DSMB) had recommended a safe and well-tolerated dose level of SBP-101 to be used for the further clinical study of SBP-101 in combination with the currently approved treatments. Therefore, the Company’s clinical team, working in conjunction with its medical advisors and potential physician investigators, has developed a protocol the Company intends to submit for a study of SBP-101 administered in combination with gemcitabine and nab-paclitaxel in newly diagnosed patients with metastatic PDA. The study is expected to include a dose-escalation phase with up to six months of treatment at each dose level. The dose-escalation phase is intended to include treatment at up to three dose levels and would be followed by an expansion phase at the recommended dose level determined. Enrollment is expected to begin in the first quarter of 2018

“The absence of non-target organ adverse events at the DSMB recommended dose level corroborates our pre-clinical data which suggests non-overlapping toxicity in combination therapy with gemcitabine and nab-paclitaxel,” noted Suzanne Gagnon, MD, Sun BioPharma’s Chief Medical Officer. “We are very encouraged and looking forward to demonstrating the ability of SBP-101, in a combination therapy, to improve outcomes for newly diagnosed PDA patients.”

“Completion of enrollment in our first Phase 1a study with SBP-101, and now just following a few patients for survival data has been a significant milestone for our Company. We also are very excited to be working on designing our next clinical trial. Work is underway at this time to develop the protocol for the next study, determine our clinical study sites, and engage our Principal Investigators for the study. This is a key step in our Company’s progress” said David Kaysen, President and CEO. “We extend our gratitude to our physician investigators and advisors who have been instrumental in supporting our efforts to develop SBP-101, and of course thank the patients and their families that have been incredibly instrumental in our clinical progress.”

Reverse Stock Split

The Company implemented a 1-for-10 reverse stock split, effective as of the close of business on November 7, 2017 and the Company's common stock commenced trading on a split-adjusted basis at the beginning of trading on November 8, 2017. The reverse stock split was intended to increase the market price per share of the Company's common stock to aid in qualifying for a potential listing on The Nasdaq Capital Market. The Company is taking additional actions to satisfy other listing requirements. Until the Company meets the criteria for listing and an application for listing is accepted by Nasdaq, which may not happen within a reasonable time frame, if at all, the common stock will continue to be eligible for quotation on the OTCQB Venture Marketplace tier of the over-the-counter markets administered by the OTC Markets Group, Inc.

Financial Results for the Three and Nine Months Ended September 30, 2017

General and administrative (“G&A”) expenses increased 3.2% to \$515,000 in the third quarter of 2017, up from \$499,000 in the third quarter of 2016. G&A expenses increased 61.0% to \$2.3 million in the nine months ended September 30, 2017, up from \$1.4 million in the comparable period of 2016. These increases resulted primarily from increases in non-cash, share-based compensation expense during the current year partially offset by current year reductions in legal and accounting costs.

Research and development (“R&D”) expenses decreased 16.7% to \$530,000 in the third quarter of 2017, down from \$636,000 in the third quarter of 2016. R&D expenses increased 18.0% to \$2.0 million for the nine months ended September 30, 2017, up from \$1.7 million in the nine months ended September 30, 2016. The current quarter decrease in R&D expense was due primarily to reduced costs of manufacturing and manufacturing process development, which was materially completed in 2016, and fewer study patient enrollments in the third quarter of 2017, partially offset by contract research costs incurred in conjunction with the Company's NIH sponsored pancreatitis study. The increased costs for the nine months ended September 30, 2017 resulted primarily from the costs of the Phase 1 clinical trial and non-cash share-based compensation expense recorded during the current year. There was no share-based compensation expense recorded during the first nine months of 2016.

Other expense, net, was \$371,000 in the current quarter compared to other income, net, of \$11,000 in the third quarter of 2017. Other expense, net, increased to \$4.5 million for the nine

months ended September 30, 2017, up from \$70,000 in the same period of the prior year. The increase in the current quarter was primarily due to increased interest expense resulting from the amortization of the discount on the 2017 convertible notes payable, partially offset by grant income earned during the current year received under a research grant awarded to the Company in 2016. On a year-to-date basis, the increase was due primarily to charges recorded related to the induced conversion of debt and increased interest expense resulting from the amortization of the discount on the 2017 convertible notes payable. These expenses were partially offset by foreign currency transaction gains recognized by our Australian subsidiary and grant income earned during the current year period.

Net loss for the three months ended September 30, 2017 was \$1.2 million, or \$0.33 per diluted share, compared to a net loss of \$1.1 million, or \$0.34 per diluted share, for the same period in 2016. The net loss for the first nine months of 2017 was \$8.2 million, or \$2.33 per diluted share, compared to a net loss of \$2.9 million, or \$0.94 per diluted share, for the first nine months of 2016.

Balance Sheet and Cash Flow

Total cash resources were \$943,000 as of September 30, 2017, compared to \$438,000 as of December 31, 2016. Total current assets were \$1.5 million and \$877,000 as of September 30, 2017, and December 31, 2016, respectively. These increases resulted from our current year sale of convertible promissory notes raising gross proceeds of approximately \$3.1 million, partially offset by the use of cash to fund operations.

Current liabilities decreased to \$2.1 million as of September 30, 2017, compared to \$5.5 million as of December 31, 2016. The decrease in current liabilities resulted primarily from the conversion of approximately \$3.1 million of previously outstanding debt and accrued interest into 418,332 shares of our common stock and from the reductions in outstanding accounts payable.

Net cash used in operating activities was \$2.6 million for the nine months ended September 30, 2017, 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. In the nine months ended September 30,

2017, the net loss is also offset by non-cash charges recorded for the loss on induced debt conversion and share-based compensation.

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.

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 Mayo Clinic Scottsdale, the Austin Health Cancer Trials Centre in Melbourne, Australia and the Ashford Cancer Centre in Adelaide, 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. 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.

Forward-Looking Statements Safe Harbor

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, 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 September 30,			Nine Months Ended June 30,		
	2017	2016	Percent Change	2017	2016	Percent Change
Operating expenses:						
General and administrative	\$ 515	\$ 499	3.2%	\$ 2,252	\$ 1,399	61.0%
Research and development	530	636	(16.7)	1,955	1,657	18.0
Operating loss	(1,045)	(1,135)	(7.9)	(4,207)	(3,056)	37.7
Other income (expense):						
Interest income	1	—	nm	1	2	(50.0)
Grant income	27	—	nm	110	—	nm
Interest expense	(474)	(45)	953.3	(1,145)	(135)	748.1
Loss on induced debt conversions	—	—	—	(3,696)	—	nm
Other income	75	56	33.9	264	63	319.0
Total other income (expense)	(371)	11	nm	(4,466)	(70)	nm
Loss before income tax benefit	(1,416)	(1,124)	26.0	(8,673)	(3,126)	177.4
Income tax benefit	197	45	337.8	460	252	82.5
Net loss	\$ (1,219)	\$ (1,079)	13.0	\$ (8,213)	\$ (2,874)	185.8
Foreign currency translation adjustment loss	(62)	(61)	1.6	(246)	(94)	161.7
Comprehensive loss	\$ (1,281)	\$ (1,140)	12.4%	\$ (8,459)	\$ (2,968)	185.0%
Basic and diluted net loss per share						
	\$ (0.33)	\$ (0.34)	(2.9%)	\$ (2.33)	\$ (0.94)	147.9%
Weighted average shares outstanding—basic and diluted						
	3,670,443	3,201,700	14.6%	3,518,839	3,069,195	14.7%

“nm” = not meaningful.

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

	<u>September 30, 2017</u>	<u>December 31, 2016</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 943	\$ 438
Prepaid expenses and other current assets	250	118
Income tax receivable	340	321
Total current assets	<u>1,533</u>	<u>877</u>
Total assets	<u>\$ 1,533</u>	<u>\$ 877</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 874	\$ 1,245
Accrued expenses	1,218	842
Convertible notes payable – current portion, net	—	2,733
Term debt	—	294
Demand notes payable	—	250
Accrued interest	57	155
Total current liabilities	<u>2,149</u>	<u>5,519</u>
Long-term liabilities:		
Convertible notes payable, net of unamortized debt discount	1,096	—
Term debt	300	—
Accrued interest	87	—
Total long-term liabilities	<u>1,483</u>	<u>—</u>
Stockholders' deficit:		
Preferred stock, \$0.001 par value; 10,000,000 authorized; no shares issued or outstanding as of September 30, 2017 and December 31, 2016	—	—
Common stock, \$0.001 par value; 100,000,000 authorized; 3,670,443 and 3,220,111 shares issued and outstanding, as of September 30, 2017 and December 31, 2016, respectively	4	3
Additional paid-in capital	25,059	14,058
Accumulated deficit	(26,992)	(18,779)
Accumulated other comprehensive gain (loss), net	(170)	76
Total stockholders' deficit	<u>(2,099)</u>	<u>(4,642)</u>
Total liabilities and stockholders' deficit	<u>\$ 1,533</u>	<u>\$ 877</u>

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

	Nine Months Ended September 30,	
	2017	2016
Cash flows from operating activities:		
Net loss	\$ (8,213)	\$ (2,874)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on induced debt conversions	3,696	—
Share-based compensation	1,167	—
Amortization of debt discount	961	—
Amortization of debt issuance costs	53	21
Non-cash interest expense	87	9
Changes in operating assets and liabilities:		
Income and other tax receivables	9	512
Prepaid expenses and other current assets	(131)	(25)
Accounts payable	(654)	377
Accrued liabilities	406	410
Net cash used in operating activities	(2,619)	(1,570)
Cash flows from financing activities:		
Proceeds from the sale of convertible promissory notes, net of offering costs of \$16	3,059	—
Proceeds from the exercise of stock options	28	—
Proceeds from the exercise of stock purchase warrants	19	—
Proceeds from issuance of common stock and warrants, net of offering costs of \$152	—	1,873
Net cash provided by financing activities	3,106	1,873
Effect of exchange rate changes on cash and cash equivalents	18	1
Net increase (decrease) in cash and cash equivalents	505	304
Cash and cash equivalents at beginning of period	438	925
Cash and cash equivalents at end of period	\$ 943	\$ 1,229
Supplemental disclosure of cash flow information:		
Cash paid during period for interest	\$ 5	\$ 70
Supplemental disclosure of non-cash transactions:		
Conversion of promissory notes and accrued interest into common stock	\$ 2,888	\$ —
Intrinsic value of beneficial conversion feature in convertible notes	2,954	—
Conversion of demand notes into common stock	250	—
Deferred compensation exchanged for common stock and warrants	—	196
Issuance of common stock for services	—	75