Sun BioPharma, Inc. Provides Business Update and Reports Q2 2020 Financial Results

MINNEAPOLIS, MN, August 11, 2020 (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 June 30, 2020. The second quarter of 2020 was marked by meaningful corporate, financial and clinical progress.

Highlights

- New CEO appointed on July 15, 2020
- Enrollment in clinical trial of SBP-101 has resumed, after temporary, Covid-19 related pause
- Fast Track designation received for SBP-101
- Additional funds raised through sale of equity securities

CEO Appointment

In July, the company appointed of Jennifer K. Simpson, PhD, MSN, CRNP as President and Chief Executive Officer and as a member of the Board of Directors. Dr. Simpson brings more than two decades of public company executive and fundraising experience in oncology drug development and commercialization to the company. Sun BioPharma co-founder Michael T. Cullen, MD, MBA, has continued to serve as Executive Chairman of our Board of Directors.

"I'm excited that we were able to resume enrollment in our clinical trial of SBP-101 in order to keep advancing this program for the patients who need it most," said Jennifer K. Simpson, PhD, MSN, CRNP President & Chief Executive Officer of Sun BioPharma. "The company is well positioned to maximize the opportunity for value of this product candidate for patients, caregivers and investors, and we look forward to completing the design of our Phase 2 development program shortly."

Enrollment Resumed in Ongoing Clinical Trial of SBP-101

In June, Sun BioPharma authorized clinical trial sites to resume enrollment in the expansion cohort of its Phase 1a/b clinical trial of SNBP-101. Enrollment in many clinical trials across the industry had been temporarily paused earlier this year to enable hospitals to prioritize the treatment of patients with COVID-19. This trial, a Phase 1a/1b study of the combination of SBP-101 with gemcitabine and nab-paclitaxel in patients previously untreated for metastatic pancreatic ductal adenocarcinoma (PDA), is being conducted at 6 sites in the United States and Australia.

FDA Fast Track Designation Received for SBP-101

During the second quarter, the company received Fast Track Designation from the U.S. Food and Drug Administration (FDA) for SBP-101 for first-line treatment of patients with metastatic PDA when administered in combination with gemcitabine and nab-paclitaxel. One of FDA's Expedited Programs for Serious Conditions, Fast Track is a process designed to facilitate the development and potentially expedite the review of drugs intended to treat serious conditions and address unmet medical needs. This designation is expected to enhance Sun BioPharma's ability to develop SBP-101 as efficiently as possible.

Recent Sales of Common Stock and Warrants Raised $1.7 Million

In May and June, the company sold common stock and warrants in private placements resulting in net proceeds totaling approximately $1.7 million, which the company intends to use primarily to support its ongoing clinical trial. A total of 437,000 shares of common stock were issued in addition to warrants to purchase an equal number of shares of common stock.

Second Quarter ended June 30, 2020 Financial Results

General and administrative expenses increased to $0.7 million in the second quarter of 2020, up from $0.6 million in the second quarter of 2019. The increase in the second quarter is due to higher consulting and legal expense offset in part by lower stock compensation expense.

Research and development expenses decreased to $0.4 million in the second quarter of 2020, down from $0.5 million in the second quarter of 2019. The decrease in the second quarter is due to lower spending on preclinical studies and lower stock compensation expense.

Operating expenses in the second quarter were partially offset by a foreign currency exchange gain on the intercompany receivable balance. In the second quarter of 2019, other expense was primarily interest expense which resulted from the amortization of debt discount on convertible notes sold in 2018 and 2019.

Net loss in the second quarter of 2020 was $0.4 million, or $0.06 per diluted share, compared to a net loss of $2.3 million, or $0.45 per diluted share, in the second quarter of 2019.

Total cash was $2.3 million as of June 30, 2020. Total current assets were $3.3 million and current liabilities were $1.7 million as of the same date.

About SBP-101

SBP-101 is a proprietary polyamine analogue designed to induce polyamine metabolic inhibition (PMI) by exploiting an observed high affinity of the compound for the exocrine pancreas and pancreatic ductal adenocarcinoma. The molecule has shown signals of tumor growth inhibition in clinical studies of US and Australian metastatic pancreatic cancer patients, suggesting complementary activity with an existing FDA-approved chemotherapy regimen. In clinical studies to date, SBP-101 has not shown exacerbation of the typical chemotherapy-related adverse

events of bone marrow suppression and peripheral neuropathy. The safety data and PMI profile observed in Sun BioPharma's current clinical trial provides support for continued evaluation of the compound in a randomized clinical trial. For more information, please visit https://clinicaltrials.gov/ct2/show/NCT03412799.

About Sun BioPharma

Sun BioPharma Inc. is a clinical-stage biopharmaceutical company developing disruptive therapeutics for patients with urgent unmet medical needs. The company's initial product candidate is SBP-101 for the treatment of patients with metastatic pancreatic ductal adenocarcinoma, the most common type of pancreatic cancer. Sun BioPharma Inc. is dedicated to treating patients with pancreatic cancer and fully exploring SBP-101's potential for efficacy in combination with other agents and in treating other types of cancer. SBP-101 was invented by Raymond J. Bergeron, PhD, 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," "expects," "intends," "may," or "plans." Examples of forward-looking statements include, among others, statements we make regarding, potential effects of FDA Fast Track designation, future determinations of the characteristics of SBP-101 and its effectiveness, uses of proceeds from recent financings. 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 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) our ability to obtain additional funding to complete Phase 1 clinical trial; (ii) progress and success of our Phase 1 clinical trial; (iii) the impact of the current COVID-19 pandemic on our ability to complete enrollment in our current clinical trial; (iv) our ability to demonstrate the safety and effectiveness of our SBP-101 product candidate (v) our ability to obtain regulatory approvals for our SBP-101 product candidate in the United States, the European Union or other international markets; (vi) the market acceptance and level of future sales of our SBP-101 product candidate; (vii) the cost and delays in product development that may result from changes in regulatory oversight applicable to our SBP-101 product candidate; (viii) the rate of progress in establishing reimbursement arrangements with third-party payors; (ix) the effect of competing technological and market developments; (x) the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims; and (xi) such other factors as discussed in Part I, Item 1A under the caption "Risk Factors" in our most recent Annual Report on Form 10-K, any additional risks presented in our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K. Any forward-looking statement made by us in this press release is based 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,		
	2020	2019	Percent Change	2020	2019	Percent Change
Operating expenses:						
General and administrative	$ 670	$ 580	15.5%	$ 1,125	$ 883	27.4%
Research and development	434	508	-14.6%	1,032	858	20.3%
Operating loss	(1,104)	(1,088)	1.5%	(2,157)	(1,741)	23.9%
Other income (expense):						
Interest expense	(4)	(1,152)	-99.7%	(9)	(2,184)	-99.6%
Other income	649	(101)	-742.6%	(184)	(68)	170.6%
Total other income (expense)	645	(1,253)	-151.5%	(193)	(2,252)	-91.4%
Loss before income tax benefit	(459)	(2,341)	-80.4%	(2,350)	(3,993)	-41.1%
Income tax benefit	40	70	-42.9%	133	141	-5.7%
Net loss	(419)	(2,271)	-81.5%	(2,217)	(3,852)	-42.4%
Foreign currency translation adjustment (loss)	(715)	49	-1559.2%	82	17	382.4%
Comprehensive Loss	$ (1,134)	$ (2,222)	-49.0%	$ (2,135)	$ (3,835)	-44.3%
Basic and diluted net loss per share	$ (0.06)	$ (0.45)	-86.7%	$ (0.33)	$ (0.76)	-56.6%
Weighted average shares outstanding - basic and diluted	6,732,470	5,070,341	32.8%	6,681,889	5,071,378	31.8%

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

	June 30, 2020	December 31, 2019
ASSETS	(Unaudited)	
Current assets:		
Cash	$ 2,265	$ 2,449
Prepaid expenses and other current assets	495	283
Income tax receivable	512	361
Total current assets	3,272	3,093
Other noncurrent assets	50	51
Total assets	$ 3,322	$ 3,144
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 493	$ 597
Accrued expenses	320	304
Term debt	64	116
Payroll protection plan loan	103	-
Unsecured promissory note payable	742	742
Total current liabilities	1,721	1,759
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 authorized; no shares issued or outstanding as of June 30, 2020 and December 31 2019	-	-
Common stock, $0.001 par value; 100,000,000 authorized; 7,068,301 and 6,631,308 shares issued and outstanding as of June 30, 2020 and December 31, 2019 respectively	7	7
Additional paid-in capital	44,681	42,331
Accumulated deficit	(43,475)	(41,258)
Accumulated comprehensive income	387	305
Total stockholders' equity	1,600	1,385
Total liabilities and stockholders' equity	$ 3,322	$ 3,144

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

	Six Months Ended June 30	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (2,217)	$ (3,852)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	376	422
Amortization of debt discount	-	2,061
Amortization of debt issuance costs	-	12
Non-cash interest expense	-	102
Changes in operating assets and liabilities:		
Income tax receivable	(151)	(144)
Prepaid expenses and other current assets	7	17
Accounts payable	(14)	(12)
Accrued liabilities	23	(20)
Net cash used in operating activities	(1,976)	(1,414)
Cash flows from financing activities:		
Proceeds from sale of common stock and warrants net of offering costs of $2	1,746	-
Proceeds from the sale of convertible promissory notes, net of debt issuance costs of $7	-	810
Proceeds from payroll protection loan	103	-
Repayment of demand note	-	(25)
Repayments of term debt	(53)	(55)
Net cash provided by financing activities	1,796	730
Effect of exchange rate changes on cash	(4)	-
Net change in cash	(184)	(684)
Cash at beginning of period	2,449	1,405
Cash at end of period	$ 2,265	$ 721
Supplemental disclosure of cash flow information:		
Cash paid during period for interest	$ 4	$ 8
Supplemental disclosure of non-cash transactions:		
Warrants issued for future services	$ 228	$ -
Beneficial conversion feature on convertible notes	$ -	$ 353
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	$ -	$ 2,281
Issuance of unsecured promissory note in exchange of vendor accounts payable	$ -	$ 742