2018 Annual Report

April 16, 2019

Dear fellow Sun BioPharma, Inc. Stockholders:

I am pleased to issue our report on Form 10-K, for the year ending December 31, 2018, which has been submitted to the Securities and Exchange Commission. The Company has made significant progress in 2018 on our mission to develop disruptive therapies for the treatment of pancreatic diseases, specifically regarding the development of SBP-101 for pancreatic ductal adenocarcinoma ("PDA").

We focused on a number of initiatives during 2018, resulting in two key accomplishments that were reported previously:

- Publication of the final results of our Phase 1 dose escalation mono-therapy safety study of SBP-101, and
- Began enrolling patients in a front-line Phase 1a/1b combination therapy safety study to determine a recommended dose level (Phase 1a) for an expanded study to follow at that dose level (Phase 1b).

Published results of Phase 1 Dose Escalation Study

In May of 2018 an abstract of the results of our Phase 1 dose escalation safety study of SBP 101 in heavily pre-treated pancreatic cancer patients was published on line by the American Society of Clinical Oncology (ASCO). This study, which had completed enrollment in November 2017, was a dose escalation safety study of SBP-101 for patients with previously treated, locally advanced or metastatic PDA. In total, 29 patients who had failed all other treatments for pancreatic cancer were treated at two centers in Australia and two centers in the US.

The purpose of the Phase 1 study was to determine the safety profile of SBP-101 in humans. This study showed no drug-related adverse events below the maximum tolerated dose (MTD) and no drug-related bone marrow toxicity or peripheral neuropathy at any dose level suggesting a relatively benign safety profile at the dose recommended for future studies. Importantly, the observation of no drug-related bone marrow toxicity or peripheral neuropathy lends support to our plan to combine SBP-101 with a common standard pancreatic cancer regimen (gemcitabine and nab-paclitaxel) which is associated with those adverse events.

In addition to being evaluated for safety, 23 of the 29 patients were evaluable for preliminary signals of efficacy using the Response Evaluation Criteria in Solid Tumors ("RECIST"), the current standard for evaluating changes in the size of tumors. Eight of the 23 patients (35%) had Stable Disease ("SD") and 15 of 24 (65%) had Progressive

Disease ("PD"). It should be noted that of the 15 patients with PD, six came from cohorts one and two and are considered to have received less than potentially therapeutic doses of SBP-101. We also noted that 28 of the 29 patients had follow-up blood tests measuring the Tumor Marker CA 19-9 associated with pancreatic ductal adenocarcinoma. Eleven of these patients (39%) had reductions in the CA 19-9 levels, as measured at least once after the baseline assessment. Seven of the remaining 17 patients who showed no reduction in CA 19-9 came from cohorts one and two.

The best response outcomes and best median survival were observed in the group of patients who received total cumulative doses of approximately 6 mg/kg (cohort three). Two of four patients (50%) showed SD at week eight. Median survival in this heavily pre-treated group was 5.9 months, with two patients surviving 8 and 10 months, respectively. By total cumulative dose received, five of twelve patients (42%) who received total cumulative doses between 2.5 mg/kg and 8.0 mg/kg had reductions in the CA19-9 levels, as measured at least once after the baseline assessment. Nine of these patients (67%) exceeded three months of overall survival ("OS"), three patients (25%) exceeded nine months of OS and two patients (17%) exceeded one year of OS and were still alive at the end of the study.

Enrolling patients in 1a/1b Front-line Study in Patients with Previously Untreated Metastatic PDA

The Data Safety Monitoring Board (DSMB) recommended a well-tolerated dose level of SBP-101 to be used for the further study of SBP-101 in combination with currently approved treatments. Our clinical team, working in conjunction with our medical advisors and physician investigators, developed a protocol to study SBP-101 when administered in combination with gemcitabine and nab-paclitaxel in patients newly diagnosed with metastatic PDA. This will be a Phase 1a/1b study with the Phase 1a dose escalation safety portion intended to include treatment at up to three dose levels of SBP 101 followed by a Phase 1b expansion phase at the recommended dose level determined in the Phase 1a portion of the study.

This new study will be conducted at 4 centers in Australia, including the two centers that participated in the first study, and up to 3 centers in the US. The first US site is the University of Florida, the institution where SBP-0101 was invented. These centers were enthusiastic to begin this study and the first patient was enrolled in June of 2018.

In addition, on October 31, 2018, I resumed the role of President and Chief Executive Officer of the Company in addition to my responsibilities as Executive Chairman. I am delighted to be back at the helm of the Company I co-founded in 2011.

2019 Initiatives

We would like to also share the following developments in early 2019.

- In January of 2019 we filed an International Patent Application. This patent application claims a novel process for the production of SBP-101 and reduces the number of synthetic steps from nineteen to six. (A provisional patent was

filed on behalf of our company and accepted for this new, short synthesis process for the manufacturing of SBP-101 in January of 2018). We are continuing to review other potential patents to strengthen our intellectual property position.

- We continue to work on adequately capitalizing the company to achieve our clinical goals, with a particular focus on funding the Phase 1a / 1b clinical trial. In January of 2019 we completed a bridge financing selling $2.2 million in convertible promissory notes and warrants.

Both of these developments are described more fully in the annual report on Form 10-K included with this letter, including potential risks, uncertainties and assumptions that could affect the timing and outcome of the latest clinical trial.

2018 has been a gratifying and exciting year in our Company's evolution, having published the encouraging results of our first first-in-human clinical study with SBP-101 and initiated a front-line study of SBP 101. All of us, and our clinical partners, recognize that the real "heroes" in what we do are the patients and their families who have, and will, participate in our studies.

We at Sun BioPharma, Inc. continue to work hard to lay the foundation for building a successful company. We have a dedicated and experienced group of people working on this effort. We are excited about the progress we have made in 2018 and early 2019 as we continue to enroll patients in the Phase 1a portion of our study. We encourage you to review the materials enclosed with this letter as well as to visit our web site: www.sunbiopharma.com. We will continue to update you through our press releases.

On behalf of our employees, consultants, advisors and the Board of Directors we want to thank you, our stockholders, for your loyal support of Sun BioPharma, Inc.

Sincerely,

Michael T. Cullen, MD, MBA
Executive Chairman
President and CEO

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April 16, 2019

Dear Stockholder:

The Board of Directors of Sun BioPharma, Inc. joins us in extending an invitation to attend our 2019 Annual Meeting of Stockholders (the "Annual Meeting"), to be held on May 21, 2019, at the offices of Faegre Baker Daniels LLP, 2200 Wells Fargo Center, 90 South Seventh Street, Minneapolis, Minnesota, commencing at 2:30 p.m. local time. On or about April 16, 2019, a full set of proxy materials will be mailed to each stockholder.

It is important that your shares be represented at the Annual Meeting whether or not you plan to attend in person. Please vote electronically over the Internet or, if you request and receive a paper copy of the proxy card by mail, you may vote by Internet or telephone or by returning your signed proxy card in the envelope provided. If you do attend the Annual Meeting and desire to vote in person, you may do so by following the procedures described in the proxy statement even if you have previously voted.

On behalf of the Board of Directors and management, it is my pleasure to express our appreciation for your continued support.

We hope that you will be able to attend the Annual Meeting.

Very truly yours,

Michael T. Cullen, M.D., M.B.A.
Executive Chairman of the Board
President and Chief Executive Officer

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SUN BIOPHARMA, INC.
712 Vista Boulevard #305
Waconia, Minnesota 55387

NOTICE OF ANNUAL MEETING OF STOCKHOLDERS TO BE HELD MAY 21, 2019

To the Stockholders of Sun BioPharma, Inc.:

Notice is hereby given that the 2019 Annual Meeting of Stockholders of Sun BioPharma, Inc., a Delaware corporation, will be held on May 21, 2019, at the offices of Faegre Baker Daniels LLP, 2200 Wells Fargo Center, 90 South Seventh Street, Minneapolis, Minnesota, commencing at 2:30 p.m. local time, for the following purposes:

1. Election of one Class III director;

2. Ratify the selection of Cherry Bekaert LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2019;

3. Advisory vote to approve compensation of the Company's executive officers ("Say-on-Pay");

4. Advisory vote to recommend the frequency of future Say-on-Pay votes; and

5. Action on any other matters that may properly come before the Annual Meeting and any adjournment or postponement thereof.

Only stockholders of record at the close of business on March 29, 2018, the record date for the meeting set by the Board of Directors, are entitled to notice of the Annual Meeting and may vote at the Annual Meeting or any adjournment(s) or postponement(s) thereof.

By Order of the Board of Directors,

Michael T. Cullen, M.D., M.B.A.
Executive Chairman of the Board
President and Chief Executive Officer

YOUR VOTE IS IMPORTANT

Whether or not you plan to attend the Annual Meeting, we urge you to vote as soon as possible. If you attend the meeting, you may vote your shares in person if you wish, whether or not you submit a proxy in advance of the meeting.

IMPORTANT NOTICE REGARDING THE AVAILABILITY OF PROXY MATERIALS FOR THE STOCKHOLDER MEETING TO BE HELD ON MAY 21, 2019

Our Proxy Statement for the 2019 Annual Meeting of Stockholders and our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, are available at https://www.rdgir.com/sun-biopharma-inc.

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SUN BIOPHARMA, INC.
712 Vista Boulevard #305
Waconia, Minnesota 55387

PROXY STATEMENT

The Board of Directors of Sun BioPharma, Inc. ("our Company") is soliciting proxies for use at the Annual Meeting of Stockholders to be held on May 21, 2019, and at any adjournment or postponement of the meeting (the "Annual Meeting").

The Annual Meeting will be held at the offices of Faegre Baker Daniels LLP, 2200 Wells Fargo Center, 90 South Seventh Street, Minneapolis, Minnesota. Registration for the Annual Meeting will begin at 2:00 p.m., local time. The Annual Meeting will commence at 2:30 p.m., local time. This solicitation is being made by mail; however, we also may use our officers, directors and employees (without providing them with additional compensation) to solicit proxies from stockholders in person or by telephone, facsimile or letter. Distribution of this proxy statement and the proxy card is scheduled to begin on or about April 16, 2019.

QUESTIONS AND ANSWERS ABOUT THE ANNUAL MEETING AND VOTING

Q: Why did I receive this proxy statement?

A: The Board of Directors is soliciting your proxy for use at the Annual Meeting because you owned shares of our common stock at the close of business on March 29, 2019, the record date for the Annual Meeting (the "Record Date"), and, therefore, are entitled to notice of the Annual Meeting and may vote at the Annual Meeting or any adjournment(s) or postponement(s) thereof.

Q: What is a proxy?

A: A proxy is your legal designation of another person or persons to vote on your behalf. By completing and returning the enclosed proxy card or voting in accordance with the instructions set forth therein, you are giving Michael T. Cullen and Susan Horvath, the proxy holders, the authority to vote your shares of common stock at the Annual Meeting in the manner you indicate. If you do not give direction with respect to any nominee or other proposal, the proxy holders will vote your shares as recommended by the Board of Directors. The proxy holders are authorized to vote in their discretion if other matters are properly submitted at the Annual Meeting, or any adjournments thereof.

Q: Who can vote?

A: Holders of our common stock at the close of business on the Record Date are entitled to vote at the Annual Meeting. On that date, there were a total of 5,070,341 shares of our common stock outstanding, which shares were held by 225 record holders. This proxy statement and any accompanying proxy card, along with the annual report on Form 10-K for the fiscal year ended December 31, 2018, were first made available to stockholders beginning on or about April 16, 2019. This proxy statement summarizes the information you need to complete and submit your proxy or to vote at the Annual Meeting.

Q: Who can attend the Annual Meeting?

A: All stockholders as of the Record Date, or their duly appointed proxy holders, may attend the Annual Meeting. If you hold your shares in street name, then you must request a legal proxy from your broker or nominee to attend or vote at the Annual Meeting.

Q: What proposals am I being asked to vote on?

A: You are voting on:

- Proposal 1 – Election of one Class III director.
- Proposal 2 – Ratification of the selection of Cherry Bekaert LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2019.
- Proposal 3 – Approval, on an advisory basis, of the compensation of our named executive officers.
- Proposal 4 – Recommendation, on an advisory basis, of the frequency of future advisory votes to approve the compensation of our named executive officers.

Q: How does the Board of Directors recommend I vote on the proposals?

A: The Board is soliciting your proxy and recommends you vote:

- FOR each of the Class III director nominees (see Proposal 1); and
- FOR the ratification of our independent registered public accounting firm for the year ending December 31, 2019 (see Proposal 2); and
- FOR approval of the compensation of our named executive officers (see Proposal 3); and
- TWO YEARS for the frequency of future votes to approve the compensation of our named executive officers (see Proposal 4).

Q: What constitutes a quorum?

A: A majority of the voting power, which includes the voting power that is present in person or by proxy, regardless of whether the proxy has authority to vote on all matters, constitutes a quorum for the transaction of business at the Annual Meeting. As of the Record Date, 2,535,171 shares of our common stock constituted a majority of the voting power. If you submit a valid proxy or attend the Annual Meeting, your shares will be counted to determine whether there is a quorum. Broker non-votes and abstentions are also counted for the purpose of determining a quorum, as discussed below.

Q: What vote is required to approve each proposal?

A: **Proposal 1 – Election of one Class III Director -** Provided a quorum is present at the Annual Meeting, the one nominees receiving a plurality (i.e., greatest number) of the votes cast for all nominees will be elected, regardless of whether any such nominees receive votes from a majority of the shares represented (in person or by proxy) at the Annual Meeting.

Proposal 2 – Ratification of the selection of Cherry Bekaert LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2019 - Provided a quorum is present at the Annual Meeting, this proposal will be approved if it received the affirmative vote of a majority of the shares of stock represented at the meeting and entitled to vote on the proposal.

Proposal 3 – Advisory vote on the compensation of the Company's executive officers – We will consider our stockholders to have approved, on an advisory basis, our executive compensation if the number of votes "for" the proposal exceeds the number of votes "against" the proposal.

Proposal 4 – Advisory vote on the frequency of future votes on executive compensation – The option that receives the highest number of votes will be deemed to be the recommendation of our stockholders.

Q: What is the effect of broker non-votes and abstentions?

A: A "broker non-vote" occurs when a nominee holding shares for a beneficial owner does not vote on a particular proposal because the nominee does not have or does not exercise discretionary voting power with respect to that item and has not received voting instructions from the beneficial owner. If a broker returns a "non-vote" proxy indicating a lack of authority to vote on a proposal, then the shares covered by such a "non-vote" proxy will be deemed present at the Annual Meeting for purposes of determining a quorum, but not present for purposes of calculating the vote with respect to any non-discretionary proposals. Nominees will not have discretionary voting power with respect to any matter to be voted upon at the Annual Meeting, other than the ratification of the selection of our independent registered public accounting firm. Broker non-votes will have the effect of a vote against Proposal 2 but will have no effect on the outcomes of Proposals 1, 3 and 4.

A properly executed proxy marked "ABSTAIN" with respect to a proposal will be counted for purposes of determining whether there is a quorum and will be considered present in person or by proxy and entitled to vote but will not be deemed to have been voted in favor of such proposal. Abstentions will have the effect of a vote against Proposal 2 but will have no effect on the outcomes of Proposals 1, 3 and 4.

Q: How will the proxy holders vote on any other business brought up at the Annual Meeting?

A: By submitting your proxy, you authorize the proxy holders to use their judgment to determine how to vote on any other matter brought before the Annual Meeting, or any adjournments or postponements thereof. We do not know of any other business to be considered at the Annual Meeting.

Q: How do I vote my shares?

A: If you are a stockholder of record, you may vote your shares of common stock at the Annual Meeting using any of the following methods:

- **Proxy card**—The enclosed proxy card is a means by which a stockholder may authorize the voting of the stockholder's shares of common stock at the Annual Meeting. The shares of common stock represented by each properly executed proxy card will be voted at the Annual Meeting in accordance with the stockholder's directions. We urge you to specify your choices by marking the appropriate boxes on the enclosed proxy card. After you have marked your choices, please sign and date the proxy card and mail the proxy card to our stock transfer agent, VStock Transfer, LLC, in the enclosed envelope or via facsimile transmission at the number identified on your proxy card. If you sign and return the proxy card without specifying your choices, your shares will be voted in accordance with the recommendations of the Board of Directors.

- **Internet**—If you have Internet access, you may submit your proxy from any location in the world 24 hours a day, 7 days a week. Have your proxy card with you when you access the website and then follow the instructions to obtain your records and to create an electronic voting instruction form.

- **In person at the Annual Meeting**—All stockholders of record as of the Record Date may vote in person at the Annual Meeting. Even if you plan to attend the Annual Meeting, we recommend that you submit your proxy card or vote by internet or telephone ahead of time so that your vote can be counted if you later decide not to attend.

You are a "beneficial owner" of shares held in "street name," rather than a "stockholder of record," if your shares are held in the name of a broker, bank, trust or other nominee as a custodian, and this proxy statement and the accompanying notice were forwarded to you by that organization. As a beneficial owner, you have the right to direct your broker, bank, trust or other nominee how to vote your shares. You may vote by proxy by completing the voting instruction form provided by your custodian. Since a beneficial owner is not the stockholder of record, you may not vote your shares in person at the Annual Meeting unless you obtain a "legal proxy" from the broker, bank, trustee, or nominee that holds your shares giving you the right to vote the shares at the meeting.

Q: Can I revoke or change my vote?

A: You can revoke your proxy at any time before it is voted at the Annual Meeting by:

- Submitting a new proxy with a more recent date than that of the first proxy given before 11:59 p.m. EDT on May 20, 2019, by following the Internet voting instructions;
- Completing, signing, dating and returning a new proxy card to us, which must be received by us before the time of the Annual Meeting; or
- If you are a registered stockholder, by attending the meeting in person and delivering a proper written notice of revocation of your proxy.

Attendance at the meeting will not by itself revoke a previously granted proxy. Unless you decide to vote your shares in person, you should revoke your prior proxy in the same way you initially submitted it – that is, by Internet, facsimile or mail.

Q: Who will count the votes?

A: All proxies submitted will be tabulated by our transfer agent, VStock Transfer, LLC. All shares voted by stockholders of record present in person at the 2019 Annual meeting will be aggregated with the proxies reported by VStock Transfer, LLC by our Corporate Secretary, or her designee, who will also act as inspector of election for the Annual Meeting.

Q: Is my vote confidential?

A: All proxies and all vote tabulations that identify an individual stockholder are confidential. Your vote will not be disclosed except:

- To allow our independent proxy tabulator to tabulate the vote;
- To allow the inspector of election to certify the results of the vote; and
- To meet applicable legal requirements.

Q: What shares are included on my proxy?

A: Your proxy will represent all shares registered to your account in the same social security number and address.

Q: What happens if I don't vote shares that I own?

A: *Shares registered in your name*. If you do not vote shares that are registered in your name by voting in person at the Annual Meeting or by proxy through the Internet, facsimile or mail as described on the proxy card, your shares will not be counted in determining the presence of a quorum or in determining the outcome of the vote on the proposals presented at the Annual Meeting.

Shares held in street name. If you hold shares through a broker, you will receive voting instructions from your broker. If you do not submit voting instructions to your broker and your broker does not have discretion to vote your shares on a particular matter, then your shares will not be counted in determining the outcome of the vote on that matter at the Annual Meeting. See "What is the effect of broker non-votes and abstentions?" as described above. Your broker will not have discretion to vote your shares for any matter to be voted upon at the Annual Meeting other than the ratification of the selection of our independent registered public accounting firm. Accordingly, it is important that you provide voting instructions to your broker for the matters to be voted upon at the Annual Meeting.

Q: What if I do not specify how I want my shares voted?

A: If you are a registered stockholder and submit a signed proxy card or submit your proxy by Internet or telephone but do not specify how you want to vote your shares on a particular matter, we will vote your shares in accordance with the recommendations of the Board of Directors as set forth above with respect to matters described in the proxy statement.

If any matters not described in the proxy statement are properly presented at the Annual Meeting, the proxy holders will use their own judgment to determine how to vote your shares. If the Annual Meeting is adjourned, the proxy holders can vote your shares on the new meeting date as well, unless you have revoked your proxy instructions, as described under "*Can I revoke or change my vote?*"

Q: What does it mean if I get more than one proxy card?

A: Your shares are probably registered in more than one account. You should follow voting instructions for all proxy cards you receive.

Q: How many votes can I cast?

A: You are entitled to one vote per share on all matters presented at the Annual Meeting or any adjournment or postponement thereof. Our stockholders do not have a right to cumulate their votes for the election of directors or otherwise.

Q: When are stockholder proposals and nominees due for the 2020 Annual Meeting of Stockholders?

A: If you want to submit a stockholder proposal or nominee for the 2020 Annual Meeting of Stockholders, you must submit the proposal in writing to our Secretary at Sun BioPharma, Inc., 712 Vista Boulevard #305, Waconia, Minnesota 55387, so it is received by the relevant date set forth below under "*Submission of Stockholder Proposals and Nominations*."

Q: How is this proxy solicitation being conducted?

A: We will pay the cost of soliciting proxies. In addition to solicitation by the use of the mails, certain of our directors, officers and employees may solicit proxies by telephone, email or personal contact, and have requested brokerage firms and custodians, nominees and other record holders to forward soliciting materials to the beneficial owners of our stock and will reimburse them for their reasonable out-of-pocket expenses in so forwarding such materials.

PROPOSAL 1:
ELECTION OF CLASS III DIRECTORS

Our business is overseen by a Board of Directors divided into three classes as nearly equal in number as possible, and directors typically are elected to a designated class for a term of three years. The following table sets forth certain information regarding the current members of our Board of Directors:

Name	Age	Position(s)
Michael T. Cullen.....	73	Executive Chairman of the Board, President, Chief Executive Officer and Director
Suzanne Gagnon.....	62	Chief Medical Officer and Director
Jeffrey S. Mathiesen.....	58	Director
Paul W. Schaffer	76	Director
D. Robert Schemel	64	Director

The Board of Directors has fixed at one the number of directors to be elected to the Board at the 2019 Annual Meeting of Stockholders. Based upon the recommendation of its Nominating and Governance Committee, the Board has nominated Jeffery S. Mathieson to stand for election for a three-year term. Proxies solicited by the Board will, unless otherwise directed, be voted to elect the nominee as set forth below.

Nominee for Class III Director – Term Expiring in 2022

The nominee named below is a current director of our Company and has indicated a willingness to serve as a director for the term to which he is elected, but in case the nominee is not a candidate at the meeting for any reason, the proxy holders named in our form of proxy may vote for a substitute nominee in their discretion or our Board of Directors may recommend that the number of directors to be elected be reduced. The following table sets forth certain information regarding the director nominee:

Jeffrey S. Mathiesen has served as a director of our Company since September 2015. He has served as Chief Financial Officer of Teewinot Life Sciences, a privately held biopharmaceutical company focused on the biosynthetic production of pure pharmaceutical grade cannabinoids since March 2019. Previously he served as Chief Financial Officer of Gemphire Therapeutics Inc., a publicly traded biopharmaceutical company from September 2015 to September 2018. From August 2015 to September 2015 he was a consultant to Gemphire. He served as Chief Financial Officer of Sunshine Heart, Inc., a publicly traded medical device company, from March 2011 to January 2015. From December 2005 to April 2010, Mr. Mathiesen served as Vice President and Chief Financial Officer of Zareba Systems, Inc., a manufacturer and marketer of medical products, perimeter fencing and security systems that was purchased by Woodstream Corporation in April 2010. Mr. Mathiesen has held executive positions with publicly traded companies dating back to 1993, including vice president and chief financial officer positions. Mr. Mathiesen also serves as a director and audit committee chairman of NeuroOne Medical Technologies Corporation, a publicly traded medical device company and as a director and audit committee chairman of eNeura, Inc., a privately held medical technology company providing therapy for both acute treatment and prevention of migraine. Mr. Mathiesen holds a B.S. in Accounting from the University of South Dakota and is also a Certified Public Accountant. We believe that Mr. Mathiesen brings financial insight and leadership and a wealth of experience in capital markets to the Board of Directors, as well as knowledge of public company accounting and financial reporting requirements

Class I Directors – Terms Expiring in 2020

Suzanne Gagnon, M.D., has served as our Chief Medical Officer and as a director of our Company since September 2015. Dr. Gagnon had previously served as a director of Sun BioPharma Research, Inc. ("SBR"), a former affiliate of the Company, since June 2015 and as its Chief Medical Officer since January 2015. Previously, Dr. Gagnon served as the Lead Clinical Consultant to the Company. Dr. Gagnon has been the President of Gagnon Consulting LLC since July 2014, consulting on medical, safety and regulatory matters. From December 2001 through July 2014, Dr. Gagnon had acted as the Chief Medical Officer for three companies, ICON Clinical Research, Nupathe, Inc. and Idis, Inc.

Paul W. Schaffer has served as a director since September 2015. Mr. Schaffer had previously served as a director of SBR since January 2014. Mr. Schaffer graduated from Minnesota Pharmacy School in 1966. He owned and operated a compounding pharmacy, Bloomington Drug, for 42 years. Mr. Schaffer is an experienced biotech investor. We believe that Mr. Schaffer brings a wealth of experience in pharmaceutical development and manufacturing to the Board of Directors, as well as knowledge of regulations and issues facing pharmaceutical companies.

Class II Directors –Terms Expiring in 2021

Michael T. Cullen, M.D., M.B.A., has served as Executive Chairman of the board and as a director of our Company since September 2015. He resumed responsibilities as President and Chief Executive Officer of the Company in October 2018. Dr. Cullen brings 30 years of pharmaceutical experience to our Company, including expertise in working with development-stage companies in planning, designing and advancing drug candidates from preclinical through clinical development. Dr. Cullen co-founded SBR in November 2011 and had continuously served as Chairman its board of directors since that date. He previously served as its Chief Executive Officer and President of SBR from November 2011 to June 2015. Dr. Cullen assumed responsibility as the President and Chief Executive Officer of the Company on October 31, 2018. Dr. Cullen provided due diligence consulting to the pharmaceutical industry from 2009 to 2011, after one year in transition consulting to Eisai Co., Ltd. He developed several oncology drugs as Chief Medical Officer for MGI Pharma Inc. from 2000 to 2008, and previously at G.D. Searle, SunPharm Corporation, and as Vice President for Clinical Consulting at IBAH Inc., the world's fifth largest contract research organization, where he provided consulting services on business strategy, creating development plans, regulatory matters and designing clinical trials for several development stage companies in the pharmaceutical industry. Dr. Cullen was also a co-founder and Chief Executive Officer of IDD Medical, a pharmaceutical start-up company. Dr. Cullen joined 3M Pharmaceuticals in 1988 and contributed to the development of cardiovascular, rheumatology, pulmonary and immune-response modification drugs. Over the course of his career Dr. Cullen has been instrumental in obtaining the approval of ten drugs, including three (3) since 2004: Aloxi®, Dacogen® and Lusedra®. Board-certified in Internal Medicine, Dr. Cullen practiced from 1977 to 1988 at Owatonna Clinic, Owatonna, MN, where he served as president. Dr. Cullen earned his MD and BS degrees from the University of Minnesota and his MBA from the University of St. Thomas and completed his residency and Board certification in Internal Medicine through the University of North Carolina in Chapel Hill and Wilmington, NC.

D. Robert Schemel has served as a director since the September 2015. Mr. Schemel had previously served as a director of SBR since March 2012. Mr. Schemel has over 39 years' experience in the agriculture industry. From 1973-2005, Mr. Schemel owned and operated a farming operation in Kandiyohi County, Minnesota, building a 5,000-acre operation producing corn, soybeans and sugar beets. Mr. Schemel has extensive experience in serving on boards of directors. From 1992-1996 he served as a board member for ValAdCo and then from 1996-2003 he served as the Chairman of the Board for Phenix Biocomposites. We believe that Mr. Schemel brings business insight and leadership as well as significant experience in the development and growth of early stage companies.

Required Vote and Board Recommendation

Directors are elected by a plurality of votes present and entitled to vote. Provided that a quorum is present, the nominee receiving the highest number of votes will be elected. The votes cannot be cast for a greater number of persons than one.

The Board of Directors recommends that you vote "FOR" the nominee for Class III Director listed above.

CORPORATE GOVERNANCE

In accordance with applicable laws and our bylaws, the business and affairs of the Company are governed under the direction of the Board of Directors. The system of governance practices we follow is set forth in our corporate governance guidelines and in the charters of each of the committees of the Board of Directors. The corporate governance guidelines set forth the practices our board will follow with respect to its duties, committee matters, director qualifications and selection process, director compensation, director share ownership, director orientation and continuing education, executive evaluation, management succession and annual evaluation of the Board of Directors and committees. We also have adopted a code of business conduct and ethics relating to the conduct of our business by our employees, officers and directors. The corporate governance documents of the Company are reviewed periodically to ensure effective and efficient governance and compliance in a timely manner with all laws.

Corporate governance information, including the corporate governance guidelines, committee charters and the code of business conduct and ethics applicable to our directors, officers and employees is posted on our website at *www.sunbiopharma.com* under the "Investors" page. We plan to post to our website at the address described above any future amendments or waivers to our code of ethics and business conduct.

Board Leadership Structure

Our Board of Directors is led by our Executive Chairman, Michael T. Cullen. As Executive Chairman, Dr. Cullen (a) is responsible for calling and presiding over meetings of the Board, (b) presides over our meetings of stockholders, (c) holds primary responsibility in setting Board agendas, (d) has the ability to represent us with external stakeholders. On October 31, 2018, the Board elected Dr. Cullen to fill vacancies in the additional roles of President and Chief Executive Officer. We believe that having the same individual serve as Chairman of the Board and Chief Executive Officer is appropriate as it both maintains the functionality of our Board of Directors and is an efficient use of Company resources. Our Board of Directors has not designated a lead independent director.

Nominating Process and Board Diversity

The Nominating and Governance Committee generally identifies director candidates based upon suggestions from current directors and senior management, recommendations by stockholders or use of a director search firm. Stockholders who wish to suggest qualified candidates may write to the attention of the chairman of our Nominating and Governance Committee at Sun BioPharma, Inc., 712 Vista Boulevard #305, Waconia, Minnesota 55387. All recommendations should state in detail the qualifications of such person for consideration by the committee and should be accompanied by an indication of the recommended person's willingness to serve if elected. The committee will consider candidates recommended by stockholders in the same manner that it considers all director candidates.

Candidates for director are reviewed in the context of the current composition of our Board of Directors, our operations and the long-term interests of our stockholders. We do not have a policy regarding the consideration of diversity in identifying director nominees.

Director Independence

Our Board of Directors has reviewed the materiality of any relationship that each of our directors has with us, either directly or indirectly. Based on this review, our Board of Directors has determined that Messrs. Mathiesen, Schaffer and Schemel are "independent directors" as defined under the applicable rules of The Nasdaq Stock Market, LLC, which we have voluntarily adopted as our standard for director independence.

Communications with our Board of Directors

You may contact our Board of Directors or any director by mail addressed to the attention of our Board of Directors or the specific director identified by name or title, at 712 Vista Boulevard #305, Waconia, Minnesota 55387. All communications will be submitted to our Board of Directors or the specified director on a periodic basis.

Board Meetings and Attendance

Our Board of Directors held nine meetings during 2018. Each director, other than Mr. Schemel, attended at least 75% of the meetings of our Board of Directors and the committees on which he or she served held during their service as a director or member of the committee in the year ended December 31, 2018.

Director Attendance at Annual Meeting

We do not have a formal policy regarding attendance of directors at our annual meeting of stockholders. Two directors were present at our annual meeting of stockholders held in 2018.

Committees of the Board of Directors

Our Board of Directors has established three standing committees: Audit, Compensation, and Nominating and Governance. The membership of each committee is as follows:

	Committees			
Director	**Audit**	**Compensation**	**Nominating and Governance**	**Independent Directors**
Michael T. Cullen	–	–	–	
Suzanne Gagnon	–	–	–	
Jeffrey S. Mathiesen	Chair	–	Member	✓
Paul W. Schaffer	Member	Member	Member	✓
D. Robert Schemel	Member	Chair	–	✓

Audit Committee

The Audit Committee's primary functions, among others, are to: (a) assist the Board of Directors in discharging its statutory and fiduciary responsibilities with regard to audits of the books and records of our Company and the monitoring of its accounting and financial reporting practices; (b) carry on appropriate oversight to determine that our Company and its subsidiaries have adequate administrative and internal accounting controls and that they are operating in accordance with prescribed procedures and codes of conduct; and (c) independently review our Company's financial information that is distributed to stockholders and the general public. The Audit Committee held five meetings during 2018. The Audit Committee has a charter, which is available on our website at *www.sunbiopharma.com*.

All of the members of the Audit Committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC. Our Board of Directors has determined that Jeffrey S. Mathiesen is qualified to serve as an audit committee financial expert, as that term is defined under the applicable rules of the SEC. Each member of the Audit Committee satisfies the independence requirements of Rule 10A-3(b)(1) of the Securities Exchange Act.

AUDIT COMMITTEE REPORT

In accordance with its written charter adopted by the Board of Directors, as amended, the Audit Committee assists the Board with fulfilling its oversight responsibility regarding the quality and integrity of the accounting, auditing and financial reporting practices of the Company.

In discharging its duties, the Audit Committee:

(1) reviewed and discussed the audited financial statements included in the Form 10-K for the fiscal year ended December 31, 2018 with management;

(2) discussed with Cherry Bekaert LLP, the Company's independent registered public accounting firm, the matters required to be discussed by the applicable Public Company Accounting Oversight Board standards;

(3) received and reviewed the written disclosures and the letter from Cherry Bekaert LLP required by applicable requirements of the Public Company Accounting Oversight Board regarding Cherry Bekaert LLP's communications with the audit committee concerning independence, and the Audit Committee discussed with Cherry Bekaert LLP their independence from management and the Company; and

(4) has considered whether the provision of services by Cherry Bekaert LLP not related to the audit of the financial statements referred to above and to the reviews of the interim financial statements included in the Company's quarterly reports on Form 10-Q are compatible with maintaining Cherry Bekaert LLP's independence, and has determined that they are compatible and do not impact Cherry Bekaert LLP's independence.

Based upon the review and discussions referred to above, the Audit Committee recommended to the Board of Directors that the audited financial statements be included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 to be filed with the Securities and Exchange Commission.

Audit Committee:
Jeffrey S. Mathiesen (Chair)
D. Robert Schemel
Paul W. Schaffer

Compensation Committee

The Compensation Committee reviews and recommends to our Board of Directors on an annual basis the goals and objectives relevant to the annual compensation of our executive officers in light of their respective performance evaluations. Our Compensation Committee is responsible for administering our 2011 Equity Incentive Plan ("2011 Plan"), as amended and 2016 Omnibus Incentive Plan ("2016 Plan"), including approval of individual grants of stock options and other awards. The Compensation Committee held four meetings during 2018. The Compensation Committee has a charter, which is available on our website at *www.sunbiopharma.com*.

Nominating and Governance Committee

The Nominating and Governance Committee is primarily responsible for identifying individuals qualified to serve as members of our Board of Directors, recommending individuals to our Board of Directors for nomination as directors and committee membership, reviewing the compensation paid to our non-employee directors and recommending adjustments in director compensation, as necessary, in addition to overseeing the annual evaluation of our Board of Directors. The Nominating and Governance Committee held one meeting during 2018. The Nominating and Governance Committee has a charter that is available on our website at *www.sunbiopharma.com*.

Role of the Board in Risk Oversight

One of the key functions of our Board of Directors is informed oversight of our risk management process. The Board of Directors does not have a standing risk management committee, but rather administers this oversight function directly through the Board of Directors as a whole, as well as through various standing committees of our Board of Directors that address risks inherent in their respective areas of oversight. In particular, our Board of Directors is responsible for monitoring and assessing strategic risk exposure and our Audit Committee has the responsibility to consider and discuss our major financial

risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The Audit Committee also monitors compliance with legal and regulatory requirements. Our Nominating and Governance Committee monitors the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper liability-creating conduct. Our Compensation Committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.

Certain Relationships and Related Party Transactions

The following is a summary of transactions since January 1, 2017 to which our Company has been a party and in which the amount involved exceeded $13,000, which is approximately 1% of the average of our total assets as of the ends of our last two completed fiscal years, and in which any of our directors, executive officers, or beneficial owners of more than 10% of our capital stock had or will have a direct or indirect material interest, other than the compensation arrangements that are described under the heading "*Executive Compensation: Employment Agreements*" below.

Our Chief Medical Officer, Suzanne Gagnon, is also a member of our Board of Directors. We are party to an employment agreement with Dr. Gagnon in substantially the same form as the employment agreements with the Executives described above under the heading "*Executive Compensation: Employment Agreements*." Dr. Gagnon is eligible to participate in the other compensation and benefit programs generally available to our employees. Her employment agreement also includes customary confidentiality, non-competition and non-solicitation covenants. During 2017 and 2018, Dr. Gagnon received compensation from the Company amounting to $195,000 and $207,700, respectively. Under her employment agreement in effect for 2016, Dr. Gagnon was entitled to receive an initial annualized base salary equal to $360,000. Her employment agreement was amended to reduce her annualized base salary to $270,000, effective as of October 1, 2017. Dr. Gagnon's employment agreement, as amended, would have entitled her to a potential payment equal to $385,046, which amount was based on the amount of compensation that she had accrued prior to September 30, 2017, as a result of any change of control of Qualified Offering (described further below) occurring on or before June 30, 2018. However, Dr. Gagnon waived all right to receive the potential payment pursuant to a waiver and third amendment to her employment agreement that became effective in February 2018.

Certain directors and executive officers participated in various debt and equity offerings during the two years ended December 31, 2018. The table below summarizes those securities purchases:

Name of Related Person	Date of Investment	Securities Purchased	Amount Invested
Michael T. Cullen, ... Executive Chairman President, CEO and Director[(a)]	2/14/2018	5,000 Shares of Common Stock and Warrants to Purchase up to 5,000 additional Shares of Common Stock[(b)]	$ 25,000
Jeffrey S. Mathiesen, ... Director	2/14/2018	3,000 Shares of Common Stock and Warrants to Purchase up to3,000 additional Shares of Common Stock[(b)]	$ 15,000
Scott Kellen, ... Former Vice President and CFO	2/14/2018	1,000 Shares of Common Stock and Warrants to Purchase up to 1,000 additional Shares of Common Stock[(b)]	$ 5,000
David Kaysen, ... Former President, CEO and Director	5/16/2018	1,000 Shares of Common Stock and Warrants to Purchase up to 1,000 additional Shares of Common Stock[(b)]	$ 5,000
Paul Schaffer, ... Director	5/16/2018	5,000 Shares of Common Stock and Warrants to Purchase up to 5,000 additional Shares of Common Stock[(b)]	$ 25,000
Michael T. Cullen, ... Executive Chairman President, CEO and Director	12/31/2018	$35,000 principal amount of Convertible Promissory Notes and Warrants to purchase up to 20,000 Shares of Common Stock[(c)]	$ 35,000
Susan Horvath, ... Vice President and CFO	12/31/2018	$23,625 principal amount of Convertible Promissory Notes and Warrants to purchase up to 13,500 Shares of Common Stock[(c)]	$ 23,625

(a) As trustee of the Cullen Living Trust Dated April 23, 2009

(b) Pursuant to Securities Purchase Agreement dated February 20, 2018. The warrants are exercisable for a period of three years from the date of issuance at an exercise price of $5.00 per share.

(c) The Convertible Promissory Notes ("Notes") are part of a series of notes issued on the same terms as those issued to third parties in December 2018 and January 2019, are scheduled to mature on June 30, 2019 and bear interest at a rate of 10.0% per year. We may prepay the Notes in whole or in part at any time without penalty or premium. The Notes have a mandatory conversion of all principal and interest into common stock on the earlier of (1) June 30, 2019 or (2) the date our Company receives gross proceeds of at least $6.0 million from the sale of equity securities (subject to certain exclusions). The Notes convert at a stated conversion rate of $3.50 per share subject to downward adjustments to match the price per share of common stock or any unit containing a share of common

stock issued by the Company on or before the date of conversion. The exercise price of each warrant is $4.50 per share and they are exercisable until the 5-year anniversary of the date of issuance. The exercise price of each warrant is subject to downward adjustments to match the exercise price of any common stock warrants issued by the Company on or before June 30, 2019.

Limitation of Liability of Directors and Officers and Indemnification

Our certificate of incorporation limits the liability of the directors to the fullest extent permitted by Delaware law.

Our bylaws provide that we will indemnify and advance expenses to the directors and officers to the fullest extent permitted by law or, if applicable, pursuant to indemnification agreements. They further provide that we may choose to indemnify other employees or agents of our Company from time to time. The Delaware General Corporation Law and the bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in connection with their services to our Company, regardless of whether the bylaws permit indemnification. We maintain a directors' and officers' liability insurance policy.

At present there is no pending litigation or proceeding involving any of the current or former directors or officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC this indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Related Person Transaction Approval Policy

Our Board of Directors has adopted a written policy regarding transactions with related persons, which we refer to as our related party transaction approval policy. Our related party transaction approval policy requires that any executive officer proposing to enter into a transaction with a "related party" generally must promptly disclose to our Audit Committee the proposed transaction and all material facts with respect thereto. In reviewing a transaction, our Audit Committee will consider all relevant facts and circumstances, including (1) the commercial reasonableness of the terms, (2) the benefit and perceived benefits, or lack thereof, to us, (3) the opportunity costs of alternate transactions and (4) the materiality and character of the related party's interest, and the actual or apparent conflict of interest of the related party.

Our Audit Committee will not approve or ratify a related party transaction unless it determines that, upon consideration of all relevant information, the transaction is beneficial to our Company and stockholders and the terms of the transaction are fair to our Company. No related party transaction will be consummated without the approval or ratification of our Audit Committee. It will be our policy that a director will recuse him- or herself from any vote relating to a proposed or actual related party transaction in which they have an interest. Under our related party transaction approval policy, a "related party" includes any of our directors, director nominees, executive officers, any beneficial owner of more than 5% of our common stock and any immediate family member of any of the foregoing. Related party transactions exempt from our policy include transactions available to all of our employees and stockholders on the same terms and transactions between us and the related party that, when aggregated with the amount of all other transactions between us and the related party or its affiliates, involved less than one percent of the average of our Company's total assets at yearend for the last two completed fiscal years.

Compensation Committee Interlocks and Insider Participation

None of the members of the Compensation Committee nor any director nominee proposed to become a member of the Compensation Committee is or has at any time during the last completed fiscal year been an officer or employee of our Company. None of our executive officers has served as a member of the board of directors or as a member of the compensation or similar committee, of any entity that has one or more executive officers who served on our Board of Directors during the last completed fiscal year.

None of the members of the Compensation Committee is or has at any time during the last completed fiscal year been an officer or employee of our Company. None of our executive officers has served as a member of the board of directors, or as a member of the compensation or similar committee, of any entity that has one or more executive officers who served on our Board of Directors or Compensation Committee during the last completed fiscal year.

DIRECTOR COMPENSATION

Directors who are also our employees receive no additional compensation for serving on our Board of Directors. During 2018, our Company reimbursed non-employee directors for out-of-pocket expenses incurred in connection with attending meetings of our Board of Directors and its committees. Our non-employee directors received no compensation during the year ended December 31, 2018.

On March 19, 2019, the Compensation Committee of the Board of Directors approved a compensation program for our non-employee directors effective for 2019 and future years, consisting of annual awards of options to purchase common stock. Each non-employee director will be eligible to receive an option by dividing a target dollar amount by the Black-Scholes value of a share of our common stock as of the date of grant. The target dollar amount for each director will equal (i) $35,000 for service as a non-employee director, plus (ii) $5,000 for each committee of which the director is expected to serve as chair. The resulting common stock option will be granted as soon as practicable after the completion of our annual meeting of stockholders and will be scheduled to vest in full on the day preceding the following annual meeting of stockholders.

The Compensation Committee also determined that each current non-employee director will receive a one-time grant of an option to purchase a number of shares of our common stock equal to $10,000 divided by the Black-Scholes value of a share of our common stock on the date of grant. Each such option will vest in three substantially equal installments on the first, second and third anniversaries of the dates of grant.

All options awarded to non-employee directors under the new compensation program will bear an initial exercise price equal to the fair market value of a share of our common stock on the grant date, as determined in accordance with the applicable equity incentive plan, and, once vested, will remain exercisable through the ten-year anniversary of the date of grant.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information with respect to the beneficial ownership of our outstanding common stock as of March 29, 2019 by (i) each of our named executive officers identified in the Summary Compensation Table below; (ii) each of our directors; (iii) all of our executive officers, directors and director nominees as a group; and (iv) each other beneficial owner of 5% or more of our outstanding common stock. Ownership percentages are based on 5,070,341 shares of common stock outstanding as of the close of business on the same date. Beneficial ownership is determined in accordance with the rules of the SEC. To our knowledge and subject to applicable community property laws, each of the holders of stock listed below has sole voting and investment power as to the stock owned unless otherwise noted. The table below includes the number of shares underlying options that are exercisable within 60 days from March 29, 2019. Except as otherwise noted below, the address for each director or officer listed in the table is c/o Sun BioPharma, Inc., 712 Vista Blvd #305, Waconia, Minnesota 55387.

Name	Amount and Nature of Beneficial Ownership	Percentage of Outstanding Shares
Executive Officers and Directors		
Michael T. Cullen	589,317[(a)]	11.1%
Susan Horvath	40,412[(b)]	*
Suzanne Gagnon	225,500[(c)]	4.3%
Jeffrey S. Mathiesen	26,800[(d)]	*
Paul W. Schaffer	183,641[(e)]	3.6%
D. Robert Schemel	404,649[(f)]	7.9%
David B. Kaysen[(g)]	145,628	2.8%
Scott Kellen[(h)]	70,173	1.4%
All directors and current executive officers as a group (6 persons)	1,491,119[(i)]	26.1%
Ryan R. Gilbertson 8615 Eagle Creek Circle Savage, Minnesota 55378	583,538[(j)]	11.5%
Ryan Gilbertson 2012 Irrevocable Family Trust 8615 Eagle Creek Circle Savage, Minnesota 55378	520,003[(k)]	9.7%
Douglas M. Polinski 328 Barry Ave S., #210 Wayzata, Minnesota 55391	315,917[(j)]	6.1%

* Less than 1 percent.

(a) Includes 194,576 shares held by the Cullen Living Trust and 195,000 shares subject to stock options, 27,500 shares subject to warrants and an estimated 10,241 shares issuable pursuant to a convertible promissory note.

(b) Includes 20,000 shares subject to stock options, 13,500 shares subject to warrants and approximately 6,912 shares issuable pursuant to a convertible promissory note.

(c) Includes 1,000 shares held by the Gagnon Family Trust, 180,000 shares subject to stock options and 1,500 shares subject to warrants.

(d) Includes 20,800 shares subject to options and 3,000 shares subject to warrants.

(e) Includes 30,685 shares held by the Paul Shaffer Trust, 36,800 shares subject to stock options, 21,756 shares subject to warrants.

(f) Includes 282,654 shares held by spouse and 20,800 shares subject to stock options and 11,767 shares subject to warrants.

(g) Mr. Kaysen resigned from all positions with Company effective October 31, 2018.

(h) Mr. Kellen resigned from all positions with Company effective April 17, 2018.

(i) Includes 494,200 shares subject to stock options, 79,023 shares subject to warrants and an estimated 17,153 shares issuable pursuant to a convertible promissory note.

(j) Includes 28,000 shares held by Total Depth Foundation of which Mr. Gilbertson is the chief manager.

(k) Includes 218,455 shares subject to warrants and approximately 88,016 shares issuable pursuant to a convertible promissory note.

(l) Includes 75,301 shares subject to warrants and approximately 20,312 shares issuable pursuant to a convertible promissory note.

EXECUTIVE COMPENSATION

The following disclosure focuses on our named executive officers. For fiscal 2018 our "named executive officers" consisted of: Michael T. Cullen, Susan Horvath, David B. Kaysen and Scott Kellen.

Base salaries for each of our named executive officers were initially established based on arm's-length negotiations with the applicable executive. Our Compensation Committee reviews our executive officers' salaries annually. When negotiating or reviewing base salaries, the Compensation Committee considers market competitiveness based on the experience of its members, the executive's expected future contribution to our success and the relative salaries and responsibilities of our other executives.

Summary Compensation Table

The following table provides information regarding the compensation earned by our named executive officers for fiscal 2018 (collectively referred to as the "*Executives*"):

Name and Principal Position	Fiscal Year	Salary ($)	Option Awards[(a)] ($)	Total ($)
Michael T. Cullen	2018	221,200	491,491	712,691
Executive Chairman, President and Chief Executive Officer[(b)]	2017	208,000	–	208,000
Susan Horvath	2018	150,000	147,573	297,573
Chief Financial Officer and Vice President of Finance[(c)]				
David B. Kaysen	2018	236,250	245,745	481,995
Former President and Chief Executive Officer[(d)]	2017	302,500	–	302,500
Scott Kellen	2018	25,000	122,872	147,872
Former Chief Financial Officer and Vice President of Finance[(e)]	2017	173,333	–	173,333

(a) The values of option awards in this table represent the fair value of such awards granted during the fiscal year, as computed in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718. The assumptions used to determine the valuation of the awards are discussed in Note 9 to our consolidated financial statements, included in our annual report on Form 10-K for the fiscal year ended December 31, 2018.
(b) Dr. Cullen was elected to serve in the additional roles of President and Chief Executive Officer on October 31, 2018.
(c) Ms. Horvath joined the Company April 17, 2018.
(d) Mr. Kaysen resigned from all positions with Company effective October 31, 2018.
(e) Mr. Kellen resigned from all positions with Company effective April 17, 2018.

Outstanding Equity Awards as of December 31, 2018

		Option Awards			
Name	Grant Date	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option exercise price ($)	Option expiration Date
Michael T. Cullen	3/5/2015	80,000	–	3.18	3/5/2025
	12/12/2016	15,000	–	15.10	12/12/2026
	2/27/2018	100,000	–	8.10	2/27/2028
Susan Horvath	4/17/2018	10,000	30,000[a]	5.75	4/17/2028
David B. Kaysen[b]	12/12/2016	25,000	–	15.10	12/12/2026
	12/12/2016	61,128	–	15.10	12/12/2026
	2/27/2018	50,000	–	8.10	2/27/2028
Scott Kellen[b]	12/12/2016	15,000	–	15.10	12/12/2026
	12/12/2016	22,923	–	15.10	12/12/2026
	2/27/2018	25,000	–	8.10	2/27/2028

(a) Scheduled to vest with respect to 10,000 shares on April 17th in each of 2019, 2020 and 2021.
(b) So long as each of Mr. Kaysen and Mr. Kellen continues to provide service to the Company pursuant to his respective consulting agreement, his options will remain unexpired through their original expiration dates.

Employment Agreements

During 2018, we were party to employment agreements with each of the Executives. In addition to the specific terms summarized below, each of the named executive officers who continue to serve as an executive officer (collectively, the "*Continuing Executives*") is eligible to participate in the other compensation and benefit programs generally available to our employees, including our other executive officers, if any. Each such employment agreement also includes customary confidentiality, non-competition and non-solicitation covenants.

In accordance with the employment agreements, the base salary of each Executive is reviewed annually by the Compensation Committee of our Board of Directors. The committee may authorize an increase for the applicable year but may not reduce an Executive's base salary below its then-current level other than with the Executive's consent or pursuant to a general wage reduction in respect of substantially all of our executive officers.

In October 2017, we amended the employment agreements with Dr. Cullen, Mr. Kaysen and Mr. Kellen. For Dr. Cullen and Mr. Kaysen, the amendments established new annual base salaries representing a 25% reduction from prior levels, each effective as of October 1, 2017. Each amendment also discontinued the "accrued compensation" provision that had been introduced in earlier amendments to their respective employment agreements. As a result of the amendments, Dr. Cullen, Mr. Kaysen and Mr. Kellen continued to be eligible to receive a cash payment (each, a "Contingent Payment") in an amount equal to the amount that previously accumulated under the "accrued compensation" provision through September 30, 2017. The cash payment would have become due upon a change of control (as defined in each employment agreement) or our issuance of equity securities (including any securities that are convertible into or exercisable for equity securities) resulting in gross cash proceeds of $10,000,000 or more (a "Qualified Offering"). If neither a change of control nor a Qualified Offering had occurred on or before June 30, 2018, then the right to cash payment would have been be forfeited.

Effective February 27, 2018, we entered into a Waiver and Third Amendment with Dr. Cullen, Mr. Kaysen and Mr. Kellen, which waived all right to receive the Contingent Payment. These amendments also entitled them to common stock options to under our 2016 Plan to purchase up to 100,000 shares, 50,000 shares, and 25,000 shares of our common stock, respectively, exercisable for the following ten years at a price equal to $8.10 per share, representing fair market value as of the date of grant.

Executive Chairman, President and Chief Executive Officer

Under his original employment agreement, Dr. Cullen was entitled to receive an initial annualized base salary equal to $384,000. As discussed above, Dr. Cullen's employment agreement was amended to reduce his annualized base salary to $288,000, effective as of October 1, 2017. Notwithstanding the foregoing, Dr. Cullen received a portion of his monthly salary in cash and the remainder was accrued between October 1, 2015 and September 30, 2017. In lieu of the accrued amount, Dr. Cullen's employment agreement had entitled him to a Contingent Payment equal to $410,136 as a result of any change of control or Qualified Offering on or before June 30, 2018, as discussed in more detail above. Dr. Cullen waived all right to receive the Contingent Payment in February 2018.

Dr. Cullen is eligible to receive an annual performance-based cash bonus with a target amount equal to no less than 45% of his base salary. Payment of the bonus amount will be subject to achievement of metrics to be established by our Board of Directors and Dr. Cullen's continued employment with the Company through the end of the applicable cash bonus period. Neither our Board of Directors nor its Compensation Committee established such performance criteria for 2018 and therefore no cash bonus was paid.

No change was made to Dr. Cullen's employment agreement as a result of his election to serve in the additional roles of President and Chief Executive Officer in October 2018. Modifications to Dr. Cullen's employment agreement were discussed at the meeting of the Company's Compensation committee on March 19, 2019 but the decision to modified was deferred until a later meeting.

Chief Financial Officer

Under her employment agreement, Ms. Horvath is entitled to receive an initial annualized base salary equal to $225,000. Ms. Horvath also is eligible to receive an annual performance-based cash bonus with a target amount equal to no less than 40% of her base salary. Payment of the bonus amount will be subject to achievement of metrics to be established by our Board of Directors and Ms. Horvath's continued employment with the Company through the end of the applicable cash bonus period. Neither our Board of Directors nor its Compensation Committee established such performance criteria for 2018 and therefore no cash bonus was paid.

Potential Payments Upon Termination or Change-in-Control

Under their respective employment agreements, if Dr. Cullen or Ms. Horvath's employment is terminated by us for any reason other than for "cause" (as defined in the applicable employment agreement) or by him or her for "good reason" (as defined in the applicable employment agreement), then he or she will be eligible to receive an amount equal to their respective annualized salary plus an amount equal to a prorated portion of their cash bonus target, if any, for the year in which the termination occurred, in addition to other amounts accrued on or before the date of termination. If any such termination occurs within six months prior or two years after a "change of control" (as defined in the applicable employment agreement), then Dr. Cullen and Ms. Horvath would instead receive an amount equal to his/her respective annualized salary, plus an amount equal to his/her full cash bonus target for the year in which the termination occurred.

EQUITY COMPENSATION PLAN INFORMATION

The following table presents certain information regarding our equity compensation plans as of December 31, 2018.

Plan Category	Number of Securities to Be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance under Equity Compensation Plans
Equity compensation plans approved by security holders	1,032,211[(a)]	$8.904	732,149
Equity compensation plans not approved by security holders	–	–	–
Total	1,032,211		732,149

(a) Includes 767,851 shares underlying common stock options under the 2016 Plan and 264,360 shares underlying common stock options under the 2011 Plan. We ceased issuing awards under the 2011 Plan upon stockholder approval of the 2016 Plan in 2016.

PROPOSAL 2:
RATIFICATION OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Audit Committee has selected Cherry Bekaert LLP to serve as our independent registered public accounting firm for 2019, and the Board of Directors is asking stockholders to ratify that selection. Although current law, rules and regulations, as well as the Audit Committee charter, require our independent registered public accounting firm to be supervised by the Audit Committee and recommended to the Board of Directors for appointment and, if necessary, removal, our Board of Directors considers the selection of an independent registered public accounting firm to be a matter of stockholder concern and considers this proposal to be an opportunity for stockholders to provide direct feedback. Cherry Bekaert LLP has served as the Company's independent registered public accounting firm since 2015.

Notwithstanding its selection of Cherry Bekaert LLP, the Audit Committee, in its discretion, may appoint another independent registered public accounting firm at any time during the year if the committee believes that such a change would be in the best interests of our Company and its stockholders. If the appointment of Cherry Bekaert LLP is not ratified by our stockholders, the Audit Committee may reconsider whether it should appoint another independent registered public accounting firm. Representatives of Cherry Bekaert LLP are not expected to be present at the Annual Meeting.

Required Vote and Board Recommendation

Provided a quorum is present at the Annual Meeting, this proposal will be approved if it received the affirmative vote of a majority of the shares of stock represented at the meeting and entitled to vote on the proposal.

The Board of Directors recommends that you vote "FOR" the ratification of the selection of Cherry Bekaert LLP as the Company's independent registered public accounting firm for 2019.

Audit Fees

Cherry Bekaert LLP served as our independent registered public accounting firm for the years ended December 31, 2018 and 2017. The following table presents the aggregate fees for professional services provided by Cherry Bekaert LLP related to 2018 and 2017:

	Year Ended	
	December 31, 2018	December 31, 2017
Audit Fees[(a)]	$ 104,500	$ 124,650
Total	$ 104,500	$ 124,650

(a) Reflects the fees approved by Sun BioPharma, Inc. and billed or to be billed by Cherry Bekaert LLP with respect to services performed for the audit for the applicable fiscal year. For 2017, the amount included $20,000 for services and consents procedures in connection with the filing of a registration statement on Form S-1.

"*Audit Fees*" consisted of fees for the audit of our annual consolidated financial statements, including audited consolidated financial statements presented in our annual report on Form 10-K, review of the consolidated financial statements presented in our quarterly reports on Form 10-Q and services that are normally provided by the independent registered public accountants in connection with statutory and regulatory filings or engagements for those fiscal years. This category also includes advice on audit and accounting matters that arose during, or as a result of, the audit or the review of interim financial statements and statutory audits required by non-U.S. jurisdiction.

Pre-approval Policy

The Audit Committee has established a policy governing our use of the services of our independent registered public accountants. Under the policy, the Audit Committee is required to pre-approve all audit and permitted non-audit services performed by our independent registered public accountants in order to ensure that the provision of such services does not impair the public accountants' independence. In 2018, all fees identified above under the captions "Audit Fees" that were billed by Cherry Bekaert LLP were approved by the Audit Committee in accordance with SEC requirements.

PROPOSAL 3:
ADVISORY VOTE TO APPROVE EXECUTIVE COMPENSATION

The Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (the "Dodd-Frank Act") enables the stockholders of the Company to vote to approve, on a non-binding basis, the compensation of the Company's named Executive Officers as disclosed pursuant to Item 402 of Regulation S-K of the SEC. The Company was previously exempt from this requirement as a result of its "emerging growth company" status, which terminated on December 31, 2018.

Compensation Philosophy and Compensation of our Named Executive Officers

The Company seeks to align the interests of its named executive officers with the interests of its stockholders. Therefore, the Company's compensation programs are designed to reward the named executive officers for the achievement of strategic and operational goals and the achievement of increased stockholder value, while at the same time avoid encouraging of unnecessary or excessive risk-taking. The Board of Directors and its Compensation Committee believe that the Company's compensation policies and procedures are competitive and focused on performance and are strongly aligned with the long-term interest of its stockholders.

Form of Resolution

This proposal, commonly known as a "Say-on-Pay" proposal, gives you the opportunity to express your views regarding the compensation of our named executive officers by voting to approve or not approve such compensation as described in this proxy statement. This vote is advisory and will not be binding upon the Board of Directors or its Compensation Committee. However, both will take into account the outcome of the vote when considering future executive compensation arrangements. The vote on this resolution is not intended to address any specific element of compensation, but rather relates to the overall compensation of the named executive officers, as described in this proxy statement in accordance with the compensation disclosure rules of the Securities and Exchange Commission.

Stockholders are being asked to vote "FOR" or "AGAINST" the following resolution at the Annual Meeting:

> **RESOLVED**, that the compensation paid to the Company's executives named in the Summary Compensation Table, as disclosed in the Company's Proxy Statement for the 2019 Annual Meeting of Stockholders pursuant to the compensation disclosure rules of the Securities and Exchange Commission, is hereby APPROVED.

Required Vote and Board Recommendation

Provided a quorum is present at the Annual Meeting, this proposal will be approved if it received the affirmative vote of a majority of the shares of stock represented at the meeting and entitled to vote on the proposal.

The Board of Directors recommends that you vote "FOR" this Proposal 3.

PROPOSAL 4:
ADVISORY VOTE ON THE FREQUENCY OF FUTURE ADVISORY VOTES ON EXECUTIVE COMPENSATION

The Dodd-Frank Act requires that the Company provide stockholders with the opportunity to vote, on a non-binding advisory basis, for their preference as to how frequently the Company should consult the stockholders through an advisory Say-on-Pay vote. Stockholders may indicate whether they would prefer that the Company conduct future Say-on-Pay votes every year, every two years or every three years. Stockholders also may abstain from casting a vote on this proposal.

The Board of Directors and its Compensation Committee believes that a Say-on-Pay vote that occurs once every other year is the most appropriate option for the Company and therefore recommends that you vote in favor of conducting a Say-on-Pay vote every two years. The Board's decision was based on our goal to align the interests of executive officers with the interests of our stockholders, ensure the long-term commitment of our management team, and ensure accountability for both our overall performance and the individual's performance and contribution. We believe holding that vote every two years provides the most effective timeframe because it allows our Board and Compensation Committee sufficient time to engage with our stockholders following each such vote in order to understand any concerns they may have, and to respond with any changes to the compensation of our executive officers and/or related disclosure deemed appropriate in response to the results of an advisory vote.

This vote is advisory, which means that is not binding on the Board of Directors or its Compensation Committee. We recognize that our stockholders may have different views as to the best approach to the frequency of the Say-on-Pay vote. The Board of Directors and Compensation Committee will carefully review the outcome of this advisory vote. However, when determining the frequency of future Say-on-Pay votes, the Board of Directors and its Compensation Committee may decide that it is in the stockholders' long-term best interest to hold a Say-on-Pay vote more or less frequently than the frequency recommended by the stockholders.

The proxy card provides stockholders with the opportunity to choose among four options:

- ONE YEAR, which recommends that the Say-on-Pay vote be held every year;
- TWO YEARS, which recommends that the Say-on-Pay vote be held every two years;
- THREE YEARS, which recommends that the Say-on-Pay vote be held every three years;
- ABSTAIN, which has no effect on the outcome of this Proposal.

Stockholders are not being asked to approve or disapprove the recommendation of the Board of Directors.

Required Vote and Board Recommendation

The option that receives the highest number of votes will be deemed to be the recommendation of our stockholders.

The Board of Directors recommends that you vote "TWO YEARS" for this Proposal 4.

SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Securities and Exchange Act of 1934 requires that our directors, executive officers and beneficial owners of more than 10% of our common stock file initial reports of ownership and reports of changes in ownership with the SEC. Directors, executive officers and beneficial owners of greater than 10% of our common stock are required to furnish us with copies of all Section 16(a) forms they file. Based solely on a review of the copies of such forms furnished to us and written representations from our directors and executive officers, all Section 16(a) filing requirements were met for the fiscal year ended December 31, 2018 except for: one report by Ms. Gagnon relating to one transaction involving the receipt of a common stock option award; one report by Mr. Schaffer relating to three transactions involving the acquisition of common stock and warrants from the Company and the conversion of an outstanding promissory note; one report by Mr. Kaysen relating to two transactions involving the acquisition of common stock and warrants from the Company; and two reports by Ryan R. Gilbertson, the first relating to one transaction involving the conversion of an outstanding promissory note, and the second relating to two transactions involving the sale of the resulting common stock and warrants.

OTHER MATTERS

The Board of Directors is not aware of any matters that are expected to come before the Annual Meeting other than those referred to in this proxy statement. If any other matter should come before the Annual Meeting, the persons named in the accompanying proxy intend to vote the proxies in accordance with their best judgment.

SUBMISSION OF STOCKHOLDER PROPOSALS AND NOMINATIONS

Stockholder proposals intended to be presented at the annual meeting of stockholders to be held in the year 2020 that are requested to be included in the proxy statement for that meeting must be received by us at our principal executive office no later than December 18, 2019. We must receive any other stockholder proposals intended to be presented, and any director nominees for election, at the annual meeting of stockholders in the year 2020 at our principal executive office no earlier than January 12, 2020 and no later than February 11, 2020. Upon timely receipt of any such proposal containing the information required by our bylaws, as amended from time to time, we will determine whether or not to include such proposal in the proxy statement and proxy in accordance with applicable regulations governing the solicitation of proxies.

ADDITIONAL INFORMATION

We have adopted a procedure approved by the Securities and Exchange Commission called “householding,” by which certain stockholders who do not participate in electronic delivery of proxy materials but who have the same address and appear to be members of the same family receive only one copy of our annual report and proxy statement. Each stockholder participating in householding continues to receive a separate proxy card. Householding reduces both the environmental impact of our annual meetings and our mailing and printing expenses.

If you would like to change your householding election, request that a single copy of the proxy materials be sent to your address, or request a separate copy of the proxy materials, please contact Broadridge Financial Solutions, Inc., by calling (866) 540-7095 or by writing to Broadridge Householding Department, 51 Mercedes Way, Edgewood, New York 11717. We will promptly deliver the notice of internet availability or proxy materials to you upon receipt of your request. If you hold your shares in street name, please contact your bank, broker, or other record holder to request information about householding.

ADDITIONAL INFORMATION

The Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2018, accompanies the delivery of this proxy statement and a copy of such annual report, as filed with the Securities and Exchange Commission, is also available on the Commission’ website, www.sec.gov, and our corporate website, www.sunbiopharma.com (under “Investor Relations”). In addition, a copy of the Annual Report on Form 10-K, as amended, may be sent to any stockholder without charge (except for exhibits, if requested, for which a reasonable fee will be charged), our Chief Financial Officer and Secretary at:

Sun BioPharma, Inc.
712 Vista Boulevard #305
Waconia, Minnesota 55387

Such request must set forth a good faith representation that the requesting party was a holder of record or a beneficial owner of our common stock as of the Record Date.

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2018

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number: 000-55242

SUN BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware	**87-0543922**
(State or other jurisdiction of incorporation)	(IRS Employer Identification No.)
712 Vista Blvd, #305 **Waconia, Minnesota**	**55387**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(952) 479-1196**

Securities Registered Pursuant to Section 12(b) of the Act: **None.**

Securities Registered Pursuant to Section 12(g) of the Act: **Common Stock, $0.001 par value**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐	Accelerated filer ☐	Non-accelerated filer ☐	Smaller reporting company ☒
			Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the registrant's common stock, excluding shares beneficially owned by affiliates, computed by reference to price at which the registrant's common stock was last sold as of June 29, 2018 (the last trading day of the registrant's second fiscal quarter) was $23,751,819.

As of March 15, 2019, there were 5,070,341 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of our proxy statement for the annual meeting of stockholders to be held in 2019 are incorporated by reference into Part III of this report.

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Cautionary Note Regarding Forward-Looking Statements

This annual report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In some cases, you can identify forward-looking statements by the following words: "anticipate," "assume," "believe," "continue," "could," "estimate," "expect," "intend," "may," "ongoing," "plan," "potential," "predict," "project," "should," "will," "would," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. 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 the forward-looking statements in this report. These factors include:

- the fact that we are a company with limited operating history for you to evaluate our business;
- our lack of diversification and the corresponding risk of an investment in our Company;
- potential deterioration of our financial condition and results due to failure to diversify;
- our ability to obtain additional capital, on acceptable terms or at all, required to implement our business plan; and
- other risk factors included under the caption "Risk Factors" starting on page of this report.

You should read the matters described in "Risk Factors" and the other cautionary statements made in this report as being applicable to all related forward-looking statements wherever they appear in this report. We cannot assure you that the forward-looking statements in this report will prove to be accurate and therefore you are encouraged not to place undue reliance on forward-looking statements. You should read this report completely. Other than as required by law, we undertake no obligation to update or revise these forward-looking statements, even though our situation may change in the future.

We caution readers not to place undue reliance on any forward-looking statement that speaks only as of the date made and to recognize that forward-looking statements are predictions of future results, which may not occur as anticipated. Actual results could differ materially from those anticipated in the forward-looking statements and from historical results, due to the risks and uncertainties described in Part I, Item 1A, of this annual report, as well as others that we may consider immaterial or do not anticipate at this time. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we do not know whether our expectations will prove correct. Our expectations reflected in our forward-looking statements can be affected by inaccurate assumptions that we might make or by known or unknown risks and uncertainties, including those described in Part I, Item 1A, of this annual report. The risks and uncertainties described in Part I, Item 1A, of this annual report are not exclusive and further information concerning us and our business, including factors that potentially could materially affect our financial results or condition, may emerge from time to time. We assume no obligation to update forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements. We advise stockholders and investors to consult any further disclosures we may make on related subjects in our subsequent annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K that we file with or furnish to the U.S. Securities and Exchange Commission (the "SEC").

PART I

Item 1. Business

As used in this report, unless specifically indicated, the terms "Sun BioPharma," the "Company," "we," "us," "our" and similar references refer to Sun BioPharma, Inc. and its wholly-owned subsidiary, Sun BioPharma Australia Pty Ltd. ("SBA"). The term "common stock" refers to our common stock, par value $0.001 per share.

Overview

We are a clinical stage drug development company founded with technology licensed from The University of Florida Research Foundation ("UFRF"). The polyamine analogue compound we have licensed from UFRF, which we refer to as "SBP-101," exhibits extraordinary specificity for the exocrine pancreas, with therapeutic potential for both pancreatic cancer and certain pancreatitis indications. Xenograft studies of human pancreatic cancer cells transplanted into mice indicate that the unique specificity of SBP-101 for the exocrine pancreas facilitates suppression of both primary and metastatic pancreatic cancer which is known to originate in the exocrine pancreas. To facilitate and accelerate the development of this compound in the pancreatic cancer indication, we have also acquired data and materials related to this technology from other researchers. Studies in dogs revealed ablation, or "chemical resection," of the exocrine pancreatic architecture, while leaving the islet cells functionally unchanged. We may refer to this effect as: "pharmaceutical pancreatectomy with islet preservation" ("PP-IP"). We believe that SBP-101, if successfully developed, may represent a novel approach that effectively treats pancreatic cancer and pancreatitis, and could become a dominant product in these markets. Only three first-line treatments and one second-line drug have been approved by the U.S. Food and Drug Administration ("FDA") for pancreatic cancer in the last 25 years, and no drugs have been approved for the specific treatment of patients with pancreatitis, other than supportive care.

In August 2015, the FDA accepted our Investigational New Drug ("IND") application for our SBP-101 product candidate. We have completed an initial clinical trial of SBP-101 in patients with previously treated locally advanced or metastatic pancreatic cancer. This was a Phase 1, first-in-human, dose-escalation, safety study. From January 2016 through September 2017, we enrolled twenty-nine patients into six cohorts, or groups, in the dose-escalation phase of the Phase 1 trial. Twenty-four of the patients had received at least two prior chemotherapy regimens. No drug-related serious adverse events occurred during the first four cohorts. In cohort five, serious adverse events (klebsiella sepsis with metabolic acidosis in one patient, renal and hepatic toxicity in one patient, and mesenteric vein thrombosis with metabolic acidosis in one patient) were observed in three of the ten patients, two of whom exhibited progressive disease at the end of their first cycle of treatment and were determined by the Data Safety Monitoring Board ("DSMB") to be dose-limiting toxicities ("DLTs"). Consistent with the study protocol, the DSMB recommended continuation of the study by expansion of cohort 4, one level below that at which DLTs were observed. Four patients were enrolled in this expansion cohort. One patient developed focal pancreatitis at the site of the primary tumor after 2.3 months, but otherwise SBP-101 was considered well tolerated below dose level five. The most common drug related adverse events were nausea, vomiting, diarrhea, injection site pain and abdominal pain, which were mostly mild, grades 1 or 2, and are symptoms common in patients with pancreatic cancer. No drug-related bone marrow toxicity or peripheral neuropathy was observed at any dose level.

In addition to being evaluated for safety, 23 of the 29 patients were evaluable for preliminary signals of efficacy prior to or at the eight-week conclusion of their first cycle of treatment using the Response Evaluation Criteria in Solid Tumors ("RECIST"), the current standard for evaluating changes in the size of tumors. Eight of the 23 patients (35%) had Stable Disease ("SD") and 15 of 24 (65%) had Progressive Disease ("PD"). It should be noted that of the 15 patients with PD, six came from cohorts one and two and are considered to have received less than potentially therapeutic doses of SBP-101. We also noted that 28 of the 29 patients had follow-up blood tests measuring the Tumor Marker CA 19-9 associated with pancreatic ductal adenocarcinoma. Eleven of these patients (39%) had reductions in the CA 19-9 levels, as measured at least once after the baseline assessment. Seven of the remaining 17 patients who showed no reduction in CA 19-9 came from cohorts one and two.

By cohort, stable disease occurred in two patients in cohort 3, two patients in cohort 4 and four patients in cohort 5. The best response outcomes and best median survival were observed in the group of patients who received total cumulative doses of approximately 6 mg/kg (cohort 3). Two of four patients (50%) showed SD at week eight. Median survival in this group was 5.9 months, with two patients surviving 8 and 10 months, respectively. By total cumulative dose received, five of 12 patients (42%) who received total cumulative doses between 2.5 mg/kg and 8.0 mg/kg had reductions in the CA19-9 levels, as measured at least once after the baseline assessment. Nine of these patients (67%) exceeded 3 months of overall survival ("OS"), three patients (25%) exceeded 9 months of OS and two patients (17%) exceeded 1 year of OS and were still alive at the end of the study.

With the approval of the DSMB, we cancelled the Phase 1b portion of the first-in-human monotherapy study in order to evaluate SBP-101 as front line, combination chemotherapy in pancreatic cancer patients.

In the first quarter of 2018, we announced the initiation of a front-line dose-escalation study of SBP-101 in combination with gemcitabine and nab-paclitaxel in previously untreated patients with metastatic pancreatic cancer. We enrolled our first patients in June of 2018. Clinical sites participating in the study include the University of Florida, Gainesville, Florida, the Ashford Cancer Centre in Adelaide, the Olivia Newton-John Cancer and Wellness Centre in Melbourne and the Blacktown Cancer and Haematology Centre in Sydney, Australia. We anticipate completing the phase 1a, dose escalation portion of the study by the fourth quarter of 2019 and will immediately begin the phase 1b expansion phase. It is expected that a minimum of two additional sites will be added to complete the expansion phase of this trial. The Company further notes that it will require additional capital to complete this study.

Through December 31, 2018, we have:

- organized the Company;
- evaluated and secured intellectual property for our core technology;
- completed required pre-clinical steps in the development plan for SBP-101 for pancreatic cancer;
- secured an orphan drug designation from the FDA;
- submitted an IND application to the FDA (May 18, 2015);
- received an acceptance of an IND application from the FDA (August 21, 2015);
- received acceptance of a Clinical Trial Notification by the Australian Therapeutic Goods Administration (September 23, 2015);
- completed a Phase 1a safety study of SBP-101in the treatment of pancreatic ductal adenocarcinoma;
- commenced a second Phase 1a /1b clinical study of SBP-101, a front-line study with SBP-101 given in combination with a current standard of care in patients with pancreatic ductal adenocarcinoma who are previously untreated for metastatic disease; and
- begun pre-clinical studies for the use of SBP-101 to treat certain pancreatitis indications.

Introduction

An effective treatment for pancreatic cancer remains a major unmet medical need. Adenocarcinoma of the pancreas, which accounts for approximately 95% of all cases of pancreatic cancer, has a median overall survival of 8 to 11 months in clinical studies of patients with favorable prognostic signs and optimal standard chemotherapy. Pancreatic cancer afflicts approximately 133,000 people in Europe (GLOBOCAN2018, Global Cancer Observatory/World Health Organization), over 55,000 people in the United States annually (https://seer.cancer.gov/statfacts/html/pancreas.html), and 270,000 people worldwide – excluding Europe and United States (GLOBOCAN2018). Pancreatic cancer is now the third most common cause of cancer death in the United States (https://seer.cancer.gov/statfacts/html/common.html). A recent report from the Pancreatic Cancer Action Network states that pancreatic cancer deaths in the United States have surpassed those from breast cancer and will soon surpass deaths from colorectal cancer to rank number two in deaths, behind only lung cancer in 2020. The five-year survival rate remains less than 3% for patients diagnosed with metastatic pancreatic cancer and approximately

8.5% across all pancreatic stages, and there has been little significant improvement in survival since gemcitabine was approved in the United States in 1996.

Pancreatic cancer is generally not diagnosed early because the initial clinical signs and symptoms are vague and non-specific. By the time of diagnosis, the cancer is most often locally advanced or metastatic, having spread to regional lymph nodes, liver, lung and/or peritoneum, and is seldom amenable to surgical resection, or removal, with curative intent. Currently, surgical resection offers the only potentially curative therapy, although only approximately 20% of patients are candidates for surgical resection at the time of the diagnosis. Patients who undergo radical surgery still have a limited survival rate, averaging 23 months (Macarulla T, et al Clin Transl Oncol 2017).

The prognosis for patients diagnosed with pancreatic cancer is poor and most die from complications related to progression of the disease. The primary treatment for metastatic disease is chemotherapy. Current first-line chemotherapy treatment regimens vary from single agent gemcitabine (FDA approved 1996) and various gemcitabine combinations to the multi-chemotherapy drug combination, FOLFIRINOX, comprised of leucovorin, fluorouracil, irinotecan, and oxaliplatin (Conroy NEJM 2011), frequently supplemented with white blood cell ("WBC") growth factors. In clinical practice, the FOLFIRINOX regimen is often modified to "FOLFIRINOX Light", a non-specific term referring to various permutations based on the FOLFIRINOX regimen, but with either lower doses of one or more of the agents, or elimination of one or more of the agents, due to actual or anticipated toxicity. These two standard combination therapies deliver median survival benefits ranging from 7 weeks with gemcitabine and nab-paclitaxel (Von Hoff NEJM 2013) to 4 months FOLFIRINOX (Conroy NEJM 2011) when compared with gemcitabine alone for selected patients with good performance status, meaning that they are in relatively good physical condition at the time of diagnosis. In 2015, the FDA approved Onivyde® (irinotecan liposome injection), in combination with fluorouracil and leucovorin, to treat patients with metastatic pancreatic cancer who have been previously treated with a gemcitabine-based chemotherapy. Second-line Onivyde is not widely prescribed as indicated because most patients with good performance status receive variations of the FOLFIRINOX (which includes generic irinotecan) regimen.

University laboratory studies have demonstrated that SBP-101 induces programmed cell death, or "apoptosis," in the acinar and ductal cells of the pancreas by activation of caspase 3 and poly (adenosine diphosphate-ribose) polymerase ("PARP") cleavage. In animal models at two independent laboratories, SBP-101, alone or in combination, has demonstrated nearly complete suppression of transplanted human pancreatic cancer, including metastases. SBP-101 has demonstrated both superior and additive efficacy to gemcitabine and nab-paclitaxel in laboratory models of pancreatic cancer. We intend to develop SBP-101 as a unique and novel targeted approach to treating patients with pancreatic cancer, specifically pancreatic ductal adenocarcinoma ("PDA"), administered in combination with existing standard chemotherapy agents. With adequate funding, we also expect to continue evaluation of the potential value of SBP-101 in the treatment of patients with recurrent acute or chronic pancreatitis.

Pancreatic Cancer

Pancreatic cancer afflicts approximately 130,000 people in Europe (GLOBOCAN2018, Global Cancer Observatory/World Health Organization), over 55,000 people in the United States annually (https://seer.cancer.gov/statfacts/html/pancreas.html), and 270,000 people worldwide – excluding Europe and United States (GLOBOCAN2018). It has been identified as the seventh leading cause of death from cancer in Europe (GLOBOCAN 2018) and the third leading cause of death from cancer in the United States (SEER Cancer Statistics Factsheets 2019). On average pancreatic ductal adenocarcinoma ("PDA") represents approximately 95% of all pancreatic cancers diagnosed in given calendar year. Considering that the median overall survival for previously untreated patients with good performance status is between 8.5 months (Von Hoff 2013) and 11.1 months (Conroy 2011) with the best available treatment regimens, effective treatment for PDA has remained a major unmet medical need.

Pancreatic cancer is generally not diagnosed early because the initial clinical signs and symptoms are vague and non-specific. The most common presenting symptoms include weight loss, epigastric (upper central region of the abdomen) and/or back pain, and jaundice. The back pain is typically dull, constant, and of visceral origin radiating to the back, in contrast to the epigastric pain which is vague and intermittent. Less common symptoms include nausea, vomiting, diarrhea, anorexia, and new onset diabetes or glucose intolerance (Hidalgo 2010).

Surgery remains the only treatment option with curative intent, although only about 20% of patients are candidates for surgical resection at the time of the diagnosis. Patients who undergo radical surgery still have a limited survival rate, averaging 23 months (Macarulla T, et al Clin Transl Oncol 2017).

For the minority of patients who present with resectable disease, surgery is the treatment of choice. Depending on the location of the tumor the operative procedures may involve cephalic pancreatoduodenectomy, referred to as a "Whipple procedure", distal pancreatectomy or total pancreatectomy. Pancreatic enzyme deficiency and diabetes are frequent complications of these procedures. Up to 70% of patients with pancreatic cancer present with biliary obstruction that can be relieved by percutaneous or endoscopic stent placement. However, even if the tumor is fully resected, the outcome in patients with pancreatic cancer has been disappointing (Hidalgo 2010, Seufferlein 2012). Post-operative administration of chemotherapy improved progression-free and overall survival in three large, randomized clinical trials (Hidalgo 2010), but median post-surgical survival in patients treated in all three trials was similar, only 20-22 months.

For patients who present with unresectable, locally advanced or metastatic disease, which represent a majority of PDA patients, management options range from chemotherapy alone to combined forms of treatment with radiation therapy and chemotherapy. However, due to the increased toxicity of combined treatment, randomized trials of such combined regimens have had low enrollment, precluding a firm conclusion as to any advantage of adding radiation to chemotherapy (Hidalgo 2010).

Gemcitabine was the first chemotherapeutic agent approved for the treatment of patients with PDA, providing a median survival duration of 5.65 months (Burris 1997). Gemcitabine monotherapy was the standard of care for patients with metastatic pancreatic cancer until combination therapy with gemcitabine plus erlotinib (Tarceva®) was shown to increase median survival by two weeks. This modest benefit was tempered by a significant side effect profile and high cost, limiting its adoption as a standard treatment regimen. More recently, the multidrug chemotherapy combination FOLFIRINOX, was shown to provide a median survival benefit of 4.3 months (OS = 11.1 months) over gemcitabine alone (6.8 months), but its significant side effect profile limits the regimen to select patients with a good performance status and often requires supplementation with WBC growth factor therapy. Nab-paclitaxel (Abraxane®) received marketing authorization for use in combination with gemcitabine (FDA approved 2013) after showing an increase in overall survival of seven weeks compared to gemcitabine alone (Von Hoff 2013). Thus, combination therapies have demonstrated a modest survival benefit compared to gemcitabine alone as summarized in the table below (Thota 2014).

Current First-Line Treatment Approaches: Survival & Toxicity Profiles Across Three Major Positive Clinical Trials

	Gemcitabine vs. Gemcitabine/Erlotinib Phase 3 trial		**ACCORD 11 Trial**		**Metastatic Pancreatic Adenocarcinoma Clinical Trial (MPACT)**	
	Gemcitabine	**Gemcitabine/ Erlotinib**	**Gemcitabine**	**FOLFIRINOX[1]**	**Gemcitabine**	**Gemcitabine/ Nab-Paclitaxel**
One-Year Survival.....	17%	23%	20.6%	48.4%	22%	35%
Median Overall Survival (months).....	5.91	6.24	6.8	11.1	6.7	8.5
Median Progression-Free Survival (months)	3.55	3.75	3.3	6.4	3.7	5.5
Overall Response Rate ...	8%	8.6%	9.4%	31.6%	7%	23%
Toxicity						
Neutropenia	–	–	21%	45.7%	27%	38%
Febrile neutropenia	–	–	1.2%	5.4%	1%	3%
Thrombocytopenia.....	–	–	3.6%	9.1%	9%	13%
Diarrhea	2%	6%	1.8%	12.7%	1%	6%
Sensory neuropathy	–	–	0%	9%	1%	17%
Fatigue	15%	15%	17.8%	23.6%	7%	17%
Rash	6%	1%	–	–	–	–
Stomatitis	<1%	0%	–	–	–	–
Infection.....	17%	16%	–	–	–	–

Source: Thota R et al., Oncology 2014; Jan 28(1):70–74

[1] FOLFIRINOX represents leucovorin (folic acid), fluorouracil, irinotecan, and oxaliplatin.

Other drugs are currently under investigation, but none have received marketing authorization as a first-line treatment of PDA since the approval of Abraxane.

Pancreatitis

Additional potential indications for SBP-101 are the treatment of patients with the serious and potentially life-threatening conditions of recurrent acute and chronic pancreatitis. In the United States, acute pancreatitis occurs in approximately 300,000 patients per year, with approximately 50% of those cases considered to be recurrent acute pancreatitis. Approximately 30,000 patients progress to chronic pancreatitis each year.

Patients with chronic pancreatitis endure repeated episodes of abdominal pain, often with progression to narcotic dependency and to pancreatic enzyme deficiency, as well as insulin dependent diabetes mellitus as a consequence of the ultimate destruction of pancreatic function. Once a patient has suffered from repeated painful bouts of chronic pancreatitis, they may be offered a total pancreatectomy. A total pancreatectomy is a surgical procedure resulting in the resection, or removal, of the pancreas (guaranteeing both pancreatic enzyme deficiency as well as insulin-dependent diabetes mellitus), and often includes the spleen, gall bladder and appendix. The operation is both extensive, requiring 8+ hours in the operating room, and expensive. While the goal of a total pancreatectomy in patients with chronic pancreatitis is pain relief, as many as 60% remain narcotic dependent, and even with the isolation and reintroduction of any of the patient's remaining functional insulin producing islet cells, or islet auto-transplant, over 70% of patients remain insulin dependent. The combination of a total pancreatectomy and islet auto transplant ("TP & IAT") represents a small subset of the current surgical approaches to patients with chronic pancreatitis. Thus, a patient with chronic pancreatitis may face years of abdominal pain, narcotic dependence, the onset of diabetes mellitus, the requirement for both insulin and pancreatic enzyme replacement, and finally, an extensive and expensive surgical procedure which may not materially improve any of their symptoms.

There are no specific agents approved for treatment of acute or chronic pancreatitis, as such, current treatment is limited to supportive care with intravenous fluids, narcotics and the avoidance of oral intake.

SBP-101, which has demonstrated the specificity to target the acinar and ductal cells of the pancreas, and if successfully developed, may represent an opportunity for up to 30,000 US patients with chronic pancreatitis and approximately 150,000 patients with recurrent acute pancreatitis to receive an early, non-surgical intervention into the natural history of their disease, with the potential to avoid narcotic dependency, insulin dependency, surgery and months or years of chronic pain. Patients would still require pancreatic enzyme replacement. We believe that our consultations with pancreatitis experts at Harvard University, the Ohio State University, the University of Minnesota, Cedars Sinai Medical Center, the University of Miami, the University of Florida and the National Institute of Health ("NIH") have resulted in enthusiastic endorsement of the study of SBP-101 in the treatment of patients with recurrent acute and chronic pancreatitis.

Other than limited pre-clinical studies, the development of SBP-101 for the treatment of patients with pancreatitis is expected to proceed following the pancreatic cancer indication. This clinical development work will include FDA consultation in a pre-IND meeting, completion of a series of IND-enabling nonclinical toxicology and pharmacology studies, and submission of an IND package to the FDA. Clinical development of SBP-101 for recurrent acute and chronic pancreatitis is also contingent upon raising additional funds.

Proprietary Technology

Function and Characteristics of Polyamines

Polyamines are metabolically distinct entities within human cells that bind to and facilitate DNA replication, RNA transcription and processing, and protein (such as pancreatic enzymes) synthesis. Human cells contain three essential and naturally occurring polyamines - putrescine, spermidine, and spermine - that, in contrast to cell building blocks such as amino acids and sugars, remain as metabolically distinct entities inside the cell. Polyamines perform many functions necessary for cellular proliferation and protein synthesis. The critical balance of polyamines within cells is maintained by several enzymes such as ornithine decarboxylase ("ODC") and spermidine/spermine N1 acetyl transferase ("SSAT"). All of these homeostatic enzymes are short-lived, rapidly inducible intracellular proteins that serve to tightly and continuously regulate native polyamine pools. These enzymes constantly maintain polyamines within a very narrow range of concentration inside the cell.

Polyamine Analogue

Many tumors, including pancreatic cancer, display an increased uptake rate of polyamines. Polyamine analogues such as SBP-101 are structurally similar to naturally occurring polyamines and are recognized by the cell's polyamine uptake system, allowing these compounds to gain rapid entrance to the cell. We believe that pancreatic acinar cells, because of their extraordinary protein synthesis capacity, exhibit enhanced uptake of polyamines and polyamine analogues such as SBP-101. Because of this preferential uptake by pancreatic acinar cells, polyamine analogies such as SBP-101 disrupt the cell's polyamine balance and biosynthetic network, and induce programmed cell death, or apoptosis, via caspase 3 activation and PARP cleavage. Proof of concept has been demonstrated in multiple human pancreatic cancer models, both in vivo and in vitro, that pancreatic ductal adenocarcinoma exhibits sensitivity to SBP-101.

SBP-101

SBP-101 is a proprietary polyamine analogue, which we believe accumulates in the acinar cells due to its unique chemical structure. SBP-101 was discovered and extensively studied by Professor Raymond J. Bergeron at the University of Florida College of Pharmacy. In a key, independent, pre-clinical study we observed the accumulation of SBP-101 in the acinar cells of the beagle pancreas causing a complete pharmaceutical resection of the exocrine tissues of the pancreas and notably, without producing an inflammatory response. We believe that SBP-101, when administered in a sufficiently high pharmacologic dosage, disrupts the normal metabolic process of acinar cells and pancreatic adenocarcinoma cells, which exhibit similar responses, including programmed cell death, or apoptosis. Importantly, pancreatic islet cells, which secrete insulin, are structurally and functionally dissimilar to acinar cells and are not impacted by SBP-101.

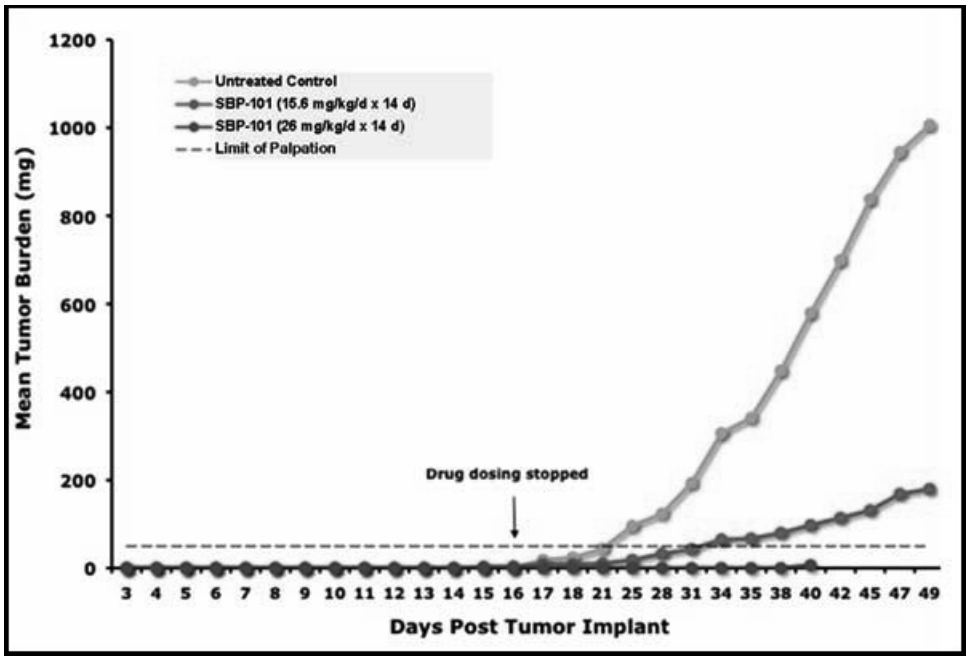
The primary mechanism of action for SBP-101 has been demonstrated to include the enhanced uptake of the compound in the exocrine pancreas. This effect leads to corresponding depressed levels of native polyamines, with caspase 3 activation, PARP cleavage and apoptotic destruction (programmed cell death) of the exocrine pancreatic acinar and ductal cells without an inflammatory response. In animal models at two independent laboratories, SBP-101 has demonstrated significant suppression of transplanted human pancreatic cancer cells, including metastatic pancreatic cancer growth. See "Proof of Principle" below.

We believe that SBP-101 will have a distinct advantage over current pancreatic cancer therapies in that it specifically targets the exocrine pancreas and may cause ablation, or pharmaceutical resection, of the acinar and ductal cells, as well as the primary and metastatic pancreatic cancer, while leaving the insulin-producing islet cells and most non-pancreatic tissue unharmed. Most current cancer therapies, including chemotherapy, radiation and surgery, are associated with significant side effects that further reduce the patient's quality of life. However, we believe that the adverse effects of SBP-101 will not overlap with or exacerbate those seen with typical chemotherapy options. It is expected that SBP-101 may produce exocrine pancreatic insufficiency and, potentially, other gastro intestinal ("GI") adverse events, many of which are generally expected to occur as common complications of advanced pancreatic cancer and as part of the natural history/progression of the disease. The dose-limiting toxicities observed in cohort five of our Phase 1a study, as noted above, were not observed at lower doses. Exocrine pancreatic insufficiency is a common complication of pancreatic cancer and is treatable with currently marketed digestive enzyme replacement capsules, such as Creon® (AbbVie). As the endocrine pancreas is expected to be unaffected by SBP-101, no new requirement for insulin is expected.

Proof of Principle

SBP-101 has been tested and found effective in reducing pancreatic tumor growth in multiple separate *in vivo* models of human pancreatic cancer. SBP-101 was used to treat mice subcutaneously implanted with human pancreatic cancer cell line PANC-1 tumor fragments. A dose-response for efficacy was demonstrated with a 26 mg/kg daily injection resulting in near complete suppression of the transplanted tumor, as shown in Figure 1.

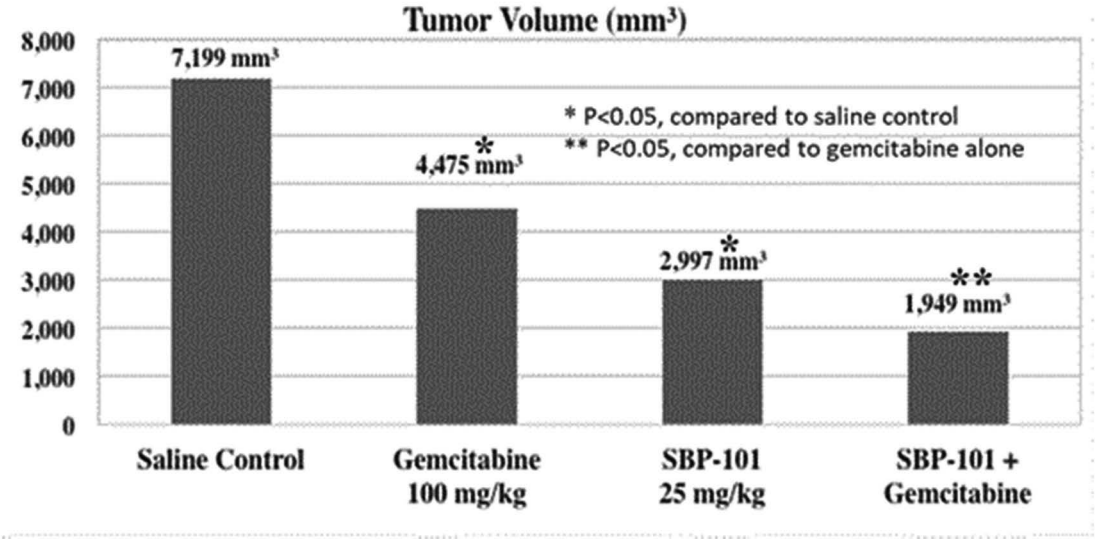
Figure 1. Impact of SBP-101 on PANC-1 Tumor Burden in a Murine Xenograft Model



Source: Study BERG20100R1a(MIR1581)

A separate orthotopic xenograft study (direct implant of human tumor cells into the pancreas of the mouse) employed a particularly aggressive human pancreatic cancer cell line, L3.6pl, that is known to metastasize from the pancreas to the liver and the peritoneum in mice. Mice implanted with L3.6pl were treated with SBP-101 and the results were compared with saline-treated control mice, with mice treated with gemcitabine alone (Gemzar®, the then current "gold standard" treatment), and the combination of both drugs. Both gemcitabine and SBP-101 significantly reduced tumor volume compared to the control group, but the combination of SBP-101 and gemcitabine was significantly better than gemcitabine alone as shown in Figure 2.

Figure 2. L3.6pl Orthotopic Xenograft Study - Mean (±SD) Tumor Volume after Treatment with SBP-101, Gemcitabine (Gemzar®) or Both



Source: Study101-Biol-101-001

The potential for SBP-101 as an effective therapy for pancreatic cancer has therefore been demonstrated *in vivo* by separate investigators, in different human pancreatic cancer cell lines and in two different animal models, using SBP-101 synthesized by two different routes, confirming nearly equal, and remarkably effective, doses of 25 and 26 mg/kg, respectively.

Additionally, when compared *in vitro* to existing therapies, SBP-101 produced superior results in suppressing growth of pancreatic cancer cells.

Development Plan for SBP-101

Development of SBP-101 for the pancreatic cancer indication includes a pre-clinical and a clinical phase. The pre-clinical phase, which was substantially completed during 2015, consists of four primary components: chemistry, manufacturing and controls ("CMC"), preclinical (laboratory and animal) pharmacology studies, preclinical toxicology studies, and regulatory submissions in Australia and the United States. In Australia, a Human Research Ethics Committee ("HREC") application was submitted with subsequent Clinical Trial Notification ("CTN") to the Therapeutic Goods Administration ("TGA"). Complementing the Australian initiative, a similar, but considerably more extensive, preclinical package has been submitted to and accepted by the FDA in support of an IND application. Our initial clinical trial in previously treated patients with locally advanced or metastatic pancreatic cancer was a Phase 1, first-in-human, dose-escalation, safety study conducted at clinical sites in both Australia and the United States. We engaged expert clinicians who treat pancreatic cancer at major cancer treatment centers in Melbourne and Adelaide, Australia as well as the Mayo Clinic Scottsdale and HonorHealth in Scottsdale, Arizona. These Key Opinion Leaders ("KOLs"), with proven performance in pancreatic cancer studies, enthusiastically agreed to participate as investigators for our Phase 1 First-in-Human study.

Enrollment in our initial Phase 1 safety trial of SBP-101 in previously treated pancreatic cancer patients commenced in January 2016 and was completed in September 2017. This study was a dose-escalation study with 8-week treatment/observation cycles at each dose level. Results from this trial are discussed in *Clinical Development – Pancreatic Cancer* below.

We began enrolling patients in our second clinical trial in June of 2018. This second clinical trial is a Phase 1a/1b study of the safety, efficacy and pharmacokinetics of SBP-101 administered in combination with two standard-of-care chemotherapy agents, gemcitabine and nab-paclitaxel. We are currently conducting the trial at four study sites (three in Australia and one in the United States). In the Phase 1a portion of this trial, we expect to enroll three cohorts of three to six patients with increased dosage levels of SBP-101 administered in the second and third cohorts. Demonstration of adequate safety in Phase 1a is expected to lead to the Phase 1b exploration of efficacy, in which we plan to enroll ten patients using the recommended dosage level determined in Phase 1a. Should we obtain adequate funding we hope to increase the number of patients enrolled in the Phase 1b portion of the trial to 36, thus providing a stronger basis for the next steps in the clinical evaluation of SBP - 101. We expect to complete Phase 1a in the fourth quarter of 2019. Early results from the Phase 1b expansion could become available as soon as the second half of 2020.

With additional funding SBP-101 may also be explored for use as a treatment for recurrent acute and chronic pancreatitis as well as for maintenance therapy in cancer patients responding to first line treatment and/or for adjuvant treatment after surgery in appropriate patients. There is also preclinical data to suggest that SBP-101 may have potential therapeutic uses outside of the pancreas, but due to the current focus on pancreatic cancer and pancreatitis, none have been formally explored.

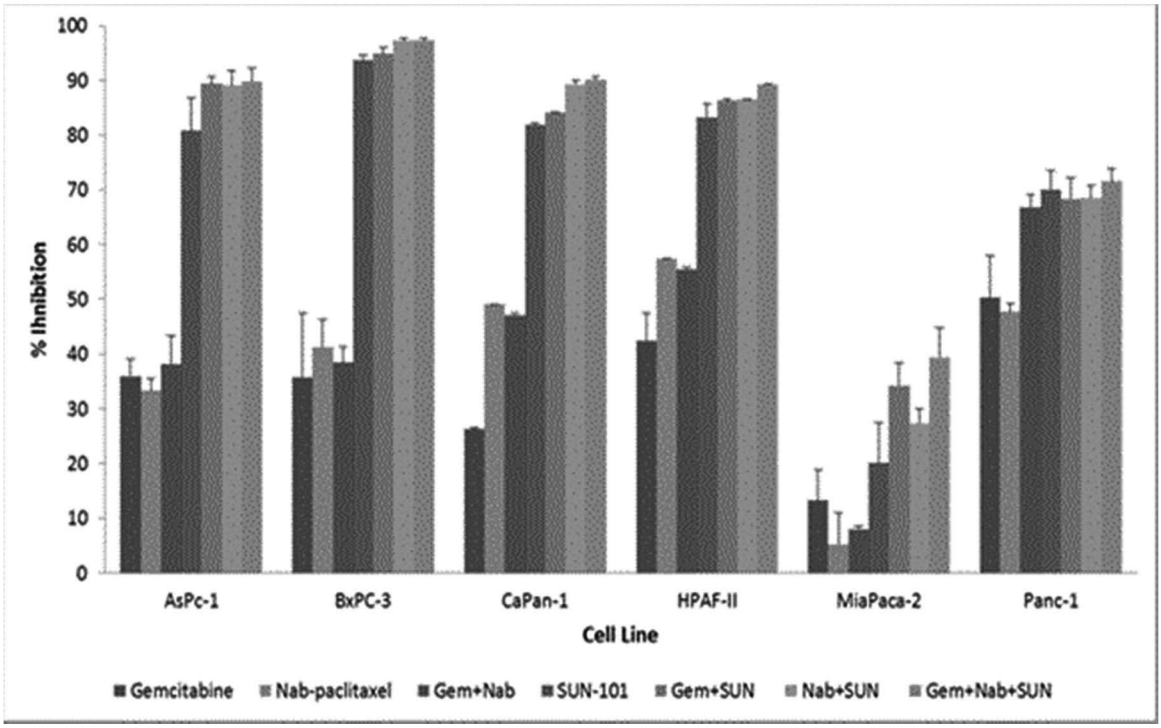
Preclinical Development

To enable IND and HREC/CTN submission and as part of our pharmacology work, we conducted plasma and urine assay development and validation in animals, in vitro metabolism studies in liver microsomes and hepatocytes, in vitro interaction studies with hepatic and renal transporters, a protein binding study, animal pharmacokinetic and metabolism/mass balance studies, and human plasma and urine assay development and validation. As a part of the pharmacology evaluation, we conducted an in vitro pharmacology screen profiling assay, a study in six human pancreatic cell lines, and studies in tumor xenograft models in mice using human pancreatic cancer PANC-1 tumor fragments, human pancreatic cancer BxPC-3 tumor fragments and human pancreatic cancer cells (L3.6pl) injected orthotopically in the tail of the pancreas of nude mice.

To meet regulatory requirements and to establish the safety profile of SBP-101, we conducted, in rodents and non-rodents, toxicology dose-ranging studies, IND-enabling general toxicology studies, and genetic toxicology studies, including an Ames test. Exploratory studies in mice and rats and a Good Laboratory Practice ("GLP")-compliant dog toxicology study have also been completed. The relationship between dose and exposure (pharmacokinetics) has been described for three animal species. We have also completed a preclinical Human Ether-a-go-go-related Gene ("hERG") assay to detect any electrocardiographic QTc interval effects (IKr potassium ion channel testing).

In anticipation of the potential for using SBP-101 in combination therapy with gemcitabine and/or nab-paclitaxel (Abraxane®), we also conducted appropriate nonclinical studies which confirmed the potential value of such combinations, including assessing the comparative efficacy of SBP-101, gemcitabine and nab-paclitaxel in various combinations as shown in Figure 3.

Figure 3. Evaluation of SBP-101 alone and in combination with gemcitabine and nab-paclitaxel in 6 human pancreatic cancer cell lines



Source: Baker CB et al Pancreas 2015;44(8) 1350

Note that maximum percent growth inhibition (mean ± SE) at 96 hours was observed with 10 μM SBP-101 alone and in combination with gemcitabine and/or nab-paclitaxel in six human pancreatic cancer cell lines.

We have met FDA-mandated Chemistry, Manufacturing and Control ("CMC") requirements with a combination of in-house expertise and contractual arrangements. Preparation of anticipated metabolites, impurities and an internal standard, as a prerequisite for analytical studies, were completed through a Sponsored Research Agreement with the University of Florida and a contract manufacturer. We have Service Agreements with Syngene International Ltd. ("Syngene") for the manufacture and supply of Good Manufacturing Practice ("GMP")-compliant SBP-101 active pharmaceutical ingredient ("API") and for the development of synthetic process improvements. Investigational product (IP or clinical trial supply) has been made and tested at Albany Molecular Research Inc. ("AMRI") in Burlington, MA. Initial lots of GMP-compliant API were prepared by Syngene and released for conversion into supply dosage form. Two clinical trial supply lots have been successfully prepared and released by AMRI. In addition, efforts have continued to refine the synthetic process at Syngene. A new shorter synthetic process has been developed and submitted for patent protection.

Pancreatic Cancer Investigational New Drug ("IND")

Our IND application package contained the following:

- Investigator's Brochure;
- Statement of general investigative plans;
- Proposed Phase 1 pancreatic cancer study protocol;
- Data management and statistical plan;
- CMC data; and
- Pharmacology, absorption, distribution, metabolism and excretion (or "ADME"), and toxicology data.

Preparation of the SBP-101 IND for pancreatic cancer required collaboration by our manufacturing, preclinical toxicology, pharmacokinetic and metabolism experts, our regulatory affairs project management, and our in-house clinical expertise. In August 2015, the FDA accepted our application and in January 2016 we commenced patient enrollment in our first Phase 1 clinical trial, which was a safety and tolerability study in patients with previously treated metastatic pancreatic ductal adenocarcinoma.

Clinical Development – Pancreatic Cancer

Phase 1 Clinical Trial Design and Completion (SBP-101 Monotherapy)

Our initial Phase 1 study in patients with pancreatic cancer commenced the enrollment of patients in January 2016 and enrollment was completed in September 2017. This study was a dose-escalation study with 8-week cycles of treatment/observation at each dose level.

A favorable characteristic of the pancreatic action of SBP-101 is the lack of an effect on the normal insulin-producing islet cells. Preservation of islet cell function implies the likely absence of diabetes as a complication of SBP-101 therapy. It is important to note that diabetes is a common co-morbidity in patients with pancreatic cancer, but it is not expected to be an adverse effect of treatment with SBP-101. The potential adverse effect of exocrine pancreatic insufficiency is mitigated by the observation that many patients with pancreatic ductal adenocarcinoma require pancreatic enzyme replacement as a feature of their underlying disease, a complication so common that pancreatic enzyme replacement with one of several commercially available products is typically covered by United States and Australian health care plans. Patients with cystic fibrosis, chronic pancreatitis and pancreatic cancer are the populations most often treated with pancreatic enzyme replacement.

Patients in our Phase 1 first-in-human trial underwent regular pancreatic and hepatic enzyme evaluation and obtained periodic chest and abdominal CT follow-up. Patients were also carefully monitored for clinical signs of GI adverse events.

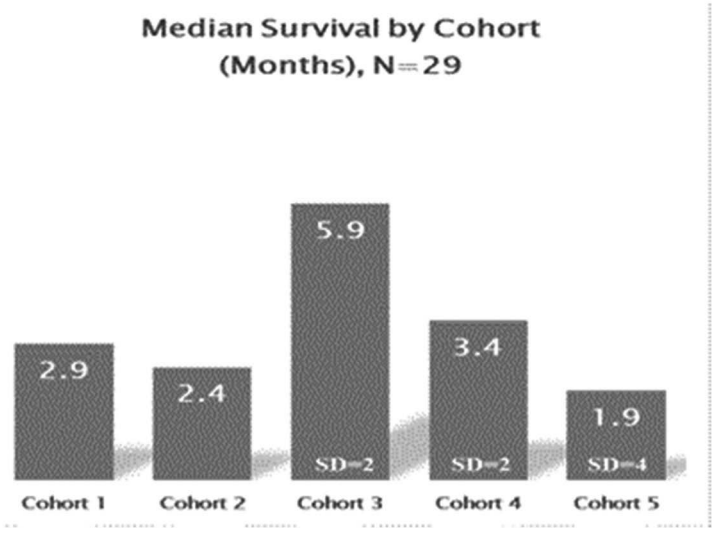
In August 2015, the FDA accepted our IND application for our SBP-101 product candidate. We have completed an initial clinical trial of SBP-101 in patients with previously treated locally advanced or metastatic pancreatic cancer. This was a Phase 1, first-in-human, dose-escalation, safety study. Between January 2016 and September 2017, we enrolled twenty-nine patients into six cohorts, or groups, in the dose-escalation phase of our Phase 1 trial. Twenty-four of the patients received at least two prior chemotherapy regimens. No drug-related serious adverse events occurred during the first four cohorts. In cohort five, serious adverse events (klebsiella sepsis with metabolic acidosis in one patient, renal and hepatic toxicity in one patient, and mesenteric vein thrombosis with metabolic acidosis in one patient) were observed in three of the ten patients, two of whom exhibited progressive disease at the end of their first cycle of treatment and were determined by the Data Safety Monitoring Board (“DSMB”) to be dose-limiting toxicities (“DLTs”). Consistent with the study protocol, the DSMB recommended continuation of the study by expansion of cohort 4, one level below that at which DLTs were observed. Four patients were enrolled in this expansion cohort. One patient developed focal pancreatitis at the site of the primary tumor after 2.3 months, but otherwise SBP-101 was considered well tolerated below dose level five. The most common drug related adverse events were nausea, vomiting, diarrhea, injection site pain and abdominal pain, which were mostly mild, grades 1 or 2, and are symptoms common in patients with pancreatic cancer. No drug-related bone marrow toxicity or peripheral neuropathy was observed at any dose level.

In addition to being evaluated for safety, 23 of the 29 patients were evaluable for preliminary signals of efficacy prior to or at the eight-week conclusion of their first cycle of treatment using the Response Evaluation Criteria in Solid Tumors (“RECIST”), the current standard for evaluating changes in the size of tumors. Eight of the 23 patients (35%) had Stable Disease (“SD”) and 15 of 24 (65%) had Progressive Disease (“PD”). It should be noted that of the 15 patients with PD, six came from cohorts one and two and are considered to have received less than potentially therapeutic doses of SBP-101. We also noted that 28 of the 29 patients had follow-up blood tests measuring the Tumor Marker CA 19-9 associated with pancreatic ductal adenocarcinoma. Eleven of these patients (39%) had reductions in the CA 19-9 levels, as measured at least once after the baseline assessment. Seven of the remaining 17 patients who showed no reduction in CA 19-9 came from cohorts one and two.

By cohort, stable disease occurred in two patients in cohort 3, two patients in cohort 4 and four patients in cohort 5. The best response outcomes and best median survival were observed in the group of patients who received total cumulative doses of approximately 6 mg/kg (cohort three). Two of four patients (50%) showed SD at week eight. Median survival in this group was 5.9 months, with two patients surviving 8 and 10 months, respectively. By total cumulative dose received, five of twelve patients (42%) who received total cumulative doses between 2.5 mg/kg and 8.0 mg/kg had reductions in the CA19-9 levels, as measured at least once after the baseline assessment. Nine of these patients (67%) exceeded three months of overall survival

("OS"), three patients (25%) exceeded nine months of OS and two patients (17%) exceeded one year of OS and were still alive at the end of the study.

Figure 4. Evaluation of SBP 101 Phase 1Mono-therapy Safety Trial - Median Survival by Cohort



The absence of adverse events which could potentially overlap with adverse events typically observed in the use of conventional chemotherapeutic agents, supports the case for combination of SBP-101 with conventional chemotherapeutic agents, such as gemcitabine, nab-paclitaxel, or even FOLFIRINOX.

Phase 1a/1b Clinical Trial Design (Front Line Combination Therapy)

Given the life-threatening nature of pancreatic ductal adenocarcinoma, the limited efficacy of current treatment options, and the long history of failures in pancreatic ductal adenocarcinoma developmental therapeutics, we will attempt to evaluate SBP-101 expeditiously as noted below.

We began enrolling patients in our current front-line clinical trial in June of 2018. This second clinical trial is a Phase 1a/1b study of the safety, efficacy and pharmacokinetics of SBP-101 administered in combination with two standard-of-care chemotherapy agents, gemcitabine and nab-paclitaxel. We are currently conducting the trial at four study sites (three in Australia and one in the United States). In the Phase 1a portion of this trial, we expect to enroll three cohorts of three to six patients with increased dosage levels of SBP-101 administered in the second and third cohorts. Demonstration of adequate safety in Phase 1a is expected to lead to the Phase 1b exploration of efficacy, in which we plan to enroll ten patients using the recommended dosage level determined in Phase 1a. Additional funding will be required to complete the current Phase 1a/1b clinical trial and should we obtain adequate funding, we hope to increase the number of patients enrolled in the Phase 1b portion of the trial to 36, thus providing a stronger basis for the next steps in the clinical evaluation of SBP - 101. We expect to complete Phase 1a in the fourth quarter of 2019. Early results from the Phase 1b expansion could become available as soon as the second half of 2020.

Phase 2 Pivotal Clinical Trial

A Phase 2 study of SBP-101 in combination with two standard chemotherapy agents, gemcitabine and nab-paclitaxel, is expected to follow the Phase 1a/1b safety study with an exploration of efficacy and may result in an expedited development pathway, leading toward a randomized pivotal trial. It may be possible to combine Phase1b/Phase 2 into a single study.

If the results of our planned Phase 2 combination clinical trial demonstrate safety and sufficiently successful efficacy results, we intend to meet with the FDA to obtain advice on potential breakthrough therapy designation, fast track designation (to both provide guidance to facilitate development and expedite review) and an accelerated approval strategy.

If we are able to successfully complete FDA recommended clinical studies, we intend to seek marketing authorization from the FDA, the EMA (European Union), Ministry of Health and Welfare (Japan) and TGA (Australia). The submission fees may be waived when SBP-101 has been designated an orphan drug in each geographic region, as described under "Orphan Drug Status."

Total Development Costs

The development of SBP-101 involves a preclinical and a clinical development phase. We have completed our initial preclinical development work for pancreatic cancer and are completing our second Phase 1 clinical trial. Additional clinical trials will be required for FDA or other similar approvals if the results of the front-line clinical trial of our SBP-101 product candidate justify continued development. The cost and timing of additional clinical trials is highly dependent on the nature and size of the trials.

Orphan Drug Status

The Orphan Drug Act ("ODA") provides special status to drugs which are intended for the safe and effective treatment, diagnosis or prevention of rare diseases that affect fewer than 200,000 people in the United States, or that affect more than 200,000 persons but for which a manufacturer is not expected to recover the costs of developing and marketing such a drug. Orphan drug designation has the advantage of reducing drug development costs by: (i) streamlining the FDA's approval process, (ii) providing tax breaks for expenses related to the drug development, (iii) allowing the orphan drug manufacturer to receive assistance from the FDA in funding the clinical testing necessary for approval of an orphan drug, and (iv) facilitating drug development efforts. More significantly, the orphan drug manufacturer's ability to recover its investment in developing the drug is also greatly enhanced by the FDA granting the manufacturer seven years of exclusive US marketing rights upon approval. Designation of a drug candidate as an orphan drug therefore may provide its sponsor with the opportunity to adopt a faster and less expensive pathway to commercializing its product. We obtained US Orphan Drug Status in 2014 and we intend to submit an application for Orphan Drug Status in Europe, Japan and Australia when we have additional clinical data.

Intellectual Property

Intellectual property licensed by us from the University of Florida includes U.S. Patent No. 6,160,022 covering the methods of using SBP-101 for the chemical reaction of the exocrine portion of the pancreas; this patent expires in July 2019.

In addition, we have filed International Patent Application No. PCT/US19/15581 Titled METHODS FOR PRODUCING (6S,15S)-3,8,13,18- TETRAAZAICOSANE-6,15-DIOL. This patent application claims a novel process for the production of SBP-101 and reduces the number of synthetic steps from nineteen to six.

Development Project Managers

Project managers have been hired or contracted to coordinate all the functions identified in our Development Plan for SBP-101. The personnel responsible for overseeing critical functions of the Development Plan are as follows:

Our CMC program is under the direction of Dr. Thomas Neenan, Ph.D., a highly experienced pharmaceutical industry synthetic chemist, who is a founding member of Sun BioPharma, Inc. and our Chief Scientific Officer. Dr. Neenan has commissioned Contract Manufacturing Organizations ("CMOs"), which have improved the process for synthesis of SBP-101, and have produced high-quality compound, chemically identical to that synthesized by Dr. Bergeron at the University of Florida. Dr. Neenan's completed work includes development, confirmation and documentation of the synthetic chemistry process, analytical purity, reproducibility, stability (shelf-life), degradation products and pharmaceutical formulation and packaging. This work has culminated in a supply of drug to support preclinical work and human clinical trials. Dr. Neenan also leads our preclinical group.

Dr. Anthony Kiorpes, Ph.D., D.V.M., is a long-term consultant with the Company. Dr. Kiorpes has responsibility for our toxicology program, a role he has assumed previously for many preclinical projects at other companies. His studies have determined single- and multiple-dose safety profiles in rodent and non-rodent species, enabling improved safety monitoring in the design of clinical trials for SBP-101. Dr. Kiorpes' results have helped management to predict and prevent potential side effects in humans.

Dr. Michael Cullen, M.D., M.B.A, is our founder and Executive Chairman, President and Chief Executive Officer (CEO). Dr. Cullen is an experienced drug development specialist with 10 prior NDA approvals and has led our overall Clinical, Regulatory Affairs and Project Management effort, including timeline and budget management, critical path timeline synchronization, IND/HREC/CTN package submissions, management of industry partner collaborative efforts, initial EU Regulatory Affairs planning, and collaboration on oversight of outsourced CMC efforts. Dr. Cullen has recruited additional experienced and talented staff in the positions of statistical analyses, manufacturing operations, clinical operations, clinical research and non-clinical studies.

Dr. Suzanne Gagnon, M.D., is our Chief Medical Officer (CMO) and a member of our Board of Directors. Dr. Gagnon is an experienced CMO, having served in that capacity for several private and public companies, including BioPharm/IBAH/Omnicare, ICON, Idis, NuPathe, Luitpold (Daiichi-Sankyo), and Rhone-Poulenc and Rorer (Sanofi) where she helped develop docetaxel, still an important chemotherapy agent. Dr. Gagnon assumed the lead in the design and implementation of our clinical trials, recruiting investigators, monitoring the safety of the patients and reporting the findings to the FDA, EMA and TGA, and in medical literature.

Dr. Michael Walker is an independent consultant for the Company and works as our Director of Pancreatic Research. Dr. Walker is an accomplished, University of Minnesota and UCLA trained pancreatic surgeon, and is currently a part-time instructor at the University of Minnesota School of Medicine. He was also the recipient of an NIH grant to study SBP-101 in collaboration with colleagues at Cedars Sinai Hospital in Los Angeles.

We have engaged Courante Oncology, an experienced clinical Contract Research Organization ("CRO"), to manage clinical operations in the United States, and have engaged Novotech Pty Ltd, another experienced CRO for our Australian operations. These two CROs will provide regulatory documentation for HREC/CTN and Investigational Review Board ("IRB") submissions, FDA 1571 regulation compliance, and informed consents, as well as clinical study site qualification, contracting and payment, study conduct monitoring, data collection, analysis and reporting.

Competition

The development and commercialization of new products to treat cancer is intensely competitive and subject to rapid and significant technological change. While we believe that our knowledge, experience and scientific resources provide us with competitive advantages, we face substantial competition from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. Many of our competitors have significantly greater financial, technical, and human resources. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do.

We face competition with respect to our current product candidates and will face competition with respect to future product candidates, from segments of the pharmaceutical, biotechnology and other related markets that pursue approaches to targeting molecular alterations and signaling pathways associated with cancer. Our competitors may obtain regulatory approval of their products more rapidly than we do or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, less costly, or possessing better safety profiles than our products, and these competitors may be more successful than us in manufacturing and marketing their products.

In addition, we may need to develop our product candidates in collaboration with diagnostic companies, and we will face competition from other companies in establishing these collaborations. Our competitors will also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Furthermore, we also face competition more broadly across the market for cost-effective and reimbursable cancer treatments. The most common methods of treating patients with cancer are surgery, radiation and drug therapy, including chemotherapy, hormone therapy and targeted drug therapy or a combination of such methods. There are a variety of available drug therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy. While our product candidates, if any are approved, may compete with these existing drug and other therapies, to the extent they are ultimately used in combination with or as an adjunct to these therapies, our product candidates may be approved as companion treatments and not be competitive with current therapies. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis. Insurers and other third-party payors may also encourage the use of generic products or specific branded products. We expect that if our product candidates are approved, they will be priced at a premium over competitive generic, including branded generic, products. As a result, obtaining market acceptance of, and gaining significant

share of the market for, any of our product candidates that we successfully introduce to the market will pose challenges. In addition, many companies are developing new therapeutics and we cannot predict what the standard of care will be as our product candidate progresses through clinical development.

SBP-101

Commercialization

We have not established a sales, marketing or product distribution infrastructure nor have we devoted significant management resources to planning such an infrastructure because our lead product candidate is still in early clinical development. We currently anticipate that we will partner with a larger pharmaceutical organization having the expertise and capacity to perform these functions.

Manufacturing and Suppliers

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing as well as for commercial manufacture of any products that we may commercialize. If needed, we intend to engage, by entering into a supply agreement or through another arrangement, third party manufacturers to provide us with additional SBP-101 clinical supply. We identified and qualified manufacturers to provide the active pharmaceutical ingredient and fill-and-finish services for our initial product candidate prior to our submission of an NDA to the FDA and expect to continue utilizing this approach for any future product candidates.

Employees

As of March 19, 2019, we had five employees, four of whom were full-time employees and one of whom was a part-time employee. This is down from the nine employees on staff during the year ended December 31, 2017. Several of the employees who left the Company at the end of 2017 became part time independent consultants for the Company. We may hire additional employees to support the growth of our businesses. We believe that operational responsibilities can be handled by our current employees and independent consultants. We have historically used, and expect to continue to use, the services of independent consultants and contractors to perform various professional services. We believe that this use of third-party service providers enhances our ability to minimize general and administrative expenses. None of our employees is represented by a labor union, and we consider our relationship with our employees and independent consultants to be good.

Material Agreements

The Standard Exclusive License Agreement dated December 22, 2011, between us and UFRF grants us an exclusive license to the proprietary technology covered by issued United States Patents Nos. US 5,962,533, which expired in February 2016, and US 6,160,022 which expires in July 2019, with reservations by UFRF for academic or government uses. Under this agreement, we agree to pay various royalties, expenses and milestone payments to UFRF. Additionally, pursuant to this agreement, we initially issued to UFRF 80,000 shares of common stock. Anti-dilution protection for UFRF pursuant to this agreement required us to issue additional shares in order for UFRF to maintain its ownership stake at ten percent (10%) of the total number of issued and outstanding shares of our common stock, calculated on a fully diluted basis, until such time as we had received a total of two million dollars ($2,000,000) in exchange for our issuance of equity securities. This requirement was met in 2012, and UFRF is therefore afforded no further anti-dilution protection. Pursuant to this anti-dilution provision, we issued an additional 34,423 shares of common stock to UFRF increasing the total shares of common stock issued to UFRF to 114,423 shares.

Under the License Agreement, we have a number of performance related milestones we must meet in order to retain our rights to the technology. Included in such milestones is the commitment to have our first commercial sale of a product incorporating the technology by the end of 2020. Also, in the event that we are not actively pursuing commercialization of the technology in any country or territory other than the United States and certain other countries by the end of 2014, UFRF may terminate the license as to that country or territory under certain circumstances. UFRF may also terminate this license for standard and similar causes such as material breach of the agreement, bankruptcy, failure to pay royalties and other customary conditions.

The foregoing description of the material terms of the License Agreement is qualified by the full text of the License Agreement, a copy of which was filed as Exhibit 10.9 to our current report on Form 8-K filed on September 11, 2015 and is incorporated herein by reference.

Government Regulation

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug and Cosmetic Act and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling and import and export of pharmaceutical products. Failure to comply with applicable US requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Pharmaceutical product development for a new product or certain changes to an approved product in the United States typically involves preclinical laboratory and animal tests, the submission to the FDA of an IND which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice ("GCP"), an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on US patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board ("IRB") for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects/patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence of effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In many cases the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in instances where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. The cost of preparing and submitting an NDA is substantial, and the fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of new drug applications to encourage timeliness. Most applications for standard review drug products are reviewed within twelve months from submission; most applications for priority review drugs are reviewed within eight months from submission. Priority review can be applied to drugs that the FDA determines offer major advances in treatment or provide a treatment where no adequate therapy exists. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an outside advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with current good manufacturing practice ("cGMP"), a quality system regulating manufacturing, is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy ("REMS") to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Fast Track Designation and Accelerated Approval

The FDA is required to facilitate the development, and expedite the review, of drugs that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the Fast Track program, the sponsor of a new product candidate may request that the FDA designate the product candidate for a specific indication as a Fast Track drug concurrent with, or after, the filing of the IND for the product candidate. The FDA must determine if the product candidate qualifies for Fast Track Designation within 60 days of receipt of the sponsor's request.

Under the Fast Track program and FDA's accelerated approval regulations, the FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions, or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow FDA to withdraw the drug from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to priority review by FDA.

If a submission is granted Fast Track Designation, the sponsor may engage in more frequent interactions with the FDA, and the FDA may review sections of the NDA before the application is complete. This rolling review is available if the applicant provides, and the FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's time period goal for reviewing an application does not begin until the last section of the NDA is submitted. Additionally, Fast Track Designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Breakthrough Therapy Designation

The FDA is also required to expedite the development and review of the application for approval of drugs that are intended to treat a serious or life-threatening disease or condition where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Under the Breakthrough Therapy program, the sponsor of a new product candidate may request that the FDA designate the product candidate for a specific indication as a breakthrough therapy. The FDA must determine if the product candidate qualifies for Breakthrough Therapy designation within 60 days of receipt of the sponsor's request.

Orphan Drug Designation and Exclusivity

The Orphan Drug Act provides incentives for the development of products intended to treat rare diseases or conditions. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug available in the United States for this type of disease or condition will be recovered from sales of the product. If a sponsor demonstrates that a drug is intended to treat a rare disease or condition, the FDA will grant orphan designation for that product for the orphan disease indication, assuming that the same drug has not already been approved for the indication for which the sponsor is seeking orphan designation. If the same drug has already been approved for the indication for which the sponsor is seeking orphan designation, the sponsor must present a plausible hypothesis of clinical superiority in order to obtain orphan designation. Orphan designation must be requested before submitting an NDA. After the FDA grants orphan designation, the FDA discloses the identity of the therapeutic agent and its potential orphan use.

Orphan designation may provide manufacturers with benefits such as research grants, tax credits, PDUFA application fee waivers and eligibility for orphan drug exclusivity. If a product that has orphan designation subsequently receives the first FDA approval of the active moiety for that disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which for seven years prohibits the FDA from approving another product with the same active ingredient for the same indication, except in limited circumstances. Orphan drug exclusivity will not bar approval of another product under certain circumstances, including if a subsequent product with the same active ingredient for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. Further, the FDA may approve more than one product for the same orphan indication or disease as long as the products contain different active ingredients. Moreover, competitors may receive approval of different products for the indication for which the orphan drug has exclusivity or obtain approval for the same product but for a different indication for which the orphan drug has exclusivity.

In the European Union, orphan drug designation also entitles a party to financial incentives such as reduction of fees or fee waivers and 10 years of market exclusivity is granted following drug or biological product approval. This period may be reduced to 6 years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Adverse event reporting and submission of periodic reports are required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, risk evaluation and mitigation strategies, or REMS, and surveillance to monitor the effects of an approved product, or FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug manufacture, packaging and labeling procedures must continue to conform to current good manufacturing practices, or cGMPs, after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with FDA subjects' entities to periodic unannounced inspections by the FDA, during which the Agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Additional Regulations and Environmental Matters

In addition to FDA restrictions on marketing of pharmaceutical products, we are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. These laws, which generally will not be applicable to us or our product candidates unless and until we obtain FDA marketing approval for any of our product candidates, include transparency laws, anti-kickback statutes, false claims statutes and regulation regarding providing drug samples, among others.

The federal Anti-Kickback Statute prohibits, among other things, individuals and entities from knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. Violations of the federal Anti-Kickback Statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs.

Federal false claims laws and civil monetary penalties, including the False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws.

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health ("HITECH") Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. Many states and foreign jurisdictions also have laws and regulations that govern the privacy and security of individually identifiable health information and such laws often vary from one another and from HIPAA.

The federal Physician Payment Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS, information related to payments or other transfers of value made to physicians and teaching hospitals, and ownership and investment interests held by the physicians and their immediate family members.

The majority of states also have statutes or regulations similar to the federal Anti-Kickback Statute and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Our activities may also be subject to certain state laws regarding the privacy and security of health information that may not be preempted by HIPAA, as well as additional tracking and reporting obligations regarding payments to healthcare providers and marketing expenditures.

In addition to regulatory schemes that apply, or may in the future apply, to our business, we are or may become subject to various environmental, health and safety laws and regulations governing, among other things, laboratory procedures and any use and disposal by us of hazardous or potentially hazardous substances in connection with our research and development activities. We do not presently expect such environmental, health and safety laws or regulations to materially impact our present or planned future activities.

Coverage and Reimbursement

Sales of any of our product candidates that may be approved will depend, in part, on the extent to which the cost of the product will be covered by third party payors. Third party payors may limit coverage to an approved list of products, or formulary, which might not include all drug products approved by the FDA for an indication. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Any product candidates for which we obtain marketing approval may not be considered medically necessary or cost-effective by third party payors and we may need to conduct expensive pharmacoeconomic studies in the future to demonstrate the medical necessity and/or cost effectiveness of any such product. Nonetheless, our product candidates may not be considered medically necessary or cost effective. The U.S. government, state legislatures and foreign governments have shown increased interest in implementing cost containment programs to limit government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Continued interest in and adoption of such controls and measures and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals such as the product candidates we are developing.

Health Reform

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

By way of example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively known as the Affordable Care Act ("ACA") became law. The ACA substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the pharmaceutical industry and was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the health industry and impose additional health policy reforms. With regard to pharmaceutical products, among other things, the ACA expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare prescription drug benefit. We continue to evaluate the effect that the ACA has on our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year effective April 1, 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2024 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and, accordingly, our financial operations.

Various lawmakers have sought to further modify, repeal or supplement certain provisions of the ACA. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

In the coming years, additional legislative and regulatory changes could be made to governmental health programs that could significantly impact pharmaceutical companies and the success of our product candidates.

Available Information

Our website is located at www.SunBioPharma.com. The information contained on or connected to our website is not a part of this report. We have included our website address as a factual reference and do not intend it to be an active link to our website.

We make available, free of charge, through our website materials we file or furnish to the SEC pursuant to Section 13(a) or 15(d) of the Exchange Act, including our annual report on Form 10-K, our quarterly reports on Form 10-Q, our current reports on Form 8-K and amendments to those reports. These materials are posted to our website as soon as reasonably practicable after we electronically file them with or furnish them to the SEC.

Members of the public may read and copy any materials we file with the SEC at its Public Reference Room at 450 Fifth Street, NW, Washington, DC 20549. Information on the operation of the Public Reference Room is available by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains reports, proxy and information statements and other information about us and other issuers that file electronically at http://www.sec.gov.

Item 1A. Risk Factors

You should carefully consider the following information about risks, together with the other information contained in this report before making an investment in our common stock. If any of the circumstances or events described below actually arises or occurs, our business, results of operations, cash flows and financial condition could be harmed.

Risks Related to Our Business

We are a company with limited revenue history for you to evaluate our business.

We have a limited operating history for you to consider in evaluating our business and prospects. As such, it is difficult for potential investors to evaluate our business.

We have experienced negative cash flows for our operating activities since inception, primarily due to the investments required to commercialize our primary drug candidate, SBP-101. Our financing cash flows historically have been positive due to proceeds from the sale of equity securities and promissory notes issuances. Our net cash used in operating activities was $2.4 million and $3.4 million for the years ended December 31, 2018 and 2017, respectively, and we had negative working capital of $1.1 million (excludes $1.3 million of debt discount) and $3.4 million as of the same dates, respectively.

Our operations are subject to all the risks, difficulties, complications and delays frequently encountered in connection with the formation of any new business, as well as those risks that are specific to the pharmaceutical and biotechnology industries in which we compete. Investors should evaluate us considering the delays, expenses, problems and uncertainties frequently encountered by companies developing markets for new products, services and technologies. We may never overcome these obstacles.

As a result of our current lack of financial liquidity, we and our auditors have expressed substantial doubt regarding our ability to continue as a "going concern."

As a result of our current lack of financial liquidity, our auditors' report for our 2018 financial statements, which are included as part of this report, contains a statement concerning our ability to continue as a "going concern." Our lack of sufficient liquidity could make it more difficult for us to secure additional financing or enter into strategic relationships on terms acceptable to us, if at all, and may materially and adversely affect the terms of any financing that we may obtain and our public stock price generally.

Our continuation as a "going concern" is dependent upon, among other things, achieving positive cash flow from operations and, if necessary, augmenting such cash flow using external resources to satisfy our cash needs. Our plans to achieve positive cash flow primarily include engaging in offerings of securities. Additional potential sources of funds include negotiating up-front and milestone payments on our current and potential future product candidates or royalties from sales of our products that secure regulatory approval and any milestone payments associated with such approved products. These cash sources could, potentially, be supplemented by financing or other strategic agreements. However, we may be unable to achieve these goals or obtain required funding on commercially reasonable terms, or at all, and therefore may be unable to continue as a going concern.

Our lack of diversification increases the risk of an investment in our Company and our financial condition and results of operations may deteriorate if we fail to diversify.

Our Board of Directors has centered our attention on our drug development activities, which are currently focused on our initial product candidate SBP-101, the polyamine analogue compound we licensed from the UFRF. Our ability to diversify our investments will depend on our access to additional capital and financing sources and the availability and identification of suitable opportunities.

Larger companies have the ability to manage their risk by diversification. However, we lack and expect to continue to lack diversification, in terms of both the nature and geographic scope of our business. As a result, we will likely be impacted more acutely by factors affecting pharmaceutical and biotechnology industries in which we compete than we would if our business were more diversified, enhancing our risk profile. If we cannot diversify our operations, our financial condition and results of operations could deteriorate.

We may be unable to obtain the additional capital that is required to execute our business plan, which could restrict our ability to grow.

Our current capital and our other existing resources will be sufficient only to provide a limited amount of working capital and will not be sufficient to fund our expected continuing opportunities. We will require additional capital to continue to operate our business.

Future acquisitions, research and development and capital expenditures, as well as our administrative requirements, such as clinical trial costs, salaries, insurance expenses and general overhead expenses, as well as legal compliance costs and accounting expenses, will require a substantial amount of additional capital and cash flow. There is no guarantee that we will be able to raise additional capital required to fund our ongoing business on commercially reasonable terms or at all.

We intend to pursue sources of additional capital through various financing transactions or arrangements, including collaboration arrangements, debt financing, equity financing or other means. We may not be successful in locating suitable financing transactions on commercially reasonable terms, in the time period required or at all, and we may not obtain the capital we require by other means. If we do not succeed in raising additional capital, our resources will not be sufficient to fund our operations going forward.

Any additional capital raised through the sale of equity may dilute the ownership percentage of our stockholders. This could also result in a decrease in the fair market value of our equity securities because our assets would be owned by a larger pool of outstanding equity. The terms of securities we issue in future capital transactions may be more favorable to our new investors, and may include preferences, superior voting rights and the issuance of warrants or other derivative securities which may have a further dilutive effect.

Our ability to obtain needed financing may be impaired by such factors as the capital markets, both generally and in the pharmaceutical and other drug development industries in particular, our status as a new enterprise without a significant demonstrated operating history, the limited diversity of our activities and/or the loss of key personnel. If the amount of capital we are able to raise from financing activities is not sufficient to satisfy our capital needs, even to the extent that we reduce our operations, we may be required to cease our operations.

We may incur substantial costs in pursuing future capital financing, including investment banking fees, legal fees, accounting fees, securities law compliance fees, printing and distribution expenses and other costs, which may adversely impact our financial condition.

U.S. federal income tax reform could adversely affect our Company and its stockholders.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 became law (the "Tax Act"). The Tax Act enacts a broad range of changes to the Internal Revenue Code of 1986, as amended (the "IRC"). The Tax Act, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest and net operating losses, allows for the expensing of capital expenditures and puts into effect the migration from a "worldwide" system of taxation to a territorial system. Our accounting for the Tax Act is complete, including the remeasurement of our deferred tax assets and liabilities using the reduced corporate federal tax rate of 21%. Tax reform did not have a material impact to our financial statements as our net deferred tax assets and liabilities are fully reserved. The impact of the Tax Act on holders of our common shares is uncertain and could be adverse. This annual report does not discuss any such tax legislation or the manner in which it might affect purchasers of our common stock. We urge our stockholders to consult with their legal and tax advisors with respect to any such legislation and the potential tax consequences of investing in our common stock.

We may not be able to effectively manage our growth, which may harm our profitability.

Our strategy envisions expanding our business. If we fail to effectively manage our growth, our financial results could be adversely affected. Growth may place a strain on our management systems and resources. We must continue to refine and expand our business development capabilities, our systems and processes and our access to financing sources. As we grow, we must continue to hire, train, supervise and manage new employees. We cannot assure you that we will be able to:

- expand our systems effectively or efficiently or in a timely manner;
- allocate our human resources optimally;
- identify and hire qualified employees or retain valued employees; or
- incorporate effectively the components of any business that we may acquire in our effort to achieve growth.

If we are unable to manage our growth, our operations and our financial results could be adversely affected by inefficiency, which could diminish our profitability.

Our business may suffer if we do not attract and retain talented personnel.

Our success will depend in large measure on the abilities, expertise, judgment, discretion, integrity and good faith of our management and other personnel in conducting our business. We have a small management team, and the loss of a key individual or inability to attract suitably qualified staff could materially adversely impact our business.

Our success depends on the ability of our management, employees, consultants and joint venture partners, if any, to interpret market data correctly and to interpret and respond to economic market and other conditions in order to locate and adopt appropriate investment opportunities, monitor such investments, and ultimately, if required, to successfully divest such investments. Further, no assurance can be given that our key personnel will continue their association or employment with us or that replacement personnel with comparable skills can be found. We will seek to ensure that management and any key employees are appropriately compensated; however, their services cannot be guaranteed. If we are unable to attract and retain key personnel, our business may be adversely affected.

The market for our product candidate is highly competitive and is subject to rapid scientific change, which could have a material adverse effect on our business, results of operations and financial condition.

The pharmaceutical and biotechnology industries in which we compete are highly competitive and characterized by rapid and significant technological change. We face intense competition from organizations such as pharmaceutical and biotechnology companies, as well as academic and research institutions and government agencies. Some of these organizations are pursuing products based on technologies similar to our technology. Other of these organizations have developed and are marketing products or are pursuing other technological approaches designed to produce products that are competitive with our product candidates in the therapeutic effect these competitive products have on the disease targeted by our product candidate. Our competitors may discover, develop or commercialize products or other novel technologies that are more effective, safer or less costly than any that we may develop. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our product candidate.

Many of our competitors are substantially larger than we are and have greater capital resources, research and development staffs and facilities than we have. In addition, many of our competitors are more experienced in drug discovery, development and commercialization, obtaining regulatory approvals and drug manufacturing and marketing.

We anticipate that the competition with our product candidate and technology will be based on a number of factors including product efficacy, safety, availability and price. The timing of market introduction of our planned future product candidates and competitive products will also affect competition among products. We expect the relative speed with which we can develop our product candidate, complete the required clinical trials, establish a strategic partner and supply appropriate quantities of the product candidate for late stage trials, if required, to be important competitive factors. Our competitive position will also depend upon our ability to attract and retain qualified personnel, to obtain patent protection in non-U.S. markets, which we currently do not have, or otherwise develop proprietary products or processes and to secure sufficient capital resources for the period between technological conception and commercial sales or out-license to a pharmaceutical partner. If we fail to develop and deploy our proposed product candidate in a successful and timely manner, we will in all likelihood not be competitive.

We face significant risks in our product candidate development efforts.

Our business depends on the successful development and commercialization of our product candidates. We are currently focused on developing our initial product candidate, SBP-101, for the treatment of PDA and are not permitted to market it in the United States until we receive approval of an NDA from the FDA, or in any foreign jurisdiction until we receive the requisite approvals from such jurisdiction. The process of developing new drugs and/or therapeutic products is inherently complex, unpredictable, time-consuming, expensive and uncertain. We must make long-term investments and commit significant resources before knowing whether our development programs will result in drugs that will receive regulatory approval and achieve market acceptance. A product candidate that appears to be promising at all stages of development may not reach the market for a number of reasons that may not be predictable based on results and data from the clinical program. A product candidate may be found ineffective or may cause harmful side effects during clinical trials, may take longer to progress through clinical trials than had been anticipated, may not be able to achieve the pre-defined clinical endpoints even though clinical benefit may have been achieved, may fail to receive necessary regulatory approvals, may prove impracticable to manufacture in commercial quantities at reasonable cost and with acceptable quality, or may fail to achieve market acceptance.

We cannot predict whether or when we will obtain regulatory approval to commercialize our initial product candidate and we cannot, therefore, predict the timing of any future revenues from this or other product candidates, if any. The FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. For example, the FDA:

- could determine that the information provided by us was inadequate, contained clinical deficiencies or otherwise failed to demonstrate the safety and effectiveness of any of our product candidates for any indication;

- may not find the data from clinical trials sufficient to support the submission of an NDA or to obtain marketing approval in the United States, including any findings that the clinical and other benefits of our product candidates outweigh their safety risks;

- may disagree with our trial design or our interpretation of data from preclinical studies or clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our trials;

- may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the manufacturing of our product candidates;

- may approve our product candidates for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials;

- may change its approval policies or adopt new regulations; or

- may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates.

Any failure to obtain regulatory approval of our initial product candidate or future product candidates we develop, if any, would significantly limit our ability to generate revenues, and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenues.

Our product candidate is based on new formulation of an existing technology which has never been approved for the treatment of any cancer and, consequently, is inherently risky. Concerns about the safety and efficacy of our product candidate could limit our future success.

We are subject to the risks of failure inherent in the development of product candidates based on new technologies. These risks include the possibility that any product candidates we create will not be effective, that our current product candidate will be unsafe, ineffective or otherwise fail to receive the necessary regulatory approvals or that our product candidate will be hard to manufacture on a large scale or will be uneconomical to market.

Many pharmaceutical products cause multiple potential complications and side effects, not all of which can be predicted with accuracy and many of which may vary from patient to patient. Long term follow-up data may reveal additional complications associated with our product candidate. The responses of potential physicians and others to information about complications could materially affect the market acceptance of our product candidate, which in turn would materially harm our business.

Clinical trials required for our product candidate are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or yield unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidate.

We must conduct extensive testing of our product candidate before we can obtain regulatory approval to market and sell it. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events, or side effects, caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors, contractors, consultants, or trial subjects to comply with the trial protocol. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting. Many clinical trials are conducted under the oversight of Independent Data Monitoring Committees ("IDMCs"). These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible IDMCs based on their review of such interim trial results.

We will need to reevaluate our product candidate if it does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon our drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication could harm the development of our product candidate and our business, financial condition and results of operations may be materially harmed.

The results of pre-clinical studies and completed clinical trials are not necessarily predictive of future results, and our current product candidates may not have favorable results in later studies or trials.

Pre-clinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a product candidate in the general population, but rather to test initial safety, to study pharmacokinetics and pharmacodynamics, to study limited efficacy in a small number of study patients in a selected disease population, and to identify and attempt to understand the product candidate's side effects at various doses and dosing schedules. Success in pre-clinical studies or completed clinical trials does not ensure that later studies or trials, including continuing pre-clinical studies and large-scale clinical trials, will be successful nor does it necessarily predict future results. Favorable results in early studies or trials may not be repeated in later studies or trials, and product candidates in later stage trials may fail to show acceptable safety and efficacy despite having progressed through earlier trials.

Due to our reliance on third-parties to conduct our clinical trials, we are unable to directly control the timing, conduct, expense and quality of our clinical trials, which could adversely affect our clinical data and results and related regulatory approvals.

We extensively outsource our clinical trial activities and expect to directly perform only a small portion of the preparatory stages for planned trials. We rely on independent third-party contract research organizations ("CROs") to perform most of our clinical trials, including document preparation, site identification, screening and preparation, pre-study visits, training, program management and bio-analytical analysis. Many important aspects of the services performed for us by the CROs are out of our direct control. If there is any dispute or disruption in our relationship with our CROs, our clinical trials may be delayed. Moreover, in our regulatory submissions, we rely on the quality and validity of the clinical work performed by third-party CROs. If a CRO's processes, methodologies or results are determined to be invalid or inadequate, our own clinical data and results and related regulatory approvals could be adversely affected or invalidated.

Regulatory and legal uncertainties could result in significant costs or otherwise harm our business.

In order to manufacture and sell our product candidate, we must comply with extensive international and domestic regulations. In order to sell our product candidate in the United States, approval from the FDA is required. The FDA approval process is expensive and time-consuming. We cannot predict whether our product candidate will be approved by the FDA. Even if our product candidate is approved, we cannot predict the time frame for such approval. Foreign regulatory requirements differ from jurisdiction to jurisdiction and may, in some cases, be more stringent or difficult to obtain than FDA approval. As with the FDA, we cannot predict if or when we may obtain these regulatory approvals. If we cannot demonstrate that our product candidate can be used safely and successfully in a broad enough segment of the indicated patient population for a satisfactory length of time, our product candidate would likely be denied approval by the FDA and the regulatory agencies of foreign governments.

We may be unable to formulate or manufacture our product candidate in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as our product candidate progresses in clinical development and is ultimately commercialized. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidate, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidate. Similarly, if we are unable to supply sufficient quantities of our product candidate or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidate.

We lack sales, marketing and distribution capabilities and currently expect to rely on third parties to market and distribute our product candidate, which may harm or delay our commercialization efforts.

We currently have no sales, marketing, or distribution capabilities and do not currently intend to develop such capabilities in the foreseeable future. If we are unable to partner with a larger pharmaceutical organization having the expertise and capacity to perform these functions, then we may be unable to sell any product that we develop. We may not be able to enter into any necessary arrangements, including marketing or distribution agreements, on acceptable terms, if at all. Should our strategic partners, if any, be unable to effectively sell our products, then our ability to generate revenues will be significantly harmed.

We may be required to defend lawsuits or pay damages for product liability claims.

Product liability is a major risk in testing and marketing biotechnology and pharmaceutical products. We may face substantial product liability exposure in human clinical trials and in the sale of products after regulatory approval. Product liability claims, regardless of their merits, could exceed policy limits, divert management's attention and adversely affect our reputation and the demand for our product. In any such event, your investment in our securities could be materially and adversely affected.

Risks Related to the Regulation of our Business

Federal and state pharmaceutical marketing compliance and reporting requirements may expose us to regulatory and legal action by state governments or other government authorities.

The Food and Drug Administration Modernization Act (the "FDMA"), established a public registry of open clinical trials involving drugs intended to treat serious or life-threatening diseases or conditions in order to promote public awareness of and access to these clinical trials. Under the FDMA, pharmaceutical manufacturers and other trial sponsors are required to post the general purpose of these trials, as well as the eligibility criteria, location and contact information of the trials. Failure to comply with any clinical trial posting requirements could expose us to negative publicity, fines and other penalties, all of which could materially harm our business.

In recent years, several states, including California, Vermont, Maine, Minnesota, New Mexico and West Virginia have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs and file periodic reports on sales, marketing, pricing and other activities. Similar legislation is being considered in other states. Many of these requirements are new and uncertain, and available guidance is limited. Unless we are in full compliance with these laws, we could face enforcement actions and fines and other penalties and could receive adverse publicity, all of which could harm our business.

If the product candidate we develop becomes subject to unfavorable pricing regulations, third party reimbursement practices or healthcare reform initiatives, our ability to successfully commercialize our product candidate may be impaired.

Our future revenues, profitability and access to capital will be affected by the continuing efforts of governmental and private third-party payors to contain or reduce the costs of health care through various means. We expect several federal, state and foreign proposals to control the cost of drugs through government regulation. We are unsure of the impact recent health care reform legislation may have on our business or what actions federal, state, foreign and private payors may take in response to the recent reforms. Therefore, it is difficult to predict the effect of any implemented reform on our business. Our ability to commercialize our product candidate successfully will depend, in part, on the extent to which reimbursement for the cost of such product candidate and related treatments will be available from government health administration authorities, such as Medicare and Medicaid in the United States, private health insurers and other organizations. Significant uncertainty exists as to the reimbursement status of newly approved health care products, particularly for indications for which there is no current effective treatment or for which medical care typically is not sought. Adequate third-party coverage may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product research and development. If adequate coverage and reimbursement levels are not provided by government and third-party payors for use of our product candidates, our product candidates may fail to achieve market acceptance and our results of operations will be harmed.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act ("PPACA"), was passed, which substantially changed the way health care is financed by both governmental and private insurers and has significantly impacted the U.S. pharmaceutical industry. PPACA, among other things, subjects biologic products to potential competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs and subjects additional drugs to lower pricing under the 340B Drug Discount Program by adding new entities to the program.

Risks Related to Our Intellectual Property

UFRF, our sole licensor, may under certain circumstances terminate our license agreement, which may be required for us to conduct our proposed business.

Our license agreement with UFRF provides it with the right to terminate our agreement upon written notice to us if we do not meet all of our requirements under the license agreement that requires us to file an IND application with the FDA, have a commercial sale of a licensed product within an agreed upon period of time and raise certain amounts of capital. If the license or any other agreement we enter into with UFRF is terminated for any reason, our business may be materially adversely affected and may cause our business to fail.

If we are unable to obtain, maintain and enforce our proprietary rights, we may not be able to compete effectively or operate profitably.

We are party to a license agreement with UFRF. The patent underlying the licensed intellectual property and those of other biopharmaceutical companies, are generally uncertain and involve complex legal, scientific and factual questions.

Our ability to develop and commercialize drugs depends in significant part on our ability to: (i) obtain and/or develop broad, protectable intellectual property; (ii) obtain additional licenses, if required, to the proprietary rights of others on commercially reasonable terms; (iii) operate without infringing upon the proprietary rights of others; (iv) prevent others from infringing on our proprietary rights; and (v) protect our corporate know-how and trade secrets.

Patents that we may acquire and those that might be issued in the future, may be challenged, invalidated or circumvented, and the rights granted thereunder may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies or duplicate any technology we develop. Because of the extensive time required for development, testing and regulatory review of a potential product candidates, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thus reducing any advantage of the patent.

Because patent applications in the U.S. and many foreign jurisdictions are typically not published until at least 12 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that either we or our licensors were the first to make the inventions claimed in issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in these patent applications.

Additionally, UFRF previously elected to seek protection for certain elements of the licensed technology only in the United States, and the time to file for international patent protection has expired. This limits the strength of the Company's intellectual property position in certain markets and could affect the overall value of the Company to a potential corporate partner.

We may be exposed to infringement or misappropriation claims by third parties, which, if determined adversely to us, could cause us to pay significant damage awards.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. We may become a party to various types of patent litigation or other proceedings regarding intellectual property rights from time to time even under circumstances where we are not using and do not intend to use any of the intellectual property involved in the proceedings.

The cost of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the cost of such litigation or proceedings more effectively than we will be able to because our competitors may have substantially greater financial resources. If any patent litigation or other proceeding is resolved against us, we or our collaborators may be enjoined from developing, manufacturing, selling or importing our drugs without a license from the other party and we may be held liable for significant damages. We may not be able to obtain any required license(s) on commercially acceptable terms or at all.

Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

Obtaining and maintaining our patent protection depends upon compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The United States Patent and Trademark Office and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

Confidentiality agreements with employees and others may not adequately prevent disclosure of our know-how, trade secrets and other proprietary information and may not adequately protect our intellectual property, which could impede our ability to compete.

Because we operate in the highly technical field of medical technology development, we rely in part on trade secret protection in order to protect our proprietary trade secrets and unpatented know-how. However, trade secrets are difficult to protect, and we cannot be certain that others will not develop the same or similar technologies on their own. We have taken steps, including entering into confidentiality agreements with all of our employees, consultants and corporate partners to protect our trade secrets and unpatented know-how. These agreements generally require that the other party keep confidential and not disclose to third parties any confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. We also typically obtain agreements from these parties which provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Enforcing a claim that a party illegally obtained and is using our trade secrets or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets or know-how. The failure to obtain or maintain trade secret protection could adversely affect our competitive position.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology industry, we employ individuals who were previously employed at other biotechnology companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Associated with Our Common Stock

Our directors, executive officers and significant stockholders have substantial control over us and could limit stockholders' ability to influence the outcome of key transactions, including changes of control.

As of December 31, 2018, our directors and executive officers beneficially owned 24.6% of our common stock and together are able to influence significantly all matters requiring approval by our stockholders. In addition, two holders of greater than five percent of our common stock beneficially owned 20.9% and, acting together, would be able to influence significantly all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other significant corporate transactions. These stockholders may have interests that differ from other stockholders, and they may vote in a way with which other stockholders disagree and that may be adverse to the interests of other stockholders. The concentration of ownership of our common stock may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our Company, and may affect the market price of our common stock. This concentration of ownership of our common stock may also have the effect of influencing the completion of a change in control that may not necessarily be in the best interests of all of our stockholders.

Our common stock is eligible for quotation on the over-the-counter-market but not listed on any national securities exchange.

Our shares of common stock are eligible for quotation on the OTCQB tier of the over-the-counter markets under the symbol "SNBP." Despite eligibility for quotation, no assurance can be given that any market for our common stock will develop or, if one develops, that it will be maintained for any period of time. Quotation on the over-the-counter markets is generally understood to be a less active, and therefore less liquid, trading market than other types of markets such as a national securities exchange. In comparison to a listing on a national securities exchange, quotation on the over-the-counter markets is expected to have an adverse effect on the liquidity of shares of our common stock, both in terms of the number of shares that can be bought and sold at a given price, but also through delays in the timing of transactions and reduction in analyst and media coverage. This may result in lower prices for our common stock than might otherwise be obtained and could also result in a larger spread between the bid and ask prices for our common stock.

Our common stock is a "penny stock," which may make it difficult to sell shares of our common stock.

Our common stock is currently categorized as a "penny stock" as defined in Rule 3a51-1 of the Exchange Act and is subject to the requirements of Rule 15g-9 of the Exchange Act. Under this rule, broker-dealers who sell penny stocks must, among other things, provide purchasers of these stocks with a standardized risk-disclosure document prepared by the SEC. Under applicable regulations, unless it becomes listed on a national securities exchange, our common stock will generally remain a "penny stock" until such time as its per-share price is $5.00 or more (as determined in accordance with SEC regulations), or until we meet certain net asset or revenue thresholds. These thresholds include the possession of net tangible assets (i.e., total assets less intangible assets and liabilities) in excess of $2 million or average revenues equal to at least $6 million for each of the last three years.

The penny-stock rules significantly limit the liquidity of securities in the secondary market, and many brokers choose not to participate in penny-stock transactions. As a result, there is generally less trading in penny stocks. If you become a holder of our common stock, you may not always be able to resell shares of our common stock in a public broker's transaction, if at all, at the times and prices that you feel are fair or appropriate.

Trading in our stock has been minimal and investors may not be able to sell as much stock as they want at prevailing prices.

As of March 15, 2019, the 30-day average daily trading volume in our common stock was less than 500 shares as reported by OTC Markets Group Inc. If trading in our stock continues at that level, it may be difficult for investors to sell or buy substantial quantities of shares in the public market at any given time at prevailing prices as significant price movement can be caused trading a relatively small number of shares. Accordingly, the market price for shares of our common stock may be made more volatile because of the relatively low volume of trading in our common stock. We cannot guarantee that a more liquid market for our common stock will develop.

Offers or availability for sale of a substantial number of shares of our common stock may cause the price of our common stock to decline and cause investors to lose part or all of their investment.

If our stockholders sell substantial amounts of our common stock in the public market or upon the expiration of any statutory holding period under Rule 144, or upon expiration of lock-up periods applicable to outstanding shares, or issued upon the exercise of outstanding options or warrants, it could create a circumstance commonly referred to as an "overhang" and in anticipation of which the market price of our common stock could fall. The existence of an overhang, whether sales have occurred or are occurring, also could make our ability to raise additional financing through the sale of equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate more difficult. As of December 31, 2018, we had outstanding stock options to purchase 1,032,211 shares of our common stock at a weighted-average exercise price of $8.90 per share, outstanding warrants to purchase 2,035,197 shares of common stock at a weighted-average exercise price of $5.28 per share and outstanding convertible notes payable, including accrued interest, convertible into an estimated 383,947 shares at a weighted-average conversion price of $3.54.

Securities analysts may not initiate coverage or continue to cover our common stock, and this may have a negative impact on the market price of our common stock.

Common stock prices are often significantly influenced by the research and reports that securities analysts publish about companies and their business. We do not have any control over these analysts. There is no guarantee that securities analysts will cover our common stock. If securities analysts do not cover our common stock, the lack of research coverage may adversely affect the market price of our common stock. If our common stock is covered by securities analysts and our stock is downgraded, our stock price will likely decline. If one or more of these analysts ceases to cover us or fails to publish regular reports on us, we can lose visibility in the financial markets, which can cause our stock price or trading volume to decline.

Raising additional capital may cause dilution to our stockholders or restrict our operations.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, stockholders' ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect their rights as stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. Any of these events could adversely affect our ability to achieve our product development and commercialization goals and harm our business. We do not anticipate any adverse effects stemming from the lack of available credit facilities at this time.

Our charter documents and Delaware law may inhibit a takeover that stockholders consider favorable.

Provisions of our certificate of incorporation and bylaws and applicable provisions of Delaware law may make it more difficult for or prevent a third party from acquiring control of us without the approval of our board of directors. These provisions:

- set limitations on the removal of directors;
- limit who may call a special meeting of stockholders;
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at stockholder meetings;
- do not permit cumulative voting in the election of our directors, which would otherwise permit less than a majority of stockholders to elect directors;
- establish a classified board of directors limiting the number of directors that are elected each year; and
- provide our board of directors the ability to designate the terms of and issue preferred stock without stockholder approval.

In addition, Section 203 of the Delaware General Corporation Law generally limits our ability to engage in any business combination with certain persons who own 15% or more of our outstanding voting stock or any of our associates or affiliates who at any time in the past three years have owned 15% or more of our outstanding voting stock unless our board of directors has pre-approved the acquisitions that lead to such ownership. These provisions may have the effect of entrenching our management team and may deprive stockholders of the opportunity to sell their shares to potential acquirers at a premium over prevailing prices. This potential inability to obtain a control premium could reduce the price of our common stock.

If we issue preferred stock, the rights of holders of our common stock and the value of such common stock could be adversely affected.

Our Board of Directors is authorized to issue classes or series of preferred stock, without any action on the part of the stockholders. The Board of Directors also has the power, without stockholder approval, to set the terms of any such classes or series of preferred stock, including voting rights, dividend rights and preferences over the common stock with respect to dividends or upon the liquidation, dissolution or winding-up of our business and other terms. If we issue preferred stock in the future that has a preference over the common stock with respect to the payment of dividends or upon liquidation, dissolution or winding-up, or if we issue preferred stock with voting rights that dilute the voting power of the common stock, the rights of holders of the common stock or the value of the common stock would be adversely affected.

The protection provided by the federal securities laws relating to forward-looking statements does not apply to us. The lack of this protection could harm us in the event of an adverse outcome in a legal proceeding relating to forward-looking statements made by us.

Although federal securities laws provide a safe harbor for forward-looking statements made by a public company that files reports under the federal securities laws, this safe harbor is not available to certain issuers, including penny stock issuers. We believe we are not currently eligible for the statutory safe harbor included in the Exchange Act of 1934. As a result, we will not have the benefit of this statutory safe harbor protection in the event of certain legal actions based upon forward-looking statements. The lack of this protection in a contested proceeding could harm our financial condition and, ultimately, the value of our common stock.

We have identified a significant deficiency in internal control over financial reporting, if we fail to maintain effective internal controls over financial reporting, the price of our common stock may be adversely affected.

We are required to establish and maintain appropriate internal controls over financial reporting. Failure to establish those controls, or any failure of those controls once established, could adversely impact our public disclosures regarding our business, financial condition or results of operations. Any failure of these controls could also prevent us from maintaining accurate accounting records and discovering accounting errors and financial fraud.

In the course of completing its assessment of internal control over financial reporting as of December 31, 2018, management did not identify any material weaknesses but did identify a significant deficiency in the number of personnel available to serve the Company's accounting function, specifically management believes that we may not be able to adequately segregate responsibility over financial transaction processing and reporting. A significant deficiency is a deficiency, or a combination of deficiencies, in internal control over financial reporting, that is less severe than a material weakness yet important enough to merit attention by those responsible for oversight of the Company's financial reporting. Although we are unable to remediate the significant deficiency with current personnel, we are mitigating its potential impact, primarily through greater involvement of senior management in the review and monitoring of financial transaction processing and reporting.

In addition, management's assessment of internal controls over financial reporting may identify additional weaknesses and conditions that need to be addressed or other potential matters that may raise concerns for investors. Any actual or perceived weaknesses and conditions that need to be addressed in our internal control over financial reporting or disclosure of management's assessment of our internal controls over financial reporting may have an adverse impact on the price of our common stock.

Item 1B. Unresolved Staff Comments

As a smaller reporting company, we are not required to provide disclosure pursuant to this item.

Item 2. Properties

Our primary business functions are conducted by our employees and independent contractors on a distributed basis. Accordingly, we do not lease or own any real property and all employees currently work from their homes. We maintain our principal mailing address at Suite 305 at 712 Vista Boulevard in Waconia, Minnesota.

Item 3. Legal Proceedings

We are not currently party to any material legal proceedings. From time to time, we may be named as a defendant in legal actions arising from our normal business activities. We believe that we have obtained adequate insurance coverage or rights to indemnification in connection with potential legal proceedings that may arise.

Item 4. Mine Safety Disclosures

None.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

There is no "established trading market" for our shares of common stock. Our common stock is quoted on the OTCQB tier of the over-the-counter markets administered by OTC Markets Group, Inc. under the symbol "SNBP" and is eligible to trade electronically through the Depository Trust Company.

Despite eligibility for quotation, no assurance can be given that any market for our common stock will develop or be maintained. If an "established trading market" ever develops in the future, the sale of shares of our common stock that are deemed to be "restricted securities" pursuant to Rule 144 of the SEC by members of management or others may have a substantial adverse impact on any such market.

Set forth below are the high and low bid prices for our common stock for each quarter of 2018 and 2017 for which data is available. These bid prices were obtained from OTC Markets Group Inc. All prices listed herein reflect inter-dealer prices, without retail mark-up, mark-down or commissions and may not represent actual transactions.

Fiscal 2018	High	Low
Fourth Quarter	$ 4.00	$ 3.25
Third Quarter	$ 5.75	$ 3.55
Second Quarter	$ 7.50	$ 5.00
First Quarter	$ 9.00	$ 4.75

Fiscal 2017	High	Low
Fourth Quarter	$ 18.00	$ 2.00
Third Quarter	$ 14.50	$ 5.70
Second Quarter	$ 29.00	$ 12.50
First Quarter	$ 40.00	$ 7.80

As of March 15, 2019, there were 225 holders of record of our common stock.

Dividends

We have never paid cash dividends on any of our securities. We currently intend to retain any earnings for use in operations and do not anticipate paying cash dividends in the foreseeable future.

Recent Sales of Unregistered Equity Securities

None.

Purchases of Equity Securities by the Company

None.

Item 6. Selected Financial Data

As a smaller reporting company, we are not required to provide disclosure pursuant to this item.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and the notes to those financial statements included elsewhere in this annual report. This discussion contains forward-looking statements, which are based on our assumptions about the future of our business. Our actual results will likely differ materially from those contained in the forward-looking statements. Please read "Cautionary Note Regarding Forward-Looking Statements" included at the beginning of this annual report for additional information.

Overview

We exist for the primary purpose of advancing the commercial development of our proprietary polyamine analogue for pancreatic cancer and for a second indication in pancreatitis. We have exclusively licensed the worldwide rights to this compound, which has been designated as SBP-101, from the University of Florida Research Foundation, Inc. ("UFRF").

In August 2015, the FDA accepted our Investigational New Drug ("IND") application for our SBP-101 product candidate. We have completed an initial clinical trial of SBP-101 in patients with previously treated locally advanced or metastatic pancreatic cancer. This was a Phase 1, first-in-human, dose-escalation, safety study. From January 2016 through September 2017, we enrolled 29 patients into six cohorts, or groups, in the dose-escalation phase of this Phase 1 trial. Twenty-four of the patients received at least two prior chemotherapy regimens. No drug-related serious adverse events occurred during the first four cohorts. In cohort five, serious adverse events (klebsiella sepsis with metabolic acidosis in one patient, renal and hepatic toxicity in one patient, and mesenteric vein thrombosis with metabolic acidosis in one patient) were observed in three of the ten patients, two of whom exhibited progressive disease at the end of their first cycle of treatment and were determined by the Data Safety Monitoring Board ("DSMB") to be dose-limiting toxicities ("DLTs"). Consistent with the study protocol, the DSMB recommended continuation of the study by expansion of cohort 4, one level below that at which DLTs were observed. Four patients were enrolled in this expansion cohort. One patient developed focal pancreatitis at the site of the primary tumor after 2.3 months, but otherwise SBP-101 was considered well tolerated below dose level five. The most common drug related adverse events were nausea, vomiting, diarrhea, injection site pain and abdominal pain, which were mostly mild, grades 1 or 2, and are symptoms common in patients with pancreatic cancer. No drug-related bone marrow toxicity or peripheral neuropathy was observed at any dose level.

In addition to being evaluated for safety, 23 of the 29 patients were evaluable for preliminary signals of efficacy prior to or at the eight-week conclusion of their first cycle of treatment using the Response Evaluation Criteria in Solid Tumors ("RECIST"), the current standard for evaluating changes in the size of tumors. Eight of the 23 patients (35%) had Stable Disease ("SD") and 15 of 24 (65%) had Progressive Disease ("PD"). It should be noted that of the 15 patients with PD, six came from cohorts 1 and 2 and are considered to have received less than potentially therapeutic doses of SBP-101. We also noted that 28 of the 29 patients had follow-up blood tests measuring the Tumor Marker CA 19-9 associated with pancreatic ductal adenocarcinoma. Eleven of these patients (39%) had reductions in the CA 19-9 levels, as measured at least once after the baseline assessment. Seven of the remaining 17 patients who showed no reduction in CA 19-9 came from cohorts one and two.

By cohort, stable disease occurred in two patients in cohort 3, two patients in cohort 4 and four patients in cohort 5. The best response outcomes and best median survival were observed in the group of patients who received total cumulative doses of approximately 6 mg/kg (cohort 3). Two of four patients (50%) showed SD at week eight. Median survival in this group was 5.9 months, with two patients surviving 8 and 10 months, respectively. By total cumulative dose received, 5 of 12 patients (42%) who received total cumulative doses between 2.5 mg/kg and 8.0 mg/kg had reductions in the CA19-9 levels, as measured at least once after the baseline assessment. Nine of these patients (67%) exceeded 3 months of overall survival ("OS"), three patients (25%) exceeded 9 months of OS and two patients (17%) exceeded 1 year of OS and were still alive at the end of the study.

This study was conducted at clinical sites in both Australia and the United States including The Mayo Clinic Scottsdale and HonorHealth in Scottsdale, AZ, the Austin Health Olivia Newton-John Cancer Wellness & Research Centre in Melbourne, Australia and the Ashford Cancer Centre in Adelaide, Australia.

With the approval of the DSMB, we cancelled the Phase 1b portion of the first-in-human monotherapy study in order to evaluate SBP-101 as front line, combination chemotherapy in pancreatic cancer patients.

We began enrolling patients in our next clinical trial in June of 2018. This second clinical trial is a Phase 1a/1b study of the safety, efficacy and pharmacokinetics of SBP-101 administered in combination with two standard-of-care chemotherapy agents, gemcitabine and nab-paclitaxel. We are currently conducting the trial at four study sites (three in Australia and one in the United States). In the Phase 1a portion of this trial, we expect to enroll three cohorts of three to six patients with increased dosage levels of SBP-101 administered in the second and third cohorts. Demonstration of adequate safety in Phase 1a is expected to lead to the Phase 1b exploration of efficacy, in which we plan to enroll ten patients using the recommended dosage level determined in Phase 1a. Should we obtain adequate funding, we hope to increase the number of patients enrolled in the Phase 1b portion of the trial to 36, thus providing a stronger basis for the next steps in the clinical evaluation of SBP - 101. We expect to complete Phase 1a in the fourth quarter of 2019. Early results from the Phase 1b expansion could become available as soon as the second half of 2020. We estimate that completion of our Phase 1a/1b clinical trial in PDA will require additional funding of approximately $6 to $12 million.

Additional clinical trials will be required for FDA or other similar approvals if the results of the front-line clinical trial of our SBP-101 product candidate justify continued development. The cost and timing of additional clinical trials is highly dependent on the nature and size of the trials; however, it is estimated that the next steps in the approval process could cost between $25 and $30 million.

Financial Overview

We have incurred losses of $35.1 million since our inception in 2011. For the year ended December 31, 2018, we incurred a net loss of $5.9 million, which includes a non-cash charge of $1.8 million related to the amortization of the debt discount on $3.1 million of convertible notes which converted to common stock and common stock and warrants during the year. We also incurred negative cash flows from operating activities of $2.4 million for this period. We expect to incur substantial losses, which will continue to generate negative net cash flows from operating activities, as we continue to pursue research and development activities and commercialize our SBP-101 product candidate.

Our increase in cash compared to December 31, 2017 was primarily due to $3.6 aggregate proceeds from equity and debt offerings completed during 2018, offset in part by cash used in operations.

On October 2018, we received a research and development tax incentive payment from the government of Australia related to the research activities of our Australian subsidiary during 2017. The incentive payment received was approximately $299,000.

To further preserve funds, effective November 1, 2018, the Company's Board of Directors and management team implemented temporary salary reductions for all employees. After the resignation of the Company's President and CEO on October 31, 2018, the Company consolidated this position with that of our Executive Chairman as of the same date. The savings associated with these changes totaled $179,000 in the year ended December 31, 2018.

As of December 31, 2018, we had cash of $1.4 million, negative working capital of $1.1 million (excluding $1.3 million of debt discount) and stockholders' equity of $0.3 million.

We will need additional funds to continue our operations and execute our business plan, including completing our current Phase 1a /1b clinical trial, planning for required future trials and pursuing regulatory approvals in the United States, the European Union and other international markets. We historically have financed our operations principally from the sale of convertible debt and equity securities. While we have been successful in the past in obtaining the necessary capital to support our operations and we are likely to seek additional financing through similar means, there is no assurance that we will be able to obtain additional financing under commercially reasonable terms and conditions, or at all. This risk would increase if our clinical data is not positive or if economic or market conditions deteriorate.

If we are unable to obtain additional financing when needed, we would need to scale back our operations taking actions which may include, among other things, reducing use of outside professional service providers, reducing staff or staff compensation, significantly modify or delay the development of our SBP-101 product candidate, license to third parties the rights to commercialize our SBP-101 product candidate for pancreatic cancer, pancreatitis or other applications that we would otherwise seek to pursue, or cease operations.

Key Components of Our Results of Operations

General and Administrative Expenses

Our selling, general and administrative expenses consist primarily of salaries, benefits and other costs, including stock-based compensation, for our executive and administrative personnel; legal and other professional fees; travel, insurance and other corporate costs.

Research and Development Expenses

Since our inception, we have focused our activities on the development of SBP-101, our initial product candidate, for the treatment of pancreatic cancer. We expense both internal and external research and development costs as incurred. Research and development costs include expenses incurred in the conduct of our human clinical trials, for third-party service providers performing various testing and accumulating data related to our preclinical studies; sponsored research agreements; developing and scaling the manufacturing process necessary to produce sufficient amounts of the SBP-101 compound for use in our pre-clinical studies and human clinical trials; consulting resources with specialized expertise related to execution of our development plan for our SBP-101 product candidate; personnel costs, including salaries, benefits and stock-based compensation; and costs to license and maintain our licensed intellectual property. During 2018 and 2017, research and development expenditures were focused primarily on costs related to the execution of our now completed Phase 1 first-in-human clinical trial and our current Phase 1a /1b front line clinical trial.

We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future preclinical studies and clinical trials of our product candidates. At this time, due to the inherently unpredictable nature of preclinical and clinical development, we are unable to estimate with any certainty the costs we will incur and the timelines we will require in the continued development of our initial product candidate for pancreatic cancer and our other potential pipeline programs. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. Our future research and development expenses will depend on the preclinical and clinical success of each product candidate that we develop, as well as ongoing assessments of the commercial potential of such product candidates. In addition, we cannot forecast whether our current or future product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Completion of clinical trials may take several years or more, and the length of time generally varies according to the type, complexity, novelty and intended use of a product candidate. The cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development, including, among others:

- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the length of time required to enroll suitable patients;
- the number of doses that patients receive;
- the number of patients that participate in the trials;
- the drop-out or discontinuation rates of patients;
- the duration of patient follow-up;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the number and complexity of analyses and tests performed during the trial;
- the phase of development of the product candidate; and
- the efficacy and safety profile of the product candidate.

Our expenses related to clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with multiple clinical trial sites and for contract research organizations, ("CRO"), which administer clinical trials on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee or unit price. Payments under the contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. Expenses related to clinical trials generally are accrued based on contracted amounts and the achievement of milestones, such as number of patients enrolled. If timelines or contracts are modified based upon changes to the clinical trial design or scope of work to be performed, we modify our estimates of accrued expenses accordingly.

We expense costs associated with obtaining licenses for patented technologies when it is determined there is no alternative future use of the intellectual property subject to the license.

Other Income (Expense)

Other income (expense) consists of interest income, cash and non-cash interest expense and transaction gains and losses resulting from transactions denominated in other than our functional currency.

Grant Income

Grant income is derived from a one-time grant awarded to the Company by the National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health (the "Grant Agreement"). The total grant awarded under the Grant Agreement was $225,000 and funded studies of SBP-101 as a potential treatment for pancreatitis. Grant income is recognized as a non-operating income when the related research and development expenses are incurred, terms of the grant have been complied with and the Company has received reimbursement under the Grant Agreement.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate these estimates and judgments, including those described below. We base our estimates on our historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates.

While our significant accounting policies are more fully described in Note 4 to our Consolidated Financial Statements starting on page F-1, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our financial statements.

Stock-based Compensation

In accounting for share-based incentive awards we measure and recognize the cost of employee and non-employee services received in exchange for awards of equity instruments based on the grant date fair value of those awards. Calculating share-based compensation expense requires the input of highly subjective assumptions, which represent our best estimates and involve inherent uncertainties and the application of management's judgment. Compensation cost is recognized ratably using the straight-line attribution method over the vesting period, which is considered to be the requisite service period. The performance date for non-employee awards is generally not met until the individual award vests. Accordingly, we re-measure the current fair value each quarter until the award vests. Compensation expense for performance-based stock option awards is recognized when "performance" has occurred or is probable of occurring.

The fair values of share-based awards are estimated at the date of grant using the Black-Scholes option pricing model. The determination of the fair value of share-based awards is affected by our stock price, as well as assumptions regarding a number of complex and subjective variables. Risk free interest rates are based upon U.S. Treasury rates appropriate for the expected term of each award. Expected volatility rates are based primarily on the volatility rates of a set of guideline companies, which consist of public and recently public biotechnology companies. The assumed dividend yield is zero, as we do not expect to declare any dividends in the foreseeable future. The expected term of options granted is determined using the "simplified"

method. Under this approach, the expected term is presumed to be the mid-point between the average vesting date and the end of the contractual term.

We grant options to employees and non-employees, including our directors. Option grants to employees generally vest quarterly over two years from the date of grant. Options granted to our non-employee directors generally vest over one-year from the date of grant. Options granted to other non-employees generally vest over two years with 50% of the total shares underlying the option vesting on the first and second anniversaries of the date of grant. Options issued to employees and non-employee directors generally have a maximum term of ten years and options issued to non-employees generally have a maximum term of five years.

Option grants to non-employees have been made in conjunction with their service as advisors to us. Certain of these advisors have also purchased shares of stock in our private placement offerings, but none beneficially own 5% or more of our outstanding common stock. The fair value of options granted to non-employees is measured at each reporting date until the option, or respective portion of the option, vests and the expense recorded by us is updated accordingly. See Note 9 to the Consolidated Financial Statements in Item 8 below for additional information.

Research and Development Costs

We charge research and development costs, including clinical trial costs, to expense when incurred. Our human clinical trials are, and will be, performed at clinical trial sites and are administered jointly by us with assistance from contract research organizations ("CROs"). Costs of setting up clinical trial sites are accrued upon execution of the study agreement. Expenses related to the performance of clinical trials generally are accrued based on contracted amounts and the achievement of agreed upon milestones, such as patient enrollment, patient follow-up, etc. We monitor levels of performance under each significant contract, including the extent of patient enrollment and other activities through communications with the clinical trial sites and CROs, and adjust the estimates, if required, on a quarterly basis so that clinical expenses reflect the actual effort expended at each clinical trial site and by each CRO.

Results of Operations

Comparison of the Results of Operations (in thousands) for the Years Ended December 31, 2018 and 2017

	Year Ended December 31,		
	2018	2017	Percent Change
Operating Expenses			
General and administrative	$ 2,108	$ 3,423	-38.4%
Research and development	1,783	2,593	-31.2%
Total operating expenses	3,891	6,016	-35.3%
Other expenses, net	(2,268)	(4,894)	-53.7%
Income tax benefit	254	536	-52.6%
Net Loss	$ (5,905)	$ (10,374)	-43.1%

General and administrative and research and development expenses include non-cash stock-based compensation expense as a result of our issuance of stock options. The terms and vesting schedules for stock-based awards vary by type of grant and the employment status of the grantee. The awards granted through December 31, 2018 vest based upon time-based and performance conditions. We expect to record additional non-cash compensation expense in the future, which may be significant. The following table summarizes the stock-based compensation expense in our Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2018 and 2017 (in thousands):

	Year ended December 31,	
	2018	2017
General and administrative	$ 1,497	$ 1,430
Research and Development	876	303
Total Stock based compensation	$ 2,373	$ 1,733

General and administrative expense

Our general and administrative ("G&A") expenses decreased 38.4% to $2.1 million in 2018, down from $3.4 million in 2017. The increase in stock compensation expense associated with the officer's waiver of accrued compensation was mostly offset by the corresponding decrease in salary expense. The net remaining decrease in G&A expenses is primarily the result of a decrease in stock-based compensation expense excluding the expense of options granted for the waiver of contingent payment rights, fewer staff members in the year and voluntary salary reductions taken at the end of 2018.

Research and product development expense

Our research and development ("R&D") expenses decreased 31.2% to $1.8 million in 2018, down from $2.6 million in 2017. The decrease in R&D expenses resulted from a decrease in Salary expense versus the prior year due to lower staff levels and less spending on clinical studies as the spending on the 2018 clinical trial did not begin until mid-2018.

Other expense, net

Other expense, net, decreased to $2.3 million for the year ended December 31, 2018, down from $4.9 million in the same period of the prior year. In 2018, these expenses were primarily the amortization of the debt discount on the 2017 Notes. The decrease versus 2017 was due primarily to charges recorded in 2017 related to the induced conversion of debt and increased interest expense resulting from the amortization of the discount on the 2017 convertible notes payable.

Income tax benefit

Income tax benefit decreased to $254,000 in 2018, down from $536,000 in 2017. Our income tax benefit is derived primarily from refundable tax credits associated with our R&D activities conducted in Australia. The current year decrease reflects a decrease in the costs eligible for the Australian R&D tax credit.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of December 31, 2018 and 2017 and for each of fiscal years ended December 31, 2018 and 2017, and is intended to supplement the more detailed discussion that follows (in thousands):

Liquidity and Capital Resources	December 31,	
	2018	2017
Cash	$ 1,405	$ 152
Working capital deficiency	$ (1,073)*	$ (3,403)

* exludes $1,289 of debt discount

Cash Flow Data	Year Ended December 31,	
	2018	2017
Cash Provided by (used in):		
Operating Activities	$ (2,387)	$ (3,402)
Investment Activities	-	-
Financing Activities	3,643	3,106
Effect of exchange rate changes on cash	(3)	10
Net increase (decrease) in cash	$ 1,253	$ (286)

Working Capital

Our total cash resources were $1.4 million as of December 31, 2018, compared to $152,000 as of December 31, 2017. As of December 31, 2018, we had $1.6 million in current liabilities and negative working capital of $1.1 million (excludes $1.3 million of debt discount). As of December 31, 2017, we had $4.2 million in current liabilities and negative net working capital of $3.4 million.

Subsequent to the end of 2018, we issued additional convertible notes per the 2018 Notes with a number of accredited purchasers. Pursuant to these closings we issued notes with a principal balance equal to the gross proceeds of $817,000 and issued 481,422 warrants to purchase common stock

Cash Flows

Net Cash Used in Operating Activities

Net cash used in operating activities was $2.4 million during 2018, compared to $3.4 million during 2017. The net cash used in each of these periods primarily reflects the net loss for these periods and is partially offset by the effects of changes in operating assets and liabilities. In the year ended December 31, 2018, the net loss is also offset by a non-cash charge of $1.8 million related to the amortization of the discount on the 2017 convertible notes payable. In the year ended December 31, 2017, the net loss is also offset by a non-cash charge of $3.7 million related to the induced conversions of $2.9 million of convertible promissory notes, including accrued but unpaid interest, and $250,000 aggregate principal amount of demand notes and a non-cash charge of $1.4 million related to the amortization of the discount on the 2017 convertible notes payable.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $3.6 million for the years ended December 31, 2018 which was comprised primarily of net proceeds from the sale of common stock and warrants ($2.3 million) and the sale of the 2018 Notes and warrants ($1.3 million). During the year ended December 31, 2017, net cash provided by financing activities was $3.1 million which resulted from net proceeds received in the sale of convertible promissory notes.

Capital Requirements

As we continue to pursue our operations and execute our business plan, including the completion of our current Phase 1a/1b clinical trial for our initial product candidate, SBP-101, in pancreatic cancer, planning for required future trials and pursuing regulatory approvals in the United States, the European Union and other international markets, we expect to continue to incur substantial and increasing losses, which will continue to generate negative net cash flows from operating activities.

Our future capital uses and requirements depend on numerous current and future factors. These factors include, but are not limited to, the following:

- the progress of clinical trials required to support our applications for regulatory approvals, including our Phase 1a /1b clinical trial, a human clinical trial in Australia and the United States;
- our ability to demonstrate the safety and effectiveness of our SBP-101 product candidate;
- our ability to obtain regulatory approval of our SBP-101 product candidate in the United States, the European Union or other international markets;
- the cost and delays in product development that may result from changes in regulatory oversight applicable to our SBP-101 product candidate;
- the market acceptance and level of future sales of our SBP-101 product candidate;
- the rate of progress in establishing reimbursement arrangements with third-party payors;
- the effect of competing technological and market developments; and
- the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims.

As of December 31, 2018, we did not have any existing credit facilities under which we could borrow funds. We historically have financed our operations principally from the sale of convertible debt and equity securities. While we have been successful in the past in obtaining the necessary capital to support our operations and we are likely to seek additional financing through similar means, there is no assurance that we will be able to obtain additional financing under commercially reasonable terms and conditions, or at all.

Indebtedness

As of December 31, 2018, we had $1.4 million aggregate principal amount of convertible promissory notes outstanding. We also had $286,000 outstanding in an unsecured loan that accrues annual interest of 4.125% and is scheduled to mature on May 1, 2019. We commenced monthly payments of principal and interest totaling $10,000 on May 1, 2018.

Issuances of Convertible Notes during 2018

On December 21 and 31of 2018 we sold convertible promissory notes (the "2018 Notes") and warrants to purchase common stock raising gross proceeds of $1.3 million. The 2018 Notes mature on June 30, 2019 and bear interest at a rate of 10.0% per year. We may prepay the 2018 Notes in whole or in part at any time without penalty or premium. The 2018 Notes have a mandatory conversion of all principal and interest into common stock on the earlier of (1) June 30, 2019 or (2) the date our Company receives gross proceeds of at least $6.0 million from the sale of equity securities (excluding this the sale of the 2018 Notes and warrants, conversion of the 2018 Notes, and exercise of the warrants sold with the 2018 Notes). The 2018 Notes convert at a stated conversion rate of $3.50 per share subject to downward adjustments to match the price per share of common stock or any unit containing a share of common stock issued by the Company on or before the date of conversion. In addition, investors in the 2018 Notes received a warrant to purchase two shares of common stock for every $3.50 principal amount of 2018 Notes purchased. In total, warrants to purchase 762,076 shares of common stock were issued in the December closings. The exercise price of each warrant is $4.50 per share and they are exercisable until the 5-year anniversary of the dates of issuance. The exercise price of each warrant is subject to downward adjustments to match the exercise price of any common stock warrants issued by the Company on or before June 30, 2019. The 2018 Notes and accrued interest will convert into approximately 395,800 shares of common stock upon maturity.

Issuance of Common Stock and Warrants during 2018

On February 20, 2018, we entered into a Securities Purchase Agreement (the "2018 Purchase Agreement") with certain accredited investors and completed an initial closing on the same date. Pursuant to the initial closing, we sold a total of 168,000 shares of common stock and warrants to purchase an aggregate of up to the same number of additional shares of common stock. The warrants issued under the 2018 Purchase Agreement are exercisable for a period of three years from the date of issuance at an exercise price of $5.00 per share. On March 16, 2018 and May 16, 2018, we completed additional closings under the 2018 Purchase Agreement, resulting in the sale of an additional 84,200 and 216,000, respectively, shares of common stock and warrants. We received aggregate gross proceeds totaling $2.3 million pursuant closing under the 2018 Purchase Agreement, of which $125,000 was received from directors and officers of the Company or its subsidiary.

Conversion of 2017 Convertible Notes during 2018

On May 16, 2018, as the result of receiving aggregate gross proceeds exceeding $2.0 million for the sale equity of securities the Company completed the conversion of previously outstanding debt. Indebtedness totaling $330,500 and accrued interest totaling approximately $19,500 was converted into 104,463 shares of common stock. Debt totaling approximately $2.7 million and accrued interest totaling approximately $163,500 was converted into 646,279 shares of common stock and warrants under the terms of the 2018 Purchase Agreements. As of the date of conversion an incremental beneficial conversion feature of $121,000 was recorded as debt discount. Unamortized debt discount totaling $1.0 million was charged to interest expense as of the date of conversion.

Issuance of Convertible Promissory Notes During 2017

During 2017 we sold convertible promissory notes (the "2017 Notes") raising gross proceeds of approximately $3.1 million. The 2017 Notes were scheduled to mature on December 1, 2018 and bore interest at a rate of 5.0% per year. Principal and interest on the 2017 Notes would have been payable at maturity. The Company had the option to prepay the 2017 Notes in whole or in part at any time without penalty or premium. The 2017 Notes were convertible into shares of common stock or other securities of the Company upon the occurrence of a "qualified financing," including the sale of equity securities or a strategic partnership, raising gross proceeds of at least $2.0 million on or before the maturity of the 2017 Notes or upon the request of a holder of any 2017 Note at a fixed conversion rate of $10.10 per share. All of the 2017 Notes converted into

equity securities during 2018 as described above. One of our stockholders, who beneficially owned more than 10% of our common stock, purchased $200,000 of the 2017 Notes.

Settlement of 2013 Convertible Notes with Common Stock

In March 2017, we offered to all holders of outstanding convertible notes payable, originally issued in the fourth quarter of 2013 (the "2013 Convertible Notes") and to all holders of the demand notes payable (collectively the "Notes"), who were accredited investors an opportunity to convert all outstanding principal and accrued interest through March 31, 2017 into shares of our common stock at a rate of $0.75 per share. The offered conversion rate represented a $0.375, or 33.3%, discount from the rate stated in the terms of the 2013 Convertible Notes, which at the time was $1.125 per share. Holders of $3,000,000 aggregate principle amount of the Notes accepted the offer. Accordingly, on March 31, 2017 we issued 4,183,333 shares of common stock in exchange for the surrender of the Notes representing $3,000,000 of principal amount and $137,500 of accrued but previously unpaid interest. See Note 6 titled "Indebtedness" to the Consolidated Financial Statements in Item 8 below for more information.

Subsequent Event and Future Capital Requirements

On January 14, 25 and 31 of 2019, we sold convertible promissory notes ("2018 Notes") and warrants to purchase a share of common stock. We received aggregate gross proceeds of $0.8 million on substantially the same terms as the December closings discussed above and issued warrants for 481,422 shares of common stock. Refer to "Subsequent Events" to the Consolidated Financial Statements appearing in Part II, Item 8, for further details.

We require additional funds to continue our operations and execute our business plan, including completing our current Phase 1 clinical trial, planning for required future trials and pursuing regulatory approvals in the United States, the European Union and other international markets. We historically have financed our operations principally from the sale of convertible debt and equity securities. While we have been successful in the past in obtaining the necessary capital to support our operations and we are likely to seek additional financing through similar means, there is no assurance that we will be able to obtain additional financing under commercially reasonable terms and conditions, or at all. We believe that our existing cash, combined with the proceeds from the sale of the 2018 Notes, will be sufficient to fund our operating expenses through the second quarter of 2019.

If we are unable to obtain additional financing when needed, we would need to scale back our operations taking actions which may include, among other things, reducing use of outside professional service providers, reducing staff or staff compensation, significantly modify or delay the development of our SBP-101 product candidate, license to third parties the rights to commercialize our SBP-101 product candidate for pancreatic cancer, pancreatitis or other applications that we would otherwise seek to pursue, or cease operations.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the interests of our current stockholders would be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our current stockholders. If we issue preferred stock, it could affect the rights of our stockholders or reduce the value of our common stock. In particular, specific rights granted to future holders of preferred stock may include voting rights, preferences as to dividends and liquidation, conversion and redemption rights, sinking fund provisions, and restrictions on our ability to merge with or sell our assets to a third party. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any of these events could adversely affect our ability to achieve our regulatory approvals and commercialization goals and harm our business.

Our future success is dependent upon our ability to obtain additional financing, the success of our current Phase 1a/1b clinical trial and required future trials, our ability to obtain marketing approval for our SBP-101 product candidate in the United States, the European Union and other international markets. If we are unable to obtain additional financing when needed, if our Phase 1 clinical trial is not successful, if we do not receive regulatory approval required future trials or if once these studies are concluded, we do not receive marketing approval for our SBP-101 product candidate, we would not be able to continue as a going concern and would be forced to cease operations. The financial statements included in this report have been prepared assuming that we will continue as a going concern and do not include any adjustments relating to the recoverability or classification of assets or the amounts of liabilities that might result from the outcome of these uncertainties.

License Agreement

On December 22, 2011, we entered into an exclusive license agreement with the University of Florida Research Foundation ("UFRF"), which was acquired in exchange for $15,000 in cash and the issuance of 10% of our common stock. Upon executing the license agreement, 80,000 shares of common stock were issued to UFRF which was determined to have a fair value of $20,000 based upon an estimated fair value of our common stock of $0.25 per share. The license agreement also contained an anti-dilution provision which required the Company to issue additional shares to UFRF sufficient for UFRF to maintain its 10% ownership interest in the Company until we secured an addition $2.0 million external investment. This investment was received during 2012.

The license agreement requires the Company to pay royalties to UFRF ranging from 2.5% to 5% of net sales of licensed products developed from the licensed technology. Minimum annual royalties are required after the initial occurrence of a commercial sale of a marketed product. Royalties are payable for the longer of (i) the last to expire of the claims in the licensed patents or (ii) ten (10) years from the first commercial sale of a licensed product in each country in which licensed product is sold. The minimum annual royalties are as follows:

- $50,000 is due 270 days after occurrence of first commercial sale;
- $100,000 is due on the first anniversary date of the first payment;
- $100,000 is due on the second anniversary date of the first payment; and
- $300,000 is due on the third anniversary date of the first payment and subsequent anniversary dates, thereafter, continuing for the life of the license agreement.

The Company is subject to six different milestone payments under the license agreement.

- $50,000 is due upon enrollment of the first subject in a Phase I clinical trial;
- $300,000 is due upon enrollment of the first subject in a Phase II clinical trial;
- $3,000,000 is due upon approval of a New Drug Application;
- $2,000,000 is due upon approval to manufacture and market in either the European Union or Japan (one time only);
- $1,000,000 is due upon the first-time annual net sales of licensed product or licensed process by the Company reaches $100,000,000; and
- $3,000,000 is due upon the first-time annual net sales of licensed product or licensed process by the Company reaches $500,000,000.

On January 4, 2016, we enrolled the first patient in our Phase 1 clinical trial of SBP-101 in patients with previously treated pancreatic cancer. Accordingly, we recorded a milestone obligation of $50,000 as a license expense as of this date. As of December 31, 2018, no royalty or milestone payments were due. The Company is also committed to pay an annual license maintenance fee of $10,000.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

Recent Accounting Pronouncements

See Note 4 to the Consolidated Financial Statements contained in Item 8 below for a discussion of recent accounting pronouncements.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

As a smaller reporting company, we are not required to provide disclosure pursuant to this item.

Item 8. Financial Statements and Supplementary Data

The financial statements and notes thereto required pursuant to this Item begin on page F-1 of this annual report on Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated our disclosure controls and procedures. Based on such evaluation, and after considering the controls implemented to mitigate the significant deficiency related to insufficient accounting personnel discussed below, our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2018, our disclosure controls and procedures were effective in ensuring that information relating to the Company required to be disclosed in the reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, including ensuring that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes to Internal Control Over Financial Reporting

We have not identified any change in our internal control over financial reporting during our most recently completed fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange. Internal control over financial reporting refers to the processes designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

(1) Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

(2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorization of our management and directors; and

(3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting cannot provide absolute assurance of preventing and detecting misstatements on a timely basis. It is possible to design into the process safeguards to reduce, though not eliminate, the risk that misstatements are not prevented or detected on a timely basis.

In the course of completing its assessment of internal control over financial reporting as of December 31, 2018, management did not identify any material weaknesses but did identify a significant deficiency in the number of personnel available to serve the Company's accounting function, specifically management believes that we may not be able to adequately segregate responsibility over financial transaction processing and reporting. A significant deficiency is a deficiency, or a combination of deficiencies, in internal control over financial reporting, that is less severe than a material weakness yet important enough to merit attention by those responsible for oversight of the Company's financial reporting. Although we are unable to remediate the significant deficiency with current personnel, we are mitigating its potential impact, primarily through greater involvement of senior management in the review and monitoring of financial transaction processing and financial reporting.

Our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework set forth in the report entitled *Internal Control—Integrated Framework* published by the Committee of Sponsoring Organizations of the Treadway Commission, known as COSO (2013 Framework). Based on this assessment, management has concluded that, as of December 31, 2018, our internal control over financial reporting was effective.

This report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to Section 989G of the Dodd-Frank Wall Street Reform and Consumer Protection Act, which exempts smaller reporting companies from the auditor attestation requirement.

Item 9B. Other Information

None.

PART III

Certain information required by Part III will be incorporated by reference from our definitive proxy statement for the annual meeting of stockholders to be held in 2019 (the "Proxy Statement"), which we expect to file with the SEC pursuant to Regulation 14A within 120 days after December 31, 2018. Except for those portions specifically incorporated in this annual report on Form 10-K by reference to the Proxy Statement, no other portions of the Proxy Statement are deemed to be filed as part of this annual report on Form 10-K.

Item 10. Directors, Executive Officers and Corporate Governance

The information appearing under the headings "Proposal No. 1 – Election of Directors" and "Section 16(a) Beneficial Ownership Reporting Compliance" in the Proxy Statement is incorporated into this Item by reference.

Executive Officers

Michael T. Cullen, M.D., M.B.A., age 73, has served as Executive Chairman of the board and as a director of our Company since the effective time of the Merger. Dr. Cullen resumed responsibilities as President and Chief Executive Officer effective October 31, 2018. Dr. Cullen brings 30 years of pharmaceutical experience to our Company, including expertise in working with development-stage companies in planning, designing and advancing drug candidates from preclinical through clinical development. Dr. Cullen co-founded the Company in November 2011 and had continuously served as Chairman its board of directors since that date. He previously served as our Chief Executive Officer and President from November 2011 to June 2015. Dr. Cullen provided due diligence consulting to the pharmaceutical industry from 2009 to 2011, after one year in transition consulting to Eisai Pharmaceuticals. He developed several oncology drugs as Chief Medical Officer for MGI Pharma Inc. from 2000 to 2008, and previously at G.D. Searle, SunPharm Corporation, and as Vice President for Clinical Consulting at IBAH Inc., the world's fifth largest contract research organization, where he provided consulting services on business strategy, creating development plans, regulatory matters and designing clinical trials for several development stage companies in the pharmaceutical industry. Dr. Cullen was also a co-founder and Chief Executive Officer of IDD Medical, a pharmaceutical start-up company. Dr. Cullen joined 3M Pharmaceuticals in 1988 and contributed to the development of cardiovascular, pulmonary, rheumatology and immune-response modification drugs. Over the course of his career Dr. Cullen has been instrumental in obtaining the approval of ten drugs, including three (3) since 2004: Aloxi®, Dacogen® and Lusedra®. Board-certified in Internal Medicine, Dr. Cullen practiced from 1977 to 1988 at Owatonna Clinic, Owatonna, MN, where he served as president. Dr. Cullen earned his MD and BS degrees from the University of Minnesota and his MBA from the University of St. Thomas and completed his residency and Board certification in Internal Medicine through the University of North Carolina in Chapel Hill and Wilmington, NC.

Susan Horvath, age 59, has served as our Vice President and Chief Financial Officer since April 17, 2018. Ms. Horvath has held both finance and operating positions within pharmaceutical, healthcare and consumer organizations. In addition to her position with the Company, Ms. Horvath sits on the Board of Directors and provides consulting financial services for Photonic Pharma, LLC, a privately held company focused on efficiencies in early stage drug discovery. Prior to joining the Sun BioPharma team Ms. Horvath served as Chief Financial Officer of Eyebobs, LLC, a private company focused on eyewear for corrective vision; Vice President and Chief Financial Officer of Tenacious Holdings, Inc. (d/b/a ergodyne) a privately held, safety products company; Chief Financial Officer and Vice President of Human Resources at Healthsense, Inc., a next generation technology (SaaS) and remote monitoring company focused on providing safety and improving quality of life while reducing overall costs of healthcare for seniors and fragile adults; Chief Financial Officer, Vice President of Operations & Human Resources of Hemosphere, Inc., an early commercialization stage medical device company and Vice President & Team Leader International of CNS, Inc, a publicly traded consumer health care products company focused on the development and marketing of strong consumer brands. Ms. Horvath holds a Bachelor of Science degree in Accounting from the University of Illinois, Champaign, and is a Certified Management Accountant and Certified Public Accountant, inactive.

Code of Ethics and Business Conduct

We have adopted a code of ethics and business conduct (the "Code") that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions, as well as other employees and our directors. The Code is posted to the Investor Relations-Corporate Governance section of our website at www.SunBioPharma.com. We intend to include on our website, with the time period required by Form 8-K, an amendment to, or waiver from, a provision of our Code that applies to our principal executive officer, principal financial officer, principal accounting officer, controller, or persons performing similar functions, and that relates to any element of the Code of Ethics definition enumerated in Item 406(b) of SEC Regulation S-K.

Item 11. Executive Compensation

The information appearing under the headings "Director Compensation" and "Executive Compensation" in the Proxy Statement is incorporated into this Item by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information appearing under the headings "Security Ownership of Principal Stockholders and Management" and "Equity Compensation Plan Information" in the Proxy Statement is incorporated into this Item by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information regarding director independence appearing under the heading "Proposal No. 1 – Election of Directors" and the information regarding related person transactions under the heading "Corporate Governance" in the Proxy Statement is incorporated into this Item by reference.

Item 14. Principal Accounting Fees and Services

The information regarding principal accounting fees and services appearing under the heading "Proposal No. 2 – Ratification of Appointment of Independent Registered Public Accounting Firm" in the Proxy Statement is incorporated into this Item by reference.

PART IV

Item 15. Exhibits, Financial Statements Schedules

(a) Financial Statements, Financial Statement Schedules, and Exhibits.

(1) ***Financial Statements***

The following financial statements are filed as part of this report:

(2) ***Financial Statement Schedules***

Schedules not listed above have been omitted because they are not applicable or not required or the information required to be set forth therein is included in the Consolidated Financial Statements and notes thereto identified above.

(3) ***Exhibits***

Unless otherwise indicated, all documents incorporated into this annual report on Form 10-K by reference to a document filed with the SEC pursuant to the Exchange Act are located under SEC file number 000-55242.

Exhibit No.	Description
3.1	Restated Certificate of Incorporation, as amended through November 8, 2017 (incorporated by reference to Exhibit 3.1 to current report on Form 8-K filed November 15, 2017)
3.2	Bylaws, as amended through May 12, 2016 (incorporated by reference to Exhibit 3.2 to quarterly report on Form 10-Q for the quarter ended June 30, 2016)
4.1	Form of Convertible Promissory Note (incorporated by reference to Exhibit 4.2 to current report on Form 8-K filed September 11, 2015)
4.2	Form of Warrant to Purchase Shares of Stock (incorporated by reference to Exhibit 4.3 to current report on Form 8-K filed September 11, 2015)
4.3	Form of Warrant to Purchase Shares of Stock issued pursuant to Securities Purchase Agreements dated June 10, 2016, June 24, 2016, August 11, 2016 and September 2, 2016 (incorporated by reference to Exhibit 10.2 to current report on Form 8-K filed June 14, 2016)
4.4	Form of Convertible Promissory Note (incorporated by reference to Exhibit 10.2 to current report on Form 8-K filed March 6, 2017)
4.5	Form of Warrant (incorporated by reference to Exhibit 10.2 to current report on Form 8-K filed February 26, 2018)
4.6	Form of Convertible Promissory Note (incorporated by reference to Exhibit 10.2 to current report on Form 8-K filed December 26, 2018)
4.7	Form of Common Stock Warrant (incorporated by reference to Exhibit 10.3 to current report on Form 8-K filed December 26, 2018)

Exhibit No.	Description
10.1*	2011 Stock Option Plan, as amended through January 1, 2015 (incorporated by reference to Exhibit 10.1 to current report on Form 8-K filed September 11, 2015)
10.2*	Form of Incentive Stock Option Agreement for awards under 2011 Stock Option Plan, as amended (incorporated by reference to Exhibit 10.2 to current report on Form 8-K filed September 11, 2015)
10.3*	Form of Non-Qualified Stock Option Agreement for awards under 2011 Stock Option Plan, as amended (incorporated by reference to Exhibit 10.3 to current report on Form 8-K filed September 11, 2015)
10.4*	2016 Omnibus Incentive Plan, as amended through March 14, 2018 (incorporated by reference to Exhibit 10.1 to current report on Form 8-K filed March 20, 2018)
10.5*	Form of Incentive Stock Option Agreement for awards under 2016 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.4 to quarterly report on Form 10-Q for quarter ended June 30, 2016)
10.6*	Form of Non-Qualified Stock Option Agreement for awards under 2016 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.4 to quarterly report on Form 10-Q for quarter ended June 30, 2016)
10.7*	Form of Performance-Based Stock Option Agreement for awards under 2016 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.7 to annual report on Form 10-K for fiscal year ended December 31, 2016)
10.8*	Indemnification Agreement, dated September 4, 2015 (incorporated by reference to Exhibit 10.4 to current report on Form 8-K filed September 11, 2015)
10.9**	Standard Exclusive License Agreement by and between the University of Florida Research Foundation, Inc. and Sun BioPharma, Inc., dated December 22, 2011 (incorporated by reference to Exhibit 10.5 to current report on Form 8-K filed September 11, 2015)
10.10*	Employment Agreement with Michael T. Cullen, dated December 2, 2015 (incorporated by reference to Exhibit 10.1 to current report on Form 8-K filed December 4, 2015)
10.11*	First Amendment to Employment Agreement with Michael T. Cullen, dated September 12, 2016 (incorporated by reference to Exhibit 10.17 to registration statement on Form S-1filed September 16, 2016, file no. 333-213687)
10.12*	Second Amendment to Employment Agreement with Michael T. Cullen, dated October 1, 2017 (incorporated by reference to Exhibit 10.1 to current report on Form 8-K filed October 13, 2017)
10.13*	Waiver and Third Amendment to Employment Agreement with Michael T. Cullen, effective as of February 27, 2018 (incorporated by reference to Exhibit 10.1 to current report on Form 8-K filed March 5, 2018)
10.14*	Employment Agreement with David B. Kaysen, dated December 2, 2015 (incorporated by reference to Exhibit 10.2 to current report on Form 8-K filed December 4, 2015)
10.15*	First Amendment to Employment Agreement with David B. Kaysen, dated September 12, 2016 (incorporated by reference to Exhibit 10.18 to registration statement on Form S-1filed September 16, 2016, file no. 333-213687)
10.16*	Second Amendment to Employment Agreement with David B. Kaysen, dated October 1, 2017 (incorporated by reference to Exhibit 10.2 to current report on Form 8-K filed October 13, 2017)
10.17*	Waiver and Third Amendment to Employment Agreement with David B. Kaysen, effective as of February 27, 2018 (incorporated by reference to Exhibit 10.2 to current report on Form 8-K filed March 5, 2018)
10.18*	Employment Agreement with Suzanne Gagnon, dated December 2, 2015 (incorporated by reference to Exhibit 10.9 to annual report on Form 10-K for fiscal year ended December 31, 2015)
10.19*	First Amendment to Employment Agreement with Suzanne Gagnon, dated September 12, 2016 (incorporated by reference to exhibit 10.17 to registration statement on Form S-1filed September 16, 2016, file no. 333-213687)

Exhibit No.	Description
10.20*	Second Amendment to Employment Agreement with Suzanne Gagnon, dated October 1, 2017 (incorporated by reference to Exhibit 10.4 to current report on Form 8-K filed October 13, 2017)
10.21*	Employment Agreement with Scott Kellen, dated December 2, 2015 (incorporated by reference to Exhibit 10.3 to current report on Form 8-K filed December 4, 2015)
10.22*	First Amendment to Employment Agreement with Scott Kellen, dated September 12, 2016 (incorporated by reference to Exhibit 10.19 to registration statement on Form S-1filed September 16, 2016, file no. 333-213687)
10.23*	Second Amendment to Employment Agreement with Scott Kellen, dated October 1, 2017 (incorporated by reference to Exhibit 10.3 to current report on Form 8-K filed October 13, 2017)
10.24*	Waiver and Third Amendment to Employment Agreement with Scott Kellen, effective as of February 27, 2018 (incorporated by reference to Exhibit 10.3 to current report on Form 8-K filed March 5, 2018)
10.25	Form of Securities Purchase Agreement, dated February 20, 2018 (incorporated by reference to Exhibit 10.1 to current report on Form 8-K filed February 26, 2018)
10.26*	Employment Agreement with Susan Horvath, dated April 17, 2018 (incorporated by reference to Exhibit 10.4 to current report on Form 10- Q filed May 14, 2018)
10.27	Consulting agreement with David Kaysen dated October 31, 2018 (incorporated by reference to exhibit 10.1 to current report on Form 8-K filed November 1, 2018)
10.28	Form of Securities Purchase Agreement, by and among the Company and Investors (incorporated by reference to Exhibit 10.1 to current report on Form 8-K filed December 26, 2018)
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 to annual report on Form 10-K for the fiscal year ended December 31, 2016)
23.1+	Consent of Independent Registered Public Accounting Firm
24.1+	Powers of Attorney
31.1+	Chief Executive Officer Certification Pursuant to Rule 13a-14(a), of the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2+	Chief Financial Officer Certification Pursuant to Rule 13a-14(a), of the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1++	Chief Executive Officer Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2++	Chief Financial Officer Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101+	Financial statements from the annual report on Form 10-K of the Company for the year ended December 31, 2018, formatted in XBRL: (i) the Consolidated Balance Sheets, (ii) Consolidated Statements of Comprehensive Loss, (iii) the Consolidated Statements of Stockholders' Deficit, (iv) the Consolidated Statements of Cash Flows, and (v) the Notes to Consolidated Financial Statements

+ Filed herewith
++ Furnished herewith
* Management compensatory plan or arrangement required to be filed as an exhibit to this report.
** Portions of exhibit omitted pursuant to order granting confidential treatment issued by the Securities and Exchange Commission.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on March 22, 2019.

SUN BIOPHARMA, INC.

By: /s/ MICHAEL T. CULLEN
Michael T Cullen
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on March 22, 2019.

/s/ MICHAEL T. CULLEN	/s/ SUSAN HORVATH
Michael T. Cullen, *President and Chief Executive Officer* *(Principal Executive Officer) and Director*	Susan Horvath, *Vice President of Finance, Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)*
*	*
Suzanne Gagnon, *Director*	Jeffrey S. Mathiesen, *Director*
*	*
Paul W. Schaffer, *Director*	D. Robert Schemel, *Director*
*	*

* Michael T Cullen, by signing his name hereto, does hereby sign this document on behalf of each of the above-named directors of the Registrant pursuant to powers of attorney duly executed by such persons.

By: /s/ MICHAEL T. CULLEN
Michael T. Cullen,
Attorney-in-Fact

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
Sun BioPharma, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Sun Biopharma, Inc. and Subsidiary (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the years then ended in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt about the Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has recurring losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's evaluations of the events and conditions and management's plans regarding those matters are also described in Note 3. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board of the United States of America ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Cherry Bekaert

We have served as the Company's auditors since 2014.

Tampa, Florida
March 22, 2019

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

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash	$ 1,405	$ 152
Prepaid expenses and other current assets	110	195
Income tax receivable	332	420
Total current assets	1,847	767
Other noncurrent assets	51	-
Total assets	$ 1,898	$ 767
LIABILITITES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 1,064	$ 1,196
Accrued expenses	212	1,254
Convertible notes payable, net of debt discounts	64	1,525
Term debt, current portion	286	14
Accrued interest	4	181
Total current liabilities	1,630	4,170
Long-term liabilities:		
Term debt, noncurrent portion	-	286
Total long-term liabilities	-	286
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value; 10,000,000 authorized; no shares issued or outstanding as of December 31 2018 and 2017	-	-
Common stock, $0.001 par value; 100,000,000 authorized; 5,077,483 and 3,841,652 shares issued and outstanding, as of December 31, 2018 and 2017, respectively	5	4
Additional paid-in capital	35,038	25,625
Accumulated deficit	(35,058)	(29,153)
Accumulated comprehensive income (loss)	283	(165)
Total stockholders' equity (deficit)	268	(3,689)
Total liabilities and stockholders' equity (deficit)	$ 1,898	$ 767

See accompanying notes to consolidated financial statements.

Sun BioPharma, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2018	2017
Operating expenses:		
General and administrative	$ 2,108	$ 3,423
Research and development	1,783	2,593
Operating loss	(3,891)	(6,016)
Other income (expense):		
Interest income	-	1
Grant income	54	163
Interest expense	(1,814)	(1,617)
Loss on induced debt conversions	-	(3,696)
Other (expense) income	(508)	255
Total other expense	(2,268)	(4,894)
Loss before income tax benefit	$ (6,159)	$ (10,910)
Income tax benefit	254	536
Net loss	(5,905)	(10,374)
Foreign currency translation adjustment	448	(241)
Comprehensive loss	$ (5,457)	$ (10,615)
Basic and diluted net loss per share	$ (1.27)	$ (2.91)
Weighted average shares outstanding - basic and diluted	4,662,080	3,566,098

See accompanying notes to consolidated financial statements.

Sun BioPharma, Inc.
Consolidated Statements of Stockholders' Equity (Deficit)
(In thousands)

	Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders' Equity
	Shares	Amount	Capital	Deficit	Gain (Loss)	(Deficit)
Balances as of January 1, 2017	3,220	$ 3	$ 14,058	$ (18,779)	$ 76	$ (4,642)
Conversion of convertible notes payable and accrued interest into common stock	385	1	5,840	-	-	5,841
Conversion of demand notes into common stock	34	-	993	-	-	993
Charge for fair market value of beneficial conversion feature		-	2,954	-	-	2,954
Exercise of common stock options	22	-	28	-	-	28
Exercise of stock purchase warrants	181	-	19	-	-	19
Stock based compensation	-	-	1,733	-	-	1,733
Net loss	-	-	-	(10,374)	-	(10,374)
Foreign currency translation adjustment	-	-	-	-	(241)	(241)
Balances at December 31, 2017	3,842	4	25,625	(29,153)	(165)	(3,689)
Sale of common stock and warrants, net and exercise of stock options	485	-	2,328	-	-	2,328
Beneficial conversion feature	-	-	716	-	-	716
Warrants issued with sale of convertible notes payable	-	-	739	-	-	739
Conversion of convertible notes payable and accrued interest into common stock and warrants	751	1	3,257	-	-	3,258
Stock based compensation	-	-	2,373	-	-	2,373
Net loss	-	-	-	(5,905)	-	(5,905)
Foreign currency translation adjustment	-	-	-	-	448	448
Balances at December 31, 2018	5,078	$ 5	$ 35,038	$ (35,058)	$ 283	$ 268

See accompanying notes to consolidated financial statements.

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

	Year Ended Decmber 31,	
	2018	2017
Cash flows from operating activities:		
Net loss	$ (5,905)	$ (10,374)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on induced debt conversions	-	3,696
Stock-based compensation	1,279	1,733
Amortization of debt discount	1,732	1,387
Amortization of debt issuance costs	9	56
Non-cash interest expense	4	162
Changes in operating assets and liabilities:		
Income tax receivable	50	(70)
Prepaid expenses and other current assets	25	(75)
Accounts payable	360	(319)
Accrued liabilities	59	402
Net cash used in operating activities	(2,387)	(3,402)
Cash flows from financing activities:		
Proceeds from the sale of convertible promissory notes, net of offering costs of $5 and $16 respectively	1,329	3,059
Proceeds from sale of common stock and warrants, net of offering costs of $27	2,328	-
Proceeds from the exercise of stock options	-	28
Proceeeds from exercise of stock purchase warrants	-	19
Repayments of term debt	(14)	$ -
Net cash provided by financing activities	3,643	3,106
Effect of exchange rate changes on cash	(3)	10
Net increase in cash	1,253	(286)
Cash at beginning of period	152	438
Cash at end of period	$ 1,405	$ 152
Supplemental disclosure of cash flow information:		
Cash paid during period for interest	$ 67	$ 11
Supplemental disclosure of non-cash transactions:		
Conversion of convertible notes payable and accrued interest into common stock	$ -	$ 2,888
Conversion of convertible notes payable and accrued interest into common stock and warrants	$ 3,258	$ -
Beneficial conversion feature in convertible notes	$ 716	$ 2,954
Warrants issued with convertible notes	$ 739	$ -
Conversion of demand notes into common stock	$ -	$ 250
Options granted in exchange for release from contingent payment obligations	$ 1,094	$ -

See accompanying notes to consolidated financial statements.

1. Business

Sun BioPharma, Inc. and its wholly-owned subsidiary Sun BioPharma Australia Pty Ltd. (collectively "we," "us," "our," and the "Company") exist for the primary purpose of advancing the commercial development of a proprietary polyamine analogue for pancreatic cancer and for a second indication in chronic pancreatitis. We have exclusively licensed the worldwide rights to this compound, which has been designated as SBP-101, from the University of Florida Research Foundation, Inc. ("UFRF"). Sun BioPharma, Inc. was incorporated under the laws of the State of Delaware on September 21, 2011. Sun BioPharma Australia Pty Ltd was established on May 24, 2013 and incorporated under the laws of Australian Securities and Investments Commission.

2. Risks and Uncertainties

The Company operates in a highly regulated and competitive environment. The development, manufacturing and marketing of pharmaceutical products require approval from, and are subject to ongoing oversight by, the Food and Drug Administration ("FDA") in the United States, the Therapeutic Goods Administration ("TGA") in Australia, the European Medicines Agency ("EMA") in the European Union, and comparable agencies in other countries. Obtaining approval for a new pharmaceutical product is never certain, may take many years, and is normally expected to involve substantial expenditures.

We have incurred losses of $35.1 million since our inception in 2011. For the year ended December 31, 2018 we incurred a net loss and negative cash flows from operating activities of $5.9 million and $2.4 million, respectively. We expect to incur substantial losses for the foreseeable future, which will continue to generate negative net cash flows from operating activities, as we continue to pursue research and development activities and the clinical development of our primary product candidate, SBP-101. As of December 31, 2018, we had cash of $1.4 million, negative working capital of $1.1 million (excluding a debt discount of $1.3 million) and stockholders' equity of $0.3 million. The Company's principal sources of cash have included the issuance of convertible debt and equity securities.

The accompanying Consolidated Financial Statements have been prepared assuming that we will continue as a going concern which contemplates the realization of assets and liquidation of liabilities in the normal course of business and do not include any adjustments relating to the recoverability or classification of assets or the amounts of liabilities that might result from the outcome of these uncertainties. Our ability to continue as a going concern, realize the carrying value of our assets and discharge our liabilities in the ordinary course of business is dependent upon a number of factors, including our ability to obtain additional financing, the success of our development efforts, our ability to obtain marketing approval for our initial product candidate, SBP-101, in the United States, Australia, the European Union or other markets and ultimately our ability to market and sell our initial product candidate. These factors, among others, raise substantial doubt about our ability to continue operations as a going concern.

3. Liquidity and Management Plans

We will need to seek additional sources of funds to support our current business plans. We may seek to raise additional funds through various sources, such as equity and debt financings, or through strategic collaborations and license agreements. We can give no assurances that we will be able to secure additional sources of funds to support our operations, or if such funds are available to us, that such additional financing will be sufficient to meet our needs or on terms acceptable to us. This risk would increase if our clinical data is not positive or economic and market conditions deteriorate.

If we are unable to obtain additional financing when needed, we would need to scale back our operations taking actions that may include, among other things, reducing use of outside professional service providers, reducing staff or staff compensation, significantly modify or delay the development of our SBP-101 product candidate, license to third parties the rights to commercialize our SBP-101 product candidate for pancreatic cancer, pancreatitis or other applications that we would otherwise seek to pursue, or cease operations.

Between March 1, 2016 and September 30, 2017, we accrued a portion of cash base salaries for all senior employees in an effort to conserve cash. In lieu of a portion of base salary, the affected employees were entitled to receive a cash payment in an amount equal to the foregone salary. The cash payment would have become due upon a change of control or the issuance of equity securities resulting in cash gross proceeds of $10 million or more. As of December 31, 2017, the contingent payments under these arrangements totaled $1.1 million. On February 27, 2018, each of the affected employees agreed to waive their rights to receive the contingent payments in exchange for common stock options. See Note 7, titled "Employment agreement amendments and waiver of contingent payment rights."

On February 20, 2018, March 16, 2018 and May 16, 2018 we entered into a Securities Purchase Agreement (the "2018 Purchase Agreement") with certain accredited investors. We sold a total of 468,200 shares of common stock and warrants to purchase an aggregate of up to the same number of additional shares of common stock. The warrants issued under the 2018 Purchase Agreement are exercisable for a period of three years from the date of issuance at an exercise price of $5.00 per share. We have received aggregate gross proceeds totaling $2.3 million pursuant to private placements under the 2018 Purchase Agreement, of which $125,000 was received from directors and officers of the Company or its subsidiary.

On May 16, 2018, as the result of receiving aggregate gross proceeds exceeding $2.0 million for the sale equity securities, under terms of the 2017 convertible debt, the Company completed the conversion of previously outstanding debt. Debt totaling $3.1 million and accrued interest totaling approximately $183,000 was converted into 104,463 shares of common stock and 646,279 units (each consisting of a share of common stock and a warrant to purchase one additional share of common stock).

To preserve funds, effective November 1, 2018 the Company's Board of Directors and management team implemented temporary salary reductions for all employees. Upon the resignation of the Company's President and CEO on October 31, 2018, the Company consolidated this position with that of our Executive Chairman as of the same date. The impact to the consolidated financial statements for the year ended December 31, 2018 was a reduction in operating expense of $179,000.

On December 21, 2018, the Company entered into a Securities Purchase Agreement (the "Securities Agreement") with certain investors and completed an initial closing on the same date. Additional closings occurred on December 31, 2018 and in January of 2019. Pursuant to these closings, the Company issued to investors approximately $2.2 million in original principal amount of unsecured convertible promissory notes (the "2018 Notes") and warrants to purchase up to 1,243,498 shares of common stock. Included in the total securities sold on December 31, 2018 was $59,000 received from officers and directors of the Company.

Our future success is dependent upon our ability to obtain additional financing, the success of our development efforts, our ability to demonstrate clinical progress for our SBP-101 product candidate in the United States or other markets and ultimately our ability to market and sell our SBP-101 product candidate. If we are unable to obtain additional financing when needed, if our clinical trials are not successful, if we are unable to obtain marketing approval, we would not be able to continue as a going concern and would be forced to cease operations and liquidate our company.

There can be no assurances that we will be able to obtain additional financing on commercially reasonable terms, or at all. The sale of additional convertible debt or equity securities would likely result in dilution to our current stockholders.

4. Summary of Significant Accounting Policies

Basis of presentation

We have prepared the accompanying Consolidated Financial Statements in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Our fiscal year ends on December 31.

Principles of consolidation

The accompanying Consolidated Financial Statements include the assets, liabilities and expenses of Sun BioPharma, Inc. and our wholly-owned subsidiary. All significant intercompany transactions and balances have been eliminated in consolidation.

Use of estimates

The preparation of Consolidated Financial Statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the Consolidated Financial Statements and the reported amount of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Concentration of credit risk

Financial instruments that potentially subject the company to significant concentrations of credit risk consist primarily of cash. Cash is deposited in demand accounts at commercial banks. At times, such deposits may be in excess of insured limits. The Company has not experienced any losses on its deposits of cash.

Beneficial conversion feature

For convertible debt where the rate of conversion is below fair market value for our common stock, the Company records a charge for the beneficial conversion feature ("BCF") and related debt discount which is presented as a direct deduction from the carrying amount of the related debt. The discount is amortized to interest expense over the life of the debt.

Debt issuance costs

Costs associated with the issuance of debt instruments are capitalized. These costs are amortized on a straight-line basis, which approximates the effective interest method, over the term of the debt agreements and are included in interest expense. The unamortized balance of debt issuance costs is presented as a direct reduction of the carrying amount of the related debt.

Research and development costs

Research and development costs include expenses incurred in the conduct of our Phase 1 human clinical trials, for third-party service providers performing various testing and accumulating data related to our preclinical studies; sponsored research agreements; developing and scaling the manufacturing process necessary to produce sufficient amounts of the SBP-101 compound for use in our pre-clinical studies and human clinical trials; consulting resources with specialized expertise related to execution of our development plan for our SBP-101 product candidate; personnel costs, including salaries, benefits and share-based compensation; and costs to license and maintain our licensed intellectual property.

We charge research and development costs, including clinical trial costs, to expense when incurred. Our human clinical trials are performed at clinical trial sites and are administered jointly by us with assistance from contract research organizations ("CROs"). Costs of setting up clinical trial sites are accrued upon execution of the study agreement. Expenses related to the performance of clinical trials generally are accrued based on contracted amounts and the achievement of agreed upon milestones, such as patient enrollment, patient follow-up, etc. We monitor levels of performance under each significant contract, including the extent of patient enrollment and other activities through communications with the clinical trial sites and CROs, and adjust the estimates, if required, on a quarterly basis so that clinical expenses reflect the actual effort expended at each clinical trial site and by each CRO.

We expense costs associated with obtaining licenses for patented technologies when it is determined there is no alternative future use of the intellectual property subject to the license.

Stock-based compensation

In accounting for stock-based incentive awards we measure and recognize the cost of employee and non-employee services received in exchange for awards of equity instruments based on the grant date fair value of those awards. Compensation cost is recognized ratably using the straight-line attribution method over the vesting period, which is considered to be the requisite service period. We record forfeitures in the periods in which they occur. The compensation expense for performance-based stock option awards is recognized when "performance" has occurred or is probable of occurring.

The fair value of stock-based awards is estimated at the date of grant using the Black-Scholes option pricing model. The determination of the fair value of stock-based awards is affected by our stock price, as well as assumptions regarding a number of complex and subjective variables. Risk free interest rates are based upon U.S. Treasury rates appropriate for the expected term of each award. Expected volatility rates are based primarily on the volatility rates of a set of guideline companies, which consist of public and recently public biotechnology companies. The assumed dividend yield is zero, as we do not expect to declare any dividends in the foreseeable future. The expected term of options granted is determined using the "simplified" method. Under this approach, the expected term is presumed to be the mid-point between the average vesting date and the end of the contractual term.

Income taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the Consolidated Financial Statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry-forwards. Deferred tax assets and liabilities are measured using enacted rates, for each of the jurisdictions in which the Company operates, expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. Valuation allowances are established when necessary to reduce deferred tax assets to the amount that is more likely than not to be realized. The Company has provided a full valuation allowance against the gross deferred tax assets as of December 31, 2018 and 2017. The Company's policy is to classify interest and penalties related to income taxes as income tax expense in the Consolidated Statements of Operations and Comprehensive Loss.

Foreign currency translation

The functional currency of Sun BioPharma Australia Pty Ltd is the Australian Dollar ("AUD"). Accordingly, assets and liabilities, and equity transactions of Sun BioPharma Australia Pty Ltd are translated into U.S. dollars at period-end exchange rates. Expenses are translated at the average exchange rate in effect for the period. The resulting translation gains and losses are recorded as a component of accumulated comprehensive gain (loss) in the Consolidated Statements of Operations and Comprehensive Loss. During the years ended December 31, 2018 and 2017, any reclassification adjustments from accumulated other comprehensive gain to operations were inconsequential.

Grant Income

Grant income is derived from a one-time grant awarded to the Company by the National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health (the "Grant Agreement"). The total grant awarded under the Grant Agreement was $225,000 and was used to fund studies of SBP-101 as a potential treatment for pancreatitis. Grant income is recognized as a non-operating income when the related research and development expenses are incurred, terms of the grant have been complied with and as of December 31, 2018 the Company has been fully reimbursed under the Grant Agreement.

Comprehensive loss

Comprehensive loss consists of our net loss and the effects of foreign currency translation.

Net loss per share

We compute net loss per share by dividing our net loss (the numerator) by the weighted-average number of common shares outstanding (the denominator) during the period. Shares issued during the period and shares reacquired during the period, if any, are weighted for the portion of the period that they were outstanding. The computation of diluted earnings per share, or EPS, is similar to the computation of basic EPS except that the denominator is increased to include the number of additional common shares that would have been outstanding if the dilutive potential common shares had been issued. Our diluted EPS is the same as basic EPS due to common equivalent shares being excluded from the calculation, as their effect is anti-dilutive.

The following outstanding potential common shares were not included in the diluted net loss per share calculations as their effects were not dilutive:

	December 31,	
	2018	2017
Employee and non-employee stock options	1,032,211	733,960
Estimated common shares issuable upon conversion of notes payable and accrued interest	383,947	319,193
Common stock issable under common stock purchase warrants	2,035,197	151,500
	3,451,355	1,204,653

Recently Adopted Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, "Revenue from Contracts with Customers," which supersedes the revenue recognition requirements of Accounting Standards Codification ("ASC") Topic 605, "Revenue Recognition" and most industry-specific guidance on revenue recognition throughout the ASC. The new standard is principles-based and provides a five-step model to determine when and how revenue is recognized. The core principle of the new standard is that revenue should be recognized when a company transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The new standard also requires disclosure of qualitative and quantitative information surrounding the amount, nature, timing and uncertainty of revenues and cash flows arising from contracts with customers. The Company has evaluated the impact of this revised guidance on its financial statements and determined it had no material impact.

In April 2016, the FASB issued ASU 2016-10, "Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing." ASU 2016-10 clarifies the implementation guidance on identifying performance obligations. These ASUs apply to all companies that enter into contracts with customers to transfer goods or services. This ASU is effective for public entities for interim and annual reporting periods beginning after December 15, 2017. The Company has evaluated the impact of this revised guidance on its financial statements and determined it had no material impact.

In July 2017, the FASB issued ASU No. 2017-11, Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815). The amendments in Part I of this Update change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. The standard is effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted upon issuance. Effective January 1,2018 the Company early adopted ASU No. 2017-11, which we were allowed to do. The adoption of ASU No. 2017-11 had a material impact on the Company's consolidated financial statements with respect to the accounting treatment of the 2018 convertible notes and related common stock warrants. As a result of the adoption of ASU 2017-11, the warrants and embedded conversion feature of the 2018 convertible notes do not require treatment as derivative liabilities, but rather qualify for classification within stockholders' equity.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, "Leases," which created a new Topic, ASC Topic 842 and established the core principle that a lessee should recognize the assets, representing rights-of-use, and liabilities to make lease payments, that arise from leases. For leases with a term of 12 months or less, a lessee is permitted to make an election under which such assets and liabilities would not be recognized, and lease expense would be recognized generally on a straight-line basis over the lease term. This standard is effective for the Company beginning in 2019, and early application is permitted. The Company has evaluated the potential impact of this guidance and does not believe it will have a material impact on the Company's financial statements.

In June 2018, the FASB issued ("ASU") 2018-07, "Compensation – Stock Compensation (Topic 718)." ASU 2018-07 simplifies the accounting for nonemployee stock-based payment transactions. This ASU is effective for public entities for interim and annual reporting periods beginning after December 15, 2018. The Company is currently evaluating the potential impact of this guidance and at this time does not believe that it will have a material impact on the Company's financial statements.

5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2018	2017
Deferred payroll and related expenses	$ -	$ 1,094
Clinical trial and related expenses	42	95
Professional services	157	61
Other	13	4
Total accrued liabilities	$ 212	$ 1,254

6. Indebtedness

2018 Convertible notes payable

On December 21 and 31, 2018, we sold convertible promissory notes (the "2018 Notes") and warrants to purchase common stock for gross proceeds of $1.3 million. The 2018 Notes mature on June 30, 2019 and bear interest at a rate of 10.0% per year. The Company may prepay the 2018 Notes in whole or in part at any time without penalty or premium. The 2018 Notes have a mandatory conversion of all principal and interest into common stock on the earlier of (1) June 30, 2019 or (2) the date the Company receives gross proceeds of at least $6.0 million from the sale of equity securities (subject to certain exclusions). The 2018 Notes convert at a stated conversion rate of $3.50 per share, which is subject to downward adjustment to match the price per share of common stock or any unit containing a share of common stock issued by the Company on or before the date of conversion. In addition to the 2018 Notes, investors received a Warrant to purchase two shares of common stock for every $3.50 principal amount of 2018 Notes purchased. In total, warrants to purchase up to 762,076 shares of common stock were issued in the December closings. The exercise price of each warrant is $4.50 per share and they are exercisable until the 5-year anniversary of the dates of issuance. The exercise price is subject to downward adjustment to match the exercise price of any common stock warrants issued by the Company on or before June 30, 2019. The warrants had a fair market value of $1.7 million upon issuance. After assigning the relative value of the warrants to the proceeds of the notes it was determined that the 2018 Notes contained a beneficial conversion feature with an aggregate intrinsic value of approximately $0.6 million. Both the relative value of the warrants and the beneficial conversion feature were recorded as a debt discount which is presented as a direct deduction from the carrying value of the 2018 Notes. The discount will be amortized through interest expense over the life of the 2018 Notes.

2017 Convertible notes payable

In 2017 we sold convertible promissory notes (the "2017 Notes") raising gross proceeds of approximately $3.1 million. The 2017 Notes had been scheduled to mature on December 1, 2018 and bore an interest at a rate of 5.0% per year. Principal and accrued interest on the 2017 Notes was payable at maturity. The 2017 Notes were convertible into shares of common stock or other securities of the Company upon the occurrence of a "qualified financing," including the sale of equity securities or a strategic partnership, raising gross proceeds of at least $2.0 million on or before the maturity of the 2017 Notes or upon the request of a holder of any 2017 Note at a fixed conversion rate of $10.10 per share. The 2017 Notes contained a beneficial conversion feature with an aggregate intrinsic value of approximately $3.0 million, which was recorded as a debt discount and is presented as a direct deduction from the carrying value of the 2017 Notes. The discount was amortized through interest expense over the life of the 2017 Notes.

On May 16, 2018, as the result of receiving aggregate gross proceeds exceeding $2.0 million for the sale equity securities, under terms of the 2017 Notes, the Company completed the conversion of previously outstanding debt. Debt totaling approximately $3.1 million and accrued interest totaling approximately $183,000 was converted into 104,463 shares of common stock and 646,279 units (each consisting of a share of common stock and a warrant to purchase one additional share of common stock). The units were available through the 2018 Purchase Agreement. The shares were issued in reliance on the exemption from registration set forth in Section 3(a)(9) of the Securities Act as securities exchanged by an issuer with existing security holders where no commission or other remuneration is paid or given directly or indirectly by the issuer for soliciting such exchange. As of the date of conversion an incremental beneficial conversion feature of $121,000 was recorded as debt discount. Unamortized debt discount totaling $1.0 million was charged to interest expense as of the date of conversion.

2013 Convertible notes payable

In 2013, we initiated an offering of convertible promissory notes (the "2013 Notes"). In total, gross proceeds raised were $3.1 million. The 2013 Notes accrued interest at 5% per year, payable quarterly, were convertible into shares of common stock at $11.25 per share at the option of the holder and were to mature in December 2018.

In March 2017, we offered to all holders of outstanding 2013 Notes, who were accredited investors, an opportunity to convert all outstanding principal and accrued interest through March 31, 2017 into shares of our common stock at a rate of $7.50 per share. The offered conversion rate represented a $3.75, or 33.3%, discount from the rate stated in the terms of the 2013 Notes, which at the time was $11.25 per share. Holders of $2,750,000 aggregate principal amount of the 2013 Notes accepted the offer to convert and on March 31, 2017 we issued 385,000 shares of common stock in exchange for the surrender of the 2013 Notes which included $138,000 of accrued but unpaid interest. The fair market value of the shares issued was $11.5 million, compared to $8.5 million under the original conversion terms, resulting in a loss on the induced debt conversion of approximately $3.0 million. One of our stockholders, who beneficially owns more than 10% of our common stock, converted $700,000 aggregate principal amount of 2013 Notes, along with $35,000 of accrued but unpaid interest, into 98,000 shares of our common stock. The shares were issued in reliance on the exemption from registration set forth in Section 3(a)(9) of the Securities Act as securities exchanged by an issuer with existing security holders where no commission or other remuneration is paid or given directly or indirectly by the issuer for soliciting such exchange.

At December 21, 2018 the one remaining 2013 Note which had not converted in 2017 matured and become a demand note. This note, with a principal balance of $25,000 was paid by the Company on January 4, 2019.

Demand notes payable

In September 2015, we assumed $250,000 of unsecured demand notes in conjunction with our merger with Cimarron Medical, Inc. that were previously issued by Cimarron (the "Demand Notes"). We included the holders of Demand Notes in our offer to convert all outstanding principal into shares of our common stock at a rate of $7.50 per share. The Demand Notes had no conversion feature. The holders of all $250,000 aggregate principal amount of the Demand Notes accepted the offer to convert and on March 31, 2017 we issued 33,332 shares of common stock in exchange for the surrender of all Demand Notes. The fair market value of the shares issued was $1.0 million resulting in a loss on induced debt conversion of $700,000. The shares were issued in reliance on the exemption from registration set forth in Section 3(a)(9) of the Securities Act as securities exchanged by an issuer with existing security holders where no commission or other remuneration is paid or given directly or indirectly by the issuer for soliciting such exchange.

The following table sets forth the changes in convertible and demand notes payable during the year ended December 31, 2018 (in thousands):

	Convertible Notes Payable	
	Principal	Accrued Interest
Principal value at December 31, 2017	$ 3,101	$ 126
Accrued Interest on 2017 notes		57
Aggregate principal value of 2017 notes and accrued interest converted into common stock and warrants	(3,076)	(183)
Aggregate principal value of 2018 notes sold	1,334	-
Accrued interest on 2018 notes	-	2
Principal value at December 31, 2018	$ 1,359	$ 2

Term debt

On October 26, 2012, we entered into an unsecured loan agreement (the "Agreement") with the Institute for Commercialization of Public Research, Inc. (the "Institute"). Under the terms of the agreement, we borrowed $300,000 at a fixed interest rate of 4.125%. No principal or interest payments were due until the maturity date, October 26, 2017, unless a mandatory repayment event occurred. Effective October 26, 2017, we entered into an amendment to our unsecured loan agreement with the Institute. Under the terms of the amendment the maturity date of the note was extended to May 1, 2019 with monthly payments of $10,000 begin on May 1, 2018 with the remaining balance due in full on May 1, 2019. The monthly payments applied first to accrued and unpaid interest. The unpaid principal balance at December 31, 2018 was $286,000.

Deferred financing costs

The following table summarizes the deferred financing costs which are presented as a direct reduction of the carrying amount of their related debt liabilities (in thousands):

	December 31, 2018		December 31, 2017	
	Convertible Notes Payable	Term Debt	Convertible Notes Payable	Term Debt
Loan principal Amount	$ 1,359	$ 286	$ 3,101	$ 300
Deferred Financing Costs	5	37	16	37
Accumulated Amortization	-	(37)	(7)	(37)
Unamortized balance	5	-	9	-
Discount on Debt	1,334	-	2,954	-
Accumulated Amortization	(44)	-	(1,387)	-
Unamortized balance	1,290	-	1,567	-
Loan carrying amounts, net	$ 64	$ 286	$ 1,525	$ 300

We recorded amortization of deferred financing costs of $9,000 and $56,000 for the years ended December 31, 2018 and 2017, respectively, which is included in interest expense in the accompanying Consolidated Statements of Operations and Comprehensive Loss.

7. Employment agreement amendments and waiver of contingent payment rights

Effective February 27, 2018, we entered into waivers and third amendments (collectively, the "Amendments") to the previously disclosed employment agreements, as amended (the "Agreements"), with our Executive Chairman, Michael T. Cullen, M.D., M.B.A., our former President and Chief Executive Officer, David B. Kaysen, and our former Chief Financial Officer, Scott Kellen, each of whom was an executive officer of the Company (collectively, the "Executives"), and our Chief Medical Officer, Suzanne Gagnon, M.D. (together with the Executives, the "Employees"). Dr. Cullen, Mr. Kaysen and Dr. Gagnon are also current members of the Company's Board of Directors.

For each of the Employees, the Amendments waived the contingent cash payment and/or equity payments that had been established by the amendments to the Agreements dated October 1, 2017, each of which could have become due upon a change of control or the Company's completion of an underwritten public offering of its common stock before June 30, 2018. The potential payments waived by the Employees totaled $1.1 million at the time of the amendments and was recorded as a reduction in salary expense. The Amendments also entitled Dr. Cullen, Mr. Kaysen, Mr. Kellen and Dr. Gagnon to grants of new non-qualified stock options to purchase up to 100,000 shares, 50,000 shares, 25,000 shares and 95,000 shares of Company common stock, respectively, at an exercise price equal to fair market value as of the date of grant. These options vested upon grant and have option terms of 10 years. The options were granted under the Company's 2016 Omnibus Incentive Plan effective as of February 27, 2018 and had a fair value of approximately $1.3 million which was recorded as stock-based compensation expense.

8. Commitments and Contingencies

License agreement

On December 22, 2011, we entered into an exclusive license agreement with the University of Florida research Foundation ("UFRF"). The license agreement requires the company to pay royalties to UFRF ranging from 2.5% to 5% of net sales of licensed products developed from the licensed technology. Minimum annual royalties are required after the initial occurrence of a commercial sale of a marketed product. Royalties are payable for the longer of (i) the last to expire of the claims in the licensed patents or (ii) ten (10) years from the first commercial sale of a licensed product in each country in which licensed product is sold. The minimum annual royalties are as follows:

- $50,000 is due 270 days after occurrence of first commercial sale;
- $100,000 is due on the first anniversary date of the first payment;
- $100,000 is due on the second anniversary date of the first payment; and
- $300,000 is due on the third anniversary date of the first payment and subsequent anniversary dates, thereafter, continuing for the life of the license agreement.

In addition, the company is subject to five remaining milestone payments under the license agreement.

- $300,000 is due upon enrollment of the first subject in a Phase 2 clinical trial;
- $3,000,000 is due upon approval of a new drug application;
- $2,000,000 is due upon approval to manufacture and market in either the European Union or Japan (one time only);
- $1,000,000 is due upon the first-time annual net sales of licensed product or licensed process by the Company reaches $100,000,000; and
- $3,000,000 is due upon the first-time annual net sales of licensed product or licensed process by the Company reaches $500,000,000.

The license agreement is subject to customary and usual termination provisions. The Company must also pay an annual license maintenance fee of $10,000. Accordingly, we recorded $10,000 as a license expense in the accompanying 2018 and 2017 Consolidated Statements of Operations and Comprehensive Loss.

9. Stockholders' Equity (Deficit)

2018 Private placement

On February 20, 2018, we entered into a Securities Purchase Agreement (the "2018 Purchase Agreement") with certain accredited investors and completed an initial closing on the same date. Pursuant to the initial closing and two subsequent closings in March and May of 2018, we sold a total of 468,200 shares of common stock and warrants to purchase an aggregate of up to the same number of additional shares of common stock. The warrants issued under the 2018 Purchase Agreement will be exercisable for a period of three years from the date of issuance at an exercise price of $5.00 per share. We received aggregate gross proceeds totaling approximately $2.3 million pursuant to private placements under the 2018 Purchase Agreement, of which $125,000 was received from directors and officers of the Company or its subsidiary. As of December 31, 2018, 468,200 warrants remained outstanding.

Shares reserved

Shares of common stock reserved for future issuance are as follows:

Shares of common stock reserved for future issuance were as follows as of December 31, 2018:

Stock options outstanding	1,032,211
Shares available for grant under equity incentive plan	732,149
Estimated common shares issuable upon conversion of notes payable and accrued interest	383,947
Common shares issuable under outstanding commons stock purchase warrants	2,035,197
	4,183,504

10. Stock-Based Compensation

2016 Omnibus Incentive Plan

Stock-based awards are granted under the Sun BioPharma, Inc. 2016 Omnibus Incentive Plan (the "2016 Plan"), which was adopted by our Board of Directors in March 2016 and approved by our stockholders at our annual meeting of stockholders in May 2016. Effective March 1, 2018, the 2016 Plan was amended and restated in accordance with its terms to (1) decrease the maximum number of shares available for issuance to reflect the 1-for-10 reverse stock split, (2) remove certain provisions relating to Section 162(m) of the Internal Revenue Code of 1986 that were no longer applicable due to the enactment of the Tax Cuts and Jobs Act of 2017 and (3) eliminate cash incentive awards as an award type in light of the same revisions to Section 162(m). The 2016 Plan permits the granting of incentive and non-statutory stock options, restricted stock, stock appreciation rights, performance units, performance shares and other stock awards to eligible employees, directors and consultants. We grant options to purchase shares of common stock under the 2016 Plan at no less than the fair market value of the underlying common stock as of the date of grant. Options granted under the 2016 Plan have a maximum term of ten years. A total of 1,500,000 shares of common stock were initially reserved for issuance under the 2016 Plan. As of December 31, 2018, options to purchase 767,851 shares of common stock were outstanding under the 2016 Plan.

2011 Stock Option Plan

Prior to approval of the 2016 Plan, stock-based awards were granted under the Sun BioPharma, Inc. 2011 Stock Option Plan (the "2011 Plan"), which was adopted by our Board of Directors in September 2011 and approved by our stockholders in January 2012. In conjunction with stockholder approval of the 2016 Plan, the Board terminated the 2011 Plan, although awards outstanding under the 2011 Plan will remain outstanding in accordance with and pursuant to the terms thereof. Options granted under the 2011 Plan have a maximum term of ten years and generally vest over zero to two years for employees. As of December 31, 2018, options to purchase 264,360 shares of common stock remained outstanding under the 2011 Plan.

We recognize stock-based compensation based on the fair value of each award as estimated using the Black-Scholes option valuation model. Ultimately, the actual expense recognized over the vesting period will only be for those shares that actually vest.

A summary of option activity is as follows:

	Shares Available for Grant	Shares Underlying Options	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Balance at January 1, 2017	1,114,400	701,960	$ 9.50	$ 3,896,235
Granted	(54,000)	54,000	10.00	
Exercised	-	(22,000)	1.25	
Cancelled	-	-	-	
Balance at December 31, 2017	1,060,400	733,960	$ 9.79	$ 2,121,985
Granted	(404,000)	404,000	7.49	
Exercised		(30,000)	2.20	
Cancelled	-	-	-	
Forfeitures	75,749	(75,749)	7.34	
Balance at December 31, 2018	732,149	1,032,211	$ 8.90	$ 169,495

A summary of the status of our unvested shares during the year ended and as of December 31, 2018 is as follows:

	Shares Under Option	Weighted Average Grant Date Fair Value
Unvested at December 31, 2017	135,200	$ 9.31
Granted	404,000	3.69
Vested	(468,751)	9.43
Forefeitures	(27,949)	9.68
Unvested at December 31, 2018	42,500	$ 4.83

Information about stock options outstanding, vested and expected to vest as of December 31, 2018, is as follows:

	Outstanding, Vested and Expected to Vest			Options Vested and Excercisable	
Per Share Exercise Price	Shares	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Options Excercisable	Weighted Average Remaining Contractual Life (Years)
$0.875 - $1.10	26,360	4.00	$ 1.029	26,360	4.00
$2.275 - $2.50	38,000	5.12	$ 2.464	38,000	5.12
$3.175	200,000	6.17	$ 3.175	200,000	6.17
$5.75 - $8.10	379,000	8.24	$ 7.488	349,000	8.15
$10.00 - $10.10	54,000	8.55	$ 10.007	52,000	8.76
$15.10	334,851	7.44	$ 15.100	324,351	7.58
Totals	1,032,211	7.37	$ 8.904	989,711	7.37

The cumulative grant date fair value of options vested during the years ended December 31, 2018 and 2017 was $2.3 and $1.9 million, respectively. During the year ended December 31, 2018, 30,000 options were exercised in a net, cashless exercise; as a result, 9,747 shares of common stock were issued.

As of December 31, 2018, total compensation expense related to unvested employee stock options not yet recognized was $85,000 which is expected to be allocated to expenses over a weighted-average period of 2.53 years.

The assumptions used in calculating the fair value under the Black-Scholes option valuation model are set forth in the following table for options issued by the Company for the years ended December 31, 2018 and 2017:

	2018	2017
Common stock fair value	$3.50 - $8.10	$10.00 - $29.80
Risk-free interest rate	2.30% - 2.94%	1.43% - 1.93%
Expected dividend yield	0	0
Expected Option life (years)	1.25 - 5.75	2.25 - 5
Expected stock price volatility	72%	75.0% - 78.0%

Nonemployee stock-based compensation

We account for stock options granted to nonemployees in accordance with FASB ASC 505. In connection with stock options granted to nonemployees, we recorded $263,000 and $495,000 for nonemployee stock-based compensation during the years ended December 31, 2018 and 2017, respectively. These amounts were based upon the fair values of the vested portion of the grants. Amounts expensed during the remaining vesting period will be determined based on the fair value at the time of vesting.

11. Income Taxes

We have incurred net operating losses since inception. We have not reflected the benefit of net operating loss carryforwards in the accompanying financial statements and have established a full valuation allowance against our deferred tax assets.

Changes in tax laws and rates may affect recorded deferred tax assets and liabilities and our effective tax rate in the future. On December 22, 2017 the Tax Cuts and Jobs Act of 2017 (the "Tax Act") became law. The Tax Act enacted significant tax law changes, largely effective for tax years beginning after December 31, 2017. The Tax Act reduces the corporate tax rate to 21%, effective January 1, 2018, for all corporations. GAAP requires the effect of a change in tax laws or rates to be recognized as of the date of enactment, therefore we have revalued our deferred tax assets and liabilities as of December 22, 2017. On December 31, 2017, as a result of the revaluation of our deferred tax assets and liabilities, we reduced the value of our deferred tax asset and the related valuation allowance by $1.8 million.

At December 31, 2018 and 2017, the Company had an income tax receivable of $332,000 and $420,000, respectively, comprised of refundable tax incentives related to research and development activities of our subsidiary Sun BioPharma Australia Pty Ltd.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes as well as operating losses and tax credit carryforwards.

The significant components of our deferred tax assets and liabilities are as follows (in thousands):

Deferred tax assets (liabilities)	December 31, 2018	2017
Net operating loss carryforwards	$ 4,807	$ 3,440
Research credit carryforwards	235	235
Stock-based compensation	971	530
Other	71	212
Deferred tax assets	6,084	4,417
Valuation allowance	(5,801)	(4,079)
Deferred tax assets, net of valuation allowance	283	338
Beneficial conversion feature, net	(283)	(338)
Deferrred tax liablities	(283)	(338)
Net deferred tax asset	$ -	$ -

Realization of the future tax benefits is dependent on our ability to generate sufficient taxable income within the carry-forward period. Because of our history of operating losses, management believes that the deferred tax assets arising from the above-mentioned future tax benefits are currently not likely to be realized and, accordingly, we have provided a full valuation allowance.

A reconciliation of the statutory tax rates and the effective tax rates is as follows:

	Year Ended December 31, 2018	2017
Statutory rate	21.0%	34.0%
Permanent differences	0.1	(13.5)
Change in effective tax rate	0.6	(17.2)
Valuation allowance	(22.6)	(6.6)
Foreign research incentives	5.7	3.8
Deferred true-up	-	3.0
Other	0.9	0.3
Effective rate	5.7%	3.8%

Net operating losses and tax credit carryforwards as of December 31, 2018, are as follows:

	Amount (in thousands)	Expiration Years
Net operating losses--federal	12,958	Beginning 2031
2018 net operating loss -- federal	4,807	No expiration
Tax credits—federal	235	Beginning 2041

Utilization of the net operating loss carryforwards and credits may be subject to a substantial annual limitation due to the ownership change limitations provided by the IRC, and similar state provisions. We have not performed a detailed analysis to determine whether an ownership change under Section 382 of the IRC has occurred. The effect of an ownership change would be the imposition of an annual limitation on the use of net operating loss carryforwards attributable to periods before the change.

The Company is subject to taxation in the United States and Australia. Tax returns, since the inception of Sun BioPharma, Inc. in 2011 and thereafter, are subject to examinations by federal and state tax authorities and may change upon examination. Tax returns of Sun BioPharma Australia Pty Ltd. for the year ended December 31, 2013 and thereafter are subject to examination by the Australian tax authorities.

12. Subsequent Events

Sale of Convertible Promissory Notes and stock purchase Warrants

In January of 2019 we entered into the Securities Agreements with certain accredited investors and completed closings on those dates. Pursuant to these closings, we sold convertible promissory notes ("2018 Notes") and Warrants to purchase a share of common stock. We received aggregate gross proceeds of $0.8 million in these private placement transactions and issued Warrants for 481,422 shares of common stock. The 2018 Notes convert at a fixed conversion rate of $3.50 per share. The conversion price of $3.50 per share of Common Stock is subject to downward adjustment to match the price per share of Common Stock or any unit containing a share of Common Stock issued by the Company on or before the date of conversion. In addition to the 2018 Notes, investors received a Warrant to purchase two shares of Common Stock for every $3.50 principal amount of Notes purchased. The Warrants have an exercise price of $4.50 per share and are subject to a downward adjustment to match the exercise price of any common stock warrants issued by the Company on or before June 30, 2019. The warrants are exercisable upon issuance, until the 5-year anniversary of date of issuance. Pursuant to the 2018 Purchase Agreements, we may be required to file a registration statement with the SEC covering the resale of the shares issued and/or warrant shares issuable thereunder.

Restoration of employee Salaries

Effective February 1, 2018 the salaries of all employees, which had been reduced in November of 2018 to conserve cash, have been restored to contracted levels.

BOARD OF DIRECTORS

Michael T. Cullen, M.D., M.B.A.
Executive Chairman of the Board
President and Chief Executive Officer
Sun BioPharma, Inc.

Suzanne Gagnon, M.D.
Chief Medical Officer
Sun BioPharma, Inc.

Jeffrey S. Mathiesen
Chief Financial Officer of Teewinot Life Sciences and Former Chief Financial Officer Gemphire Therapeutics, Inc.

Paul W. Schaffer
Former Owner and Operator of Bloomington Drug, a compounding pharmacy.

D. Robert Schemel
39 years' experience in agriculture industry and extensive experience serving on boards of directors including ValAdCo and Phenix Biocomposites.

EXECUTIVE OFFICERS

Michael T. Cullen, M.D., M.B.A.
Executive Chairman of the Board
President and Chief Executive Officer

Susan Horvath
Vice President of Finance, Chief Financial Officer and Secretary

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