2019 Annual Report

April 20, 2020

Dear Stockholder:

The Board of Directors of Sun BioPharma, Inc. joins us in extending an invitation to attend our 2020 Annual Meeting of Stockholders (the "Annual Meeting"), to be held on May 19, 2020, at the offices of Faegre Drinker Biddle & Reath LLP, 2200 Wells Fargo Center, 90 South Seventh Street, Minneapolis, Minnesota*, commencing at 2:30 p.m. local time. On or about April 20, 2020, 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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* **IMPORTANT NOTE**: We intend to hold the Annual Meeting in person at the time and place designated above. However, we are sensitive to the public health and travel concerns our stockholders may have and the protocols that federal, state, and local governments may impose in light of the coronavirus (COVID-19) pandemic. In the event it is not possible or advisable to hold our Annual Meeting in person or at the scheduled location, we will announce alternative arrangements for the meeting promptly in advance, which may include holding the meeting solely by means of remote communication. Please monitor our website at *www.sunbiopharma.com* and the filings we make with the Securities and Exchange Commission for any updated information. If you are planning to attend the Annual Meeting in person, please check the website prior to the meeting date. As always, we encourage you to vote your shares prior to the Annual Meeting.

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

NOTICE OF ANNUAL MEETING OF STOCKHOLDERS
TO BE HELD MAY 19, 2020

To the Stockholders of Sun BioPharma, Inc.:

Notice is hereby given that the 2020 Annual Meeting of Stockholders (the "Annual Meeting") of Sun BioPharma, Inc., a Delaware corporation, will be held on May 19, 2020, at the offices of Faegre Drinker Biddle & Reath LLP, 2200 Wells Fargo Center, 90 South Seventh Street, Minneapolis, Minnesota*, commencing at 2:30 p.m. local time, for the following purposes:

1. Elect two Class I directors;

2. Ratify the selection of Cherry Bekaert LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2020;

3. Approve the amendment and restatement of the 2016 Omnibus Incentive Plan ("2016 Plan"); and

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

Only stockholders of record at the close of business on March 27, 2020, 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,

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

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 19, 2020

Our Proxy Statement for the 2020 Annual Meeting of Stockholders and our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, are available at https://www.rdgir.com/sun-biopharma-inc.

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* **IMPORTANT NOTE**: We intend to hold the Annual Meeting in person at the time and place designated above. However, we are sensitive to the public health and travel concerns our stockholders may have and the protocols that federal, state, and local governments may impose in light of the coronavirus (COVID-19) pandemic. In the event it is not possible or advisable to hold our Annual Meeting in person or at the scheduled location, we will announce alternative arrangements for the meeting promptly in advance, which may include holding the meeting solely by means of remote communication. Please monitor our website at *www.sunbiopharma.com* and the filings we make with the Securities and Exchange Commission for any updated information. If you are planning to attend the Annual Meeting in person, please check the website prior to the meeting date. As always, we encourage you to vote your shares prior to the Annual Meeting.

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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 19, 2020, and at any adjournment or postponement of the meeting (the "Annual Meeting").

The Annual Meeting will be held at the offices of Faegre Drinker Biddle & Reath 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 20, 2020.

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 27, 2020, 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.

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.

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 6,631,308 shares of our common stock outstanding, which shares were held by 268 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, 2019, were first made available to stockholders beginning on or about April 20, 2020. This proxy statement summarizes the information you need to complete and submit your proxy or to vote at the Annual Meeting.

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* **IMPORTANT NOTE**: We intend to hold the Annual Meeting in person at the time and place designated above. However, we are sensitive to the public health and travel concerns our stockholders may have and the protocols that federal, state, and local governments may impose in light of the coronavirus (COVID-19) pandemic. In the event it is not possible or advisable to hold our Annual Meeting in person or at the scheduled location, we will announce alternative arrangements for the meeting promptly in advance, which may include holding the meeting solely by means of remote communication. Please monitor our website at *www.sunbiopharma.com* and the filings we make with the Securities and Exchange Commission for any updated information. If you are planning to attend the Annual Meeting in person, please check the website prior to the meeting date. As always, we encourage you to vote your shares prior to 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 two Class I directors.
- Proposal 2 – Ratification of the selection of Cherry Bekaert LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2020.
- Proposal 3 – Approval of amendment and restatement of the 2016 Plan.

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 I director nominees (see Proposal 1); and
- FOR the ratification of our independent registered public accounting firm for the year ending December 31, 2020 (see Proposal 2); and
- FOR the approval of the amendment and restatement of the 2016 Plan (see Proposal 3).

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, 3,315,655 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 two Class I Directors** - Provided a quorum is present at the Annual Meeting, the two 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, 2020 - Provided a quorum is present at the Annual Meeting, this proposal will be approved if it receives the affirmative vote of a majority of the shares of stock represented at the meeting and entitled to vote on the proposal.

Proposal 3 – **Approval of amendment and restatement of the 2016 Plan -** Provided a quorum is present at the Annual Meeting, this proposal will be approved if it receives the affirmative vote of a majority of the shares of stock represented at the meeting and entitled to vote on the proposal.

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, if any, will have the effect of a vote against Proposal 2 but will have no effect on the outcomes of Proposals 1 and 3.

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 Proposals 2 and 3 but will have no effect on the outcomes of Proposal 1.

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.

  We are sensitive to the public health and travel concerns our stockholders may have and the protocols that federal, state, and local governments may impose in light of the coronavirus (COVID-19) pandemic. In the event it is not possible or advisable to hold our Annual Meeting in person or at the scheduled location, we will announce alternative arrangements for the meeting promptly in advance, which may include holding the meeting solely by means of remote communication. Please monitor our website at *www.sunbiopharma.com* and the filings we make with the Securities and Exchange Commission for any updated information. If you are planning to attend the Annual Meeting in person, please check the website prior to the meeting date. As always, we encourage you to vote your shares prior to the Annual Meeting.

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 18, 2020, 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 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. 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 2021 Annual Meeting of Stockholders?

A: If you want to submit a stockholder proposal or nominee for the 2021 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.....	74	Executive Chairman of the Board, President, Chief Executive Officer and Director
Suzanne Gagnon.....	63	Chief Medical Officer and Director
Jeffrey S. Mathiesen.....	59	Director
Paul W. Schaffer	77	Director
D. Robert Schemel	64	Director
Arthur J. Fratamico	54	Director

The Board of Directors has fixed at two the number of directors to be elected to the Board at the Annual Meeting. Based upon the recommendation of its Nominating and Governance Committee, the Board has nominated, Suzanne Gagnon and Paul Schaffer to stand for election for a three-year term. Proxies solicited by the Board will, unless otherwise directed, be voted to elect the nominees as set forth below.

Nominees for Class I Directors – Term Expiring in 2022

Each of the nominees named below is a current director of our Company and has indicated a willingness to serve as a director for the term to which she or he is elected, but in case any 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.

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 2001 to 2014, Dr. Gagnon served as the Chief Medical Officer for three companies, ICON Clinical Research, Nupathe, Inc. and Idis, Inc. Dr. Gagon is a graduate of Boston University School of Medicine and Boston City Hospital's Medical Residency Program. We believe that Dr. Gagnon brings exceptional experience in drug development, safety, regulatory matters and executive leadership to the Board of Directors.

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 of Directors and as a director of our Company since September 2015. He assumed 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 of its Board of Directors since that date. He previously served as Chief Medical Officer from November 2011 to January 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 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.

Class III Directors –Terms Expiring in 2022

Jeffrey S. Mathiesen has served as a director of our Company since September 2015. On March 19, 2019 Mr. Mathiesen selected to service as the Vice Chair and lead independent director for the Company. He has served as Advisor to the CEO of Teewinot Life Sciences, a privately held biopharmaceutical company focused on the biosynthetic production of pure pharmaceutical grade cannabinoids from October 2019 to December 2019, and as Chief Financial Officer from March 2019 to October 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 served 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 from July 2018 to February 2020. Mr. Mathiesen holds a B.S. in Accounting from the University of South Dakota and is also a Certified Public Accountant.

Arthur J. Fratamico has served as a director of our Company since December of 2019. He is a registered pharmacist with over 25 years of experience in the pharmaceutical industry and has been the Chief Business Officer at Galera Therapeutics, Inc., a biopharmaceutical company dedicated to discovering and developing novel dismutase mimetics with the goal of transforming cancer radiotherapy, since January 2017. Prior to joining Galera, Mr. Fratamico served as Chief Business Officer of Vitae Pharmaceuticals, Inc., a Nasdaq-listed clinical-stage biotechnology company, from May 2014 until its sale to Allergan in December 2016. Prior to Vitae Pharmaceuticals, he held similar executive roles with a number of biotechnology companies leading their business development efforts, including facilitating the sales of Gemin X Pharmaceuticals, Inc. and MGI Pharma, Inc. In addition to being responsible for numerous licensing transactions and acquisitions, he also directed corporate strategy and managed external corporate communications. He also served in several senior marketing, product planning and new product development positions. Mr. Fratamico earned a bachelor's degree in pharmacy from the Philadelphia College of Pharmacy and Science and an M.B.A. from Drexel University.

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 nominees receiving the highest number of votes will be elected. The votes cannot be cast for a greater number of persons than two.

The Board of Directors recommends that you vote "FOR" each of the nominees for Class I Directors.

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, at this time, as it both maintains the functionality of our Board of Directors and is an efficient use of Company resources. On March 19, 2020 our Board of Directors designated Mr. Mathiesen as our Vice Chair and lead independent director. As Vice Chair and lead independent director Mr. Mathiesen is responsible for (a) presiding over all executive sessions of non-employee, independent directors, (b) presiding at meetings of the Board in the absence of, or upon the request of, the Chairman, (c) approving the scheduling of Board meetings as well as the agenda and materials for each Board meeting and executive session of the Board's non-employee, independent Directors, (d) serving as a liaison and supplemental channel of communication between the non-employee, independent directors and the Executive Chairman, (e) meeting regularly with the Executive Chairman, (f) communicating with stockholders as appropriate, and (g) approving and coordinating the retention of advisors and consultants who report directly to the non-employee, independent members of the Board, except as otherwise required by applicable law or any applicable exchange rules or listing standards.

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, Schemel and Fratamico 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 five meetings during 2019. Each director 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, 2019.

Director Attendance at Annual Meeting

We do not have a formal policy regarding attendance of directors at our annual meeting of stockholders. Five directors were present at our Annual Meeting of stockholders held in 2019.

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	Chair	✓
D. Robert Schemel	Member	Chair	–	✓
Arthur J. Fratamico	–	Member	Member	✓

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 2019. 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 Securities and Exchange Commission (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, 2019 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 and the SEC.

(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, 2019 to be filed with the SEC.

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 all compensation for our executive officers and, 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 also responsible for administering our equity incentive plans, including our 2011 Equity Incentive Plan, as amended (the "2011 Plan") and our 2016 Omnibus Incentive Plan, as amended (the "2016 Plan"), including approval of individual grants of stock options and other equity-based awards. The Compensation Committee held three meetings during 2019. 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 2019. 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, 2018 to which our Company has been a party and in which the amount involved exceeded $25,000, 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 below 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. Under her employment agreement as currently in effect, Dr. Gagnon was entitled to receive an initial annualized base salary of $270,000. During 2018 and 2019, Dr. Gagnon received compensation from the Company amounting to $207,700 and $250,100, respectively.

Certain directors and executive officers participated in various debt and equity offerings during the two years ended December 31, 2019. The table below summarizes those securities purchases:

Related Person Name and Position(s)	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
Paul W. 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
Michael T. Cullen, Executive Chairman President, CEO and Director	8/30/2019	30,000 Shares of Common Stock and Warrants to purchase up to 30,000 additional Shares of Common Stock[(d)]	$ 105,000
Paul W. Schaffer, Director	9/20/19	30,000 Shares of Common Stock and Warrants to Purchase up to 30,000 additional Shares of Common Stock[(e)]	$ 105,000
Suzanne Gagnon, Chief Medical Officer and Director	9/20/19	7,142 Shares of Common Stock and Warrants to Purchase up to 7,142 additional Shares of Common Stock[(e)]	$ 25,000

(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") were part of a series of notes issued on the same terms as those issued to third parties in December 2018 and January 2019, matured on June 30, 2019 and bore interest at a rate of 10.0% per year in the interim. The Notes had 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 received gross proceeds of at least $6.0 million from the sale of equity securities (subject to certain exclusions). The Notes converted at a stated conversion rate of $3.50 per share subject to downward adjustments, if any, 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. See also Note 6 to our consolidated financial statements, included in our annual report on Form 10-K for the fiscal year ended December 31, 2019.
(d) Pursuant to Securities Purchase Agreement dated August 30, 2019 the warrants are exercisable for a period of five years from the date of issuance at an exercise price of $4.00 per share.
(e) Pursuant to Securities Purchase Agreement dated September 20, 2019 the warrants are exercisable for a period of five years from the date of issuance at an exercise price of $4.00 per share.

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.

DIRECTOR COMPENSATION

The following table sets forth certain information regarding compensation of the persons who served as our non-employee directors during the year ended December 31, 20129.

Name	Option Awards ($)(a)	Total ($)
D. Robert Schemel	62,395[b]	62,395
Jeffrey S. Mathiesen	62,395[c]	62,395
Paul W. Schaffer	62,395[d]	62,395
Arthur J. Fratamico	74,992[e]	74,992

(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, 2019.
(b) Mr. Schemel held options to purchase an aggregate of 54,600 shares as of December 31, 2019.
(c) Mr. Mathiesen held options to purchase an aggregate of 54,600 shares as of December 31, 2019.
(d) Mr. Shaffer held options to purchase an aggregate of 70,600 shares as of December 31, 2019.
(e) Mr. Fratamico held options to purchase an aggregate of 38,300 shares as of December 31, 2019.

Directors who are also our employees receive no additional cash compensation for serving on our Board of Directors and non-employee directors receive no cash compensation. During 2019, 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.

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.

On the same date, the Compensation Committee also granted to each then-serving non-employee director 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 is scheduled to 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.

In connection with Mr. Fratamico's election to the Board of Directors, effective December 19, 2019, the Compensation Committee awarded him two options, one to purchase 6,500 shares, scheduled to vest in full the day before the Annual Meeting and a second to purchase 26,800 shares, 50% of which was exercisable on the date of grant and 25% of which is schedule to vest on the first and second anniversaries of the date of grant. These grants were made consistent with the director compensation program put into place in 2019 and the time remaining prior to the next annual meeting.

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 27, 2020 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 6,631,308 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 rights to acquire common stock that are exercisable within 60 days from March 27, 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	774,771[(a)]	11.0%
Susan Horvath	112,090[(b)]	1.7%
Suzanne Gagnon	339,992[(c)]	4.9%
Jeffrey S. Mathiesen	58,900[(d)]	*
Paul W. Schaffer	275,741[(e)]	4.1%
D. Robert Schemel	436,749[(f)]	7.9%
Arthur J. Fratamico	24,900[(g)]	*
All directors and current executive officers as a group (7 persons)	2,023,143[(h)]	26.4%
Ryan Gilbertson 2012 Irrevocable Family Trust 8615 Eagle Creek Circle Savage, Minnesota 55378	793,564[(i)]	11.6%

* Less than 1 percent.

(a) Includes 194,576 shares held by the Cullen Living Trust and 324,700 shares subject to stock options, and 57,500 shares subject to warrants.

(b) Includes 88,650 shares subject to stock options, and 14,928 shares subject to warrants.

(c) Includes 8,142 shares held by the Gagnon Family Trust, 287,350 shares subject to stock options and 1,500 shares subject to warrants.

(d) Includes 52,900 shares subject to options and 3,000 shares subject to warrants.

(e) Includes 30,685 shares held by the Paul Shaffer Trust, 68,900 shares subject to stock options, 51,756 shares subject to warrants.

(f) Includes 282,654 shares held by spouse and 52,900 shares subject to stock options and 11,767 shares subject to warrants.

(g) Includes 24,900 shares subject to stock options.

(h) Includes 900,300 shares subject to stock options and 140,451 shares subject to warrants.

(i) Includes 218,455 shares subject to warrants.

EXECUTIVE COMPENSATION

The following disclosure focuses on our named executive officers. For fiscal 2019 our "named executive officers" consisted of: Michael T. Cullen and Susan Horvath.

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 2019 (collectively referred to as the "*Executives*"):

Name and Principal Position	Fiscal Year	Salary ($)	Option Awards[(a)] ($)	Total ($)
Michael T. Cullen	2019	282,350	377,471	659,821
Executive Chairman, President and Chief Executive Officer[(b)]	2018	221,200	491,491	712,691
Susan Horvath	2019	220,313	181,124	401,436
Chief Financial Officer and Vice President of Finance[(c)]	2018	150,000	147,573	297,573

(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, 2019.
(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 on April 17, 2018.

Outstanding Equity Awards as of December 31, 2019

		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
	5/21/2019	71,500	84,600[(a)]	2.95	5/21/2029
	9/24/19	30,000	–	5.00	9/24/2029
Susan Horvath	4/17/2018	20,000	20,000[(b)]	5.75	4/17/2028
	5/21/19	21,575	36,225[(c)]	2.95	5/21/2029
	9/24/19	25,000	–	5.00	9/24/2029

(a) Scheduled to vest with respect to 28,200 on May 21st in each of 2020, 2021 and 2022.
(b) Scheduled to vest with respect to 10,000 on April 17th in each of 2020 and 2021.
(c) Scheduled to vest with respect to 12,075 on May 21st in each of 2020, 2021 and 2022.

Employment Agreements

During 2019, we were party to employment agreements with each of the Executives. In addition to the specific terms summarized below, each Executive 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 non-competition and non-solicitation covenants and a requirement that the Executive execute a supplemental agreement regarding confidentiality and assignment of intellectual property.

In accordance with the employment agreements, the base salary of each Executive is reviewed annually by the Compensation Committee of our Board of Directors. Pursuant to the employment agreements, 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.

Executive Chairman, President and Chief Executive Officer

Under his employment agreement, as last amended, Dr. Cullen was entitled to receive an initial annualized base salary equal to $288,000. He 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 2019 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 until May 21, 2019. On that date the Compensation Committee increased Dr. Cullen's annualized base salary to $315,000.

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 2019 and therefore no cash bonus was paid.

Potential Payments Upon Termination or Change-in-Control

Under their respective employment agreements, if Dr. Cullen's 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 or Ms. Horvath, as applicable, would instead receive an amount equal to his or her respective annualized salary, plus an amount equal to his or her full cash bonus target for the year in which the termination occurred.

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 2020, 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 receives 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 2020.

Audit Fees

Cherry Bekaert LLP served as our independent registered public accounting firm for the years ended December 31, 2019 and 2018. The following table presents the aggregate fees for professional services provided by Cherry Bekaert LLP related to 2019 and 2018:

	Year Ended	
	December 31, 2019	December 31, 2018
Audit Fees	$ 104,500	$ 104,500
Total	$ 104,500	$ 104,500

"*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 2019, 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:
APPROVAL OF AMENDMENT AND RESTATEMENT OF THE 2016 OMNIBUS INCENTIVE PLAN

Introduction

On April 9, 2020, our Board of Directors, upon recommendation of its Compensation Committee (as used in this section of this proxy statement, the "Committee"), approved the amendment and restatement of the Sun BioPharma, Inc. 2016 Omnibus Incentive Plan, as amended (the "Amended 2016 Plan"), subject to stockholder approval. The purpose of the Amended 2016 Plan is to provide long-term incentives to persons with responsibility for success and growth at our Company. The Amended 2016 Plan authorizes the issuance of up to 2,800,000 shares of our common stock pursuant to awards granted thereunder, which includes 1,500,000 shares previously approved by stockholders at our 2016 Annual Meeting of Stockholders as well as 1,300,000 additional shares.

Key Features of the Amended 2016 Plan

Our Board of Directors believes that equity-based incentives are an important part of total compensation for our executives as well as for employees and our non-employee directors and aligns their interests with the interests of our stockholders. We believe that stockholders should approve the Amended 2016 Plan for the following reasons:

- *No Repricing, Replacement or Repurchase of Underwater Options or Stock Appreciation Rights*. The Amended 2016 Plan prohibits, without stockholder approval, actions to reprice, replace or repurchase options or stock appreciation rights ("SARs") when the exercise price per share of an option or SAR exceeds the fair market value of the underlying shares.

- *No In-the-Money Option or SAR Grants*. The Amended 2016 Plan prohibits the grant of options or SARs with an exercise price less than the fair market value of our common stock on the date of grant (except in the limited case of "substitute awards" as described below).

- *No Liberal Share Counting*. Shares delivered or withheld to pay the exercise price or satisfy a tax withholding obligation in connection with option awards and SARs, shares that we repurchase using option exercise proceeds, and shares subject to a SAR that are not issued in connection with the stock settlement of that award upon its exercise may not be used again for new grants.

- *Dividend Equivalents Subject to Performance Conditions*. Dividends and dividend equivalents payable with respect to the unvested portion of full value awards whose vesting is subject to the satisfaction of performance conditions will be subject to the same restrictions as the underlying shares or units.

- *No Liberal Definition of "Change in Control."* No change in control would be triggered solely because of stockholder approval of a business combination transaction.

- *Double Trigger Accelerated Vesting Following a Change in Control.* The Amended 2016 Plan provides that if outstanding awards are continued, assumed or replaced in connection with a change in control that constitutes a corporate transaction, then accelerated vesting of an award will occur only if employment is terminated (other than for "cause" or "good reason") within 12 months of the change of control.

The descriptions set forth below are in all respects qualified by the terms of the Amended 2016 Plan, which is attached to this Proxy Statement as Appendix A.

Purpose

The purpose of the Amended 2016 Plan is to promote the interests of our Company and our stockholders by providing key personnel of our Company and our affiliates with an opportunity to acquire a proprietary interest in the Company and thereby develop a stronger incentive to put forth maximum effort for the continued success and growth of our Company and our affiliates. In addition, the opportunity to acquire a proprietary interest in our Company will aid in attracting and retaining key personnel of outstanding ability. The Amended 2016 Plan is also intended to provide non-employee directors of the Company with an opportunity to acquire a proprietary interest in the Company, to compensate non-employee directors for their contributions to the Company and to aid in attracting and retaining non-employee directors.

Administration

The Amended 2016 Plan is administered by the Committee. The Committee has the authority to adopt, revise and waive rules relating to the Amended 2016 Plan and to determine the timing and identity of participants, the amount of any awards and other terms and conditions of awards. The Committee may delegate its responsibilities under the Amended 2016 Plan to one or more of its members or to one or more directors or executive officers of the Company with respect to the selection and grants of awards to employees of the Company who are not deemed to be officers, directors or 10% stockholders of the Company under applicable federal securities laws. The Board of Directors will perform the duties and have the responsibilities of the Committee with respect to awards made to non-employee directors.

Eligibility

All employees of our Company and our affiliates, non-employee directors of our Company and any consultant or advisor who is a natural person and provides services to us or our affiliates are eligible to receive awards under the Amended 2016 Plan at the discretion of the Committee or the Board, as applicable. No awards may be granted under the Amended 2016 Plan in conjunction with a capital-raising transaction or the promotion or maintenance of a market for our securities. Incentive stock options under the Amended 2016 Plan may be awarded to employees of the Company. As of April 3, 2020, there were approximately 9 total employees and non-employee directors. Such employees, directors and others who currently or may in the future provide services to us and our affiliates may be considered for the grant of awards under the Amended 2016 Plan at the discretion of the Committee or the Board, as applicable.

Shares Available

The total number of shares of Company Common Stock available for distribution under the Amended 2016 Plan is 2,800,000 (which reflects 1,500,000 shares approved at the 2016 Annual Meeting of Stockholders, after giving effect to the 2017 1-for-10 reverse stock split, plus an additional 1,300,000 shares), subject to adjustment for future stock splits, stock dividends and similar changes in the capitalization of the Company. In addition, the Amended 2016 Plan provides that the number of shares of Common Stock available for issuance under the Amended 2016 Plan will increase on January 1 of each year beginning in 2021 and ending on January 1, 2025 in an amount equal to the lesser of (i) 20% of the total number of Fully Diluted Shares (as defined in the Amended 2016 Plan) as of December 31 of the immediately preceding calendar year and (ii) such lesser number of shares as may be determined by the Board of Directors or the Committee prior to January 1st of any calendar year. The shares of our Common Stock covered by the Amended 2016 Plan may be treasury shares or authorized but unissued shares.

Any shares subject to an award under the Amended 2016 Plan that expires, is cancelled or forfeited or is settled for cash shall, to the extent of such expiration, cancellation, forfeiture or cash settlement, remain in the pool of shares available for grant under the Amended 2016 Plan. The following shares will, however, continue to be charged against the foregoing maximum share limitations and will not again become available for grant: (i) shares tendered by the participant or withheld by us in payment of the purchase price of an Option, (ii) shares tendered by the participant or withheld by us to satisfy any tax withholding obligation with respect to an Option of SAR, (iii) shares subject to a SAR that are not issued in connection with the settlement of the SAR upon its exercise and (iv) shares repurchased by us with proceeds received from the exercise of a stock option issued under the Amended 2016 Plan.

Types of Awards

The Amended 2016 Plan allows us to grant stock options, SARs, restricted stock, restricted stock units and other stock-based awards. The Committee may provide that the vesting or payment of any award will be subject to the attainment of certain performance objectives established by the Committee, in addition to completion by the plan participant of a specified period of service. The Committee may amend the terms of any award previously granted, but no amendment may materially impair the rights of any participant with respect to an outstanding award without the participant's consent, unless such amendment is necessary to comply with applicable laws or stock exchange rules.

Stock Options

Stock options granted under the Amended 2016 Plan may be either incentive stock options ("ISOs"), which are specifically designated as such for purposes of compliance with Section 422 of the Internal Revenue Code of 1986, as amended (the "Code"), or non-statutory stock options ("NSOs"). Options will vest as determined by the Committee, subject to statutory limitations regarding the maximum term of ISOs and the maximum value of ISOs that by vest in a single year. The exercise price of options may not be less than the fair market value of our Common Stock on the date of grant, which, if our shares or not readily tradable on an established securities market will be determined by the Committee as the result of a reasonable application of a reasonable valuation method that satisfies the requirements of Section 409A of the Code. The exercise price must be paid in full at the time of exercise and may be paid in cash or such other manner as permitted by the Committee, including by withholding shares issuable upon exercise or by delivery of shares already owned by a participant. Although not necessarily indicative of fair market value, the most recent sale price of a share of our common stock on the over the counter markets, which sale occurred on April 1, 2020, was $5.25 per share.

Stock Appreciation Rights

SARs provide for payment to the participant of all or a portion of the excess of the fair market value of a specified number of shares of our Common Stock on the date of exercise over a specified exercise price, which may not be less than the fair market value of our Common Stock on the date of grant. Payment may be made in cash or shares of our Common Stock or a combination of both, as determined by the Committee.

Restricted Stock

Restricted stock awards are awards of shares of our Common Stock that are subject to vesting conditions, and the corresponding lapse or waiver of forfeiture conditions and other restrictions, based on such factors and occurring over such period of time as the Committee may determine.

Restricted Stock Units

Restricted stock units provide a participant with the right to receive, in cash or shares of our Common Stock or a combination of both, the fair market value of a specified number of shares of our Common Stock, and will be subject to such vesting and forfeiture conditions and other restrictions as the Committee determines.

Other Stock-Based Awards

The Committee may grant other awards under the Amended 2016 Plan that are valued by reference to and/or payable in whole or in part in shares of our Common Stock.

Terms of Awards and Other Plan Provisions

Substitute Awards

Awards may be granted under the Amended 2016 Plan in substitution for awards granted by another entity acquired by our company or with which our company combines. The terms and conditions of these substitute awards will be comparable to the terms of the awards replaced and may therefore differ from the terms and conditions otherwise set forth in the Amended 2016 Plan. Shares subject to substitute awards will not count against the Amended 2016 Plan share reserve.

Repricing of Awards

The Committee may not reduce the exercise price of stock options or SARs granted under the Amended 2016 Plan, exchange outstanding stock options or SARs with new stock options or SARs with a lower exercise price or a new full value award, repurchase underwater stock options or SARs or take any other action that would constitute a "repricing," unless such action is first approved by our stockholders.

Transferability of Awards

Except as noted below, during the lifetime of a person to whom an award is granted, only that person, or that person's legal representative, may exercise an option or SAR, or receive payment with respect to performance units or any other award. No award may be sold, assigned, transferred, exchanged or otherwise encumbered other than to a successor in the event of a participant's death or pursuant to a qualified domestic relations order. However, the Committee may provide that awards, other than incentive stock options, may be transferable to members of the participant's immediate family or to one or more trusts for the benefit of such family members or partnerships in which such family members are the only partners, if the participant does not receive any consideration for the transfer.

Termination of Service

Unless otherwise provided in an award agreement, upon termination of a participant's service with us, all unvested and unexercisable portions of the participant's outstanding awards will immediately be forfeited. If a participant's service with us terminates other than for cause (as defined in the Amended 2016 Plan), death or disability, the vested and exercisable portions of the participant's outstanding stock options and SARs generally will remain exercisable for 90 days after termination. If a participant's service terminates due to death or disability, the vested and exercisable portions of the participant's outstanding stock options and SARs generally will remain exercisable for one year after termination. Upon termination for cause, all unexercised stock options and SARs will be forfeited.

Withholding

The Amended 2016 Plan permits us to withhold from cash awards, and to require a participant receiving Common Stock under the Amended 2016 Plan to pay us in cash, an amount sufficient to cover any required withholding taxes. In lieu of cash, the Committee may permit a participant to cover withholding obligations through a reduction in the number of shares delivered to such participant or a surrender of shares then owned by the participant.

Change in Control

If a change in control (as defined in the Amended 2016 Plan) that involves a corporate transaction (as defined in the Amended 2016 Plan) occurs and any outstanding award is continued, assumed or replaced by our Company or the surviving or successor entity in connection with such change in control, and if within 12 months after the change in control a participant's employment or other service is terminated without cause or with good reason (as defined in the Amended 2016 Plan), then (i) each of the participant's outstanding options and SARs will become exercisable in full, and (ii) each of the participant's unvested full value awards will fully vest. If any outstanding award is not continued, assumed or replaced in connection with such change in control, then the same consequences as specified in the previous sentence with respect to a termination of employment or other service will occur in connection with a change in control unless and to the extent the Committee elects to terminate such award in exchange for a payment in an amount equal to the intrinsic value of the award (or, if there is no intrinsic value, the award may be terminated without payment). The Committee may, in its discretion, take such other action as it deems appropriate with respect to outstanding awards for a change in control not involving a corporate transaction or may generally provide for different circumstances upon any change in control in an individual award agreement.

Adjustment of Awards

In the event of an equity restructuring, such as a stock dividend or stock split, that affects the per share value of our Common Stock, the Committee will make appropriate adjustment to: (i) the number and kind of securities reserved for issuance under the Amended 2016 Plan, (ii) the number and kind of securities subject to outstanding awards under the Amended 2016 Plan, (iii) the exercise price of outstanding options and SARs, and (iv) any maximum limitations prescribed by the Amended 2016 Plan as to grants of certain types of awards. The Committee may also make similar adjustments in the event of any other change in our company's capitalization, including a merger, consolidation, reorganization or liquidation.

Amendment and Termination

The Amended 2016 Plan has a term of ten years from its effective date, or the earlier termination of the Amended 2016 Plan by our Board of Directors. Our Board may amend the Amended 2016 Plan at any time, but no amendment may materially impair the rights of any participant with respect to outstanding awards without the participant's consent. Stockholder approval of any amendment of the Amended 2016 Plan will be obtained if required by applicable law or the rules of any securities exchange on which our Common Stock may then be listed. Awards that are outstanding on the Amended 2016 Plan's termination date will remain in effect in accordance with the terms of the Amended 2016 Plan and the applicable award agreements.

U.S. Federal Income Tax Consequences

The following is a summary of the principal United States federal income tax consequences to the Company and to participants subject to U.S. taxation with respect to awards granted under the Amended 2016 Plan, based on current statutes, regulations and interpretations.

Non-statutory Stock Options

If a participant is granted a non-statutory stock option under the Amended 2016 Plan, the participant will not recognize taxable income upon the grant of the option. Generally, the participant will recognize ordinary income at the time of exercise in an amount equal to the difference between the fair market value of the shares acquired at the time of exercise and the exercise price paid. The participant's basis in the common stock for purposes of determining gain or loss on a subsequent sale or disposition of such shares generally will be the fair market value of our common stock on the date the option was exercised. Any subsequent gain or loss will be taxable as a capital gain or loss. The Company will generally be entitled to a federal income tax deduction at the time and for the same amount as the participant recognizes as ordinary income.

Incentive Stock Options

If a participant is granted an incentive stock option under the Amended 2016 Plan, the participant will not recognize taxable income upon grant of the option. Additionally, if applicable holding period requirements (a minimum of two years from the date of grant and one year from the date of exercise) are met, the participant will not recognize taxable income at the time of exercise. However, the excess of the fair market value of the shares acquired at the time of exercise over the aggregate exercise price is an item of tax preference income potentially subject to the alternative minimum tax. If shares acquired upon exercise of an incentive stock option are held for the holding period described above, the gain or loss (in an amount equal to the difference between the fair market value on the date of sale and the exercise price) upon disposition of the shares will be treated as a long-term capital gain or loss, and the Company will not be entitled to any deduction. Except in the event of death, if the holding period requirements are not met, the incentive stock option will be treated as one that does not meet the requirements of the Code for incentive stock options and the tax consequences described for nonqualified stock options will generally apply.

Other Awards

The current federal income tax consequences of other awards authorized under the Amended 2016 Plan generally follow certain basic patterns. An award of restricted stock results in income recognition by a participant in an amount equal to the fair market value of the shares received at the time the restrictions lapse and the shares vest, unless the participant elects under Code Section 83(b) to accelerate income recognition and the taxability of the award to the date of grant. Stock unit awards generally result in income recognition by a participant at the time payment of such an award is made in an amount equal to the amount paid in cash or the then-current fair market value of the shares received, as applicable. SAR awards result in income recognition by a participant at the time such an award is exercised in an amount equal to the amount paid in cash or the then-current fair market value of the shares received by the participant, as applicable. In each of the foregoing cases, the

Company will generally have a corresponding deduction at the time the participant recognizes ordinary income, subject to Code Section 162(m) with respect to covered employees.

Section 162(m) of the Code

Code Section 162(m) denies a deduction to any publicly held corporation for compensation paid to certain "covered employees" in a taxable year to the extent that compensation to the covered employee exceeds $1,000,000.

Section 409A of the Code

The foregoing discussion of tax consequences of awards under the Amended 2016 Plan assumes that the award discussed is either not considered a "deferred compensation arrangement" subject to Section 409A of the Code or has been structured to comply with its requirements. If an award is considered a deferred compensation arrangement subject to Section 409A but fails to comply, in operation or form, with the requirements of Section 409A, the affected participant would generally be required to include in income when the award vests the amount deemed "deferred," would be required to pay an additional 20% income tax on such amount, and would be required to pay interest on the tax that would have been paid but for the deferral.

New Plan Benefits

No benefits or amounts have been granted, awarded or received under the Amended 2016 Plan that are subject to stockholder approval. In addition, the Committee will determine the number and types of awards that will be granted under the Amended 2016 Plan. Thus, it is not possible to determine the benefits that will be received by eligible participants if the Amended 2016 Plan is approved by our stockholders.

Equity Compensation Plan Information

The following table presents the number of securities authorized for issuance under the Company's equity compensation plans as of December 31, 2019:

Plan Category	Number of Securities to Be Issued Upon Exercise of Outstanding Options, Warrants and Rights[(a)]	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	1,744,811	$ 6.526	19,549
Equity compensation plans not approved by security holders	–	–	–
Total	1,744,811		19,549

(a) Includes 1,480,451 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.

Required Vote and Board Recommendation

Provided a quorum is present at the Annual Meeting, this proposal will be approved if it receives 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 unanimously recommends that you vote "FOR" approval of the Amended 2016 Plan.

DELINQUENT SECTION 16(a) REPORTS

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, 2019 except for one report by Ryan R. Gilbertson, reporting the sale of common stock.

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 2021 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 17, 2020. 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 2021 at our principal executive office no earlier than January 12, 2021 and no later than February 11, 2021. 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.

HOUSEHOLDING

We have adopted a procedure approved by the SEC 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, 2019, accompanies the delivery of this proxy statement and a copy of such annual report, as filed with the SEC, 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.

SUN BIOPHARMA, INC.
2016 OMNIBUS INCENTIVE PLAN

Amended and Restated as of April 9, 2020

1. Purpose. The purpose of the Sun BioPharma, Inc. Company 2016 Omnibus Incentive Plan (the "Plan") is to attract and retain the best available personnel for positions of responsibility with the Company, to provide additional incentives to them and align their interests with those of the Company's stockholders, and to thereby promote the Company's long-term business success.

2. Definitions. In this Plan, the following definitions will apply.

(a) "*Affiliate*" means any entity that is a Subsidiary or Parent of the Company.

(b) "*Agreement*" means the written or electronic agreement, notice or other document containing the terms and conditions applicable to each Award granted under the Plan. An Agreement is subject to the terms and conditions of the Plan.

(c) "*Award*" means a grant made under the Plan in the form of Options, Stock Appreciation Rights, Restricted Stock, Stock Units or an Other Stock-Based Award.

(d) "*Board*" means the Board of Directors of the Company.

(e) "*Cause*" means what the term is expressly defined to mean in a then-effective written agreement (including an Agreement) between a Participant and the Company or any Affiliate, or in the absence of any such then-effective agreement or definition means, a Participant's (i) failure or refusal to perform satisfactorily the duties reasonably required of the Participant by the Company (other than by reason of Disability); (ii) act or acts of dishonesty intended to result in substantial gain or personal enrichment of the Participant at the expense of Company or any Affiliate; (iii) being convicted of, or pleading guilty or no-contest to, a gross misdemeanor or any felony; (iv) breach of the Company's business conduct or ethics code or of any fiduciary duty or nondisclosure, non-solicitation, non-competition or similar obligation owed to the Company or any Affiliate that, in any case is willful and deliberate on the Participant's part and is materially injurious to Company or any Affiliate; or (v) unlawful conduct or gross misconduct that, in any case is willful and deliberate on Employee's part and is materially injurious to Company.

(f) "*Change in Control*" means, unless otherwise provided in an Agreement, one of the following:

(1) An Exchange Act Person becomes the beneficial owner (within the meaning of Rule 13d-3 under the Exchange Act) of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding Voting Securities, except that the following will not constitute a Change in Control:

(A) any acquisition of securities of the Company by an Exchange Act Person directly or indirectly from the Company for the purpose of providing financing to the Company;

(B) any formation of a Group consisting solely of beneficial owners of the Company's Voting Securities as of the effective date of this Plan;

(C) any repurchase or other acquisition by the Company of its Voting Securities that causes any Exchange Act Person to become the beneficial owner of more than 50% of the Company's Voting Securities; or

(D) with respect to any particular Participant, any acquisition of securities of the Company by the Participant, any Group including the Participant, or any entity controlled by the Participant or a Group including the Participant.

If, however, an Exchange Act Person or Group referenced in clause (A), (B) or (C) above acquires beneficial ownership of additional Company Voting Securities, after initially becoming the beneficial owner of more than 50% of the combined voting power of the Company's Voting Securities by one of the means described in those clauses, then a Change in Control

will be deemed to have occurred. Furthermore, a Change in Control will occur if a Person becomes the beneficial owner of more than 50% of the Company's Voting Securities as the result of a Corporate Transaction only if the Corporate Transaction is itself a Change in Control pursuant to subsection 2(f)(3).

(2) Individuals who are Continuing Directors cease for any reason to constitute a majority of the members of the Board.

(3) A Corporate Transaction is consummated, unless, immediately following such Corporate Transaction, all or substantially all of the individuals and entities who were the beneficial owners of the Company's Voting Securities immediately prior to such Corporate Transaction beneficially own, directly or indirectly, more than 50% of the combined voting power of the then outstanding Voting Securities of the surviving or acquiring entity resulting from such Corporate Transaction (including beneficial ownership through the ultimate Parent of such entity) in substantially the same proportions as their ownership, immediately prior to such Corporate Transaction, of the Company's Voting Securities.

Notwithstanding the foregoing, to the extent that any Award constitutes a deferral of compensation subject to Code Section 409A, and if that Award provides for a change in the time or form of payment upon a Change in Control, then no Change in Control shall be deemed to have occurred upon an event described in this Section 2(g) unless the event would also constitute a change in ownership or effective control of, or a change in the ownership of a substantial portion of the assets of, the Company under Code Section 409A.

(g) "*Code*" means the Internal Revenue Code of 1986, as amended and in effect from time to time. For purposes of the Plan, references to sections of the Code shall be deemed to include any applicable regulations thereunder and any successor or similar statutory provisions.

(h) "*Committee*" means two or more Non-Employee Directors designated by the Board to administer the Plan under Section 3, each member of which shall be (i) an independent director within the meaning of the rules and regulations of the Nasdaq Stock Market, and (ii) a non-employee director within the meaning of Exchange Act Rule 16b-3.

(i) "*Company*" means Sun BioPharma, Inc., a Delaware corporation, or any successor thereto.

(j) "*Continuing Director*" means an individual (i) who is, as of the effective date of the Plan, a director of the Company, or (ii) who is elected as a director of the Company subsequent to the effective date hereof pursuant to a nomination or board representation right of preferred stockholders of the Company, or (iii) who becomes a director of the Company after the effective date hereof and whose initial election, or nomination for election by the Company's stockholders, was approved by at least a majority of the then Continuing Directors, but excluding, for purposes of this clause (ii) or (iii), an individual whose initial assumption of office occurs as a result of an actual or threatened proxy contest relating to the election of directors.

(k) "*Corporate Transaction*" means (i) a sale or other disposition of all or substantially all of the assets of the Company, or (ii) a merger, consolidation, share exchange or similar transaction involving the Company, regardless of whether the Company is the surviving corporation.

(l) "*Disability*" means (A) any permanent and total disability under any long-term disability plan or policy of the Company or its Affiliates that covers the Participant, or (B) if there is no such long-term disability plan or policy, "total and permanent disability" within the meaning of Code Section 22(e)(3).

(m) "*Employee*" means an employee of the Company or an Affiliate.

(n) "*Exchange Act*" means the Securities Exchange Act of 1934, as amended and in effect from time to time.

(o) "*Exchange Act Person*" means any natural person, entity or Group other than (i) the Company or any Affiliate; (ii) any employee benefit plan (or related trust) sponsored or maintained by the Company or any Affiliate; (iii) an underwriter temporarily holding securities in connection with a registered public offering of such securities; or (iv) an entity whose Voting Securities are beneficially owned by the beneficial owners of the Company's Voting Securities in substantially the same proportions as their beneficial ownership of the Company's Voting Securities.

(p) "*Exchange Program*" means a program under which (i) outstanding Options or SARs are surrendered or cancelled in exchange for Options or SARs of the same type (which may have lower or higher exercise prices and different terms), Awards of a different type and/or cash, or (ii) the exercise price of an outstanding Option or SAR is reduced.

(q) "*Fair Market Value*" of a Share means the fair market value of a Share determined as follows:

(1) If the Shares are readily tradable on an established securities market (as determined under Code Section 409A), then Fair Market Value will be the closing sales price for a Share on the principal securities market on which it trades on the date for which it is being determined, or if no sale of Shares occurred on that date, on the next preceding date on which a sale of Shares occurred, as reported in *The Wall Street Journal* or such other source as the Committee deems reliable; or

(2) If the Shares are not then readily tradable on an established securities market (as determined under Code Section 409A), then Fair Market Value will be determined by the Committee as the result of a reasonable application of a reasonable valuation method that satisfies the requirements of Code Section 409A.

(r) "*Full Value Award*" means an Award other than an Option Award or Stock Appreciation Right Award.

(s) "*Fully Diluted Shares*" as of a date means the number of Shares (i) outstanding and (ii) issuable upon exercise, conversion or settlement of outstanding options, warrants or other securities of the Company that are (directly or indirectly) convertible into, or exchangeable or exercisable for, Shares, in each case as of the close of business of the Company on such date, without regard to any vesting conditions or other limitations on the immediate ability to convert, exchange or exercise such rights. For purposes of determining the number of Fully Diluted Shares, if the number of Shares subject to a right to acquire Shares is variable, then the number of Shares issuable upon conversion, exchange or exercise of such right will equal the maximum number of shares that could be received under such right.

(t) "*Good Reason*" means what the term is expressly defined to mean in a then-effective written agreement (including an Agreement) between a Participant and the Company or any Affiliate or, in the absence of any such then-effective agreement or definition and subject to the last sentence of this definition, means with respect to any Participant any of the following events that has not been consented to by the Participant:

(1) A material reduction or diminution in the Participant's job responsibilities, authority or duties, or in the job responsibilities, authority or duties of the supervisor to whom the Participant is required to report, but a mere change in title alone or reassignment to a substantially similar position will not constitute Good Reason;

(2) A material reduction in the Participant's base compensation in the absence of a similar general reduction of the base compensation of similarly situated Service Providers; or

(3) The relocation of the Participant's primary work location, on a permanent basis, to a location that is more than 50 miles from the Participant's primary work location immediately prior to such change.

The foregoing events will only be considered "*Good Reason*" for a Participant to voluntarily resign from his or her position as Service Provider if, following the occurrence of one or more of the foregoing events, the Participant (i) provides written notice to the Company or its applicable Affiliate of the event(s) constituting Good Reason within 30 days after the first occurrence of such event(s), (ii) the Company or its applicable Affiliate fails to reasonably cure such event(s) within 30 days after receiving such notice, and (iii) the Participant's termination of his or her status as a Service Provider is effective not later than 30 days after the end of the period in which the event(s) may be cured.

(u) "*Grant Date*" means the date on which the Committee approves the grant of an Award under the Plan, or such later date as may be specified by the Committee on the date the Committee approves the Award.

(v) "*Group*" means two or more persons who act, or agree to act together, as a partnership, limited partnership, syndicate or other group for the purpose of acquiring, holding, voting or disposing of securities of the Company.

(w) "*Non-Employee Director*" means a member of the Board who is not an Employee.

(x) "*Option*" means a right granted under the Plan to purchase a specified number of Shares at a specified price. An "*Incentive Stock Option*" or "*ISO*" means any Option designated as such and granted in accordance with the requirements of Code Section 422. A "*Non-Qualified Stock Option*" or "*NQSO*" means an Option other than an Incentive Stock Option.

(y) "*Other Stock-Based Award*" means an Award described in Section 11 of this Plan.

(z) "*Parent*" means a "parent corporation," as defined in Code Section 424(e).

(aa) "*Participant*" means a person to whom a then-outstanding Award has been granted under the Plan.

(bb) "*Plan*" means this Sun BioPharma, Inc. Company 2016 Omnibus Incentive Plan, as amended and in effect from time to time.

(cc) "*Restricted Stock*" means Shares issued to a Participant that are subject to such restrictions on transfer, vesting conditions and other restrictions or limitations as may be set forth in this Plan and/or the applicable Agreement.

(dd) "*Retirement*" means any termination of a Participant's Service, other than for Cause, occurring at or after age 65, or at or after age 55 with 10 years or more of continuous service to the Company and its Affiliates.

(ee) "*Service*" means the provision of services by a Participant to the Company or any Affiliate in any Service Provider capacity. A Service Provider's Service shall be deemed to have terminated either upon an actual cessation of providing services to the Company or any Affiliate or upon the entity to which the Service Provider provides services ceasing to be an Affiliate. Except as otherwise provided in this Plan or any Agreement, Service shall not be deemed terminated in the case of (i) any approved leave of absence; (ii) transfers among the Company and any Affiliates in any Service Provider capacity; or (iii) any change in status so long as the individual remains in the service of the Company or any Affiliate in any Service Provider capacity.

(ff) "*Service Provider*" means an Employee, a Non-Employee Director, or any consultant or advisor who is a natural person and who provides services (other than in connection with (i) a capital-raising transaction or (ii) promoting or maintaining a market in Company securities) to the Company or any Affiliate.

(gg) "*Share*" means a share of Stock.

(hh) "*Stock*" means the Company's common stock, $.001 par value per share.

(ii) "*Stock Appreciation Right*" or "*SAR*" means the right to receive, in cash and/or Shares as determined by the Committee, an amount equal to the appreciation in value of a specified number of Shares between the Grant Date of the SAR and its exercise date.

(jj) "*Stock Unit*" means a right to receive, in cash and/or Shares as determined by the Committee, the Fair Market Value of a Share, subject to such restrictions on transfer, vesting conditions and other restrictions or limitations as may be set forth in this Plan and the applicable Agreement.

(kk) "*Subsidiary*" means a "subsidiary corporation," as defined in Code Section 424(f), of the Company.

(ll) "*Substitute Award*" means an Award granted upon the assumption of, or in substitution or exchange for, outstanding awards granted by a company or other entity acquired by the Company or any Affiliate or with which the Company or any Affiliate combines. The terms and conditions of a Substitute Award may vary from the terms and conditions set forth in the Plan to the extent that the Committee at the time of the grant may deem appropriate to conform, in whole or in part, to the provisions of the award in substitution for which it has been granted.

(mm) "*Voting Securities*" of an entity means the outstanding equity securities entitled to vote generally in the election of directors of such entity.

3. Administration of the Plan.

(a) Administration. The authority to control and manage the operations and administration of the Plan shall be vested in the Committee in accordance with this Section 3.

(b) Scope of Authority. Subject to the terms of the Plan, the Committee shall have the authority, in its discretion, to take such actions as it deems necessary or advisable to administer the Plan, including:

(1) determining the Service Providers to whom Awards will be granted, the timing of each such Award, the types of Awards and the number of Shares covered by each Award, the terms, conditions, performance criteria, restrictions and other provisions of Awards, and the manner in which Awards are paid or settled;

(2) cancelling or suspending an Award, accelerating the vesting or extending the exercise period of an Award, or otherwise amending the terms and conditions of any outstanding Award, subject to the requirements of Sections 6(b), 15(c) and 15(d);

(3) adopting sub-plans or special provisions applicable to Awards, establishing, amending or rescinding rules to administer the Plan, interpreting the Plan and any Award or Agreement, reconciling any inconsistency, correcting any defect or supplying an omission in the Plan or any Agreement, and making all other determinations necessary or desirable for the administration of the Plan;

(4) granting Substitute Awards under the Plan;

(5) taking such actions as are provided in Section 3(c) with respect to Awards to foreign Service Providers; and

(6) instituting an Exchange Program, the terms and conditions of which shall be determined by the Committee in its sole discretion.

Notwithstanding the foregoing, the Board shall perform the duties and have the responsibilities of the Committee with respect to Awards made to Non-Employee Directors.

(c) Awards to Foreign Service Providers. The Committee may grant Awards to Service Providers who are foreign nationals, who are located outside of the United States or who are not compensated from a payroll maintained in the United States, or who are otherwise subject to (or could cause the Company to be subject to) legal or regulatory requirements of countries outside of the United States, on such terms and conditions different from those specified in the Plan as may, in the judgment of the Committee, be necessary or desirable to comply with applicable foreign laws and regulatory requirements and to promote achievement of the purposes of the Plan. In connection therewith, the Committee may establish such sub-plans and modify exercise procedures and other Plan rules and procedures to the extent such actions are deemed necessary or desirable, and may take any other action that it deems advisable to obtain local regulatory approvals or to comply with any necessary local governmental regulatory exemptions.

(d) Acts of the Committee; Delegation. A majority of the members of the Committee shall constitute a quorum for any meeting of the Committee, and any act of a majority of the members present at any meeting at which a quorum is present or any act unanimously approved in writing by all members of the Committee shall be the act of the Committee. Any such action of the Committee shall be valid and effective even if the members of the Committee at the time of such action are later determined not to have satisfied all of the criteria for membership in clauses (i) and (ii) of Section 2(h). To the extent not inconsistent with applicable law or stock exchange rules, the Committee may delegate all or any portion of its authority under the Plan to any one or more of its members or, as to Awards to Participants who are not subject to Section 16 of the Exchange Act, to one or more directors or executive officers of the Company or to a committee of the Board comprised of one or more directors of the Company. The Committee may also delegate non-discretionary administrative responsibilities in connection with the Plan to such other persons as it deems advisable.

(e) Finality of Decisions. The Committee's interpretation of the Plan and of any Award or Agreement made under the Plan and all related decisions or resolutions of the Board or Committee shall be final and binding on all parties with an interest therein.

(f) Indemnification. Each person who is or has been a member of the Committee or of the Board, and any other person to whom the Committee delegates authority under the Plan, shall be indemnified by the Company, to the maximum extent permitted by law, against liabilities and expenses imposed upon or reasonably incurred by such person

in connection with or resulting from any claims against such person by reason of the performance of the individual's duties under the Plan. This right to indemnification is conditioned upon such person providing the Company an opportunity, at the Company's expense, to handle and defend the claims before such person undertakes to handle and defend them on such person's own behalf. The Company will not be required to indemnify any person for any amount paid in settlement of a claim unless the Company has first consented in writing to the settlement. The foregoing right of indemnification shall not be exclusive of any other rights of indemnification to which such person or persons may be entitled under the Company's Certificate of Incorporation or Bylaws, as a matter of law, or otherwise.

4. Shares Available Under the Plan.

(a) Maximum Shares Available. Subject to Section 4(b) and Section 4(d) and to adjustment as provided in Section 12(a), the number of Shares that may be the subject of Awards and issued under the Plan shall be 2,800,000.* Shares issued under the Plan may come from authorized and unissued shares or treasury shares.

(b) Effect of Forfeitures and Other Actions. Any Shares subject to an Award that expires, is cancelled or forfeited or is settled for cash shall, to the extent of such cancellation, forfeiture, expiration or cash settlement, again become available for Awards under this Plan, and the share reserve under Section 4(a) shall be correspondingly replenished as provided in Section 4(c) below. The following Shares shall not, however, again become available for Awards or replenish the share reserve under Section 4(a): (i) Shares tendered (either actually or by attestation) by the Participant or withheld by the Company in payment of the purchase price of a stock option issued under this Plan, (ii) Shares tendered (either actually or by attestation) by the Participant or withheld by the Company to satisfy any tax withholding obligation with respect to the exercise of a stock option or stock appreciation right award under this Plan, (iii) Shares repurchased by the Company with proceeds received from the exercise of a stock option issued under this Plan, and (iv) Shares subject to a stock appreciation right award issued under this Plan that are not issued in connection with the stock settlement of that award upon its exercise.

(c) Counting Shares Again Available. Each Share that again becomes available for Awards as provided in Section 4(b) shall correspondingly increase the share reserve under Section 4(a), with such increase based on the same share ratio by which the applicable share reserve was decreased upon the grant of the applicable award.

(d) Automatic Share Reserve Increase. The share reserve specified in Section 4(a) will be increased on January 1 of each year commencing in January 1, 2021 and ending on (and including) January 1, 2025 in an amount equal to the lesser of (i) 20% of the total number of Fully Diluted Shares as of December 31 of the immediately preceding calendar year and (ii) such lower number of Shares determined by the Board or its Committee in advance of January 1 of each year.

(e) Effect of Plans Operated by Acquired Companies. If a company acquired by the Company or any Subsidiary or with which the Company or any Subsidiary combines has shares available under a pre-existing plan approved by stockholders and not adopted in contemplation of such acquisition or combination, the shares available for grant pursuant to the terms of such pre-existing plan (as adjusted, to the extent appropriate, using the exchange ratio or other adjustment or valuation ratio or formula used in such acquisition or combination to determine the consideration payable to the holders of common stock of the entities party to such acquisition or combination) may be used for Awards under the Plan and shall supplement the Share reserve under Section 4(a). Awards using such available shares shall not be made after the date awards or grants could have been made under the terms of the pre-existing plan absent the acquisition or combination and shall only be made to individuals who were not Employees or Non-Employee Directors prior to such acquisition or combination.

(f) No Fractional Shares. Unless otherwise determined by the Committee, the number of Shares subject to an Award shall always be a whole number. No fractional Shares may be issued under the Plan, but the Committee may, in its discretion, pay cash in lieu of any fractional Share in settlement of an Award.

5. Eligibility. Participation in the Plan is limited to Service Providers. Incentive Stock Options may only be granted to Employees.

* Share amount reflects an increase of 1,300,000 shares.

6. General Terms of Awards.

(a) Award Agreement. Except for any Award that involves only the immediate issuance of unrestricted Shares, each Award shall be evidenced by an Agreement setting forth the amount of the Award together with such other terms and conditions applicable to the Award (and not inconsistent with the Plan) as determined by the Committee. If an Agreement calls for acceptance by the Participant, the Award evidenced by the Agreement will not become effective unless acceptance of the Agreement in a manner permitted by the Committee is received by the Company within 30 days of the date the Agreement is delivered to the Participant. An Award to a Participant may be made singly or in combination with any form of Award. Two types of Awards may be made in tandem with each other such that the exercise of one type of Award with respect to a number of Shares reduces the number of Shares subject to the related Award by at least an equal amount.

(b) Vesting and Term. Each Agreement shall set forth the period until the applicable Award is scheduled to expire (which shall not be more than ten years from the Grant Date), and any applicable performance period. The Committee may provide in an Agreement for such vesting conditions and timing as it may determine.

(c) Transferability. Except as provided in this Section 6(c), (i) during the lifetime of a Participant, only the Participant or the Participant's guardian or legal representative may exercise an Option or SAR, or receive payment with respect to any other Award; and (ii) no Award may be sold, assigned, transferred, exchanged or encumbered, voluntarily or involuntarily, other than by will or the laws of descent and distribution. Any attempted transfer in violation of this Section 6(c) shall be of no effect. The Committee may, however, provide in an Agreement or otherwise that an Award (other than an Incentive Stock Option) may be transferred pursuant to a domestic relations order or may be transferable by gift to any "family member" (as defined in General Instruction A(5) to Form S-8 under the Securities Act of 1933) of the Participant. Any Award held by a transferee shall continue to be subject to the same terms and conditions that were applicable to that Award immediately before the transfer thereof. For purposes of any provision of the Plan relating to notice to a Participant or to acceleration or termination of an Award upon the death or termination of Service of a Participant, the references to "*Participant*" shall mean the original grantee of an Award and not any transferee.

(d) Designation of Beneficiary. To the extent permitted by the Committee, a Participant may designate a beneficiary or beneficiaries to exercise any Award or receive a payment under any Award that is exercisable or payable on or after the Participant's death. Any such designation shall be on a form approved by the Company and shall be effective upon its receipt by the Company.

(e) Termination of Service. Unless otherwise provided in an applicable Agreement or another then-effective written agreement between a Participant and the Company, and subject to Section 12 of this Plan, if a Participant's Service with the Company and all of its Affiliates terminates, the following provisions shall apply (in all cases subject to the scheduled expiration of an Option or SAR Award, as applicable):

(1) Upon termination of Service for Cause, or upon conduct during a post-termination exercise period that would constitute Cause, all vested and unexercised Option and SAR Awards and all unvested portions of any other outstanding Awards shall be immediately forfeited without consideration.

(2) Upon termination of Service for any reason other than Cause, all unvested and unexercisable portions of any outstanding Awards shall be immediately forfeited without consideration.

(3) Upon termination of Service for any reason other than Cause, death or Disability, the currently vested and exercisable portions of Option and SAR Awards may be exercised for a period of ninety (90) days after the date of such termination. However, if a Participant thereafter dies during such ninety (90) day period, the vested and exercisable portions of the Option and SAR Awards may be exercised for a period of one year after the date of such termination.

(4) Upon termination of Service due to death or Disability, the currently vested and exercisable portions of Option and SAR Awards may be exercised for a period of one year after the date of such termination.

(f) Rights as Stockholder. No Participant shall have any rights as a stockholder with respect to any Shares covered by an Award unless and until the date the Participant becomes the holder of record of the Shares, if any, to which the Award relates.

(g) Performance-Based Awards. Any Award may be granted as a performance-based Award if the Committee establishes one or more measures of corporate, business unit or individual performance which must be attained, and the performance period over which the specified performance is to be attained, as a condition to the grant, vesting, exercisability, lapse of restrictions and/or settlement in cash or Shares of such Award. In connection with any such Award, the Committee shall determine the extent to which performance measures have been attained and other applicable terms and conditions have been satisfied, and the degree to which vesting, exercisability, lapse of restrictions and/or settlement of such Award has been earned. The Committee shall also have the authority to provide, in an Agreement or otherwise, for the modification of a performance period and/or an adjustment or waiver of the achievement of performance measures upon the occurrence of certain unusual or nonrecurring events, which may include a Change of Control, a Corporate Transaction, a recapitalization, a change in the accounting practices of the Company, or the Participant's death or Disability.

(h) Dividends and Dividend Equivalents. No dividends, dividend equivalents or distributions will be paid with respect to Shares subject to an Option or SAR Award. Any dividends or distributions paid with respect to Shares that are subject to the unvested portion of a Restricted Stock Award will be subject to the same restrictions as the Shares to which such dividends or distributions relate, except for regular cash dividends on Shares subject to the unvested portion of a Restricted Stock Award that is subject only to service-based vesting conditions. In its discretion, the Committee may provide in an Award Agreement for a Stock Unit Award or an Other Stock-Based Award that the Participant will be entitled to receive dividend equivalents on the units or other Share equivalents subject to the Award based on dividends actually declared and paid on outstanding Shares. The terms of any dividend equivalents will be as set forth in the applicable Agreement, including the time and form of payment and whether such dividend equivalents will be credited with interest or deemed to be reinvested in additional units or Share equivalents. Dividend equivalents paid with respect to units or Share equivalents that are subject to the unvested portion of a Stock Unit Award or an Other Stock-Based Award whose vesting is subject to the satisfaction of specified performance objectives will be subject to the same restrictions as the units or Share equivalents to which such dividend equivalents relate. The Committee may, in its discretion, provide in an Agreement for restrictions on dividends and dividend equivalents in addition to those specified in this Section 6(h). Any Shares issued or issuable during the term of this Plan as the result of the reinvestment of dividends or the deemed reinvestment of dividend equivalents in connection with an Award shall be counted against, and replenish upon any subsequent forfeiture, the Plan's share reserve as provided in Section 4.

7. Stock Option Awards.

(a) Type and Exercise Price. The Agreement pursuant to which an Option Award is granted shall specify whether the Option is an Incentive Stock Option or a Non-Qualified Stock Option. The exercise price at which each Share subject to an Option Award may be purchased shall be determined by the Committee and set forth in the Agreement, and shall not be less than the Fair Market Value of a Share on the Grant Date, except in the case of Substitute Awards (to the extent consistent with Code Section 409A and, in the case of Incentive Stock Options, Code Section 424).

(b) Payment of Exercise Price. The purchase price of the Shares with respect to which an Option Award is exercised shall be payable in full at the time of exercise. The purchase price may be paid in cash or in such other manner as the Committee may permit, including by payment under a broker-assisted sale and remittance program, by withholding Shares otherwise issuable to the Participant upon exercise of the Option or by delivery to the Company of Shares (by actual delivery or attestation) already owned by the Participant (in each case, such Shares having a Fair Market Value as of the date the Option is exercised equal to the purchase price of the Shares being purchased).

(c) Exercisability and Expiration. Each Option Award shall be exercisable in whole or in part on the terms provided in the Agreement. No Option Award shall be exercisable at any time after its scheduled expiration. When an Option Award is no longer exercisable, it shall be deemed to have terminated.

(d) Incentive Stock Options.

(1) An Option Award will constitute an Incentive Stock Option Award only if the Participant receiving the Option Award is an Employee, and only to the extent that (i) it is so designated in the applicable Agreement and (ii) the aggregate Fair Market Value (determined as of the Option Award's Grant Date) of the Shares with respect to which Incentive Stock Options held by the Participant first become exercisable in any calendar year (under the Plan and all other plans of the Company and its Affiliates) does not exceed $100,000 or such other amount specified by the Code. To the extent an Option granted to a Participant exceeds this limit, the Option shall be treated as a Non-Qualified Stock Option. The maximum number of Shares that may be issued upon the exercise of Incentive Stock Options shall equal the maximum number of Shares that may be the subject of Awards and issued under the Plan as provided in Section 4(a).

(2) No Participant may receive an Incentive Stock Option Award under the Plan if, immediately after the grant of such Award, the Participant would own (after application of the rules contained in Code Section 424(d)) Shares possessing more than 10% of the total combined voting power of all classes of stock of the Company or an Affiliate, unless (i) the per Share exercise price for such Award is at least 110% of the Fair Market Value of a Share on the Grant Date and (ii) such Award will expire no later than five years after its Grant Date.

(3) For purposes of continued Service by a Participant who has been granted an Incentive Stock Option Award, no approved leave of absence may exceed three months unless reemployment upon expiration of such leave is provided by statute or contract. If reemployment is not so provided, then on the date six months following the first day of such leave, any Incentive Stock Option held by the Participant shall cease to be treated as an Incentive Stock Option and shall be treated for tax purposes as a Non-Qualified Stock Option.

(4) If an Incentive Stock Option Award is exercised after the expiration of the exercise periods that apply for purposes of Code Section 422, such Option shall thereafter be treated as a Non-Qualified Stock Option.

(5) The Agreement covering an Incentive Stock Option Award shall contain such other terms and provisions that the Committee determines necessary to qualify the Option Award as an Incentive Stock Option Award.

8. Stock Appreciation Right Awards.

(a) Nature of Award. An Award of Stock Appreciation Rights shall be subject to such terms and conditions as are determined by the Committee, and shall provide a Participant the right to receive upon exercise of the SAR Award all or a portion of the excess of (i) the Fair Market Value as of the date of exercise of the SAR Award of the number of Shares as to which the SAR Award is being exercised, over (ii) the aggregate exercise price for such number of Shares. The per Share exercise price for any SAR Award shall be determined by the Committee and set forth in the applicable Agreement, and shall not be less than the Fair Market Value of a Share on the Grant Date, except in the case of Substitute Awards (to the extent consistent with Code Section 409A).

(b) Exercise of SAR. Each SAR Award may be exercisable in whole or in part at the times, on the terms and in the manner provided in the Agreement. No SAR Award shall be exercisable at any time after its scheduled expiration. When a SAR Award is no longer exercisable, it shall be deemed to have terminated. Upon exercise of a SAR Award, payment to the Participant shall be made at such time or times as shall be provided in the Agreement in the form of cash, Shares or a combination of cash and Shares as determined by the Committee. The Agreement may provide for a limitation upon the amount or percentage of the total appreciation on which payment (whether in cash and/or Shares) may be made in the event of the exercise of a SAR Award.

9. Restricted Stock Awards.

(a) Vesting and Consideration. Shares subject to a Restricted Stock Award shall be subject to vesting and the lapse of applicable restrictions based on such conditions or factors and occurring over such period of time as the Committee may determine in its discretion. The Committee may provide whether any consideration other than Services must be received by the Company or any Affiliate as a condition precedent to the grant of a Restricted Stock Award, and may correspondingly provide for Company reacquisition or repurchase rights if such additional consideration has been required and some or all of a Restricted Stock Award does not vest.

(b) Shares Subject to Restricted Stock Awards. Unvested Shares subject to a Restricted Stock Award shall be evidenced by a book-entry in the name of the Participant with the Company's transfer agent or by one or more Stock certificates issued in the name of the Participant. Any such Stock certificate shall be deposited with the Company or its designee, together with an assignment separate from the certificate, in blank, signed by the Participant, and bear an appropriate legend referring to the restricted nature of the Restricted Stock evidenced thereby. Any book-entry shall be subject to comparable restrictions and corresponding stop transfer instructions. Upon the vesting of Shares of Restricted Stock, and the Company's determination that any necessary conditions precedent to the release of vested Shares (such as satisfaction of tax withholding obligations and compliance with applicable legal requirements) have been satisfied, such vested Shares shall be made available to the Participant in such manner as may be prescribed or permitted by the Committee. Except as otherwise provided in the Plan or an applicable Agreement, a Participant with a Restricted Stock Award shall have all the rights of a shareholder, including the right to vote the Shares of Restricted Stock.

10. Stock Unit Awards.

(a) Vesting and Consideration. A Stock Unit Award shall be subject to vesting and the lapse of applicable restrictions based on such conditions or factors and occurring over such period of time as the Committee may determine in its discretion. If vesting of a Stock Unit Award is conditioned on the achievement of specified performance goals, the extent to which they are achieved over the specified performance period shall determine the number of Stock Units that will be earned and eligible to vest, which may be greater or less than the target number of Stock Units stated in the Agreement. The Committee may provide whether any consideration other than Services must be received by the Company or any Affiliate as a condition precedent to the settlement of a Stock Unit Award.

(b) Payment of Award. Following the vesting of a Stock Unit Award, and the Company's determination that any necessary conditions precedent to the settlement of the Award (such as satisfaction of tax withholding obligations and compliance with applicable legal requirements) have been satisfied, settlement of the Award and payment to the Participant shall be made at such time or times in the form of cash, Shares (which may themselves be considered Restricted Stock under the Plan) or a combination of cash and Shares as determined by the Committee.

11. Other Stock-Based Awards. The Committee may from time to time grant Shares and other Awards that are valued by reference to and/or payable in whole or in part in Shares under the Plan. The Committee shall determine the terms and conditions of such Awards, which shall be consistent with the terms and purposes of the Plan. The Committee may direct the Company to issue Shares subject to restrictive legends and/or stop transfer instructions that are consistent with the terms and conditions of the Award to which the Shares relate.

12. Changes in Capitalization, Corporate Transactions, Change in Control.

(a) Adjustments for Changes in Capitalization. In the event of any equity restructuring (within the meaning of FASB ASC Topic 718) that causes the per share value of Shares to change, such as a stock dividend, stock split, spinoff, rights offering or recapitalization through an extraordinary dividend, the Committee shall make such adjustments as it deems equitable and appropriate to (i) the aggregate number and kind of Shares or other securities issued or reserved for issuance under the Plan, (ii) the number and kind of Shares or other securities subject to outstanding Awards, (iii) the exercise price of outstanding Options and SARs, and (iv) any maximum limitations prescribed by the Plan with respect to certain types of Awards or the grants to individuals of certain types of Awards. In the event of any other change in corporate capitalization, including a merger, consolidation, reorganization, or partial or complete liquidation of the Company, such equitable adjustments described in the foregoing sentence may be made as determined to be appropriate and equitable by the Committee to prevent dilution or enlargement of rights of Participants. In either case, any such adjustment shall be conclusive and binding for all purposes of the Plan. No adjustment shall be made pursuant to this Section 12(a) in connection with the conversion of any convertible securities of the Company, or in a manner that would cause Incentive Stock Options to violate Section 422(b) of the Code or cause an Award to be subject to adverse tax consequences under Section 409A of the Code.

(b) Corporate Transactions. Unless otherwise provided in an applicable Agreement, the following provisions shall apply to outstanding Awards in the event of a Change in Control that involves a Corporate Transaction.

(1) *Continuation, Assumption or Replacement of Awards*. In the event of a Corporate Transaction, then the surviving or successor entity (or its Parent) may continue, assume or replace Awards outstanding as of the date of the Corporate Transaction (with such adjustments as may be required or permitted by Section 12(a)), and such Awards or replacements therefor shall remain outstanding and be governed by their respective terms, subject to Section 12(b)(4) below. A surviving or successor entity may elect to continue, assume or replace only some Awards or portions of Awards. For purposes of this Section 12(b)(1), an Award shall be considered assumed or replaced if, in connection with the Corporate Transaction and in a manner consistent with Code Sections 409A and 424, either (i) the contractual obligations represented by the Award are expressly assumed by the surviving or successor entity (or its Parent) with appropriate adjustments to the number and type of securities subject to the Award and the exercise price thereof that preserves the intrinsic value of the Award existing at the time of the Corporate Transaction, or (ii) the Participant has received a comparable equity-based award that preserves the intrinsic value of the Award existing at the time of the Corporate Transaction and contains terms and conditions that are substantially similar to those of the Award.

(2) *Acceleration*. If and to the extent that outstanding Awards under the Plan are not continued, assumed or replaced in connection with a Corporate Transaction, then (i) all outstanding Option and SAR Awards shall become fully vested and exercisable for such period of time prior to the effective time of the Corporate Transaction as is deemed fair and equitable by the Committee, and shall terminate at the effective time of the Corporate Transaction. The Committee shall provide written notice of the period of accelerated exercisability of Option and SAR Awards to all affected Participants. The exercise of any Option or SAR Award whose exercisability is accelerated as provided in this Section 12(b)(2) shall be conditioned upon the consummation of the Corporate Transaction and shall be effective only immediately before such consummation.

(3) *Payment for Awards*. If and to the extent that outstanding Awards under the Plan are not continued, assumed or replaced in connection with a Corporate Transaction, then the Committee may provide that some or all of such outstanding Awards shall be canceled at or immediately prior to the effective time of the Corporate Transaction in exchange for payments to the holders as provided in this Section 12(b)(3). The Committee will not be required to treat all Awards similarly for purposes of this Section 12(b)(3). The payment for any Award surrendered shall be in an amount equal to the difference, if any, between (i) the fair market value (as determined in good faith by the Committee) of the consideration that would otherwise be received in the Corporate Transaction for the number of Shares subject to the Award, and (ii) the aggregate exercise price (if any) for the Shares subject to such Award. If the amount determined pursuant to clause (i) of the preceding sentence is less than or equal to the amount determined pursuant to clause (ii) of the preceding sentence with respect to any Award, such Award may be canceled pursuant to this Section 12(b)(3) without payment of any kind to the affected Participant. With respect to an Award whose vesting is subject to the satisfaction of specified performance goals, the number of Shares subject to such an Award for purposes of this Section 12(b)(3) shall be the number of Shares as to which the Award would have been deemed "fully vested" for purposes of Section 12(b)(2). Payment of any amount under this Section 12(b)(3) shall be made in such form, on such terms and subject to such conditions as the Committee determines in its discretion, which may or may not be the same as the form, terms and conditions applicable to payments to the Company's stockholders in connection with the Corporate Transaction, and may, in the Committee's discretion, include subjecting such payments to vesting conditions comparable to those of the Award surrendered, subjecting such payments to escrow or holdback terms comparable to those imposed upon the Company's stockholders under the Corporate Transaction, or calculating and paying the present value of payments that would otherwise be subject to escrow or holdback terms.

(4) *Termination After a Corporate Transaction*. If and to the extent that Awards are continued, assumed or replaced under the circumstances described in Section 12(b)(1), and if within twelve months after the Corporate Transaction a Participant experiences an involuntary termination of Service for reasons other than Cause, or voluntarily terminates his or her Service for Good Reason, then (i) outstanding Options and SARs issued to the Participant that are not yet fully exercisable shall immediately become exercisable in full and shall remain exercisable for one year following the Participant's termination of employment, and (ii) any Full Value Awards that are not yet fully vested shall immediately vest in full (at an assumed target level of performance if vesting of the Award is subject to the satisfaction of specified performance goals).

(c) Other Change in Control. In the event of a Change in Control that does not involve a Corporate Transaction, the Committee may, in its discretion, take such action as it deems appropriate with respect to outstanding Awards, which may include: (i) providing for the cancellation of any Award in exchange for payments in a manner similar to that provided in Section 12(b)(3) or (ii) making such adjustments to the Awards then outstanding as the Committee deems appropriate to reflect such Change in Control, which may include the acceleration of vesting in full or in part. The Committee will not be required to treat all Awards similarly in such circumstances and may include such further provisions and limitations in any Award Agreement as it may deem equitable and in the best interests of the Company.

(d) Dissolution or Liquidation. Unless otherwise provided in an applicable Agreement, in the event of a proposed dissolution or liquidation of the Company, the Committee will notify each Participant as soon as practicable prior to the effective date of such proposed transaction. An Award will terminate immediately prior to the consummation of such proposed action.

13. Plan Participation and Service Provider Status. Status as a Service Provider shall not be construed as a commitment that any Award will be made under the Plan to that Service Provider or to eligible Service Providers generally. Nothing in the Plan or in any Agreement or related documents shall confer upon any Service Provider or Participant any right to continued Service with the Company or any Affiliate, nor shall it interfere with or limit in any way any right of the Company or any Affiliate to terminate the person's Service at any time with or without Cause or change such person's compensation, other benefits, job responsibilities or title.

14. Tax Withholding. The Company or any Affiliate, as applicable, shall have the right to (i) withhold from any cash payment under the Plan or any other compensation owed to a Participant an amount sufficient to cover any required withholding taxes related to the grant, vesting, exercise or settlement of an Award, and (ii) require a Participant or other person receiving Shares under the Plan to pay a cash amount sufficient to cover any required withholding taxes before actual receipt of those Shares. In lieu of all or any part of a cash payment from a person receiving Shares under the Plan, the Committee may permit the individual to cover all or any part of the required tax withholdings (but not to exceed the minimum statutory amount required to be withheld if such limitation is necessary to avoid an adverse accounting impact) by authorizing the Company to withhold a number of the Shares that would otherwise be delivered to the Participant, or by delivering to the Company Shares already owned by the Participant, with the Shares so withheld or delivered having a Fair Market Value on the date the taxes are required to be withheld equal to the amount of taxes to be withheld.

15. Effective Date, Duration, Amendment and Termination of the Plan.

(a) Effective Date. The Plan shall become effective on the date it is approved by the Company's shareholders, which shall be considered the date of its adoption for purposes of Treasury Regulation §1.422-2(b)(2)(i). No Awards shall be made under the Plan prior to its effective date. If the Company's shareholders fail to approve the Plan by August 31, 2016, the Plan will be of no further force or effect.

(b) Duration of the Plan. The Plan shall remain in effect until all Shares subject to it are distributed, all Awards have expired or terminated, the Plan is terminated pursuant to Section 15(c) or the tenth anniversary of the effective date of the Plan, whichever occurs first (the "*Termination Date*"). Awards made before the Termination Date shall continue to be outstanding in accordance with their terms and the terms of the Plan unless otherwise provided in the applicable Agreements.

(c) Amendment and Termination of the Plan. The Board may at any time terminate, suspend or amend the Plan. The Company shall submit any amendment of the Plan to its stockholders for approval only to the extent required by applicable laws or regulations or the rules of any securities exchange on which the Shares may then be listed. No termination, suspension, or amendment of the Plan may materially impair the rights of any Participant under a previously granted Award without the Participant's consent, unless such action is necessary to comply with applicable law or stock exchange rules.

(d) Amendment of Awards. Subject to Section 15(e), the Committee may unilaterally amend the terms of any Agreement evidencing an Award previously granted, except that no such amendment may materially impair the rights of any Participant under the applicable Award without the Participant's consent, unless such amendment is necessary to comply with applicable law or stock exchange rules or any compensation recovery policy as provided in Section 17(i).

(e) No Option or SAR Repricing. Except as provided in Section 12(a), no Option or Stock Appreciation Right Award granted under the Plan may be (i) amended to decrease the exercise price thereof, (ii) cancelled in conjunction with the grant of any new Option or Stock Appreciation Right Award with a lower exercise price, (iii) cancelled in exchange for cash, other property or the grant of any Full Value Award at a time when the per share exercise price of the Option or Stock Appreciation Right Award is greater than the current Fair Market Value of a Share, or (iv) otherwise subject to any action that would be treated under accounting rules as a "repricing" of such Option or Stock Appreciation Right Award, unless such action is first approved by the Company's stockholders.

16. Substitute Awards. The Committee may also grant Awards under the Plan in substitution for, or in connection with the assumption of, existing awards granted or issued by another corporation and assumed or otherwise agreed to be provided for by the Company pursuant to or by reason of a transaction involving a merger, consolidation, acquisition of property or stock, separation, reorganization or liquidation to which the Company or an Affiliate is a party. The terms and conditions of the Substitute Awards may vary from the terms and conditions set forth in the Plan to the extent that the Committee at the time of the grant may deem appropriate to conform, in whole or in part, to the provisions of the awards in substitution for which they are granted.

17. Other Provisions.

(a) Unfunded Plan. The Plan shall be unfunded and the Company shall not be required to segregate any assets that may at any time be represented by Awards under the Plan. Neither the Company, its Affiliates, the Committee, nor the Board shall be deemed to be a trustee of any amounts to be paid under the Plan nor shall anything contained in the Plan or any action taken pursuant to its provisions create or be construed to create a fiduciary relationship between the Company and/or its Affiliates, and a Participant. To the extent any person has or acquires a right to receive a payment in connection with an Award under the Plan, this right shall be no greater than the right of an unsecured general creditor of the Company.

(b) Limits of Liability. Except as may be required by law, neither the Company nor any member of the Board or of the Committee, nor any other person participating (including participation pursuant to a delegation of authority under Section 3(d) of the Plan) in any determination of any question under the Plan, or in the interpretation, administration or application of the Plan, shall have any liability to any party for any action taken, or not taken, in good faith under the Plan.

(c) Compliance with Applicable Legal Requirements and Company Policies. No Shares distributable pursuant to the Plan shall be issued and delivered unless and until the issuance of the Shares complies with all applicable legal requirements, including compliance with the provisions of applicable state and federal securities laws, and the requirements of any securities exchanges on which the Company's Shares may, at the time, be listed. During any period in which the offering and issuance of Shares under the Plan is not registered under federal or state securities laws, Participants shall acknowledge that they are acquiring Shares under the Plan for investment purposes and not for resale, and that Shares may not be transferred except pursuant to an effective registration statement under, or an exemption from the registration requirements of, such securities laws. Any stock certificate or book-entry evidencing Shares issued under the Plan that are subject to securities law restrictions shall bear or be accompanied by an appropriate restrictive legend or stop transfer instruction. Notwithstanding any other provision of this Plan, the acquisition, holding or disposition of Shares acquired pursuant to the Plan shall in all events be subject to compliance with applicable Company policies, including those relating to insider trading, pledging or hedging transactions and minimum holding periods.

(d) Other Benefit and Compensation Programs. Payments and other benefits received by a Participant under an Award made pursuant to the Plan shall not be deemed a part of a Participant's regular, recurring compensation for purposes of the termination, indemnity or severance pay laws of any country and shall not be included in, nor have any effect on, the determination of benefits under any other employee benefit plan, contract or similar arrangement provided by the Company or an Affiliate unless expressly so provided by such other plan, contract or arrangement, or unless the Committee expressly determines that an Award or portion of an Award should be included to accurately reflect competitive compensation practices or to recognize that an Award has been made in lieu of a portion of competitive cash compensation.

(e) Governing Law. To the extent that federal laws do not otherwise control, the Plan and all determinations made and actions taken pursuant to the Plan shall be governed by the laws of the State of Delaware without regard to its conflicts-of-law principles and shall be construed accordingly.

(f) Severability. If any provision of the Plan shall be held illegal or invalid for any reason, the illegality or invalidity shall not affect the remaining parts of the Plan, and the Plan shall be construed and enforced as if the illegal or invalid provision had not been included.

(g) Code Section 409A. It is intended that (i) all Awards of Options, SARs and Restricted Stock under the Plan will not provide for the deferral of compensation within the meaning of Code Section 409A and thereby be exempt from Code Section 409A, and (ii) all other Awards under the Plan will either not provide for the deferral of compensation within the meaning of Code Section 409A, or will comply with the requirements of Code Section 409A, and Awards shall be structured and the Plan administered and interpreted in accordance with this intent. The Plan and any Agreement may be unilaterally amended by the Company in any manner deemed necessary or advisable by the Committee or Board in order to maintain such exemption from or compliance with Code Section 409A, and any such amendment shall conclusively be presumed to be necessary to comply with applicable law. Notwithstanding anything to the contrary in the Plan or any Agreement, with respect to any Award that constitutes a deferral of compensation subject to Code Section 409A:

(1) If any amount is payable under such Award upon a termination of Service, a termination of Service will be deemed to have occurred only at such time as the Participant has experienced a "separation from service" as such term is defined for purposes of Code Section 409A;

(2) If any amount shall be payable with respect to any such Award as a result of a Participant's "separation from service" at such time as the Participant is a "specified employee" within the meaning of Code Section 409A, then no payment shall be made, except as permitted under Code Section 409A, prior to the first business day after the earlier of (i) the date that is six months after the Participant's separation from service or (ii) the Participant's death. Unless the Committee has adopted a specified employee identification policy as contemplated by Code Section 409A, specified employees will be identified in accordance with the default provisions specified under Code Section 409A.

None of the Company, the Board, the Committee nor any other person involved with the administration of this Plan shall (i) in any way be responsible for ensuring the exemption of any Award from, or compliance by any Award with, the requirements of Code Section 409A, (ii) have any obligation to design or administer the Plan or Awards granted thereunder in a manner that minimizes a Participant's tax liabilities, including the avoidance of any additional tax liabilities under Code Section 409A, and (iii) shall have any liability to any Participant for any such tax liabilities.

(h) Rule 16b-3. It is intended that the Plan and all Awards granted pursuant to it shall be administered by the Committee so as to permit the Plan and Awards to comply with Exchange Act Rule 16b-3. If any provision of the Plan or of any Award would otherwise frustrate or conflict with the intent expressed in this Section 17(h), that provision to the extent possible shall be interpreted and deemed amended in the manner determined by the Committee so as to avoid the conflict. To the extent of any remaining irreconcilable conflict with this intent, the provision shall be deemed void as applied to Participants subject to Section 16 of the Exchange Act to the extent permitted by law and in the manner deemed advisable by the Committee.

(i) Forfeiture and Compensation Recovery.

(1) The Committee may specify in an Agreement that the Participant's rights, payments, and benefits with respect to an Award will be subject to reduction, cancellation, forfeiture or recovery by the Company upon the occurrence of certain specified events, in addition to any otherwise applicable vesting or performance conditions of an Award. Such events may include termination of Service for Cause; violation of any material Company or Affiliate policy; breach of noncompetition, non-solicitation or confidentiality provisions that apply to the Participant; a determination that the payment of the Award was based on an incorrect determination that financial or other criteria were met or other conduct by the Participant that is detrimental to the business or reputation of the Company or its Affiliates.

(2) Awards and any compensation associated therewith may be made subject to forfeiture, recovery by the Company or other action pursuant to any compensation recovery policy adopted by the Board or the Committee at any time, including in response to the requirements of Section 10D of the Exchange Act and any implementing rules and regulations thereunder, or as otherwise required by law. Any Agreement may be unilaterally amended by the Committee to comply with any such compensation recovery policy.

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, 2019

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 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):

	Accelerated filer ☐
Large accelerated filer ☐	Smaller reporting company ☒
Non-accelerated filer ☐	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 30, 2019 was $9,495,538.

As of March 20, 2020, there were 6,631,308 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 2020 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 (the "Exchange Act").

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;
- progress and success of our Phase 1 clinical trial;
- our ability to demonstrate safety and effectiveness of our product candidate;
- our ability to obtain regulatory approvals for our product candidate in the United States, the European Union or other international markets;
- the market acceptance and future sales of our product candidate;
- the cost and delays in product development that may result from changes in regulatory oversight applicable to our product candidate;
- the rate of progress in establishing reimbursement arrangement with third-party payors;
- the effect of competing technological and market developments;
- the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims; and
- other risk factors included under the caption "Risk Factors" starting on page 22 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"). Sun BioPharma, Inc. was incorporated under the laws of the State of Delaware in 2011. The term "common stock" refers to our common stock, par value $0.001 per share.

Overview

Our product candidate, SBP-101, is a proprietary polyamine analogue designed to induce polyamine metabolic inhibition ("PMI"), a metabolic pathway of critical importance in multiple tumor types. Sun BioPharma initially licensed SBP-101 from the University of Florida Research Foundation ("UFRF") in 2011. SBP-101 has been shown to be an effective tumor growth inhibitor in preclinical studies of human pancreatic cancer models, demonstrating superior and complementary activity to existing U.S. Food and Drug Administration ("FDA")-approved chemotherapy agents. SBP-101 has demonstrated encouraging activity against primary and metastatic disease in clinical trials of patients with pancreatic cancer. The safety results and PMI profile demonstrated in our completed first-in-human safety study provide support for the study of SBP-101 in combination with current standard pancreatic cancer treatment in patients previously untreated for metastatic pancreatic cancer.

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. We believe that SBP-101, if successfully developed, may represent a novel approach that effectively treats pancreatic cancer and could become a dominant product in that market. Only three first-line treatment combinations, a single maintenance treatment for a subset (3-7%) of patients, and one second-line drug have been approved by the FDA for pancreatic cancer in the last 25 years.

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 have 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, and 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 change 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, SD 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 a first line, combination chemotherapy in pancreatic cancer patients.

We began enrolling patients in our current first-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 six study sites (four in Australia and two in the United States). In the Phase 1a portion of this trial, we enrolled three cohorts of four to nine patients with increased dosage levels of SBP-101 administered in the second and third cohorts. We completed enrollment in the first three cohorts of Phase 1a in the fourth quarter of 2019, and, based on preliminary safety findings, a 4th cohort began enrollment in January 2020. We completed enrollment in this 4th cohort in February 2020. Demonstration of adequate safety in Phase 1a has enabled Phase 1b exploration of efficacy, in which we plan to enroll a maximum 36 patients using the recommended dosage regimen determined in Phase 1a. We began enrolling in this expansion phase in February of 2020. Additional funding will be required to complete the Phase 1b clinical trial and to plan a randomized phase 2 study. As of December 31, 2019, preliminary efficacy results from evaluable patients in cohorts 2 and 3 (N=13) showed manageable toxicity, an objective response rate of 62% and a disease control rate of 85%, with several patients still ongoing. Interim results from the Phase 1b expansion are expected to become available in the second half of 2020.

Through December 31, 2019, 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 investigational new drug ("IND") application to the FDA (May 18, 2015);
- received 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 monotherapy safety study of SBP-101in the treatment of patients with metastatic pancreatic ductal adenocarcinoma;
- completed synthetic process improvement measures expected to be scalable for commercial use and secured intellectual property on this process; and
- 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; through early February 2020 25 subjects have been enrolled in the Phase 1a portion of the study.

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. 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 US cancer 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 who have been previously treated with a gemcitabine-based chemotherapy receive variations of the FOLFIRINOX (which includes generic irinotecan) regimen. On December 27, 2019, the FDA approved olaparib (LYNPARZA®, AstraZeneca Pharmaceuticals LP) for the maintenance treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) metastatic pancreatic adenocarcinoma (PDAC), as detected by an FDA-approved test, whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Approximately 3% to 7% of individuals with PDAC harbor a BRCA1 or BRCA2 mutation, which are among the most frequently mutated genes in PDAC (Rainone M, et al, An Emerging Paradigm for Germline Testing in Pancreatic Ductal Adenocarcinoma and Immediate Implications for Clinical Practice: A Review. JAMA Oncol. 2020 Feb 13. doi: 10.1001/jamaoncol.2019.5963. [Epub ahead of print]).

University research laboratory studies at select dose levels 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 three 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 commence evaluation of the potential value of SBP-101 in other chemotherapy combinations.

Pancreatic Cancer

Pancreatic cancer afflicts approximately 133,000 people in Europe (GLOBOCAN2018, Global Cancer Observatory/World Health Organization), approximately 57,000 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 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 two most commonly 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 in the modern regulatory era, 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. Subsequently, 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

Other drugs are currently under investigation, but none have received marketing authorization as a first-line treatment of PDA since the approval of Abraxane**.** Lynparza®, (olaparib) was approved in December 2019 for maintenance therapy of patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen.

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. Polyamines perform many functions necessary for cellular proliferation, apoptosis 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 ready 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 analogues such as SBP-101 disrupt the cell's polyamine balance and biosynthetic network, and induce programmed cell death, or apoptosis, via processes including caspase 3 activation and poly ADP ribose polymerase (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.

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

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.

Laboratory studies suggest the primary mechanism of action for SBP-101 has been demonstrated to include the enhanced uptake of the compound in the exocrine pancreas. Sufficiently high dosing leads to correspondingly 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. Importantly, pancreatic islet cells, which secrete insulin, are structurally and functionally dissimilar to acinar cells and are not impacted by SBP-101. 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.

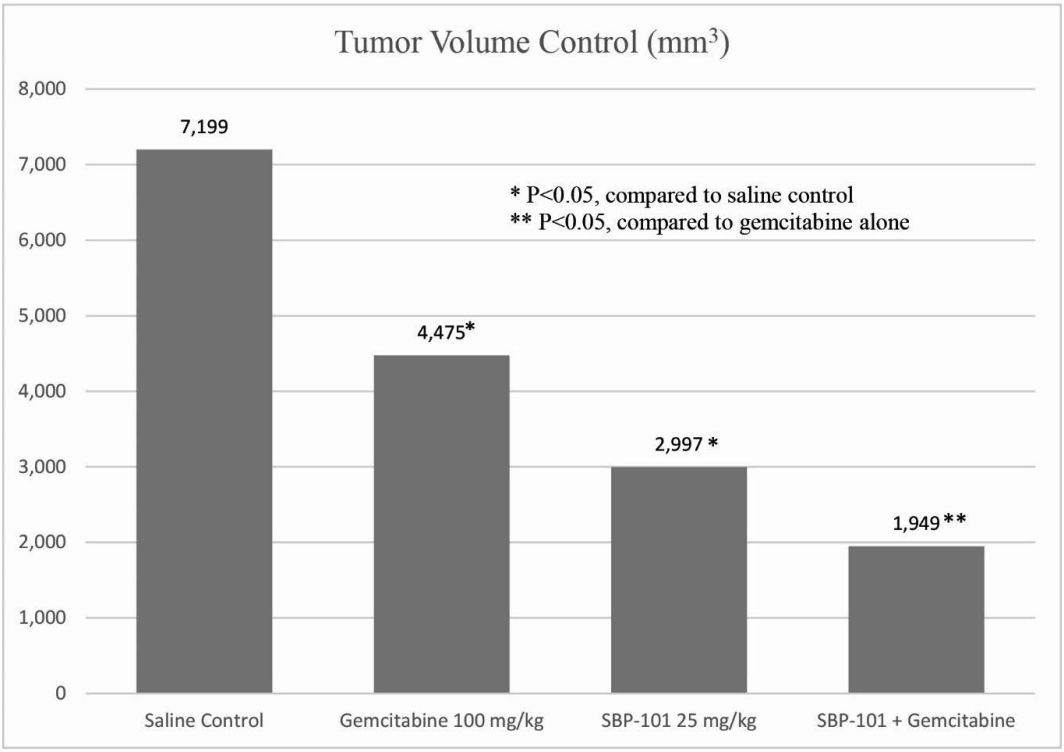
We believe that SBP-101 exploits the natural affinity of the exocrine pancreas, the liver and kidney, and pancreatic ductal adenocarcinoma cells while leaving the insulin-producing islet cells unharmed. Most current cancer therapies, including chemotherapy, radiation and surgery, are associated with significant side effects that further reduce the patient's quality of life. However, we believe that the adverse effects of SBP-101 do not overlap with or exacerbate those seen with typical chemotherapy options. The dose-limiting toxicities observed in cohort five of our Phase 1a study, as noted above, were not observed at lower doses and are not expected to overlap with the adverse events of bone marrow suppression and peripheral neuropathy commonly associated with standard chemotherapy. As the endocrine pancreas is expected to be unaffected by SBP-101, no impact on insulin requirement 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.

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. SBP-101 significantly reduced tumor volume compared to gemcitabine alone and the control group, but the combination of SBP-101 and gemcitabine was significantly better than gemcitabine alone as shown in Figure 1.

Figure 1. 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 been demonstrated *in vivo* by separate investigators, in different human pancreatic cancer cell lines and in three different animal models, using SBP-101 synthesized by two different routes, confirming nearly equal, and 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"). Preceding 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, 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 six study sites (four in Australia and two in the United States). In the Phase 1a portion of this trial, we have completed enrollment in the fourth quarter of 2019 of three cohorts of four to nine patients with increased dosage levels of SBP-101 administered in the second and third cohorts and completed enrollment in February of 2020 in a fourth cohort to explore an alternate dosing schedule. Demonstration of adequate safety in Phase 1a allowed us to immediately begin enrollment in February 2020 in the Phase 1b exploration of efficacy. We expect to enroll up to 36 patients using the recommended dosage level and schedule determined in Phase 1a. Early results from the Phase 1b expansion could become available in the second half of 2020.

With additional funding SBP-101 may also be explored for neo-adjuvant and/or adjuvant treatment in appropriate patients. There is also preclinical data to suggest that SBP-101 may have potential therapeutic uses for cancers other than pancreatic, but due to the current focus on pancreatic cancer, none have been formally explored.

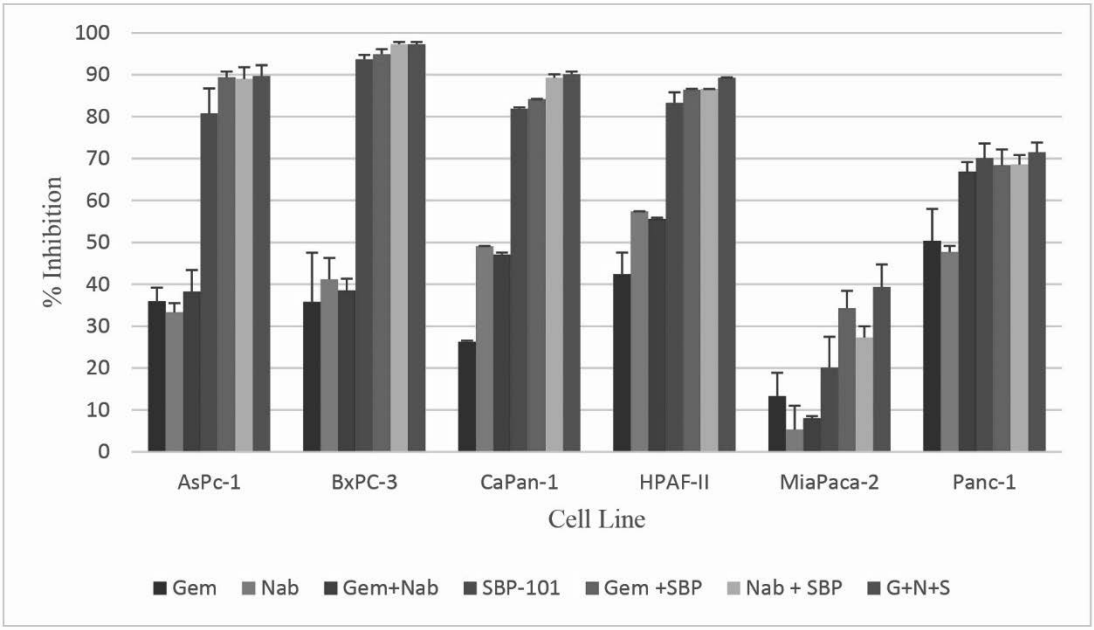
Preclinical Development

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 flank transplants of human pancreatic cancer PANC-1 tumor fragments and human pancreatic cancer BxPC-3 tumor fragments as well as human pancreatic cancer cells (L3.6pl) injected orthotopically into 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 GLP (good laboratory practice) toxicology studies, and genetic toxicology studies, including an Ames test. Exploratory studies in mice and rats and a 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 assay to detect any electrocardiographic QTc interval effects (IKr potassium ion channel testing).

In anticipation of the human 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 2.

Figure 2. 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 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 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.

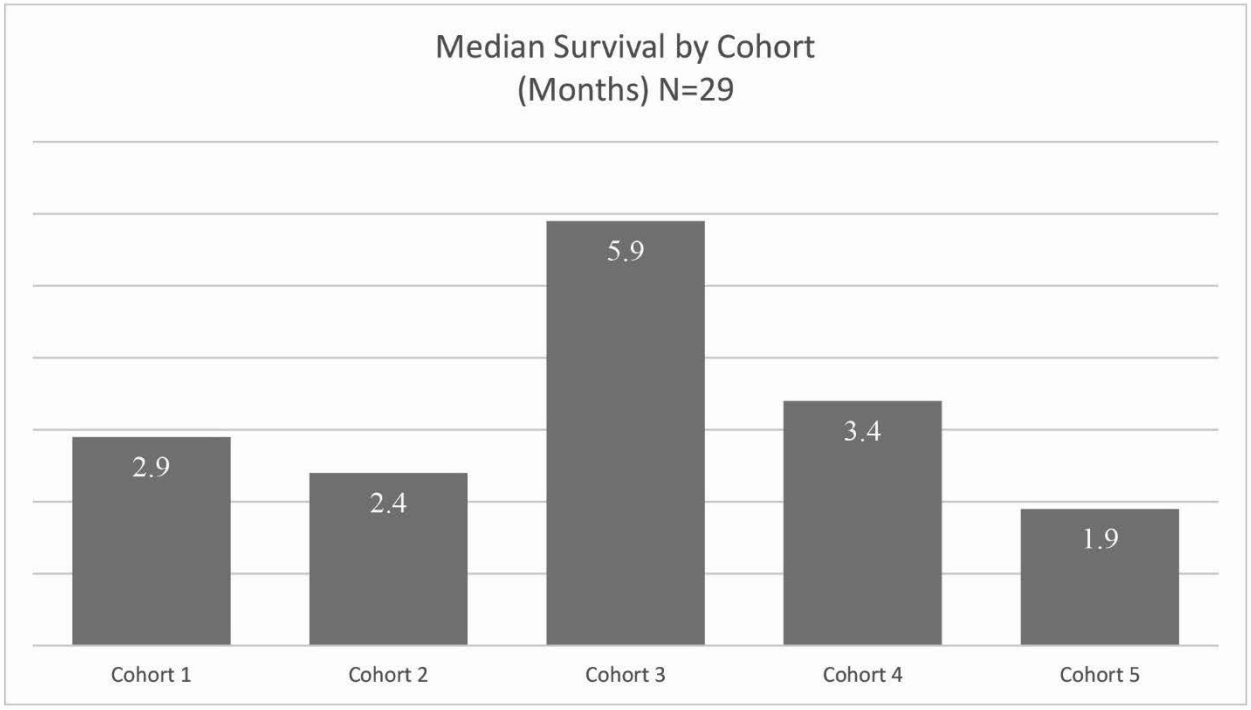
Patients in our Phase 1 first-in-human trial underwent regular pancreatic and hepatic enzyme evaluation and obtained periodic chest and abdominal CT follow-up. Patients were also carefully monitored for clinical signs of GI adverse events, but no new onset of exocrine pancreatic insufficiency was attributed to SBP-101 therapy.

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 DSMB to be 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 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 RECIST, the current standard for evaluating changes in the size of tumors. Eight of the 23 patients (35%) had SD and 15 of 24 (65%) had 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 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 3. Evaluation of SBP 101 Phase 1Mono-therapy Safety Trial - Median Survival by Cohort



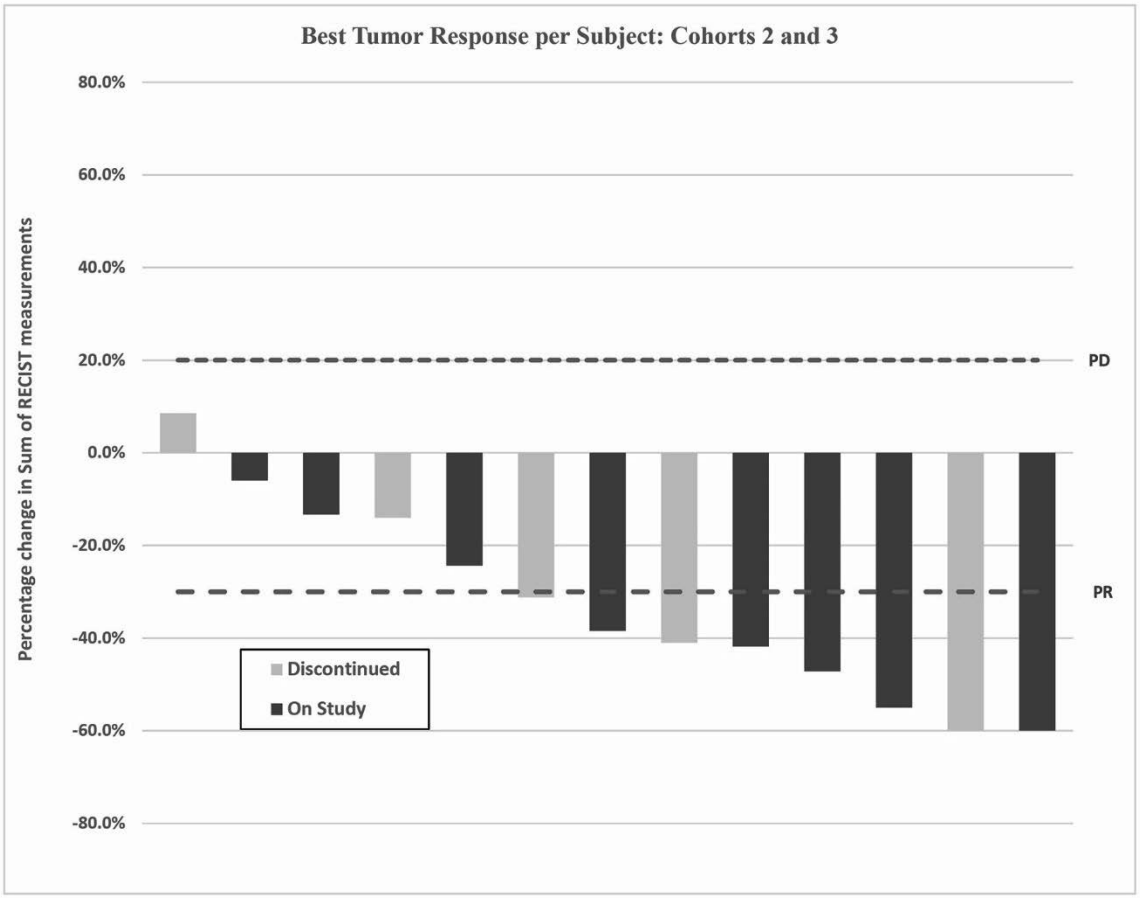
The absence of adverse events which could potentially overlap with adverse events typically observed in the use of conventional chemotherapeutic agents, supports the case for combination of SBP-101 with conventional chemotherapeutic agents, such as gemcitabine, nab-paclitaxel, or even FOLFIRINOX.

Phase 1a/1b Clinical Trial Design (First 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 first-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 six study sites (four in Australia and two in the United States). In the Phase 1a portion of this trial, we enrolled in three planned cohorts of four to nine patients with increased dosage levels of SBP-101 administered in the second and third cohorts. We completed enrollment in the 3 planned cohorts of Phase 1a in the fourth quarter of 2019, however, based on preliminary safety findings, a fourth cohort was added to explore an alternate dosing schedule. Enrollment in this 4th cohort was completed in February 2020. Demonstration of adequate safety in Phase 1a has led to a Phase 1b exploration of efficacy, in which we anticipate enrolment of up to thirty-six (36) patients using the recommended dosage level and schedule determined in Phase 1a. We began enrolling in this expansion phase in February 2020. As of December 31, 2019, preliminary efficacy results from evaluable patients in cohorts 2 and 3 (N=13) showed manageable toxicity, an objective response rate of 62% and a disease control rate of 85%, with several patients still ongoing. Early results from the Phase 1b expansion are expected to become available in the second half of 2020.

Figure 4. Evaluation of SBP 101 Phase 1a First-line combo-therapy Safety Trial – Best Response Rate



Best Response per Subject – Cohorts 2 and 3, N=13. Best response in evaluable subjects was PR in 8 (62%), SD in 5 (38%)**.** Three subjects did not have post baseline scans with RECIST tumor assessments. Source: Kotasek D, Abstract 710, ASCO GI 2020

Phase 2 Clinical Trial

A randomized 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 providing continued evaluation of safety and efficacy.

If we are able to successfully complete all 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 approvals in foreign jurisdictions 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 product 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

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 adequate supplies of drug to support preclinical work and human clinical trials. Dr. Neenan also leads our preclinical group.

Dr. Anthony L. 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 T. 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, 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 J. 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, immunotherapy, 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 December 31, 2019, we had five employees, four of whom were full-time employees. 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.

Material Agreements

The Standard Exclusive License Agreement ("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 expired in July 2019 and Know-How as defined by the License Agreement, with reservations by UFRF for academic or government uses. Under this agreement, we had agreed 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.

The License Agreement was Amended on December 12, 2016 ("First Amendment") and then again on October 3, 2019 ("Second Amendment").

Under the Second Amendment all minimum royalty payments and milestone payments defined in the License Agreement were eliminated. In addition, the period of payment royalties was changed to be the shorter of (i) ten (10) years from first commercial sale or (ii) the period of market exclusivity on a country by country basis. 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, as amended, is qualified by the full text of the License Agreement, and the Second Amendment, both of which are 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 the Investigator's Brochure, information about product chemistry, manufacturing and controls, potential perceived side effects and risks, 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, pivotal, or 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 an NDA is approved, a Phase 4 trial may be undertaken to evaluate safety over a long period of time, quality of life or cost effectiveness.

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, toxicology, manufacture, controls and any proposed labeling. 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 NDAs 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. If priority review is achieved, the FDA's goal is to take action on the application within six months. 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 (1) intended for the treatment of a serious or life-threatening disease or (2) 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, Prescription Drug User Fee Act ("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 the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare and Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, and our activities may implicate the privacy provisions of the Health Insurance Portability and Accountability Act ("HIPAA") and similar state laws, each as amended.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. While we reasonably believe our practices to be in compliance with the Anti-Kickback Statute, our practices may not in all cases meet all the criteria for protection under a statutory exception or regulatory safe harbor.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Affordable Care Act ("ACA") to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it to have committed a violation. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act (as further discussed below).

The Civil Monetary Penalties statute authorizes the imposition of severe financial penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses.

HIPAA created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of, or payment for healthcare benefits, items or services.

Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH) and its implementing regulations, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Additionally, the federal Physician Payments Sunshine Act within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report information related to certain payments or other transfers of value made or distributed to physicians, other specified health care professionals and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians, other specified health care professionals and teaching hospitals and to report annually certain ownership and investment interests held by physicians and other specified health care professionals and their immediate family members. Some states have analogous laws requiring manufacturers to report certain transfers of value to covered individuals and entities.

To distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All our activities are potentially subject to federal and state consumer protection and unfair competition laws.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for such products. In the United States, third-party payors include federal and state healthcare programs, privately managed care providers, health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all the FDA-approved products for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. This is also true of Medicare reimbursement, where different vendors process payments, so that coverage by one vendor does not assure that all other vendors will provide coverage. 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. In addition, the United States federal government position on matters related to drug pricing is evolving and uncertain, and any changes could have a material impact on drug pricing generally in the United States, including for our product candidates if approved.

Different pricing and reimbursement schemes exist in other countries. In the EU, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The National Institute for Health and Care Excellence (NICE) in the United Kingdom also requires consideration of cost-benefit analysis. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third- party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on healthcare pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

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 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 $2.7 million and $2.4 million for the years ended December 31, 2019 and 2018, respectively, and we had working capital of $1.3 million and $0.2 million as of the same dates respectively. Working capital at December 31, 2018 includes $1.3 million of debt discount

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 2019 financial statements, which is 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.

Our business is subject to risks arising from epidemic diseases, such as the recent outbreak of the COVID-19 illness.

The recent outbreak of COVID-19, which has been declared by the World Health Organization to be a pandemic, has spread across the globe and is impacting worldwide economic activity. A pandemic, including COVID-19, or other public health epidemic poses the risk that we or our employees, contractors, suppliers, and other partners may be prevented from conducting business activities for an indefinite period of time, including due to the spread of the disease within these groups or due to shutdowns that may be requested or mandated by governmental authorities. While it is not possible at this time to estimate the impact that COVID-19 could have on our business, the continued spread of COVID-19 and the measures taken by the governments of countries affected could disrupt the supply chain and the manufacture or shipment of both drug substance and finished drug product for our product candidates for preclinical testing and clinical trials and adversely impact our business, financial condition or results of operations. We often attend and present clinical updates at various medical and investor conferences throughout the year. The COVID-19 outbreak has caused, and is likely to continue to cause, cancellations or reduced attendance of these conferences and we may need to seek alternate methods to present clinical updates and to engage with the medical and investment communities. The spread of COVID-19 may also slow potential enrollment of clinical trials and reduce the number of eligible patients for our clinical trials. The COVID-19 outbreak and mitigation measures may also have an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition and our potential to conduct financings on terms acceptable to us, if at all. The extent to which the COVID-19 outbreak impacts our results will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact.

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.

In January of 2020 Dr. Michael Cullen, our Executive Chairman, President and CEO, announced his intention to resign as CEO of the Company. He intends to continue as the Executive Chairman and is expected to remain an employee of the company focused on drug development. The Company has initiated a search for a new CEO and Dr. Cullen intends to continue to serve as CEO to facilitate a successful transition.

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.

Legislative and regulatory actions affecting government prescription drug procurement and reimbursement programs occur relatively frequently. In the United States, the ACA was enacted in 2010 to expand healthcare coverage. Since then, numerous efforts have been made to repeal, amend or administratively limit the ACA in whole or in part. For example, the Tax Cuts and Jobs Act, signed into law by President Trump in 2017, repealed the individual health insurance mandate, which is considered a key component of the ACA. In December 2018, a Texas federal district court struck down the ACA on the grounds that the individual health insurance mandate is unconstitutional, although this ruling has been stayed pending appeal. The ongoing challenges to the ACA and new legislative proposals have resulted in uncertainty regarding the ACA's future viability and destabilization of the health insurance market. The resulting impact on our business is uncertain and could be material.

Efforts to control prescription drug prices could also have a material adverse effect on our business. For example, in 2018, President Trump and the Secretary of the U.S. Department of Health and Human Services ("HHS") released the "American Patients First Blueprint" and have begun implementing certain portions. The initiative includes proposals to increase generic drug and biosimilar competition, enable the Medicare program to negotiate drug prices more directly and improve transparency regarding drug prices and ways to lower consumers' out-of-pocket costs. The Trump administration also proposed to establish an "international pricing index" that would be used as a benchmark to determine the costs and potentially limit the reimbursement of drugs under Medicare Part B. Among other pharmaceutical manufacturer industry-related proposals, Congress has proposed bills to change the Medicare Part D benefit to impose an inflation-based rebate in Medicare Part D and to alter the benefit structure to increase manufacturer contributions in the catastrophic phase. The volume of drug pricing-related bills has dramatically increased under the current Congress, and the resulting impact on our business is uncertain and could be material.

In addition, many states have proposed or enacted legislation that seeks to indirectly or directly regulate pharmaceutical drug pricing, such as by requiring biopharmaceutical manufacturers to publicly report proprietary pricing information or to place a maximum price ceiling on pharmaceutical products purchased by state agencies. For example, in 2017, California's governor signed a prescription drug price transparency state bill into law, requiring prescription drug manufacturers to provide advance notice and explanation for price increases of certain drugs that exceed a specified threshold. Both Congress and state legislatures are considering various bills that would reform drug purchasing and price negotiations, allow greater use of utilization management tools to limit Medicare Part D coverage, facilitate the import of lower-priced drugs from outside the United States and encourage the use of generic drugs. Such initiatives and legislation may cause added pricing pressures on our products.

Changes to the Medicaid program at the federal or state level could also have a material adverse effect on our business. Proposals that could impact coverage and reimbursement of our products, including giving states more flexibility to manage drugs covered under the Medicaid program and permitting the re-importation of prescription medications from Canada or other countries, could have a material adverse effect by limiting our products' use and coverage. Furthermore, state Medicaid programs could request additional supplemental rebates on our products as a result of an increase in the federal base Medicaid rebate. To the extent that private insurers or managed care programs follow Medicaid coverage and payment developments, they could use the enactment of these increased rebates to exert pricing pressure on our products, and the adverse effects may be magnified by their adoption of lower payment schedules.

Other proposed regulatory actions affecting manufacturers could have a material adverse effect on our business. It is difficult to predict the impact, if any, of any such proposed legislative and regulatory actions or resulting state actions on the use and reimbursement of our products in the United States, but our results of operations may be adversely affected.

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 affected.

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, 2019, our directors and executive officers beneficially owned 24.5% of our common stock and together may be able to influence significantly all matters requiring approval by our stockholders. As of the same date, one holder of greater than five percent of our common stock beneficially owned 11.6% and would, along with certain other shareholders, 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. The 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 may be a "penny stock," which may make it difficult to sell shares of our common stock.

Our common stock was recently categorized as a "penny stock" as defined in Rule 3a51-1 of the Exchange Act and may be 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 20, 2020, 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, 2019, we had outstanding options to purchase 1,744,811 shares of our common stock at a weighted-average exercise price of $6.53 per share and outstanding warrants to purchase 3,422,099 shares of common stock at a weighted-average exercise price of $4.45 per share.

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 may 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. To the extent our common stock is considered a penny stock, we will not be 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, 2019, 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

None.

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 2019 and 2018 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 2019	High	Low
Fourth Quarter	$ 5.82	$ 4.00
Third Quarter	$ 5.25	$ 2.25
Second Quarter	$ 3.00	$ 2.00
First Quarter	$ 3.50	$ 2.10

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

As of March 20, 2020, there were 268 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. 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 Food and Drug Administration ("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. 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 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 six study sites (four in Australia and two in the United States). In the Phase 1a portion of this trial, we have completed enrollment in the fourth quarter of 2019 of three cohorts of four to nine patients with increased dosage levels of SBP-101 administered in the second and third cohorts and completed enrollment in February of 2020 in a fourth cohort to explore an alternate dosing schedule. Demonstration of adequate safety in Phase 1a allowed us to promptly begin enrollment in February 2020 in the Phase 1b exploration of efficacy. We plan to enroll up to 36 patients using the recommended dosage level and schedule determined in Phase 1a. Early results from the Phase 1b expansion could become available in the second half of 2020.

We estimate that completion of our Phase 1b clinical trial in PDA will require additional funding of approximately $4 to 6 million.

Additional clinical trials will be required for FDA or other country 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 $20 and $40 million.

Financial Overview

We have incurred losses of $41.3 million since our inception in 2011. For the year ended December 31, 2019, we incurred a net loss of $6.2 million, which includes a non-cash charge of $2.1 million related to the amortization of the debt discount on $2.1 million of convertible notes which converted to common stock during the year. We also incurred negative cash flows from operating activities of $2.7 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 $1.0 million increase in cash compared to December 31, 2018 was primarily due to $3.8 aggregate proceeds from equity and debt offerings completed during 2019, offset in part by cash used in operations.

In August 2019, we received a research and development tax incentive payment from the government of Australia related to the research activities of our Australian subsidiary during 2018. The incentive payment received was approximately $376,000.

As of December 31, 2019, we had cash of $2.4 million, working capital of $1.3 million and stockholders' equity of $1.4 million. This is not expected to be sufficient to sustain operations through December 31, 2020.

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 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 2019 and 2018, research and development expenditures were focused primarily on costs related to the execution 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 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. Grants made to new employees are awarded on a case by case basis. Option grants to employees generally vest annually over three 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 three years. Options issued to employees and non-employees generally have a maximum term of ten 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.

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 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, 2019 and 2018

	Year Ended December 31,		
	2019	2018	Percent Change
Operating Expenses			
General and administrative	$ 1,973	$ 2,108	-6.4%
Research and development	2,349	1,783	31.7%
Total operating expenses	4,322	3,891	11.1%
Other expenses, net	(2,293)	(2,268)	1.1%
Income tax benefit	415	254	63.4%
Net Loss	$ (6,200)	$ (5,905)	5.0%

General and administrative ("G&A") and research and development ("R&D") 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, 2019 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, 2019 and 2018 (in thousands):

	Year ended December 31,	
	2019	2018
General and administrative	$ 695	$ 1,497
Research and development	398	876
Total Stock based compensation	$ 1,093	$ 2,373

General and administrative expense

G&A expenses decreased 6.4% to $2.0 million in 2019, down from $2.1 million in 2018. The decrease in G&A expenses is primarily the result of fewer staff members in the year offset in part by increased legal fees and franchise tax expense.

Research and product development expense

Our R&D expenses increased 31.7% to $2.3 million in 2019, up from $1.8 million in 2018. The increase in R&D expenses resulted primarily from an increase in spending on manufacturing of SBP 101 for use in our clinical studies. As we expand our clinical studies it is expected that R&D will continue to increase.

Other expense, net

Other expense, net, was $2.3 million for both years ended December 31, 2019 and 2018. In 2019, these expenses were primarily the amortization of the debt discount on the 2018 Notes which converted on June 30, 2019. In 2018, these expenses were primarily the amortization of the debt discount on the 2017 Notes which converted in 2018.

Income tax benefit

Income tax benefit increased to $415,000 in 2019, up from $254,000 in 2018. Our income tax benefit is derived primarily from refundable tax incentives associated with our R&D activities conducted in Australia. The current year increase reflects an increase in the costs eligible for the Australian R&D tax incentive.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of December 31, 2019 and 2018 and for each of fiscal years ended December 31, 2019 and 2018, and is intended to supplement the more detailed discussion that follows (in thousands):

Liquidity and Capital Resources	December 31,	
	2019	2018
Cash	$ 2,449	$ 1,405
Working capital (deficiency)	$ 1,334	$ 217*

* includes $1,289 of debt discount

Cash Flow Data	Year Ended December 31,	
	2019	2018
Cash Provided by (used in):		
Operating Activities	$ (2,739)	$ (2,387)
Investment Activities	-	-
Financing Activities	3,784	3,643
Effect of exchange rate changes on cash	(1)	(3)
Net increase in cash	$ 1,044	$ 1,253

Working Capital

Our total cash resources were $2.4 million as of December 31, 2019, compared to $1.4 million as of December 31, 2018. As of December 31, 2019, we had $1.8 million in current liabilities and working capital of $1.3 million. As of December 31, 2018, we had $1.6 million in current liabilities and working capital of $0.2 million (includes $1.3 million of debt discount). Working capital is calculated as current assets less current liabilities.

On June 30, 2019 the principal balance and accrued interest on promissory notes payable by us were converted into common stock per the terms of the underlying promissory notes, resulting in the issuance of 651,758 shares of common stock.

Cash Flows

Net Cash Used in Operating Activities

Net cash used in operating activities was $2.7 million during 2019, compared to $2.4 million during 2018. 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 years ended December 31, 2019 and 2018 respectively, the net loss was offset by a non-cash charge of $2.0 million and $1.8 million related to the amortization of the discount on convertible notes payable.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $3.8 million for the years ended December 31, 2019 which was comprised primarily of net proceeds from the sale of common stock and warrants ($3.2 million) and the sale of the convertible promissory notes and warrants ($0.8 million). During the year ended December 31, 2018, net cash provided by financing activities was $3.6 million which resulted from net proceeds received in the sale of common stock and warrants and 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, 2019, 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, 2019, we had a balance of $0.7 million due under an unsecured, non-interest-bearing promissory note. This balance is scheduled to become due on the earlier of December 31, 2020 or when the Company is listed on a national exchange. We also had a balance of $116,000 due under an unsecured loan that accrues annual interest of 4.125% and is scheduled to mature on December 31, 2020. We commenced monthly payments of principal and interest on that loan totaling $10,000 on May 1, 2018.

Issuance of Common Stock and Warrants during 2019

In closings occurring in August, September and October of 2019, we issued an aggregate of 909,209 shares of our common stock and warrants to purchase an aggregate of up to the same number of additional shares of common stock pursuant to closings under securities purchase agreements. Total proceeds from the sales of common stock and warrants was approximately $3.2 million, of this approximately $240,000 was received from officers and directors of the Company. The warrants issued under these purchase agreements are exercisable for a period of five years from the date of issuance at an initial exercise price of $4.00 per share.

Issuances of Convertible Notes during 2019 and 2018 and Conversion of Notes in 2019

In December of 2018 and January of 2019, we sold convertible promissory notes (the "2018 Notes") and warrants to purchase common stock for gross proceeds of $2.2 million. The 2018 Notes were scheduled to mature on June 30, 2019 and bore an interest at a rate of 10.0% per year. The 2018 Notes had 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 received gross proceeds of at least $6.0 million from the sale of equity securities (subject to certain exclusions). The stated conversion rate was $3.50 per share. 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 1,243,498 shares of common stock were issued in the December and January 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 warrants had a fair market value of $2.5 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 $0.9 million. Both the relative value of the warrants and the beneficial conversion feature were recorded as a debt discount which was fully amortized through interest expense over the life of the 2018 Notes. On June 30, 2019, all $2.2 million aggregate principal balance of Notes outstanding plus $105,000 of accrued interest was converted at a conversion rate of $3.50 per share of common stock into 651,758 shares of common stock.

Future Capital Requirements

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, will be sufficient to fund our operating expenses through the second quarter of 2020.

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 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

Pursuant to our exclusive license agreement with UFRF, which was last amended on October 4, 2019, we are required to pay royalties ranging from 2.5% to 5% of net sales of licensed products developed from the licensed technology for the shorter of: ten (10) years from the first commercial sale of a licensed product or the period of market exclusivity on a country by country basis. The latest amendment eliminated all future milestone payments. But the Company remains 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, 2019, 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 in 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 Act. 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, 2019, 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, 2019, 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 2020 (the "Proxy Statement"), which we expect to file with the SEC pursuant to Regulation 14A within 120 days after December 31, 2019. 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," "Security Ownership of Principal Stockholders and Management," and, if applicable, "Delinquent Section 16(a) Reports" in the Proxy Statement is incorporated into this Item by reference.

Information about our Executive Officers

Michael T. Cullen, M.D., M.B.A., age 74, has served as Executive Chairman of the board and as a director of our Company since its co-founding in November 2011 and as President and Chief Executive Officer since 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. He previously served as our Chief Medical 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 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 60, has served as our Vice President and Chief Financial Officer since April 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 financial consulting 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, from December 2016 to January 2018; Vice President and Chief Financial Officer of Tenacious Holdings, Inc. (d/b/a ergodyne) a privately held, safety products company, from January 2014 to December 2016; 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, from August 2011 to February 2014; Chief Financial Officer, Vice President of Operations & Human Resources of Hemosphere, Inc., an early commercialization stage medical device company, from July 2008 to December 2010; 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, from November 2004 to March 2007. 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***

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 quarter ended June 30, 2016)
4.1+	Description of Securities
4.3	Form of Common Stock Warrant issued prior to September 2015 (incorporated by reference to Exhibit 4.3 to current report on Form 8-K filed September 11, 2015)
4.4	Form of Common Stock Warrant issued June through September 2016 (incorporated by reference to Exhibit 10.2 to current report on Form 8-K filed June 14, 2016)
4.6	Form of Common Stock Warrant issued February through May 2018 (incorporated by reference to Exhibit 10.2 to current report on Form 8-K filed February 26, 2018)
4.7	Form of Convertible Promissory Note issued December 2018 and January 2019 (incorporated by reference to Exhibit 10.2 to current report on Form 8-K filed December 28, 2018)
4.8	Form of Common Stock Warrant issued December 2018 and January 2019 (incorporated by reference to Exhibit 10.3 to current report on Form 8-K filed December 28, 2018)
4.9	Common Stock Warrant issued April 2, 2019 (incorporated by reference to Exhibit 10.3 to quarterly report on Form 10-Q for quarter ended March 31, 2019)
4.9	Form of Common Stock Warrant issued August through October 2019 (incorporated by reference to Exhibit 10.2 to current report on Form 8-K filed August 29, 2019)
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 Plan (incorporated by reference to Exhibit 10.2 to current report on Form 8-K filed September 11, 2015)

Exhibit No.	Description
10.3*	Form of Non-Qualified Stock Option Agreement for awards under 2011 Plan (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 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 10.5 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*	Form of Indemnification Agreement with non-employee directors (incorporated by reference to Exhibit 10.4 to current report on Form 8-K filed September 11, 2015)
10.9**	Standard Exclusive License Agreement with University of Florida Research Foundation, 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+	Form of First Amendment to License Agreement with University of Florida Research Foundation, Inc. dated December 12, 2016
10.11	Second Amendment to License Agreement with University of Florida Research Foundation, Inc., dated October 3, 2019 (incorporated by reference to Exhibit 10.1 to current report on Form 8-K filed October 9, 2019)
10.12*	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)
10.13*	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)
10.14*	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)
10.15*	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)
10.16*	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)
10.17*	First Amendment to Employment Agreement with Suzanne Gagnon, dated September 12, 2016 (incorporated by reference to Exhibit 10.20 to registration statement on Form S-1 filed September 16, 2016)
10.18*	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)
10.19*	Waiver and Third Amendment to Employment Agreement with Suzanne Gagnon, effective as of February 27, 2018 (incorporated by reference to Exhibit 10.4 to current report on Form 8-K filed March 5, 2018)
10.20*	Employment Agreement with Susan Horvath, dated April 17, 2018 (incorporated by reference to Exhibit 10.4 to quarterly report on Form 10-Q for quarter ended March 31, 2018)
10.21	Form of Securities Purchase Agreement, dated December 21 and 31, 2018, January 14, 25, and 31, 2019 (incorporated by reference to Exhibit 10.1 to current report on Form 8-K filed December 28, 2018)

Exhibit No.	Description
10.22+	Seed Capital Accelerator Loan Agreement and Seed Capital Loan Note dated October 26, 2012
10.23	First Amendment to Seed Capital Accelerator Loan Agreement and Seed Capital Loan Note dated October 13, 2017 (incorporated by reference to Exhibit 10.1 to quarterly report on Form 10-Q for quarter ended March 31, 2019)
10.24	Second Amendment to Seed Capital Accelerator Loan Agreement and Seed Capital Loan Note dated April 5, 2019 (incorporated by reference to Exhibit 10.2 to quarterly report on Form 10-Q for quarter ended March 31, 2019
10.25+	Third Amendment to Seed Capital Accelerator Loan Agreement and Seed Capital Loan Noted dated December 31,2019
10.26	Form of Securities Purchase Agreement dated August 23, 31 and September 20, 2019 (incorporated by reference to Exhibit 10.1 to current report on Form 8-K filed August 29, 2019)
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, 2019, 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 24, 2020.

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 24, 2020.

/s/ MICHAEL T. CULLEN	/s/ SUSAN HORVATH
Michael T. Cullen, *President, Chief Executive Officer and Executive Chairman and Director* *(Principal Executive Officer)*	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*
*	
Arthur J. Fratamico, 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, 2019 and 2018, 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, 2019 and 2018, 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 24, 2020

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

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

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,	
	2019	2018
Operating expenses:		
General and administrative	$ 1,973	$ 2,108
Research and development	2,349	1,783
Operating loss	(4,322)	(3,891)
Other (expense) income:		
Grant income	-	54
Interest expense	(2,194)	(1,814)
Other expense	(99)	(508)
Total other expense	(2,293)	(2,268)
Loss before income tax benefit	(6,615)	(6,159)
Income tax benefit	415	254
Net loss	(6,200)	(5,905)
Foreign currency translation adjustment	22	448
Comprehensive loss	$ (6,178)	$ (5,457)
Basic and diluted net loss per share	$ (1.09)	$ (1.27)
Weighted average shares outstanding - basic and diluted	5,700,314	4,662,080

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'
	Shares	Amount	Capital	Deficit	Gain (Loss)	Equity (Deficit)
Balances as of January 1, 2018	3,842	$ 4	$ 25,625	$ (29,153)	$ (165)	$ (3,689)
Sale of common stock and warrants	485	-	2,328	-	-	2,328
Beneficial conversion feature	-	-	716	-	-	716
Conversion of convertible notes payable and accrued interest into common stock and warrants	751	1	3,257	-	-	3,258
Warrants issued with sale of convertible notes payable	-	-	739	-	-	739
Stock-based compensation	-	-	2,373	-	-	2,373
Net loss	-	-	-	(5,905)	-	(5,905)
Foreign currency translation adjustment	-	-	-	-	448	448
Balances as of December 31, 2018	5,078	$ 5	$ 35,038	$ (35,058)	$ 283	$ 268
Beneficial conversion feature on convertible notes payable	-	-	353	-	-	353
Warrants issued with sale of convertible notes payable	-	-	419	-	-	419
Conversion of convertible notes payable and accrued interest into common stock	651	1	2,280	-	-	2,281
Common stock converted into convertible notes payable	(7)	-	(25)	-	-	(25)
Sale of common stock and warrants	909	1	3,159	-	-	3,160
Warrants issued in exchange for modification of term debt	-	-	14	-	-	14
Stock-based compensation	-	-	1,093	-	-	1,093
Net loss	-	-	-	(6,200)	-	(6,200)
Foreign currency translation adjustment	-	-	-	-	22	22
Balances as of December 31, 2019	6,631	$ 7	$ 42,331	$ (41,258)	$ 305	$ 1,385

See accompanying notes to consolidated financial statements.

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

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

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. 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 $41.3 million since our inception in 2011. For the year ended December 31, 2019 we incurred a net loss and negative cash flows from operating activities of $6.2 million and $2.7 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, 2019, we had cash of $2.4 million, working capital of $1.3 million and stockholders' equity of $1.4 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 or other applications that we would otherwise seek to pursue, or cease operations.

In closings occurring in August, September and October 2019 the Company sold 909,209 shares of common stock and an equal number of warrants to purchase common stock in a private placement to certain accredited investors pursuant to a Securities Purchase Agreement. Net proceeds from these sales totaled approximately $3.2 million. The warrants are exercisable for a period of five years from the date of issuance at an initial exercise price of $4.00.

In closings occurring in December 2018 and January 2019 the Company sold $2.2 million principal amount of unsecured convertible promissory notes (the "Notes") and warrants to purchase up to 1,243,498 shares of common stock in a private placement to certain investors. On June 30, 2019 the entire principal balance and accrued interest of $105,000 converted into 651,758 shares of common stock per the terms of the Notes at a conversion rate of $3.50. See Note 6 titled "Indebtedness" for a detailed discussion of the material terms of the Notes. The warrants are exercisable for a period of five years from the date of issuance at an initial exercise price of $4.50.

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 presented as a direct deduction from the carrying amount of the related debt. 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.

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 carryforwards. 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, 2019 and 2018. 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, 2019 and 2018, 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,	
	2019	2018
Employee and non-employee stock options	1,744,811	1,032,211
Estimated common shares issuable upon conversion of notes payable and accrued interest	-	383,947
Common stock issuable under common stock purchase warrants	3,422,099	2,035,197
	5,166,910	3,451,355

Recently Adopted Accounting Pronouncements

In June 2018, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2018-07, "Compensation – Stock Compensation (Topic 718)." ASU 2018-07 simplifies the accounting for nonemployee stock-based payment transactions. This ASU was adopted by the Company effective for the fiscal year beginning January 1, 2019. Historically, the ultimate stock-based compensation related to non-employee common stock options would fluctuate based on changes in the underlying option pricing model as the awards vest. Under the new guidance, the total compensation cost of non-employee options is determined at grant date. The Company has evaluated the impact of this new guidance on its financial statements and has determined that it will affect how the Company records stock-based compensation related to common stock options and other equity-based compensation, if any, granted to non-employees in the future.

In February 2016, the FASB issued ASU 2016-02, "Leases," which created a new Topic, Accounting Standards Codification ("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 was adopted by the Company for the year beginning January 1, 2019. The Company has evaluated the impact of this revised guidance on its financial statements and determined it had no material impact, as the Company has no leasing arrangements with terms greater than one year.

5. ACCRUED EXPENSES

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2019	2018
Clinical trial and related expenses	$ 147	$ 42
Professional services	125	157
Other	32	17
Total accrued liabilities	$ 304	$ 216

6. INDEBTEDNESS

2018 Convertible notes payable

In December of 2018 and January of 2019, we sold convertible promissory notes (the "2018 Notes") and warrants to purchase common stock for gross proceeds of $2.2 million. The 2018 Notes were scheduled to matured on June 30, 2019 and bore an interest at a rate of 10.0% per year. The 2018 Notes had 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 stated conversion rate was $3.50 per share. 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 1,243,498 shares of common stock were issued in the December and January 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 warrants had a fair market value of $2.5 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 $0.9 million. Both the relative value of the warrants and the beneficial conversion feature were recorded as a debt discount which was fully amortized through interest expense over the life of the 2018 Notes. On June 30, 2019, all $2.2 million aggregate principal balance of Notes outstanding plus $105,000 of accrued interest was converted at a conversion rate of $3.50 per share of common stock into 651,758 shares of common stock per the terms of the 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.

The following table sets forth the changes in convertible notes payable during the year ended December 31, 2019 (in thousands):

	Convertible Notes Payable	
	Principal	Accrued Interest
Balances at January 1, 2019	$ 1,359	$ 2
Aggregate principal value of notes sold	816	-
Accrued Interest on notes	-	103
Aggregate principal value of notes and accrued interest converted into common stock	(2,175)	(105)
	-	-
Balances at December 31, 2019	$ -	$ -

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 beginning on May 1, 2018 with the remaining balance due in full on May 1, 2019. Effective April 5, 2019 the terms of our unsecured loan (the "Term Debt") payable to the Institute were amended again to extend the maturity date from May 1, 2019 to December 31, 2019. The Institute agreed to the amendment in exchange for a warrant to purchase 5,555 shares of common stock at an exercise price of $4.50. The warrant expires five years from issuance. On December 16, 2019 the Institute again modified the terms of repayment. In exchange for a payment $50,000 payable on December 31, 2019 and a warrant to purchase 5,000 shares of common stock at an exercise price of $4.00 the maturity date of the loan was extended from December 31, 2019 to December 31, 2020. The total fair market value of the warrants issued for both amendments was calculated at $14,000 and was recorded as a discount to the debt, which will be amortized over the remaining period until maturity of the debt. The amendment requires the continuation of monthly payments of principal and interest totaling $10,000 with monthly payments applied first to accrued and unpaid interest. The unpaid principal balance, net of unamortized debt discount, at December 31, 2019 was $116,000.

7. Commitments and Contingencies

License agreement

On December 22, 2011, we entered into an exclusive license agreement with the University of Florida research Foundation ("UFRF"). This license agreement was amended on first of December 12, 2016 ("First Amendment") and again on October 3, 2019 ("Second Amendment"). 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. The Second Amendment eliminated all minimum annual royalties and modified the duration of royalty payments to the shorter of (1) ten years from first commercial sale of licensed products or (2) the expiration of the period of regulatory exclusivity on a country by country basis. All future milestone payments contemplated in the original agreement were eliminated in the Second Amendment.

The amended license agreement remains 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 2019 and 2018 Consolidated Statements of Operations and Comprehensive Loss.

8. Stockholders' Equity (Deficit)

2019 Private placement

On closings occurring in August, September and October of 2019, we issued an aggregate of 909,209 shares of our common stock and warrants to purchase an aggregate of up to the same number of additional shares of common stock pursuant to closings under 2019 Securities Purchase Agreements. Total proceeds from the sale of common stock and warrants was approximately $3.2 million, of which $240,000 was received from directors and officers of the Company or its subsidiary. The warrants issued under the 2019 Purchase Agreement will be exercisable for a period of five years from the date of issuance at an exercise price of $4.00 per share See Note 4, titled "Liquidity and Management's Plans".

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, 2019, 468,200 warrants remained outstanding.

Shares reserved

Shares of common stock reserved for future issuance were as follows as of December 31, 2019:

Stock options outstanding	1,744,811
Shares available for grant under equity incentive plan	19,549
Common shares issuable under outstanding common stock purchase warrants	3,422,099
	5,186,459

9. Stock-Based Compensation

2016 Omnibus Incentive Plan

Stock-based awards are granted under the Sun BioPharma, Inc. 2016 Omnibus Incentive Plan (the "2016 Plan"). 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, 2019, options to purchase 1,480,451 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"). 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, 2019, 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, 2018	1,060,400	733,960	$ 9.79	$ 169,495
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	$ 56,225
Granted	(733,400)	733,400	3.42	
Exercised	-	-	-	
Cancelled	-	-	-	
Forfeitures	20,800	(20,800)	15.10	
Balance at December 31, 2019	19,549	1,744,811	$ 6.53	$ 1,030,547

A summary of the status of our unvested shares during the year ended and as of December 31, 2019 is as follows:

	Shares Under Option	Weighted Average Grant Date Fair Value
Unvested at December 31, 2018	42,500	$ 4.83
Granted	733,400	2.09
Vested	(378,025)	2.41
Forefeitures	-	-
Unvested at December 31, 2019	397,875	$ 2.03

Information about stock options outstanding, vested and expected to vest as of December 31, 2019, 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	3.00	$ 1.029	26,360	3.00
$2.275 - $2.50	38,000	4.12	$ 2.464	38,000	4.12
$2.95 - $3.70	774,100	8.32	$ 3.040	411,525	7.36
$4.50 - $8.10	538,300	7.97	$ 6.742	506,500	7.92
$10.00 - $10.10	54,000	7.55	$ 10.007	54,000	7.55
$15.10	314,051	6.41	$ 15.100	310,551	6.46
Totals	1,744,811	7.67	$ 6.526	1,346,936	7.19

As of December 31, 2019, total compensation expense related to unvested employee stock options not yet recognized was $372,000 which is expected to be allocated to expenses over a weighted-average period of 2.4 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, 2019 and 2018:

	2019	2018
Common stock fair value	$2.95 - $5.00	$3.50 - $8.10
Risk-free interest rate	1.55% - 2.25%	2.30% - 2.94%
Expected dividend yield	0	0
Expected Option life (in years)	5.00 - 5.50	1.25 - 5.75
Expected stock price volatility	72%	72%

Nonemployee stock-based compensation

We account for stock options granted to nonemployees in accordance with Accounting Standards Update ("ASU") 2018-07, "Compensation – Stock Compensation (Topic 718). In connection with stock options granted to nonemployees, we recorded $288,000 and $263,000 for nonemployee stock-based compensation during the years ended December 31, 2019 and 2018, respectively.

10. 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.

At December 31, 2019 and 2018, the Company had an income tax receivable of $361,000 and $332,000, 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, 2019	2018
Net operating loss carryforwards	$ 6,307	$ 4,807
Research credit carryforwards	235	235
Stock-based compensation	1,230	971
Other	72	71
Deferred tax assets	7,844	6,084
Valuation allowance	(7,844)	(5,801)
Deferred tax assets, net of valuation allowance	-	283
Beneficial conversion feature, net	-	(283)
Deferrred tax liabilities	-	(283)
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, 2019	2018
Statutory rate	21.0%	21.0%
Permanent differences	(5.9)	0.1
Change in effective tax rate	-	0.6
Valuation allowance	(32.4)	(22.6)
Foreign research incentives	5.7	5.7
Deferred true-up	16.3	-
Other	1.0	0.9
Effective rate	5.7%	5.7%

Net operating losses and tax credit carryforwards as of December 31, 2019, are as follows:

	Amount (in thousands)	Expiration Years
Net operating losses – federal	12,958	Expires beginning 2031
2019 net operating loss – federal	3,153	Never expires
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 for the year ended December 31, 2015 and thereafter are subject to examinations by federal and state tax authorities. Tax returns of Sun BioPharma Australia Pty Ltd. for the year ended December 31, 2014 and thereafter are subject to examination by the Australian tax authorities.

11. Subsequent Events

On February 21, 2020 the company entered an agreement with an investment banking firm. A portion of the retainer fee was paid via the issuance of 75,000 5-year warrants. The fair market value of the warrants issued of approximately $148,000 will be capitalized and charged against future proceeds.

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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

Paul W. Schaffer

D. Robert Schemel

Arthur J. Fratamico

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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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