Aravive, Inc.
Form 10-K
March 15, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018

OR

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

Commission File Number 001-36361

Aravive, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware (State or Other Jurisdiction of Incorporation or Organization)	26-4106690 (I.R.S. Employer Identification No.)
LyondellBasell Tower 1221 McKinney Street, Suite 3200	77010

Houston, Texas
(Address of Principal Executive Offices) (Zip Code)
Registrant's telephone number, including area code: (936) 355-1910

Securities registered pursuant to Section 12(b) of the Act:

Common Stock, Par Value $0.0001 Per Share; Common stock traded on the Nasdaq Global Select Market
Securities registered pursuant to Section 12(g) of the Act:

None

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 15(d) of the Act. YES NO

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

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

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

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

Large accelerated filer Accelerated filer

Non-accelerated filer Small reporting company
Emerging growth company
If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The Nasdaq Global Select Market on June 30, 2018, the last business day of the registrant's most recently completed second fiscal quarter, was $59,763,689.

The number of shares of registrant's Common Stock outstanding as of March 8, 2019 was 11,276,500.

Portions of the Registrant's Definitive Proxy Statement relating to the Annual Meeting of Shareholders, are incorporated by reference into Part III of this Report.

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PART I

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains “forward-looking statements” that involve risks and uncertainties. Our actual results could differ materially from those discussed in the forward-looking statements. The statements contained in this report that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the “Securities Act”, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Forward-looking statements are often identified by the use of words such as, but not limited to, “anticipate,” “believe,” “can,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “proje “should,” “strategy,” “target,” “will,” “would” and similar expressions or variations intended to identify forward-looking statements. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Such forward-looking statements are subject to risks, uncertainties and other important factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section titled “Risk Factors” included under Part I, Item 1A below. Furthermore, such forward-looking statements speak only as of the date of this report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

This Annual Report on Form 10-K also contains market data related to our business and industry. These market data include projections that are based on a number of assumptions. If these assumptions turn out to be incorrect, actual results may differ from the projections based on these assumptions. As a result, our markets may not grow at the rates projected by these data, or at all. The failure of these markets to grow at these projected rates may harm on our business, results of operations, financial condition and the market price of our common stock.

Item 1. Business.

Merger of Versartis, Inc. and Aravive Biologics, Inc.

On October 12, 2018, we, then known as Versartis, Inc. and Aravive Biologics, Inc. or Private Aravive, completed a merger and reorganization, or the Merger, pursuant to which Private Aravive survived as our wholly owned subsidiary. In connection with the completion of the Merger, on October 15, 2018, we changed our name from Versartis, Inc. to "Aravive, Inc." and on October 16, 2018, we effected a reverse split of our common stock at a ratio of 1-for-6, or the Reverse Split, On October 16, 2018, our common stock began trading on the Nasdaq Global Market under the symbol "ARAV." Unless otherwise stated, all share and per share amounts for all periods presented in this Annual Report on Form 10-K have been adjusted to reflect the Reverse Split.

Immediately following the completion of the Reverse Split and the Merger, there were approximately 11,182,025 shares of our common stock outstanding, of which approximately 5,141,915 were owned by the former Private Aravive stockholders. In addition, we assumed Private Aravive's equity incentive plans and all of the stock options outstanding under the Private Aravive's equity incentive plans, with such stock options representing at the effective time of the Merger the right for the former Private Aravive stockholders to purchase approximately 1,183,950 shares of our common stock.

Unless otherwise indicated, all references to "Aravive," "we," "us," "our" or the "Company" in this Annual Report on Form 10-K refer to Aravive, Inc.(the combined company formerly known as Versartis, Inc.) and references to "Versartis, Inc." or "Private Aravive." refer to those respective companies prior to the completion of the Merger.

Overview

Upon effecting the Merger, we became a clinical-stage biotechnology company focused on developing new therapies that target important survival pathways for both advanced solid tumors as well as hematologic malignancies.

Our primary therapeutic focus is the GAS6-AXL pathway, where AXL receptor signaling plays an important role in multiple types of malignancies by promoting metastasis, cancer cell survival, resistance to treatments, and immune suppression. Our technology originated in the laboratories of Dr. Amato Giaccia and his colleagues at Stanford University. In August 2018, the U.S. Food and Drug Administration, or FDA, designated as a Fast Track development program the investigation of our lead development candidate, AVB-S6-500, for platinum-resistant recurrent ovarian cancer.

Our AXL decoy program, referred to as AVB-S6, is comprised of a family of novel, high-affinity, soluble Fc-fusion proteins designed to block the activation of the GAS6-AXL signaling pathway by intercepting the binding of GAS6 to its receptor AXL. We have generated preclinical data for AVB-S6 proteins in both acute myeloid leukemia and certain advanced solid tumors including ovarian, renal, pancreatic, and breast cancers.

Our current development program benefits from the availability of a complementary serum-based biomarker that we expect will help accelerate drug development and reduce risk by allowing us to select a pharmacologically active dose, to better monitor therapeutic responses and potentially to better select responder patient populations.

In our recently completed Phase 1 clinical trial with AVB-S6-500, the lead development candidate selected from the AVB-S6 family of proteins, we demonstrated clinical proof-of-mechanism for AVB-S6-500 in neutralizing GAS6. In an analysis of the single ascending dose portion of the trial, all doses of AVB-S6-500 administration resulted in a decrease measurable, circulating free GAS6 in serum. The duration of suppression of serum GAS6 increased with increasing AVB-S6-500 doses. Importantly, AVB-S6-500 had a favorable safety profile in this first in human trial and in preclinical studies. In December 2018, we initiated the Phase 1b portion of our first Phase 1b/2 clinical trial in in patients with platinum- resistant recurrent ovarian cancer. In February 2019, we announced our plans to initiate

clinical trials with AVB-S6-500 in our second oncology indication, patients with Clear Cell Renal Cell Carcinoma (ccRCC), and we also announced our plans to conduct a small open label clinical trial with AVB-S6-500 in patients with immunoglobulin A nephropathy (IgAN).

In 2016, Private Aravive was approved for a $20 million Product Development Award from the Cancer Prevention & Research Institute of Texas, or CPRIT, which is one of the largest single grants that CPRIT has awarded to date based on information published on CPRIT's website. All of our revenue for the year ended December 31, 2018 was grant revenue received from CPRIT.

Phase 1 Clinical Trial

We recently completed our initial Phase 1 clinical trial with our lead protein, AVB-S6-500, in 42 dosed normal healthy volunteers. Subjects in the Phase 1 trial were given single ascending intravenous, or IV, doses and 4 weekly repeat IV doses of AVB-S6-500. The primary objective of the trial was to evaluate the safety and tolerability in healthy subjects of intravenous AVB-S6-500. Secondary objectives were to characterize the pharmacokinetics and pharmacodynamics of intravenous AVB-S6-500 over a range of dose levels and at a single dose level (5mg/kg) for a total of 4 weekly doses.

There were no adverse events, or AEs, classified as serious and no dose-related AEs. Treatment-emergent AEs were generally mild, transient, and self-limiting. No anti-drug antibodies were noted. As anticipated from preclinical studies, a maximum tolerated dose was not reached and AVB-S6-500 was well-tolerated across all doses (1-10mg/kg single doses and 4 weekly 5mg/kg doses). The clinical trial met the safety and tolerability endpoints for the trial and demonstrated clinical proof-of-mechanism for AVB-S6-500 at all doses in neutralizing GAS6, as all doses tested in human subjects suppressed serum GAS6 for at least one week. Serum GAS6 levels were suppressed until 22 and 29 days following the 5 mg/kg and 10 mg/kg doses, respectively. Weekly administration of 5mg/kg resulted in suppression of sGAS6 in 4 out of 6 subjects for at least 3 weeks after the fourth dose.

In August 2018, the FDA, designated as a Fast Track development program the investigation of our lead development candidate, AVB-S6-500, for platinum-resistant recurrent ovarian cancer.

By conducting the Phase 1 trial in healthy volunteers, we expect that we will not need to conduct any additional Phase 1 studies for other indications in which AVB-S6-500 is the product candidate, and instead expect to have the ability to have as our first clinical trial for such other indications a Phase 1b or Phase 2 trial, pending FDA review.

Phase 1b/2 Clinical Trial for the Treatment of Platinum-Resistant Recurrent Ovarian Cancer

In December 2018, we began treating patients in the Phase 1b portion of our Phase 1b/2 clinical trial combining AVB-S6-500 with standard-of-care therapies (specifically, paclitaxel (“Pac”), and pegylated liposomal doxorubicin (“PLD”)) in patients with platinum- resistant recurrent ovarian cancer. The decision to select platinum-resistant recurrent ovarian cancer as our first indication was based upon the preclinical data that we had generated with AVB-S6-500 in platinum resistant ovarian cancer, the fact that platinum resistant ovarian tumors are highly AXL positive and the high unmet medical need for effective therapies to treat platinum resistant ovarian cancer.

Ovarian Cancer and Current Market Opportunity

Ovarian cancer is the fifth most common malignancy in women and is the leading cause of death among gynecological cancers. According to the American Cancer Society, it is estimated that in 2019 there will be approximately 22,530 new cases of ovarian cancer diagnosed and approximately 13,980 ovarian cancer deaths in the United States. A woman's risk of getting ovarian cancer during her lifetime is about 1 in 78. Her lifetime chance of dying from ovarian cancer is about 1 in 108. Ovarian cancer accounts for just 2.5% of all female cancer cases, but 5% of cancer deaths because of the disease's low survival rate. Due to the nonspecific nature of disease symptoms, currently the majority of ovarian cancer patients are diagnosed with advanced-stage disease, at which point their prognosis is poor. Improving the ability to detect ovarian cancer early is a research priority, given that women diagnosed with localized-stage disease have more than a 90% five-year survival rate.

Current standard of care treatments for ovarian cancer include surgery and chemotherapy (cisplatin and carboplatin). The median progressive free survival rate for patients given standard of care (paclitaxel or doxil) to treat platinum-resistant recurrent ovarian cancer is 3-4 months with a median overall survival of 9-12 months. Targeted therapies include bevacizumab (Avastin), and other drugs, such as immune checkpoint inhibitors, are being investigated as well. Drugs that inhibit the enzyme PARP-1 (called PARP inhibitors) have been approved for patients with ovarian cancer caused by mutations in BRCA1 and BRCA2 or as maintenance treatment following a platinum-based chemotherapy. New evidence shows that ovarian cancers can also become resistant to treatment with PARP inhibitors, and research is being conducted in the field to find ways to counteract this process.

Decision Resources Group in its July 2018 Ovarian Cancer Disease Landscape and Forecast estimates the ovarian cancer market to grow at an annual compound rate of 14% during the 2017-2027 period from approximately $1.4B to $5.3 billion in the seven major markets, which comprise the United States, France, Germany, Italy, Spain, the United Kingdom and Japan.

Phase 1b portion of the Phase 1b/2 Clinical Trial

The open-label, Phase 1b portion of the trial is expected to enroll up to 36 patients. The Phase 1b portion of the Phase 1b/2 clinical trial is designed, in part, to confirm the dosing regimen predicated on the Phase 1 trial in healthy volunteers. The primary objective of the Phase 1b portion of the Phase 1b/2 clinical trial is to assess the safety and tolerability of AVB-S6-500 in combination with Pac and PLD, and secondary objectives are to assess PK/PD (serum GAS6 levels), efficacy, and potential immunogenicity of AVB-S6-500. Exploratory objectives include exploration of efficacy endpoints in biomarker (GAS6, AXL) defined populations based on expression of those biomarkers in serum and/or tumor tissue. Initial safety data from the Phase 1b portion of a Phase 1b/2 clinical trial is expected in the third quarter of 2019.

Planned Phase 2 Portion of the Phase1b/2 Clinical Trial

The Phase 2 portion of the Phase 1b/2 clinical trial is expected to enroll the first patient in the second half of 2019 and will be a double-blind, randomized, controlled trial comparing AVB-S6-500 plus standard of care (PLD or Pac) to standard of care alone (placebo). This Phase 2 portion is expected to enroll approximately 120 patients who will be randomized on a 2:1 basis to active arm versus placebo. The primary objective of the Phase 2 portion of the Phase 1b/2 clinical trial is to assess anti-tumor activity of AVB-S6-500 in combination with Pac or PLD as a measure by progression free survival (PFS). Secondary objectives include assessment of PK/PD and additional efficacy endpoints (objective response rate (ORR), overall survival (OS), duration of response (DOR), disease control rate (DCR)). Topline data is expected at the end of 2020. Depending upon results, this clinical trial can be amended to include more patients to potentially become a pivotal trial after discussions with the FDA.

Second Oncology Indication-Clear Cell Renal Cell Carcinoma (ccRCC)

In February 2019, we announced our plans to develop AVB-S6-500 in our second oncology indication, Clear Cell Renal Cell Carcinoma (ccRCC). The decision to select ccRCC as our second indication was based upon the strong preclinical data that we had derived with AVB-S6-500 and the fact that AXL expression in primary tumors of ccRCC patients has been shown, in, third party studies as well as our own studies (Rankin et al, Direct regulation of GAS6/AXL signaling by HIF promotes renal metastasis through SRC and MET, PNAS September 16, 2014 vol. 111 no. 37 13373–13378), to correlate with aggressive tumor behaviors. We expect to initiate a phase 1b/2 clinical trial with AVB-S6-500 in patients with clear cell renal cell carcinoma in the second half of 2019.

Clear Cell Renal Cell Carcinoma and Current Market Opportunity

Kidney cancer is a leading cause of cancer-related deaths in the United States and is among the 10 most common cancers in both men and women. Metastasis to distant organs including the lung, bone, liver and brain is the primary cause of death in kidney cancer patients as only 12% of metastatic kidney cancer will survive past 5 years. According to the American Cancer Society, it is estimated that there will be approximately 73,820 new cases of kidney cancer (44,120 in men and 29,700 in women) and 14,770 people will die from this disease (9,820 men and 4,950 women) in 2019.

Clear cell renal cell carcinoma is a cancer of the kidney. The name "clear cell" refers to the appearance of the cancer cells when viewed with a microscope. Clear cell renal cell carcinoma occurs when cells in the kidney quickly increase in number, creating a lump (mass). Though the exact cause of clear cell renal cell carcinoma is unknown, smoking, the excessive use of certain medications, and genetic predisposition conditions, e.g. von Hippel Lindau syndrome which involves genetic mutation in VHL, a tumor suppressor gene controlling tumor initiation in 90% of ccRCC tumors, may contribute to the development of this type of cancer. The primary function ascribed to VHL is the regulation of HIF protein stability. In VHL-deficient tumors, HIF transcriptional activity is constitutively active and contributes to both ccRCC tumor initiation and metastasis. Reports have established a molecular link between HIF stabilization and AXL expression in metastatic ccRCC (Rankin et al, PNAS, September 16, 2014, vol. 111, no. 37,

13373–13378; Boysen G, Bausch-Fluck D, Thoma CR, et al. Identification and functional characterization of pVHL-dependent cell surface proteins in renal cell carcinoma. Neoplasia 2012;14:535–46. Jun). The expression of the receptor tyrosine kinase AXL in tumors has been postulated as a biomarker and increased mRNA levels of AXL is associated with poor differentiation grade and survival in renal cell cancer. (Gustafsson A, Martuszewska D, Johansson M, et al. Differential expression of AXL and Gas6 in renal cell carcinoma reflecting tumor advancement and survival. Clin Cancer Res 2009;15: 4742–9. Jul 15; Boysen G, Bausch-Fluck D, Thoma CR, et al. Identification and functional characterization of pVHL-dependent cell surface proteins in renal cell carcinoma. Neoplasia 2012;14:535–46. Jun; Zhou L, Liu XD, Sun M, et al. Targeting MET and AXL overcomes resistance to sunitinib therapy in renal cell carcinoma. Oncogene, 2016 May; 35(21): 2687–2697. doi:10.1038/onc.2015.343.)

Treatment often begins with surgery to remove as much of the cancer as possible, and may be followed by radiation therapy, chemotherapy, biological therapy, or targeted therapy. Most kidney cancer is chemotherapy and radiation resistant, resulting in a large unmet need for treatment therapies.

Non-Oncology Planned Trial-P2a IgA Nephropathy Trial

In February 2019, we also announced our intent to develop AVB-S6-500 for potential use in patients with immunoglobulin A nephropathy (IgAN). IgAN is a nonsystemic renal disease that is characterized by predominant IgA deposition in the glomerular mesangium, causing mesangial proliferation and fibrosis. IgA Nephropathy (IgAN) is the most common cause of primary glomerulonephritis and responsible for 10% of patients on dialysis affecting approximately 150,000-180,000 people in the United States. IgAN is caused by IgA deposits in the kidneys, causing mesangial proliferation and fibrosis. Up to 50% of patients with IgAN develop end-stage renal disease and require dialysis within 20 years of diagnosis. There is a high unmet medical need for treatment for IgAN as there are currently no therapies approved for treatment of IgAN.

There are no approved drugs for the treatment of IgA nephropathy and a few therapies are currently in development. Three current development programs target the complement pathway: Omeros Corporation is conducting a phase 3 clinical trial with an injectable MASP-2 inhibitor; Novartis AG is conducting a phase 2 clinical trial with their oral compound, LNP023; and Apellis Pharmaceuticals, Inc. is conducting a phase 2 clinical trial with APL2. Two other programs target B cell activity: EMD Serono Research & Development Institute, Inc. is testing Atacicept in a phase 2 clinical trial and Visterra Inc. is in the midst of testing VIS649in a phase I healthy volunteer clinical trial. AVB-S6-500 has a mechanism of action unique from these other therapies.

GAS6 is a growth factor that causes proliferation of mesangial cells in the development of glomerulonephritis. GAS6 is upregulated in either endothelial/mesangial cells or podocytes in IgAN (Nagai K, Miyoshi M, Kake T, Fukushima N, Matsuura M, et al. (2013) Dual Involvement of Growth Arrest-Specific Gene 6 in the Early Phase of Human IgA Nephropathy. PLoS ONE 8(6): e66759. doi:10.1371/journal.pone.0066759). and expression in the diseased kidney tissue correlates with severity of IgA nephropathy (Nagai K, Miyoshi M, Kake T, Fukushima N, Matsuura M, et al. (2013) Dual Involvement of Growth Arrest-Specific Gene 6 in the Early Phase of Human IgANephropathy. PLoS ONE 8(6): e66759. doi:10.1371/journal.pone.0066759). Preclinical data demonstrated that a lower affinity GAS6-trap improves fibrosis and proteinurea in experimental glomerulonephritis (Am J Pathol. 2001 Apr; 158(4): 1423–1432.doi: 10.1016/S0002-9440(10)64093-X). Aravive has assessed serum levels in a small number of IgAN patients and found that they are elevated in comparison to age-matched subjects who do not have IgAN.

As currently discussed within the company, we believe the clinical trial with AVB-S6-500 in patients with IgAN will be a small open label clinical trial of 10-12 patients with IgAN treated for a 2 month period with 4 doses of AVB-S6-500. The primary objective of the clinical trial will be to evaluate the safety and tolerability of AVB-S6-500 IV in IgAN patients. Secondary objectives will be to characterize the pharmacokinetics and pharmacodynamics of IV AVB-S6-500 to ensure GAS6 levels are suppressed over the dosing interval. The clinical trial will monitor proteinuria, hematuria and other renal functions and biopsies of patients will be taken before and after treatment to assess the effect on renal tissue and AXL activity. We intend, following discussions with FDA and allowance to proceed, to initiate a phase 1b clinical trial in the second half of 2019.

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Other Indications

We expect, subject to sufficient funding, to initiate additional clinical trials. Such additional clinical trials may involve combining AVB-S6-500 with standard of care in a number of tumor types, which may include in addition to ovarian cancer and clear cell renal cell carcinoma, acute myeloid leukemia, triple negative breast cancer and pancreatic cancer. We are also considering conducting studies in non-oncology indications such as kidney, lung or liver fibrosis in addition to the planned clinical trial with patients with IgAN.

GAS6-AXL Pathway

As illustrated in the following graphic, AXL receptor signaling plays an important role in multiple types of malignancies by promoting metastasis, cancer cell survival, resistance to treatments, and immune suppression.

In preclinical studies, we have also identified high AXL expression on tumors resistant to the combination of radiotherapy and immunotherapy and that genetically inactivating AXL in tumors resistant to immunotherapy and radiotherapy restored anti-tumor immune response.

In preclinical studies conducted in Dr. Giaccia's laboratories at Stanford University, Dr. Giaccia was able to demonstrate that the immune response generated by loss of AXL leads to adaptive immune resistance through PD-L1 expression and Treg (regulatory T cells) infiltration. This resulted in tumors that became sensitive to checkpoint immunotherapy when they were previously resistant. Thus, GAS6-AXL pathway inhibitors, in combination with radiation or chemotherapy and immunotherapy, may be a promising treatment regimen and restore anti-tumor immune response.

Aravive-S6 (AVB-S6)

AVB-S6 is comprised of a family of novel, high-affinity, soluble Fc-fusion proteins designed to block the activation of the GAS6-AXL signaling pathway by intercepting GAS6 and interfering with its binding to its receptor AXL. AVB-S6 proteins have been engineered to have approximately 50 to 200 times greater affinity for human GAS6 compared to the native AXL receptor, effectively sequestering GAS6 and abrogating AXL signaling. We believe this 'decoy receptor' approach is well suited for AXL inhibition compared to small molecule receptor tyrosine kinase inhibitors or antibodies, as illustrated by the following graphic.

Approaches to Inhibiting the GAS6/AXL Signaling

RTK - receptor tyrosine kinase

mAb - monoclonal antibody

Preclinical Results

Our AVB-S6 proteins have been shown to bind GAS6 with higher affinity than the endogenous AXL protein and inhibit the GAS6/AXL signaling. Initial preclinical pharmacology studies were conducted with a variety of engineered AVB-S6 proteins. The preclinical program demonstrated that high GAS6 binding affinity was critical and correlative with the ability of AVB-S6 to inhibit metastasis and disease progression in vivo. AVB-S6 proteins have demonstrated significant efficacy in mouse models of metastatic ovarian, breast, renal, and pancreatic cancers.

AVB-S6 proteins are selective for the AXL signaling pathway and demonstrate potent anti-metastatic activity in preclinical models. The following graphic indicates that AVB-S6 is selective for the AXL signaling pathway and is potent in a preclinical breast cancer lung metastasis model. The left panel shows western blot analysis of OVCAR8 (human platinum-resistant ovarian cancer) cells after 4-hour treatment with BGB324, foretinib, or AVB-S6. The right panel shows representative bioluminescent images of lung metastases in the 4T1 mouse model following treatment with vehicle (negative control), foretinib, BGB324 or AVB-S6.

Figure 4 of OVCAR8 JCI 2017 127(1) 183-195

The following graphic indicates that the affinity of AVB-S6 proteins relates to anti-metastatic effect in preclinical studies. The left panel shows the number of metastases from the peritoneum of OVCAR8 (human platinum-resistant ovarian cancer) mouse model following treatment with three AVB-S6 proteins having different affinity (330 fM, 10 pM and >2 nM). The right panel shows the total tumor weight from the peritoneum of OVCAR8 mouse model following treatment with the same three AVB-S6 proteins.

AVB-S6 proteins inhibit invasion and migration of highly invasive and metastatic cells, MDA-MB-231 and OVCAR8. In vivo studies with AVB-S6 proteins demonstrated significant reductions in metastatic tumor weight and number in platinum resistant ovarian (SKOV3.IP and OVCAR8) cancer models. In combination with the chemotherapy drug doxorubicin (Dox), the anti-metastatic effect was greater, and 20-30% of the animals were tumor-free after the combination treatment in both platinum-resistant ovarian cancer studies.

The following graphic indicates that AVB-S6 augments the efficacy of doxorubicin in a preclinical platinum resistant ovarian cancer model (SKOV3.IP).

Figure 6B from JCI 2017; (127)(1) 183-198

AVB-S6 proteins also demonstrated significant reductions in metastatic disease in triple negative breast (4T1), pancreatic (PDA1-1), and renal (SN12L1) cancer models. Additionally, in an orthotopic pancreatic model (LM-P) the AVB-S6 protein significantly increased survival in combination with the chemotherapy drug gemcitabine relative to gemcitabine or vehicle alone. The combination studies also demonstrated a relationship between AXL signaling and the cellular response to DNA damage in breast, pancreatic and ovarian cancer models. This relationship was even more pronounced in combination with cytotoxic chemotherapies such as doxorubicin and gemcitabine.

Notably, treatment with the AVB-S6 protein alone or in combination with gemcitabine demonstrated a significant decrease in tumor fibrosis. Decreasing fibrosis in the tumor microenvironment may increase efficacy of co-administered chemotherapeutics and potentially immuno-therapeutics by allowing greater access of T cells to the tumor cells. Once the development candidate, AVB-S6-500, was selected, in vitro and in vivo pharmacology studies were conducted to demonstrate that AVB-S6-500 had the same biological activity as the other AVB-S6 proteins.

Biomarker

GAS6 expression in tumors has been reported to be an adverse prognostic factor in several cancers, including urothelial, ovarian, lung adenocarcinoma, gastric cancer, glioblastoma, oral squamous cell carcinoma, liver carcinoma, and renal cell carcinoma. In studies conducted by us, AVB-S6proteins bind GAS6 with higher affinity than the endogenous AXL protein and prevent GAS6 signaling at the AXL receptor. Preclinical efficacy data for the AVB-S6 program demonstrated a relationship between reduced serum GAS6 and an anti-metastatic effect. We have developed an assay designed to measure GAS6 levels in the blood before and after dosing of Our development candidate. In the presence of a pharmacologically active dose of AVB-S6, serum GAS6 has not been detectable. Thus, GAS6 levels in the blood of patients may be a pharmacodynamic biomarker that can aid AVB-S6 dose selection and potentially serve as a predictive biomarker for response to treatment with AVB-S6.

The following graphic indicates the relationship between AVB-S6-500 protein levels and GAS6 levels in blood from humans participating in the AVB-S6-500 first in human trial.

Manufacturing

Manufacturing of our clinical trial material consists of three main phases, the production of bulk protein (drug substance), formulation/filling operations, and labelling/packaging operations of the finished product. The protein has been manufactured at high yield and with high purity. The clinical bulk drug substance is produced using industry standard manufacturing processes, as is the drug product.

Since September 2017, we have relied on a third party contract manufacturer to manufacture clinical bulk drug substance and drug product of AVB-S6-500 using a cell line and process developed by our contract manufacturer that has been licensed to us on a non-exclusive basis. We have manufactured enough AVB-S6-500 to dose approximately 400 patients for a six-month period, which is expected to be sufficient to complete the planned Phase 1b/Phase 2 ovarian cancer trial. The clinical bulk drug substance and drug product is manufactured pursuant to the terms of a five year Master Manufacturing Services Agreement that we entered into with our contract manufacturer in July 2016, which agreement automatically renews for successive one (1) year periods, unless either party provides written notice to the other party of its desire not to renew at least 90 days prior to the expiration of the then-current term. The Master Manufacturing Services Agreement is terminable by us upon 45 days prior written notice, by our contract manufacturer Limited upon 190 days prior written notice provided that all statements of work in progress at such time are completed and upon 60 days prior written notice upon a breach of the terms of the agreement if such breach is not cured within such 60 day period.

We have also contracted with an independent third party located in Texas for the labeling, packaging, and distribution of our injectable protein.

Our personnel have significant technical, manufacturing, analytical, quality and project management experience to execute and manage manufacturing process development, plus oversee the manufacture, testing, quality release, storage and distribution of drug products according to the current Good Manufacturing Practice, or cGMPs, promulgated by the FDA and other regulatory requirements. The cGMP regulations include requirements relating to the organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. Our facilities, and our third-party manufacturers, may be subject to periodic inspections by FDA and local authorities, which include, but are not limited to procedures and operations used in the testing and manufacture of our biological drug candidates to assess our compliance with applicable regulations. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including warning letters, the seizure or recall of products, injunctions, and consent decrees causing significant restrictions on or suspending manufacturing operations plus causing possible civil and criminal penalties. These actions could have a material impact on the availability of its biological drug candidates. Similar to contract manufacturers, we may encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel.

Research and Development

We have made and will continue to make substantial investments in research and development. Our research and development expenses totaled $11.1 million and $94.6 million for the years ended December 31, 2018 and 2017, respectively.

In the ordinary course of business, we enter into agreements with third parties, such as clinical research organizations, medical institutions, clinical investigators and contract laboratories, to conduct clinical trials and aspects of research and preclinical testing. These third parties provide project management and monitoring services and regulatory consulting and investigative services.

Competition

The biotechnology and pharmaceutical industries are characterized by intense competition to develop new technologies and proprietary products. We face competition from many different sources, including biotechnology and pharmaceutical companies, academic institutions, government agencies, as well as public and private research institutions. Any products that we may commercialize will have to compete with existing products and therapies as well as new products and therapies that may become available in the future.

At this time, there are no FDA- or European Medicines Agency-approved therapies targeting GAS6. We believe this mechanism of action represents a novel approach to inhibiting tumor growth and metastasis, as well as addressing tumor immune evasion and resistance to other anticancer agents. Exelixis, Inc. markets cabozantinib, the only currently marketed AXL inhibitor. We are aware of a number of companies focused on developing AXL inhibitors in various indications, including BerGenBio ASA, Astellas Pharma Inc., Mirati Therapeutics, Inc., Les Laboratoires Servier, SAS, Eli Lilly and Company, Bristol-Myers Squibb Company, Tolero Pharmaceuticals, Inc., Ignyta, Inc., as well as several companies addressing AXL inhibitors, and PARP 1/2 inhibitors and related signaling pathways.

Our competition may also include companies that are or will be developing therapies for the same therapeutic areas that we are targeting, including ovarian cancer, pancreatic cancer, acute myeloid leukemia, renal cell carcinoma, and liver fibrosis. Many of our potential competitors, alone or with their strategic partners may have substantially greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personal, establishing clinical trial sites and patient registration for clinical trials, and in acquiring technologies complementary to, or necessary for our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that it may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our product candidates, which could result in our competitors establishing a strong market position before it is able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third party payors seeking to encourage the use of generic products.

License Agreement

In 2012, Private Aravive entered into an exclusive license agreement with Leland Stanford Junior University, or Stanford University, for intellectual and tangible property rights relating to biologic inhibitors for therapeutic targeting the receptor tyrosine kinase AXL. The license agreement was amended in 2012, 2015 and 2017 to modify certain of the stated milestones and expand the patent rights granted to Private Aravive. The term of the license is the length of the last to expire patent. The license agreement grants Private Aravive exclusive, worldwide rights to make, use or sell licensed materials based upon the following patent-related rights:

- U.S. patent application: Serial number PCT/US2012/069841, filed December 14, 2012; Serial Number 13/714,875, filed December 14, 2012 ; Serial Number PCT/US2013/074786, filed December 12, 2013; Serial Number 14/650,854, filed June 9, 2015; Serial Number PCT/US2015/066498, filed December 17, 2015; Serial Number 15/535,995, filed June 14, 2017; which patents are jointly owned with Private Aravive and all U.S. patents and

foreign patents and patent applications based on the application; as well as all divisionals, continuations, and those claims in continuations-in-parts to the extent they are sufficiently described in the application, and any re-examinations or reissues of the foregoing.

- U.S. patent application: Serial Number PCT/US2011/022125, filed January 21, 2011; Serial Number 13/554,954, filed July 20, 2012; Serial Number 13/595,936, filed August 27, 2012; Serial Number 13/950,111, filed July 24, 2013; Serial Number 14/712,731, filed May 14, 2015; which patents are solely owned by Stanford University, and all U.S. patents and foreign patents and patent applications based on the application; as well as all divisionals, continuations, and those claims in continuations-in-parts to the extent they are sufficiently described in the application, and any re-examinations or reissues of the foregoing.

As consideration for the rights granted in the license agreement, Private Aravive is obligated to pay Stanford University yearly license fees and milestone payments, and a royalty based on net sales of products covered by the patent-related rights set forth above. More specifically, Private Aravive is obligated to pay Stanford University (i) annual license payments, (ii) milestone payments of up to an aggregate of $1,000,000 upon achievement of clinical and regulatory milestones, and (iii) royalties equal to a percentage (in the low single digits) of net sales of licensed products; provided that the annual license payments made will offset (and be credited against) any royalties due in such license year. In the event of a sublicense to a third party of any rights based on the patents that are solely owned by Stanford University, Private Aravive is obligated to pay royalties to Stanford University equal to a percentage of what Private Aravive would have been required to pay to Stanford University had it sold the products under sublicense itself. In addition, in such event Private Aravive is required to pay to Stanford University a percent of sublicensing income. The license agreement may be terminated by Stanford University upon 30 days written notice if Private Aravive breaches its obligations thereunder, including failing to make any milestone or other required payments or to exercise diligence to bring licensed products to market. In the event of a termination, Private Aravive will be obligated to pay all amounts that accrued prior to such termination. The license agreement also contains other customary clauses and terms as are common in similar agreements between industry and academia, including the licensee's agreement to indemnify Stanford University for any liabilities arising out of or related to the licensee's exercise of its rights under, or breach of, the license agreement, the reservation of the licensor of the right to use the licensed intellectual property rights for its internal, non-commercial purposes, limitations/disclaimers of various warranties.

CPRIT Grant

In 2016, Private Aravive was approved for a $20.0 million grant, or the CPRIT Grant, from CPRIT for development of AVB-S6. The CPRIT Grant is subject to customary CPRIT funding conditions including a matching funds requirement whereby Private Aravive was required to match $0.50 for every $1.00 from CPRIT. Consequently, Private Aravive was required to raise $10.0 million in matching funds, and it has raised $11.4 million since 2016. The grant award, as is customary for all CPRIT awards, contains a requirement that Private Aravive pay CPRIT a tiered royalty on sales of commercial products developed using CPRIT funds equal to a low- to mid-single digit percentage of revenue until such time as CPRIT has been paid an aggregate amount equal to 400% of the grant award proceeds. After 400% of the grant award proceeds has been paid, Private Aravive Biologics will be obligated to pay CPRIT a royalty of less than one percent for as long as Private Aravive maintains government exclusivity. The CPRIT Grant contract terminates on May 31, 2019, unless extended with CPRIT's approval. After the termination date, we are not permitted to retain any unused grant award proceeds without CPRIT's approval, but our royalty and other obligations, including our obligation to repay the disbursed grant proceeds under certain circumstances, survive the termination of the agreement. We have received $18.0 million of the grant award proceeds and expect to expend all of the grant award proceeds by the agreement termination date. We expect to receive the remaining $2.0 million grant award as reimbursement of future expenses once we have expended the $18.0 million of grant award proceeds already received.

The CPRIT Grant is subject to us complying with all terms set forth in the CPRIT Grant, including maintaining our status with CPRIT as a Texas-based entity. In order to qualify as a Texas-based entity, a company must fulfill a majority of the following seven requirements: (i) its US headquarters must be physically located in Texas; (ii) its chief executive officer must reside in Texas; (iii) a majority of its personnel, including at least two other senior-level employees, must reside in Texas; (iv) its manufacturing activities must take place in Texas; (v) at least 90% of its grant award funds must be paid to individuals and entities in Texas, including salaries and personnel costs for employees and contractors: (vi) at least one clinical trial site must be in Texas; and (vii) it must collaborate with a medical research organization in Texas, including a public or private institution of higher education. Currently, we meet a majority of these seven requirements.

Intellectual Property

We strive to protect and enhance the proprietary technology, inventions and improvements that are commercially important to our business, including seeking, maintaining, and defending patent rights. We also rely on trade secrets relating to our technology and know-how to develop, strengthen and maintain our proprietary position in the field of targeting the GAS6-AXL pathway for the identification and development of therapeutic candidates for cancer therapy and fibrosis. In addition, we rely on regulatory protection afforded through data exclusivity, market exclusivity and patent term extensions where available. We also utilize trademark protection for our company name, and expect to do so for products and/or services as they are marketed.

Our commercial success will depend in part on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business; defend and enforce our patents; preserve the confidentiality of our trade secrets; and operate without infringing the valid enforceable patents and proprietary rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell or importing our therapeutic candidates may depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. With respect to both licensed and company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our commercial products and methods of manufacturing the same.

Our patent position with respect to the GAS6-AXL program is comprised of six patent portfolios containing composition of matter claims relating to novel GAS6-binding fusion proteins, and claims to the use of our novel fusion proteins for the treatment of various oncological conditions, as well as antiviral and antifibrotic disorders. Our license agreement with Stanford University provides us with exclusive rights to intellectual property, or IP, that is either solely owned by Stanford (Portfolio I below) or co-owned by Stanford and us (Portfolios II, III, and V below). We also have rights to IP that we solely own (Portfolio IV and VI below)

As of February 28, 2019, we have exclusive rights to more than 10 issued patents and 9 pending patent applications that are solely owned by Stanford University and licensed to us. The expiration date for those patents/patent applications is 2031. We also have exclusive rights to 5 issued patents and more than 10 pending applications that are jointly owned with Stanford University and are also subject to the license agreement with Stanford. The expiration dates for those patents/patent applications range from 2033-2035. We have one issued patent and two pending patents that we solely own. The expiration dates for those patents range from 2035-2038. Additional details on our relevant portfolios is provided below:

- Portfolio I— “Inhibition of AXL Signaling in Anti-Metastatic Therapy” More than 10 Granted Patents in the United States, Australia, China, Europe, Japan, Korea, Russia, and South Africa—9 Pending Applications in United States, Brazil, Canada, China, Europe, Hong Kong, India, and South Korea.

- Portfolio II— “Inhibition Of AXL/GAS6 Signaling in the Treatment Of Liver Fibrosis” 1 Granted Patent in the United States—1 Pending Application in the United States.

- Portfolio III— “Modified AXL Peptides and Their Use in Inhibition of AXL Signaling in Anti- Metastatic Therapy” 4 Granted Patents in the United States, Australia, Europe, and Japan—6 Pending Applications in the United States, Australia, Canada, Europe, Japan, and Hong Kong.

- Portfolio IV— “Antiviral Activity of GAS6 Inhibitor” 1 Granted Patent in the United States—1 Pending Application in Canada.

- Portfolio V— “Antifibrotic Activity of GAS6 Inhibitor” 5 Pending Applications in the United States, Australia, Canada, Europe, and Hong Kong.

- Portfolio VI— “Methods of Treating Metastatic Cancers Using Axl Decoy Receptors” 1 Pending Application in the United States.

In the future, we expect to continue prosecuting broader coverage of certain composition of matter applications. Additionally, we will seek to file new patents related to novel candidates, manufacturing, clinical formulations, dose, and indications, as well as evaluate the acquisition of other innovative IP.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the date of filing the non-provisional application.

In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office in granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier-filed patent.

The term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration of a U.S. patent as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Moreover, a patent can only be extended once, and thus, if a single patent is applicable to multiple products, it can only be extended based on one product. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. When possible, depending upon the length of clinical trials and other factors involved in the filing of a new drug application, or NDA, we expect to apply for patent term extensions for patents covering its therapeutics candidates and their methods of use.

We may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these procedures, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Government Regulation

Federal, state and local government authorities in the United States and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of biological and pharmaceutical products such as those we are developing. Our product candidates must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in foreign countries. The process for obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Drug Approval Process

In the United States, the FDA regulates pharmaceutical and biological products under the Federal Food, Drug and Cosmetic Act, Public Health Service Act, or PHSA, and implementing regulations. Products are also subject to other federal, state and local statutes and regulations. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a drug or biological product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to good laboratory practices, or GLPs, and applicable requirements for the humane use of laboratory animals or other applicable regulations;

- submission to the FDA of an IND or Investigational New Drug which must become effective before human clinical trials may begin;

- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practices, or GCPs, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;

- submission to the FDA of a Biologics License Application, or BLA, for marketing approval that meets applicable requirements to ensure the continued safety, purity, and potency of the product that is the subject of the BLA based on results of nonclinical testing and clinical trials;

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced, to assess compliance with cGMP, to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity;

- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA; and

- FDA review and approval, or licensure, of the BLA.

Before testing any biological development candidate in humans, the candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trials.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations composing the GCP requirements, including the requirement that all research subjects provide informed consent. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The biological product is initially introduced into healthy human volunteers and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients with the targeted disease.

- Phase 2. The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.

- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to subjects.

Concurrently with clinical trials, companies usually complete additional studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other criteria, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. The FDA may grant deferrals for submission of data, or full or partial waivers. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee on approved biological products. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. No user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs and biological products that meet certain criteria. Specifically, new biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. For a Fast Track biological product, the FDA may consider review of completed sections of a BLA on a rolling basis provided the sponsor provides, and the FDA accepts, a schedule for the submission of the completed sections of the BLA. Under these circumstances, the sponsor pays any required user fees upon submission of the first section of the BLA. A Fast Track designated drug candidate may also qualify for priority review, under which the FDA reviews the BLA in a total of six months rather than ten months after it is accepted for filing.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission, and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, potent, and/or effective for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an 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 and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve a BLA without a REMS, if required.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements. To assure cGMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. If the agency decides not to approve the BLA in its present form, the FDA will issue a complete response letter that describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product.

Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

In addition, under the Pediatric Research Equity Act, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers.

Post-Approval Requirements

Any products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses, known as 'off-label' use, limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available products for off-label uses, if the physicians deem to be appropriate in their professional medical judgment, manufacturers may not market or promote such off-label uses.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the product. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and claims, are also subject to further FDA review and approval.

The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our product candidates under development.

Other U.S. Healthcare Laws and Compliance Requirements

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, for instance 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, the physician payment transparency laws, the privacy and security provisions of HIPAA, as amended by HITECH, 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 a number of 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. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor, however, 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 of its facts and circumstances. Violations of this law are punishable by imprisonment, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs.

Additionally, the intent standard under the anti-kickback statute was amended by the Affordable Care Act 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 in order to have committed a violation. In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, provides that the government may assert 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 civil False Claims Act., as discussed below.

The civil monetary penalties statute imposes penalties against any person or entity that, 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.

Although we would not submit claims directly to payors, drug manufacturers can be held liable under the federal civil False Claims Act, which imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services; making a false statement or record material to payment of a false claim; or avoiding, decreasing or concealing an obligation to pay money to the federal government. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties for each separate false claim, the potential for exclusion from participation in federal healthcare programs and, although the federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Claims which include items or services resulting from a violation of the federal Anti-Kickback Statute are false or fraudulent claims for purposes of the False Claims Act. Our future marketing and activities relating to the reporting of wholesaler or estimated retail prices for our products, if approved, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our product and any future product candidates, are subject to scrutiny under this law. 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. Similar to the federal anti-kickback statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct business. HIPAA, as amended by the HITECH Act, and their respective 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, defined as independent contractors or agents of covered entities, which include health care providers, health plans, and healthcare clearinghouse, that create, receive, or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and 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 attorney's fees and costs associated with pursuing federal civil actions. In addition, certain state laws govern the privacy and security of health information in specified circumstances, some of which are more stringent and many of which differ from each other in significant ways, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can

result in the imposition of significant civil and criminal penalties.

Additionally, the Federal Physician Payments Sunshine Act under 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 annually report to the Centers for Medicare and Medicaid, or CMS, information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately, and completely the required information may result in civil monetary penalties. of up to an aggregate of $150,000 per year and up to an aggregate of $1 million per year for "knowing failures". Certain states also mandate implementation of compliance programs, impose restrictions on pharmaceutical manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to healthcare providers and entities.

In order to distribute products commercially, we must also 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 of 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 it, we may be subject to penalties, including without limitation, significant civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, 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 enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company’s attention from the business.

Coverage, Pricing 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 that 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, private 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 of 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 in order to demonstrate the medical necessity and cost-effectiveness of our product candidates, 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. Adequate third party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

Different pricing and reimbursement schemes exist in other countries. 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 countries allow

companies to fix their own prices for medicines, but monitor and control company profits. 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 candidate 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 the pressure on healthcare pricing will continue to increase. 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.

U.S. Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. Among other things, the Tax Cuts and Jobs Act of 2017, or TCJA, includes a provision repealing, effective January 1, 2019, the tax based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the Affordable Care Act are invalid as well. The Texas District Court Judge, as well as the Trump Administration and CMS, have stated that the ruling will have no immediate effect, and on December 30, 2018 the Texas District Court Judge issued an order staying the judgment pending appeal. It is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act.

Congress also could consider additional legislation to repeal, replace, or further modify elements of the ACA. Thus, the full impact of the ACA, or any law replacing elements of it, and the political uncertainty regarding any repeal and replacement on the ACA, on our business remains unclear. Many of the details regarding the implementation of the ACA are yet to be determined, and at this time, it remains unclear the full effect that the ACA would have on our business. There have been judicial and Congressional challenges to the ACA, and we expect such challenges and amendments to continue in the future.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. Additionally, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs.

We cannot predict what healthcare reform initiatives may be adopted in the future. Further federal, state and foreign legislative and regulatory developments are likely, and we expect ongoing initiatives to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from product candidates and may affect our overall financial condition and ability to develop product candidates.

We anticipate that current and future U.S. legislative healthcare reforms may result in additional downward pressure on the price that we receive for any approved product, if covered, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors.

Foreign Regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, it would need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA

approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

European Data Collection

The collection and use of personal health data in the European Economic Area (EEA) is governed by the General Data Protection Regulation 2016/679 (or GDPR), which became effective May 25, 2018. The GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EU or the monitoring of the behavior of data subjects in the EU. The GDPR enhances data protection obligations for data controllers of personal data (including stringent requirements relating to the consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct privacy impact assessments for "high risk" processing, limitations on retention of personal data, mandatory data breach notification and "privacy by design" requirements) and creates direct obligations on service providers acting as data processors. The GDPR also imposes strict rules on the transfer of personal data outside of the EEA to countries that do not ensure an adequate level of protection, like the U.S. Failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA Member States may result in fines up to 20 million Euros or 4% of a company's global annual revenues for the preceding financial year, whichever is higher. Moreover, the GDPR grants data subjects the right to claim material and non material damages resulting from infringement of the GDPR. Given the breadth and depth of changes in data protection obligations, maintaining compliance with the GDPR, will require significant time, resources and expense, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects.

Employees

Our management and scientific teams possess considerable experience in drug discovery, research, manufacturing, clinical development and regulatory matters. Our research team includes Pharm.D. Ph.D.-level scientists with expertise in cancer biology. As of December 31, 2018, we had 14 employees, all of whom were full-time employees. We have no collective bargaining agreements with our employees and have not experienced any work stoppages. We consider our relations with our employees to be good.

Facilities

Our principal executive offices are located in Houston, Texas where we occupy office space. Our lease term expires on December 31, 2019. We also occupy office space in Palo Alto, California and our lease term expires on August 31, 2020.

Legal Proceedings

We are not currently the subject of any legal proceedings or claims. From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities. Litigation, regardless of the outcome, could have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Corporate Information

We were incorporated under the laws of the State of Delaware in December 2008 under the name Versartis, Inc. and completed our initial public offering in March 2014. Private Aravive was incorporated under the laws of the State of Delaware in April 2007, originally under the name of Hypoximed, Inc, which name was changed to Ruga Corporation in July 2009 and changed to Aravive Biologics, Inc. in October 2016.

Available Information

Our website address is www.aravive.com. We file Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy statements and other materials with the Securities and Exchange Commission, or SEC. We are subject to the informational requirements of the Exchange Act and file or furnish reports, proxy statements and other information with the SEC. Such reports and other information filed by the Company with the SEC are available free of charge on our website at http://ir.aravive.com/investors/financial-information.

The SEC also maintains a website that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should consider carefully the following risks, together with all the other information in this Annual Report on Form 10-K, including our consolidated financial statements and notes thereto. If any of the following risks actually materializes, our operating results, financial condition and liquidity could be materially adversely affected. As a result, the trading price of our common stock could decline and you could lose part or all of your investment.

Risks related to our financial position and capital requirements.

We have a limited operating history and have incurred significant losses since our inception, and we anticipate that we will continue to incur substantial and increasing losses for the foreseeable future. We have only one product candidate and no commercial sales, which, together with our limited operating history, makes it difficult to evaluate our business and assess our future viability.

We are a clinical-stage biopharmaceutical company with a limited operating history. We have never generated any product revenue and do not have any products approved for sale. From our inception (under our former corporate name, Versartis, Inc.) in 2008 through September 2017, we were focused on developing a single product candidate, somavaratan, a long-acting form of recombinant human growth hormone. The Phase 3 clinical trial of somavaratan failed to meet its primary endpoint, and we subsequently discontinued our somavaratan development effort. In October 2018, we acquired Private Aravive in a merger whereby Private Aravive became our wholly owned subsidiary. All of our clinical development activities are now carried out through Private Aravive.

Private Aravive was founded in 2007, and its operations to date have been primarily limited to organizing and staffing its company and developing its only product candidate, AVB-S6-500. Private Aravive has not yet successfully completed any clinical trials in the target patient population, obtained marketing approval, manufactured AVB-S6-500 product at commercial scale, or conducted sales and marketing activities that will be necessary to successfully commercialize AVB-S6-500. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing product candidates.

Even if we receive regulatory approval for the sale of any of our product candidates, we do not know when we will begin to generate revenue, if at all. Our ability to generate revenue depends on a number of factors, including our ability to:

- set an acceptable price for our products and obtain coverage and adequate reimbursement from third-party payors;
- establish sales, marketing, manufacturing and distribution systems;
- add operational, financial and management information systems and personnel, including personnel to support our clinical, manufacturing and planned future clinical development and commercialization efforts and operations as a public company;
- develop manufacturing capabilities for bulk materials and manufacture commercial quantities of product candidates at acceptable cost levels;
- achieve broad market acceptance of our product candidates in the medical community and with third-party payors and consumers;
- attract and retain an experienced management and advisory team;
- launch commercial sales of our products, whether alone or in collaboration with others; and
- maintain, expand and protect our intellectual property portfolio.

Because of the numerous risks and uncertainties associated with development and manufacturing, we are unable to predict if we will generate revenue. If we cannot successfully execute on any of the factors listed above, our business may not succeed, we may never generate revenue and your investment will be adversely affected.

We have incurred significant losses since inception and expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

We have incurred significant operating losses in each year since our inception and expect to incur substantial and increasing losses for the foreseeable future. As of December 31, 2018, we had an accumulated deficit of $450.6 million. Other than our financial statements for the year ended December 31, 2018, our historical financial statements are solely those of Versartis, Inc., our accumulated deficit does not reflect the cumulative deficit of Private Aravive.

To date, we have financed our operations primarily through private placements of our convertible preferred stock, the initial public offering of our common stock in 2014 and follow-on public offerings of our common stock in 2015 and 2016. A significant portion of Private Aravive's funding has been through a $20 million grant it received from the Cancer Prevention and Research Institute of Texas, or CPRIT. We have devoted substantially all of our efforts to research and development, including clinical studies, but have not completed development of any product candidate, and our Phase 3 clinical trial of somavaratan failed to meet its primary endpoint. We anticipate that our expenses will increase to the extent we:

- continue the research and development of our only product candidate, AVB-S6-500, and any future product candidates;
- conduct additional clinical studies of AVB-S6-500 in the future;
- seek to discover or in-license additional product candidates;
- seek regulatory approvals for AVB-S6-500 and any future product candidates that successfully complete clinical studies;
- establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize AVB-S6-500 or other future product candidates if they obtain regulatory approval, including process improvements in order to manufacture AVB-S6-500 at commercial scale; and
- enhance operational, financial and information management systems and hire more personnel, including personnel to support development of AVB-S6-500 and any future product candidates and, if a product candidate is approved, our commercialization efforts.

To be profitable in the future, we must succeed in developing and eventually commercializing AVB-S6-500 as well as other products with significant market potential. This will require us to be successful in a range of activities, including advancing AVB-S6-500 and any future product candidates, completing clinical studies of these product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling those products for which we may obtain regulatory approval. We may not succeed in these activities and may never generate revenue that is sufficient to be profitable in the future. Even if we are profitable, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to achieve sustained profitability would depress the value of our company and could impair our ability to raise capital, expand our business, diversify our product candidates, market our product candidates, if approved, or continue our operations.

To date, our only completed clinical trial with AVB-S6-500 has been our recently completed Phase 1 clinical trial with 42 dosed subjects. We expect our research and development expenses to increase significantly as our product candidate advances in clinical development. Because of numerous risks and uncertainties involved in our business, the timing or amount of increased development expenses cannot be accurately predicted and, our expenses could increase beyond expectations if we are required by the FDA, or comparable non-U.S. regulatory authorities, to perform studies or clinical trials in addition to those we currently anticipate. Even if our product candidate is approved for commercial sale, we anticipate incurring significant costs associated with the commercial launch of and the related commercial-scale manufacturing requirements for our product candidate. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. Because of the numerous risks and uncertainties associated with biopharmaceutical product development and commercialization, we are unable to accurately predict the timing or amount of future expenses or when, or if, we will be able to achieve or maintain profitability. These losses have had and will continue to have an adverse effect on our financial position and working capital.

We will need additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all, which would force us to delay, reduce or suspend our research and development programs and other operations or commercialization efforts. Raising additional capital may subject us to unfavorable terms, cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates and technologies.

The completion of the development and the potential commercialization of AVB-S6-500 and any future product candidates, should they receive approval, will require substantial funds. As of December 31, 2018, we had approximately $57 million in cash and cash equivalents. We believe that our existing cash and cash equivalents, will be sufficient to sustain operations for at least the next 12 months based on our existing business plan; however, our existing cash and cash equivalents will not be sufficient to enable us to complete the clinical development and commercialization of AVB-S6-500. Our future financing requirements will depend on many factors, some of which are beyond our control, including the following: the rate of progress and cost of our future clinical studies;

- the rate of progress and cost of our future clinical studies;
- the timing of, and costs involved in, seeking and obtaining approvals from the FDA and other regulatory authorities;
- the cost of preparing to manufacture AVB-S6-500 on a larger scale, should we elect to do so;
- the costs of commercialization activities if AVB-S6-500 or any future product candidate is approved, including product sales, marketing, manufacturing and distribution;

- the degree and rate of market acceptance of any products launched by us or future partners;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- our ability to enter into additional collaboration, licensing, commercialization or other arrangements and the terms and timing of such arrangements;
- the emergence of competing technologies or other adverse market developments; and
- the costs of attracting, hiring and retaining qualified personnel.

We do not have any material committed external source of funds or other support for our development efforts, and the failure of our Phase 3 VELOCITY trial to meet its primary endpoint may make it more difficult to raise funds in the future. Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. Additional financing may not be available to us when we need it or it may not be available on favorable terms. In addition, certain SEC and Nasdaq limitations with respect to fundraising may make it more difficult to raise additional funds. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to AVB-S6-500 or potential future product candidates, technologies, future revenue streams or research programs, or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of, or suspend one or more of our clinical studies or research and development programs or our commercialization efforts.

We recently completed the Merger with Private Aravive and the failure to successfully integrate could adversely affect our future results.

Our success will depend, in significant part, on our ability to integrate successfully and to manage successfully the challenges presented by the integration process in the Merger with Private Aravive that was completed in October 2018. Potential difficulties that may be encountered in the integration process include the following:

- using our cash and assets efficiently to develop our business;
- appropriately managing our liabilities;
- potential unknown liabilities associated with the Merger and our operations;
- difficulties in integrating the members of the Private Aravive management team with our prior management team; and
- performance shortfalls as a result of the diversion of the management's attention caused by integrating the companies' operations.

Raising additional funds by issuing securities may cause dilution to existing stockholders, and raising funds through lending and licensing arrangements may restrict our operations or require it to relinquish proprietary rights.

We expect that significant additional capital will be needed in the future to continue our planned operations and commercialize AVB-S6-500. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, strategic alliances and license and development agreements in connection with any collaborations. We do not currently have any committed external source of funds. To the extent that we raise additional capital by issuing equity securities, existing stockholders' ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity 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, declaring dividends, creating liens, redeeming its stock or making investments.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, or through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties on acceptable terms, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise develop and market.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into collaboration agreements with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under any potential future collaboration and license agreements and sales of our products, if approved. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next. In addition, our manufacturing and clinical trial expenses, which are anticipated to be significant, may fluctuate significantly quarter to quarter based upon whether or not we are engaged in clinical trials or manufacturing our product candidate, and timing of our process development work. Furthermore, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to AVB-S6-500 and any future product candidates, which will change from time to time;
- our ability to enroll patients in clinical trials and the timing of enrollment;
- the cost of manufacturing AVB-S6-500 and any future product candidates, which may vary depending on FDA guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies;
- the timing and outcomes of clinical studies for AVB-S6-500 and any future product candidates or competing product candidates;
- changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of AVB-S6-500 or any of our future product candidates;
    - the level of demand for AVB-S6-500 and any future product candidates, should they receive approval, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our products candidates, if approved, and existing and potential future drugs that compete with our product candidates;
- competition from existing and potential future drugs that compete with AVB-S6-500 or any of our future product candidates;
- our ability to commercialize AVB-S6-500 or any future product candidate inside and outside of the United States, either independently or working with third parties;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue and/or earnings guidance we may

provide.

The recently passed comprehensive tax reform bill passed in 2017 could adversely affect our business and financial condition.

In December 2017, new legislation known as the Tax Cuts and Jobs Act, or TCJA, significantly revised the Internal Revenue Code of 1986, as amended, or the Code. The TCJA, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain, and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. Stockholders should consult with their legal and tax advisors with respect to this legislation and its potential tax consequences under their particular circumstances.

Because of the Merger and other factors, our pre-merger U.S. net operating loss carryforwards and certain other tax attributes will be subject to limitations.

At December 31, 2018, we had net operating loss carryforwards for federal income tax purposes of approximately $11.1 million, of which $4.3 million was generated post December 31, 2017 (after section 382 limitation) and will have no expiration date. The remaining $6.8 million of net operating loss carryforwards begin to expire in 2037. We also have federal research and development tax credits of approximately $0.2 million, which begin to expire in 2037.

At December 31, 2018, our total gross deferred tax assets were $11.1 million. Due to our lack of earnings history and uncertainties surrounding our ability to generate future taxable income, the net deferred tax assets have been fully offset by a valuation allowance. The deferred tax assets were primarily comprised of federal and state tax net operating losses and tax credit carryforwards. Utilization of net operating losses and tax credit carryforwards may be limited by the “ownership change” rules, as defined in Section 382 of the Internal Revenue Code (any such limitation, a “Section 382 limitation”). Similar rules may apply under state tax laws. We have performed an analysis to determine whether an “ownership change” occurred from inception up to the Private Aravive's acquisition date. Based on this analysis, management determined that both Versartis, Inc. and Private Aravive did experience ownership changes, which resulted in a significant impairment of the net operating losses and credit carryforwards. As such, the net operating loss carryforwards have been reduced by $306 million. The tax credit carryforwards have been reduced by $39.5 million. Future changes in our stock ownership, some of which are outside of our control, could result in a further ownership change under Section 382 of the Code. Furthermore, our ability to utilize NOLs of Aravive Biologics or other companies that we may acquire in the future may be subject to limitations. For these reasons, we may not be able to utilize a material portion of the NOLs, even if we were to achieve profitability.

The TCJA changed certain of the rules governing net operating loss carryforwards. For NOLs arising in tax years beginning after December 31, 2017, the TCJA limits a taxpayer’s ability to utilize NOL carryforwards to 80% of taxable income. In addition, NOLs arising in tax years ending after December 31, 2017 can be carried forward indefinitely, but carryback is generally prohibited. NOLs generated in tax years beginning before January 1, 2018 will not be subject to the taxable income limitation, and NOLs generated in tax years ending before January 1, 2018 will continue to have a two-year carryback and 20-year carryforward period. Deferred tax assets for NOLs will need to be measured at the applicable tax rate in effect when the NOL is expected to be utilized. The changes in the carryforward/carryback periods as well as the new limitation on use of NOLs may significantly impact the merged company’s valuation allowance assessments for NOLs generated after December 31, 2017.

Risks Related To Our Business

Reliance on government funding for our programs may impose requirements that limit our ability to take certain actions, and subject us to potential financial penalties, which could materially and adversely affect our business, financial condition and results of operations.

A significant portion of our funding has been through a grant Private Aravive received from CPRIT. The CPRIT Grant (as described below) includes provisions that reflect the government's substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to potentially require repayment of all or a portion of the grant award proceeds, in certain cases with interest, in the event we violate certain covenants pertaining to various matters that include any potential relocation outside of the State of Texas. The CPRIT Grant contract terminates on May 31, 2019, unless extended with CPRIT's approval. After the termination date, we are not permitted to retain any unused grant award proceeds without CPRIT's approval, but our royalty and other obligations, including our obligation to repay the disbursed grant proceeds under certain circumstances, survive the termination of the agreement. We have received $18.0 million of the grant proceeds and expect to expend all of the grant award proceeds by the agreement termination date. We expect to receive the remaining $2.0 million grant award as reimbursement of future expenses once we have expended the grant award proceeds already received.

Our award from CPRIT requires us to pay CPRIT a portion of our revenues from sales of certain products by us, or received from our licensees or sublicensees, at tiered percentages of revenue in the low- to mid-single digits until the aggregate amount of such payments equals 400% of the grant award proceeds, and thereafter at a rate of less than one percent for as long as we maintain government exclusivity, subject to our right, under certain circumstances, to make a one-time payment in a specified amount to CPRIT to terminate such payment obligations. In addition, the grant contract also contains a provision that provides for repayment to CPRIT of some amount not to exceed the full amount of the grant proceeds under certain specified circumstances involving relocation of our principal place of business outside Texas.

The CPRIT Grant requires us, as a Texas-based company, to meet certain criteria, including among other things, that we maintain our headquarters in Texas and use certain vendors, consultants and employees that are located in Texas. As we expand our operations, we will need to hire additional qualified personnel with expertise in preclinical testing, clinical research and testing, government regulation, formulation and manufacturing, sales and marketing and accounting and financing located in Texas. We will compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and there can be no assurance that the search for such personnel will be successful, especially in light of the territorial restrictions imposed by CPRIT. Attracting and retaining qualified personnel will be critical to our access to the CPRIT Grant.

If we fail to maintain compliance with any such requirements that may apply to us now or in the future, we may be subject to potential liability and to termination of our contracts, including potentially the CPRIT Grant, which could result in significant expense to us.

We rely on licenses to use various technologies that are material to our business and if the agreements underlying the licenses were to be terminated or if other rights that may be necessary for commercializing our intended products cannot be obtained, it would halt our ability to market our products and technology, as well as have an immediate material adverse effect on our business, operating results and financial condition.

Our prospects are significantly dependent upon our license with Stanford University, or the Stanford License. The Stanford License grants us exclusive, worldwide rights to certain existing patents and related intellectual property that cover AVB-S6-500, the lead development candidate selected from the AVB-S6 family of proteins. If we breach the terms of the Stanford License, including any failure to make minimum royalty payments required thereunder or failure to reach certain developmental milestones and by certain deadlines or other factors, including but not limited to, the failure to comply with material terms of the Stanford License, the licensor has the right to terminate the license. If we were to lose or otherwise be unable to maintain the license on acceptable terms, or find that it is necessary or appropriate to secure new licenses from other third parties, we would not be able to market our products and technology, which would likely require us to cease our current operations which would have an immediate material adverse effect on our business, operating results and financial condition.

If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.

In addition to the Stanford License, we are a party to intellectual property license agreements with third parties, and we expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that our future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate these agreements, in which event we may not be able to develop and market any product that is covered by these agreements. For example, we license substantially all of the intellectual property relating to somavaratan from Amunix. Amunix has the right to terminate the license upon 30 days' written notice with respect to a particular target and the related products if (i) during any consecutive 18 month period our cumulative funding of research, development and commercialization activities in respect of such target is not at least $250,000, in which case we

would have the right to extend the applicable 18 month period by paying Amunix $150,000; or (ii) if we do not use commercially reasonable measures to develop and commercialize licensed products based on such target. Termination of this license, or reduction or elimination of our licensed rights under it or any other license, may result in our having to negotiate new or reinstated licenses on less favorable terms or our not having sufficient intellectual property rights to operate our business. The occurrence of such events could materially harm our business and financial condition.

The risks described elsewhere pertaining to our intellectual property rights also apply to the intellectual property rights that we license, and any failure by us or our licensors to obtain, maintain, defend and enforce these rights could have a material adverse effect on our business. In some cases we do not have control over the prosecution, maintenance or enforcement of the patents that we license, and may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents. We are responsible for preparing, filing, and prosecuting broad patent claims (including any interference or reexamination actions) for Stanford University’s benefit and for maintaining all licensed patents and we are also required to reimburse Amunix for certain costs incurred in prosecuting, maintaining, defending and enforcing the licensed patents.

We rely extensively on our information technology systems and are vulnerable to damage and interruption.

We rely on our information technology systems and infrastructure to process transactions, summarize results and manage our business, including maintaining client and supplier information. Additionally, we utilize third parties, including cloud providers, to store, transfer and process data. Our information technology systems, as well as the systems of our suppliers and other partners, whose systems we do not control, are vulnerable to outages and an increasing risk of continually evolving deliberate intrusions to gain access to company sensitive information. Likewise, data security incidents and breaches by employees and others with or without permitted access to our systems pose a risk that sensitive data may be exposed to unauthorized persons or to the public. A cyber-attack or other significant disruption involving our information technology systems, or those of our vendors, suppliers and other partners, could also result in disruptions in critical systems, corruption or loss of data and theft of data, funds or intellectual property. We may be unable to prevent outages or security breaches in our systems. We remain potentially vulnerable to additional known or yet unknown threats as, in some instances, we, our suppliers and our other partners may be unaware of an incident or its magnitude and effects. We also face the risk that we expose our vendors or partners to cybersecurity attacks. Any or all of the foregoing could adversely affect our results of operations and our business reputation.

Any failure to maintain the security of information relating to our customers, employees and suppliers, whether as a result of cybersecurity attacks or otherwise, could expose us to litigation, government enforcement actions and costly response measures, and could disrupt our operations and harm our reputation.

In connection with the sales and marketing of our products and services, we may from time to time transmit confidential information. We also have access to, collect or maintain private or confidential information regarding our clinical trials and the patients enrolled therein, employees, and suppliers, as well as our business. Cyberattacks are rapidly evolving and becoming increasingly sophisticated. It is possible that computer hackers and others might compromise our security measures, or security measures of those parties that we do business with now or in the future, and obtain the personal information of patients in our clinical trials, vendors, employees and suppliers or our business information. A security breach of any kind, including physical or electronic break-ins, computer viruses and attacks by hackers, employees or others, could expose us to risks of data loss, litigation, government enforcement actions, regulatory penalties and costly response measures, and could seriously disrupt our operations. Any resulting negative publicity could significantly harm our reputation, which could cause us to lose market share and have an adverse effect on our results of operations.

We currently have only one product candidate in clinical development and are dependent on the success of this product candidate, which requires significant additional clinical testing before seeking regulatory approval. If our clinical product candidate does not receive regulatory approval or is not successfully commercialized, our business may be harmed.

We are currently developing one clinical product candidate, AVB-S6-500, as a potential treatment for several types of cancer and fibrosis. AVB-S6-500 is currently being tested in clinical trials, and, to date, we have not had any product candidate approved for commercial sale. It is possible that we may never be able to develop a marketable product candidate. Our main focus is the development of AVB-S6-500, for which we recently completed a Phase 1 clinical trial, commenced the Phase 1b portion of our planned Phase 1b/2 clinical trial for the treatment of platinum-resistant recurrent ovarian cancer and announced our intention to commence clinical trials for the treatment of clear cell renal cell carcinoma.

We may need to engage in further dose-finding studies for AVB-S6-500. In our Phase 1 clinical trial of AVB-S6-500, single doses ranging from 1 mg per kg to 10 mg per kg were evaluated and repeat doses of 5 mg per kg per week (for a total of 4 doses) were evaluated. Based upon the results of our Phase 1 clinical trial, in the Phase 1b portion of our Phase 1b/2 clinical trial we are using a 10mg per kg dose for all patients receiving AVB-S6-500; however, we may discover that 10mg per kg is not an adequate dose. In order for AVB-S6-500 to successfully complete development, we may need to continue to refine its dosage, which will increase our costs and slow down our product candidate development and approval process.

We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to AVB-S6-500. Accordingly, our business currently depends heavily on the successful development, regulatory approval and commercialization of AVB-S6-500, which may not receive regulatory approval or be successfully commercialized even if regulatory approval is received. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of product candidates are and will remain subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market any product in the United States unless and until we receive approval of a BLA, from the FDA, or in any foreign countries unless and until we receive the requisite approval from regulatory authorities in such countries. We have never submitted a BLA to the FDA or comparable applications to other regulatory authorities and do not expect to be in a position to do so for the foreseeable future. Obtaining approval of a BLA is an extensive, lengthy, expensive and inherently uncertain process, and the FDA may delay, limit or deny approval of its product for many reasons.

Our success depends largely upon our ability to advance our clinical product candidate, which is in early stages of development, through the various stages of drug development. If we are unable to successfully advance or develop our clinical product candidate, our business will be materially harmed.

Our clinical product candidate is in early stages of clinical development, and its commercial viability remains subject to the successful outcome of future preclinical studies, clinical trials, manufacturing processes, regulatory approvals and the risks generally inherent in the development of pharmaceutical product candidates. Failure to advance the development of our clinical product candidate may have a material adverse effect on our business. The long-term success of our business ultimately depends upon our ability to advance the development of our product candidate through clinical trials, appropriately formulate and consistently manufacture it in accordance with strict specifications and regulations, obtain approval for sale by the FDA or similar regulatory authorities in other countries, and ultimately successfully commercialize it directly or with a strategic partner or licensee. We cannot assure you that the results of our ongoing or future research, preclinical studies or clinical trials will support or justify the continued development of our clinical product candidate or that we will ultimately receive approval from the FDA, or similar regulatory authorities in other countries, to advance the development of AVB-S6-500.

AVB-S6-500 must satisfy rigorous regulatory standards of safety, efficacy and manufacturing before we can advance or complete its development and before it can be approved for sale by the FDA or similar regulatory authorities in other countries. To satisfy these standards, we must engage in expensive and lengthy studies and clinical trials, develop acceptable and cost effective manufacturing processes, and obtain regulatory approval of our clinical product candidate. Despite these efforts, our clinical product candidate may not:

- demonstrate clinically meaningful therapeutic or other medical benefits as compared to a patient receiving no treatment or over existing drugs or other product candidates in development to treat the same patient population;
- be shown to be safe and effective in future preclinical studies or clinical trials;
- have the desired therapeutic or medical effects;
- be tolerable or free from undesirable or unexpected side effects;
- meet applicable regulatory standards;
- be capable of being appropriately formulated and manufactured in commercially suitable quantities or scale and at an acceptable cost; or
- be successfully commercialized by us or our licensees or collaborators.

Even if we demonstrate favorable results in preclinical studies and early-stage clinical trials, we cannot assure you that the results of late-stage clinical trials will be sufficient to support the continued development of our clinical product candidate. Many, if not most, companies in the pharmaceutical and biopharmaceutical industries have experienced significant delays, setbacks and failures in all stages of development, including late-stage clinical trials, even after achieving promising results in preclinical testing or early-stage clinical trials. Accordingly, results from completed preclinical studies and early-stage clinical trials of our clinical product candidate may not be predictive of the results we may obtain in future late-stage trials. Furthermore, even if the data collected from preclinical studies and clinical trials involving any of our clinical product candidate demonstrate a satisfactory safety, tolerability and efficacy profile, such results may not be sufficient to obtain regulatory approval from the FDA in the United States, or other similar regulatory agencies in other jurisdictions, which is required to market and sell the product.

Clinical trials are risky, lengthy and expensive. We incur substantial expense for, and devote significant time and resources to, preclinical testing and clinical trials, yet cannot be certain that these tests and trials will demonstrate that a product candidate is effective and well-tolerated, or will ever support its approval and commercial sale. For example, clinical trials require adequate supplies of clinical trial material and sufficient patient enrollment to power the trial. Delays in patient enrollment can result in increased costs and longer development times. Even if we, or a licensee or

collaborator, if applicable, successfully complete clinical trials for our clinical product candidate, we or they might not file the required regulatory submissions in a timely manner and may not receive marketing approval for the clinical product candidate. We cannot assure you that our clinical product candidate will successfully progress further through the drug development process, or ultimately will result in an approved and commercially viable product.

We have limited experience as a combined company conducting clinical trials.

We are an early stage clinical stage company, and our success is dependent upon our ability to obtain regulatory approval for and commercialization of our clinical product candidate, and we have not demonstrated an ability to perform the functions necessary for the approval or successful commercialization of any product candidate. The successful commercialization of any product candidate may require us to perform a variety of functions, including:

- continuing to undertake preclinical development and successfully enroll subjects in clinical trials;

- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales and marketing activities.

We have limited experience conducting and enrolling subjects in clinical trials. While certain members of our management and staff have significant experience in conducting clinical trials, to date, we have only limited experience conducting clinical trials as a combined company. In part because of this lack of experience, we cannot guarantee that planned clinical trials will be completed on time, if at all. Large-scale trials require significant additional financial and management resources, monitoring and oversight, and reliance on third-party clinical investigators, consultants or contract research organizations, or CROs. Relying on third-party clinical investigators, CROs and manufacturers, which are all also subject to governmental oversight and regulations, may also cause us to encounter delays that are outside of our control.

If the actual or perceived therapeutic benefits, or the safety or tolerability profile of our clinical product candidate is not equal to or superior to other competing treatments approved for sale or in clinical development, we may terminate the development of our clinical product candidate at any time, and our business prospects and potential profitability could be harmed.

We are aware of a number of companies marketing or developing product candidates for the treatment of patients with cancer that are either approved for sale or further advanced in clinical development than ours, such that their time to approval and commercialization may be shorter than that for AVB-S6-500.

There are currently FDA approved biological drugs that target the GAS6/AXL pathway. However, if ever approved, AVB-S6-500 would indirectly compete with drugs approved to treat various types of cancer, such as those that regulate T-cell proliferation, including nivolumab, pembrolizumab, atezolizumab and other small molecule chemically manufactured drugs that target this pathway or other classes of drugs that are used for the clinical indications that ours is currently pursuing in clinic.

If at any time we believe that AVB-S6-500 may not provide meaningful or differentiated therapeutic benefits, perceived or real, equal to or better than its competitor’s products or product candidates, or we believe that it may not have as favorable a safety or tolerability profile as potentially competitive compounds, we may delay or terminate its development. We cannot provide any assurance that the future development of AVB-S6-500 will demonstrate any meaningful therapeutic benefits over potentially competitive compounds currently approved for sale or in development, or an acceptable safety or tolerability profile sufficient to justify its continued development.

For the Phase 1b portion of our Phase 1b/2 clinical trial testing AVB-S6-500 in patients with platinum-resistant recurrent ovarian cancer, we are administering our clinical product candidate in combination with other approved standard of care drugs. Any problems obtaining the standard of care drugs could result in a delay or interruption in our clinical trials.

For the Phase 1b portion of our Phase 1b/2 clinical trial of AVB-S6-500 for the treatment of patients with platinum-resistant recurrent ovarian cancer, we are administering our clinical product candidate in combination with already approved standard of care drugs. Therefore, our success will be dependent upon the continued use of these other standard of care drugs. We expect that in any other clinical trials we conduct for additional indications, our clinical product candidate will also be administered in combination with drugs owned by third parties. If any of the standard of care drugs that are used in our clinical trials are unavailable while the trials are continuing, the timeliness and commercialization costs could be impacted. In addition, if any of these other drugs are determined to have safety or efficacy problems, our clinical trials and commercialization efforts would be adversely affected.

If our product candidate would require or would commercially benefit from a companion diagnostic, and if we are unable to successfully validate, develop and obtain regulatory clearance or approval for such a companion diagnostic test, or experience significant delays in doing so, we may not realize the full commercial potential of our product candidates.

In connection with the clinical development of AVB-S6-500 or other product candidates for certain indications, we may work with collaborators to develop or obtain access to in vitro companion diagnostic tests to identify patient subsets within a disease category who may derive selective and meaningful benefit from our drug candidates. Such companion diagnostics may be used during our clinical trials as well as in connection with the commercialization of our product candidates. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. The FDA and comparable foreign regulatory authorities regulate in vitro companion diagnostics as medical devices and, under that regulatory framework, will likely require the conduct of clinical trials to demonstrate the safety and effectiveness of any diagnostics we may develop, which we expect will require separate regulatory clearance or approval prior to commercialization. We may be unable to successfully validate, develop and obtain regulatory clearance or approval for any such companion diagnostic tests or may experience delays in doing so, which could materially harm or limit the commercial potential of our product candidates.

Our clinical product candidate may exhibit undesirable side effects when used alone or in combination with other approved pharmaceutical products, which may delay or preclude its development or regulatory approval, or limit its use if ever approved.

Throughout the drug development process, we must continually demonstrate the activity, safety and tolerability of our clinical product candidate in order to obtain regulatory approval to further advance our clinical development, or to eventually market it. Even if our clinical product candidate demonstrates adequate biologic activity and clear clinical benefit, any unacceptable side effects or adverse events, when administered alone or in the presence of other pharmaceutical products, may outweigh these potential benefits. We may observe adverse or serious adverse events or drug-drug interactions in preclinical studies or clinical trials of our clinical product candidate, which could result in the delay or termination of its development, prevent regulatory approval, or limit its market acceptance if it is ultimately approved.

For our clinical product candidate, we rely upon one third party to manufacture its drug substance. Any problems experienced by either our third-party manufacturer or our vendors could result in a delay or interruption in the supply of our clinical product candidate to us until the third-party manufacturer or its vendor cures the problem or until we locate and qualify an alternative source of manufacturing and supply.

For our clinical product candidate, we currently rely on one third-party manufacturer located in China to manufacture our clinical product candidate for our clinical studies and that manufacturer purchases materials from our third-party vendors and transports the materials necessary to produce our clinical product candidate, such as the required reagents and containers. If the third-party manufacturer were to experience any prolonged disruption for our manufacturing, we could be forced to seek additional third party manufacturing contracts, thereby increasing our development costs and negatively impacting our timelines and any commercialization costs . If we change manufacturers at any point during the development process or after approval of a product candidate, we will be required to demonstrate comparability between the product manufactured by the old manufacturer and the product manufactured by the new manufacturer. If we are unable to do so we may need to conduct additional clinical trials with product manufactured by the new manufacturer.

If our manufacturer is not able to manufacture sufficient quantities of our clinical product candidate, our development activities would be impaired. In addition, the manufacturing facility where our clinical product candidate is manufactured is subject to ongoing, periodic inspection by the FDA or other comparable regulatory agencies to ensure compliance with current Good Manufacturing Practice, or cGMP. Any failure to follow and document the manufacturer’s adherence to such cGMP regulations or other regulatory requirements may lead to significant delays in the availability of clinical bulk drug substance and finished product for clinical trials, which may result in the termination of or a hold on a clinical trial, or may delay or prevent filing or approval of marketing applications for our clinical product candidate. We also may encounter problems with the following:

- achieving adequate or clinical-grade materials that meet FDA or other comparable regulatory agency standards or specifications with consistent and acceptable production yield and costs;
- Our contract manufacturers failing to develop an acceptable formulation to support late-stage clinical trials for, or the commercialization of, our clinical product candidate;
- Our contract manufacturer being unable to increase the scale of or the capacity for, or reformulate the form of our clinical product candidate, which may cause us to experience a shortage in supply, or cause the cost to manufacture our clinical product candidate to increase. We cannot assure you that our contract manufacturers will be able to manufacture our clinical product candidate at a suitable commercial scale, or that we will be able to find alternative manufacturers acceptable to us that can do so;
- Our contract manufacturer placing a priority on the manufacture of other customers’ or its own products, rather than our products;
- Our contract manufacturer or our vendors failing to perform as agreed, including failing to properly package, transport or store our clinical product candidate or its reagents, or exiting from the contract manufacturing business;

- Our contract manufacturers' plants being closed as a result of regulatory sanctions or a natural disaster;
- Shortages of qualified personnel, raw materials or key contractors;
- Our contract manufacturers failing to obtain FDA approval for commercial scale manufacturing; and
- Ongoing compliance with cGMP regulations and other requirements of the FDA or other comparable regulatory agencies.

If we encounter any of these problems or are otherwise delayed, or if the cost of manufacturing in the China facility is not economically feasible or we cannot find another third-party manufacturer, we may not be able to produce our clinical product candidate in a sufficient quantity to meet future demand.

In addition, since we rely on a third-party manufacturer located in China, our business is subject to risks associated with doing business in China, including:

- adverse political and economic conditions, particularly those potentially negatively affecting the trade relationship between the United States and China;
- trade protection measures, such as tariff increases, and import and export licensing and control requirements;
- potentially negative consequences from changes in tax laws;
- difficulties associated with the Chinese legal system, including increased costs and uncertainties associated with enforcing contractual obligations in China;
- historically lower protection of intellectual property rights;
- changes and volatility in currency exchange rates;
- unexpected or unfavorable changes in regulatory requirements;
- possible patient or physician preferences for more established pharmaceutical products and medical devices manufactured in the United States; and
- difficulties in managing foreign relationships and operations generally.

These risks are likely to be exacerbated by our limited experience with our current products and manufacturing processes. If demand for our products materializes, we may have to invest additional resources to purchase materials, hire and train employees, and enhance our manufacturing processes. It may not be possible for us to manufacture our clinical product candidate at a cost or in quantities sufficient to make its clinical product candidate commercially viable. Any of these factors may affect our ability to manufacture our products and could reduce gross margins and profitability.

Reliance on third-party manufacturers and suppliers entails risks to which we would not be subject if we manufactured our clinical product candidate itself, including:

- reliance on the third parties for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreements by the third parties because of factors beyond our control or the insolvency of any of these third parties or other financial difficulties, labor unrest, natural disasters or other factors adversely affecting their ability to conduct their business; and
- possibility of termination or non-renewal of the agreements by the third parties, at a time that is costly or inconvenient for us, because of our breach of the manufacturing agreement or based on their own business priorities.

If our contract manufacturer or its suppliers fail to deliver the required commercial quantities of our clinical product candidate required for our clinical trials and, if approved, for commercial sale, on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement manufacturers or suppliers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality, and on a timely basis, we would likely be unable to meet demand for our products and would have to delay or terminate our pre-clinical or clinical trials, and we would lose potential revenue. It may also take a significant period of time to establish an alternative source of supply for our clinical product candidate and to have any such new source approved by the FDA or any applicable foreign regulatory authorities. Furthermore, any of the above factors could cause the delay or suspension of initiation or completion of clinical trials, regulatory submissions or required approvals of our clinical product candidate, cause it to incur higher costs and could prevent us from commercializing our clinical product candidate successfully.

We may not be able to manufacture AVB-S6-500 in sufficient quantities for commercialization.

In order to receive FDA approval of our clinical product candidate, we will need to manufacture such clinical product candidate in larger quantities. Our third party manufacturer may not be willing or able to increase successfully the manufacturing capacity for our clinical product candidate in a timely or economic manner, or at all. In the event FDA approval is received, we will need to increase production of our clinical product candidate. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If we are unable to successfully increase the manufacturing capacity for our clinical product candidate, the clinical trials as well as the

regulatory approval or commercial launch of our clinical product candidate may be delayed or there may be a shortage in supply. Our clinical product candidate requires precise, high quality manufacturing. Failure to achieve and maintain high quality manufacturing, including the incidence of manufacturing errors, could result in patient injury or death, delays or failures in testing or delivery, cost overruns or other problems that could harm our business, financial condition and results of operations.

In the event that we need to change our third-party contract manufacturer, our preclinical studies or our clinical trials, the commercialization of our clinical product candidate could be delayed, adversely affected or terminated, or such a change may result in the need for us to incur significantly higher costs, which could materially harm our business.

Due to various regulatory restrictions in the United States and many other countries, as well as potential capacity constraints on manufacturing that occur from time-to-time in our industry, various steps in the manufacture of our clinical product candidate is solely-sourced from certain contract manufacturers. In accordance with cGMPs, changing manufacturers may require the re-validation of manufacturing processes and procedures, and may require further preclinical studies or clinical trials to show comparability between the materials produced by different manufacturers. Changing our current or future contract manufacturers may be difficult, if not impossible for us, and could be extremely costly if we do make such a change, which could result in our inability to manufacture our clinical product candidate for an extended period of time and a delay in the development of our clinical product candidate. Further, in order to maintain our development timelines in the event of a change in a third-party contract manufacturer, we may incur significantly higher costs to manufacture our clinical product candidate.

If third-party vendors, upon whom we rely to conduct our preclinical studies or clinical trials, do not perform or fail to comply with strict regulations, these studies or trials may be delayed, terminated, or fail, or we could incur significant additional expenses, which could materially harm our business.

We have limited resources dedicated to designing, conducting and managing our preclinical studies and clinical trials. We have historically relied on, and intend to continue to rely on, third parties, including clinical research organizations, or CROs, consultants and principal investigators, to assist us in designing, managing, conducting, monitoring and analyzing the data from our preclinical studies and clinical trials. We rely on these vendors and individuals to perform many facets of the clinical development process on our behalf, including conducting preclinical studies, the recruitment of sites and subjects for participation in our clinical trials, maintenance of good relations with the clinical sites, and ensuring that these sites are conducting our trials in compliance with the trial protocol and applicable regulations. If these third parties fail to perform satisfactorily, or do not adequately fulfill their obligations under the terms of our agreements with them, we may not be able to enter into alternative arrangements without undue delay or additional expenditures, and therefore the preclinical studies and clinical trials of our clinical product candidate may be delayed or prove unsuccessful.

Further, the FDA, the EMA, or similar regulatory authorities in other countries, may inspect some of the clinical sites participating in our clinical trials or our third-party vendors' sites to determine if our clinical trials are being conducted according to good clinical practices, or GCPs, or similar regulations. If we or a regulatory authority determine that our third-party vendors are not in compliance with, or have not conducted our clinical trials according to applicable regulations, we may be forced to exclude certain data from the results of the trial, or delay, repeat or terminate such clinical trials.

We rely on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and we expect to have limited influence over their actual performance.

We also rely upon CROs to monitor and manage data for our clinical programs, as well as the execution of future nonclinical studies. We expect to control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs will be required to comply with the Good Laboratory Practices and GCPs, which are regulations and guidelines enforced by the FDA and are also required by the Competent Authorities of the Member States of the

European Economic Area and comparable foreign regulatory authorities in the form of International Conference on Harmonization of Technical Requirements for Pharmaceuticals for Human Use guidelines for any of our product candidates that are in preclinical and clinical development. The Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process.

Our CROs will not be our employees, and we will not control whether or not they devote sufficient time and resources to our future clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develops. As a result, our financial results and the commercial prospects for any product candidate that it develops would be harmed, its costs could increase, and our ability to generate revenues could be delayed.

If our relationship with these CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that it will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects.

We may seek to selectively establish collaborations, and, if we are unable to establish them on commercially reasonable terms, it may have to alter our development and commercialization plans.

Our product development programs and the potential commercialization of our clinical product candidate will require substantial additional cash to fund expenses. For some of our product candidates we may decide to collaborate with governmental entities or additional pharmaceutical and biotechnology companies for the development and potential commercialization of our product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator’s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator’s evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with our product candidate.

Our future success depends on our ability to retain executive officers and attract, retain and motivate qualified personnel.

We are highly dependent on our executive officers and the other principal members of our executive and scientific teams. The employment of our executive officers is at-will and our executive officers may terminate their employment at any time. The loss of the services of any of our senior executive officers could impede the achievement of our research, development and commercialization objectives. We do not maintain “key person” insurance for any executive officer or employee.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel is also critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel especially in light of the CPRIT Grant requirements, including the requirement that we maintain our headquarters in Texas and use certain vendors, consultants and employees that are located in Texas. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Our industry has experienced an increasing rate of turnover of management and scientific personnel in recent years. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist it in devising our research and development and commercialization strategy. Our consultants and advisors may be employed by third parties and have commitments under consulting or advisory contracts with other entities that may limit their availability to advance our strategic objectives. If any of these advisors or consultants can no longer dedicate a sufficient amount of time to the company, our business may be harmed.

Many of the other pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates and consultants than what it has to offer. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can select and develop our clinical product candidate and our business will be limited.

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt operations.

Our future financial performance, our ability to commercialize our clinical product candidate and our ability to compete effectively will depend, in part, on our ability to effectively manage any future growth. As of December 31, 2018, we had 14 full time employees. We expect to hire additional employees for our managerial, clinical, scientific and engineering, operational, manufacturing, sales and marketing teams. We may have operational difficulties in connection with identifying, hiring and integrating new personnel, especially in light of the CPRIT Grant requirements, including the requirement that we maintain our headquarters in Texas and use certain vendors, consultants and employees that are located in Texas. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in its infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our clinical product candidate. If we are unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy.

Our business and operations would suffer in the event of system failures.

Our computer systems and those of our service providers, including its CROs, are vulnerable to damage from computer viruses, unauthorized access, natural disasters (including hurricanes), terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our or their operations, it could result in a material disruption of our development programs and other aspects of our business. For example, the loss of preclinical or clinical trial data from completed, ongoing or planned trials could result in delays in its regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of our clinical product candidate could be delayed.

Risks Related to Clinical Development, Regulatory Approval and Commercialization

If the results from preclinical studies or clinical trials of AVB-S6-500 are unfavorable, we could be delayed or precluded from its further development or commercialization, which could materially harm our business.

In order to further advance the development of, and ultimately receive marketing approval to sell AVB-S6-500, we must conduct extensive preclinical studies and clinical trials to demonstrate our safety and efficacy to the satisfaction of the FDA or similar regulatory authorities in other countries, as the case may be. Preclinical studies and clinical trials are expensive, complex, can take many years to complete, and have highly uncertain outcomes. Delays, setbacks, or failures can and do occur at any time, and in any phase of preclinical or clinical testing, and can result from concerns about safety, tolerability, toxicity, a lack of demonstrated biologic activity or improved efficacy over similar products that have been approved for sale or are in more advanced stages of development, poor study or trial design, and issues related to the formulation or manufacturing process of the materials used to conduct the trials. The results of prior preclinical studies or early-stage clinical trials are not predictive of the results we may observe in late-stage clinical trials, especially since the number of subjects in our Phase 1 clinical trial was small and all were healthy volunteers with larger number of subjects and with our drug candidate in combinations with standard of care may have different results. In many cases, product candidates in clinical development may fail to show the desired tolerability, safety and efficacy characteristics, despite having favorably demonstrated such characteristics in preclinical studies or early-stage clinical trials.

In addition, we may experience numerous unforeseen events during, or as a result of, preclinical studies and the clinical trial process, which could delay or impede our ability to advance the development of, receive marketing approval for, or commercialize our clinical product candidate, including, but not limited to:

- communications with the FDA, or similar regulatory authorities in different countries, regarding the scope or design of a trial or trials, or placing the development of a product candidate on clinical hold or delaying the next phase of development until questions or issues are satisfactorily resolved, including performing additional studies to answer their queries;
- regulatory authorities or institutional review boards, or IRBs, not authorizing us to commence or conduct a clinical trial at a prospective trial site;
- enrollment in our clinical trials being delayed, or proceeding at a slower pace than we expected, because we have difficulty recruiting participants or participants drop out of our clinical trials at a higher rate than we anticipated;
- our third-party contractors, upon whom we rely to conduct preclinical studies, clinical trials and the manufacturing of our clinical trial materials, failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;
- having to suspend or ultimately terminate a clinical trial if participants are being exposed to unacceptable health or safety risks;
- regulatory authorities or IRBs requiring that we hold, suspend or terminate our preclinical studies and clinical trials for various reasons, including non-compliance with regulatory requirements; and
- the supply or quality of material necessary to conduct our preclinical studies or clinical trials being insufficient, inadequate or unavailable.

Even if the data collected from preclinical studies or clinical trials involving our clinical product candidate demonstrate a satisfactory tolerability, safety and efficacy profile, such results may not be sufficient to support the submission of a BLA to obtain regulatory approval from the FDA in the United States, or other similar regulatory authorities in other foreign jurisdictions, which is required for us to market and sell its clinical product candidate.

Clinical trials are very expensive, time-consuming, difficult to design and implement and involve an uncertain outcome, and if they fail to demonstrate safety and efficacy to the satisfaction of the FDA, or similar regulatory authorities, we will be unable to commercialize its clinical product candidate.

Our clinical product candidate is still in early-stage clinical development and will require extensive additional clinical testing before we are prepared to submit a BLA for regulatory approval for any indication or for any treatment regime. We cannot predict with any certainty if or when we might submit a BLA for regulatory approval for AVB-S6-500, which recently completed a Phase 1 clinical trial and began the Phase 1b portion of a Phase 1b/2 clinical trial for ovarian cancer or whether any such future BLA would be approved by the FDA. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For instance, the FDA may not agree with endpoints for any clinical trial we propose, which may delay the commencement of our clinical trials. The clinical trial process is also time-consuming. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. A product candidate in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials, and the results of our Phase 1 clinical trial of the clinical product candidate as well as the pre-clinical results may not be predictive of the results of our Phase 2 trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, including us with respect to our phase 3 VELOCITY trial, of notwithstanding promising results in earlier trials.

Moreover, preclinical and clinical data are often susceptible to multiple interpretations and analyses. Many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Success in preclinical testing and early clinical trials does not ensure that later clinical trials, which involve many more subjects and the results of later clinical trials may not replicate the results of prior clinical trials and preclinical testing.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our clinical product candidate, including that:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of our clinical product candidate may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of subjects required for clinical trials of our clinical product candidate may be larger than we anticipate; enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- Our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our clinical product candidate may be greater than it anticipates; and
- the supply or quality of our clinical product candidate or other materials necessary to conduct clinical trials of our clinical product candidate may be insufficient or inadequate.

If we are required to conduct additional clinical trials or other testing of our clinical product candidate beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our clinical product candidate or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our clinical product candidate require additional funding not budgeted for;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Product development costs will also increase if we experience delays in testing or in receiving marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our clinical product candidate, could allow our competitors to bring products to market before we do, and could impair our ability to successfully commercialize our clinical product candidate, any of which may harm our business and results of operations.

Enrollment and retention of subjects in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.

We may encounter delays in enrolling, or be unable to enroll, a sufficient number of participants to complete any of our clinical trials. Once enrolled, we may be unable to retain a sufficient number of participants to complete any of

our trials. Late-stage clinical trials of our clinical product candidate may require the enrollment and retention of large numbers of subjects. Subject enrollment and retention in clinical trials depends on many factors, including the size of the subject population, the nature of the trial protocol, the existing body of safety and efficacy data with respect to the trial drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of subjects to clinical sites and the eligibility criteria for the trial.

Furthermore, any negative results we may report in clinical trials of our clinical product candidate or negative results of similar product candidates may make it difficult or impossible to recruit and retain participants in other clinical trials of that same clinical product candidate. Delays or failures in planned subject enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on its ability to develop its clinical product candidate, or could render further development impossible. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing our services, we will be limited in our ability to compel our actual performance in compliance with applicable regulations. Enforcement actions brought against these third parties may cause further delays and expenses related to our clinical development programs.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

Development of cancer treatments is highly competitive and subject to rapid and significant technological advancements. In particular, we face competition from various sources, including larger and better funded pharmaceutical, specialty pharmaceutical and biotechnology companies, as well as academic institutions, governmental agencies and public and private research institutions. These competitors are focused on delivering therapeutics for the treatment of various cancers with products that are available and have gained market acceptance as the standard treatment protocol. Further, it is likely that additional drugs or other treatments will become available in the future for the treatment of certain cancers.

Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of products for the treatment of cancer, as well as in obtaining regulatory approvals of those products in the United States and in foreign countries. Our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a small number of our competitors.

Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, drugs that are more effective or less costly than any product candidate that we may develop.

We will face competition from other drugs currently approved or that will be approved in the future for the treatment of the other infectious diseases we are currently targeting. Therefore, our ability to compete successfully will depend largely on our ability to:

- develop and commercialize product candidates that are superior to other products in the market;
- demonstrate through our clinical trials that our clinical product candidate is differentiated from existing and future therapies;
- attract qualified scientific and commercial personnel;
- obtain patent or other proprietary protection for its clinical product candidate;
- obtain required regulatory approvals;
- obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third-party payors; and
- successfully develop and commercialize, independently or with collaborators, new product candidates.

The availability of our competitors' products could limit the demand, and the price we are able to charge, for any product candidate we develop. The inability to compete with existing or subsequently introduced therapies would

have an adverse impact on our business, financial condition and prospects.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidate less competitive. In addition, any new products that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving the FDA’s approval for or commercializing medicines before we do, which would have an adverse impact on our business and results of operations.

Our clinical product candidate may cause adverse effects or have other properties that could delay or prevent our regulatory approval or limit the scope of any approved label or market acceptance.

Adverse events caused by our clinical product candidate could cause reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval. If an unacceptable frequency or severity of adverse events are reported in our clinical trials for our clinical product candidate, our ability to obtain regulatory approval for such clinical product candidate may be negatively impacted.

Furthermore, if any of our products are approved and then cause serious or unexpected side effects, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product candidate or impose restrictions on its distribution or other risk management measures;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to conduct additional clinical trials;
- we could be sued and held liable for injuries sustained by patients;
- we could elect to discontinue the sale of its product candidate; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercialization.

Our employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our employees and contractors, including principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies, manufacturing standards, federal and state healthcare fraud and abuse and health regulatory laws and other similar foreign fraudulent misconduct laws, or laws that require the true, complete and accurate reporting of financial information or data. Misconduct by these parties may also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter third party misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting it from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, our clinical product candidate, and our ability to generate revenue will be impaired.

Our clinical product candidate and the activities associated with our development and commercialization, including our design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a clinical product candidate will prevent us from commercializing the clinical product candidate. We have not received approval to market our clinical product candidate from regulatory authorities in any jurisdiction. We only have limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on CROs to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the clinical product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our clinical product candidate may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may prevent it from obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and elsewhere, is expensive, may take many years and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidate involved. We cannot assure you that it will ever obtain any marketing approvals in any jurisdiction. The fact that the FDA has designated the investigation of our lead development candidate for platinum-resistant recurrent ovarian cancer as a Fast Track development program, while potentially favorable, provides no assurance as to the timing or outcome of any FDA regulatory process. Fast Track status may be withdrawn if the conditions for such designation are no longer met. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical or other studies, and clinical trials. In addition, varying interpretations of the data obtained from preclinical testing and clinical trials could delay, limit or prevent marketing approval of a product candidate. Additionally, any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Even if we obtain FDA approval in the United States, we may never obtain approval for or commercialize our clinical product candidate in any other jurisdiction, which would limit our ability to realize each product's full market potential.

In order to market our clinical product candidate in a particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product candidate testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our clinical product candidate in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and it does not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product candidate we develop will be unrealized.

Even if we obtain regulatory approval, we will still face extensive ongoing regulatory requirements and our clinical product candidate may face future development and regulatory difficulties.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising and promotional activities for such product candidate, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety, efficacy and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with current Good Manufacturing Practice, or cGMP, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and current GCP requirements for any clinical trials that we conduct post-approval. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product candidate may be marketed or to the conditions of approval. If our clinical product candidate receives marketing approval, the accompanying label may limit the approved use of our product, which could limit sales.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety and/or efficacy of our clinical product candidate. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our clinical product candidate for its approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to FDA enforcement actions and investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our clinical product candidate, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on manufacturing such clinical product candidate;
- restrictions on the labeling or marketing of such clinical product candidate;

- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters;
- withdrawal of the clinical product candidate from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of such clinical product candidate;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of such clinical product candidate;
- clinical product candidate seizure; or
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our clinical product candidate. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained.

Even if our clinical product candidate receives marketing approval, we may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

If our clinical product candidate receives marketing approval, we may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If we do not achieve an adequate level of acceptance, we may not generate significant revenues and become profitable. The degree of market acceptance, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the efficacy and potential advantages compared to alternative treatments;
- effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments;
- our ability to offer our clinical product candidate for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the willingness of the medical community to offer customers our product candidate option in addition to or in the place of our clinical product candidate;
- the strength of marketing and distribution support;
- the availability of third party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our product together with other medications.

Because we expect sales of our clinical product candidate to be based on the same mechanism of action, the failure of our first product candidate to achieve market acceptance would harm our business and could require us to seek additional financing sooner than we otherwise planned.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Our product candidates may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices, or healthcare reform initiatives, which would harm our business. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

The regulations that govern marketing approvals, pricing, coverage, and reimbursement for new drugs vary widely from country to country. In the United States, recently enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries

require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval.

Our ability to successfully commercialize our product candidates also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments such as gene therapy products. Sales of these or other product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of our clinical product candidate that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of our clinical product candidate will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only on a limited basis, we may not be able to successfully commercialize our clinical product candidate. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain adequate pricing that will allow it to realize a sufficient return on our investment.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries may cause us to price our clinical product candidate on less favorable terms that we currently anticipate. In many countries, particularly the countries of the European Union, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our clinical product candidate to other available therapies. In general, the prices of products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that it is able to charge for its clinical product candidate. Accordingly, in markets outside the United States, the reimbursement for its products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

Moreover, increasing efforts by governmental and third-party payors, in the United States and internationally, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for its clinical product candidate. We expect to experience pricing pressures in connection with the sale of our clinical product candidate due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected for new products entering the marketplace.

If we fail to comply with state and federal healthcare regulatory laws, we could face substantial penalties, damages, fines, disgorgement, exclusion from participation in governmental healthcare programs, and the curtailment of its operations, any of which could harm our business.

Although we do not provide healthcare services or submit claims for third party reimbursement, we are subject to healthcare fraud and abuse regulation and enforcement by federal and state governments which could significantly impact our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal anti-kickback statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it;
- the civil False Claims Act, or FCA, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent; knowingly making using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; or knowingly making, using, or causing to be made or used, a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the criminal FCA, which imposes criminal fines or imprisonment against individuals or entities who make or present a claim to the government knowing such claim to be false, fictitious or fraudulent;
- HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal civil monetary penalties statute, which prohibits, among other things, the offering or giving of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a Federal or state governmental program;
- the federal physician sunshine requirements under the Affordable Care Act, which require certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members; and
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the device industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

Further, the Affordable Care Act, among other things, amended the intent requirements of the federal anti-kickback statute and certain criminal statutes governing healthcare fraud. A person or entity can now be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provided that the government may assert 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 FCA. Moreover, while it does not submit claims and its customers make the ultimate decision on how to submit claims, from time to time, we may provide reimbursement guidance to our customers. If a government authority were to conclude that we provide improper advice to our customers or encouraged the submission of false claims for reimbursement, we could face action against us by government authorities. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

We have entered into consulting and scientific advisory board arrangements with physicians and other healthcare providers. Compensation for some of these arrangements includes the provision of stock options. While we have worked to structure our arrangements to comply with applicable laws, because of the complex and far-reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with providers who influence the ordering of and use our products to be in violation of applicable laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Responding to investigations can be time- and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on its business.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit the commercialization of any product candidates we may develop.

We face an inherent risk of product liability exposure related to the testing of our clinical product candidate in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop after approval. Any adverse reactions in our clinical trials could be deemed to be related to our clinical product candidate and could result in claims from these injuries and we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;

- significant costs to defend any related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue; and
- the inability to commercialize any products we may develop.

Although we maintain product liability insurance coverage in the amount of up to $10 million per claim and in the aggregate, we may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage as we continue clinical trials and if we successfully commercialize any products. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

If we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing our clinical product candidate, if approved.

We do not have any infrastructure for the sales, marketing or distribution of our clinical product candidate, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any product candidate that may be approved, we must build our sales, distribution, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. To achieve commercial success for any product candidate for which we have obtained marketing approval, we will need a sales and marketing organization. We expect to build a focused sales, distribution and marketing infrastructure to market any other product candidates in the United States, if approved. There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could delay any product candidate launch, which would adversely impact commercialization.

Factors that may inhibit our efforts to commercialize our clinical product candidate on our own include:

- Our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or attain adequate numbers of physicians to administer our products; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

We intend to pursue collaborative arrangements regarding the sale and marketing of our clinical product candidate, if approved, for certain international markets; however, we may not be able to establish or maintain such collaborative arrangements, if able to do so, that our collaborators may not have effective sales. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful.

If we are unable to build our own sales force in the United States or negotiate a collaborative relationship for the commercialization of our clinical product candidate outside the United States we may be forced to delay the potential commercialization or reduce the scope of our sales or marketing activities. We may have to enter into arrangements with third parties or otherwise at an earlier stage than we would otherwise choose and we may be required to relinquish rights to our intellectual property or otherwise agree to terms unfavorable to us, any of which may have an adverse effect on our business, operating results and prospects.

We may be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

If we obtain approval to commercialize our clinical product candidate outside of the United States, a variety of risks associated with international operations could harm our business.

If our clinical product candidate is approved for commercialization, we intend to enter into agreements with third parties to market them in certain jurisdictions outside the United States. We expect that we will be subject to additional risks related to international operations or entering into international business relationships, including:

- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;

- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign reimbursement, pricing and insurance regimes;
- foreign taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential noncompliance with the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions;
- product shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by both the European Union and many of the individual countries in Europe with which we will need to comply.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our clinical product candidate and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our clinical product candidate, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidate for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect our business, financial condition and results of operations.

Among policy makers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the Affordable Care Act, or ACA, was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (70% as of January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA’s individual mandate to carry health insurance and delaying the implementation of certain ACA-mandated fees. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act of 2017, the remaining provisions of the Affordable Care

Act are invalid as well. While the Texas District Court Judge, as well as the Trump Administration and the Centers for Medicare & Medicaid Services, or CMS, have stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and our business.

Moreover, the Drug Supply Chain Security Act imposes obligations on manufacturers of prescription drugs in finished dosage forms. We have not yet adopted the significant measures that will be required to comply with this law. We are not sure whether additional legislative changes will be enacted, or whether the current regulations, guidance or interpretations will be changed, or what the impact of such changes on our business, if any, may be.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products, which could result in reduced demand for our clinical product candidate or additional pricing pressures. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our clinical product candidate or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our drug development programs and clinical product candidate. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our development programs and clinical product candidate. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the United States or in other countries. There is no assurance that all potentially relevant prior art that could invalidate our patents or that could prevent our pending patent applications from issuing as patents have been found. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of our product candidates or companion diagnostic that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate and companion diagnostic under patent protection could be reduced.

If the patent applications we hold with respect to our platform technology and clinical product candidate fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our clinical product candidate, it could dissuade companies from collaborating with us to develop future product candidates, and threaten our ability to commercialize future drugs. Any such outcome could harm our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our technology or product

candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of ours issued patents. In 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The U.S. Patent Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its

implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business and financial condition.

Moreover, we may be subject to a third party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. In other countries, we may be subject to or become involved in opposition proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission or proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and its owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Moreover, patents have a limited lifespan. In the United States and other countries, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however the life of a patent, and the protection it affords, is limited. Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, we owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

We may be involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors and other third parties may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that such patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, nonenablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future

patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common stock.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our clinical product candidate.

The United States has recently enacted and implemented wide-ranging patent reform legislation. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future.

If a third party claims we are infringing on their intellectual property rights, we could incur significant expenses, or be prevented from further developing or commercializing our clinical product candidate, which could materially harm our business.

Our success will also depend on our ability to operate without infringing the patents and other proprietary intellectual property rights of third parties. This is generally referred to as having “freedom to operate.” We have not conducted an in-depth freedom to operate search which would be time consuming and costly. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. The defense and prosecution of intellectual property claims, interference proceedings and related legal and administrative proceedings, both in the United States and internationally, involve complex legal and factual questions. As a result, such proceedings are lengthy, costly and time-consuming, and their outcome is highly uncertain. We may become involved in protracted and expensive litigation in order to determine the enforceability, scope and validity of the proprietary rights of others, or to determine whether we have freedom to operate with respect to the intellectual property rights of others. For example, we are aware of an issued US patent that claims a method of treating cancer using an AXL-Fc fusion protein. In the event that this patent or another patent is successfully asserted against our GAS6-AXL program in the future, we may be unable to market the product, absent a license from the patentee, which may not be available on commercially reasonable terms, if at all.

Patent applications in the United States are, in most cases, maintained in secrecy until approximately 18 months after the patent application is filed. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made. Therefore, patent applications relating to product candidates similar to ours may have already been filed by others without our knowledge. In the event that a third party has also filed a patent application covering our clinical product candidate, we may have to participate in an adversarial proceeding, such as an interference proceeding, in the U.S. Patent and Trademark Office, or USPTO, or similar proceedings in other countries, to determine the priority of invention. In the event an infringement claim is brought against us, we may be required to pay substantial legal fees and other expenses to defend such a claim and, if we are unsuccessful in defending the claim, we may be prevented from pursuing the development and commercialization of a product candidate and may be subject to injunctions and/or damage awards.

In the future, the USPTO or a foreign patent office may grant patent rights covering our clinical product candidate to third parties. Subject to the issuance of these future patents, the claims of which will be unknown until issued, we may need to obtain a license or sublicense to these rights in order to have the appropriate freedom to further develop or commercialize them. Any required licenses may not be available to us on acceptable terms, if at all. If we need to obtain such licenses or sublicenses, but is unable to do so, we could encounter delays in the development of our clinical product candidate, or be prevented from developing, manufacturing and commercializing our clinical product candidate at all. If it is determined that we have infringed an issued patent and do not have freedom to operate, we could be subject to injunctions, and/or compelled to pay significant damages, including punitive damages. In cases where we have in-licensed intellectual property, our failure to comply with the terms and conditions of such agreements could harm our business.

It is becoming common for third parties to challenge patent claims on any successfully developed product candidate or approved drug. If we or our licensees or collaborators become involved in any patent litigation, interference or other legal proceedings, we could incur substantial expense, and the efforts and attention of our technical and management personnel could be significantly diverted. A negative outcome of such litigation or proceedings may expose us to the loss of our proprietary position or to significant liabilities, or require us to seek licenses that may not be available from third parties on commercially acceptable terms, if at all. We may be restricted or prevented from developing, manufacturing and selling our clinical product candidate in the event of an adverse determination in a judicial or administrative proceeding, or if we fail to obtain necessary licenses.

We may not be able to protect our intellectual property rights throughout the world, which could impair our business.

Filing, prosecuting and defending patents covering our clinical product candidate throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These other products may compete with our clinical product candidate in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

We seek to protect our proprietary technology in part by entering into confidentiality agreements with third parties and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor’s discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor’s discovery of our trade secrets would impair our

competitive position and have an adverse impact on our business.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submissions, 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.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary fee payments and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If us and our licensors fail to maintain the patents and patent applications covering our clinical product candidate, our competitive position would be adversely affected.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make products that are similar to our product candidates but that are not covered by the claims of the patents that we license;
- Our licensors or collaborators might not have been the first to make the inventions covered by an issued patent or pending patent application;
- Our licensors or collaborators might not have been the first to file patent applications covering an invention;
- Others may independently develop similar or alternative technologies or duplicate any of our or our licensors' technologies without infringing our intellectual property rights;
- Pending patent applications may not lead to issued patents;
- Issued patents may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- We may not develop or in-license additional proprietary technologies that are patentable; and
- The patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

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

Many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies. These employees typically executed proprietary rights, non-disclosure and non-competition agreements in connection with our previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We are not aware of any threatened or pending claims related to these matters, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to the ownership of our common stock

Our stock price may be volatile, and investors in our common stock could incur substantial losses.

Our stock price has fluctuated in the past and may be volatile in the future. From January 1, 2015 through December 31, 2018 the reported sale price of our common stock has fluctuated between $3.07 and $144.00 per share. Following the announcement of the failure of our Phase 3 clinical trial to meet its primary endpoint in September 2017, our stock price declined substantially. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may experience losses on their investment in our common stock. The market price for our common stock may be influenced by many factors, including the following:

- investor reaction to our new business strategy resulting from the Merger;
- the success of competitive products or technologies;

- results of clinical studies of AVB-S6-500 or future product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our products;
- introductions and announcements of new products by us, results of clinical trials, our commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our products, clinical studies, manufacturing process or sales and marketing terms;

- variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional products or product candidates;
- developments concerning our collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;
- developments concerning our ability to bring our manufacturing processes to scale in a cost-effective manner;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- trading volume of our common stock;
- sales of our common stock by us or our stockholders;
- general economic, industry and market conditions; and
- the other risks described in this “Risk factors” section.

These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management’s attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

Our executive officers, directors, and entities under our control, and principal stockholders will continue to maintain the ability to control or significantly influence all matters submitted to stockholders for approval.

As of December 31, 2018, our executive officers, directors and entities under our control, and principal stockholders, in the aggregate, owned shares representing approximately 33% of our common stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these stockholders, if they choose to act together, will control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

We incur significant costs as a result of operating as a public company, and our management devotes substantial time to new compliance initiatives.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, the other rules and regulations of the Securities and Exchange Commission, or SEC, and the rules and regulations of The Nasdaq Global Select Market, or Nasdaq. Compliance with the various reporting and other requirements applicable to public companies requires considerable time and attention of management. For example, the Sarbanes-Oxley Act and the rules of the SEC and national securities exchanges have imposed various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel are devoting and will continue to need to devote a substantial amount of time to these compliance initiatives. These rules and regulations will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. The impact of these events could also make it more difficult for us to attract and retain qualified personnel to serve on our board of directors, our board committees, or as executive officers

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The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. In addition, we will be required to have our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting beginning with our annual report on Form 10-K following the date on which we are once again an accelerated filer and are no longer an emerging growth company. Our compliance with Section 404 of the Sarbanes-Oxley Act will require that we incur substantial accounting expense and expend significant management efforts. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would require additional financial and management resources.

Our ability to successfully implement our business plan and comply with Section 404 requires us to be able to prepare timely and accurate condensed consolidated financial statements. We expect that we will need to continue to improve existing, and implement new operational and financial systems, procedures and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls, may cause our operations to suffer and we may be unable to conclude that our internal control over financial reporting is effective and to obtain an unqualified report on internal controls from our auditors as required under Section 404 of the Sarbanes-Oxley Act. This, in turn, could have an adverse impact on trading prices for our common stock, and could adversely affect our ability to access the capital markets.

We are an “emerging growth company,” and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act and may remain an emerging growth company through 2019. For so long as we remain an emerging growth company, we will be permitted to and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may choose to take advantage of some, but not all, of the available exemptions. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and the price of our common stock price may be more volatile.

An active trading market for our common stock may not be maintained, or we may fail to satisfy applicable Nasdaq listing requirements.

Our common stock is currently traded on Nasdaq, but we can provide no assurance that we will be able to maintain an active trading market for our shares on Nasdaq or any other exchange in the future. The fact that a significant portion of our outstanding shares of common stock is closely held by a few individuals, results in it being more difficult for us to maintain an active trading market. If there is no active market for our common stock, it may be difficult for our

stockholders to sell shares without depressing the market price for the shares or at all, our stock price could decline, and we may be unable to maintain compliance with applicable Nasdaq listing requirements.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. We currently do not have any analyst coverage. Even if we should have analyst coverage, securities and industry analysts may cease to publish research on our company at any time in their discretion. If one or more of these analysts cease coverage of our company after commencing coverage, or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price and trading volume to decline. In addition, if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If our operating results fail to meet the forecast of analysts, our stock price would likely decline.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. Among others, these provisions include the following:

- our board of directors is divided into three classes with staggered three-year terms which may delay or prevent a change of our management or a change in control;
- our board of directors has the right to elect directors to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- our stockholders are not able to act by written consent or call special stockholders' meetings; as a result, a holder, or holders, controlling a majority of our capital stock are not able to take certain actions other than at annual stockholders' meetings or special stockholders' meetings called by the board of directors, the chairman of the board, the chief executive officer or the president;
- our certificate of incorporation prohibits cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- our stockholders are required to provide advance notice and additional disclosures in order to nominate individuals for election to the board of directors or to propose matters that can be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of our company; and
- our board of directors are able to issue, without stockholder approval, shares of undesignated preferred stock, which makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our employment arrangements with our executive officers may require us to pay severance benefits to any of those persons who are terminated in connection with a change in control of us, which could harm our financial condition or results.

Certain of our executive officers are parties to employment or other agreements or participants under plans that contain change in control and severance provisions providing for aggregate cash payments for severance and other benefits and acceleration of vesting of stock options in the event of a termination of employment in connection with a change in control of us. The accelerated vesting of options could result in dilution to our existing stockholders and harm the market price of our common stock. The payment of these severance benefits could harm our financial condition and results. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be our stockholders' sole source of gain.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of existing or any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

Item 1B. Unresolved Staff Comments.

None

Item 2. Properties.

We do not own any real property and lease facilities in Palo Alto and Menlo Park, California and Houston, Texas. Our principal executive offices are located in Houston, Texas where we occupy office space pursuant to the terms of a sublease that expires on December 31, 2019. Our rent under the sublease is $7,000 per month.

In March 2017, we entered into an operating facility lease agreement with Bohannon Associates, a California partnership, dated March 17, 2017 (the "Master Lease") for approximately 34,500 rentable square feet located at 1020 Marsh Road, Menlo Park, California and for approximately 17,400 rentable square feet located at 1060 Marsh Road. In September 2017, we opted out of ours intent to occupy 1060 Marsh Road. The lease for 1020 Marsh Road commenced in August 2017 for a period of 86 months with one renewal option for a five-year term. The total obligation for us under this lease is approximately $17.0 million as of December 31, 2018.

On September 14, 2018, the Sublease dated August 21, 2018 (the "Sublease Agreement") by and between us and EVA Automation, Inc. ("Subtenant") became effective, whereby we agreed to sublease to Subtenant all of the approximately 34,500 rentable square feet of office space at 1020 Marsh Road, Menlo Park, California currently leased pursuant to the Master Lease. The sublease commenced on October 1, 2018 and the term of the sublease is through October 31, 2024, unless the Master Lease is terminated earlier due to a breach by Subtenant. The aggregate base rent due to us under the Sublease is approximately $12.8 million.

In October 2018, we executed a lease agreement in Palo Alto, California for approximately 4,240 square feet for office space. The rental term of the lease commences on October 30, 2018 and expires August 31, 2020. The total obligation for us under this lease is approximately $0.3 million.

We believe that our existing facilities are adequate for our current needs.

Item 3. Legal Proceedings.

We are not currently subject to any material legal proceedings

Item 4. Mine Safety Disclosures.

Not Applicable

PART II

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

Market for Registrant's Common Equity

Since October 16, 2018, our common stock has been listed on The Nasdaq Global Select Market under the symbol "ARAV". Prior to that, from March 21, 2014 until October 16, 2018, our common stock traded under the symbol "VSAR". In connection with the completion of the Merger, on October 15, 2018, our amended and restated certificate of incorporation was amended to effect, on October 16, 2018, a reverse split of our common stock at a ratio of 1-for-6.

Holders

On February 28, 2019, there were 37 stockholders of record of our common stock, one of which was Cede & Co., a nominee for Depository Trust Company (DTC). All of the shares of our common stock held by brokerage firms, banks and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC and are therefore considered to be held of record by Cede & Co. as one stockholder.

Dividend Policy

We have not paid dividends on our common stock. We currently intend to retain any earnings for use in the development and expansion of our business. We, therefore, do not anticipate paying cash dividends on our common stock in the foreseeable future.

Sales of Unregistered Equity Securities

There were no unregistered sales of equity securities by us during the year ended December 31, 2018.

Performance Graph

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 6. Selected Financial Data.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion and other parts of this Form 10-K contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this Form 10-K entitled "Risk Factors."

Recent Developments

On October 12, 2018, we, then known as Versartis, Inc., and Private Aravive completed the Merger, pursuant to which Private Aravive survived as our wholly owned subsidiary. In connection with the completion of the Merger, on October 15, 2018, we changed our name from Versartis, Inc. to "Aravive, Inc." and on October 16, 2018, we effected a reverse split of our common stock at a ratio of 1-for-6, or the Reverse Split, On October 16, 2018, our common stock began trading on the Nasdaq Global Market under the symbol "ARAV." Unless otherwise stated, all share and per share amounts for all periods presented in this Annual Report on Form 10-K have been adjusted to reflect the Reverse Split.

Immediately following the completion of the Reverse Split and the Merger, there were approximately 11,182,025 shares of our common stock outstanding, of which approximately 5,141,915 were owned by the former Private Aravive stockholders. In addition, we assumed Private Aravive's equity incentive plans and all of the stock options outstanding under the Private Aravive's equity incentive plans, with such stock options representing at the effective time of the Merger the right for the former Private Aravive stockholders to purchase approximately 1,183,950 shares of our common stock.

The Merger was accounted for as an asset acquisition by us. To determine the accounting for this transaction under GAAP, we assessed whether an integrated set of assets and activities were accounted for as an acquisition of a business or an asset acquisition. The guidance requires an initial screen test to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single asset or group of similar assets. If that screen is met, the set is not a business. In connection with the acquisition of Private Aravive, we determined that substantially all the fair value is included in in-process research and development of Private Aravive's lead asset, AVB-S6-500 and, as such, the acquisition is treated as an asset acquisition. The net tangible and intangible assets acquired and liabilities assumed in connection with the transaction were recorded based on their relative fair values allocation as of October 12, 2018 and the value associated with in-process research and development will be expensed as it was determined to have no alternative future use.

Overview

As a result of the Merger, our historic business operations ceased and our going forward operations have been those of Private Aravive. Accordingly, the results of operations reported for the years ended December 31, 2018 and 2017, in this Management's Discussion and Analysis are not indicative of the results of operations expected in 2019 and future years due to the termination of our historic business operations in September 2018.

Upon effecting the Merger, we became a clinical-stage biotechnology company focused on developing new therapies that target important survival pathways for both advanced solid tumors as well as hematologic malignancies. Prior to the Merger, we were an endocrine-focused biopharmaceutical company that was developing a long-acting recombinant human growth hormone for the treatment of growth hormone deficiency.

Revenue

We have never generated revenue from operations on an annual basis that have exceeded our operating expenses, and, at December 31, 2018, we had an accumulated deficit of approximately $450.6 million and working capital of $56.1 million, primarily as a result of research and development and general and administrative expenses. We have never earned revenue from commercial sales of any of our product candidates. We generated grant revenue of $1.4 million for the year ended December 31, 2018 from the CPRIT grant and contract revenue of $40.0 million for the year ended December 31, 2017 from our agreement with Teijin or Teijin, a pharmaceutical company based in Japan. In August 2016, we entered into an exclusive license and supply agreement with Teijin or the Teijin agreement, pursuant to which we granted to Teijin an exclusive license to develop, use, sell, offer for sale, import, and otherwise commercialize, in Japan, any pharmaceutical product incorporating somavaratan. In exchange for such rights, we received a nonrefundable upfront payment of $40.0 million in 2016. We recognized the $40.0 million as revenue in 2017 our obligations under the agreement were substantively complete at December 31, 2017.

In the future, we may generate revenue from a variety of sources, including product sales if we develop products which are approved for sale, license fees, milestones, research and development and royalty payments in connection with strategic collaborations or government contracts, or licenses of our intellectual property.

General and administrative expenses

General and administrative expenses consist principally of personnel-related costs, professional fees for legal, consulting, audit and tax services, rent and other general operating expenses not included in research and development. We anticipate general and administrative expenses will decrease in future periods, reflecting our reduced headcount and infrastructure as noted above.

Other income (expense), net

Other income (expense), net is primarily comprised of gains and losses on foreign currency transactions related to third party contracts with foreign-based contract manufacturing organizations, gains and losses on foreign currency exchange contracts, as well as sublease income for our build-to-suit lease.

Critical accounting policies, significant judgments and use of estimates

Our management's discussion and analysis of financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, ("U.S. GAAP"). The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, and expenses. On an ongoing basis, we evaluate our critical accounting policies and estimates. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable in the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Grant Revenue

Revenues from the CPRIT Grant are recognized when qualifying costs are incurred and there is reasonable assurance that the conditions of the award have been met for collection. Proceeds received prior to the costs being incurred or the conditions of the award being met are recognized as deferred revenue until the services are performed and the conditions of the award are met.

Research and development expense

Research and development costs are expensed as incurred. Research and development expense includes payroll and personnel expenses; consulting costs; external contract research and development expenses; and allocated overhead, including rent, equipment depreciation and utilities, and relate to both company-sponsored programs as well as costs incurred pursuant to reimbursement arrangements. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed.

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing contracts and purchase orders, reviewing the terms of our license agreements, communicating with our applicable personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each consolidated balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees to:

- contract manufacturers in connection with the production of clinical trial materials;
- contract research organizations and other service providers in connection with clinical studies;
- investigative sites in connection with clinical studies;
- vendors in connection with preclinical development activities; and
- professional service fees for consulting and related services.

We base our expenses related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and contract research organizations that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows and expense recognition. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual accordingly. Our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in our reporting changes in estimates in any particular period. To date, there have been no material differences from our estimates to the amount actually incurred. However, due to the nature of these estimates, we cannot assure you that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical studies or other research activity.

Build-to-Suit Lease Accounting

In certain lease arrangements, we are involved in the construction of the building. To the extent we are involved with structural improvements of the construction project or take construction risk prior to the commencement of a lease, Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, 840-40, “Leases – Sale-Leaseback Transactions (Subsection 05-5)”, requires us to be considered the owner for accounting purposes of these types of projects during the construction period. Therefore, we record an asset in property and equipment, net on the consolidated balance sheets, including capitalized interest costs, for the replacement cost of the pre-existing building plus the amount of estimated construction costs and tenant improvements incurred by the landlord and us as of the balance sheet date. We record a corresponding build-to-suit lease obligation on our consolidated balance sheets representing the amounts paid by the lessor.

Once construction is complete, we consider the requirements for sale-leaseback accounting treatment, including evaluating whether all risks of ownership have been transferred back to the landlord, as evidenced by a lack of continuing involvement in the leased property. If the arrangement does not qualify for sale-leaseback accounting treatment, the building asset remains on our consolidated balance sheets at its historical cost, and such asset is depreciated over its estimated useful life of 38 years. We bifurcate our lease payments into a portion allocated to the building, and a portion allocated to the parcel of land on which the building has been built. The portion of the lease

payments allocated to the land are treated for accounting purposes as operating lease payments, and therefore recorded as ground rent expense in the consolidated statements of operations.

The interest rate used for the build-to-suit lease obligation represents our estimated incremental borrowing rate, adjusted to reduce any built-in loss.

The initial recording of these assets and liabilities is classified as non-cash investing and financing items, respectively, for purposes of the consolidated statements of cash flows.

The most significant estimates used by management in accounting for build-to-suit leases and the impact of these estimates are as follows:

- Economic life- Our estimated economic life of the building considers life added back due to tenant improvements.
- Incremental borrowing rate- We estimate our incremental borrowing rate. For build-to-suit leases recorded on our consolidated balance sheets with a related build-to-suit lease obligation, the incremental borrowing rate is used in allocating our rental payments between interest expense and ground rent expense.
- Fair market value of leased asset- The fair market value of a build-to-suit lease property is based on replacement cost of the pre-construction shell and comparable market data. Fair market value is used in determining the amount of the property asset and related build-to-suit lease obligation to be recognized on our consolidated balance sheet for build-to-suit leases.

Stock-based compensation expense

For the years ended December 31, 2018 and 2017, stock-based compensation expense was $16.1 million and $13.3 million, respectively. As of December 31, 2018, we had approximately $4.8 million of total unrecognized compensation expense, which we expect to recognize over a weighted-average period of approximately 1.4 years. The intrinsic value of all outstanding stock options as of December 31, 2018 was approximately $3.7 million, of which all related to vested options. We expect to continue to grant equity incentive awards in the future as we seek to retain our existing employees. The stock-based compensation expense that we recognized beginning with the first quarter of 2014 and for each quarter thereafter through the first quarter of 2018 reflects our conclusion to calculate that expense based on a deemed fair value of our common stock that was higher than the exercise price of certain stock options granted during the first quarter 2014 prior to our initial public offering.

Stock-based compensation costs related to stock options granted to employees are measured at the date of grant and to the options assumed in connection with the Merger are measured at the date of the Merger based on the estimated fair value of the award, net of estimated forfeitures. We estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model. The grant date fair value of stock-based awards is recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the award. Stock options we grant to employees generally vest over four years. The fair value of options assumed in connection with the Merger were determined using the Black-Scholes option-pricing model with assumptions derived immediately following the completion of the Merger and were recognized as operating expenses in the 2018 consolidated statement of operations.

The Black-Scholes option-pricing model requires the use of highly subjective assumptions to estimate the fair value of stock-based awards. If we had made different assumptions, our stock-based compensation expense, net loss and net loss per share of common stock could have been significantly different. These assumptions include:

- Expected volatility: As we do not have an extensive trading history for our common stock, the expected stock price volatility for our common stock was estimated by taking the average historical price volatility for industry peers based on daily price observations over a period equivalent to the expected term of the stock option grants. Industry peers consist of several public companies in the biopharmaceutical industry that are similar in size, stage of life cycle and financial leverage. We did not rely on implied volatilities of traded options in our industry peers' common stock because the volume of activity was relatively low. We intend to continue to consistently apply this process using the same or similar public companies until a sufficient amount of historical information regarding the volatility of our own common stock price becomes available, or unless circumstances change such that the identified companies are no longer similar to us, in which case, more suitable companies whose share prices are publicly available would be utilized in the calculation. Beginning in 2018, we had enough historical stock price information in order to value the options assumed in the Merger.
- Expected term: We do not believe we are able to rely on our historical exercise and post-vesting termination activity to provide accurate data for estimating the expected term for use in estimating the fair value-based measurement of our options. Therefore, we have opted to use the "simplified method" for estimating the expected term of options.

- Risk-free rate: The risk-free interest rate is based on the yields of U.S. Treasury securities with maturities similar to the expected time to liquidity.
- Expected dividend yield: We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future. Consequently, we used an expected dividend yield of zero.

See Note 10 to our audited consolidated financial statements included elsewhere in this annual report on Form 10-K for information concerning certain of the specific assumptions used in applying the Black-Scholes option-pricing model to determine the estimated fair value of employee stock options assumed in the Merger and granted in 2017. In addition to the assumptions used in the Black-Scholes option-pricing model, we must also estimate a forfeiture rate to calculate the stock-based compensation expense for our awards. We will continue to use judgment in evaluating the expected volatility, expected terms, and forfeiture rates utilized for our stock-based compensation expense calculations on a prospective basis.

Income taxes

We file U.S. federal income tax returns, Texas and California state tax returns. To date, we have not been audited by the Internal Revenue Service or any state income tax authority; however, all tax years remain open for examination by federal and state tax authorities. We use the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. We assess the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is deemed more likely than not that some portion or all of a deferred tax asset will not be realized.

As of December 31, 2018, our total gross deferred tax assets were $11.1 million. Due to our lack of earnings history and uncertainties surrounding our ability to generate future taxable income, the net deferred tax assets have been fully offset by a valuation allowance. The deferred tax assets were primarily comprised of federal and state tax net operating losses and tax credit carryforwards. Utilization of net operating losses and tax credit carryforwards may be limited by the “ownership change” rules, as defined in Section 382 of the Internal Revenue Code (any such limitation, a “Section 382 limitation”). Similar rules may apply under state tax laws. We have performed an analysis to determine whether an “ownership change” occurred from inception up to the Private Aravive's acquisition date. Based on this analysis, management determined that both Versartis, Inc. and Private Aravive did experience ownership changes, which resulted in a significant impairment of the net operating losses and credit carryforwards. As such, the net operating loss carryforwards have been reduced by $306 million. The tax credit carryforwards have been reduced by $39.5 million.

The Tax Cuts and Jobs Act ("the Act") was enacted on December 22, 2017. The Act reduces the U.S. federal corporate tax rate from 35% to 21%, requires companies to pay a one-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred and creates new taxes on certain foreign sourced earnings. We are required to recognize the effect of the tax law changes in the period of enactment, such as determining the estimated transition tax, re-measuring our U.S. deferred tax assets and liabilities at a 21% rate as well as reassessing the net realizability of our deferred tax assets and liabilities.

Accordingly, we remeasured certain deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future. The provisional amount related to the re-measurement of our deferred tax balance is a reduction of approximately $33 million. Due to the corresponding valuation allowance fully offsetting deferred taxes, there is no income statement impact.

In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act (SAB 118) which allows us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. In Q4 2018, we completed our analysis within the measurement period in accordance with SAB 118, and found no change to the provisional amount on 2017 tax provision.

Results of operations

Comparison of the years ended December 31, 2018 and 2017

The following table summarizes our net loss during the periods indicated (in thousands, except percentages):

	Year Ended December 31,		Increase/ (Decrease)		
	2018	2017			
Revenue:					
Contract revenue	$—	$40,000	$(40,000)	NM	(1)
Grant revenue	1,371	—	$1,371	NM	(1)
Total revenue	1,371	40,000	(38,629)	-97	%
Operating expenses:					
Research and development	$11,075	$94,612	$(83,537)	-88	%
Write-off of acquired in-process research and development	38,313	—	38,313	NM	(1)
General and administrative	27,395	29,870	(2,475)	-8	%
Total operating expenses	76,783	124,482	(47,699)	-38	%
Loss from operations	(75,412)	(84,482)	(9,070)	-11	%
Interest income	989	847	142	17	%
Interest expense	(2,429)	(528)	(1,901)	360	%
Other income (expense), net	519	(1,063)	1,582	-149	%
Net loss before benefit for income taxes	(76,333)	(85,226)	(8,893)	-10	%
Benefit from for income taxes	—	(247)	247	NM	(1)
Net loss	$(76,333)	$(84,979)	$(8,646)	-10	%

(1) Not meaningful.

Revenue

In 2018, we completed the Merger with Private Aravive. Private Aravive has a grant with CPRIT. Grant revenue for the year ended December 31, 2018 amounted to $1.4 million and was derived solely from the CPRIT grant.

In 2017, upon termination of the Teijin Agreement, we recognized the nonrefundable $40.0 million upfront payment received from Teijin as contract revenue. In September 2017, the Phase 3 VELOCITY trial of somavaratan failed to reach its primary endpoint. As a result, because Japanese approval relied upon a positive Phase 3 VELOCITY trial result, the Japan pediatric GHD Phase 3 trial and its related long-term safety study were discontinued. In January 2018, we received notice from Teijin that it was, pursuant to the agreement's terms, terminating the Teijin Agreement, effective as of January 31, 2018. The notice of termination followed discussions between us and Teijin regarding the failure of our Phase 3 VELOCITY trial to meet its primary endpoint during which it was determined that continuing with the Teijin Agreement was no longer in the best interests of either party. Upon termination of the license agreement, we assessed whether to recognize the upfront payment as revenue in accordance with ASC 605-25 Multiple-Element Arrangements, as of December 31, 2017. From receipt of the $40.0 million in August 2016 through September 30, 2017, we concluded that persuasive evidence of an arrangement did not yet exist as certain key economic terms that may have significantly impacted economics of the Teijin Agreement were yet to be negotiated and finalized by the Parties as part of the commercial supply agreement. We reviewed the Teijin Agreement noting that remaining efforts made by the Company from October 2017 through January 2018 were not deemed a deliverable under the Teijin Agreement. These remaining efforts consisted solely of activities related to shutting down the clinical sites due to the outcome of our VELOCITY trial. The actions undertaken to close sites would have occurred with or without a third party and were not an obligation specific to, nor were they described, in the Teijin Agreement. As such, our obligations under the Teijin Agreement were substantively complete at December 31, 2017.

Research and development expense

Research and development expense decreased by $83.5 million, or 88%, to $11.1 million in 2018 from $94.6 million for the same period in 2017. The decrease in research and development expense was primarily due to the termination of clinical and manufacturing related contracts that supported our Phase 3 clinical trials for somavaratan following the Phase 3 VELOCITY trial failing to meet its primary endpoint, as well as a substantial reduction in our workforce. For the year ended December 31, 2017, substantially all of our research and development expense relates to our somavaratan drug development activity. In 2018, we also had a large write-off of our in-process research and development intangible asset of $38.3 million related to the Merger with Private Aravive which is considered to be part of our research and development expense. For the period from October 13, 2018 through December 31, 2018, research and development costs mostly related to AVB-S6-500 clinical trials along with additional costs incurred with winding down our somavaratan program.

General and administrative expense

General and administrative (G&A) expense decreased by $2.5 million, or 8%, to $27.4 million in 2018 from $29.9 million for the same period in 2017. The decrease was attributable to the reduction in workforce and our continued efforts to reduce consulting and professional services expenses following the Phase 3 VELOCITY trial failing to meet its primary endpoint, partially offset by an increase in professional services attributable to our Merger transaction with Private Aravive.

Interest income

Interest income increased $0.1 million, from approximately $0.8 million in 2017 to approximately $1.0 million in 2018. The increase in interest income was primarily due to rising interest rates earned on proceeds from our public offering in 2016 and the $40.0 million upfront payment received from Teijin, also received in 2016.

Interest expense

Interest expense increased $1.9 million, from $0.5 million in 2017 to $2.4 million in 2018. The increase in interest expense was primarily due to our build-to suit lease obligation where construction was completed in the later part of 2017.

Other income (expense), net

Other income (expense), net increased $1.6 million, from other expense of $1.1 million in 2017 to $0.5 million of other income in 2018. This increase was primarily due to sublease income recognized where we subleased our build-to-suit lease to another party in the later half of 2018. We had foreign currency losses incurred on payments to our European manufacturing suppliers in 2017 that didn’t occur in 2018 which contributed to the increase.

Liquidity and capital resources

Since our inception and through December 31, 2018, we have financed our operations through private placements of our equity securities, debt financing and, our initial public offering in 2014, additional common stock offerings in January 2015 and October of 2016, as well as a $40.0 million upfront payment received from our strategic license agreement with Teijin. At December 31, 2018, we had cash and cash equivalents of $57.0 million, a majority of which is invested in money market funds at several highly rated financial institutions. As a result of the Merger, we acquired approximately $5.3 million of additional cash and cash equivalents, and as a merged company our primary use of our capital will be to fund our clinical development programs, specifically for our product candidate AVB-S6-500.

While our current cash is expected to be sufficient in order to fund our operations for at least the next 12 months, we will need to obtain additional financing to advance our clinical development program to later stages of development and commercialize our clinical product candidate and we will continue to seek funds through equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing, such as a strategic transaction. Although management has been successful in raising capital in the past, most recently $59.1 million in October and November 2016, there can be no assurance that we will be successful or that any needed financing will be available in the future at terms acceptable to us. In addition, our ability to raise capital through the sales of securities may be limited by the rules of the SEC and Nasdaq that place limits on the number of securities that may be sold under certain circumstances. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. We anticipate that we will need to raise substantial additional capital to advance our clinical development program to later stages of development, the requirements of which will depend on many factors, including:

- the rate of progress and cost of our clinical studies;
- the timing of, and costs involved in, seeking and obtaining approvals from the FDA and other regulatory authorities;
- the cost of preparing to manufacture on a larger scale;
- the costs of commercialization activities if any future product candidate is approved, including product sales, marketing, manufacturing and distribution;
- the degree and rate of market acceptance of any products launched by us or future partners;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- our ability to enter into additional collaboration, licensing, commercialization or other arrangements and the terms and timing of such arrangements; and
- the emergence of competing technologies or other adverse market developments.

If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to others technologies or clinical product candidates or programs that we would prefer to develop and commercialize ourselves.

Cash flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented below:

	Year Ended December 31,	
	2018	2017
	(In thousands)	
Net cash (used in) provided by:		
Operating activities	$(29,257)	$(116,289)
Investing activities	3,168	(4,303)

Financing activities	1,948	2,968
Net decrease in cash and cash equivalents	$(24,141)	$(117,624)

Cash used in operating activities

Net cash used in operating activities was $29.3 million and $116.3 million in 2018 and 2017, respectively, which was primarily due to the use of funds in our operations related to the development of our product candidates. Cash used in operating activities in 2018 decreased compared to 2017 due to the termination of a number of supplier contracts, including commercial contracts with contract manufacturers as a result of the failure of the Phase 3 VELOCITY trial to meet its primary endpoint. Cash used in operating activities in 2017 of $116.3 million reflects a net loss of $85.0 million. Cash used in operating activities in 2018 of $29.3 million reflects a net loss of $76.3 million and was mostly related to operational expenses this loss was reduced by some large noncash amounts related to the write-off of acquired IPR&D and stock-based compensation expense.

Cash provided by (used in) investing activities

Net cash provided by investing activities was $3.2 million in 2018 and net cash used in investing activities was $4.3 million in 2017. Cash provided by investing activities in 2018, primarily relates to cash received in association with our Merger with Private Aravive and cost to acquire IPR&D. Cash used in investing activities in 2017 is primarily due to construction costs associated with our Menlo Park facility, and related fixed assets for the build out of this facility. Cash used in investing activities also consisted of investment in furniture, equipment, leasehold improvements, and letter of credit held for the office space in Menlo Park, California, for which the lease commenced in August 2017.

Cash provided by financing activities

Net cash provided by financing activities was $2.0 million and $3.0 million in 2018 and 2017, respectively. Cash provided by financing activities primarily relates to inducement payments received from the landlord of our leased facility in Menlo Park, thereby increasing our build-to-suit lease obligation, and proceeds from issuance of common stock in connection with employee benefit plans.

As of December 31, 2018, we had cash and cash equivalents of approximately $57.0 million. We believe that our existing cash and cash equivalents will be sufficient to sustain operations for at least the next 12 months from the issuance of these financial statements as we continue the development of AVB-S6-500. We will need to obtain additional financing to advance our clinical development program to later stages of development and fund operations for the foreseeable future and we will continue to seek funds through equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing.

Off-balance sheet arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

JOBS Act accounting election

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have chosen to “opt out” of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted. This decision to opt out of the extended transition period under the JOBS Act is irrevocable.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

The Company is a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and is not required to provide the information required under this item.

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Item 8. Financial Statements and Supplementary Data.

The following consolidated financial statements of the registrant, related notes and reports of independent registered public accounting firms are set forth beginning on page F-1 of this report.

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

None

Item 9A. Controls and Procedures.

(a) Evaluation of Disclosure Controls and Procedures

An evaluation as of December 31, 2018 was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our “disclosure controls and procedures,” which are defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), as controls and other procedures of a company that are designed to ensure that the information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms, and 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. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at December 31, 2018.

(b) Management's 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 Rule 13a-15(f) of the Exchange Act. Our internal control system is designed to provide reasonable assurance regarding the preparation and fair presentation of financial statements for external purposes in

accordance with generally accepted accounting principles. All internal control systems, no matter how well designed, have inherent limitations and can provide only reasonable assurance that the objectives of the internal control system are met.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting, based on criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its 2013 Internal Control-Integrated Framework. Based on our evaluation, we concluded that our internal control over financial reporting was effective as of December 31, 2018.

As an Emerging Growth Company, as defined under the terms of the JOBS Act of 2012, our independent registered public accounting firm is not required to issue an attestation report on our internal control over financial reporting.

(c) Changes in Internal Control over Financial Reporting

Our management, including our Chief Executive Officer and Chief Financial Officer, has evaluated any changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2018, and has concluded that there was no change during such period that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

On March 12, 2019, we filed a Certificate of Correction to the Certificate of Amendment of Amended and Restated Certificate of Incorporation to correct an inaccuracy in the number of authorized shares of Common Stock that was incorrectly set forth in the

Certificate of Amendment of Amended and Restated Certificate of Incorporation filed with the Secretary of State of Delaware on October 15, 2018 as being fifty million shares, when in fact one hundred million shares of Common Stock had been authorized for issuance.

Effective March 11, 2019, we terminated our Common Stock Sales Agreement (the Sales Agreement") that we had entered into on August 7, 2017 with Cowen and Company, LLC ("Cowen"), pursuant to which we could sell shares of our Common Stock having aggregate sales proceeds of up to $150 million, from time to time, through an "at the market offering" program through Cowen as our sales agent. A description of the Sales Agreement was included in the registration statement on Form S-3 filed with the SEC on August 7, 2017. No sales of Common Stock had been made under the Sales Agreement.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K because we intend to file our definitive proxy statement for our 2019 annual meeting of shareholders, or the 2019 Proxy Statement, pursuant to Regulation 14A of the Exchange Act, not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information to be included in the Proxy Statement is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance.

Information required by this Item will be included in the 2018 Proxy Statement, under the sections labeled “Proposal—Election of Directors” and “Section 16(a) Beneficial Ownership Reporting Compliance”, and is incorporated herein by reference. The 2019 Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year to which this report relates.

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics that applies to all of our employees, officers, and directors, including those officers responsible for financial reporting. Our code of business conduct and ethics is available on our website at www.aravive.com. We intend to disclose any amendments to the code, or any waivers of its requirements, on our website. You may also request a printed copy of our code of ethics, without charge, by writing to us at LydondellBasell Tower, 1221 McKinney Street, Suite 3200, Houston, Texas, 77010, Attn: Investor Relations.

Item 11. Executive Compensation.

Information required by this Item will be included in the sections labeled “Executive Compensation”, “Summary Compensation Table”, “Outstanding Equity Awards at Fiscal Year End”, and “Director Compensation” appearing in our 2019 Proxy Statement, and is incorporated herein by reference.

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

Information required by this Item will be included in the sections labeled “Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” appearing in our 2019 Proxy Statement, and is incorporated herein by reference.

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

Information required by this Item will be included in the section labeled “Transactions with Related Persons” and “Independence of the Board of Directors” appearing in our 2019 Proxy Statement, and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

Information required by this Item will be included in the section labeled “Proposal 2—Ratification of Selection of Independent Registered Public Accounting Firm” appearing in our 2019 Proxy Statement, and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedule.

(1) Consolidated Financial Statements;
See Index to Consolidated Financial Statements at page F-1 of this Annual Report on Form 10-K.

(2) Financial Statement Schedule
All schedules are omitted because they are not required or the required information is included in the consolidated financial statements or notes thereto.

(3) Exhibits:
The exhibits listed in the accompanying index to exhibits are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Shareholders and Board of Directors

Aravive, Inc.

Houston, Texas

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of Aravive, Inc. (formerly known as Versartis, Inc.) (the "Company") and subsidiaries as of December 31, 2018, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for the year then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company and subsidiaries at December 31, 2018, and the results of their operations and their cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("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 audit 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 consolidated 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 audit 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 audit 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 consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2018.

Raleigh, North Carolina

March 14, 2019

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Aravive, Inc.:

Opinion on the Financial Statements

We have audited the consolidated balance sheet of Aravive, Inc. (formerly known as Versartis, Inc.) and its subsidiaries (the “Company”) as of December 31, 2017, and the related consolidated statements of operations, comprehensive loss, stockholder’s equity and cash flows for the period ended December 31, 2017, including the related notes and schedule of valuation and qualifying accounts as of and for the period ended December 31, 2017 appearing under Item 15(2) (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017, and the results of its operations and its cash flows for the period ended December 31, 2017 in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (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 of these consolidated financial statements 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 consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

San Jose, California

March 6, 2018, except for the effects of the reverse stock split discussed in Note 16 to the consolidated financial statements, as to which the date is March 14, 2019.

We served as the Company's auditor from 2013 to 2018.

ARAVIVE, INC. (FORMERLY KNOWN AS VERSARTIS, INC.)

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

	December 31,	
	2018	2017
Assets		
Current assets		
Cash and cash equivalents	$56,992	$81,146
Prepaid expenses and other current assets	1,038	562
Total current assets	58,030	81,708
Restricted cash	2,396	2,383
Property and equipment, net	32	798
Build-to-suit lease asset, net (Note 7)	8,651	8,888
Intangible asset, net	341	—
Other assets	20	—
Total assets	$69,470	$93,777
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$426	$1,500
Accrued liabilities	1,365	4,093
Deferred revenue	146	—
Total current liabilities	1,937	5,593
Contingent payable	264	—
Build-to-suit lease obligation (Note 7)	7,324	5,428
Total liabilities	9,525	11,021
Commitments and contingencies (Note 8)		
Stockholders' equity		
Preferred stock, $0.0001 par value, 5,000,000 shares authorized at December 31, 2018 and December 31, 2017; zero shares issued and outstanding at December 31, 2018 and December 31, 2017	—	—
Common stock, $0.0001 par value, 100,000,000 shares authorized at December 31, 2018 and December 31, 2017; 11,266,151 and 5,989,688 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	1	1
Additional paid-in capital	510,509	456,987
Accumulated deficit	(450,565)	(374,232)
Total stockholders' equity	59,945	82,756
Total liabilities and stockholders’ equity	$69,470	$93,777

The accompanying notes are an integral part of these consolidated financial statements.

ARAVIVE, INC. (FORMERLY KNOWN AS VERSARTIS, INC.)

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

	Year Ended December 31,	
	2018	2017
Revenue		
Contract revenue	$—	$40,000
Grant revenue	1,371	—
Total revenue	1,371	40,000
Operating expenses		
Research and development	11,075	94,612
Write-off of acquired in-process research and development	38,313	—
General and administrative	27,395	29,870
Total operating expenses	76,783	124,482
Loss from operations	(75,412)	(84,482)
Interest income	989	847
Interest expense	(2,429)	(528)
Other income (expense), net	519	(1,063)
Net loss before provision for income taxes	(76,333)	(85,226)
Benefit from income taxes	—	(247)
Net loss	$(76,333)	$(84,979)
Net loss per share- basic and diluted	$(10.64)	$(14.47)
Weighted-average common shares used to compute net loss per share- basic and diluted	7,171	5,871

The accompanying notes are an integral part of these consolidated financial statements.

ARAVIVE, INC. (FORMERLY KNOWN AS VERSARTIS, INC.)

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

	Year Ended December 31,	
	2018	2017
Net loss	$(76,333)	$(84,979)
Other comprehensive loss:		
Unrealized loss on cash flow hedge	—	350
Comprehensive loss	$(76,333)	$(84,629)

ARAVIVE, INC. (FORMERLY KNOWN AS VERSARTIS, INC.)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands, except share and per share amounts)

	Common Stock Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
Balances at January 1, 2017	5,807,314	$ 1	$ 440,670	$ (350)	$ (289,253)	$ 151,068
Issuance of common stock upon exercise of options	141,833	—	2,504	—	—	2,504
Issuance of common stock under employee benefit plans	40,541	—	464	—	—	464
Stock-based compensation	—	—	13,349	—	—	13,349
Other comprehensive income	—	—	—	350	—	350
Net loss	—	—	—	—	(84,979)	(84,979)
Balances at December 31, 2017	5,989,688	1	456,987	—	(374,232)	82,756
Issuance of common stock upon exercise of options	3,643	—	35	—	—	35
Issuance of common stock under employee benefit plans	130,905	—	17	—	—	17
Stock-based compensation	—	—	16,139	—	—	16,139
Issuance of common stock for the merger transaction	5,141,915	—	37,331	—	—	37,331
Net loss	—	—	—	—	(76,333)	(76,333)
Balances at December 31, 2018	11,266,151	$ 1	$ 510,509	$ —	$ (450,565)	$ 59,945

The accompanying notes are an integral part of these consolidated financial statements.

ARAVIVE, INC. (FORMERLY KNOWN AS VERSARTIS, INC.)

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,	
	2018	2017
Cash flows from operating activities		
Net loss	$(76,333)	$(84,979)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	1,060	311
Write-off of acquired IPR&D	38,313	—
Stock-based compensation expense	16,139	13,349
Changes in assets and liabilities, net of acquisition		
Prepaid expenses and other assets	(224)	3,940
Accounts payable	(1,744)	142
Deferred revenue	(1,371)	—
Accrued liabilities	(5,097)	(8,805)
Income taxes payable	—	(247)
Upfront payment from collaboration partner	—	(40,000)
Net cash used in operating activities	(29,257)	(116,289)
Cash flows from investing activities		
Purchase of property and equipment	(33)	(745)
Leasehold improvements for build-to-suit asset	—	(3,558)
Cash paid to acquire IPR&D	(2,076)	—
Cash acquired in the merger transaction	5,277	—
Net cash provided by (used in) investing activities	3,168	(4,303)
Cash flows from financing activities		
Inducement on build-to-suit lease obligation	1,896	—
Proceeds from issuance of common stock	52	2,968
Net cash provided by financing activities	1,948	2,968
Net decrease in cash, cash equivalents and restricted cash	(24,141)	(117,624)
Cash, cash equivalents and restricted cash at beginning of period	83,529	201,153
Cash, cash equivalents and restricted cash at end of period	$59,388	$83,529
Supplemental disclosure of noncash items		
Build-to-suit lease transaction	$—	$5,428
Issuance of common stock for the merger transaction	$37,331	$—

The accompanying notes are an integral part of these consolidated financial statements.

ARAVIVE, INC. (FORMERLY KNOWN AS VERSARTIS, INC.)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Formation and Business of the Company

Aravive, Inc. (“Aravive” or the “Company”) was incorporated on December 10, 2008 in the State of Delaware. Aravive is a clinical stage biopharmaceutical company focused on developing innovative therapies that target important survival pathways for cancer. Prior to the Merger, as described in Note 16, “Merger with Aravive Biologics, Inc.,” Aravive (then known as Versartis, Inc.) was an endocrine-focused biopharmaceutical company that was developing a long-acting recombinant human growth hormone for the treatment of growth hormone deficiency. The “Company” refers to Aravive as a combined company following the completion of the Merger with Aravive Biologics, Inc. (“Private Aravive”). The Merger became effective on October 12, 2018. On October 15, 2018, Versartis, Inc. changed its name to Aravive, Inc.

The Company has been primarily performing research and development activities, including clinical trials, filing patent applications, hiring personnel, and raising capital to support and expand these activities. Its headquarters and principal operations are located in Houston, Texas.

The Company’s product candidates, Aravive-S6 (AVB-S6), are a set of novel, high-affinity, soluble Fc-fusion proteins designed to block the activation of the GAS6-AXL signaling pathway by intercepting the binding of GAS6 to its receptor AXL. The Company has generated preclinical data for AVB-S6 proteins in both acute myeloid leukemia and certain advanced solid tumors including ovarian, renal, pancreatic, and breast cancers. The Company’s current development program benefits from the availability of a complementary serum-based biomarker that it expects will help accelerate drug development and reduce risk by allowing the Company to select a pharmacologically active dose, better monitoring of therapeutic responses and perhaps better selection of responder patient populations. In its recently completed Phase 1 clinical trial with its clinical product candidate, AVB-S6-500, the Company established proof of mechanism by demonstrating full GAS6 neutralization at all doses tested. Importantly, the lead protein candidate had a favorable safety profile preclinically and in the first in human study.

In July 2016, Private Aravive was approved for a $20 million Product Development Award from the Cancer Prevention Institute of Texas (“CPRIT Grant”). The CPRIT Grant is expected to allow Private Aravive to develop the product candidates referenced above through clinical trials. The CPRIT Grant is effective as of June 1, 2016 and terminates on May 31, 2019, unless extended with CPRIT’s approval. After the termination date, Aravive is not permitted to retain any unused grant award proceeds without CPRIT’s approval, but Aravive’s royalty and other obligations, including its obligation to repay the disbursed grant proceeds under certain circumstances, survive the termination of the agreement. The CPRIT Grant is subject to customary CPRIT funding conditions including a matching funds requirement where Aravive will match 50% of funding from the CPRIT Grant. Consequently, Aravive is required to raise $10.0 million in matching funds over the three-year project. Aravive has raised all of its required $10.0 million in matching funds.

Private Aravive’s award from CPRIT requires it to pay CPRIT a portion of its revenues from sales of certain products by it, or received from its licensees or sublicensees, at tiered percentages of revenue in the low- to mid-single digits until the aggregate amount of such payments equals 400% of the grant award proceeds, and thereafter at a rate of less than one percent for as long as Aravive maintains government exclusivity. In addition, the grant contract also contains a provision that provides for repayment to CPRIT of the full amount of the grant proceeds under certain specified

circumstances involving relocation of Aravive's principal place of business outside Texas.

As consideration for the rights granted as part of a license agreement with Stanford University, Private Aravive is obligated to pay yearly license fees and milestone payments, and a royalty based on net sales of products covered by the patent-related rights. More specifically, Aravive is obligated to pay Stanford University (i) annual license payments (ii) milestone payments of up to an aggregate of $1,000,000 upon achievement of clinical and regulatory milestones, and (iii) royalties equal to a percentage (in the low single digits) of net sales of licensed products; provided that the annual license payments made will offset (and be credited against) any royalties due in such license year. In the event of a sublicense to a third party of any rights based on the patents that are solely owned by Stanford University, Private Aravive is obligated to pay royalties to Stanford University equal to a percentage of what Aravive would have been required to pay to Stanford University had it sold the products under sublicense itself. In addition, in such event Aravive is required to pay to Stanford University a percent of sublicensing income. In the event of a termination, Private Aravive will be obligated to pay all amounts that accrued prior to such termination.

In connection with the completion of the Merger, on October 15, 2018, the amended and restated certificate of incorporation of the Company was amended to effect, at 12:01 a.m. Eastern Time on October 16, 2018, a reverse split of Company Common Stock at a ratio of 1-for-6 (the "Amended Certificate").

All share and per share amounts in the consolidated financial statements have been retroactively adjusted for all periods presented to give effect to the reverse split, including reclassifying an amount equal to the reduction in par value to additional paid-in capital.

The Reverse Split affected all issued and outstanding shares of Common Stock, as well as Common Stock underlying stock options and restricted stock units outstanding immediately prior to the effectiveness of the Reverse Split.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”). The preparation of the accompanying consolidated financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

The accompanying consolidated financial statements are consolidated for the years ended December 31, 2018 and 2017 and include the accounts of Aravive, Inc. and its wholly-owned subsidiaries, Versartis Cayman Holdings Company, incorporated in 2014, Versartis GmbH, incorporated in 2015 and Private Aravive, incorporated in 2007, which was not included as a subsidiary in 2017. After 2015, the Cayman and GmbH subsidiaries became dormant. All intercompany accounts and transactions have been eliminated. The U.S. dollar is the functional currency for all of the Company's subsidiaries and consolidated operations.

Liquidity and Capital Resources

Since inception, the Company has incurred net losses and negative cash flows from operations. At December 31, 2018, the Company had an accumulated deficit of $450.6 million and working capital of $56.1 million. Since inception, the Company has incurred net losses and negative cash flows from operations. The Company expects to continue to incur losses from costs related to the development of AVB-S6-500 and related administrative activities for the foreseeable future. As of December 31, 2018, the Company had a cash and cash equivalents balance of $57.0 million consisting of cash and investments in highly liquid U.S. money market funds. While the Company believes that its existing cash and cash equivalents will be sufficient to sustain operations for at least the next 12 months from the issuance of these financial statements, based on its current business plan, the Company will need to obtain additional financing to advance our clinical development program to later stages of development and commercialize our clinical product candidate. Although management has been successful in raising capital in the past, including $59.1 million in October and November 2016, there can be no assurance that the Company will be successful or that any needed financing will be available in the future at terms acceptable to the Company.

Correction of Quarterly Information

During the fourth quarter ended December 31, 2018, the Company determined that the amount related to the inducement on build-to-suit lease obligation as reflected within one line in the investing activities section of the unaudited consolidated statement of cash flows for the three-, six-, and nine-month periods ended March 31, 2018, June 30, 2018, and September 30, 2018, respectively, filed on Form 10-Q, should have been classified as cash flows provided from financing activities. There is no impact to the consolidated statements of operations and comprehensive loss or consolidated balance sheets for any of these periods. The Company evaluated the effect of this misclassification and concluded it was not material to any of its previously issued unaudited consolidated financial

statements. Upon revision, cash flows from investing activities for the three-, six-, and nine-month periods ended March 31, 2018, June 30, 2018, and September 30, 2018, decreased by $1.5 million, $1.9 million, and $1.9 million, respectively and cash flows from financing activities for the respective periods increased by $1.5 million, $1.9 million, and $1.9 million, respectively. This adjustment had no impact to the Company's financial position, results of operations or cash flows as of and for the year ended December 31, 2018.

Segments

The Company operates in one segment. Management uses one measurement of profitability and does not segregate its business for internal reporting. All long-lived assets are maintained in the United States of America.

Concentration of credit risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. All of the Company's cash and cash equivalents are held at several financial institutions that management believes are of high credit quality. Such deposits may exceed federally insured limits.

During 2017, the Company entered into forward foreign currency contracts that exposed it to credit risk to the extent that the counterparties may be unable to meet the terms of the agreement. The Company does, however, seek to mitigate such risks by limiting its counterparties to major financial institutions. In addition, the potential risk of loss with any one counterparty resulting from this type of credit risk is monitored. Management does not expect material losses as a result of defaults by counterparties.

Derivative Financial Instruments

The Company engages in transactions denominated in foreign currencies and, as a result, is exposed to changes in foreign currency exchange rates. To manage the volatility resulting from fluctuating foreign currency exchange rates, the Company has in the past entered into option and forward foreign currency exchange contracts.

The Company accounts for its derivative instruments as either assets or liabilities on the balance sheet and measures them at fair value. The Company assesses, both at inception and on an ongoing basis, whether the derivatives that are used in hedging transactions are highly effective in offsetting the changes in cash flows of the hedged items. If the Company determines that a forecasted transaction is no longer probable of occurring, it discontinues hedge accounting for the affected portion of the hedge instrument, and any related unrealized gain or loss on the contract is recognized in other comprehensive income (expense).

Risk and Uncertainties

The Company’s future results of operations involve a number of risks and uncertainties. Factors that could affect the Company’s future operating results and cause actual results to vary materially from expectations include, but are not limited to, uncertainty of results of clinical trials and reaching milestones, uncertainty of regulatory approval of the Company’s potential drug candidates, uncertainty of market acceptance of the Company’s products, competition from substitute products and larger companies, securing and protecting proprietary technology, strategic relationships and dependence on key individuals and sole source suppliers.

Products developed by the Company require clearances from the U.S. Food and Drug Administration (“FDA”), the Pharmaceuticals Medicines and Devices Agency (“PMDA”), or other international regulatory agencies prior to commercial sales. There can be no assurance that the products will receive the necessary clearances. If the Company was denied clearance, clearance was delayed or the Company was unable to maintain clearance, it could have a material adverse impact on the Company.

The Company expects to incur substantial operating losses for the next several years and will need to obtain additional financing in order to launch and commercialize any product candidates for which it receives regulatory approval.

Cash and cash equivalents, Restricted Cash

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. At December 31, 2018 and 2017 the Company’s cash and cash equivalents were held in multiple institutions with the United States and Europe and included deposits in money market funds which were unrestricted as to withdrawal or use. Restricted cash consists of a letter of credit to secure the Company’s obligations under the build-to-suit lease.

Property and equipment, Net

Property and equipment are stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets, generally between three and five years. Leasehold improvements are amortized on a straight-line basis over the lesser of their useful life or the term of the lease. Maintenance and repairs are charged to expense as incurred, and improvements are capitalized. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the consolidated balance sheet and any resulting gain or loss is reflected in operations in the period realized.

Build-to-Suit Lease

In the Company's recent lease arrangement (as described in Note 7), the Company was involved in the construction of the building. To the extent the Company is involved with the structural improvements of the construction project or takes construction risk prior to the commencement of a lease, accounting guidance requires the Company to be considered the owner for accounting purposes of these types of projects during the construction period. Therefore, the Company records an asset in property and equipment on the consolidated balance sheet for the replacement cost of the Company's leased portion of the pre-existing building. The Company records a corresponding build-to-suit lease obligation on its consolidated balance sheets representing the amounts paid by the lessor.

Upon completion of construction, the Company considered the requirements for sale-leaseback accounting treatment, including evaluating whether all risks of ownership have been transferred back to the landlord, as evidenced by a lack of continuing involvement in the leased property. The Company's assessment of the arrangement did not qualify for sale-leaseback accounting treatment; therefore the building asset remains on the Company's consolidated balance sheets at its historical cost, and such asset is depreciated over its estimated useful life. The initial recording of these assets and liabilities is classified as non-cash investing and financing items, respectively, for purposes of the consolidated statements of cash flows.

Impairment of Long-Lived Assets

The Company reviews property and equipment for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by the comparison of the carrying amount to the future net cash flows which the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value (i.e. determined through estimating projected discounted future net cash flows or other acceptable methods of determining fair value) arising from the asset. There have been no such impairments of long-lived assets during the years ended December 31, 2018 and 2017.

Fair Value of Financial Instruments

The carrying value of the Company's cash and cash equivalents, restricted cash, accounts payable and accrued liabilities approximate fair value due to the short-term nature of these items.

Fair value is defined as the exchange price that would be received for an asset or an exit price paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The fair value hierarchy defines a three-level valuation hierarchy for disclosure of fair value measurements as follows:

Level I	Unadjusted quoted prices in active markets for identical assets or liabilities;
Level II	Inputs other than quoted prices included within Level I that are observable, unadjusted quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and
Level III	Unobservable inputs that are supported by little or no market activity for the related assets or liabilities.

The categorization of a financial instrument within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

The Company's financial instruments consist of Level I assets as of December 31, 2018 and 2017. Level I securities are comprised of highly liquid money market funds.

Preclinical and Clinical Trial Accruals

The Company's clinical trial accruals are based on estimates of patient enrollment and related costs at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and clinical research organizations ("CROs") that conduct and manage clinical trials on the Company's behalf.

The Company estimates preclinical and clinical trial expenses based on the services performed, pursuant to contracts with research institutions and clinical research organizations that conduct and manage preclinical studies and clinical trials on its behalf. In accruing service fees, the Company estimates the time period over which services will be performed and the level of patient enrollment and activity expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the receipt of the related services are recorded as prepaid expenses until the services are rendered.

Research and development

Research and development costs are charged to operations as incurred. Research and development costs include, but are not limited to, payroll and personnel expenses, laboratory supplies, consulting costs, external research and development expenses and allocated overhead, including rent, equipment depreciation, and utilities. Costs to acquire technologies to be used in research and development

that have not reached technological feasibility and have no alternative future use are expensed to research and development costs when incurred.

Income taxes

The Company accounts for income taxes under the asset and liability approach. Under this method, deferred tax assets and liabilities are determined based on the difference between the consolidated financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized. The provision for income taxes includes income taxes paid or payable for the current year plus the change in deferred taxes during the year.

The Company assesses all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and the Company will determine whether (i) the factors underlying the sustainability assertion have changed and (ii) the amount of the recognized tax benefit is still appropriate. The recognition and measurement of tax benefits requires significant judgment. Judgments concerning the recognition and measurement of a tax benefit might change as new information becomes available.

Stock-Based compensation

For stock options granted to employees, the Company recognizes compensation expense for all stock-based awards based on the grant-date estimated fair value. The value of the portion of the award that is ultimately expected to vest is recognized as expense ratably over the requisite service period. The fair value of stock options is determined using the Black-Scholes option pricing model. The determination of fair value for stock-based awards on the date of grant using an option pricing model requires management to make certain assumptions regarding a number of complex and subjective variables.

Stock-based compensation expense related to stock options granted to nonemployees is recognized based on the fair value of the stock options, determined using the Black-Scholes option pricing model, as they are earned. The awards generally vest over the time period the Company expects to receive services from the nonemployee.

Consolidated Statement of Operations and Comprehensive Loss

Comprehensive loss is defined as a change in equity of a business enterprise during a period, resulting from transactions from non-owner sources. Specifically, the Company includes cumulative foreign currency translation adjustments and net unrealized gains and losses on effective cash flow hedges.

Net Loss per Share of Common Stock

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, stock options and restricted stock units are considered to be potentially dilutive securities. Because the Company has reported a net loss for the years ended December 31, 2018 and 2017, diluted net loss per common share is the same as basic net loss per common share for those periods.

In-process Research & Development

In-process research and development, or IPR&D, was recorded at its relative fair value using a discounted cash flow model and was assigned to acquired research and development assets that were not fully developed as of the completion of the Merger. IPR&D acquired in an asset purchase is capitalized on the Company's balance sheet at its acquisition-date fair value if the acquired IPR&D has alternative future use. For the IPR&D that was acquired from the Merger it was determined that the IPR&D had no alternative future use and therefore it was expensed immediately following the Merger. Fair value measurement was classified as Level 3 under the fair value hierarchy.

Intangible Asset

Intangible assets consist of an assembled workforce which was acquired as part of the Merger. Intangible assets with definite lives are amortized based on their pattern of economic benefit over their estimated useful lives and reviewed periodically for impairment. The estimated useful life of the assembled workforce is 3 years.

Revenue Recognition

The Company's sole source of revenue for 2018 was grant revenue related to the CPRIT contract, which is being accounted for under ASC 606. ASC 606 introduces a new framework for analyzing potential revenue transactions by identifying the contract with a customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations in the contract, and recognizing revenue when (or as) the Company satisfies a performance obligation.

The performance obligations of the Contract include developing AVB-S6-500 for use in cancer patients through research and development efforts and a noncommercial license from CPRIT.

Management has concluded that the license and R&D services should be combined into a single performance obligation as both are highly interdependent - a license cannot be effectively granted without the corresponding research basis and CPRIT cannot benefit from the license without the R&D services and are therefore not capable of being distinct.

As of the Merger date, Private Aravive had received $15.4 million from the CPRIT grant. Aravive received $2.6 million in February 2019, subsequent to December 31, 2018. Funds received are reflected in deferred revenue as a liability until revenue is earned. Grant revenue is recognized when qualifying costs are incurred. As of December 31, 2018, the Company had deferred revenue of $0.1 million.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, or other standard setting bodies and adopted by us as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective is not expected to have a material impact on the Company's financial position or results of operations upon adoption.

In June 2018, the FASB issued ASU No. 2018-07, Compensation – Stock Compensation (Topic 718) - Improvements to Nonemployee Share-Based Payment Accounting. This amendment provides additional guidance related to share-based payment transactions for acquiring goods or services from nonemployees. The guidance will be effective for the Company for fiscal years beginning after December 15, 2018, including the interim periods within that fiscal year. The Company has not yet adopted this new guidance and does not expect it to have a material impact on the Company's consolidated financial statements when the new standard is implemented.

In June 2018, the FASB issued ASU No. 2018-08, Not-For-Profit Entities (Topic 958): Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made, which is intended to clarify and improve the scope and the accounting guidance for contributions received and contributions made. The amendments in ASU No. 2018-08 should assist entities in (1) evaluating whether transactions should be accounted for as contributions (nonreciprocal transaction) within the scope of Topic 958, Not-for-Profit Entities, or as exchange (reciprocal) transactions subject to other guidance and (2) determining whether a contribution is conditional. This amendment applies to all entities that make or receive grants or contributions. This ASU is effective for public companies serving as a resource recipient for fiscal years beginning after June 15, 2018, including interim periods within that fiscal year.

The Company is currently evaluating the impact of adoption on its consolidated financial statements.

In May 2017, the FASB issued, ASU-2017-09, Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting. This guidance clarifies when changes to the terms and conditions of share-based awards must be accounted for as modifications. The guidance does not change the accounting treatment for modifications. The guidance, which became effective on January 1, 2018, has not had a material impact on the Company's consolidated financial statements.

In January 2017, the FASB issued, ASU-2017-01, Business Combinations (Topic 805) – Clarifying the Definition of a Business. This guidance clarifies changes to the definition of a business for accounting purposes. Under the new guidance, an entity first determines whether substantially all of the fair value of a set of assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets, also known as the screen test. If this threshold is met under the screen test, the set of assets is not deemed to be a business. If the threshold is not met, the entity then evaluates whether the set of assets meets the requirement to be deemed a business, which at a minimum, requires there to be an input and a substantive process that together significantly contribute to the ability to create outputs. In October 2018, the Company, then known as Versartis, Inc., completed a merger whereby Private Aravive

merged with a wholly owned subsidiary of Versartis, Inc. in an all-stock transaction and Private Aravive was the surviving corporation of such merger as a wholly owned subsidiary of the Company (formerly known as Versartis, Inc.). The Merger was accounted for as an acquisition by the Company of Private Aravive's net assets or a group of similar identifiable assets. Substantially all of the fair value of the net acquired assets is concentrated in a single identifiable asset or a group of similar identifiable assets, and as such the set of net assets acquired is not deemed to be a business. The guidance, which has become effective for the Company on January 1, 2018, has a material impact on the Company's consolidated financial statements upon close of the Merger, as the application of the screen test under the new guidance results in the transaction to be accounted for as an asset acquisition.

In November 2016, the FASB issued, ASU-2016-18, Statement of Cash Flows (Topic 230) - Restricted Cash. This guidance requires that a statement of cash flows present the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total cash amounts shown on the statement of cash flows. The guidance has become effective on a retrospective basis for the Company on January 1, 2018. The Company retrospectively adjusted the prior periods presented in the Company's consolidated statement of cash flows, which resulted in a reclassification of restricted cash of $2.4 million to the beginning and ending period balances of cash amounts shown on the statement of cash flows prior to the adoption date. The following is a reconciliation of the captions in the consolidated balance sheet to the consolidated statements of cash flows (in thousands):

	As of December 31, 2018	December 31, 2017
Consolidated Balance Sheets		
Cash and cash equivalents	$56,992	$ 81,146
Restricted cash	2,396	2,383
Cash, cash equivalents and restricted cash in Consolidated Statements of Cash Flows	$59,388	$ 83,529

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. The new standard is required to be adopted using a modified retrospective method and is effective for reporting periods beginning after December 15, 2018, with early adoption permitted. In July 2018, the FASB provided an alternative transition method of adoption through ASU No. 2018-11, Targeted Improvements, which provides entities with an optional transition method to apply the transition provisions of ASU 2016-02 at the beginning of the period of adoption.

The Company elected to adopt the standard on January 1, 2019 using the alternative transition method provided by ASU 2018-11 whereby the Company will record right-of-use ("ROU") assets and lease liabilities for its existing leases as of January 1, 2019, as well as a cumulative-effect adjustment to retained earnings of initially applying the new standard as of January 1, 2019.

The new standard provides a number of optional practical expedients in transition. The Company expects to elect the practical expedients to not reassess its prior conclusions about lease identification under the new standard, to not

reassess lease classification, and to not reassess initial direct costs. The Company will not elect the practical expedient allowing the use-of-hindsight which would require the Company to reassess the lease term of its leases based on all facts and circumstances through the effective date.

The new guidance also provides practical expedients for ongoing lease accounting. The Company expects to elect the recognition exemption for short-term lease for all leases that qualify. Under this exemption, the Company will not recognize ROU assets or lease liabilities for those leases that qualify as a short-term lease, which includes not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition. The Company also will elect the practical expedient to not separate lease and non-lease components for all equipment and real-estate leases.

The Company is evaluating the effect of this guidance on the Company's consolidated financial statements, disclosures, and internal controls, which includes, but is not limited to, the impact on the lease of its 1020 Space location in Menlo Park, California, its office space in Palo Alto, California, and its headquarters in Houston, Texas. The Company currently expects to derecognize the existing asset and liabilities on the consolidated balance sheet resulting from the build-to-suit lease arrangement at the 1020 Space, which did not meet the criteria for "sale-leaseback" treatment at the time construction was completed in 2017, and apply the general lessee transition guidance to this lease. The Company is in the process of evaluating the impact the adoption of this standard will have on the 1020 Space Sublease. The Company does not anticipate that adoption of the new standard will have a significant impact on its consolidated results of operations or cash flows.

In May 2014, the FASB issued a new accounting standard that amends the guidance for the recognition of revenue from contracts with customers to transfer goods and services. The FASB has subsequently issued additional, clarifying standards to address issues arising from implementation of the new revenue recognition standard. The new revenue recognition standard and clarifying standards are effective for interim and annual periods beginning on January 1, 2018, and may be adopted earlier, but not before January 1, 2017.

The revenue standards are required to be adopted by taking either a full retrospective approach or a modified retrospective approach. The Company has adopted the new revenue standard as of January 1, 2018 using a modified retrospective application to each prior reporting period presented. Through January 1, 2018 the Company had no open contracts and previously recorded a total of $40.0 million of contract revenues at December 31, 2017 received from Teijin Limited under an exclusive license and supply agreement which was considered substantially complete as of December 31, 2017. The adoption did not have an effect on the Company's consolidated financial statements on the adoption date and no adjustment to retained earnings as of January 1, 2018 was required.

3. Balance Sheet Components

Prepaid expenses and other current assets (in thousands)

	December 31,	
	2018	2017
Preclinical and clinical	$416	$261
Lease receivable	606	—
Other	16	301
Total	$1,038	$562

Property and equipment, net (in thousands)

	December 31,	
	2018	2017
Equipment and furniture	$1,442	$1,409
Buildings, leasehold and building improvements	134	134
	1,576	1,543
Less: Accumulated depreciation and amortization	(1,544)	(745)
Property and equipment, net	$32	$798

Depreciation expense was approximately $1.1 million and $0.3 million for the years ended December 31, 2018 and 2017, respectively.

Intangible asset, net (in thousands)

	December 31,	
	2018	2017
Assembled workforce	$366	$ —
	366	—

Less: Accumulated amortization	(25)	—
Intangible asset, net	$ 341	$ —

Amortization expense is expected to be approximately $0.1 million in each year over the next 2.5 years.

Build-to-suit lease asset, net (in thousands)

	December 31,	
	2018	2017
Build-to-suit lease asset	$8,986	$8,986
	8,986	8,986
Less: Accumulated depreciation and amortization	(335)	(98)
Build-to-suit lease asset, net	$8,651	$8,888

Accrued liabilities (in thousands)

	December 31,	
	2018	2017
Payroll and related	$509	$2,058
Preclinical and clinical	563	1,694
Professional services	—	204
Other	293	137
Total	$1,365	$4,093

4. Fair Value Measurements

The Company's financial instruments consist principally of cash and cash equivalents, prepaid expenses, foreign currency exchange contracts, accounts payable and accrued liabilities. The remaining financial instruments are reported on the Company's consolidated balance sheets at amounts that approximate current fair value. The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	Fair Value Measurements at December 31, 2018	
	Total	Level 1
Assets		
Money market funds	$48,389	$48,389

	Fair Value Measurements at December 31, 2017	
	Total	Level 1
Assets		
Money market funds	$62,428	$62,428

The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers within the hierarchy during the years ended December 31, 2018 or 2017.

5. Derivative Financial Instruments

The Company’s relationships with vendors in foreign countries expose it to market risk associated with foreign currency exchange rate fluctuations between the U.S. dollar and various foreign currencies, the most significant of which is the Euro. In order to manage this risk, the Company hedges a portion of its foreign currency exposures related to certain forecasted operating expenses using foreign currency exchange forward or option contracts. In general, the market risk related to these contracts is offset by corresponding gains and losses on the hedged transactions. By working only with major financial institutions and closely monitoring current market conditions, the Company seeks to limit its counterparty risk to these contracts. Therefore, the Company’s overall risk of loss in the event of a counterparty default is exposed to the currency risk. The Company does not enter into derivative contracts for trading or speculative purposes.

The Company hedges its exposure to foreign currency exchange rate fluctuations for forecasted operating expenses that are denominated in a non-functional currency. The derivative instruments the Company uses to hedge this exposure are designated as cash flow hedges and have maturity dates of 12 months or less. Upon executing a hedging contract and quarterly thereafter, the Company assesses both retrospective and prospective hedge effectiveness using regression analysis to assert the hedge is highly effective at offsetting changes in cash flow. The Company includes time value in its effectiveness assessment and recognizes any ineffectiveness in other income (expense). The effective component of the Company’s hedge is recorded in accumulated other comprehensive income (OCI) within stockholders' equity and subsequently reclassified into earnings when the hedged exposure affects earnings. Derivatives not designated as hedges are not speculative and are used to manage the Company’s economic exposure to foreign exchange rate movements but do not meet the strict hedge accounting requirements. Changes in the fair value of derivatives not designated in hedging relationships are recorded directly in earnings. All of the gains and losses related to the hedged forecasted transaction reported in accumulated other comprehensive income at December 31, 2016 were reclassified to research and development expenses as of December 31, 2017.

While all of the Company's derivative contracts allow it the right to offset assets or liabilities, the Company has presented amounts on a gross basis. Under the International Swap Dealers Association, Inc. master agreements with the respective counterparties of the foreign currency exchange contracts, subject to applicable requirements, the Company is allowed to net settle transactions of the same currency with a single net amount payable by one party to the other. The Company does not have any credit contingent features associated with its derivatives.

The following table summarizes the effect of our foreign currency exchange contracts on the Company's consolidated financial statements (in thousands):

	As of December 31, 2018	2017
Derivatives designated as hedges:		
Gains (losses) reclassified from accumulated OCI into operating expenses (effective portion)	$—	$(350)

From time to time, the Company may discontinue cash flow hedges and as a result, record related amounts in other income (expense), net on its consolidated statements of operations. The Company did not record any amounts in other income (expense), net at December 31, 2018 or December 31, 2017 as a result of the discontinuance of cash flow hedges.

As of December 31, 2018 and 2017, the Company held no derivative contracts.

6. Teijin Agreement

In August 2016, the Company, entered into an Exclusive License and Supply Agreement (the "Agreement") with Teijin Limited, or Teijin, a pharmaceutical company based in Japan, pursuant to which the Company granted to Teijin an exclusive license to develop, use, sell, offer for sale, import, and otherwise commercialize, in Japan, any pharmaceutical product incorporating somavaratan (VRS-317), while the Company retains exclusive rights to somavaratan in the rest of the world. In exchange for such rights, the Company received an upfront payment of $40.0 million from Teijin, as well as the potential to receive a development milestone of $35.0 million, regulatory milestones of up to $55.0 million, and sales milestones of up to $35.0 million, in addition to sales-based payments.

Under the Agreement, the development and commercialization of somavaratan products in Japan would have been overseen by a joint steering committee composed of representatives of Teijin and the Company. The Company would have been responsible for completing (at the Company's expense) all ongoing clinical studies, including the current pediatric Growth Hormone Deficiency (GHD) Phase 2/3 trial, and its related long-term safety study, and the Company would have also been responsible for a portion of the costs associated with any additional trials, if they are required by the Japanese authorities for approval of the Marketing Authorization Application, or MAA, in Japan in the pediatric indication, up to a cap on our share of such costs of $5.0 million. Following the MAA submission in Japan, Teijin

would have been responsible for conducting any additional Japanese studies for the pediatric or any other indications, at its own expense.

In September 2017, the Phase 3 VELOCITY trial of somavaratan failed to reach its primary endpoint. As a result, because Japanese approval relied upon a positive Phase 3 Velocity trial result, the Japan pediatric GHD Phase 3 trial and its related long-term safety study have been discontinued. In January 2018, the Company received notice from Teijin that it was, pursuant to the agreement's terms, terminating the Agreement, effective as of January 31, 2018. The notice of termination followed discussions between the Company and Teijin regarding the failure of the Company's Phase 3 VELOCITY trial to meet its primary endpoint during which the Company and Teijin determined that continuing with the Agreement was no longer in the best interests of either party.

Under the Agreement, the Company had granted to Teijin an exclusive license to develop, use, sell, offer for sale, import and otherwise commercialize, in Japan, any pharmaceutical product incorporating somavaratan (VRS-317). In exchange for such rights, the Company received an upfront fixed and non-refundable payment of $40 million from Teijin and could potentially have also received up to $125 million in development, regulatory and sales milestone payments, in addition to transfer pricing and a royalty calculated on net sales in Japan. The termination is not associated with any early termination penalty or any further payments by either party.

Upon termination of the license agreement, the Company assessed whether to recognize the upfront payment as revenue in accordance with ASC 605-25 Multiple-Element Arrangements, as of December 31, 2017. From receipt of the $40.0 million in August 2016 through September 30, 2017, the Company concluded that persuasive evidence of an arrangement did not yet exist as certain key economic terms that may have significantly impacted economics of the Agreement were yet to be negotiated and finalized by the parties as part of the commercial supply agreement. The Company reviewed the Agreement noting that remaining efforts made by the Company from October 2017 through January 2018 were not deemed a deliverable under the Agreement. These remaining efforts

consisted solely of activities related to shutting down the clinical sites because of the VELOCITY trial failing to meet its primary endpoint. The actions undertaken to close sites would have occurred with or without a third party and were not an obligation specific to, nor were they described, in the agreement. As such, the Company's obligations under the Agreement were substantively complete at December 31, 2017.

7. Build-to-Suit Lease

In March 2017, the Company entered into an operating facility lease agreement for approximately 34,500 rentable square feet located at 1020 Marsh Road, Menlo Park, California and for approximately 17,400 rentable square feet located at 1060 Marsh Road. In September 2017, the Company opted out of its intent to occupy 1060 Marsh Road. The Company began occupying 1020 Marsh Rd in August 2017. The lease has a term of 86 months from the commencement date as defined in the lease agreement with the Company's option to extend the term of the lease for an additional five years. The Company is obligated to make lease payments totaling approximately $20.0 million over the initial term of the lease. In connection with this lease, the landlord is providing a tenant improvement allowance of approximately $1.9 million for the 1020 Space, for costs associated with the design, development and construction of the Company's improvements. The Company is obligated to fund all costs incurred in excess of the tenant improvement allowance. The Company provided the Landlord with a letter of credit to secure its obligations under the lease in the initial amount of approximately $2.4 million, reported as restricted cash on the consolidated balance sheet which is subject to reductions in future years if certain financial hurdles are met.

Under the terms of the lease agreement, the Company has indemnified the landlord during the construction period. Accordingly, for accounting purposes, the Company has concluded that it is the deemed owner of the building during the construction period and the Company capitalized approximately $8.9 million within property and equipment and recognized an $7.3 million corresponding build-to-suit obligation in non-current liabilities in the consolidated balance sheet as of December 31, 2018. Of the $8.9 million, approximately $3.5 million has been recorded as a build-to-suit asset related to construction costs incurred by the Company as of December 31, 2018.

In August 2018, the Company entered into an operating sublease agreement with EVA Automation, Inc. ("EVA") for the 1020 Space referenced above. The 1020 Space Sublease commenced on October 1, 2018 for 72 months. EVA is entitled to an abatement of base rent of approximately $0.9 million for the first five full calendar months of the term of the sublease. Lease income associated with this sublease is recorded in other income in the accompanying consolidated statement of operations. The Company has recorded lease income associated with this sublease of approximately $0.6 million for the year ended December 31, 2018. This sublease income has been recorded as a receivable in prepaid expenses and other current assets on the accompanying consolidated balance sheet.

Future base rent and additional rent EVA shall pay to the Company over the sublease term as of December 31, 2018, are as follows (in thousands):

Year Ending December 31,	
2019	$2,068
2020	2,479
2021	2,544
2022	2,611

2023	2,680
Thereafter	2,284
	$14,666

8. Commitments and Contingencies

Facility Leases

In March 2014, the Company entered into an operating facility lease agreement to lease approximately 12,900 square feet in Menlo Park, California for its headquarters building for a period of thirty-nine months. The term of this lease ended in August 2017.

In December 2015, the Company entered into an operating sublease agreement to lease approximately 10,900 square feet of additional office space in Menlo Park for a period of twenty-four months. The term of this lease ended in December 2017.

In March 2017, the Company entered into an operating facility lease agreement for approximately 34,500 rentable square feet located at 1020 Marsh Road, Menlo Park, California. The lease commenced in August 2017 for a period of 86 months with one

renewal option for a five-year term. The total obligation under this lease is approximately $17.0 million as of December 31, 2018. The Company is considered the "accounting owner" of the 1020 Space as a build-to-suit lease asset and has recorded a build-to-suit lease obligation on its consolidated balance sheets. Additional information regarding the build-to-suit lease is included in Note 7.

In October 2018, the Company executed a sublease agreement in Palo Alto, California for approximately 4,240 square feet for office space. The rental term of the sublease commenced on October 30, 2018 and expires August 31, 2020. The total obligation for the Company under this lease is approximately $0.3 million.

Rent expense was $0.3 million and $1.5 million, for the years ended December 31, 2018 and 2017, respectively.

Future minimum payments under the Company’s lease obligations as of December 31, 2018, are as follows (in thousands):

Year Ending December 31,	
2019	$3,048
2020	2,980
2021	2,930
2022	3,009
2023	3,089
Thereafter	2,364
	$17,420

Boehringer Ingelheim Commercial Supply Agreement

In December 2016, through the Company’s subsidiary, Versartis GmbH, entered into a Commercial Supply Agreement with Boehringer Ingelheim Biopharmaceuticals GmbH (“BI”), pursuant to which the Company engaged BI as a contract manufacturer to manufacture the bulk drug substance for our proprietary long-acting human growth hormone, somavaratan, fill it into the final container and closure and supply such drug product to us for commercial use.

Under the agreement, each calendar year the Company was required to reserve minimum drug substance manufacturing capacity, order from BI a minimum number of batches of drug substance, and purchase and take possession of a minimum number of batches of drug product. If the Company did not order and purchase these minimum quantities, it would have needed to pay fees to BI based on the shortfalls in its product orders or purchases, unless there was a supply failure or supply interruption by BI. The agreement included customary terms and conditions relating to, among other things, forecast, ordering, delivery, inspection, acceptance and product warranties. In September 2017, the Phase 3 VELOCITY trial of somavaratan failed to reach its primary endpoint. As a result, the Company notified BI of its termination of their commercial supply agreement in September 2017 which termination became effective in December 2017.

Owen Mumford Manufacture and Supply Agreement

In May 2016, the Company entered into a Manufacture and Supply Agreement with Owen Mumford Limited, a leading medical device manufacturer, pursuant to which the Company engaged Owen Mumford to: (1) manufacture a proprietary disposable autoinjector device and (2) assemble and supply a final combination product including the device and somavaratan, its proprietary long-acting form of human growth hormone. The Company agreed to supply somavaratan in prefilled syringes to Owen Mumford for incorporation into the final combination product. In September 2017, the Phase 3 VELOCITY trial of somavaratan failed to reach its primary endpoint. As a result, the Company terminated its manufacture and supply agreement with Owen Mumford in October 2017.

Purchase Commitments

The Company conducts research and development programs through a combination of internal and collaborative programs that include, among others, arrangements with contract manufacturing organizations and contract research organizations. The Company had contractual arrangements with these organizations including license agreements with milestone obligations and service agreements with obligations largely based on services performed.

In the normal course of business, the Company enters into various firm purchase commitments related to certain preclinical and clinical studies.

Contingencies

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but have not yet been made. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

As of December 31, 2018 and 2017 the Company is contingently committed to make development and sales-related milestone payments of up to $30.0 million under certain circumstances, and other payments of $10.0 million, as well as royalties relating to potential future product sales under the License Agreement with Amunix. The amount, timing and likelihood of these payments are unknown as they are dependent on the occurrence of future events that may or may not occur, including approval by the FDA of potential drug candidates.

Indemnification

In accordance with the Company's amended and restated Certificate of Incorporation and amended and restated bylaws, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company's request in such capacity. There have been no claims to date and the Company has a director and officer insurance policy that may enable it to recover a portion of any amounts paid for future claims.

Litigation

The Company may from time to time be involved in legal proceedings arising from the normal course of business. There are no pending or threatened legal proceedings as of December 31, 2018.

Contingent payable

As part of the Merger, the Company acquired a settlement with former creditors in 2014, Private Aravive had agreed to make an initial 7.5% cash payment to the creditors with the remainder contingent on future milestone payments, or Contingent Payments, until full repayment of the payables is made. The contingent Payments are to be made from the proceeds received by Private Aravive from any future licensing transactions. The Contingent Payments will be distributed on a pro rata basis with other secured creditors and will be made from at least 10% of any proceeds from any future licensing transactions. The proceeds from any future licensing transactions will be held in an escrow account which will be administered by an independent third party. The creditors agree that the Initial payment and any Contingent Payments represents settlement in full of all outstanding obligations owed to the creditors by Private Aravive and released Private Aravive from all claims. As a result of and in connection with the Merger, the Company determined the fair value of the contingent payable to be approximately $264,000, based upon an appraisal (or valuation) of the assets and liabilities assumed to determine fair values.

9. Common Stock

The Amended and Restated Certificate of Incorporation, authorizes the Company to issue 100,000,000 shares of common stock as of December 31, 2018. Common stockholders are entitled to dividends as and when declared by the

Board of Directors, subject to the rights of holders of all classes of stock outstanding having priority rights as to dividends. There have been no dividends declared to date. The holder of each share of common stock is entitled to one vote.

The Company had reserved shares of common stock for future issuances as follows:

	December 31,	
	2018	2017
Issuance of equity based awards under stock plan	1,201,581	—
Issuance upon exercise of options under stock plan	1,515,923	607,511
Issuance of restricted stock units under stock plan	117,597	419,163
Total	2,835,101	1,026,674

In connection with the completion of the Merger, on October 15, 2018, the amended and restated certificate of incorporation of the Company was amended to effect, at 12:01 a.m. Eastern Time on October 16, 2018, a reverse split of Company Common Stock at a ratio of 1-for-6 (the “Amended Certificate”). The accompanying financial statements and notes to financial statements give retroactive effect to the reverse stock split for all periods presented.

10. Stock Based Awards

2009 Equity Incentive Plan

In February 2009, the Company adopted the Versartis, Inc. 2009 Stock Plan, which was amended in June 2011 (“2009 Plan”) for eligible employees, outside directors and consultants. The 2009 Plan provides for the granting of incentive stock options (“ISO”), non-statutory stock options (“NSO”), and stock purchase rights to acquire restricted stock. Terms of the stock option agreements, including vesting requirements, are determined by the compensation committee of the board of directors, subject to the provisions in the 2009 Plan. Options granted by the Company generally vest over a period of four years and expire no later than ten years after the date of grant. Options may be exercised prior to vesting, subject to a right of repurchase by the Company. The board of directors determines the fair value of the underlying common stock at the time of the grant of each option. Upon the exercise of options, the Company issues new common stock from its authorized shares.

Options under the 2009 Plan may be granted for periods of up to ten years. All options issued to date have had a ten year life. The exercise price of an ISO shall not be less than 100% of the estimated fair value of the shares on the date of grant, as determined by the Board of Directors. The exercise price of an ISO and NSO granted to a 10% shareholder shall not be less than 110% of the estimated fair value of the shares on the date of grant, respectively, as determined by the board of directors. The exercise price of a NSO shall not be less than the par value per share of common stock. To date, options granted generally vest over four years and vest at a rate of 25% upon the first anniversary of the issuance date and 1/36th per month thereafter.

Upon adoption of the 2014 Equity Incentive Plan described below, no further grants will be made under the 2009 Plan.

2014 Equity Incentive Plan

In March 2014, the Company’s board of directors adopted, and the Company’s stockholders approved, the 2014 Equity Incentive Plan, or the 2014 Plan. The 2014 Plan became effective at the time of the initial public offering and is the successor to the 2009 Plan. The 2014 Plan provides for the grant of ISOs to employees and for the grant of NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based stock awards, performance-based cash awards and other forms of equity compensation to employees, directors and consultants. Additionally, the 2014 Plan provides for the grant of performance cash awards to employees, directors and consultants.

Initially, the aggregate number of shares of common stock that may be issued pursuant to stock awards under the 2014 Plan after the initial public offering is approximately 0.7 million, which includes options outstanding under the 2009 Plan. The number of shares of common stock reserved for issuance under the 2014 Plan will automatically increase on January 1 of each year, beginning on January 1, 2015 and ending on and including January 1, 2024, by 4.5% of the total number of shares of the Company’s capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the board of directors. The maximum number of shares that may be issued upon the exercise of ISOs under the 2014 Plan is 2,000,000.

The Company’s board of directors, or a duly authorized committee of the board of directors, will administer the 2014 Plan. The board of directors may also delegate to one or more of the Company’s officers the authority to (i) designate employees (other than officers) to receive specified stock awards, and (ii) determine the number of shares of our common stock to be subject to such stock awards. Subject to the terms of our 2014 Plan, the board of directors has the authority to determine the terms of awards, including recipients, the exercise, purchase or strike price of stock awards, if any, the number of shares subject to each stock award, the fair market value of a share of the Company’s common

stock, the vesting schedule applicable to the awards, together with any vesting acceleration, and the form of consideration, if any, payable upon exercise or settlement of the award and the terms of the award agreements. Options granted under the 2014 Plan have a contractual life of ten years and generally vest over four years and vest at a rate of 25% upon the first anniversary of the issuance date and 1/36th per month thereafter. The exercise price shall not be less than 100% of the fair market value of the shares on the date of grant.

2010 Equity Incentive Plan

As part of the Merger, the Company assumed the 2010 Stock Option Plan (the "2010 Plan") from Private Aravive. The Company has reserved a total of 600,000 shares of common stock for issuance under the 2010 Plan. The 2010 Plan provides for granting of equity awards, including restricted stock and incentive and nonqualified stock options to purchase common stock, to employees, directors, officers and independent consultants of the Company. Options granted to employees and consultants under the Plan generally vest 25% after one year of service, and ratably on a monthly basis over the following three years. Options expire ten years from the date of grant.

2017 Equity Incentive Plan

As part of the Merger, the Company assumed the 2017 Stock Option Plan (the "2017 Plan") from Private Aravive. The Company has reserved a total of approximately 461,000 shares of common stock for issuance under the 2017 Plan. The 2017 Plan provides for granting of equity awards, including restricted stock and incentive and nonqualified stock options to purchase common stock, to employees, directors, officers and independent consultants of the Company. Options granted to employees and consultants under the Plan generally vest 25% after one year of service, and ratably on a monthly basis over the following three years. Options expire ten years from the date of grant

Activity under the Company's stock option plans is set forth below:

	Shares Available for Grant	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Balances, January 1, 2017	174,019	742,052	$ 66.96		
Additional shares authorized	261,329	—	—		
Options granted	(227,450)	227,450	95.50		
Restricted stock units granted	(428,056)	—	—		
Options exercised	—	(141,833)	17.62		
Options cancelled	220,158	(220,158)	87.90		
Balances, December 31, 2017	—	607,511	81.60		
Additional shares authorized	269,535	—	—		
Assumption of option plans associated with the merger	660,151	1,183,950	0.44		
Options granted	—	—	—		
Restricted stock units granted	—	—	—		
Options exercised	—	(3,643)	9.66		
Options cancelled	271,895	(271,895)	80.09		
Balances, December 31, 2018	1,201,581	1,515,923	$ 18.65	6.5	$ 3,650
Vested and expected to vest as of December 31, 2018		1,514,245	$ 18.58	6.5	$ 3,650
Exercisable as of December 31, 2018		1,469,854	$ 16.76	6.5	$ 3,650

The intrinsic values of outstanding, vested and exercisable options were determined by multiplying the number of shares by the difference in exercise price of the options and the fair value of the common stock. The intrinsic value of stock options exercised during the years ended December 31, 2018 and 2017, was none and $11.5 million, respectively.

The following table summarizes information with respect to stock options outstanding and currently exercisable and vested as of December 31, 2018:

Range of Exercise Prices	Options Outstanding Number Outstanding	Weighted Average Remaining Contractual Life (in Years)	Options Exercisable and Vested Number Outstanding	Weighted Average Remaining Contractual Life (in Years)
$0.06-$0.06	86,867	2.5	86,867	2.5
$0.24-$0.24	621,098	6.4	621,098	6.4
$0.66-$0.90	475,985	8.5	475,985	8.5
$7.59-$126.00	312,679	5.1	266,644	5.1
$127.80-$191.76	19,294	3.8	19,260	3.8
	1,515,923		1,469,854	

Stock Options Granted to Employees

During the year ended December 31, 2018, the Company assumed fully vested stock options in accordance with the Merger agreement with Private Aravive. During the year ended December 31, 2017, the Company granted stock options to employees to purchase shares of common stock with a weighted-average grant date fair value of $11.10 per share. The fair value is being expensed over the vesting period of the options, which is usually 4 years on a straight-line basis as the services are being provided. No tax benefits were realized from options and other share-based payment arrangements during the periods.

As of December 31, 2018, total unrecognized employee stock-based compensation related to stock options granted was $ 2.2 million, which is expected to be recognized over the weighted-average remaining vesting period of 1.4 years.

The fair value of employee stock options was estimated using the Black-Scholes model with the following weighted-average assumptions:

	Year Ended December 31,	
	2018	2017
Expected volatility	132.0%	78.0%
Risk-free interest rate	3.0 %	2.1 %
Dividend yield	0.0 %	0.0 %
Expected life (in years)	3.3	6.2

For the year ended December 31, 2018 the fair value assumptions noted above, were all related to the assumed fully vested stock options in accordance with the Merger. No stock options were granted to employees in 2018.

Determining Fair Value of Stock Options

The fair value of each grant of stock options was determined by the Company using the methods and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment to determine.

Expected Volatility – The expected stock price volatility assumption was determined by examining the historical volatilities of a group of industry peers, as the Company did not have any trading history for the Company's common stock. The Company will continue to analyze the historical stock price volatility and expected term assumptions as more historical data for the Company's common stock becomes available. Beginning in 2018, the Company had enough historical stock price information in order to value the options assumed in the Merger.

Expected Term – The expected term of stock options represents the weighted average period the stock options are expected to be outstanding. For option grants that are considered to be "plain vanilla", the Company has opted to use the simplified method for estimating the expected term as provided by the Securities and Exchange Commission. The simplified method calculates the expected term as the average time-to-vesting and the contractual life of the options. For other option grants, the expected term is derived from the Company's historical data on employee exercises and post-vesting employment termination behavior taking into account the contractual life of the award.

Risk-Free Interest Rate – The risk free rate assumption was based on the U.S. Treasury instruments with terms that were consistent with the expected term of the Company's stock options.

Expected Dividend – The expected dividend assumption was based on the Company's history and expectation of dividend payouts.

Forfeiture Rate – Forfeitures were estimated based on historical experience.

Fair Value of Common Stock – The fair value of the shares of common stock underlying the stock options has historically been the responsibility of and determined by the Company's board of directors. Because there had been no public market for the Company's common stock prior to the initial public offering, the board of directors determined the fair value of common stock at the time of grant of the option by considering a number of objective and subjective factors including independent third party valuations of the Company's common stock, sales of convertible preferred stock to unrelated third parties, operating and financial performance, the lack of liquidity of capital stock and general and industry specific economic outlook, amongst other factors. Since the initial public offering in March 2014, the fair value of the underlying common stock is based upon quoted prices on the Nasdaq Global Select Market.

Stock-based compensation expense, net of estimated forfeitures, is reflected in the statements of operations and comprehensive loss as follows (in thousands):

	Year Ended December 31,	
	2018	2017
Operating Expenses		
Research and development	$2,946	$4,549
General and administrative	13,193	8,800
Total	$16,139	$13,349

The assumed options associated with the Merger were fully vested awards as outlined in the Merger agreement. These assumed options were expensed immediately following the Merger and are included in the stock-based compensation expense for the year ended December 31, 2018.

2014 Employee Stock Purchase Plan

The board of directors adopted, and the Company's stockholders approved, the 2014 Employee Stock Purchase Plan, or the ESPP, in March 2014. The ESPP became effective on March 20, 2014.

The maximum aggregate number of shares of common stock that may be issued under the ESPP is 25,000 shares (subject to adjustment to reflect any split of our common stock). Additionally, the number of shares of common stock reserved for issuance under the ESPP will increase automatically each year, beginning on January 1, 2015 and continuing through and including January 1, 2024, by the lesser of (i) 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year; and (ii) 50,000 shares of common stock (subject to adjustment to reflect any split of our common stock). The board of directors may act prior to the first day of any calendar year to provide that there will be no January 1 increase or that the increase will be for a lesser number of shares than would otherwise occur. Shares subject to purchase rights granted under the ESPP that terminate without having been exercised in full will not reduce the number of shares available for issuance under the ESPP.

An employee may not be granted rights to purchase stock under the ESPP if such employee (i) immediately after the grant would own stock possessing 5% or more of the total combined voting power or value of the Company's common stock, or (ii) holds rights to purchase stock under the ESPP that would accrue at a rate that exceeds $25,000 worth of our stock for each calendar year that the rights remain outstanding.

The administrator may approve offerings with a duration of not more than 27 months, and may specify one or more shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of common stock will be purchased for the employees who are participating in the offering. The administrator, in its discretion, will determine the terms of offerings under the ESPP.

The ESPP permits participants to purchase shares of our common stock through payroll deductions with up to 15% of their earnings. The purchase price of the shares will be not less than 85% of the lower of the fair market value of our common stock on the first day of an offering or on the date of purchase. The fair value of the ESPP grants were immaterial for the years ended December 31, 2018 and 2017, respectively.

Restricted Stock Units

Restricted stock units are shares of common stock which are forfeited if the employee leaves the Company prior to vesting. These stock units offer employees the opportunity to earn shares of the Company's stock over time, rather than options that give the employee the right to purchase stock at a set price. As a result of these restricted stock units, the Company recognized $3.2 million and $3.5 million, in compensation expense during the years ended December 31, 2018 and 2017, respectively. As all of the restricted stock vests through 2018 and beyond, the Company will continue to recognize stock-based compensation expense related to the grants of these restricted stock units. If all of the remaining restricted stock units that were granted in prior years vest, the Company will recognize approximately $2.6 million in compensation expense over a weighted average remaining period of 2 years. However, no compensation expense will be recognized for restricted stock units that do not vest.

A summary of the Company's restricted stock activity is presented in the following tables:

	Number of Shares	Weighted Average Grant Date Fair Value
Restricted Stock Units		
Unvested at December 31, 2017	419,163	$ 32.56
Granted	—	—
Vested	(128,136)	35.60
Forfeited/canceled	(173,430)	31.12
Unvested at December 31, 2018	117,597	$ 31.37

11. Comprehensive loss

The following table summarizes amounts reclassified out of Accumulated Other Comprehensive Loss (AOCI) and their effect on the Company's consolidated statements of operations for the year ended December 31, 2017. There was no comprehensive income items for the year ended December 31, 2018 (in thousands).

	Unrealized Gains and Losses on Cash Flow Hedges	Total
Balance at December 31, 2016	$ (350)	$(350)
Amounts reclassified out of other comprehensive loss	350	350
Net current period other comprehensive loss	350	350
Balance at December 31, 2017	$ —	$—

12. Income Taxes

The provision (benefit) for federal income taxes in 2018 and 2017 is as follows (in thousands):

	December 31, 2018	2017
Current		
Federal	$—	$(247)
State	—	—
	—	(247)
Deferred		
Federal	$—	$—
State	—	—
Total deferred tax expense	—	—
Total income tax expense	$—	$(247)

	December 31, 2018	2017
United States	$(76,256)	$(125,093)
Foreign	(77)	39,867
Net loss before provision for income taxes	$(76,333)	$(85,226)

Income tax expense (benefit) in 2018 and 2017 differed from the amount expected by applying the statutory federal tax rate to the income or loss before taxes as summarized below:

	December 31,	
	2018	2017
Federal tax benefit at statutory rate	21 %	34 %
Change in valuation allowance	99 %	(7)%
Research and development credits	—	16 %
Section 382 limitation	(109)%	—
Other non-deductible expenses	(11)%	(3)%
Change in rate differential	—	(38)%
Build-to-suit adjustments	—	(2)%
Total	0 %	0 %

Deferred income taxes reflect the net tax effects of net operating loss and tax credit carryforwards and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's net deferred tax assets at December 31, 2018 and 2017 are as follows (in thousands):

	December 31,	
	2018	2017
Net operating loss carry forwards	$2,335	$69,281
Research and development tax credits	168	34,891
Stock based compensation and other	8,567	5,693
Total deferred tax assets	11,070	109,865
Less: Valuation allowance	(10,336)	(108,782)
Deferred tax liabilities	(734)	(1,083)
Net deferred tax assets	$—	$—

The Company's accounting for deferred taxes involves the evaluation of a number of factors concerning the realizability of its net deferred tax assets. The Company primarily considered such factors as its history of operating losses, the nature of the Company's deferred tax assets, and the timing, likelihood and amount, if any, of future taxable income during the periods in which those temporary differences and carryforwards become deductible. At present, the Company does not believe that it is more likely than not that the deferred tax assets will be realized; accordingly, a full valuation allowance has been established and no deferred tax asset is shown in the accompanying balance sheets.

The valuation allowance decreased by approximately $98.4 million and increased by approximately $60.8 million in 2018 and 2017, respectively.

At December 31, 2018, the Company has net operating loss carryforwards for federal income tax purposes of approximately $11.1 million, of which $4.3 million was generated post December 31, 2017 (after section 382 limitation) and will have no expiration date. The remaining $6.8 million of net operating loss carryforwards begin to expire in 2037. The Company also has federal research and development tax credits of approximately $0.2 million,

which begin to expire in 2037.

As of December 31, 2018, the Company’s total gross deferred tax assets were $11.1 million. Due to the Company’s lack of earnings history and uncertainties surrounding our ability to generate future taxable income, the net deferred tax assets have been fully offset by a valuation allowance. The deferred tax assets were primarily comprised of federal tax net operating losses and tax credit carryforwards. Utilization of net operating losses and tax credit carryforwards may be limited by the “ownership change” rules, as defined in Section 382 of the Internal Revenue Code (any such limitation, a “Section 382 limitation”). Similar rules may apply under state tax laws. The Company has performed an analysis to determine whether an “ownership change” occurred from inception up to the Private Aravive's acquisition date. Based on this analysis, management determined that both Versartis, Inc. and Private Aravive did experience ownership changes, which resulted in a significant impairment of the net operating losses and credit carryforwards. As such, the net operating loss carryforwards have been reduced by $306 million. The tax credit carryforwards have been reduced by $39.5 million.

The Company follows the provisions of FASB Accounting Standards Codification 740-10 (ASC 740-10), Accounting for Uncertainty in Income Taxes. ASC 740-10 prescribes a comprehensive model for the recognition, measurement, presentation and disclosure in consolidated financial statements of uncertain tax positions that have been taken or expected to be taken on a tax return. No liability related to uncertain tax positions is recorded in the consolidated financial statements. At December 31, 2018 and 2017, the Company's reserve for unrecognized tax benefits is approximately $72,000, and $3,934,000, respectively. Due to the above-mentioned Section 382 limitation and impairment of tax attributes, there was a decrease in prior year unrecognized tax benefits of $3.9 million. Due to the full valuation allowance at December 31, 2018, current adjustments to the unrecognized tax benefit will have no impact on the Company's effective income tax rate; any adjustments made after the valuation allowance is released will have an impact on the tax rate. The Company does not anticipate any significant change in its uncertain tax positions within 12 months of this reporting date. The Company includes penalties and interest expense related to income taxes as a component of other expense and interest expense, respectively, as necessary.

Because the statute of limitations does not expire until after the net operating loss and credit carryforwards are actually used, the statute is effectively open for all tax years. However, due to the above-mentioned ownership change and impairment of net operating loss and credit carryforwards, only net operating loss and credit carryforwards post-January 14, 2017 are carried forward to future years for federal and state tax purposes.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

	Amount
Balance at January 1, 2017	$10,116
Gross increase/ (decrease) related to prior year tax positions[1]	(7,776)
Gross increase related to current year positions	1,594
Reductions to unrecognized tax benefits related to lapsing statute of limitations	—
Balance at December 31, 2017	$3,934
Gross increase/ (decrease) related to prior year tax positions	(3,934)
Gross increase related to current year positions	72
Reductions to unrecognized tax benefits related to lapsing statute of limitations	—
Balance at December 31, 2018	$72

[1] During 2017, the Company received new information related to its Orphan Drug Credit which provides clarification regarding tax positions previously taken. As a result of this new information, Management re-assessed its Orphan Drug Credit uncertain tax position and made its best estimate to account for the higher level of certainty. The change in unrecognized tax benefit is fully offset by a corresponding change in valuation allowance and therefore has no impact on the income statement.

All tax years remain open for examination by federal and state tax authorities.

The Tax Cuts and Jobs Act ("the Act") was enacted on December 22, 2017. The Act reduces the U.S. federal corporate tax rate from 35% to 21%, requires companies to pay a one-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred and creates new taxes on certain foreign sourced earnings. The

Company is required to recognize the effect of the tax law changes in the period of enactment, such as determining the estimated transition tax, remeasuring our U.S. deferred tax assets and liabilities at a 21% rate as well as reassessing the net realizability of our deferred tax assets and liabilities.

Accordingly, the Company remeasured certain deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future. The provisional amount related to the re-measurement of our deferred tax balance is a reduction of approximately $33 million. Due to the corresponding valuation allowance fully offsetting deferred taxes, there is no income statement impact.

In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act (SAB 118) which allows companies to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. In Q4 2018, the Company completed its analysis within the measurement period in accordance with SAB 118, and found no change to the provisional amount on 2017 tax provision.

13. Restructuring Plan

In October 2017, the Board of Directors of the Company approved a plan of termination to eliminate a number of positions effective October 20, 2017 (the "Restructuring Plan"), as part of its commitment to reduce costs following the failure of the Phase 3 VELOCITY trial of somavaratan to reach its primary endpoint. The reduction included 45 employees, which represented approximately 62% of its workforce as of October 6, 2017. Affected employees were notified of the Restructuring Plan on October 6, 2017. Simultaneously with the Restructuring Plan the Company established a Severance Benefit Plan (the "Plan") for affected employees as well as a retention plan for retained employees. The Plan provides payment of severance benefits to affected employees of the Company. The Company granted approximately 907,000 restricted stock units to retained employees with a two year vesting schedule and offered a cash retention bonus of 50% of each retained employees then current base salary, which will be earned and payable subject to continued employment for an additional 12 months.

Employee severance costs are accrued when the restructuring actions are probable and estimable. Costs for one-time termination benefits in which the employee is required to render service until termination in order to receive the benefits are recognized ratably over the future service period. During the year ended December 31, 2017, as a result of the Restructuring Plan, the Company incurred a one-time severance-related charge totaling $3.4 million, of which $0.7 million is included within general and administrative expenses and $2.7 million is included within research and development expenses. The Company accrued $0.8 million related to the cash retention bonus as of December 31, 2017. During the year ended December 31, 2018, the Company incurred severance-related charges totaling $4.2 million, of which $1.7 million is included within general and administrative expenses and $2.5 million is included within research and development expenses. There was no balance owed under these restructuring plans as of December 31, 2018.

14. Employee Benefit Plans

Defined Contribution Plan

The Company sponsors a 401(k) Plan, which stipulates that eligible employees can elect to contribute to the 401(k) Plan, subject to certain limitations of eligible compensation. The Company may match employee contributions in amounts to be determined at the Company's sole discretion. To date, the Company has not made any matching contributions.

Severance Benefit Plan & Retention Cash Bonus

Simultaneously with the Restructuring Plan, the Company established a Severance Benefit Plan (the "Plan") for affected employees (See Note 13) as well as a retention plan for retained employees. The Plan provides payment of severance benefits to affected employees of the Company. The Company granted approximately 151,000 restricted stock units to retained employees with a two year vesting schedule and offered a cash retention bonus of 50% of each retained employees then current base salary, of which $1.5 million was paid in October 2018.

15. Net loss per share

The following table summarizes the computation of basic and diluted net loss per share attributable to common stockholders of the Company (in thousands, except per share data):

	December 31,	
	2018	2017
Net loss attributable to common stockholders- basic and diluted	$(76,333)	$(84,979)
Net loss per share- basic and diluted	$(10.64)	$(14.47)
Weighted-average common shares used to compute net loss per share- basic and diluted	7,171	5,871

Basic net loss attributable to common stockholders per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted net loss attributable to common stockholders per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and dilutive common stock equivalents outstanding for the period, determined using the treasury-stock method and the as-if converted method, for convertible securities, if inclusion of these is dilutive. Because the Company has reported a net loss for the years ended December 31, 2018 and 2017, the Company did not have dilutive common stock equivalents and therefore diluted net loss per common share is the same as basic net loss per common share for those years.

The following potentially dilutive securities outstanding at the end of the years presented have been excluded from the computation of diluted shares outstanding:

	December 31,	
	2018	2017
Options to purchase common stock	1,515,923	607,511
Restricted stock units	117,597	419,163

16. Merger with Aravive Biologics, Inc.

On October 12, 2018, pursuant to the terms of the Agreement and Plan of Merger and Reorganization, dated as of June 3, 2018, by and between the Company, then known as Versartis, Inc., Velo Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of the Company ("Merger Sub"), and Private Aravive, Merger Sub was merged with and into Private Aravive (the "Merger"), with Private Aravive surviving the Merger as a wholly-owned subsidiary of the Company. Pursuant to the terms of the Merger Agreement, at the Effective Time, each outstanding share of capital stock of Private Aravive (other than any shares held as treasury stock) was converted into the right to receive 2.2801 shares of the Company's common stock, par value $0.0001 per share (the "Company Common Stock"), without giving effect to any adjustment for the reverse stock split described below, and (b) each outstanding Private Aravive stock option, all of which were in-the-money, whether vested or unvested, that had not previously been exercised prior to the Effective Time was converted into an option to purchase 2.2801 shares of the Company Common Stock for each share of Private Aravive common stock covered by such option. The aggregate consideration issued in the Merger to the former security holders of Private Aravive, was approximately 5,141,915 shares of Company Common Stock.

The Merger was accounted for as an asset acquisition by the Company. To determine the accounting for this transaction under GAAP, the Company assessed whether an integrated set of assets and activities were accounted for as an acquisition of a business or an asset acquisition. The guidance requires an initial screen test to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single asset or group of similar assets. If that screen is met, the set is not a business. In connection with the acquisition of Private Aravive, the Company determined that substantially all the fair value is included in in-process research and development of Private Aravive's lead asset, AVB-S6-500 and, as such, the acquisition is treated as an asset acquisition. The net tangible and intangible assets acquired and liabilities assumed in connection with the transaction were recorded based on their relative fair values allocation as of October 12, 2018 and the value associated with in-process research and development will be expensed as it was determined to have no alternative future use. The estimate of the purchase price for the fair value of the identifiable tangible and intangible assets acquired and liabilities assumed, were as follows.

	Amount (in thousands)

Consideration	
Common stock issued - 5,141,915 shares issued at $7.26 per share	$ 37,331
Transaction costs	2,076
Total consideration	$ 39,407
Assets acquired and liabilities assumed	
Cash	$ 5,277
In-process research and development	38,313
Assembled workforce	366
Deferred revenue	(1,517)
Contingent payable	(264)
Other assets and liabilities	(2,768)
Total net assets acquired	$ 39,407

Corporate Name Change

On October 15, 2018, the Company changed its name to “Aravive, Inc.” from Versartis, Inc. Shares of Company Common Stock were previously listed on the Nasdaq Global Select Market under the symbol “VSAR.” The Company filed with The Nasdaq Stock Market, LLC (“Nasdaq”) a notification form for the listing of additional shares with respect to the shares of Company Common Stock to be issued to the holders of Aravive Biologics, Inc. capital stock in the Merger so that these shares are listed on Nasdaq. The Company Common Stock began trading on the Nasdaq Global Select Market under the symbol “ARAV” on October 16, 2018.

Exhibit Index

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation (Incorporated herein by reference to the same numbered exhibit of our current report on Form 8-K (File No. 001-36361), as filed with the SEC on March 26, 2014).
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Versartis, Inc. (Incorporated herein by reference to exhibit number 3.1 of our current report on Form 8-K (File No. 001-36361), as filed with the SEC on June 1, 2017).
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Versartis, Inc. (Incorporated herein by reference to exhibit number 3.1 of our current report on Form 8-K (File No. 001-36361), as filed with the SEC on September 12, 2017).
3.4	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Versartis, Inc. (Incorporated herein by reference to exhibit number 3.1 of our current report on Form 8-K (File No. 001-36361), as filed with the SEC on October 16, 2018).
3.5	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Versartis, Inc. (Incorporated herein by reference to exhibit number 3.2 of our current report on Form 8-K (File No. 001-36361), as filed with the SEC on October 16, 2018).
3.6#	Certificate of Correction to Certificate of Amendment of Amended and Restated Certificate of Incorporation of Aravive, Inc.
3.7	Amended and Restated Bylaws. (Incorporated herein by reference to Exhibit 3.4 of our registration statement on Form S-1, as amended (File No. 333-193997), as filed with the SEC on March 6, 2014).
4.1	Form of Stock Certificate. (Incorporated herein by reference to the same numbered exhibit of our quarterly report on Form 10-Q (File No. 001-36361), for the quarterly period ended March 31, 2014, as filed with the SEC on May 14, 2014).
10.1	Fourth Amended and Restated Investors' Right Agreement by and among the Company and the parties thereto, dated as of February 14, 2014. (Incorporated herein by reference to the same numbered exhibit of our registration statement on Form S-1 (File No. 333-193997), as filed with the SEC on February 18, 2014).
10.2	Lease by and between the Company and CA-Shorebreeze Limited Partnership, dated as of August 31, 2011. (Incorporated herein by reference to the same numbered exhibit of our registration statement on Form S-1 (File No. 333-193997), as filed with the SEC on February 18, 2014).
10.3*	2009 Stock Plan, as amended. (Incorporated herein by reference to the same numbered exhibit of our registration statement on Form S-1 (File No. 333-193997), as filed with the SEC on February 18, 2014).
10.4*	Form of Notice of Stock Option Grant and Incentive Stock Option Agreement under 2009 Stock Plan. (Incorporated herein by reference to the same numbered exhibit of our registration statement on Form S-1

(File No. 333-193997), as filed with the SEC on February 18, 2014).

10.5* Form of Notice of Stock Option Grant and Non-Statutory Stock Option Agreement under 2009 Stock Plan. (Incorporated herein by reference to the same numbered exhibit of our registration statement on Form S-1 (File No. 333-193997), as filed with the SEC on February 18, 2014).

10.6* 2014 Equity Incentive Plan. (Incorporated herein by reference to Exhibit 3.4 of our registration statement on Form S-1, as amended (File No. 333-193997), as filed with the SEC on March 6, 2014).

10.7* Form of 2014 Equity Incentive Plan Stock Option Grant Notice and Stock Option Agreement. (Incorporated herein by reference to Exhibit 99.5 of our registration statement on Form S-8 (File No. 333-194949), as filed with the SEC on April 1, 2014).

10.8* Form of 2014 Equity Incentive Plan Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement. (Incorporated herein by reference to Exhibit 10.1 of our current report on Form 8-K (File No. 001-36361), as filed with the SEC on April 17, 2014).

10.9* Change in Control Severance Plan. (Incorporated herein by reference to Exhibit 10.7 of our registration statement on Form S-1, as amended (File No. 333-193997), as filed with the SEC on March 10, 2014).

Exhibit Number	Description
10.10*	2014 Employee Stock Purchase Plan. (Incorporated herein by reference to Exhibit 10.9 of our registration statement on Form S-1, as amended (File No. 333-193997), as filed with the SEC on March 6, 2014).
10.11*	Form of Indemnification Agreement by and between the Company and each of its directors and officers. (Incorporated herein by reference to Exhibit 10.10 of our registration statement on Form S-1, as amended (File No. 333-193997), as filed with the SEC on March 6, 2014).
10.12†	Technology Transfer and Clinical Supply Agreement by and between the Company and Boehringer Ingelheim RCV GmbH & Co KG, dated as of October 23, 2012. (Incorporated herein by reference to Exhibit 10.11 of our registration statement on Form S-1, as amended (File No. 333-193997), as filed with the SEC on March 19, 2014).
10.13†	Amendment No. 1 to the Technology Transfer, Clinical Supply Agreement by and between the Company and Boehringer Ingelheim RCV GmbH & Co KG, effective as of October 1, 2013. (Incorporated herein by reference to Exhibit 10.12 of our registration statement on Form S-1, as amended (File No. 333-193997), as filed with the SEC on March 19, 2014).
10.14†	Assignment of Technology Transfer and Clinical Supply Agreement by and between the Company and Boehringer Ingelheim RCV GmbH & Co KG, effective as of January 1, 2014. (Incorporated herein by reference to Exhibit 10.13 of our registration statement on Form S-1 (File No. 333-193997), as filed with the SEC on February 18, 2014).
10.15†	Services Agreement by and between the Company and Amunix Operating Inc., dated as of March 18, 2013. (Incorporated herein by reference to Exhibit 10.14 of our registration statement on Form S-1 (File No. 333-193997), as filed with the SEC on February 18, 2014).
10.16†	Second Amended and Restated Licensing Agreement by and between the Company and Amunix Operating, Inc., dated as of December 30, 2010. (Incorporated herein by reference to Exhibit 10.15 of our registration statement on Form S-1 (File No. 333-193997), as filed with the SEC on February 18, 2014).
10.17†	Letter Agreement by and between the Company and Amunix Operating, Inc., dated as of February 3, 2011. (Incorporated herein by reference to Exhibit 10.16 of our registration statement on Form S-1 (File No. 333-193997), as filed with the SEC on February 18, 2014).
10.18†	Amendment No. 1 to the Second Amended and Restated Licensing Agreement by and between the Company and Amunix Operating, Inc., dated as of January 7, 2013. (Incorporated herein by reference to Exhibit 10.17 of our registration statement on Form S-1 (File No. 333-193997), as filed with the SEC on February 18, 2014).
10.19	Amendment No. 2 to Second Amended and Restated Licensing Agreement by and between the Company and Amunix Operating, Inc., dated as of February 25, 2014. (Incorporated herein by reference to Exhibit 10.21 of our registration statement on Form S-1, as amended (File No. 333-193997), as filed with the SEC on March 06, 2014).
10.20*	Offer letter between the Company and Jeffrey L. Cleland, Ph.D., dated as of December 20, 2010. (Incorporated herein by reference to Exhibit 10.18 of our registration statement on Form S-1 (File No.

333-193997), as filed with the SEC on February 18, 2014).

10.21* Offer letter between the Company and Joshua T. Brumm, dated as of November 8, 2013. Incorporated herein by reference to Exhibit 10.19 of our registration statement on Form S-1 (File No. 333-193997), as filed with the SEC on February 18, 2014.

10.22* Amended and restated offer letter between the Company and Paul Westberg, dated as of February 10, 2011. (Incorporated herein by reference to Exhibit 10.20 of our registration statement on Form S-1 (File No. 333-193997), as filed with the SEC on February 18, 2014).

10.23 Office Lease by and between the Company and Kilroy Realty, L.P., dated as of February 27, 2014. (Incorporated herein by reference to Exhibit 10.22 of our registration statement on Form S-1, as amended (File No. 333-193997), as filed with the SEC on March 06, 2014).

10.24* Non-employee Director Compensation Policy, adopted by the Board of Directors March 3, 2014, as amended May 21, 2015. (Incorporated herein by reference to Exhibit 10.5 of our quarterly report on Form 10-Q (File No. 001-36361), as filed with the SEC on August 8, 2015).

10.25* Separation and Consulting Agreement with Jeffrey L. Cleland, dated May 6, 2015. (Incorporated herein by reference to Exhibit 10.6 of our quarterly report on Form 10-Q (File No. 001-36361), as filed with the SEC on August 8, 2015).

Exhibit Number	Description
10.26*	Offer letter between the Company and Jay Shepard dated as of May 12, 2015. (Incorporated herein by reference to Exhibit 10.7 of our quarterly report on Form 10-Q (File No. 001-36361), as filed with the SEC on August 8, 2015).
10.27*	Non-Employee Director Compensation Policy, as amended March 17, 2016. (Incorporated herein by reference to Exhibit 10.1 of our quarterly report on Form 10-Q (File No. 001-36361), as filed with the SEC on May 4, 2016).
10.28*	Offer letter with Shane Ward, dated March 6, 2015. (Incorporated herein by reference to Exhibit 10.2 of our quarterly report on Form 10-Q (File No. 001-36361), as filed with the SEC on May 4, 2016).
10.29*	Offer letter with Colin Hislop, dated February 18, 2016. (Incorporated herein by reference to Exhibit 10.3 of our quarterly report on Form 10-Q (File No. 001-36361), as filed with the SEC on May 4, 2016).
10.30†	Owen Mumford Manufacturing Supplier Agreement, by and between Versartis GmbH and Owen Mumford Limited, dated May 27, 2016. (Incorporated herein by reference to Exhibit 10.1 of our quarterly report on Form 10-Q (File No. 001-36361), as filed with the SEC on August 3, 2016).
10.31†	Exclusive License and Supply Agreement by and between the Company and Teijin Limited, dated August 5, 2016 (Incorporated herein by reference to Exhibit 10.1 of our quarterly report on Form 10-Q (File No. 001-36361), as filed with the SEC on November 4, 2016).
10.32†	Exclusive Commercial Supply Agreement by and between Versartis, Inc. and Boehringer Ingelheim Biopharmaceutical GmbH, dated December 21, 2016. (Incorporated herein by reference to Exhibit 10.32 of our annual report on Form 10-K (File No. 001-36361), as filed with the SEC on March 9, 2017).
10.33	Operating Lease Agreement by and between Versartis, Inc. and Bohannon Associates dated March 17, 2017 (Incorporated herein by reference to Exhibit 10.1 of our quarterly report on Form 10-Q (File No. 001-36361), as filed with the SEC on May 10, 2017).
10.34†	Amended Boehringer Ingelheim Technology Transfer, Clinical Supply Agreement by and between Versartis, Inc. and Boehringer Ingelheim dated October 23, 2012 (Incorporated herein by reference to Exhibit 10.1 of our quarterly report on Form 10-Q (File No. 001-36361), as filed with the SEC on August 7, 2017).
10.35†	Amended Amunix License Agreement by and between Versartis, Inc. and Amunix Operating, Inc. dated March 22, 2016 (Incorporated herein by reference to Exhibit 10.1 of our quarterly report on Form 10-Q (File No. 001-36361), as filed with the SEC on August 7, 2017).
10.36	Sales Agreement by and between Versartis, Inc. and Cowen and Company, LLC. dated August 7, 2017 (Incorporated herein by reference to Exhibit 10.1 of our current report on Form 8-K (File No. 001-36361), as filed with the SEC on August 10, 2017).
10.37*	Offer Letter with Robert Gut, dated August 30, 2017 (Incorporated herein by reference to Exhibit 10.37 of our annual report on Form 10-K (File No. 001-36361), as filed with the SEC on March 6, 2018).

10.38*	Reduction in Force Severance Benefit Plan, dated October 4, 2017 (Incorporated herein by reference to Exhibit 10.38 of our annual report on Form 10-K (File No. 001-36361), as filed with the SEC on March 6, 2018).
10.39*	Separation Agreement with Joshua T. Brumm, dated November 4, 2017 (Incorporated herein by reference to Exhibit 10.39 of our annual report on Form 10-K (File No. 001-36361), as filed with the SEC on March 6, 2018).
10.40	Agreement and Plan of Merger and Organization among Versartis, Inc., Velo Merger Sub, Inc. and Aravive Biologics, Inc. dated as of June 3, 2018 (Incorporated herein by reference to Exhibit 2.1 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on June 4, 2018).
10.41	Form of Support Agreement, by and between Versartis, Inc. and Aravive Biologics, Inc.'s directors, officers and certain stockholders (Incorporated herein by reference to Exhibit 2.2 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on June 4, 2018).
10.42	Form of Support Agreement, by and between Aravive Biologics, Inc. and Versartis, Inc.'s directors, officers and certain stockholders (Incorporated herein by reference to Exhibit 2.3 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on June 4, 2018).

Exhibit Number	Description
10.43	Cancer Research Grant Contract, dated December 1, 2015, by and between the Cancer Prevention and Research Institute of Texas and Ruga Corporation (Incorporated herein by reference to Exhibit 10.1 of our registration statement on Form S-4/A (File No. 333-226594 as filed with the SEC on August 24, 2018).
10.44†	Exclusive License Agreement, dated January 25, 2012, by and between The Board of Trustees of the Leland Stanford Junior University and Ruga Corporation (Incorporated herein by reference to Exhibit 10.2 of our registration statement on Form S-4/A (File No. 333-226594 as filed with the SEC on August 24, 2018).
10.45†	Amendment to the Exclusive License Agreement, dated July 26, 2012, by and between the Board of Trustees of Leland Stanford Junior University and Ruga Corporation (Incorporated herein by reference to Exhibit 10.3 of our registration statement on Form S-4 (File No. 333-226594 as filed with the SEC on August 3, 2018).
10.46†	Amendment No. 2 to the Exclusive License Agreement, dated September 25, 2017, by and between The Board of Trustees of the Leland Stanford Junior University and Ruga Corporation (Incorporated herein by reference to Exhibit 10.4 of our registration statement on Form S-4 (File No. 333-226594 as filed with the SEC on August 3, 2018).
10.47†	Amendment No. 3 to the Exclusive License Agreement, dated September 25, 2017, by and between The Board of Trustees of the Leland Stanford Junior University and Ruga Corporation (Incorporated herein by reference to Exhibit 10.5 of our registration statement on Form S-4 (File No. 333-226594 as filed with the SEC on August 3, 2018).
10.48†	Master Manufacturing Services Agreement, dated July 11, 2016, by and between WuXi Biologics (Hong Kong) Limited and Aravive Biologics, Inc. (Incorporated herein by reference to Exhibit 10.6 of our registration statement on Form S-4/A (File No. 333-226594 as filed with the SEC on August 24, 2018).
10.49†	License Agreement dated December 1, 2017, by and between WuXi Biologics (Hong Kong) Limited and Aravive Biologics, Inc. (Incorporated herein by reference to Exhibit 10.7 of our registration statement on Form S-4 (File No. 333-226594 as filed with the SEC on August 3, 2018).
10.50†	Indemnification Agreement dated October 17, 2016, by and between Ruga Corporation and Vinay Shah (Incorporated herein by reference to Exhibit 10.8 of our registration statement on Form S-4 (File No. 333-226594 as filed with the SEC on August 3, 2018).
10.51	Sublease dated August 21, 2018, by and among Versartis, Inc. and Eva Automation, Inc. (Incorporated herein by reference to Exhibit 10.1 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on September 20, 2018)
10.52*	Aravive, Inc. 2017 Equity Incentive Plan (Incorporated herein by reference to Exhibit 4.9 of our registration statement on Form S-8 (File No. 333-227865), as filed with the SEC on October 17, 2018)
10.53*	Aravive, Inc. 2010 Equity Incentive Plan, as amended (Incorporated herein by reference to Exhibit 4.10 of our registration statement on Form S-8 (File No. 333-227865), as filed with the SEC on October 17, 2018).

10.54*	Separation Agreement with Paul Westberg effective November 15, 2018 (Incorporated herein by reference to Exhibit 10.1 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on November 20, 2018).
10.55*	Separation Agreement with Tracy Woody effective November 15, 2018 (Incorporated herein by reference to Exhibit 10.2 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on November 20, 2018)
10.56*	Amendment to Jay Shepard Offer Letter dated as of February 6, 2019 (Incorporated herein by reference to Exhibit 10.1 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on February 12, 2019)
10.57*	Offer Letter dated February 1, 2017 and the amendment thereto dated May 30, 2018 by and between Aravive Biologics, Inc. and Vinay Shah (Incorporated herein by reference to Exhibit 10.2 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on February 12, 2019)
10.58*	Severance Agreement dated May 31, 2018 and amendment thereto dated September 24, 2018 between Aravive Biologics, Inc. and Vinay Shah (Incorporated herein by reference to Exhibit 10.3 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on February 12, 2019)
10.59*	Offer Letter dated January 1, 2017 by and between Aravive Biologics, Inc. and Gail McIntyre (Incorporated herein by reference to Exhibit 10.4 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on February 12, 2019)
10.60#*	Non-Employee Director Compensation Policy, as amended January 3, 2019

Exhibit Number	Description
10.61*	Amendment to Jay Shepard Offer Letter effective as of February 28, 2019 (Incorporated herein by reference to Exhibit 10.1 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on March 6, 2019)
10.62*	First Amendment to Aravive, Inc. 2014 Equity Incentive Plan (Incorporated herein by reference to Exhibit 10.2 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on March 6, 2019)
21.1#	List of Subsidiaries
23.1#	Consent of BDO USA, LLP
23.2#	Consent of PricewaterhouseCoopers LLP
24.1#	Power of Attorney (included in the signature page hereto)
31.1#	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2#	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1#	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2#	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

#Filed herewith

†Registrant has been granted confidential treatment for certain portions of this agreement. The omitted portions have been filed separately with the SEC.

* Indicates management contract or compensatory plan.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Aravive, Inc.

Date: March 14, 2019 By: /s/ Jay P. Shepard
Jay P. Shepard
Chief Executive Officer

(Principal Executive Officer)

Date: March 14, 2019 By: /s/ Vinay Shah
Vinay Shah
Chief Financial Officer

(Principal Financial Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Jay Shepard and Vinay Shah, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or either of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Signature	Title	Date
/s/ Jay P. Shepard Jay P. Shepard	Chief Executive Officer and Director (Principal Executive Officer)	March 14, 2019
/s/ Vinay Shah Vinay Shah	Chief Financial Officer (Principal Financial Officer)	March 14, 2019
/s/ Kevin Haas Kevin Haas	Vice President of Finance (Principal Accounting Officer)	March 14, 2019
/s/ Srinivas Akkaraju, M.D., Ph.D. Srinivas Akkaraju, M.D., Ph.D.	Director	March 14, 2019
/s/ Amato Giaccia, Ph. D. Amato Giaccia, Ph. D.	Director	March 14, 2019
/s/ Robert E. Hoffman Robert E. Hoffman	Director	March 14, 2019
/s/ Ray Tabibiazar, M.D. Ray Tabibiazar, M.D.	Director	March 14, 2019
/s/ Shahzad Malik, M.D. Shahzad Malik, M.D.	Director	March 14, 2019
/s/ Eric Zhang Eric Zhang	Director	March 14, 2019