UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 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	**2834**	**26-4106690**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification Number)**

LyondellBasell Tower
1221 McKinney Street, Suite 3200
Houston, Texas 77010
(936) 355-1910
(Address, including zip code, and telephone number, including area code, of principal executive offices)

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 than the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See 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	☐	Smaller reporting company	☐
Emerging growth company	☒		

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

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

As of October 31, 2018, there were 11,182,025 outstanding shares of common stock, par value $0.0001 per share, of Aravive, Inc.

ARAVIVE, INC.

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTERLY PERIOD ENDED September 30, 2018

PART I. FINANCIAL INFORMATION

PART II. OTHER INFORMATION

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

ARAVIVE, INC. (FORMERLY KNOWN AS VERSARTIS, INC.)
CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited)
(in thousands, except share and per share data)

	September 30, 2018	December 31, 2017
Assets		
Current Assets		
Cash and cash equivalents	$ 62,605	$ 81,146
Prepaid expenses and other current assets	464	562
Total current assets	63,069	81,708
Restricted cash	2,392	2,383
Property and equipment, net	—	798
Build-to-suit lease asset	8,710	8,888
Total assets	74,171	93,777
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 335	$ 1,500
Accrued liabilities	2,794	4,093
Total current liabilities	3,129	5,593
Build-to-suit lease obligation	7,324	5,428
Total liabilities	10,453	11,021
Commitments and contingencies (Note 5)		
Stockholders' equity		
Common stock, $0.0001 par value, 100,000,000 shares authorized at September 30, 2018 and December 31, 2017; 6,040,112 and 5,989,688 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	4	4
Additional paid-in capital	463,325	456,984
Accumulated deficit	(399,611)	(374,232)
Total stockholders' equity	63,718	82,756
Total liabilities and stockholders’ equity	$ 74,171	$ 93,777

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

ARAVIVE, INC. (FORMERLY KNOWN AS VERSARTIS, INC.)
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)
(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Operating expenses				
Research and development	$ 1,027	$ 42,673	$ 8,065	$ 93,295
General and administrative	5,191	7,073	16,111	22,301
Total operating expenses	6,218	49,746	24,176	115,596
Loss from operations	(6,218)	(49,746)	(24,176)	(115,596)
Interest income	261	220	703	661
Other income (expense), net	(593)	(262)	(1,906)	(1,044)
Net loss before provision for income taxes	$ (6,550)	$ (49,788)	$ (25,379)	$ (115,979)
Provision for income taxes	—	—	—	128
Net loss	$ (6,550)	$ (49,788)	$ (25,379)	$ (116,107)
Net loss per share - basic and diluted (1)	$ (1.08)	$ (8.37)	$ (4.23)	$ (19.72)
Weighted-average common shares used to compute basic and diluted net loss per share (1)	6,040	5,945	5,998	5,889

(1) Net loss per share and the number of shares used in the per share calculations for all periods presented reflect the one-for-six reverse stock split effective on October 16, 2018.

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

ARAVIVE, INC. (FORMERLY KNOWN AS VERSARTIS, INC.)
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2018	2017
Cash flows from operating activities		
Net loss	$ (25,379)	$ (116,107)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	975	190
Stock-based compensation expense	6,289	11,101
Changes in assets and liabilities		
Prepaid expenses and other assets	98	(93)
Accounts payable	(1,163)	2,876
Accrued and other liabilities	(1,300)	22,995
Income taxes payable	—	(247)
Net cash used in operating activities	(20,480)	(79,285)
Cash flows from investing activities		
Purchase of property and equipment	—	(3,532)
Inducement on build-to-suit lease obligation	1,896	—
Net cash provided by and (used in) investing activities	1,896	(3,532)
Cash flows from financing activities		
Proceeds from issuance of common stock in connection with employee benefit plans	52	2,829
Net cash provided by financing activities	52	2,829
Net change in cash, cash equivalents, and restricted cash	(18,532)	(79,988)
Cash, cash equivalents, and restricted cash at beginning of period	83,529	201,153
Cash, cash equivalents, and restricted cash at end of period	$ 64,997	$ 121,165
Supplemental disclosure		
Income taxes paid	$ —	$ 375
Supplemental disclosure of noncash items		
Build-to-suit leasehold improvements	$ —	$ 5,428

The accompanying notes are an integral part of these condensed 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 9, "Subsequent Events," 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 standalone company following the completion of the Merger. The Merger became effective on October 12, 2018 and 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.

Unaudited Interim Financial Information

In the opinion of the Company's management, the accompanying unaudited condensed consolidated financial statements contain all adjustments, consisting of only normal recurring adjustments, necessary for a fair statement of its financial position as of September 30, 2018 and, its results of operations and cash flows for the three- and nine- months period ended September 30, 2018, and 2017. The December 31, 2017 condensed consolidated balance sheet was derived from audited financial statements, but does not include all disclosures required by generally accepted accounting principles in the United States of America, or GAAP. The results for interim periods are not necessarily indicative of the results for the entire year or any other interim period. The accompanying condensed consolidated financial statements and related financial information should be read in conjunction with the audited financial statements and the related notes thereto for the year ended December 31, 2017 included in the Company's annual report on Form 10-K filed by Versartis, Inc. on March 6, 2018 with the U.S. Securities and Exchange Commission, or the SEC.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The accompanying condensed consolidated financial statements have been prepared in accordance with GAAP. The preparation of the accompanying condensed consolidated financial statements in accordance with 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 condensed consolidated financial statements, and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

The accompanying unaudited condensed consolidated financial position as of September 30, 2018 and as of December 31, 2017, and the results of operations and cash flows for the three- and nine-months period ended September 30, 2018 and 2017 include the accounts of Versartis, Inc. and its wholly-owned subsidiaries, Versartis Cayman Holdings Company and Versartis GmbH. All intercompany accounts and transactions have been eliminated. The U.S. dollar is the functional currency for all the Company's consolidated operations.

As of September 30, 2018, the Company had a cash and cash equivalents balance of $62.6 million consisting of cash and cash equivalents in highly liquid U.S. money market funds. As a result of the Merger with Aravive Biologics, the merged company has acquired additional capital including cash and cash equivalents of approximately $5.7 million from Aravive Biologics. Cash and cash equivalents as of September 30, 2018 for both the Company and Aravive Biologics do not reflect estimated remaining merger transaction related costs. 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 merged company's expected primary use of cash will be to fund the merged company's clinical development programs, specifically for its product candidate AVB-S6-500. Since inception, the Company has incurred net losses and negative cash flows from operations supporting the Company's clinical development programs and related general and administrative expenses. At September 30, 2018, the Company had an accumulated deficit of $399.6 million and working capital of $59.9 million. The merged company expects to continue to incur losses supporting its clinical development program as a result of the Merger and related administrative expenses. The merged company anticipates it may need additional financing to support its business plan as it moves forward as a merged company. Although management has been successful in raising capital in the past, there can be no assurance that the merged company will be successful or that any needed financing will be available in the future at terms acceptable to the merged company.

As described in Note 9, "Subsequent Events," the Company effected a 1-for-6 reverse stock split. Accordingly, all share and per share amounts for all periods presented in these condensed consolidated financial statements and notes have been adjusted retroactively to reflect this reverse stock split.

Except as described in Note 9, "Subsequent Events," the accompanying unaudited condensed consolidated financial statements do not give effect to the Merger.

Segments

The Company operates in one segment. Management uses one measurement of performance 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.

The Company entered into forward foreign currency contracts that exposed it to credit risk to the extent that the counterparties potentially were unable to meet the terms of the agreement. The Company did, 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 did not expect material losses as a result of defaults by counterparties.

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 or a strategic transaction and dependence on key individuals and sole source suppliers.

Products developed by the Company require clearances from the U.S. Food and Drug Administration, or the FDA, the Pharmaceuticals Medicines and Devices Agency, or the 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 materially 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 develop, launch and commercialize any product candidates for which it receives regulatory approval.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. At September 30, 2018 and December 31, 2017, the Company's cash and cash equivalents were held in multiple institutions in the United States and Europe and included deposits in money market funds which were unrestricted as to withdrawal or use.

Restricted Cash

Restricted cash includes cash and cash equivalents that is restricted through legal contracts, regulations or the Company's intention to use the cash for a specific purpose. The Company's restricted cash primarily relates to the letter of credit provided to its Landlord for the Company's facilities in Menlo Park, California (as described in Note 5) to secure its obligations under the 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 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 5), 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 condensed 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 condensed 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 where construction has been completed. The Company's assessment of the arrangement determined that they did not qualify for sale-leaseback accounting treatment; therefore, the building asset remains on the Company's condensed 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 as of September 30, 2018 or December 31, 2017.

Fair Value of Financial Instruments

The carrying value of the Company's cash and cash equivalents, prepaid expenses, 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 September 30, 2018. Level I securities are comprised of highly liquid money market funds.

The Company's foreign currency derivative contracts have maturities over a 12-month time horizon and is with a counterparty that has a minimum credit rating of A- or equivalent by Standard & Poor's, Moody's Investors Service, Inc. or Fitch, Inc. These contracts are reported as Level II assets, however there were none outstanding as of September 30, 2018.

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, or 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. In September 2017, the Company announced that the VELOCITY Phase 3 clinical trial of somavaratan in pediatric growth hormone deficiency (GHD) failed to meet its primary endpoint of non-inferiority. All ongoing clinical trials of somavaratan have concluded and as such, there were no material preclinical and clinical trial accruals as of September 30, 2018.

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 financial statement and tax basis 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 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Operating Expenses				
Research and development	$ 95	$ 1,419	$ 1,855	$ 4,400
General and administrative	1,218	2,160	4,434	6,701
Total	$ 1,313	$ 3,579	$ 6,289	$ 11,101

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. There was no difference between net loss and comprehensive loss for all periods presented.

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, restricted stock units and shares issued under the Company's Employee Stock Purchase Plan are considered to be potentially dilutive securities. Because the Company has reported a net loss for all of the periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods.

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 May 2017, the FASB issued, ASU-2017-09, Compensation—Stock Compensation (Topic 718). 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)- 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, Versartis, Inc. completed a merger whereby Aravive Biologics merged with a wholly owned subsidiary of Versartis, Inc. in an all-stock transaction and Aravive Biologics was the surviving corporation of such merger as a wholly owned subsidiary of Versartis, Inc. (now named Aravive, Inc.). The Merger is expected to be accounted for as an acquisition by Versartis, Inc. of Aravive Biologics' net assets in an asset acquisition. 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 and cash equivalents at September 30, 2018. The following is a reconciliation of the captions in the consolidated balance sheet to the consolidated statements of cash flows (in thousands):

	As of			
	September 30, 2018	December 31, 2017	September 30, 2017	December 31, 2016
Consolidated Balance Sheets				
Cash and cash equivalents	$ 62,605	$ 81,146	$ 118,783	$ 201,153
Restricted cash (included in other current assets)	2,392	2,383	2,382	—
Cash, cash equivalents and restricted cash in Consolidated Statements of Cash Flows	$ 64,997	$ 83,529	$ 121,165	$ 201,153

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). This ASU is a comprehensive new leases standard that amends various aspects of existing guidance for leases and requires additional disclosures about leasing arrangements. The new standard requires that all lessees recognize the assets and liabilities that arise from leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements. The classification criteria for distinguishing between finance leases and operating leases are substantially similar to the classification criteria for distinguishing between capital leases and operating leases in the previous lease guidance. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, and interim periods within those years, with early adoption permitted. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. In July 2018, the FASB issued ASU 2018-11, Leases (Topic 842)-- Targeted Improvements, that allows entities to apply the provisions of the new standard at the effective date (e.g. January 1, 2019), as opposed to the earliest period presented under the modified retrospective transition approach (January 1, 2017) and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The modified retrospective approach includes a number of optional practical expedients primarily focused on leases that commenced before the effective date of Topic 842, including continuing to account for leases that commence before the effective date in accordance with previous guidance, unless the lease is modified. The Company currently expects that its operating lease commitments will be subject to the new standard and recognized as operating lease liabilities and right-of-use assets upon its adoption of Topic 842, which will increase the total assets and total liabilities that the Company reports relative to such amounts prior to adoption. In addition, the Company plans to adopt ASC Topic 842 using the modified retrospective approach with the cumulative effect of adoption recognized to retained earnings on January 1, 2019.

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 September 30, 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)

	September 30, 2018	December 31, 2017
Preclinical and clinical (1)	$ 31	$ 261
Other	433	301
Total	$ 464	$ 562

(1) These prepayments consist primarily of advances to the Company's contract manufacturers and contract research organizations

Accrued Liabilities (in thousands)

	September 30, 2018	December 31, 2017
Payroll and related	$ 1,946	$ 2,058
Preclinical and clinical	91	1,694
Professional services	11	204
Other	746	137
Total	$ 2,794	$ 4,093

4. Fair Value Measurements

The Company's financial instruments consist principally of cash and cash equivalents, prepaid expenses, accounts payable and accrued liabilities. 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 September 30, 2018 (unaudited)			
	Total	Level 1	Level 2	Level 3
Assets				
Money market funds	$ 56,117	$ 56,117	$ —	$ —
	$ 56,117	$ 56,117	$ —	$ —

	Fair Value Measurements at December 31, 2017			
	Total	Level 1	Level 2	Level 3
Assets				
Money market funds	$ 62,428	$ 62,428	$ —	$ —
	$ 62,428	$ 62,428	$ —	$ —

5. Commitments and Contingencies

Facility Leases

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 ("1020 Space") and for approximately 17,400 rentable square feet located on the second floor of the building located at 1060 Marsh Road. In September 2017, the Company terminated its lease specific to 1060 Marsh Road. The 1020 space served as the Company's corporate headquarters until the completion of the Merger.

The delivery of the 1020 Space to the Company occurred in April 2017. The 1020 Space lease commenced on August 8, 2017 for a period of 86 months, with one renewal option for a five-year term. The total obligation under this lease for the Company is approximately $17.7 million as of September 30, 2018.

As an inducement to enter the lease, the Landlord provided the Company with an approximately $1.9 million tenant improvement allowance for the 1020 Space. In January 2018, the Company received approximately $1.5 million, or 80% of the tenant improvement allowance. The remaining 20% of $0.4 million was received in May 2018. The Company has 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 balance sheet, which is subject to reductions in future years if certain financial hurdles are met.

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. The total base rent and additional rent EVA shall pay to the Company over the sublease term is approximately $14.7 million as of September 30, 2018. 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.

Future minimum lease payments under all of the Company's noncancelable operating and facility leases, as of September 30, 2018, were as follows (in thousands):

Year Ending December 31,		
2018	$	690
2019		2,780
2020		2,854
2021		2,930
2022		3,009
Thereafter		5,449
Total	$	17,712

Build-to-Suit

In March 2017, the Company entered into an operating facility lease agreement, as described above, to lease office space located in Menlo Park, California in a building to be constructed by the landlord. The company began occupying the 1020 Space 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. The obligation under this lease is approximately $17.7 million as of September 30, 2018. In connection with this lease, the landlord provided 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 funded all costs incurred in excess of the tenant improvement allowance. As of September 30, 2018, the Company received all of the tenant improvement allowance. The $1.9 million inducement payment received increased the build-to-suit lease obligation to $7.3 million as of September 30, 2018.

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 they were deemed the owner of the building during the construction period and the Company capitalized approximately $8.7 million within property and equipment and recognized a $7.3 million corresponding build-to-suit obligation in non-current liabilities in the condensed consolidated balance sheet as of September 30, 2018. Of the $8.7 million, approximately $3.5 million has been recorded as a build-to-suit asset related to construction costs incurred as of September 30, 2018.

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. 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 September 30, 2018 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.

6. Stockholders' Equity

Equity Incentive Plans

The Company's Board of Directors, or Board, and stockholders previously approved the 2014 Equity Incentive Plan, or the 2014 Plan, which became effective on March 21, 2014. As of September 30, 2018, the total number of shares of common stock available for issuance under the 2014 Plan was approximately 445,000. Unless the Board provides otherwise, beginning on January 1, 2015, and continuing until the expiration of the 2014 Plan, the total number of shares of common stock available for issuance under the 2014 Plan will automatically increase annually on January 1 by 4.5% of the total number of issued and outstanding shares of common stock as of December 31 of the immediately preceding year. As of September 30, 2018, approximately 660,100 shares of common stock were subject to outstanding awards under the 2014 Plan.

In March 2014, the Board and stockholders approved the 2014 Employee Stock Purchase Plan, or the ESPP, which became effective as of March 5, 2014. The Company initially reserved a total of 150,000 shares of common stock for issuance under the ESPP. Unless the Board provides otherwise, beginning on January 1, 2015, and continuing until the expiration of the ESPP, the total number of shares of common stock available for issuance under the ESPP will automatically increase annually on January 1 by the lesser of (i) 1% of the total number of issued and outstanding shares of common stock as of December 31 of the immediately preceding year, or (ii) 300,000 shares of common stock. As of September 30, 2018, the Company has issued approximately 37,300 shares of common stock under the ESPP.

7. Net loss per share of Common Stock

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net loss	$ (6,550)	$ (49,788)	$ (25,379)	$ (116,107)
Weighted-average shares used to compute basic and diluted net loss per share (1)	6,040	5,945	5,998	5,889
Basic and diluted net loss per common share (1)	$ (1.08)	$ (8.37)	$ (4.23)	$ (19.72)

(1) Net loss per share and the number of shares used in the per share calculations for all periods presented reflect the one-for-six reverse stock split effective on October 16, 2018.

Basic net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss per common share 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 all periods presented, diluted net loss per share is the same as basic net loss per common share for those periods.

8. 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. 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.

As part of the Company's commitment to reduce operating expenses and preserve cash, the Company eliminated additional positions effective May, June, and July 2018. The reduction included a total of 14 employees, which represented approximately 59% of its workforce as of June 26, 2018, the date affected employees were notified. Pursuant to the Plan, affected employees received certain severance benefits. The Company incurred a one-time severance-related charge totaling approximately $3.5 million for the period ended June 30, 2018 and $0.2 million for the period ended September 30, 2018, total severance payment of $3.7 million was paid out as of September 30, 2018. Of the $3.7 million severance-related charge, $1.2 million is included within general and administrative expenses and $2.5 million is included within research and development expenses.

9. Subsequent Event

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 Versartis, Inc., Velo Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of Versartis ("Merger Sub"), and Aravive Biologics, Merger Sub was merged with and into Aravive Biologics (the "Merger"), with Aravive Biologics surviving the Merger as a wholly-owned subsidiary of Versartis, Inc. Pursuant to the terms of the Merger Agreement, at the Effective Time, each outstanding share of capital stock of Aravive Biologics (other than any shares held as treasury stock) was converted into the right to receive 2.2801 shares of Versartis' 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 Aravive Biologics 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 Aravive common stock covered by such option. The aggregate consideration issuable in the Merger to the former security holders of Aravive Biologics, without giving effect to any adjustment for the reverse stock split described below, was approximately 30,851,600 shares of Company Common Stock and options to purchase approximately 7,103,859 shares of Company Common Stock.

The Merger is expected to be accounted for as an asset acquisition by Versartis, Inc. To determine the accounting for this transaction under GAAP, Versartis, Inc. 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 Aravive Biologics, the Company expects substantially all the fair value is included in in-process research and development of Aravive Biologics' lead asset, AVB-S6-500 and, as such, the acquisition will be treated as an asset acquisition. Management of Versartis, Inc. and Aravive Biologics have made a preliminary estimate of the purchase price of approximately $54.2 million for the fair value of the identifiable tangible and intangible assets acquired and liabilities assumed as of June 30, 2018. The net tangible and intangible assets acquired and liabilities assumed in connection with the transaction will be 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.

Corporate Name Change

On October 15, 2018, Versartis, Inc. changed its name to "Aravive, Inc." ("Aravive, Inc."). Shares of Company Common Stock were previously listed on the Nasdaq Global Select Market under the symbol "VSAR." Versartis 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 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.

Reverse Stock Split One-for-Six

In connection with the completion of the Merger, on October 15, 2018, the amended and restated certificate of incorporation of Versartis 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.

2479 E. Bayshore Blvd Sublease

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 commences on October 30, 2018 and expires August 31, 2020. The total obligation for the Company under this lease is approximately $0.3M.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following management's discussion and analysis of our financial condition and results of operations in conjunction with our unaudited condensed consolidated financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q and with our audited financial statements and notes thereto for the year ended December 31, 2017, included in our annual report on Form 10-K filed on March 6, 2018 with the U.S. Securities and Exchange Commission (SEC).

Special note regarding forward-looking statements

This report 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 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," "project," "seek," "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 II, 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.

Recent Developments

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 Versartis, Inc., a Delaware corporation ("Versartis"), Velo Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of Versartis ("Merger Sub"), and Aravive Biologics, Inc., a Delaware corporation ("Aravive Biologics"), Merger Sub was merged with and into Aravive Biologics (the "Merger"), with Aravive Biologics surviving the Merger as a wholly-owned subsidiary of Versartis, Inc. The Merger became effective on October 12, 2018, when the certificate of merger of Aravive Biologics and Merger Sub was filed with the Secretary of State of the State of Delaware (the "Effective Time"). At the Effective Time, (a) each outstanding share of capital stock of Aravive Biologics (other than any shares held as treasury stock) was converted into the right to receive 2.2801 shares of Versartis' common stock, par value $0.0001 per share (the "Company Common Stock"), and (b) each outstanding Aravive Biologics 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 Company Common Stock for each share of Aravive Biologics common stock covered by such option. The aggregate consideration issuable in the Merger to the former security holders of Aravive Biologics, was approximately 30,851,600 (pre-reverse split) shares of Company Common Stock and options to purchase approximately 7,103,859 (pre-reverse split) shares of Company Common Stock. On October 15, 2018, Versartis changed its name to "Aravive, Inc."

In connection with the completion of the Merger, on October 15, 2018, the amended and restated certificate of incorporation of Versartis, Inc. was amended to effect, on October 16, 2018, a reverse split of Company Common Stock at a ratio of 1-for-6 (the "Amended Certificate"). Accordingly, unless otherwise stated, all share and per share amounts for all periods presented in these condensed consolidated financial statements and notes have been adjusted retroactively to reflect this reverse stock split

The merged company is a clinical stage biopharmaceutical company focusing on developing innovative, novel, highly selective therapies designed to treat serious cancers and certain fibrotic diseases. Prior to the Merger, 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.

At the Effective Time, the size of the merged company's board of directors was set at seven, and Amato Giaccia, Ph.D., Robert E. Hoffman, Raymond Tabibiazar, M.D. and Eric Zhang were appointed directors of the merged company, while Srinivas Akkaraju, M.D., Ph.D., Shahzad Malik, M.D. and Jay P. Shepard remained on the board of directors, each director to hold office in accordance with the certificate of incorporation and bylaws of the merged company and until his successor is duly elected and qualified or until his earlier death, resignation or removal. At the Effective Time, Robert E. Hoffman, Srinivas Akkaraju, M.D., Ph.D. and Eric Zhang were appointed to serve on the audit committee, Shahzad Malik, M.D., Robert E. Hoffman and Raymond Tabibiazar, M.D. were appointed to serve on the compensation committee, and Srinivas Akkaraju, M.D., Ph.D., Amato Giaccia, Ph.D. and Robert E. Hoffman were appointed to serve on the nominating and corporate governance committee.

In connection with the resignation and appointment of directors, the board of directors approved a process to realign its members, such that following the Merger, the board of directors will be divided into three classes as nearly equal in size as is practicable in accordance with the merged company's certificate of incorporation. At the Effective Time, (i) Srinivas Akkaraju, M.D.,

Ph.D. resigned as a Class III director and the board of directors appointed him a Class I director and (ii) Shahzad Malik, M.D. resigned as a Class II director and the board of directors appointed him a Class III director, in each case to be effective immediately after the effectiveness of such director's resignation. The board of directors then appointed (i) Raymond Tabibiazar, M.D. and Robert E. Hoffman as Class I directors, (ii) Amato Giaccia, Ph.D. a Class II director and (iii) Eric Zhang a Class III director. Jay P. Shepard remains a Class II director. The terms of the Class I directors will expire at the annual meeting of stockholders held in 2021, the terms of the Class II directors will expire at the annual meeting of stockholders held in 2019, and the terms of the Class III directors will expire at the annual meeting of stockholders held in 2020.

Immediately after the Effective Time, Vinay Shah was appointed Chief Financial Officer of the merged company. Mr. Shepard remains President and Chief Executive Officer of the merged company.

Further information about the Merger, including a copy of the Merger Agreement, a description of Aravive Biologics, historical financial statements of Aravive Biologics and pro forma condensed combined financial statements of Versartis, Inc. and Aravive Biologics can be found in the Proxy Statement/Prospectus/Information Statement filed by Versartis, Inc. with the Securities and Exchange Commission (the "SEC") on September 6, 2018 (the "Proxy Statement").

Important Note

Consistent with the requirements of Form 10-Q, the following discussion and analysis focuses on the historical financial statements of Versartis, Inc. through September 30, 2018. Due to the substantial changes in our assets, liabilities and operations resulting from the completion of the Merger on October 12, 2018, Versartis, Inc.'s historical financial results do not provide a reasonable basis from which to predict the merged company's future financial results or condition. References in this report to "we," "us," "our" and similar first-person expressions refer to Aravive, Inc. (formerly known as Versartis, Inc.) and its subsidiaries, including Aravive Biologics. References to "Versartis, Inc." or "Aravive Biologics." refer to those respective companies prior to the completion of their merger in October 2018.

Financial overview

Revenue

We have never generated net income from operations on an annual basis, and, as of September 30, 2018, we had an accumulated deficit of $399.6 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. In August 2016, we entered into an exclusive license and supply agreement with Teijin, a pharmaceutical company based in Japan, 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 contract revenue in Q4 2017 upon termination of the agreement in January 2018 as 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.

Research and development expenses

We recognize both internal and external research and development expenses as incurred. Our external research and development expenses consist primarily of:

- the cost of acquiring and manufacturing clinical trial and other materials, including expenses incurred under agreements with contract manufacturing organizations;
- expenses incurred under agreements with contract research organizations, investigative sites, and consultants that conduct our clinical trials and a substantial portion of our preclinical activities; and
- other costs associated with development activities, including additional studies.

Internal research and development costs consist primarily of salaries and related fringe benefit costs for our employees (such as workers' compensation and health insurance premiums), stock-based compensation charges, travel costs, and allocated overhead expenses.

Since the results of our Phase 3 VELOCITY trial in 2017, we have restructured our company to reduce costs, which included a substantial reduction in our workforce.

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 increase in future periods, as we expand our activities to support our expanded research and development activities and incur costs related to the expanded infrastructure, administrative expenses and increased professional fees associated with being a public reporting company.

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 interest charges associated with our build-to-suit lease obligation.

Critical accounting policies, significant judgments and use of estimates

Our management's discussion and analysis of financial condition and results of operations are based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate 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. Our significant accounting policies are more fully described in Note 2 of the accompanying unaudited condensed consolidated financial statements and in Note 2 to our audited consolidated financial statements contained in the Annual Report on Form 10-K filed on March 6, 2018 with the Securities Exchange Commission, or the SEC. There have been no significant or material changes in our critical accounting policies during the nine months ended September 30, 2018, as compared to those disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Use of Estimates" in the Annual Report on Form 10-K.

Results of operations

Comparison of the Three and Nine Months Ended September 30, 2018 and 2017

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

	Three Months Ended September 30,		Increase/ (Decrease)		Nine Months Ended September 30,		Increase/ (Decrease)	
	2018	2017			2018	2017		
Operating expenses:								
Research and development	$ 1,027	$ 42,673	(41,646)	-98%	$ 8,065	$ 93,295	$ (85,230)	-91%
General and administrative	5,191	7,073	(1,882)	-27%	16,111	22,301	(6,190)	-28%
Loss from operations	(6,218)	(49,746)	(43,528)	-88%	(24,176)	(115,596)	(91,420)	-79%
Interest income	261	220	41	19%	703	661	42	6%
Other income (expense), net	(593)	(262)	331	126%	(1,906)	(1,044)	862	83%
Net loss before provision for income taxes	(6,550)	(49,788)	(43,238)	-87%	(25,379)	(115,979)	(90,600)	-78%
Provision for income taxes	—	-	-	NM	—	128	(128)	NM
Net loss	$ (6,550)	$ (49,788)	$ (43,238)	-87%	$ (25,379)	$ (116,107)	$ (90,728)	-78%

Research and development expense

Research and development expense decreased by $41.6 million, or 98%, to $1.0 million for the three months ended September 30, 2018 from $42.6 million for the same period in 2017. For the nine months ended September 30, 2018 research and development expense decreased by $85.2 million or 91%, to $8.1 million from $93.3 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.

General and administrative expense

General and administrative expense decreased by $1.9 million, or 27%, to $5.2 million for the three months ended September 30, 2018 from $7.1 million for the same period in 2017. For the nine months ended September 30, 2018 general and administrative expense decreased by $6.2 million or 28%, to $16.1 million from $22.3 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 Aravive Biologics.

Other income (expense), net

Other expense, increased $0.9 million to $1.9 million of other expense for the nine months ended September 30, 2018 from other expense of $1.0 million for the same period in 2017. This increase was primarily due to interest charges related to our build-to-suite lease obligation.

Liquidity and capital resources

Since our inception and through September 30, 2018, we have financed our operations through private placements of our equity securities, debt financing and our initial public offering in 2014 and, more recently, additional common stock offerings in January 2015 and October and November of 2016, as well as a $40.0 million upfront payment received from our strategic license agreement with Teijin. At September 30, 2018, we had cash and cash equivalents of $62.6 million, a majority of which is invested in money market funds at several highly rated financial institutions. As a result of the Merger with Aravive Biologics, we have acquired approximately $5.7 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.

We will need to obtain additional financing to pursue our clinical development programs, build out our pipeline 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. Although management has been successful in raising capital in the past, 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. 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, the requirements of which will depend on many factors, including:

- the rate of progress and cost of any future potential 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 potential 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:

	Nine Months September 30,	
	2018	2017
	(In thousands)	
Net cash (used in) provided by:		
Operating activities	$ (20,480)	$ (79,285)
Investing activities	1,896	(3,532)
Financing activities	52	2,829
Net increase (decrease) in cash and cash equivalents	$ (18,532)	$ (79,988)

Cash used in operating activities

Net cash used in operating activities was $20.5 million and $79.3 million in the nine months ended September 30, 2018 and 2017, respectively. Cash used in operating activities in 2017 is primarily attributable to the use of funds in our operations related to the development of somavaratan, our product candidate. 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 investing activities

Net cash provided by and used in investing activities was $1.9 million and $3.5 million in the nine months ended September 30, 2018 and 2017, respectively. Cash provided by investing activities in 2018, primarily relates to inducement payments received from the Landlord of our leased facility in Menlo Park, California. 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 provided by financing activities

Net cash provided by financing activities was $.05 million and $2.8 million in the nine months ended September 30, 2018 and 2017, respectively. Cash provided by financing activities consisted of proceeds from issuance of common stock in connection with employee benefit plans.

As of September 30, 2018, we had cash and cash equivalents of approximately $62.6 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, based on our current business plan and the capital we acquired as a result of the Merger with Aravive Biologics.

Contractual obligations and commitments

In August 2018, we entered into an operating sublease agreement with EVA Automation, Inc. (EVA). for the 1020 Space referenced in Note 5. The 1020 Space Sublease commenced on October 1, 2018 for 72 months. The total base rent and additional rent EVA shall pay to us over the sublease term is approximately $14.7 million as of September 30, 2018. 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 term.

During the nine months ended September 30, 2018, there were no other material changes to our contractual obligations and commitments described under Management's Discussion and Analysis of Financial Condition and Results of Operations in the Annual Report on Form 10-K for the year ended December 31, 2017.

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.

Item 3. Quantitative and qualitative disclosures about market risk

Interest Rate and Market Risk

The primary objective of our investment activities is to preserve our capital to fund our operations. We also seek to maximize income from our cash and cash equivalents without assuming significant risk. To achieve our objectives, we invest our cash and cash equivalents in money market funds. As of September 30, 2018, we had cash and cash equivalents of $62.6 million consisting of cash and investments in highly liquid U.S. money market funds. A portion of our investments may be subject to interest rate risk and could

fall in value if market interest rates increase. However, because our investments are substantially all short-term in duration, we believe that our exposure to interest rate risk is not significant and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio. We actively monitor changes in interest rates.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

An evaluation as of September 30, 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." Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended, or the "Exchange Act," defines "disclosure controls and procedures" 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 SEC's rules and forms, and that such information is accumulated and communicated to the company's management, including its 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 have concluded that our disclosure controls and procedures were effective at September 30, 2018.

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 September 30, 2018, and has concluded that there was no change during such quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met. As set forth above, our Chief Executive Officer and Chief Financial Officer have concluded, based on the evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were effective to provide reasonable assurance that the objectives of our disclosure control system were met.

PART II: OTHER INFORMATION

Item 1. Legal proceedings

We are not currently subject to any material legal proceedings.

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 Form 10-Q, including our condensed 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 Aravive Biologics ("Aravive Biologics") in a merger whereby Aravive Biologics became our wholly owned subsidiary. All of our clinical development activities are now carried out through Aravive Biologics. References in this report to "we," "us," "our" and similar first-person expressions refer to Aravive, Inc. (formerly known as Versartis, Inc.) and its subsidiaries, including Aravive Biologics. References to "Versartis, Inc." or "Aravive Biologics, Inc." refer to those respective companies prior to the completion of their merger in October 2018.

Aravive Biologics was founded in 2007, and its operations to date have been primarily limited to organizing and staffing its company and developing its only clinical product candidate, AVB-S6-500. Aravive Biologics 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 clinical product candidate, 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 clinical product candidate 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 its clinical product candidate at acceptable cost levels;
- achieve broad market acceptance of our clinical product candidate 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 clinical product candidate, 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 September 30, 2018, we had an accumulated deficit of $399.6 million. Since our historical financial statements are those of Versartis, Inc., our accumulated deficit does not reflect the cumulative deficit of Aravive Biologics.

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 Aravive Biologics' 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, Aravive Biologics' only clinical trial has been its 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 U.S. Food and Drug Administration, or 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 clinical 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 clinical 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 September 30, 2018, we had approximately $62.6 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. 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 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. 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.

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 our clinical product candidate. 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, 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 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, 2017, we had net operating loss carryforwards for federal income tax purposes of approximately $230 million and federal research and development tax credits of approximately $860,000, which begin to expire in 2029. We also had net operating loss carryforwards for state income tax purposes of approximately $55 million, which begin to expire in 2029, and state research and development tax credits of approximately $2,460,000 which have no expiration date. Additionally, we have an Orphan Drug Credit of approximately $32 million for federal income tax purposes, which begins to expire in 2033. We have foreign net operating loss carryforwards of $171 million, which begin to expire in 2023.

At December 31, 2017, our total gross deferred tax assets were $109.9 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"). An analysis was conducted through December 31, 2017 to determine whether an ownership change had occurred since inception. The analysis indicated that because an ownership change occurred in a prior year, federal and state net operating losses were limited pursuant to IRC 382. This limitation has been accounted for in calculating the available net operating loss carryforwards. If we underwent another ownership change as a result of the Merger, which is likely, our ability to utilize NOLs could be further limited by Section 382 of the Code. 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 its ability to take certain actions, and subject it to potential financial penalties, which could materially and adversely affect its business, financial condition and results of operations.

A significant portion of our funding has been through a grant it received from CPRIT. The CPRIT Grant (as defined 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. 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.

Our award from CPRIT requires us to pay CPRIT a portion of its revenues from sales of certain products by it, 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.

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 also required to reimburse Amunix for certain costs incurred in prosecuting, maintaining, defending and enforcing the licensed patents.

We currently have only one clinical 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. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to AVB-S6-500, which is initially being developed for the treatment of platinum-resistant recurrent ovarian cancer. Accordingly, our business currently depends heavily on the successful development, regulatory approval and commercialization of AVB-S6-500. Our clinical product candidate 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 biologics license application, or 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 its clinical product candidate through clinical trials, appropriately formulate and consistently manufacture them in accordance with strict specifications and regulations, obtain approval of our clinical product candidate for sale by the FDA or similar regulatory authorities in other countries, and ultimately have our clinical product candidate successfully commercialized by us or 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 our clinical product candidate.

Our clinical product candidate 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 study. 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 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 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 we fail to continue to develop and refine the dosage of our clinical product candidate, we may not obtain regulatory approvals, and, even if it is approved, the commercial acceptance of our clinical product candidate would likely be limited.

In our Phase clinical 1 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. We believe that, in order for our clinical product candidate to be approved and become commercially successful, we may need to continue to refine its dosage, which will increase our costs and slow down our product candidate development and approval process. Increasing the dosage of our clinical product candidate may also affect its safety profile and our manufacturing needs, which could adversely affect our business.

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 our clinical product candidate.

Currently, there are no approved biological drugs related to GAS6/AXL inhibition. However, if ever approved, our clinical product candidate 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 our clinical product candidate 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 our clinical product candidate may not have as favorable a safety or tolerability profile as potentially competitive compounds, we may delay or terminate the future development of our clinical product candidate. We cannot provide any assurance that the future development of our clinical product candidate 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 our continued development.

For our planned Phase 1b/2 clinical trial testing AVB-S6-500 in patients with platinum-resistant recurrent ovarian cancer, we intend to administer 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 our planned Phase 1b/2 clinical trial of AVB-S6-500 for the treatment of patients with platinum-resistant recurrent ovarian cancer, we intend to administer 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.

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 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 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 our clinical product candidate in sufficient quantities to commercialize our clinical product candidate.

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 October 31, 2018, we had 16 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 our clinical product candidate are unfavorable, we could be delayed or precluded from the further development or commercialization of our clinical product candidate, which could materially harm our business.

In order to further advance the development of, and ultimately receive marketing approval to sell our clinical product candidate, 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. 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 an NDA 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 Biologics License Application, or BLA, for regulatory approval for any indication or for any other treatment regime. We cannot predict with any certainty if or when we might submit a BLA for regulatory approval for our clinical product candidate, which we have recently completed a Phase 1 clinical trial, or whether any such BLA will 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 our proposed 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 planned 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 study 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 study.

Furthermore, any negative results we may report in clinical trials of our clinical product candidate 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.

If we fail to obtain or maintain adequate coverage and reimbursement for our clinical product candidate, our ability to generate revenue could be limited.

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 ours 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 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. For instance, since our Phase 1 clinical trial was conducted in healthy human volunteers, any adverse reactions will 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 iwe 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.

For example, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, collectively the Affordable Care Act, was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Although the full effect of the Affordable Care Act may not yet be fully understood, the law has continued the downward pressure on pharmaceutical pricing, especially under the Medicare program, and increased the industry's regulatory burdens and operating costs.

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.

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.

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-licenses 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 the entire potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a

pending patent application. 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 its 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 which 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, non- enablement 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 our 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 the "freedom to operate." We have only conducted routine searches related to third party patent filings and publications and has not conducted an in depth freedom to operate search which is extremely 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 the freedom to operate with respect to the intellectual property rights of others.

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 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 or other claims, we may have to participate in an adversarial proceeding, known 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 to our clinical product candidate or other claims 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 does not have the 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 our 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 its 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 October 31, 2018 the reported sale price of our common stock has fluctuated between $5.10 and $140.76 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 the Merger and 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, 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 principal stockholders will continue to maintain the ability to control or significantly influence all matters submitted to stockholders for approval.

As of October 31, 2018, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock, in the aggregate, beneficially owned shares representing approximately 49.8% 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

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 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.

In connection with our preparations for becoming a public company, we identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our condensed consolidated financial statements. If we fail to remediate one or more of our material weaknesses in the future or if we fail to establish and maintain effective control over financial reporting, our ability to accurately and timely report our financial results could be adversely affected.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of condensed consolidated financial statements in accordance with U.S. generally accepted accounting principles. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim condensed consolidated financial statements will not be prevented or detected on a timely basis.

Prior to the completion of our initial public offering, we were a private company with limited accounting personnel and other resources to address our internal control over financial reporting. During the course of preparing for our initial public offering, we determined that material adjustments to various accounts were necessary, which required us to restate the financial statements as of and for the years ended December 31, 2012 and 2011 and for the period from inception (December 10, 2008) through December 31, 2012 that had been previously audited by another independent audit firm. These adjustments leading to a restatement of those financial statements led us to conclude that we had a material weakness in internal control over financial reporting as of December 31, 2012. The material weakness that we identified was that we did not maintain a sufficient complement of resources with an appropriate level of accounting knowledge, experience and training commensurate with our structure and financial reporting requirements.

This material weakness contributed to adjustments to previously issued financial statements principally, but not limited to, the following areas: equity accounting in connection with our issuance of Series A and B convertible preferred stock and period-end cutoff for clinical trial related expenses.

While we have been successful in our efforts to remediate this particular material weakness we cannot assure you that we will be able to prevent or remediate any additional weaknesses in the future, which could impair our ability to accurately and timely report our financial position, results of operations or cash flows. If we are unable to successfully prevent or remediate any additional material weaknesses in the future, and if we are unable to produce accurate and timely consolidated financial statements, including our filing of quarterly reports with the SEC on a timely and accurate basis, our stock price may be adversely affected and we may be unable to maintain compliance with applicable Nasdaq listing requirements.

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. 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. 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, 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 2. Unregistered Sales of Equity Securities and Use of Proceeds

None

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
2.1	Agreement and Plan of Merger and Reorganization, dated as of June 3, 2018, by and among Versartis, Inc., Aravive Biologics, Inc. and Velo Merger Sub, Inc. (incorporated by reference to Annex A to Versartis, Inc.'s Proxy Statement/Prospectus/Information Statement filed with the SEC on September 6, 2018).	S-4	333-226594		08/03/2018
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-36361	3.1	03/26/2014
3.1.1	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant (reverse stock split).	8-K	001-36361	3.1	10/16/2018
3.1.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant (corporate name change).	8-K	001-36361	3.2	10/16/2018
3.2	Amended and Restated Bylaws of the Registrant.	S-1/A	333-193997	3.4	03/06/2014
4.1	Form of Stock Certificate	10-Q	001-36361	4.1	05/14/2014
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act .				
31.2*+	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act.				
32.1*+	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act.				
32.2*+	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act.				
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.

^ Confidential treatment has been requested as to certain portions, which portions have been separately filed with the Securities and Exchange Commission.

\+ This certification accompanies the Quarterly Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ARAVIVE, INC.
(Registrant)

Date: November 8, 2018

/s/ Jay P. Shepard
Jay P. Shepard
Chief Executive Officer
(Principal Executive Officer)

ARAVIVE, INC.
(Registrant)

Date: November 8, 2018

/s/ Vinay Shah
Vinay Shah
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

Certification of President and Chief Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Jay P. Shepard, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Aravive, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2018

/s/ Jay P. Shepard

Jay P. Shepard
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Chief Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Vinay Shah, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Aravive, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2018

/s/ Vinay Shah

Vinay Shah
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Jay Shepard, Chief Executive Officer (Principal Executive Officer) of Aravive, Inc. (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2018, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 8, 2018

In Witness Whereof, the undersigned have set their hands hereto as of the 8th day of November, 2018.

/s/ Jay P. Shepard
Jay P. Shepard
Chief Executive Officer (Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Vinay Shah, Chief Financial Officer (Principal Accounting Officer) of Aravive, Inc. (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2018, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 8, 2018

In Witness Whereof, the undersigned have set their hands hereto as of the 8th day of November, 2018.

/s/ Vinay Shah
Vinay Shah
Chief Financial Officer (Principal Financial Officer)